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DIMINISHED CAPACITY: CAN THE FDA ASSURE THE SAFETY AND SECURITY OF THE NATION'S FOOD SUPPLY?

HEARINGS

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

FIRST SESSION

OCTOBER 11, NOVEMBER 13, 2007

Serial No. 110–33 Pt. B

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DIMINISHED CAPACITY: CAN THE FDA ASSURE THE SAFETY AND SECURITY OF THE NATION'S FOOD SUPPLY

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DIMINISHED CAPACITY: CAN THE FDA ASSURE THE SAFETY AND SECURITY OF THE NATION'S FOOD SUPPLY? PART III

THURSDAY, OCTOBER 11, 2007

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 9:30 a.m., in room 2123, Rayburn House Office Building, Hon. Bart Stupak (chairman) presiding.

Present: Representatives DeGette, Melancon, Waxman, Green, Dingel, Whitfield and Burgess.

Staff present: John Sopko, Scott Schoyel, David Nelson, Joanne Royce, Kevin Barstow, Richard Wilfong, Kyle Chapman, Alan Slobodin, Pete Spencer, Garrett Golding, and John Stone.

OPENING STATEMENT OF HON. BART STUPAK, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. STUPAK. This meeting will come to order.

Today we have a hearing on Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation's Food Supply, Part III. Each Member will be recognized for a 5-minute opening statement.

Today we hold the third hearing of the subcommittee dealing with the safety and security of the Nation's food supply. This hearing will focus on the safety of food imported into the United States and the adequacy of the efforts of both the FDA and the USDA to protect Americans from unsafe imported food. We will also examine what food safety and quality control systems other countries use to protect their food imports.

Due to the globalization of the American economy, there has been a dramatic increase in the amount of imported food in recent years. In the last decade alone, USDA regulated meat and poultry imports have increased by 87 percent. In the same time, overall imports to the United States have tripled to almost 2 trillion per year. At a time when food imports are sharply increasing, FDA inspectors of imported food have decreased by 90 percent from 50,000 inspections in 1972 to just 5,000 in 2006. The FDA now inspects less than 1 percent of all imports, and only a fraction of that number are even tested. This is simply unacceptable.

We need a food safety system capable of combating dangerous food imports. Unfortunately, the Food and Drug Administration's

current system is woefully inadequate. Approximately 150 countries import food into the United States. Because of recent high-profile events such as melamine contaminated wheat gluten and seafood laced with unapproved antibiotics, imports from China have received most of the attention. As with other countries, Chinese imports in the United States have steadily increased. However, Chinese imports have increased more rapidly than the global average.

Between 1996 and 2006, the last 10 years, the volume of imports of Chinese agricultural and seafood products have increased by 346 percent. China is now the third largest exporter of agricultural and seafood products into the United States. Because of the concerns regarding the safety of Chinese food imports, on August 17, Chairman Dingell and I dispatched committee staff to China to ascertain whether food from that country could be imported safely into the United States and to determine whether China has taken or is taking the necessary steps to assure the safety of its food exports. While in China, committee staff met with government officials from China, Hong Kong and the United States. They met with American and other multinational executives and news reporters that covered food issues for their media outlets.

In our first panel today, we will hear directly from the committee staff about their findings.

Testifying on the second panel will be Dr. Michael Martin of the Congressional Research Service. Dr. Martin is an expert in Asian trade practices and has familiarity with Japan and Hong Kong's quality control systems for dealing with imported foods. He will testify regarding the methods employed by Japan and Hong Kong to ensure the safety of food imports from China. The committee would like to extend a special thank you to the Congressional Research Service for its valuable work in detailing food import issues. The work of Geoffrey Becker is especially appreciated.

Also testifying on the second panel will be Mr. James Rice, vice president and country manager for Tyson Foods in China. He is an executive with over 20 years of experience in China. He will testify about quality control issues in China, including steps that the Japanese take to ensure the safety of imports coming from China and the quality control measures that Tyson employs in China to ensure the safety of the food it produces there.

Finally, the third panel will be comprised of officials from both the USDA and FDA. Dr. Richard Raymond of the USDA will testify regarding the policies that his agency pursues to ensure the safety of beef, pork, poultry and egg imports. Dr. David Acheson and Ms. Margaret Glavine of the FDA will testify about the process that the FDA employs to ensure the safety of FDA-regulated food imports. We also expect them to address specific issues of imported food safety.

Recently, Chairman Dingell and I introduced a bill that will address many of the FDA's deficiencies. The bill would give the FDA a credible start in obtaining the resources it needs to deal with the flood of imported food. This hearing will also explore whether the FDA has the system or the will to use any new resources wisely. This subcommittee has already uncovered evidence of the FDA's ability to squander resources through giving excessive bonuses to

personnel at headquarters, attempting to consolidate decision making at headquarters instead of deploying urgently needed resources in the field and the fraudulent abuse of religious leave.

Simply put, the FDA must use its resources more wisely to accomplish its mandate of protecting the Nation's food supply. American consumption of imported food will continue to rise in the future. So now more than ever our country's Federal food safety system needs to be strong enough to protect the public health, our national security and our economy. Today's hearing will discuss what must be done to make this a reality.

That's the end of my opening statement. I would now like to recognize the gentleman from Kentucky, the ranking member, Mr. Whitfield, for his opening statement

OPENING STATEMENT OF HON. ED WHITFIELD, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF KENTUCKY

Mr. WHITFIELD. Chairman Stupak, thank you very much. We look forward to this hearing today as we continue our efforts to answer the question, can the FDA assure the safety and the security of the Nation's food supply? That's a question that most Americans want answered, and they want to feel comfortable with that answer. Every day we read it seems about additional problems with imports of our food supply such as tainted pet food, wheat gluten. Seafood from China, for example, made national headlines earlier this year.

Our concerns over weaknesses and FDA's food import system persists. Minority committee staff recently learned that, in February 2006, FDA received information from its pilot program called Predict that a cancer-causing disinfectant, malachite green, was detected in Chinese farm-raised seafood in South Korea and Canada. Canada announced the detentions of all Chinese eel products starting January 31, 2006, but it took FDA over 6 months before it imposed an import alert, and still bad products were shipped into the country.

This morning we will hear about China's food safety system as well as neighboring systems in Hong Kong and Japan. And we're hopeful that that information will shed light on measures that may increase our confidence in the safety of our food imports. As we examine these issues today, I think we can agree that FDA, many of us feel, requires fundamental reform of its approach to import safety. We know that the FDA employees are dedicated and committed to accomplishing this task. But all of us are interested in looking at ways that we can improve their efforts.

The agency's 100-year-old regulatory approach to food safety cannot deal with the huge growth in food imports over the past decade. This import surge is really astounding. In 1980, there were 1 million food lines of entry into America. And today, there are well over 10 million food lines. Imports have risen 15 percent annually over the last 10 years, and this number is expected to rise.

At the same time, while imports represent a larger portion of our food supply, roughly 15 percent overall, some products such as imported fresh fruits account for up to 60 percent of our food supply in that category and even 80 percent for seafood. The percentage

of imports inspected by FDA has plummeted from roughly 8 percent in 1992 to my understanding roughly 1 percent today. This is a situation with an agency that has jurisdiction over the 80 percent of our food supply but operates with only about 20 percent of the U.S. food safety budget. And that's because the Department of Agriculture has the largest percent of that budget.

But numbers don't fully explain the problem. As we've discussed in past hearings, the FDA's import system is not really set up to deal with the realities of global commerce. We can no longer rely upon border operations as the primary line of defense to ensure imported food safety. Giving more money alone is not the answer. The FDA must deploy a risk-based import inspection system where the agency identifies and prioritizes important risks well before a shipment reaches our shores. To do this, the agency needs to increase its information about foreign food manufacturers, their products, their distribution chains. FDA must profile food control agencies in foreign countries, understand what they do, and where they are developing new programs. It needs better information about particular food facilities and production practices abroad. This requires modern information systems as well as an increased overseas presence for inspections and information-gathering activities. To accomplish this, FDA should have a separate foreign inspections program with inspectors assigned full time.

An effective system also requires FDA to implement new information and risk-modelling systems. We understand some of this information technology already exists today, but the agency, for whatever reason, has been slow to deploy it. For example, Predict, an automated import entry system, supports risk assessments and has been operating only at one port and only for seafood for the past 3 years. FDA, we hope, will move quickly to expand use of this system or one similar to it.

I would also just point out that the minority committee staff requested recently names and locations of individuals that work at FDA who work full time on import inspections. And FDA provided the information, showing that there were only 30 full-time import entry reviewers. There were zero full-time import inspectors and zero full-time import investigators. Now FDA did provide the name of 213 employees who spend the majority of their time working on import activities. But even using the measuring term that FDA has called full-time equivalents, they said there are 454 investigational operational import full-time equivalents today. And back in 1992, there were 631. And yet we see this dramatic increase in the number of imports. And yet the full-time equivalents working on this area of food inspection safety seems to be decreasing. So, hopefully, this hearing will supply some answers for us.

And, Mr. Chairman, we look forward to working with you as we move forward on this important issue.

Mr. STUPAK. I thank the gentleman for his opening statement.

Ms. DeGette for an opening, please.

OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Ms. DEGETTE. Thank you, Mr. Chairman. The most important thing that this subcommittee can do is continue to be a watchdog for public health and safety. And I appreciate you holding this series of hearings.

Until quite recently, it never occurred to ordinary Americans that they needed to be concerned about the safety of the food they purchased from their neighborhood grocery store. But with products affecting ground beef, peanut butter, spinach, toothpaste, cough syrup, lettuce and even pet food in the news almost daily over the last year, people no longer assume, and rightly so, that what they buy is safe.

A recent survey showed an all-time low in consumer confidence in their food. And who can blame them? Our food safety system was simply designed for a different era. In 2007, we are at the mercy of a food safety system that was designed for the 1970s. If you look at my chart, today we are importing a dramatically larger percentage of our food than even a decade ago. If you look at this chart, imports just from China have skyrocketed in the past 5 years. In fact, according to the Congressional Research Service, imports of Chinese agricultural and seafood products alone have increased almost 350 percent since 1996 from $880 million to over $4 billion in 2006 alone. And this is just the imports from China. The red line would be even more dramatic if we looked at food imports from other countries as well.

At the same time that these imports have increased though, the FDA's food budget has stayed nearly constant but with more demands on that budget. The FDA's food division operated under a shortfall of nearly $140 million in 2006 due to a combination of increased personnel costs and new terrorism responsibilities. So that results in essence in a budget cut of nearly 25 percent.

And as Mr. Stupak said, this indefensible resource shortfall has been combined with mismanagement of resources at the FDA. While increasing numbers of imports have provided consumers with lower prices and more choices, I'm going to guarantee you, if you asked my constituents, they never bargained for a corresponding decline in food safety with those lower prices. They want the lower prices, yes, but they also want us to ensure that the food coming into this country is safe for them to consume.

The rise in imports is not necessarily problematic in and of itself. But when you couple that with an outdated and underfunded screening system, we've seen the results. And worse is to come if we don't fix the problem. Adding more inspectors and finding a way to pay for them is one step, but there are other steps that we need to take. And some of the members of this committee I'm sure will talk about it today.

We need to, first of all, ensure that safety is built into the system so that we eliminate contamination in the first place. And second, we need to build the regulatory framework required to effectively deal with an outbreak should one occur.

We all realize this is not just an issue of imported foods. The Topps beef contamination and yesterday's Sam Club's recall are

just the most recent examples of problems right here at home. It seems like every time we have a hearing, there's been a recall about a day before. And that just shows the extent of the problem.

There's a lot of legislation. Chairman Dingell has introduced a bill. I have a bill, H.R. 3484, the Safer Foods Act, which gives the FDA and USDA mandatory recall authority in the event of an outbreak. And there are other bills as well. Another bill I introduced was H.R. 3485, the Trace Act, which sets up a food product traceability system so that we can trace where our food is coming from so that we can recall it and make sure it comes off of the shelves.

In today's digital age, there's no reason we can't track food products from farm to fork. And the fact that many other industrialized nations are already doing it proves that point. And finally, we can't pretend to reform our food safety system while keeping in tact the complex regulatory structure in which 15 separate agencies share food safety jurisdiction. We must create a single food safety agency to ensure accountability once and for all.

I want to thank you, Mr. Chairman, for having this hearing. I expect to hear the latest on what the FDA's doing to combat this crisis. I also am continuing to monitor the status, as you mentioned, of a laboratory closing plan because it makes no sense to consolidate food safety labs at a time like this. We need to get a grip on this, both legislatively and in an oversight way. And I welcome this additional hearing in our series of hearings.

Thank you, Mr. Chairman.

Mr. STUPAK. I thank the gentlewoman.

Mr. Burgess for an opening statement for 5 minutes.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. Thank you, Mr. Chairman. And I appreciate you having the hearing today.

So, Mr. Chairman, we've seen recall upon recall all summer long, consumer product safety questions, consumer confidence dives. The number of recalls this summer has been alarming. This committee must take an active role. We're here to provide oversight to safeguard America from dangerous food, dangerous consumer products. The public health and the public confidence are both at stake in this. You just can't help but notice that all of the products and all of the foods that turn out to be problematic, all emanate from a single foreign source.

While I want to thank the leadership of this committee for holding this hearing, third in the series on the Nation's food supply, the subcommittee has been appropriately aggressive and pursued a bipartisan investigation on the matter. Really I want to urge my colleagues on both sides of the dais that this committee and the full Energy and Commerce Committee aggressively pursue legislation to deal with this problem. Chairman Dingell, of course, has introduced H.R. 3610. I don't know that that's a perfect piece of legislation, but I hope we get a chance to visit about that in both the subcommittee and the full committee. And whether we ultimately agree on all of the points or not, I thank the chairman for introducing the legislation on this important matter and certainly hope

there will be an opportunity this time for some bipartisan interaction on what will be important legislation that will affect the course of this country for decades to come. Its intentions are good. It's always details, details, details, and again look forward to really aggressively working on that legislation.

I think we need to look at how other Federal agencies have dealt with problems and what tools they have at their disposal and whether it would be appropriate for the FDA to have similar tools, similar authorities. I hope that today's hearing will help us further the goal of transforming the Food and Drug Administration because truly this is transformational. We're beyond the point of reform. Reform is, if you've got a little problem, you need to manage it around the edges.

This is a big problem, and it is going to require true transformation of the Food and Drug Administration into an agency that can fully cope with the importation problems of the 21st century. They are not problems that were created by the FDA. They are problems that are created by where we are in the world right now, and the FDA right now needs to be able to respond to those problems. If the FDA needs additional authorities, needs additional resources to be able to truly protect Americans, then we need to have a frank conversation about this, and I look forward to engaging in a candid conversation with the witnesses today. I continue to be very interested. We heard from Dr. Bill Hubbard, former FDA associate commissioner of this committee on several occasions. His prior proposal, that has been discussed at length and mentioned in previous hearings, would grant the FDA the authority to embargo a specified food from a specified country much like similar authority to the USDA has in regard to meat and meat products. If this standard is good enough for meat products, then it makes sense that it should be good enough for all food and drink imported into this country. And Mr. Chairman, we might even argue that it also should apply to other imported goods, such as toys.

While I had hoped to have legislation addressing Mr. Hubbard's concerns available to introduce, it has been tough sledding. There are a lot of things that I hadn't considered when I originally took that project on and my staff, my personal staff, took that project on. We've had some difficulty getting answers. It seems that those difficulties seem to be evaporating now. But I actually welcome the fact to have both the USDA and the FDA side by side on the panel today. Perhaps we can pursue some of those questions that have been particularly vexing. And certainly I welcome an open discussion regarding the proposal that I've had and Chairman Dingell's proposal. Again, Mr. Chairman, thank you for holding this hearing. And in the interest of time, I'm going to yield back the balance of my time.

Mr. STUPAK. I thank the gentleman.

And Members should realize this is the third of five hearings we have scheduled. The next one will be November 1. It's going to be drugs that are imported from overseas. On November 13—that is a Tuesday—we are going to do it on domestic foods, going back to domestic food. It will be our second hearing on domestic foods. That hearing is a Tuesday. It is at 10:00 a.m. If you need us to adjust the time, such as Members like Mr. Waxman, Ms. DeGette or Mr.

Burgess coming in from Texas, if you need us to shove that back an hour or so, we can accommodate Members. Some of us will be in on Monday. So think about it so we can accommodate everybody.

Mr. Inslee, opening statement, please.

OPENING STATEMENT OF HON. JAY INSLEE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WASHINGTON

Mr. INSLEE. Thank you. I appreciate the chairman talking about these other hearings because I think it's important that, while today we focus on the Chinese problem, that this is just one hole in a safety net that has many holes. The kids who were damaged by spinach, it wasn't from China. It was from fields in California, and I'm told we had more food rejected in our inspection process from India last year than from China. So I just don't think we can lose sight of the fact that this entire scheme needs to be changed, and I appreciate the chair's leadership on that.

I hope today that we'll hear answers to three questions I'd like to pose. First, do we need to have at least as aggressive a food safety program as Hong Kong? We will hear testimony about the Hong Kong process that requires certificates to allow entry of at least Chinese imports. And the question arises, should we at least have as vigorous a program as they do? Second, I'd like to hear whether it's time to have at least as rigorous an inspection protocol from the FDA as the USDA. Why are we not providing the same level of protection for nonmeat and fish products? And I think we're starting to see hazards associated with those that would justify that action. And third, I hope we'll have a discussion of the plans or at least a discussion of the closure of labs at the very moment we have this continued increase in threats—and it is a great decrease in confidence; 70 percent of Americans now do not trust these overseas products. So I hope we'll have a discussion of that, what appears to me to be a very short-sighted effort. With that, I yield back.

Thanks, Mr. Chairman.

Mr. STUPAK. I thank the gentleman.

Mr. Waxman, an opening statement, please.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you very much, Mr. Chairman, for your vigorous efforts in oversight in the area of the safety of food and drugs and other products that are consumed by the American people.

Over the years, we have had a lot of hearings when there has been a scare but not a lot of sustained activity after the hearings to make sure that we do protect the American people from unsafe products. We are seeing the downside of two predominant views of our economy. One has been that we should rely more and more on a globalized economy. Well, the downside of that is that we don't have control, as we would like, for the evaluation of the safety problems when we bring in products from other countries. In many ways, we rely on these other countries to assure us that we are importing a product that is maybe not otherwise available here but is going to be safe when it is consumed here.

The other theory that we are seeing the downside is deregulation. For years now, we've seen proposals to deregulate, to get government out of the way, to allow the private sector to solve problems. And thus, we now have an FDA with diminished resources to do its job, with inadequate authority to do its job. So for those who have argued that we need to deregulate, to starve the regulatory agencies, we are seeing the results come home.

In the great tradition of oversight, this committee has sent our investigators to China. And what they've reported back to us is really pretty startling. They have indicated that what they have seen is that the Chinese food supply chains do not meet international standards. The Chinese Government is very concerned about bad press or bad appearances or embarrassment in the export market, and the branding of "Made in China" in a negative way around the world. But they have no meaningful regulatory system to make sure that the farming and food processing in China will lead to safety even for their own consumers. There have been many outspreads, wide outspreads of poisoning of Chinese from unsafe foods. So when they have problems, they don't do enough to stop the entrepreneurs, so-called, from smuggling in food supplies into the export market even if they are unsafe.

Well, what can we do about this? We have had hearings, and we have certainly come to the conclusion the FDA is not doing its job. Well, we want to rely on an FDA that can and will do its job. So we need to give them the resources. We need to give them the authority. But other proposals have been put forward, such as the legislation by Chairman Dingell, to say that we ought to not just rely on inspections here in the United States but to try to ascertain that a country has a regulatory system in place to protect the supply that is going to be brought into the U.S. market.

Well, that sounds like an ideal way to resolve things, but I don't think in the real world it's going to happen for quite a while. Then the legislation suggests that we ought to have the FDA certify individual marketers. Well, if that is what we are going to rely on, that is going to involve thousands and thousands of individual places to inspect. We have to deal with a modernization of a regulatory system, a modernization of an effort here in the United States to protect the American consumers.

Our colleague, Ms. DeGette, just talked about how consumers welcome globalization when it leads to a wider variety of products that are not available and to lower prices for those products. But her consumers nor do my consumers want to have a lower price for a food product that may cause genuine harm. I am encouraged that we are holding hearings; we are looking at legislation, not only for imported product safety but for domestic safety as well.

I commend you, Mr. Chairman, for your efforts. We have got to make sure that we are not just holding hearings but that we follow through so that the daily press that we see of food problems becomes something that is dealt with in a realistic way. Thank you.

Mr. STUPAK. Thank the gentleman.

The chairman of the full committee, Mr. Dingell, for an opening statement please.

OPENING STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. DINGELL. Mr. Chairman, I thank you. And I commend you for holding this hearing and for the superb leadership you are giving in terms of protecting the American consumers. I also want to commend you for the excellent and far-reaching investigation into the effectiveness of our laws and the administration activities in support of those things.

The food safety challenges our country now faces and the questions that we confront with regard to prescription pharmaceuticals, plants and devices is a matter of great concern to this committee. As we have seen in prior hearings, food safety affects us all. But it is particularly most dangerous to the most vulnerable, the poor the young the very old and those with compromised immune systems.

Today we focus on food imports, not only from China but also from other countries with regulatory systems that are not the equivalent or even close to ours. Importing food from such countries is risky to begin with and even more dangerous if the resources for the regulatory agencies entrusted with ensuring their safety are bigger and their management is passive or ineffective.

Mr. Chairman, we sent committee staff, as you know, to China to help us understand whether importing food from that country made sense, given the spate of recent incidents involving tainted food imports. By sending committee staff to look at these problems firsthand, we have gained insights that are unique from other congressional committees now looking at food import safety. I very much look forward to the staff's testimony today.

I am interested in the analysis of our expert witnesses, Mr. Rice and Dr. Martin, regarding regulatory efforts of Hong Kong and Japan, which import a substantial amount of the food that they use from China. The subcommittee will also hear from representatives in the Department of Agriculture and the Food and Drug Administration, the primary regulatory agencies that ensure the safety of our food imports.

I look forward to comparing and contrasting their budgets and their efforts. I especially look forward to hearing from USDA regarding efforts to protect Americans from contaminated beef, pork, chicken and eggs. I understand their system is far more selective as to who can import into this country and from where and that the USDA inspects a larger portion of the imports that they are responsible for regulating than does FDA. Most of all, I look forward to the testimony of FDA witnesses today. Two weeks ago, when the FDA was called in to discuss food safety in the context of the bill that you and I and other members of this committee have offered, Mr. Chairman, H.R. 3610, they sent one of the least-prepared witnesses ever to testify before this committee. That FDA official, Dr. Lutter, repeatedly told us how ignorant he was of the most basic facts regarding the food import crisis. I hope that we will have better performance from the FDA today.

I also trust that FDA witnesses are not going to try to sell that old often repeated falsehood that we can do more with less. The only thing FDA has established with regard to this particular point

is that they can do less with less. FDA needs resources to deal with the cavalcade of imports from China and other countries that cannot or will not ensure the quality of their food imports to the United States. I intend to see that the FDA gets the budget that it so sorely needs.

Finally, Mr. Chairman, I understand that you intend to hold hearings in November dealing with the safety of drug imports and the inadequate regulation of our domestic food supply. I endorse your plans, and I commend you for doing this because it is an activity by this committee desperately needed. The bill that you and I and other Members of this committee sponsor addresses these matters as well as providing the crucial resources necessary to strengthen the import protections. I expect that the hearings today and in the future will help us to refine the legislation. I've always found that legislation informed by the work of the Subcommittee on Oversight and Investigations makes for far better law and far better public policy. I also look forward to contrasting and comparing budgets and efforts at FDA. I especially look forward to hearing from USDA regarding its efforts to protect Americans that we so desperately need.

In any event, Mr. Chairman, if anyone here has been to China, many of us have, they will know that you have to be darn careful about what you eat over there. I see nothing which has changed, the quality of the food that they send us, from the quality of the food which they send to their own people. And I intend to see to it that the best food and drug law in the world, which we have, is properly administered, properly enforced and properly financed. I commend you for these hearings. And I thank you, Mr. Chairman.

Mr. STUPAK. I thank the gentleman and thank the chairman of the full committee. And thank you for your continued support of our efforts as we reach out globally to address this issue of food imports.

Next I would like to hear the gentleman from Texas, Mr. Green, for an opening statement, please.

OPENING STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. GREEN. Thank you, Mr. Chairman, for holding this additional hearing and also the announcement for the hearings later. I would also like to thank the chairman of our full committee for authorizing the staff delegation trip to China over the August recess. I am grateful for the ONI staff for making the trip so we can learn firsthand about the regulatory scheme present in that country which is one of the top food importers to the U.S. We cannot necessarily dictate how food is regulated in another country. This knowledge of Chinese regulation will help us identify the safety gaps in China and implement the necessary safeguards to protect the American people from dangerous contaminated food products bound for our country. As we examine the Chinese regulatory scheme for food, we should keep in mind that China is not our country's top food importer from the developing world; Mexico is.

The problems also are not coming disproportionately from China. According to FDA import alerts, there are 20 Mexican firms on import alerts while there are 16 import alerts facing Chinese firms.

The monthly tally of imports refused at the border also indicates that Mexico, China and India are at the top of the list of oasis refusals by country in any given month.

Whatever policies we implement based on our understanding of the Chinese system must be applicable to all our trading partners, including Canada and Mexico, which are the top exporters of agriculture and seafood products to the U.S. The staff investigators' trip to China shed light on the fractured regulatory framework for food in China and the numerous agencies involved. The lengthy supply chain and food processing procedures in China give us important insight on how these problems arise.

In our country, we celebrate the family owned small business and consider a family's entrepreneurial success a realization of the American dream. As the investigators pointed out in their report, however, family farmers in China often face difficult economic conditions and downward pressure on prices to make crop survival the highest priority, even at the expense of safety. With such fragmented regulation, a Chinese farmer is probably willing to take that gamble.

It appears the Japanese have protected their citizens from this problem by allowing only Chinese imports from a certain number of certified producers who have met their quality standards. Hong Kong has taken a different route by implementing a robust registration and inspection regulatory framework.

It is unclear whether any of these systems can be applied to a country as large as the United States and with such demand for the products. We can certainly learn from them and determine what elements can be workable for the U.S. supply system that is in dire need of improvement. And as my colleagues have pointed out, it is not just our imports. Whether it is hamburger meat, whether it is spinach, whether it is any other issue, we need an active and robust FDA. And I am glad that the chairman of the full committee is committed to providing the resources to the FDA so they can do not only what we expect them to do on the drug side but also on our food safety.

Thank you, Mr. Chairman. I yield back my time.

Mr. STUPAK. I thank the gentleman.

Mr. Melancon for an opening statement.

Mr. MELANCON. Thank you, Mr. Chairman. I would just submit my remarks for an opening and reserve my time for questions if you would.

[The prepared statement of Mr. Melancon follows:]

PREPARED STATEMENT OF HON. CHARLIE MELANCON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF LOUISIANA

Mr. Chairman, Thank you for holding this hearing today. I am quite concerned about the lack of screening of 80 percent of the United States' food supply. My district, which depends largely on the fishing industry—shrimp, crawfish, fresh caught fish, is struggling to compete with imports from foreign countries that do not have the same food safety standards as we have in the United States. Countries like China, Taiwan, and Vietnam—just to name a few—import seafood that is produced in farms, not fresh caught. Catching wild shrimp and fish is much more labor- and capital-intensive, so fresh caught seafood is more expensive than farm raised. Farms try to produce as much product as possible, so they overpopulate ponds. Because the ponds have no fresh water circulation, they become filled with bacteria. The farmers then pump antibiotics and other chemicals into the water to kill the bacteria. These chemicals have been shown to cause cancer in animals and humans.

Since the Food and Drug Administration only tests 1 percent of food imports, Louisiana's Department of Agriculture has taken it upon themselves to test for these dangerous chemicals. They have repeatedly found concentrations of chloramphenicol and fluoroquinolones, among other chemicals, in imported seafood—particularly from producers based in China. Despite evidence of chemicals and antibiotics in imported seafood, the FDA still allows tainted food to enter the United States.

I am happy that the FDA finally made an Import Alert for farm-raised catfish, basa, dace, eel, and shrimp from China in June, but we've known about tainted and contaminated imports from China for years. Louisiana's Department of Agriculture has also found evidence of chemicals and antibiotics in crawfish tail meat from China, yet the FDA is still allowing this tainted meat to enter our food supply.

Furthermore, an Import Alert does not necessarily mean that these tainted products will be prevented from entering the United States. Rather, an Import Alert means that field agents detain the product—not destroy it or return it to the originating country—and wait for the importer to show that the shipment is not tainted. The FDA requires an independent lab test for proof, but the FDA doesn't certify labs, so anyone can open a lab and provide test results.

These are just a few of the problems that we in this committee have discussed previously and will continue to examine until the food we import is safe. I am seriously concerned about the safety of food imported from countries that lack food safety standards equivalent to those in the United States and hope that we can soon find a better system for monitoring food imports.

Thank you, Mr. Chairman.

Mr. STUPAK. Very good. That concludes the opening statements by members of the committee. I will now call our first panel of witnesses to come forward.

On our first panel, we have Mr. David Nelson, senior investigator for the Committee on Energy and Commerce; Mr. Kevin Barstow, investigative counsel for the Energy and Commerce Committee; Mr. Richard Wilfong, investigator with the Energy and Commerce Committee.

It is a policy of this subcommittee to take all testimony under oath. Please be advised that our witnesses have the right under the Rules of the House to be advised by counsel during their testimony. Do any of you wish to be represented by counsel? Indicating no one wishes to be represented by counsel, please raise your right hand to take the oath.

[Witnesses sworn.]

Mr. STUPAK. Let the record reflect the witnesses have answered in the affirmative. You are now under oath. And Mr. Nelson, I understand you are going to give the opening statement, a 5-minute opening statement. You may submit a longer statement for inclusion in the hearing record.

Mr. Nelson.

STATEMENT OF DAVID NELSON, SENIOR INVESTIGATOR, COMMITTEE ON ENERGY AND COMMERCE; ACCOMPANIED BY KEVIN S. BARSTOW, INVESTIGATIVE COUNSEL, AND RICHARD A. WILFONG, INVESTIGATOR

Mr. NELSON. Thank you, Mr. Chairman.

Good morning, I am David Nelson, an investigator with the Committee on Energy and Commerce. I am accompanied by Kevin Barstow, counsel, and Richard Wilfong, an investigator with the committee staff.

Mr. Chairman, you and Chairman Dingell dispatched us to China on August 17 to ascertain whether food stuffs from that country could be imported safely into the United States. We met

with Chinese and Hong Kong government officials, U.S. Government officials, American and other multinational executives involved in processing and distributing food in China and Hong Kong and reporters from bureaus in Beijing and Hong Kong that cover food issues for their media outlets. The report of that trip is attached to this summary statement.

Based on information gathered before and during the trip, the staff made the following observations:

First, the Chinese food supply chain does not meet international safety standards. It is in fact responsible for very serious domestic Chinese food-poisoning outbreaks.

Second, the Chinese Government appears determined to avoid embarrassing food safety outbreaks in its export markets due to the damaging and potentially lasting effect this would have upon the Made in China branding.

Third, the lack of meaningful internal regulation of farming and food processing in China, the advanced development of the document counterfeiting industry and the willingness of some entrepreneurs in both China and the United States to smuggle foodstuffs that do not meet quality standards necessitates a much more vigorous program of inspection and laboratory testing in China and in U.S. ports of entry than the Food and Drug Administration has been willing or able to pursue today.

The responsibility for quality assurance both of imports and exports rests with the AQSIQ in China, the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China. The AQSIQ officials issued a white paper on August 17, 2007, which is included in the exhibit book dealing with food safety. This paper details China's export quality assurance program.

While in China, we had an opportunity to discuss the components of this program with AQSIQ officials as well as other Chinese agency officials. We were advised that a sample from each lot of product for export is pulled by a government inspector and tested in a government laboratory to ensure it meets Chinese standards and the standards of the importing country. Export certificates are then granted by the local Chinese inspection and quarantine CIQ offices, CIQ or local municipal equivalents to AQSIQ.

We are shown how importers' paperwork is joined with laboratory test results before the certificate is issued. When the certificate is issued, the information is sent to the port of exit electronically to ensure that the fiscal goods correspond to the export certificate before loading. The Chinese position is that theirs is a closed system that ensures the safety of foods that bear the CIQ certificates and seal.

Today, FDA has refused to acknowledge the Chinese certificates. If the Chinese system worked as described, it would be a very safe system. However, we did not find any American or other multinational executive operating in China that believed that China has a competent independent inspector overseeing each of the 12,714 plants that are approved for export or even of the 3,700 plants that according to Chinese officials are fully HACCP controlled. Nor did we find anyone that believed that every single lot was sampled.

Finally, it was widely believed that the export certificates were subject to counterfeiting. There was agreement among everyone we talked to about the sincerity and scope of the AQSIQ's efforts but much less enthusiasm about the willingness of local CIQs to follow the central government's dictates. And we were told it's at the local level where the system succeeds or fails.

We made inquiries about two possible models. One of the models, the Chinese food exports to Hong Kong, was broached directly with the Hong Kong Government. The other, the Chinese food delivered to Japan, was discussed with knowledgeable sources but not the Japanese Government due to the time limitations of the trip. An overview of their findings of our findings regarding these two models is presented in the trip report.

Can food be imported from China safely? The Japanese and Hong Kong models are each safer than the FDA's system for regulating food imports. The Hong Kong system involves massive sampling and thus may not be practical for an economy of our size. Last year, the Hong Kong Government tested in their laboratory 64,000 samples. If we were to test an equivalent proportion of samples to a country the size of the United States, it would be over 2 million in FDA labs. That simply is so far beyond the capacity that it's hard to even imagine if we could build that much laboratory space very quickly.

The Japanese system of inspecting a very limited number of facilities that are permitted to supply food to China does appear to offer a much better control system than currently employed by the FDA. But the Japanese also inspects and tests 15 percent of their food imports. We inspect 1 percent and test a fraction of that. However to the extent that the Chinese products for the Japanese market are insulated from excessive downward pressure on prices—and that's a real problem, the incessant pressure on downward prices on people that are producing at the margin causes a lot of shortcuts to be taken in a lot of products over there—to the extent they're insulated from downward pressure on prices, the Japanese consumers pay for the added safety in the form of somewhat higher prices. The size of the price effect is not known. At a minimum, it would appear the U.S. could cut safety risks significantly were FDA to limit food imports to China to those firms that have obtained the appropriate certificates from the Chinese Government.

For all the reasons noted in this report, such certificates are no guarantee of safe imports, particularly if there's not an electronic transmittal system in place of the paper certificates. However, the absence of such certificates most certainly means the Chinese quality control system has been evaded by their exporters.

Mr. Chairman, thank you for the opportunity to testify before this subcommittee. Mr. Barstow, Mr. Wilfong and myself look forward to answering any questions you or other Members may have about our testimony or the investigation.

[The prepared statement of Mr. Nelson follows:]

STAFF STATEMENT
BEFORE THE SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
COMMITTEE ON ENERGY AND COMMERCE
"DIMINISHED CAPACITY: CAN THE FDA ASSURE THE SAFETY AND SECURITY OF THE NATION'S FOOD SUPPLY – PART 3"

OCTOBER 11, 2007

Good Morning, I am David Nelson, an investigator with the Committee on Energy and Commerce. I am accompanied by Kevin Barstow, counsel and Richard Wilfong, an investigator on the Committee staff. Mr. Chairman, you and Chairmen Dingell dispatched us to China on August 17, 2007, to ascertain whether foodstuffs from that country could be imported safely into the United States. We met with Chinese and Hong Kong Government officials, U.S. Government officials, American and other multinational executives involved in processing or distributing food in China and Hong Kong, and reporters from bureaus in Beijing and Hong Kong that cover food issues for their media outlets. The report of that trip is attached to this summary statement.

Based on information gathered before and during this trip, the staff has made the following observations:

- The Chinese food supply chain does not meet international safety standards. It is, in fact, responsible for very serious domestic Chinese food poisoning outbreaks.

- The Chinese Government appears determined to avoid embarrassing food safety outbreaks in export markets due to the damaging and potentially lasting effect this would have upon their "Made in China" branding.

- The lack of meaningful internal regulation of farming and food processing in China, the advanced development of the document counterfeiting industry, and the willingness of some entrepreneurs in both China and the United States to smuggle foodstuffs that do meet quality standards, necessitates a much more vigorous program of inspection and laboratory testing in China and at U.S. ports of entry than the Food and Drug Administration (FDA) has been able or willing to pursue to date.

The responsibility for quality assurance of both imports and exports rests with the General Administration of Quality Supervision, Inspection, and Quarantine of the People's Republic of China (AQSIQ). The AQSIQ officials issued a white paper on August 17, 2007,

dealing with food safety. This paper details China's export quality assurance program. While in China, we had the opportunity to discuss components of this program with AQSIQ officials.

We were advised that a sample from each lot of product for export is pulled by a Government inspector and tested in a Government laboratory to ensure it meets Chinese standards and the standards of the importing country. Export certificates are then granted by local China Inspection and Quarantine (CIQ) offices, the provincial or municipal equivalent of AQSIQ.

We were shown how the exporter's paperwork is joined with the laboratory test results before the certificate is issued. When the certificate is issued, the information is sent to the port of exit electronically to assure that the physical goods correspond to the export certificate before loading. The Chinese position is that they have a closed system that assures the safety of foods which bear the CIQ certificates and seal. To date, FDA has refused to acknowledge the Chinese certificates for safety or export purposes.

If the Chinese system works as described, it would be a very safe system. We did not, however, find an American or other multinational executive operating in China who believed that China has a competent, independent inspector overseeing each of the 3,700; nor did we find anyone who believed that every single lot was sampled. Finally, it was widely believed that the export certificates were subject to counterfeiting.

There was agreement about the sincerity and scope of AQSIQ's efforts, but less enthusiasm about the willingness of local CIQs to follow the Central Government's dictates. And, we were told that it is at the local level where the system succeeds or fails.

We made inquires about two possible models of food safety systems. One of the models, Chinese food exports to Hong Kong, was described to us directly by the Hong Kong Government. The other, Chinese food delivered to Japan, was discussed with knowledgeable sources, but not the Japanese Government, due to the time limitations of the trip. An overview of our findings is presented in the trip report.

Can food be imported from China safely? The Japanese and Hong Kong models are each safer than the FDA system for regulating food imports. The Hong Kong system involves massive sampling and therefore may not be practical for an economy of our size. The Japanese system of inspecting the very limited number of facilities that are permitted to supply food from China does appear to offer much better control than that system currently employed by FDA. To the extent, however, that Chinese producers for the Japanese market are insulated from excessive downward pressure on prices, the Japanese consumer pays for the added safety in the form of higher prices. The size of the price effect is not known.

At a minimum, it would appear the U.S. could cut the safety risk significantly if FDA were to limit food imports from China to only those firms that have obtained the appropriate certificate from the Chinese Government. For all the reasons noted in this report, such certificates are no guarantee of safe imports, particularly if there is not an electronic transmittal system in place to replace paper certificates. The absence of such a certificate, however, most certainly means that the Chinese quality control system has been evaded.

Mr. Chairman, thank you for the opportunity to testify before the Subcommittee. We look forward to answering any questions you or other Members may have regarding our testimony and investigation.

Mr. STUPAK. Thank you, Mr. Nelson.

We'll begin questioning. We can go 5 minutes, maybe we can go two rounds. We do not have votes today, so we should not be interrupted.

Mr. Nelson, in your report, it states that the USDA does not permit any beef, pork, chicken or eggs into the U.S. from China. You say that it would be impractical for the FDA to take the same stance. Would you explain that?

Mr. NELSON. Well, yes, there's a far different matter excluding four specific products versus all the rest of the food products. And we say, and truthfully, that USDA has responsibility for 20 percent of our food supply. But it's 20 percent by value. It's not 20 percent by volume or by number of products. If we were to exclude all food products from China, it would have substantial effects on the economy of the United States. We get a large proportion of fish, of amino acids, of vitamins, of intermediate products like wheat gluten and a lot of finished products. I mean, and those exports to us are growing.

Mr. STUPAK. In your opinion, based on the last answer then, in your opinion, are imports from China more or less dangerous than food from other parts of the world, such as India, Mexico or the Dominican Republic, all which are important food suppliers to the United States?

Mr. NELSON. No, not necessarily. We have a substantial portion of the rejections of foods for—because they're unsanitary, contaminated, decomposing, from these other countries that have less developed economies and less developed regulatory systems. China is certainly one of the problem countries. But it is only one of the problem countries.

Mr. STUPAK. China indicates they will certify the food. That is, certified to their standards, not necessarily the country that they're exporting the food to, in this case the United States. It's not U.S. standards. When they certify, it is to the Chinese standards.

Mr. NELSON. They claim it is the U.S., it is the standards of any country for which they're exporting.

Mr. STUPAK. That's what they claim. But what did you find when you were there?

Mr. NELSON. We found laboratories, at least the one we looked at in Beijing is comparable to the FDA laboratories we have here.

Mr. STUPAK. How many of those type laboratories did they have?

Mr. NELSON. They claimed to have 323 laboratories.

Mr. STUPAK. Three hundred and twenty-three laboratories? How many farms supply those laboratory samples from their farms? How many farms are there that grow food for export?

Mr. NELSON. They claim that they've approved some 360,000 hectares of land, farm land for export.

Mr. STUPAK. Three hundred and sixty hectares, but how many farms?

Mr. NELSON. Three hundred and sixty thousand. I'm not sure how many farms that translates to.

Mr. STUPAK. But a hectare can be as large as a basketball court, or it could be much larger, can it not?

Mr. NELSON. It could be. But it could be as small as a basketball court. Much of the Chinese domestic food supply anyway—we're talking about literally hundreds of millions of farmers——

Mr. STUPAK. Correct.

Mr. NELSON. Are from these very, very small parcels of land the products of which are then gathered by intermediaries and consolidated. There's simply no way that the Chinese Government can have control over the conditions of farming on so many farms.

Mr. STUPAK. Well, I understand the central government in China does not have complete control of what happens at the provincial or the local government level. So what does that mean for food safety if you have tens of millions of farms, which first contact would be local government, then you have provincial government; then you have the central government. You have three layers of government there. How do they work government to government?

Mr. NELSON. Well, I don't think anybody knowledgeable about the system can say that the Chinese food supply is safe, even their export systems.

Mr. STUPAK. Who puts forth the regulatory regime on food safety? Is it the central government, provincial government or the local government?

Mr. NELSON. The provincial and local governments are where the rubber meets the road. They're the ones that are issuing certificates.

Mr. STUPAK. So can each local government or each province have a different regulatory scheme in which chemicals or pesticides they use?

Mr. NELSON. They are bound by a common national scheme, which is to meet the Chinese national standards and the importing country's standards. But whether or not they do, whether or not those regulations are enforced is very problematic.

Mr. STUPAK. On reading your report, I found a lot of issues that—not only from government to government but government to the farmer, there's less regulation. And when we deal with the certification, China has a rather sophisticated counterfeiting—is that what you found?

Mr. NELSON. There was unanimity on virtually everybody outside of the Chinese Government themselves as to the quality of counterfeiting. And it's not limited to documents. But modern publishing techniques make counterfeiting very, very easy anywhere in the world. And the Chinese technology in such matters is as good as anywhere in the world.

Mr. STUPAK. Well, I have many more questions for Mr. Barstow and Mr. Wilfong. My time's up. Hopefully, we'll get a second round of questions in.

Mr. Whitfield for questions, please.

Mr. WHITFIELD. Thank you, Mr. Chairman.

Mr. Nelson, in your testimony, you state emphatically that the Chinese food supply chain does not meet international standards. And it is, in fact, responsible for very serious domestic Chinese food poisoning outbreaks. Now, one of the areas that I'm a little bit puzzled about relates to this concept known as equivalence. And that basically means that although food products imported into the United States must meet the same safety standards as domesti-

cally produced foods, international trade rules permit a foreign country to apply its own differing standards, regulatory authorities in institutional systems in meeting standards under this internationally recognized concept known as equivalence. And so my question is, if the Chinese food system does not meet international standards even though we can apply this equivalence standard, how is it that we're able to bring their food into America in a safe way?

Mr. NELSON. Well, U.S. law is bifurcated in that regard. USDA, for meat and eggs, has an equivalence standard. And as a consequence, we import no eggs, pork, chicken or beef from China. And it's unlikely——

Mr. WHITFIELD. Because they don't meet the safety standards?

Mr. NELSON. They don't meet the equivalence standard.

Mr. WHITFIELD. All right. So we don't allow any meat, poultry products, eggs from China?

Mr. NELSON. Right. That same standard is not in the Food, Drug and Cosmetic Act.

Mr. WHITFIELD. The same standard is not in the Food, Drug and Cosmetic Act?

Mr. NELSON. That's correct.

Mr. WHITFIELD. So the USDA, their inspection responsibilities of the meat products, they can prevent these items from coming in. But you are saying the FDA does not have the authority to prevent——

Mr. NELSON. The Food, Drug and Cosmetic Act does not have an equivalence standard. Now, there are very strong authorities for—and very strong authorities and much discretion for FDA at the border, much more than there is within the United States. But there is no equivalency standards. So FDA does not go over and determine whether or not the spinach or fish or wheat gluten or toothpaste from China is produced under standards that are equivalent to the United States.

Mr. WHITFIELD. Well, your statement, that's a pretty strong statement. I mean, you all went there, and you met with officials, and you looked at processing plants and facilities. And you make the statement, the Chinese food supply does not meet international safety standards.

Mr. NELSON. That's right.

Mr. WHITFIELD. That's all food; correct?

Mr. NELSON. That's all food, in terms of the country as a whole. Now it's really important to understand that the food for export is handled and treated by the government much differently than food for domestic consumption. And USDA's laws, as I understand it, or law, requires an evaluation of the entire system of growing chickens, for example, plucking chickens, processing chickens and preparing them for consumption, whether for export or for import. And under those standards, it's hard to imagine China reaching an equivalence level in my lifetime.

Mr. WHITFIELD. Yes. Mr. Nelson, we're going to have some other people testifying today from FDA and Tyson's and others who are experts in this field. But you have a long history and background in this area also, and certainly one of the experts on this committee. But if you were speaking to a Rotary Club say in the State of

Kentucky and you were going to just make a statement to the members of that Rotary Club if they ask you a question, "do you think it is safe to eat food from China that comes into the U.S.," what would your answer be?

Mr. NELSON. I would say that you're taking your chances on any imported food and some processed foods within the United States. But those chances of any single person being seriously harmed from food are really small.

Mr. WHITFIELD. OK.

Mr. NELSON. Food of any kind.

Mr. WHITFIELD. My time is expired.

Mr. STUPAK. My time has expired. Thank you, gentlemen. Mr. Dingell for questions, please.

Mr. DINGELL. Mr. Chairman, I thank you.

Gentlemen, can FDA under current circumstances protect American food supplies from unsafe imports with the resources which it has?

Mr. NELSON. That would be an emphatic "no."

Mr. DINGELL. Gentlemen, should we continue to allow food imports to enter through 321 ports of entry?

Mr. NELSON. That would not appear to make any common sense at all. We have 321 ports of entry in the United States and the Food and Drug Administration doesn't cover but a fraction.

Mr. DINGELL. How many of the Nation's ports—air, sea and land—are staffed by FDA personnel?

Mr. NELSON. They tell us it is 90 ports, but it is highly doubtful that that is 24/7 coverage of those ports.

Mr. DINGELL. What percentage of imports are checked at these 90-some ports, and what is the success in terms of protecting consumers.

Mr. NELSON. Well, the agency says they inspect less than 1 percent. They test a fraction of what they inspect. And I think there is still substantial risk. I mean, they don't make a serious—they don't test enough to make a statistical statement about the safety of food. I mean, the Japanese test 15 percent of a highly regulated import system that goes to the countries which supply the food. Inspections there. And they still test 15 percent, because that is a large enough sample for them to have confidence that the food coming in is safe. But our tests are so meager it is hard for me to imagine anybody having much confidence in the results of the FDA inspections.

Mr. DINGELL. Is the Chinese food production system comparable to the United States system?

Mr. NELSON. No.

Mr. DINGELL. What are you telling us there?

Mr. NELSON. When China ceded to the WTO, and perhaps before, the collectivized farming systems collapsed. And you have now literally hundreds of millions of small farm—some, as the report said, no larger than the size of a basketball court, producing the food supply. You have a lot of Chinese bureaucrats, but nowhere near enough to police the number of farms that they have and the number of small processors, which is another issue. I mean, most of the food processed in China, we are told, is by family processors, plants

that employ less than 10 people, that are just as marginal as the farms they get the produce from.

Mr. DINGELL. Is the Chinese regulatory system, in terms of protecting consumers' health and safety, comparable to that in this country?

Mr. NELSON. Not at all.

Mr. DINGELL. Why do you say that? What percentage of the foods that the Chinese produce are inspected or undergo some kind of a safety procedure in China with regard to domestic consumption or with regard to export?

Mr. NELSON. I would say virtually none with regard to domestic consumption.

Mr. DINGELL. Is it true that we can import food from China safely under current Chinese practices and under current U.S. practices?

Mr. NELSON. No.

Mr. DINGELL. You have discussed briefly how Hong Kong protects the food supply. Would you like to amplify on that?

Mr. NELSON. First of all, Hong Kong is a city of 7 million people. It is about the size of Chicago. It is an administrative district of China itself now, after the British left in 1997. It is under special administration. It has got 40 more years to run before it is fully integrated into the governmental system of China. It keeps its own tariff territory. Importing in Hong Kong is separate and distinct from importing into China, and China imports into Hong Kong. They grossly limit the number of ports of entry for fish, or other foods being brought in by sea, to perhaps two or three; land, one or two.

They test intently because the SARS and other outbreaks threaten not just the health of Hong Kong's citizens, the physical health, they really have threatened the economic viability of that entity. So food safety is a huge issue in Hong Kong. They do a lot of testing, 64,000 samples last year, of which only 0.3 percent were out of spec. That is partly because the Chinese themselves are very, very concerned that food outbreaks not occur in Hong Kong. It reduces the political stability of the administrative entity, and they are constantly aware of and concerned about the level of engagement of the Hong Kong citizenry in policy issues and just as soon things keep as quiet as possible.

Mr. DINGELL. Mr. Chairman, I have used my time. I thank you for your courtesy.

Mr. STUPAK. Thank you. Mr. Burgess for questions, please.

Mr. BURGESS. Thank you, Mr. Chairman.

Mr. Nelson, you and members of your staff and minority staff who were there in China—and you have partly already answered this question—but China internally has a domestic problem with their food supply?

Mr. NELSON. A serious problem.

Mr. BURGESS. And did you see evidence of that in either news reports or did people talk about that when you were there?

Mr. NELSON. Yes.

Mr. BURGESS. Many years ago, probably 15 years ago, as a physician I went on a trip to China with some other doctors, and I re-

member getting very ill when I was there in China. So I was wondering, what did you and your staff eat?

Mr. NELSON. We ate what was served to us.

Mr. BURGESS. Are you OK?

Mr. NELSON. I was. That is not true of everyone at this table.

Mr. BURGESS. And I note the absence of the minority staff. Were they your testers?

Mr. NELSON. We have always joked about taking the minority along to taste the food, yes.

Mr. BURGESS. And, of course, we are teasing about it, but I remember over there seeing some of those small farms that you talk about, the size of basketball fields. And at the time, the collective system was still very much up and running, but these were small individual plots that were allowed, and people were allowed to develop, as entrepreneurs, small farms.

There wasn't much in the way of automobile or truck traffic in 1993, but there was a lot of bicycle traffic. So there was, in my mind at least—and I wasn't a student of the issue by any means at the time. But you had these small farms that were irrigated and fertilized essentially by raw sewage. And that raised a host of questions. And then to get these products to market, they were put on the backs of these bicycles, in large baskets or things that would then run along the road, and all of the water, of course, whipped up by the bicycle wheel splattered up on the basket. And you couldn't help but wonder if a bacteria or two would find its way through the basket weaving. So I did wonder about that at the time.

So that is why I was interested if you found the problem was still, in fact, still present or maybe worse than what I saw.

Ranking Member Whitfield asked some questions about equivalency, which I think are particularly relevant to the discussions that we are going to have not only today but in the hearings to come, whatever legislative markups we have in the future. Why do you think there is no equivalency standard written into the Food and Drug Act?

Mr. NELSON. I mean, I think it is a matter of the way that the commodities have been treated historically. I think there are far more serious outbreaks regarding meat historically in the United States than there have been for other products.

Mr. BURGESS. Well, I have, I guess, a paper from the United States Department of Agriculture, the Food Safety Inspection Service Office of Internal Affairs. Under "definitions," equivalence is defined as a state wherein sanitary measures applied in an exporting country, though different from measures applied in the importing country achieve, as demonstrated by the importing country, the importing country's appropriate level of sanitary protection; hence, the term "equivalence."

That seems like a pretty reasonable standard that the USDA applies. Is there some problem from just a trade perspective that prevents us from having an equivalency standard in the Food and Drug Act?

Mr. NELSON. Well, we would cut off a substantial portion of food imports from the world if we had such a standard. The USDA is

here today and we invited them—Mr. Stupak invited them specifically so we could get a better understanding of the two systems.

Mr. BURGESS. Correct. And I am anxious to hear that—on page 14 of this document that has been provided to me. Paragraph 8, "equivalence verification," they give their equivalence triad a little description or drawing of how document analysis is balanced with port-of-entry reinspection, balanced with on-site audit. And that just seems so reasonable applied to what we are talking about today that would prevent problems. Yes, expensive perhaps, but we see the Japanese are willing to pay that premium.

And I have got to tell you, if I went to Kentucky Fried Chicken tonight and they said, You can have this bucket of chicken for eight bucks but you are maybe going to get sick, or you can buy this one for nine bucks and you will probably stay well, I'll take the $9 chicken, please.

It doesn't seem that from the consumer side—we sat here and saw just really moving testimony from the family whose daughter had the renal damage from eating the spinach, and that wasn't even an imported product. That, at least we were told, was grown in the United States. It was not imported. I have got to believe that consumers would go to the ends of the Earth not to bring bad products home to feed their family. I mean, it is not even common sense. I don't even think we would have to debate it.

Let me just ask you one question before my time expires. I am interested in the comment you make on the very last page of your testimony in talking about the Hong Kong—the methods they use there would not be viable even if the political environment were not a factor. How is the political environment a factor in the Hong Kong-type of regulation?

Mr. NELSON. Well, the Chinese Government generally, and the Guangdong Government specifically—which is a province across the border from Hong Kong—are very concerned that Hong Kong be stable. And bad food, particularly poultry coming in from China, destabilizes the—it is not a colony anymore—administrative district much more than they would like.

For example, the person with food safety responsibility in Hong Kong told us that if an import—and again, they test so much. If that 0.3 percent that is out of spec comes in and is just marginally out of spec, the central government in Beijing will shut down the ability of that food processor or that farm to ship to Hong Kong or anywhere else until the problem is taken care of.

Mr. BURGESS. Mr. Chairman, I know my time is up, but that is such an important point. They have the ability to hit the red button on the conveyor belt, stop the process so no one else gets sick. And really what I'd like to see, whatever we do legislatively, I want us to have that red button in this country for our consumers.

And I will yield back the balance of my time.

Mr. STUPAK. I thank the gentleman.

And country-of-origin labeling we have been trying to do since 2002. Hopefully the administration will allow that in, so we know if it is an $8 bucket of chicken or a $9 bucket of chicken, so we know.

Second, the poultry issue in Hong Kong and the Guangdong province is because of the bird flu and SARS and all the other

problems we face. Why is it there, but not in the rest of the world where it doesn't seem to be concerned about it——

Mr. BURGESS. I do need to make a comment about the country-of-origin labeling, because Dr. Hubbard addressed this. When you have got Canadian olive oil, unless global warming is a lot worse than I thought, you can't have Canadian olive oil if you have got appropriate country-of-origin labeling.

Mr. STUPAK. But you certainly wouldn't know where the poultry, the beast, the eggs and all the way down the line, where it comes from.

Mr. BURGESS. Country-of-origin labeling is meaningless because the——

Mr. STUPAK. Let the consumer decide.

Mr. BURGESS. If you have Canadian olive oil—clearly there are no olives grown in Canada. How can you have Canadian olive oil, again, unless Al Gore was absolutely right.

I yield back.

Mr. STUPAK. Ms. DeGette for questions.

Ms. DEGETTE. Thank you, Mr. Chairman.

Mr. Nelson, you had told several other members that you toured a food laboratory in Beijing, part of the China inspection and quarantine offices, one of those. I take it that those offices are roughly the equivalent of an FDA district or regional office with a lab; is that right?

Mr. NELSON. That is correct.

Ms. DEGETTE. Can you talk about what you saw at that food laboratory during your visit to that lab?

Mr. NELSON. Well, none of us here is a scientist, much less a food scientist. But as you are aware, we have been to a number of FDA labs during the course of this investigation, particularly those that the FDA has threatened to shut down, And we have some acquaintanceship with what the various and sundry machines look like. And the Beijing CIQ lab was equipped, the visual opinion of a nonscientist here, was equipped at least as well as any FDA lab we saw in the United States. And we have no reason to believe that their food scientists are any less qualified. The question is: Is Beijing atypical? And the response is "probably."

Ms. DEGETTE. It is atypical?

Mr. NELSON. Yes.

Ms. DEGETTE. And why do you say it is probably atypical.

Mr. NELSON. Because everyone—not everyone. People we talk to in the U.S. Government or our multinational corporations that have businesses throughout China that have knowledge of the way things operate throughout China believe that the quality of inspection, the quality of sampling, the quality of regulation varies widely among the provinces.

Ms. DEGETTE. How many of these labs are there throughout China?

Mr. NELSON. The Ministry of Agriculture told us there were 323 labs capable of certifying that food meets international standards. When we got talking to the AQSIQ, they reduced that number to 50.

Ms. DEGETTE. What is the AQSIQ?

Mr. NELSON. That is the agency in China responsible for food exports.

Ms. DEGETTE. And what did they say?

Mr. NELSON. They said 50.

Ms. DEGETTE. Fifty. And you don't have any idea what the staffing levels or the technological levels of those offices are?

Mr. NELSON. No.

Ms. DEGETTE. Now, did you talk to the Chinese about the problems we have been having here, in particular the melamine and the wheat gluten? Any of you? Mr. Barstow?

Mr. BARSTOW. Yes.

Ms. DEGETTE. How did they explain that? Mr. Wilfong.

Mr. WILFONG. Yes, ma'am. The wheat gluten—we had a long discussion with AQSIQ, with Vice Minister Wei, and it was repeatedly brought up that while China is willing to certify—they are willing to certify their food exports, which they require all their food exports to be certified, tested and certified as food, the wheat gluten incident, the melamine and wheat gluten was a way since the U.S. doesn't recognize the certification, the FDA doesn't require it for imports from China, so therefore it is not looked for on the paperwork on this end. The wheat gluten was actually exported from China as industrial use.

Ms. DEGETTE. So they didn't consider that to be food? Is that what you are saying.

Mr. WILFONG. On their end it was exported as industrial use, not as food. And then the disconnect between the two systems on this end—since that certification isn't required and looked for for a food import on this end, it was actually imported as a food product;.

Ms. DEGETTE. So it was a problem in the two countries' standards in what it was called and what was required to be reported?

Mr. WILFONG. Yes, ma'am. And that is their main contention, is that they are willing to certify that there are exports of food, that they do certify all food they export. Yet our lack of recognition and requirement for these certifications leaves a big loophole for valid companies to actually import into the United States or export to the United States.

Ms. DEGETTE. They say that is not their problem if there is a loophole. That is not their problem.

Mr. WILFONG. They recognize the problem. We probably had a 1-hour discussion with the vice minister and they brought it up three times, that they really wish we would recognize their certifications. They are doing their work on their end; we are just not requiring that certification paperwork on our end.

Ms. DEGETTE. Yes. I mean, what about the processing system? I mean, that is at the lab. What about coming up to the export level?

Mr. NELSON. What their system is—and we watched this in the Beijing CIQ—an export certificate has to come from a farm or food processor that is approved, registered and approved for exporting, and that requires some form of local inspection. So only a certain number of entities can bring a request for an export certificate to the CIQs. And allegedly, a CIQ inspector samples the proposed lot from the lot, brings it to the CIQ laboratory where it is then tested to both Chinese and international standards. If it meets those

standards, it is granted a certificate and that information is transferred electronically to the proposed port of exit so that people can feel assured that what has been tested is what gets loaded.

Now, if the system worked like that, it is a very safe, closed system. No one that we talked to in the industry really thinks that it works that well. But it certainly works better than products that are exported from China without those certificates.

Ms. DEGETTE. Thank you. My time has expired.

Mr. STUPAK. Thanks, Ms. DeGette. Mr. Inslee for questions, please.

Mr. INSLEE. Thank you. I appreciate Ms. DeGette's questions about this not accepting or reviewing the Chinese certification process, which apparently was one reason for the melamine problem, because there is a disconnect.

What possible reason is there for us not requiring at least that? Even if the Chinese system internally is ineffective, or at least not totally proficient, why wouldn't we at least require their certification process to be complied with before we accept any product that could end up in our food chain here? Does that make any sense?

Mr. NELSON. No. We posed that question to some of the people that are engaged in negotiations, with HHS on FDA's behalf, with China right now. And the responses we got were, Well, we might not want to exclude small farms and small processors from exporting to the United States; that somehow or another that was ideologically unacceptable; and the Chinese could use it, possibly to exclude American firms that wanted to set up operations in China for export to the United States. These were some of the excuses. But we have FDA witnesses. You best put those questions to them.

Mr. INSLEE. But these are excuses by our side of——

Mr. NELSON. By our side.

Mr. INSLEE. Do we do that in any other context for other countries? To me it is difficult to understand in any country that has any regulatory system, to not at least allow that minimal level of inspection to require that. Do we do that in any other context?

Mr. NELSON. None comes to mind. What's important about the certification system in China is that it excludes almost all producers—it is a very small percentage of farms and food processors that qualify for those export certificates. It doesn't mean that the food they produce is going to be 100 percent safe or 100 percent inspected, as the Chinese Government maintains it is. But at least you are not getting it from the 90, 95 percent of the food industry in China that doesn't go through the system.

Mr. INSLEE. And do you sense one of our failures to require that is actually some fear that American firms would be disadvantaged somehow?

Mr. NELSON. That is one of the excuses that we heard. I don't think that the administration has really thought this through. At least the people we were talking to didn't seem to be aware of how the system works, for example.

Mr. INSLEE. If you were going to rank the top three priorities from your experience in China for us to adopt, where would you put them?

Let me ask it a little easier. The most cost-effective. Tell us, from your observations, what would be the three most cost-effective things we could do to tighten this net?

Mr. NELSON. As an economist, I'd tell you, first, you would have to tell me how you value safety. If you put a high value on safety, the system that we heard about that the Japanese employ appears to be a far safer system than we have, because they actually have government inspectors going to a limited number of plants who produce food for the Japanese market. So those plants are not only part of this Chinese certification system, they are also part of a Japanese inspection system.

And then Japan, on top of that, does 15 percent laboratory testing of the imports. That is a pretty expensive proposition both in terms of the government resources involved in Japan and in terms of the prices of these products in China.

One of the real problems with toys or food or anything else in China is the incessant downward pressure to get cheaper and cheaper and cheaper. And we are dealing with entities, people that are living at the margin. That means that niceties, like the downside safety effects of what they do, get less and less important. And what the Japanese system does is—as far as I can tell—as it has been described to me—is create some pretty valuable franchises, franchises whose prices can't be depressed. So there is a price effect to that. There is a price premium and food is more expensive, I understand, in Japan than it is here. And they get a lot of it from China.

Mr. INSLEE. Thank you.

Mr. STUPAK. Thank you, Mr. Inslee. Mr. Waxman for questions, please.

Mr. WAXMAN. Thank you, Mr. Chairman.

Mr. Nelson, does China treat the food that is going to be consumed domestically differently than the food that is going to be exported?

Mr. NELSON. That is what we are told.

Mr. WAXMAN. What do they do differently for the exported food?

Mr. NELSON. For the exported food, they tell us they inspect every lot, that they largely come from HACCP-controlled plants, which means there is an ongoing testing program at various stages of the production process, and that they sample every lot and test it in a government lab to both Chinese standards and the standards of the country to which it is to be sent. And certainly that is not done for the domestic food.

Mr. WAXMAN. This is what they tell you they are doing for the exported food. Do you believe it?

Mr. NELSON. We couldn't find anyone that thinks that that practice is universal throughout China. But I think that the Chinese Government certainly wants that system. The AQSIQ wants that system to function well.

Mr. WAXMAN. They want it to function well. But you cannot testify to us that it is functioning well?

Mr. NELSON. That is right. All of this is done at the local level and the quality of the local officialdom, we are told, varies widely.

Mr. WAXMAN. I'm really stunned by the amount of imports that we are taking into the United States. In 2005, 84 percent of all fish

and shellfish consumed in the United States was imported; 54 percent of all tree nuts, 43 percent of all noncitrus fresh fruit, 37 percent of all processed fruit in the U.S. were imported in the same year. That is not just from China; that is from other countries as well. Is China better or worse than some of these other countries where we are importing food?

Mr. NELSON. We haven't been to other countries, but to the extent that you can rely on FDA's very small sample, China is in the top three. Virtually all categories for rejected food. But it is not the top one. We reject more food from India. We reject more food from Mexico.

Mr. WAXMAN. We have to rely on our Food and Drug Administration here in the United States when it comes to these agricultural products, including fish. One of the proposed alternatives that we have pending in the Congress is to have the FDA see whether a country has a certification process that would indicate that it is checking the safety of the food that might be imported. And it appears that China claims that they have such a system, but it doesn't sound like one we can rely on. Is that where you come down on that issue?

Mr. NELSON. From the evaluation of the investigation we have done today, yes. But a certification system, an evaluation of equivalence, anything like that would require far more work than we have done. The legislation that we are considering in the committee not only requires a certification for the country's evaluation of the safety, but if that is not adequate enough, then the Food and Drug Administration could go to each individual farm. Is that what it would be? Or a processing plant? What would we then do if the country didn't meet the standards?

Mr. NELSON. Without commenting on the legislation per se, which is not our assignment, we would need a lot more people if we were going to adopt a Japanese-like system of going over and inspecting every plant that was going to be shipping food to the United States from China. And that is just China. I mean, there is still the Dominican Republic, there is still India, there is still Mexico.

Mr. WAXMAN. So, when we hear about 15 percent of all food consumed in the United States is imported, the American consumers assume that they are taking on the risk because we are not confident that the food that is brought into the United States is safe?

Mr. NELSON. Consumers are taking that risk. They also take risks with food that is produced here. Almost all of the really, truly serious outbreaks last year, that you experienced in 2007, has come from domestically produced food. Now, part of that is great good fortune, and the good fortune was that wheat gluten was intended for pet food and not human food. If it had been put in the human food supply, I don't think the statistics would be the same.

Mr. WAXMAN. Thank you, Mr. Chairman.

Mr. STUPAK. Mr. Melancon for questions, please. You have some extra time also.

Mr. MELANCON. Thank you, Mr. Chairman. I appreciate the time. And I come from an agriculture background. And one of the things I have attested to on all of these free trade agreements is that we have taken away the authority of the Congress to govern or oversee

the commerce in this country. And now it has taken us to have hearings about food safety, when we had the safest food supply in the whole world until the time we started giving away that entity, I guess, to foreign producers.

I have a lot of seafood in my district, as you are quite aware. I believe in country of origin labeling. It is as complicated as putting produced or grown and produced in whatever country or State it was, and bottled and shipped from whatever State it is, and those computers do that quite easily these days. So I don't think it is such a complicated task to ask for that.

On seafood, does Hong Kong allow seafood from China with any evidence or traces of antibiotics into their country?

Mr. NELSON. No. And they also very much limit the ports of entry. And they take one added step. Hong Kong is China. I mean, the stuff is coming down from the Pearl River. So they limit the imports to two piers, and they have gone to a system where not only does the stuff have to be certified at the fish farm, but they put a net over the hold and physically seal it, like you would seal a container in order to prevent bad fish from being substituted for good fish along the way.

The mainland Chinese—the PRC and the Hong Kong Government are very, very sensitive to the quality of food that is imported into the administrative district.

Mr. MELANCON. It kind of sounds like the piece of drum I had the other night that was called Chilean sea bass. And there is a distinct difference between the two. But I guess they figure that most people wouldn't know. When the farm-raised fish, the farm-raised shrimp, the produce that comes into the United States from China—or from any other country for that matter—we have a limited—well, we have an enormous number of ports, as I appreciate it, that will accept imports, whether it is agency-tested, or take samples or not.

How many do we have in this country for food or seafood imports? Do you know?

Mr. NELSON. Well, there are 321, as we understand it. Customs mans 321 ports of entry.

Mr. MELANCON. And I understand in Europe they will send back, or not allow into the country, food that doesn't meet their standards. They have limited, I believe, the number of ports that foodstuffs can come through in the European Union.

Mr. NELSON. I don't know.

Mr. MELANCON. Do you know how many ports they may have for importation into the European Union.

Mr. NELSON. No.

Mr. MELANCON. I'm trying to get an analogy for myself, because we have in the United States the importers all up in arms because you want to constrain where you bring your foodstuff in, which they all want to bring it in wherever they want to bring it in. Those that don't want to abide by the rule, obviously because they are not going to get tested, and they will get it in. I saw a copy of an ad for a firm that was advertising, "If you have been rejected by FDA, get in touch with us; we can help you market your seafood."

Is that a repackaged resell, or is that they are going to send it to another country?

Mr. NELSON. Well, it could be they are a laboratory that is going to assure the importer gets the kind of results that will get through the FDA system. Back in June, the FDA issued an import alert. And that import alert covered five varieties of fish, one of which is shrimp; so four varieties, and shrimp from China for antibiotic and possible fungicide, malachite green contamination.

Now, the Chinese, when we were over there, kept telling us that this was awful, that it was going to cost them $500 million because we were banning the import of fish. And I don't think they had any appreciation of how lax the regulations regarding import alerts are, and we had to explain to them that nothing was being banned. In fact, the fish were going to exactly the same place, that they would go through without an import alert. That is to say, they were going to be delivered to the importer's premises, at which point the importer is required to have the fish in this case tested to see whether or not it is contaminated with antibiotics or malachite green.

And any source from China, not the country but the processing plant, the entity that is exporting, if they pass muster on these private lab tests five times, then they are off the import alert and can bypass the requirement of private laboratory testing.

But we have become very, very skeptical about laboratory testing for a lot of reasons—private laboratory testing for a lot of reasons, and our skepticism is growing.

Mr. MELANCON. It wouldn't have anything to do with you get what you request when you pay?

Mr. NELSON. We have heard there are laboratories that don't find products—fish, produce, whatever they are testing—ever to be out of compliance. And then we find other laboratories that do something we would never allowed in the drug area. If a drug company did was a clinical study, the efficacy didn't show up, or the safety problems developed and they told the people doing the study to throw it away, they would be in very serious trouble, both the clinicians that were doing the study and the sponsoring company.

But apparently there is no real penalty, and it is in fact, we are told, a practice within the food system that if a private laboratory gets a result that the importer doesn't like, that they work not for the FDA—in fact, they were not inspected or certified or in any way controlled by the FDA—they have nothing on the line. The FDA can't even ban them from being used by these importers. They work for the importer, and if the importer tells them to put the test results in a dust bin and just send them a bill, that is very common practice.

Mr. MELANCON. Do we in this country have the ability to get away from the contractors' lists and utilize universities, would that give us more credibility in the results? If, in fact, we are not able to stand up enough labs because of the cost, are there enough universities that could take samples and do the work for us, and do you think the integrity of the tests would be pretty upstanding?

Mr. NELSON. We do use universities in what is called the FERN system, and the FDA does contract with universities to do some of the testing now. And those universities are qualified, the ones that are in the system, to do testing of—particularly involved in——

Mr. MELANCON. Is there a standard regimen of tests they are required to make when they are a contractor?

Mr. NELSON. FDA witnesses are coming up. I'd suggest if you want the specific details you talk to them about it. We do use universities, though.

Mr. MELANCON. One more question. Does Hong Kong use private contractors or is that state-run?

Mr. NELSON. No. That is all government labs. They, of course, don't have to maintain all the other governmental expenses that we do.

Mr. MELANCON. Thank you, sir.

Mr. STUPAK. Thank you, Mr. Melancon. Mr. Green for questions.

Mr. GREEN. Thank you, Mr. Chairman.

First I'd like to thank our investigators for spending part of their August in China. Having been there once, but having both family and friends who have gone there to spend a lot more time in doing work like what you do, it is probably not as pleasant as what we did in just meeting with officials.

One of the interests I have is comparing what, for example, Hong Kong and Japan is doing with—Hong Kong actually has a vigorous inspection system, whereas Japan actually has the preferred importers, so to speak, I guess they investigate what they do in China, for example. Does the Japanese, though, have a food inspector at every port of entry that brings in food or is authorized to bring food in?

Mr. NELSON. That is my understanding. We are very fortunate, in the next panel, of having people with a lot of expertise on Hong Kong and Japanese and Chinese regulatory systems.

Mr. GREEN. One of the interests I have, though, is I note for example, the testimony we will hear in a few minutes is that FDA has inspectors at 90 ports now, and USDA has it at 140 ports, both land and ocean, and yet FDA has 80 percent of the responsibilities as compared to the USDA which has 20 percent. I would assume that the countries that you looked at would have that percentage reversed; you would actually have more inspectors for the food that the FDA would do under ours as compared to the Department of Agriculture. But anyway, that is just a question, and I will wait until our next panel.

You mentioned the Chinese efforts to strengthen the safety of imports through what's called a red list and a black list. And can you talk about the effectiveness of that red list and black list in rooting out some of the bad actors? Was that part of your investigation?

Mr. NELSON. We talked with the AQSIQ about the systems. They listed it as one of five essential parts of their program for guaranteeing the safety of the food exports. They told us that there were 55 firms on the black list, which, given the press reports of what happens to people when the Government of China is truly upset with them, is a list I wouldn't want to be on. It was not clear what the preferential treatment for the good actors was.

Mr. GREEN. Another question is the export certificates are certificates granted at the local level? And the political situation I know varies from province to province and there has always been a geopolitical question about how much the central government controls in some of the provinces as compared to the local officials.

Can you speak to any of the concerns about corruption? Is there any particular—that the Federal Government may not actually have the apparatus to make sure those export certificates are valid when they are issued by the local government.

Mr. NELSON. Except for the power to yank a firm's ability to acquire an export certificate, all of the decisions are made on a local level. I mean, if a firm gets caught exporting something out of spec, then the Beijing Government will yank their authority to export until the problem is solved. But they don't do any of the inspections, they don't control any of the budgets.

The rubber meets the road at the local level, and we are told that that varies widely. Some provinces like Guangdong have apparently very effective CIQ systems. The province that is immediately across the sea from Japan that sends a lot of the produce on a just-in-time basis to Japan apparently has a fairly good regulatory system, but other provinces may not.

Mr. GREEN. Mr. Chairman, one last question, I guess, is that if produce is exported to Hong Kong, it is rigorously inspected, is there any transshipment of that produce? Could Hong Kong, because of their rigorous system, be someplace that would be a preferred export port, for example, because of their effort as compared to the other ports in China?

Mr. NELSON. I don't think Hong Kong exports food. They import 95 percent of the food they consume. And almost all of that is from China. I mean, you can get French wine, you can get some form of Iowa beefsteaks without the bone. But they are not a food exporter.

Mr. GREEN. Thank you, Mr. Chairman.

Mr. STUPAK. Thank you, Mr. Green.

If anyone else has questions, we will just do another quick round here. You mentioned a couple of times the AQSIQ. That stands for the Administration of Quality, Supervision, Inspection and Quarantine?

Mr. NELSON. Yes.

Mr. STUPAK. Mr. Barstow, when you met with Chinese officials, what was their opinion about the concerns Americans have concerning the quality and safety of Chinese food?

Mr. BARSTOW. The AQSIQ said they had been studying the concerns that Americans have, and the exported food problems are perceived to come from China. And they came up with three conclusions.

The first conclusion was that there are some real safety and quality problems in China. The example they cited for this conclusion was the melamine in wheat gluten. They said when this kind of problem happens, they are dealt with according to law and regulations. In the melamine case, they said that they shut down the factories as soon as they learned about it and that they filed suit against the two companies that were responsible.

Mr. STUPAK. Did you ask why they wouldn't let the FDA inspectors in to check these melamine plants?

Mr. BARSTOW. That is another issue.

Second, they said that there are different international standards that create problems. In this conclusion, they cited the toothpaste example. Earlier this year, toothpaste from China was found to

contain diethylene glycol, or DEG. In China, it is permitted to be present in up to 15.6 percent of toothpaste there, and international standards said that DEG could not be in any toothpaste. China said that there were no real safety problems with DEG in toothpaste but they succumbed to international pressures and now banned its use.

However, that still doesn't explain why the DEG was listed as glycerin, which is the harmless ingredient that it replaces.

Third, they said that they believed the Western media, particularly the media in the United States, has blown the safety and quality problems out of proportion. They believe press reports have been unfair.

Mr. STUPAK. Thank you.

Mr. Nelson, at the last food safety hearing, we spoke about the FDA food import alerts, specifically import alerts that contained the instruction, "detention without physical examination."

Remind us again, what does that mean, "detention without physical examination"?

Mr. NELSON. I think all import alerts contain that. It means that the product goes to the importer's premises. And before it can be released into the commerce of the United States, the importer has an obligation to prove to the agency that it is nonviolative. That is done by the importer contracting with a lab to test it.

Mr. STUPAK. So the FDA doesn't take control of it. They don't send their inspectors in. The processor or the importer has the food, and then he hires a private lab to test the product?

Mr. NELSON. That is overwhelmingly the case.

Mr. STUPAK. At the last hearing you spoke about port shopping and how some importers choose to shift their products to places without FDA inspectors or labs, and how some importers try to get around the import alerts. Have you learned of schemes being used?

Mr. NELSON. The one that was most disturbing was in talking to people about private labs. An issue arose as to whether not only—foods under import alert, but the surveillance testing that the FDA does, the more randomized testing of imports coming into the United States, there was a proposal that that be contracted out to private labs. So we have been talking to people in private laboratories. And the most shocking thing that we have learned is that there is no apparent ethic within the community nor is there any regulatory concern about taking negative results, results that would indicate the food is contaminated or decomposed or otherwise unfit for human consumption, and just discarding them if the importer gives them that instruction.

Mr. STUPAK. If the Chinese Government says they certify their labs and they certify these farms and things like this, does the FDA certify the labs that the importers use to check the results or for suspicious——

Mr. NELSON. Neither the FDA or any other governmental agency.

Mr. STUPAK. So these labs are unregulated. They work for the importer and basically they get the results that they pay for?

Mr. NELSON. Right. The FDA does audit. I doubt whether it is significant. We have asked them what percentage. I suspect it is very small. But the audits are largely an audit of the paper. It is

not an audit of the lab or its capacities to produce the results that they claim to produce.

Mr. STUPAK. You mentioned on drugs it does not occur. Are those labs certified by the FDA for drug imports?

Mr. NELSON. Those labs—well, actually not necessarily. University labs certainly are well supervised, and some of the other labs that are used by drug companies for testing are not anything more than doctors' offices, and some of them are even done overseas now. But if a drug company gets caught cheating, the FDA treats it as a criminal offense with serious consequences for the individuals involved.

Mr. STUPAK. What happens if a food importer gets caught cheating at these labs?

Mr. NELSON. Nobody asks whether the food importer cheats or not.

Mr. STUPAK. So no one inquires?

Mr. NELSON. No.

Mr. STUPAK. And, of course, your teams work on food safety issues. I brought up last time other areas of concern, particularly when we uncovered evidence of questionable compensation at the FDA. Have you uncovered other questionable practices?

Mr. NELSON. One of the practices which is detailed in—well, the FDA information was received so far from—it has been placed in the exhibit book and presumably into this record, as well as into the record of the last hearing.

Mr. STUPAK. Tab No. 35.

Mr. NELSON. Yes. It involves the abuse of the concept of religious compensation, a concept where people are allowed to work some overtime, so that they can take a religious holiday every now and then, without taking vacation time. This has been grossly abused in some cases.

Mr. STUPAK. All right. I mentioned that we're going to have a hearing on November 1 on drug imports, and November 13 on domestic food again. You and your team will continue to work on these issues, plus compensation issues at the FDA; is that correct?

Mr. NELSON. That is our instruction.

Mr. STUPAK. Thank you and thank you for your investigation.

Mr. Whitfield, any questions? Mr. Green any questions? Mr. Melancon.

Mr. MELANCON. I am back on seafood. Does China allow a high concentration of antibiotics in their seafood domestically than we do in the U.S.?

Mr. NELSON. Certainly more than we do. I don't know whether it would be considered high. But we don't permit it.

Mr. MELANCON. But we don't permit it, but we don't check it?

Mr. NELSON. We haven't been doing a very good job of it. The FDA has known about this problem since 2000, 2001. But they didn't act on a countrywide basis until June 2006, about a month after the first letter came from the subcommittee requesting information about their regulation of seafood imports.

Mr. MELANCON. And we talked about shipping products and the problem of different countries, different regulations and guidelines and whatever. Don't you think it could be done, particularly in these trade agreements on a WTO level, if we are going to do it

on a level playing field, that we have a minimum requirement for all countries, and then each country has its own specific requirements that these things can be adjusted or adhered to if these countries want to export their products to countries that have higher standards?

Mr. NELSON. They're supposed to meet our standards for entry and they are supposed be denied entry if they don't meet our standards. That's the law.

Mr. MELANCON. But there are no teeth there to get them if they don't?

Mr. NELSON. We don't have the resources to do the inspections and the testing that we need to assure that the problem is under control.

Mr. MELANCON. Thank you. Thank you, Mr. Chairman.

Mr. STUPAK. Mr. Burgess, we have been going around with last-minute questions of this panel before we excuse them. Do you have any further questions of this panel.

Mr. BURGESS. Yes, Mr. Chairman. Thank you.

For a point of clarification, Mr. Nelson, when you talked about the FDA testing only a fraction of what they inspect, you made the statement they don't test enough and that there was no confidence in their statistical standards. Did I understand that correctly?

Mr. NELSON. Yes, sir.

Mr. BURGESS. I'm not a statistician and I'm not really a student of statistics. But from the very brief and unfortunate association I had with the study of statistics in college and graduate school, I recall that there were some scientific tests and some scientific standards by which you could assure yourself or—you didn't just pick a sample size out of the air. There were actually formulas that could be followed to arrive at a statistical number over which you'd have a certain degree of confidence. So are you telling us that the principles of statistics are not being applied in the metrics that are used in our inspection facilities?

Mr. NELSON. Not only are the principles of statistics not being applied, we have seriously degraded the percentage of imports that we have tested for the last two decades.

Mr. BURGESS. But there should be someone—not up here on this dais—but someone who knows statistics, who is able to advise our FDA on what is the sample size you should be testing and what are the confidence limits that you can then project from that sample size you've tested. Is that not correct?

Mr. NELSON. Theoretically.

Mr. BURGESS. In your observation, were those statistical methods not applied?

Mr. NELSON. The sample size is so small relative to the size of the imports that I think probably you can't generalize across all food imports.

Mr. BURGESS. But we shouldn't have to intuit whether a sample size is too small, just right, or too large. Someone, presumably, who knows the science of statistics, should be able to tell us this is the sample size that should be tested if you want these confidence limits on the results that you are seeking.

Mr. NELSON. I have seen that for drug safety, actually. There have been some articles in journals published in the last year on

drug safety as a whole in the United States. I have never seen it done for food.

Mr. BURGESS. But again, presumably, the science of statistics has developed enough where someone would have this information and be able to share it with us.

Mr. NELSON. Quantitative risk assessment is possible. The data isn't there.

Mr. BURGESS. Well, whether the data is there or not from the FDA standpoint, someone should be able to tell us if we are doing not enough, if we are doing just right, or if we are doing too much, as you may think in Hong Kong. Someone should be able to rationally tell us what the sample size is we should be testing. We shouldn't, again, be making that up as legislators. We shouldn't be asked to make that up on the basis of emotion, this looks right, this looks too small. Someone should be able to tell us scientifically what the number is. That would be my estimation.

Thank you, Mr. Chairman. I will yield back.

Mr. STUPAK. Thank you, Mr. Burgess. With no further questions, we'll excuse this panel. Thank you, gentlemen, for your work.

And I will call our second panel of witnesses to come forward. On our second panel we have Dr. Michael Martin, who is an analyst in Asian political economy at the Congressional Research Service. Mr. James Rice is vice president and country manager for Tyson Foods in China.

It is the policy of this subcommittee to take all testimony under oath.

Please be advised that witnesses have the right under the rules of the House to be advised by counsel during their testimony. Do any of you gentlemen wish to be represented by counsel at this time?

Let the record reflect that both witnesses indicate that they do not.

[Witnesses sworn.]

Mr. MELANCON [presiding]. Let the record reflect the witnesses replied in the affirmative. You are now under oath.

Dr. Martin, would you like to start with the opening statement for 5 minutes?

STATEMENT OF MICHAEL F. MARTIN, ANALYST, ASIAN TRADE AND FINANCE, FOREIGN AFFAIRS, DEFENSE, AND TRADE DIVISION, CONGRESSIONAL RESEARCH SERVICE, LIBRARY OF CONGRESS

Mr. MARTIN. Chairman Stupak, Ranking Member Whitfield, distinguished members of the subcommittee, thank you for the opportunity to appear before you today. With your permission I would like to submit my statement for the record and provide you with a brief summary of its contents.

You have asked me to testify on how Hong Kong and Japan ensure the safety of their food imports from mainland China. While concern about the safety of food imported from China has arisen in the United States in 2007, this issue has been important to Hong Kong and Japan for a number of years. In December 1997, Hong Kong slaughtered over 1.5 million chickens to combat an outbreak of avian flu that claimed the lives of six people. Virtually all

those chickens had been imported from China. In July 2002, Japan banned the import of frozen spinach from China after several shipments were found to contained an unacceptable level of pesticides. Prior to the ban, China had supplied Japan with 99 percent of its imported spinach.

As a result, the Hong Kong Government has been aware of the issue for at least 10 years and the Japanese Government has been aware of it for at least 5 years. Food imports from China are of particular concern to the Hong Kong and Japanese Governments because China's an important source of food. China supplies Hong Kong with about 80 percent of its food and Japan with more than 10 percent of its food, second only to the United States.

Under Hong Kong law, the primary responsibility to ensure the safety of all food imported or domestically produced is placed in the Hong Kong Food and Environmental Hygiene Department in its recently established Centre for Food Safety. In 2006, the Centre for Food Safety was given specific responsibility for planning and implementing Hong Kong's food safety policies, negotiating and managing relations with overseas food authorities, including China, and consulting with the businesses and people of Hong Kong about its food safety system.

Over the last 10 years Hong Kong's Food and Environmental Hygiene Department and its mainland China counterpart have agreed to a set of administrative procedures to ensure the safety of food shipped to Hong Kong. These special procedures include joint visits to farms and food production facilities in China, technical exchanges and frequent meetings to discuss food safety issues.

In order to expedite inspection, Hong Kong limits the number of points of entry for imported food. Failure to comply with Hong Kong's laws and regulations governing the imported food is punishable by up to 6 months in jail and a maximum fine of about 50,000 Hong Kong dollars, or about 6,400 U.S. dollars.

In 2006, the Centre for Food Safety took over 64,000 samples for microbiological and chemical testing. The overall failure rate was 0.3 percent. However, in its latest report, which covers from July until August 2007, the center found a slightly higher failure rate of 0.6 percent. Neither report indicated what percentage of the imports were tested.

Turning to Japan, the Food Safety Basic Law disseminates the enforcement of food safety throughout Japan's federal, provincial and local governments. In general terms, the federal agencies handle food safety enforcement for imported goods and the provincial and local governments focus their efforts on domestic enforcement issues. The Food Safety Basic Law also created the Food Safety Commission, a cabinet-level independent agency that overseas the government's activities on food safety.

Food imported into Japan is subject to inspection by roughly 300 inspectors located at 300 quarantine stations. Inspections cover over 300 food products, nearly 800 agriculture chemicals and include nearly 55,000 inspection criteria. Between April and September 2006 the ministry inspected 10.3 percent of the shipments, 0.7 percent were found to be in violation of Japanese law. The most recent amendment to Japan's food sanitation law raised the highest

penalty for violation of the law to up to 3 years in jail or a fine of up to 3 million yen, approximately 26,000 U.S. dollars.

Relations between Japan and China on the issue of food safety take place in two separate arenas, government-to-government relations and company-to-company relations. On the government-to-government side, Japan has negotiated over 30 separate agreements with China, specifying equivalency standards for the range of food items. Under these agreements, Chinese health officials certify that specific farms and food production facilities meet the agreed standards. In Japan, food shipments from these certified Chinese farms and facilities are afforded preferential treatment to imports from noncertified farms and facilities. As a result, on the business-to-business side, Japanese importers tend to source their food products from the certified farms and facilities, often offering a higher price for the goods in order to lower the risk of shipments being inspected or impounded.

Based on the preceding summary as well as my written testimony, I would like to offer four somewhat interrelated observations. First, collaboration generally has been used more than confrontation. Part of the overall strategy of Hong Kong and Japanese food safety officials when dealing with their mainland Chinese counterparts seems to be focusing on the shared issue of protecting people from unsafe and unsanitary food.

Second, the carrot has been used more often than the stick. In their dealings with Japanese officials and businesses, both Hong Kong and Japan appear to have adopted an approach of providing incentives for the Chinese Government to cooperate rather than penalizing failures to comply.

Third, food safety is not simply a matter of laws and regulations. Another element of the Hong Kong and Japanese approach to food product safety is the apparent focus on creating incentives for businesses to comply with the laws and regulations. Both Hong Kong and Japan seek to create an environment in which it's in the best interest of the Chinese food producers and exporters as well as the Hong Kong and Japanese food importers to make sure that the imported food are safe and sanitary.

Fourth, no system is perfect. No matter how well designed the policy or how well the policy is implemented, it is impossible to guarantee that every morsel of imported food, whether it's from mainland China or some other location, is 100 percent safe and sanitary. The Hong Kong and Japanese Governments have food safety policies in place but they both continue to experience problems with tainted and unsafe imported food products.

Chairman Stupak, Ranking Member Whitfield, distinguished members of the subcommittee, this concludes my statement. Thank you again for the opportunity to testify on these issues. I will be pleased to respond to any questions you might have.

[The prepared statement of Mr. Martin follows:]

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HOUSE ENERGY AND COMMERCE COMMITTEE

WRITTEN TESTIMONY OF

MICHAEL F. MARTIN

ANALYST IN ASIAN POLITICAL ECONOMY

CONGRESSIONAL RESEARCH SERVICE

BEFORE THE

HOUSE ENERGY AND COMMERCE COMMITTEE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

HEARING ON

DIMINISHED CAPACITY: CAN THE FDA ASSURE THE SAFETY AND SECURITY OF THE NATION'S FOOD SUPPLY? - PART III

OCTOBER 11, 2007

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HOUSE ENERGY AND COMMERCE COMMITTEE

Opening Statement

Chairman Stupak, Ranking Member Whitfield, distinguished members of the subcommittee, thank you for the opportunity to appear before you today. I am Michael F. Martin, Analyst in Asian Trade and Finance, of the Congressional Research Service. I ask that my full, written statement be included in the record.

As requested, this statement provides observations and analysis on how the governments of Hong Kong[1] and Japan seek to insure the safety of food products imported from mainland China. To a limited extent, I will comment on possible lessons the United States may be able to learn from the practices of Hong Kong and Japan. However, my area of expertise does not include current U.S. food safety policy, and I would defer to the analysis of my colleagues at CRS and other experts in the field on the strengths and weaknesses of the present U.S. food safety laws, regulations and practices.[2]

Also, before I begin my testimony, I would like to thank the Japanese embassy and the Hong Kong Economic and Trade Office in Washington, D.C. for their help and assistance in learning more about their government's food safety policies. Any analysis or opinion expressed in this testimony are my own in my capacity as an analyst at the Congressional Research Service, and should not be construed or inferred as a reflection of the views of the Japanese embassy or the Hong Kong Economic and Trade Office unless directly attributed to those entities.

Importance of the Food Safety Issue

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[1] For purposes of this testimony, the term "Hong Kong" will be used to refer to the "Hong Kong Special Administrative Region."

[2] For information on the U.S. regulatory system for imported foods, see CRS general distribution memorandum of July 26, 2007, "Survey of Statutory Authorities Involved in Import Safety," and CRS Report RS22664, *U.S. Food and Agricultural Imports: Safeguards and Selected Issues*, by Geoffrey S Becker.

There has been extensive press coverage and public concern about the safety of food imported from China this year.[3] In May, the U.S. Food and Drug Administration, or FDA, began the recall of a wide range of pet foods because wheat and rice protein imported from China – which was added to pet food manufactured in the United States – had been adulterated with melamine, leading to the death of hundreds of cats and dogs.[4] According to the FDA, some of the tainted protein was used as feed for livestock and fish that were eaten by U.S. consumers, but the assessed risk to human health was deemed small.[5] In June, the FDA announced it was detaining all imports of farm-raised seafood from China because of their concern that these goods may contain unsafe drug residues.[6]

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[3] For more information on the issue of U.S. food safety and imports from China, see CRS Report RS22713, *Health and Safety Concerns Over U.S. Imports of Chinese Products: An Overview*, by Wayne M. Morrison and CRS Report RL34080, *Food and Agricultural Imports from China*, by Geoffrey S. Becker.

[4] For details on the recall of pet food tainted with adulterated Chinese wheat gluten, see the FDA web page: [http://www.fda.gov/oc/opacom/hottopics/petfood.html#situation].

[5] "Joint Update: FDA/USDA Update on Tainted Animal Feed," U.S. Food and Drug Administration press release, April 27, 2007.

[6] "FDA Detains Imports of Farm-Raised Chinese Seafood ," U.S. Food and Drug Administration press release, June 28, 2007.

Events such as the preceding have apparently raised public concern about the safety of food in the United States, and particularly the safety of food imported from China. In a joint Reuters/Zogby poll of over 1,000 U.S. consumers conducted in mid-September, about 78% of the respondents "worry about the safety of Chinese imports, and a quarter have stopped buying food from China."[7] In a similar poll conducted in June by Consumers Union, the publishers of *Consumer Reports*, 92% of the over 1,000 respondents stated that they wanted to know the country of origin of the food they are buying.[8]

Food Safety Is Not a New Issue in Hong Kong and Japan

While concern about the safety of food imported from China has arisen in the United States in 2007, this issue has been important to Hong Kong and Japan for a number of years. In December 1997, Hong Kong's Agriculture, Fisheries, and Conservation Department slaughtered every live chicken in the city – over 1.5 million chickens – to combat an outbreak of avian flu that claimed the lives of six people.[9] Virtually all of those chickens had been imported from China. In July 2002, Japan banned the import of frozen spinach from China after several shipments were found to contain unacceptable levels of pesticides.[10] Prior to the ban, China had supplied Japan with 99% of its imported spinach – approximately 50,000 metric tons per year. In both Hong Kong and Japan, the perceived threat to food safety touched off a period of heightened public concern and greater government scrutiny of food imports from China. As a result, the Hong Kong government has been

[7] Most Americans concerned with China imports," *Reuters*, September 19, 2007.

[8] "Poll: 92 Percent Want 'Country of Origin' Labels," *Reuters*, July 11, 2007.

[9] "The Next Influenza Pandemic: Lessons from Hong Kong, 1997," by René Snacken, Alan P. Kendal, Lars R. Haaheim, and John M. Wood, *Emerging Infectious Diseases*, Vol. 5, No. 2, March-April 1999, pp. 195-203.

[10] "Challenges for China's Agricultural Exports: Compliance with Sanitary and Phytosanitary Measures," by Fenfxia Dong and Helen H. Jensen, *Choices*, Vol. 22, No. 1, 1st Quarter 2007, pp. 19-24.

aware of the issue for at least 10 years, and the Japanese government has been aware for at least five years.

Food imports from China are of particular concern to the Hong Kong and Japanese governments because of China's importance as a source of food for the city of Hong Kong and the nation of Japan. According to a recent press account, China supplies Hong Kong with about 80% of its food.[11] According to its Ministry of Health, Labour, and Welfare, or MHLW, more than 10% of Japan's food comes from China.[12] According to news sources, Japan relies on China for about 80% of its vegetable imports.[13] On July 24, 2007, Tomohiko Taniguchi, deputy press secretary for Japan's Foreign Ministry, stated "it is too late" to control the quantity of food imports from China.[14] According to Taniguchi, the safety of imports from China is "one of the biggest concerns I can tell you ordinary people in Japan are having these days ... and it's going to remain one of the most biggest concerns for the foreseeable future."[15]

Distinctive Characteristics of the Hong Kong and Japanese Markets[16]

[11] "China Scares Spur Hong Kong Organic Food, Vegetable Tracking," by Laurie Burkitt, *Bloomberg*, July 27, 2007.

[12] Data from the Ministry's webpage [http://www.mhlw.go.jp/english/topics/imported foods/index.html] and Japan External Trade Organization, Trade and Investment Statistics.

[13] "Japan Now Relies More on Chinese Food Imports," *Brunei Times*, September 5, 2007; "Japan's New Import Standards Threaten Chinese Farmers," *China View*, May, 28, 2007.

[14] "China's Food Safety 'Biggest Concern' for Japanese: Official," *Agence France-Presse*, July 24, 2007.

[15] Ibid.

[16] Unless otherwise noted, observations made in this section of the testimony are based on first-hand experience living in Hong Kong and Japan, as well as continued contact with people living in Hong Kong and Japan.

While the extended experiences of Hong Kong and Japan may provide some useful insights for the United States on how to deal with imported food from China, there are distinctive characteristics of the food markets in both locations to be taken into consideration. First, the food consumption patterns of Hong Kong and Japanese households are different from those of U.S. households. Second, the food distribution systems in Hong Kong and Japan are different from the U.S. food distribution system. Third, the attitudes of consumers in Hong Kong and Japan about food are arguably different from the typical U.S. consumer.

The food consumption patterns of Hong Kong, Japanese and U.S. households are distinct from each other. For example, the typical Hong Kong household purchases the groceries for its evening meal in a wet market[17] near its home the same day of the meal. In part, this is due to the small size of the typical Hong Kong kitchen and refrigerators and in part, it is due to their strong preference for fresh food. Often times, the fresh vegetables, meat and fruit are bought by an adult in the household on their way home from work or during the afternoon.

Any meat purchased for the evening meal was more than likely slaughtered in Hong Kong or in China that same morning. Any produce purchased in the wet market was likely either harvested earlier that day in China or arrived at the port in Hong Kong that morning. Produce or meat not sold on its first day in the wet market is often thrown away as rubbish because Hong Kong consumers generally do not trust day-old produce or meat. The larger grocery stores in Hong Kong – Park'n'Shop and Wellcome – mostly sell canned and frozen foods, beverages, condiments and sauces used by Hong Kong households when preparing the fresh vegetables and meat.

[17] Hong Kong wet markets are typically located in or near a set of apartment buildings in a government-run community center or a commercially-run shopping center. The wet markets contain food stalls for rent to vendors selling fresh produce, meat, seafood or other food items. There is often a section of inexpensive restaurants nearby which are commonly known as "dai pai dongs."

Hong Kong households also eat out quite frequently, often at nearby neighborhood restaurants, ranging from "dai pai dongs"[18] (open-air street restaurants) to internationally renowned restaurants. Whatever type of restaurant they are, most Hong Kong restaurants also purchase their produce and meat at wet markets every day to meet the expectations for freshness among their customers.

Japanese households also purchase much of their food as fresh produce and meat. Much like the case in Hong Kong, this is partially due to the small size of the typical Japanese kitchen and refrigerator. In comparison to Hong Kong, more of Japan's shopping is done at supermarkets and specialty food stores, such as fishmongers and fruit and vegetable stores. Like Hong Kong households, Japanese households usually purchase any meat or vegetables for their evening meal earlier that day. While Japanese households eat their evening meal out less often than Hong Kong households, when they do eat out, the restaurant generally serve fresh meat and vegetables purchased that same day.

The food distribution systems of Hong Kong and Japan are also different from that of the United States. In Hong Kong, most of the fresh food enters either on land from China or by sea from overseas and proceeds directly to wholesale markets near the point of entry. At the wholesale markets, a mixture of food vendors, purchasers for restaurants and representatives from the supermarkets select the items they want and then transport them to the wet markets scattered

[18] "Dai pai dong" literally means "big license stall" after the oversized licenses issued to street food stalls by the Hong Kong government in the 1940s. These informal restaurants are commonly located near wet markets, street markets or major bus terminals. A common characteristic of dai pai dongs is the use of folding tables and stools that are often shared among the neighboring food stalls in the dai pai dong.

throughout the city, take them back to their restaurants, or transfer them to the supermarkets' food distribution facilities. As a result, the distribution of food at the wholesale level is highly centralized and highly competitive.

In Japan, there is a split in the market between the small food vendors, and the large supermarket chains and the emerging big box stores. The large supermarket chains (such as Daiei, Itoyokado, Jusco, and Seiyu) and the big box stores usually procure their meat, produce and other food items directly from their overseas suppliers, often using long-term procurement contracts. By contrast, the smaller food vendors – especially sellers of seafood and fresh produce – typically buy their merchandise in wholesale markets.

Finally, there is a common perception that Hong Kong and Japanese consumers are generally highly concerned about the safety of their food. A survey of Japanese households on food discovered that food safety was the top concern of 70% of the respondents; price was the top concern for 8% of the respondents.[19] Day-old, damaged or blemished produce or meat usually cannot be sold to Hong Kong and Japanese consumers, even at highly discounted prices. Also, in response to the recent problems with tainted food from China, there are reports of growing interest in organic produce and meats in Hong Kong.[20] Japanese consumers have also shown increasing interest in organic food products, but ironically, much of Japan's organic food is imported from China.[21]

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[19] Results from presentation by Paul Young, "Food Safety Regulation: Comparing the EU and Japanese Systems," at the symposium, "Regulating Food Safety in China," held at the Woodrow Wilson International Center for Scholars on September 20, 2007.

[20] "China Scares Spur Hong Kong Organic Food, Vegetable Tracking," by Laurie Burkitt, Bloomberg, July 27,

2007.

[21] "Organic Farming Grips China," by Juliana Liu, *BBC*, October 4, 2007.

Under Hong Kong law, the responsibility to ensure the safety of imported food is placed in the Food and Environmental Hygiene Department. On May 2, 2006, the Food and Environmental Hygiene Department established the Centre for Food Safety, which was given specific responsibility for planning and implementing Hong Kong's food safety policies, negotiating and managing relations with overseas food authorities (including China), and maintaining a consultative structure to allow the businesses and people of Hong Kong with an opportunity to comment on Hong Kong's food safety system. In addition, Hong Kong's Customs and Excise Department[22] has the authority to inspect baggage and materials brought into Hong Kong to see if they contain any illegal materials, including prohibited food items.

Centre for Food Safety. The Centre for Food Safety is organized into three divisions. The Food Surveillance and Control Division is responsible for planning and implementing Hong Kong's food surveillance system, running Hong Kong's food import control and export certification, managing any food incidents that pose a threat to public health, liaising with foreign food authorities, and overseeing the testing of imported food from Mainland China. The Risk Assessment and Communication Division oversees risk assessment studies, conducts food consumption surveys, advises on the establishment of food safety standards, communicates food safety information to the public, organizes consultative meetings with Hong Kong businesses and consumers, and communicates with international bodies to strengthen the food safety systems of Hong Kong. The

[22] Although Hong Kong is legally part of China, under the terms of the 1984 "Joint Declaration of the Government of the United Kingdom of Great Britain and Northern Ireland and the Government of the People's Reblic of China On the Question of Hong Kong," the Hong Kong Special Administrative Region will "retain the status of a free port and a separate customs territory."

final division of the Centre for Food Safety is its Administrative Division, which is responsible for administrative support services.

Enforcement. Under current Hong Kong law, a food import declaration form is required to legally import food into Hong Kong. The form includes information on the date of import, particulars of the person making the import declaration, the name and contact information for both the importer and exporter of the food, and a description of the imported food items, including the physical quantity and place of origin. The form specifically requests the name and address of the farm from which the food came. While not legally required for all food products, the Centre for Food Safety "encourages" food importers to obtain health certificates issued by the appropriate authorities of the country of origin for the food products, and have copies of those certificates accompany the food products when imported into Hong Kong. For certain "perishable or high-risk" food items – such as game, meat, and poultry; milk and milk beverages; frozen confections; and marine products – health certificates are required. Also, importers of frozen or chilled beef, mutton, pork and poultry must obtain an import license from the Centre for Food Safety before shipping these food products to Hong Kong.

Failure to comply with Hong Kong's laws and regulations governing the import of food is punishable by up to six months in jail or a maximum fine of 50,000 Hong Kong dollars, or about $6,400. However, it is unusual that a company or person will be given the maximum penalty. In many cases, the illegally imported food or the imported food found in violation of Hong Kong's health standards will be impounded and destroyed. According to the Centre for Food Safety, Hong Kong did prosecute over 500 food safety violations in 2006.

In order to expedite the inspection of food imports, Hong Kong limits the number of points of entry for imported food. In general, fresh food imports are to enter Hong Kong either via Man Kam To (near the center of the border with Mainland China), the pier by the Western Wholesale Food Market (on the northwest corner of Hong Kong Island), the pier by the Cheung Sha Wan Wholesale Food Market, or the Hong Kong International Airport at Chek Lap Kok. Other food items may also enter Hong Kong at Lok Ma Chau (on the western edge of the border with Mainland China) or Sha Tau Kok (on the eastern edge of the border).

Recent Legal Developments. According to the Centre for Food Services, "in response to a series of food incidents concerning imported food, the [Hong Kong] Government has announced a package of new measures to ensure the safety of imported food. One of these new initiatives is to require food importers to Hong Kong to register with the Centre for Food Safety."[23] Although the new law has not yet been introduced to Hong Kong's Legislative Council, the Centre for Food Safety has developed a pre-statutory voluntary notification scheme to encourage importers and distributors of food to register. The notification scheme is a phased program that started in August 2007 with the registration of importers of game, meat and poultry meat, and is to continue into 2008. It is not known when the new law will be introduced to Hong Kong's Legislative Council.[24]

Relations with China. Because of the importance and sensitivity of food imports from Mainland China, the Centre for Food Safety has developed special procedures for food imported from China, and has established close ties with food and health authorities in Mainland China. Over

[23] "Pre-statutory Voluntary Notification Scheme for Food Importers/Distributors," press release of the Centre for Food Safety, available online at:
[http://www.cfs.go.hk/english/whatsnew/whatsnew_fstr/ whatsnew_fstr_pre_stat_vol_scheme.html].

[24] Under Hong Kong law, most proposed legislation is initiated by the Chief Executive and is subject to the approval of the Legislative Council.

the last 10 years, the Hong Kong's Food and Environmental Hygiene Department and China's State General Administration of Quality Supervision, Inspection, and Quarantine (AQSIQ) have agreed to a set of administrative procedures to ensure the safety of food shipped to Hong Kong. These special procedures cover fresh produce, livestock, poultry and marine products.[25]

In general, under the special procedures, AQSIQ inspects, certifies and registers food producers in China that meet specified safety standards. Only food from registered farms and facilities in China that are accompanied by AQSIQ health certificates are to be allowed into Hong Kong by Hong Kong Customs and the Centre for Food Safety's inspection facilities. All food imports from China are also subject to inspection by the Centre for Food Safety. At present, Hong Kong generally relies on international established sanitary and phytosanitary standards when inspecting imported food. For example, Hong Kong has not established its own maximum residue levels (MRLs) for pesticides, but uses the Codex Alimentarius Commission's standards.

In cases where shipments from a registered Chinese farm or facility fail inspection, representatives of AQSIQ and the Centre for Food Safety may conduct a joint investigation of facility to determine the cause of the problem. In addition, AQSIQ and the Centre for Food Safety have agreed to notify each other of "major incidents" related to food exports or imports.

[25] In 1997, Hong Kong and China made special arrangements for the certification and inspection of poultry in response to the outbreak of Avian flu. In 1999, special arrangements were made for cattle imported from China. Special arrangements for pork and marine products were made in 2005. Special arrangements for fresh produce were made in 2006.

To facilitate better relations and communications across the border, AQSIQ and the Centre for Food Safety hold periodic meetings to discuss various aspects of their relationship, including the notification system, farm registration and certification, updated food standards, and new food safety technology. For example, in October 2006, China and Hong Kong began utilizing radi-frequency identification (RFID) tags on live pigs imported into Hong Kong as part of a pilot program to study the feasibility of using RFID techniques to trace imported food.[26] As explained in an interview with a Hong Kong official, the goal of these meetings is to develop a better rapport with Mainland Chinese officials and to ensure that enforcement standards are maintained in China.

[26] "Centre for Food Safety - the First Year,"special report, Centre for Food Safety,

Internal Relations. To improve communications and relations within Hong Kong, the Centre for Food Safety has developed a variety of consultative and communications mechanisms. For example, the Centre for Food Safety created three formal bodies – the Expert Committee on Food Safety, the Trade Consultation Forum, and the Consumer Liaison Group – for consultation with different stakeholders in Hong Kong on the issue of food safety. In addition, the Centre for Food Safety releases a variety of newsletters, fliers and handouts on food safety to provide the public with information about changes in policies and regulations, or updates on recent food safety incidents.[27] Finally, like all executive agencies in Hong Kong, the Centre for Food Safety may be asked to answer questions posed by the Legislative Council.

In response to the overall regulatory environment, Hong Kong food importers and consumers generally rely on establishing supply networks that they consider trustworthy. For the smaller wholesalers, vendors and consumers in Hong Kong, this network tends to be based on personal relationships; people will return to the same wholesalers or vendors to purchase food items rather than shop around for the best price. For the large supermarket chains, the companies often sign long-term supply contracts with Mainland China farms that they consider safe and reliable. These contracts often provide a price premium to the suppliers as a way to provide an incentive to the farms to protect the safety and quality of their products.

Japan's Approach to Imported Food Safety

Historical Background. Recent Japanese concern about the safety of food imported from China dates back to the spring of 2002, when several shipments of Chinese-grown spinach were found to contain excessive pesticide residue. Public concern about the tainted Chinese-grown

[27] The most recent food safety alert release by the Centre for Food Safety was an August 8, 2007 warning about oysters imported from the United States that might be infected with *Vibrio parahaemolyticus*.

spinach was heightened by the earlier death of a Japanese woman who had used diet pills made in Guangdong Province in China that contained fenfluramine, as well as a fear that had emerged in September 2001of mad cow disease in Japanese beef.

In response to the discovery of the tainted spinach, several Japanese food companies —Ajinomoto, Nichiro, and S&B Foods — temporarily stopped the import of Chinese vegetables. In addition, the Japanese Diet amended the nation's Food Sanitation Law (originally passed in 1947) in July 2002 allowing the ban of imported food products from a country or area when successive violations of the law have been found. The amendment also increased the penalty for Japanese importers of banned food products to up to six months in prison or a fine of up to 300,000 yen (approximately $2,400 at that time).

In May 2003, the Japanese Diet passed the Food Safety Basic Law to strengthen its existing measures designed to protect the public from unsafe food. The Food Safety Basic Law was designed to work in coordination with Japan's existing laws governing food safety, including the Food Sanitation Law, the Abattoir Law, and the Poultry Slaughtering Business Control and Poultry Inspection Law. In addition to "clarifying the responsibilities of the state, local governments, and food-related business operators and the roles of consumers," the Food Safety Basic Law also created the Food Safety Commission, a Cabinet-level independent agency given oversight authority over the food safety activities of various government ministries and departments.

Current Japanese Food Safety Laws. There are four main laws currently governing food safety in Japan — 1. the Food Sanitation Law; 2. the Food Safety Basic Law; 3. the Abattoir Law; and 4. the Poultry Slaughtering Business Control and Poultry Inspection Law.

The Food Sanitation Law. The Food Sanitation Law was originally passed in 1947, but amended in 2002 and more recently in 2006. The basic purpose of the law as written is to "prevent

the occurrence of health hazards arising from the consumption of food, by making necessary regulations and taking any measure so as to work for the protection of the health of the people." As Japan's most general food safety law, it covers a wide range of topics including: food safety standards; permissible and prohibited food additives; food processing requirements; food labeling requirements; inspection procedures and regulations; designation of enforcement agencies; import regulations and procedures; penal provisions; and registered laboratories. The most recent amendment of the Food Sanitation Law raised the highest penalty for violation of the law to up to three years in jail or a fine of up to 3,000,000 yen (approximately $26,000).

The Food Safety Basic Law. The Food Safety Basic Law sets out the responsibilities of the various government agencies responsible for ensuring that Japan's food is safe. Under Japan's administrative procedures, provincial and local authorities are part of the food product safety system in addition to federal government agencies. The general administration of food product safety is under the jurisdiction of the Department of Food Safety of the Ministry of Health, Labour, and Welfare, of MHLW. Within the Department of Food Safety, the main enforcement agencies are: the Office of Port Health Administration, which manages Japan's 31 quarantine centers and inspects imported foods; the Inspection and Safety Division, which handles domestic food inspection; the Office of Import Food Safety, which "assures import food safety;" and the Office of International Food Safety, which manages the general coordination of international issues of food safety.

The Food Safety Basic Law also created the Food Safety Commission, a Cabinet-level independent agency that oversees the government's activities on food safety. The representative of the Food Safety Commission in the Japanese Cabinet is the Minister of State for Food Safety. Its main function is to conduct risk assessments of food products and the government's enforcement of food safety standards. It oversees the work of the Ministry of Health, Labour, and Welfare in their

activities pertaining to food sanitation and safety, and the Ministry of Agriculture, Forestry, and Fisheries in their oversight of food products from agriculture, forestry and fisheries.

The Abattoir Law. As the name implies, the Abattoir Law was established to regulate the operations of Japan's slaughterhouses in order to protect public health. The law stipulates which government entities are responsible for the inspection and regulation of slaughterhouses, as well as setting standards for cleanliness and safety.

The Poultry Slaughtering Business Control and Poultry Inspection Law. Similar to the Abattoir Law, the Poultry Slaughtering Business Control and Poultry Inspection Law regulates the slaughtering of poultry, including chickens, ducks, turkeys, and other fowl.

Enforcement. The actual enforcement of Japan's food safety system is disseminated throughout the nation's federal, provincial and local governments. In general terms, the federal agencies handle food safety enforcement for imported goods, and the provincial and local government agencies focus their efforts on domestic enforcement issues.

Imported foods, from China or other locations, are subject to inspection by the roughly 300 inspectors located at 31 quarantine stations run by the Ministry of Health, Labour, and Welfare. Prior to the import of any food product, the importer must notify the Ministry of its intent to import food products. The Ministry's inspectors review the notification materials, and then determine if an inspection of the shipment is warranted. The usual practice is to inspect a company's first food shipment to Japan. A history of past violations also tends to result in a shipment being selected for testing.

If the shipment is to be inspected, it is temporarily quarantined and the importer is informed of the decision to inspect the shipment. If the food products are deemed unsafe or unfit for human

consumption by the inspection, the importer is to be informed of the inspector's decision, and the products are to be either destroyed or returned to their point of embarkation.

Under current Japanese law, the inspections cover over 300 food products, nearly 800 agricultural chemicals and include nearly 55,000 inspection criteria.

Once the imported food products enter Japan, they are still subject to inspection by provincial and local health and food safety officials under the terms of Japan's Food Safety Law and the Food Safety Basic Law.

Recent Developments. Japanese and Chinese health officials recently held a series of meetings to discuss ways of insuring the safety of food products imported into Japan from China. Also, Japanese officials indicated that food product safety would be a major topic of discussion at then upcoming Asia Pacific Economic Cooperation meetings held in Sydney between September 3 and 7, 2007. Various press accounts of these meetings report that Japan's Economic Minister Akira Amari had pressed China's Commerce Minister Bo Xilai for a "full explanation" of China's efforts to improve the safety of food and other products from China.

Also, Japan implemented a "positive list" system in May 2006 to tighten its review of food imports for agricultural chemicals. According to a report in Mainichi Shimbun, during the first year since the implementation of the "positive list," the frequency of violations of Japanese standards has increased more than eight-fold.[28]

[28] "Imported Food Violations Increase Eight-fold in Year since New System Introduced," Mainichi Shimbun (in Japanese), July 9, 2007.

Relations with China. Relations between Japan and China on the issue of food safety take place in two separate arenas – government-to-government relations and company-to-company relations. On the government-to-government side, Japan has negotiated over 30 separate arrangements with China specifying safety standards for a range of food items. Under these arrangements, Chinese health officials is to certify specific farms and food production facilities meet the agreed quality standards. In Japan, food shipments from these certified Chinese farms and facilities are afforded preferential treatment to imports from non-certified farms and facilities. As a result, on the business-to-business side, Japanese importers tend to source their food products from the certified farms and facilities – often offering a higher price for the goods – in order to lower the risk of the shipment being inspected or impounded, as well as lower the chance that the importer may be legally liable if the products are subsequently found to be unsafe or unsanitary.[29]

On March 23, 2007, the Director of Japan's Department of Food Safety issued an imported food monitoring and guidance plan for fiscal year 2007 to the heads of the quarantine stations.[30] The sixth basic point of the plan states:

> In order to prevent any violation of the Law during the production process in exporting countries, the MHLW shall support promotion of sanitation measures in exporting countries by (i) providing information on food-sanitation regulations to embassies located in Japan and to importers, (ii) holding bilateral discussions, (iii) conducting on-site inspections, and (iv) providing technical support.

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[29] For a more detailed description of one company's sourcing system in China (in Japanese), see Aqlifoods webpage: [http://www.aqli.co.jp/action/action_02.html].

[30] "Development of Imported Food Monitoring and Guidance Plan for FY 2007," Department of Food Safety, March 23, 2007.

As part of their efforts to promote better sanitation conditions in exporting countries, the MHLW plans on providing overseas suppliers information on samples cases of violations, hold seminars on Japanese food-sanitation regulations, and introduce pre-export inspections. The guidelines also indicate that if 5% of the food imports from a specific country, area or business entity violate Japanese food safety laws, and if such violations are highly likely to continue, the MHLW shall ban the importation of such foods.

Safety Record of Hong Kong and Japan

It is inherently difficult to determine the effectiveness of a food safety system because it involves proving that something did ***not*** happen – exporters did ***not*** try to ship unsafe food to your country, a shipment of unsafe food did ***not*** get past inspectors, and consumers did ***not*** eat or drink unsafe food that did enter your national food distribution system. In addition, it is unclear how to interpret the data that is available. For example, does a low rate of failure in pesticide residue testing on imported vegetable samples indicate that very few tainted vegetables are being imported or that the sampling process is not identifying the tainted shipments. Also, it is uncertain if one can extrapolate the amount or volume of unsafe food imports that are entering a country from the failure rate from the inspected sampling without knowing if the sample population is representative of all import shipments. In the end, the most one can readily say is how strict a government's food safety system appears to be.

Hong Kong's Record. Hong Kong's Centre for Food Safety reports on the results of its food surveillance program every two months via its web page.[31] In 2006, the Centre for Food Safety

[31] The Centre for Food Safety's webpage is: [http://www.cfs.gov.hk/].

took over 64,000 samples for microbiological and chemical testing; the overall failure rate was 0.3% – the same as it was in 2005.[32] In its latest report, which covers July and August 2007, the Centre for Food Safety found a slightly higher failure rate of 0.6% out of 12,800 samples.[33] Neither report indicated what percentage of food imports were sampled, nor did they indicate if the sampling method was considered representative of Hong Kong's food imports in general.

In its report on its first year of operation, Hong Kong's Centre for Food Safety reported that it handled over 550 "food incidents" and over 6,600 "food complaints," but did not provide any specific information about the nature or seriousness of these incidents and complaints. Nor did it provide data on how many of these events involved imported food or food from China.

Japan's Record. Between April and September 2006, the Ministry received 923,968 shipment notifications of intent to import food products, and conducted inspections on 94,920, or 10.3% of the shipments. Of the shipments inspected, 629, or 0.7% were found to be in violation of Japanese law.

Problems Continue to Exist. However, as demonstrated by recent anecdotes, problems with imported food safety continue to occur on both Hong Kong and Japan. One of the most unusual stories involved the sale of fake chicken eggs. According to the several Hong Kong newspapers, people were finding that chicken eggs they bought in the wet market were actually artificial eggs – complete with shells – made out of various chemicals. By all accounts, the fake eggs looked and felt like real eggs, but tasted different and didn't cook like real eggs. One article described

[32] "Food Surveillance Results for 2006," press release, Centre for Food Safety, April 2, 2007.

[33] "Latest Food Safety Report Released," press release, Centre for Food Safety, September 27, 2007.

how the fake eggs were manufactured and reported that the production cost of making the fake eggs was about one-twelfth the retail price of eggs in Hong Kong.

Another interesting story of unsafe imported foods discovered in Hong Kong involved fish from Indonesia sold in a major Hong Kong supermarket.[34] According to the news account, ParknShop imported "cod fish" from Indonesia that actually turned out to be oil fish, a distant cousin of tuna that looks similar to cod fish. Also known as "blue codfish," oil fish is considered toxic by Australia and Japan because people often complain of severe stomach aches and diarrhea after eating the fish. ParknShop removed all the oil fish from its stores after receiving complaints, and Hong Kong fish traders, restaurants, and businesses agreed to a self-imposed ban on the sale of oil fish in the city.

[34] "Hong Kong Voluntarily Bans Oil Fish after Labelling Blunder at ParknShop," *Channel News Asia*, January 25, 2007.

In July 2007, prefectural health inspectors in the Japanese city of Maebashi discovered a banned synthetic antibacterial drug in broiled eels processed in China.[35] According to the news account, the eel was imported into Japan in March by a fish wholesaler in Tokushima and sold to vendors in the Kanto region. After the discovery, the Tokushima prefectural government asked the fish wholesaler to organize a voluntary recall of the fish. Supermarkets and retailers complied with the recall, and pulled the eels from their shelves.

Four Observations from the Experience of Hong Kong and Japan

Based on the preceding analysis of the experience of Hong Kong and Japan with the import of food from Mainland China, CRS offers four, somewhat interrelated key observations.

First, collaboration generally has been used more than confrontation. Part of the overall strategy of Hong Kong and Japanese food safety officials when dealing with Mainland Chinese counterparts seems to be to work together to solve the problem of protecting people from unsafe or unsanitary food items. For example, Japanese food safety officials often travel to China to meet with Chinese officials to share information about Japanese food safety standards, and develop "equivalency" standards for Mainland Chinese exports to Japan. These "equivalency" arrangements are then sometimes transformed into more formal agreements between the two governments. Plus, when Japanese inspectors discover a food shipment from Mainland China is tainted or unsanitary, Japanese officials have often traveled to China for consultations about the suspect shipment.

Second, the carrot has been used more than the stick. In their dealings with Chinese officials and businesses, both Hong Kong and Japan appear to have adopted an approach of providing incentives to cooperate, rather than penalizing failures to comply. For example, in Hong

[35] *Yomiuri Shimbun*, July 15, 2007.

Kong, the greatest penalty for the import of unsafe food is six months in jail. By contrast, current U.S. law sets the maximum penalty at three years in jail. On the flip side, the Japanese food importers are frequently willing to pay higher prices for produce and food products from Chinese suppliers that have met specified production quality standards – often relying on certification procedures jointly developed by the Chinese and Japanese food safety officials – rather than buy from less expensive, uncertified suppliers. Similarly, Hong Kong food importers tend to take their business back to reliable food vendors with clean records rather than simply buy the lowest price produce.

Third, food safety is not simply a matter of laws and regulations. Another element of the Hong Kong and Japanese approach to food product safety is the apparent focus on including the private sector in the development and implementation of the food safety program. Both governments have standing food safety consultative committees that include representatives of the private sector. Among other things, the presence of the private sector on these committees provides a "reality check" on proposed policy or regulatory changes. Also, both Hong Kong and Japan seek to create an environment where it is in the best interest of the Chinese food producers and exporters, as well the Hong Kong or Japanese food importers, to make sure that the imported goods are safe and sanitary.

Fourth, no system is perfect. No matter how well designed the policy or how well the policy is implemented, it is impossible to guarantee that every morsel of imported food – whether it is from Mainland China or some other location – is 100% safe and sanitary. The Hong Kong and Japanese governments have food safety policies in place, but they both continue to experience problems with tainted and unsafe imported food products.

Chairman Stupak, Ranking Member Whitfield, distinguished members of the subcommittee, this concludes my statement. Thank you again for the opportunity to testify on these issues. I will be pleased to respond to any questions you might have.

Mr. MELANCON. Thank you, Dr. Martin. We appreciate your testimony. And I will wait for questioning.

Mr. Rice, you have a 5-minute opening statement if you would, and if you have anything longer, if you would like to submit it.

STATEMENT OF JAMES M. RICE, VICE PRESIDENT AND COUNTRY MANAGER, TYSON FOODS, INC.

Mr. RICE. Thank you. My name is James Rice, and I am vice president of Tyson Foods, Inc. I also served on the Board of Governors of the American Chamber of Commerce in Shanghai. I've worked with Tyson for the last 3½ years, but my involvement in China began 20 years ago when I was an exchange student from the University of California in 1987. In 1991, I returned to China and have worked and lived there continuously until now.

Tyson Foods has a significant export business from the United States to China. Of the U.S. poultry industry's $500 million in exports to China this year, Tyson's share will be approximately $200 million, and our business is growing at 25 percent a year. China is now the largest destination of U.S. poultry exports, and the largest U.S. exporter to China by dollar value is poultry. Tyson also exports cattle hides and pork from the U.S. to China.

In China, Tyson produces meat and poultry products for both domestic and export consumption through two joint venture operations. We maintain relationships with Chinese poultry companies who produce products on our behalf for global customers in Japan and in Hong Kong. So I hope to draw from this experience to share with you some insights on China's quality management processes.

Despite wide news coverage, China does have modern food producers who are able to produce quality products for domestic and for export consumption. China's General Administration of Quality Supervision, Inspection and Quarantine, commonly known as the AQSIQ, has processes that ensure quality food products are exported. The evidence on the ground from what I have seen indicates that modern manufacturers and the AQSIQ can do their jobs, and their processes are improving.

China has a vital interest in improving its food safety programs for many reasons, and the country is learning that national food safety assurance systems require time, resources and flexibility to accommodate industrial technological changes. For example, the AQSIQ is now developing a food recall system, improving labor requirements and also a traceability system. Another example is China's Export Food Safety Program, which requires that all export food must originate from an AQSIQ-registered plant and be certified by a local China inspection and quarantine agency, which is the local version of AQSIQ.

The AQSIQ only authorizes 12,700 of the country's 450,000 food producing companies to export. This list is expanded and shortened by the AQSIQ based on the performance of companies, just like the USDA maintains a list of authorized meat and poultry exporters in the United States. The way it works is that Chinese food processors are certified to export. They will notify the AQSIQ when they are going to produce for export, and the AQSIQ or CIQ inspectors will be present during the process. These inspectors will evaluate the suppliers, the raw materials, the production process and

the finished products. Only after this process will they issue a certificate for export. It is my understanding that for the most part food safety issues we have heard about in the United States have come from companies other than those authorized by the AQSIQ.

Chinese poultry exports to Japan have an additional level of quality assurance. The AQSIQ has selected 35 of the best poultry producers in China to be eligible to export to Japan. Then Japanese Ministry of Agriculture, Forestry and Fisheries, the MAFF, visited and certified these plants. They are inspected annually by Japan's MAFF, but it's the AQSIQ that has responsibility to ensure these 35 plants meet compliance with both the Japanese import regulations and also the Chinese export regulations. Today these plants operate at a higher level than do their competitors, not only because the Japanese customers require it but because the responsibility for food quality and safety is shared equally and completely between the manufacturer, the AQSIQ and the Japanese MAFF.

When Tyson manufactures products in China, both for domestic and for export consumption, we use only these Japanese certified suppliers, ensuring that we start with the best suppliers. These suppliers and their suppliers are audited regularly by our American quality assurance manager and we practice at our facility 100 percent inspection of all incoming raw materials. When Tyson products are manufactured by our partners, our quality assurance manager and our American plant manager are in those facilities to ensure the same quality standards are maintained. Our global customers also audit our plants and our suppliers, and the net result is that regulators, the manufacturer, and the customers are working together to ensure the quality of our products.

As a brand owner, our job is to be certain that all levels of private and public sector quality assurance work together to identify, manage and mitigate all food safety risks. In this way, regulators, brand owners share food safety responsibility with foreign regulators and manufacturers. Not that the responsibility is divided but that every entity shares 100 percent responsibility to be sure the product is right before it leaves the Chinese plant.

There's no question that China plays an enormous role in the global economy as both an importer and an exporter of foods and many other products, but we need to consider how to work with China and make sure that relationship is mutually beneficial. The end result is that both countries can implement the same quality standards and sell the same high-quality products to both countries.

Thank you.

[The prepared statement of Mr. Rice follows:]

TESTIMONY OF JAMES M. RICE

My name is James Rice and I am vice president of Tyson Foods, Inc. and Country Manager for Tyson's China Operations. I also serve on the Board of Governors of the American Chamber of Commerce in Shanghai. I have worked with Tyson for the last three and a half years. My involvement with China began 20 years ago when I was an exchange student from the University of California in 1987. I returned to work in China in 1991 and have lived and worked continuously in China ever since.

Tyson Foods, Inc. has a significant export business from the U.S. to China. Of the U.S. poultry industry's $500 million in exports to China this year, Tyson's share will be approximately $200 million and our business continues to grow at a rate of more

than 25 percent a year. China is now the largest destination for U.S. poultry exports. And the largest U.S. export to China, by dollar value, is poultry. Tyson also exports cattle hides and pork from the U.S. to China.

Tyson also produces meat and poultry products in China for both domestic and export consumption through two joint venture food processing facilities. We maintain relationships with local Chinese poultry companies who produce products on our behalf for global customers in Japan and Hong Kong. I hope to draw from this array of experience to share with you some insights on China's quality management processes.

Despite wide news coverage of its challenges, China does have modern food producers who are able to produce quality products for domestic and export consumers. China's General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) has processes that ensure quality food products are exported. The evidence on the ground indicates that the modern manufacturers and the AQSIQ can do their jobs, and they are rapidly improving their processes.

China has a vital interest in improving its food safety programs for many reasons, and the country is learning that national food safety assurance systems require time, resources and flexibility to accommodate industrial and technological changes—as well as shifting global demands. For example, the AQSIQ, from what I understand, is developing a food recall system, improved labeling requirements and a product traceability system.

Another example is China's export food safety program, which requires that all exported food must originate from AQSIQ-registered plants and be certified by the local China Inspection and Quarantine agency, or CIQ. From what I understand, AQSIQ only authorizes 12,700 of the country's 450,000 food companies to produce for export. This list is expanded and shortened by the AQSIQ based on the performance of the companies, just like the USDA maintains a list of authorized meat and poultry exporters in the US.

The way it works is that Chinese food processors certified to export will notify the AQSIQ when they are producing for export, and AQSIQ inspectors will be present during the process. They will evaluate the suppliers, raw materials, production processes and finished products. Only after this will a Certificate for Export be issued. It is my understanding that for the most part, food safety issues we have heard about have come from companies other than those authorized by the AQSIQ.

Chinese poultry exports for Japan have an additional level of quality assurance. The AQSIQ selected the 35 best poultry producers for eligibility to export to Japan. Then, Japan's Ministry of Agriculture, Forestry, and Fisheries (MAFF) visited and certified these plants. They are inspected annually by Japan's MAFF, but it is China's AQSIQ that is responsible for ensuring these 35 plants' continuous compliance with both the Japanese import standards and the Chinese export standards. Today, these plants operate at a higher quality level than do their competitors not only because their Japanese customers demand it, but because the responsibility for food quality and safety is shared equally and completely by the manufacturer, the AQSIQ and the Japanese MAFF.

When Tyson manufactures products in China—for both domestic and export consumption—we use only suppliers that are already certified for Japanese export, ensuring that we start with the best suppliers. These suppliers, and their suppliers, are audited regularly by our American quality assurance manager, and we practice 100 percent inspection on all raw materials coming into our facility. When Tyson products are manufactured by our partners, our quality assurance manager and our American production manager are in those facilities ensuring that the same quality standards are maintained. Our global customers also audit our plants and our suppliers. The net result is that regulators, the manufacturer, and customers are working together to ensure the quality of our products.

As the brand owner, our job is to be certain that all levels of private and public sector quality assurance work together to identify, manage and mitigate all food safety risks. In this way, U.S. regulators and brand owners share food safety responsibilities with foreign regulators and manufacturers. Not that the responsibility is divided, but that each entity shares 100 percent responsibility to be sure the product is right before it leaves the Chinese plant for the United States.

There is no question: China plays an enormous role in the global economy as both an importer and exporter of foods and many other products. We need to consider how we work with China to be sure our relationship is mutually beneficial. The end result will be that both countries can implement the same quality standards, and guarantee that high quality products could be sold to consumers in both countries.

Mr. MELANCON. Thank you, Mr. Rice. Appreciate your testimony. Mr. Green, would you like to entertain some questions?

Mr. GREEN. Thank you, Mr. Chairman. Mr. Rice, in your testimony, you stated that Tyson manufactures products in China and uses only suppliers that are already certified for Japanese export. Do you pay a premium for that?

Mr. RICE. Yes. The purchasing of raw meat from a Japanese certified supplier will cost us about 20 to 30 percent more than any other uncertified poultry company.

Mr. GREEN. I know there are lots of other companies that import from China. Do you know any of the other companies that make that determination to only use the Japanese export certification?

Mr. RICE. No, I don't. It's our policy because we want to start with the higher quality. I don't know about the other guys.

Mr. GREEN. You state that 35 poultry producers are eligible to export to Japan, these producers selected by China's AQSIQ. Do you know how many of these 35 plants actually export to Japan?

Mr. RICE. All 35 of them.

Mr. GREEN. All 35 are eligible. How many actually do?

Mr. RICE. All 35 plants actually export to Japan.

Mr. GREEN. I'd like to ask about the quality control in China. Is it possible to use manufacturing processes with application of Western standards in Chinese production?

Mr. RICE. Yes. For our plant, and I'm sure for many American companies, we use the same processes that we use in the United States.

Mr. GREEN. And is it possible to use the same quality internal mechanisms that are here in the United States?

Mr. RICE. Yes.

Mr. GREEN. Is it possible to use the same HACCP programs in China?

Mr. RICE. Yes. Our plant uses this.

Mr. GREEN. Can you explain the importance of producers using those HACCP programs?

Mr. RICE. Can I explain the what? I didn't understand the question.

Mr. GREEN. The importance of the producers using those programs.

Mr. RICE. Well like I say, it works for us. It's a proven process. It's one of many quality control tools that you can use in your plant. And for Tyson, we use it in all of our facilities. So it's very successful for us.

Mr. GREEN. Since you're on the Board of Governors, American Chamber of Commerce in Shanghai and you have contact with other counterparts, I would assume, and do other firms in China operate—American firms use that same quality control practices? Or I know you said earlier your competitors, you don't know what they do. But you know what you do. Do you know of any other companies that, for example, just in talking with your other members of the Chamber?

Mr. RICE. Yes. I believe that most of my counterparts are using the same quality standards. And I think that is the case for any consumer products company that's using their brand. And I think

you will want to protect your brand by using your same quality standards that you have in the United States.

Mr. GREEN. You told the staff that good manufacturing processes can be summed up in one phrase, inspect what you expect.

Mr. RICE. That's right.

Mr. GREEN. And could you elaborate on that?

Mr. RICE. That, I was speaking in the context of when you're using third-party plants to manufacture your products. In some cases where we use a copacker. And in this case if you want high quality results, you have to put people on the ground to make sure you do it. When we run products at a facility that we work with that we don't own, in that case I have five quality control people from my plant there to be sure that that's the right product.

Mr. GREEN. And in China—I know, Mr. Chairman, we're talking about food today. But it seems like with the other jurisdiction in our committee, on the toys and with Mattel, it would seem like that would have been a good example for maybe some of our product manufacturers other than food to use that if they inspect what you expect. So it would seem like they would check the paint that they would use on those toys even before they bring them over.

Thank you, Mr. Rice.

Mr. RICE. Thank you.

Mr. GREEN. I yield back my time, Mr. Chairman.

Mr. MELANCON. Thank you, Mr. Green. Mr. Burgess, did you have some questions?

Mr. BURGESS. Yes. Thank you. Dr. Martin, on the issue of the safety record in Hong Kong and Japan, I think you referenced 0.3 failure rate and 0.6 failure rate for each of those countries respectively. Or I may have got that backwards. And I will just preface this by saying any time that you have me up here talking about statistics, it's a bad day for me and whoever I'm talking to. But since this is the subject we're on, and you heard the discussions that I had with the previous panel, I guess my question to you is, at this point from your testimony and your observation, your study of the two systems in Hong Kong and Japan, we can kind of get an idea of how strict they are, but do we really have an idea of how good they are? That is, do we know if they in fact are detecting, and you reference it in your testimony, it's difficult to prove a negative. Do we know that they were only getting the very best products coming in to them because after all, they're Japan and Hong Kong and they're going to look real hard? Or is this the normal stream of products that would go to any importer and this is the failure rate that's discovered from just the native stream of exports?

Mr. MARTIN. The figure 0.3 percent was from Hong Kong for 2006; 0.6 was in 2007, the most recent 2-month period in Hong Kong. In Japan 0.7. As far as I could ascertain, USDA and the FDA do not come out with a comparable figure. And you do have statistical problems in coming up with comparable figures. But I think you're putting your finger on a very important issue, which is when you are looking at a large population, you're taking out a select sample from it, inspecting those and then finding out an incident rate in which they failed to meet whatever your standards are. Are you representative of the population in general? Can you

extrapolate from the smaller sample to the larger one? And as you were asking earlier, yes, there are statisticians out there that could give you that information. But then the question becomes, is that the result you want? In other words, if you find out that 0.3 percent of the subpopulation is indeed representative of the overall population, of all the goods coming in you're effectively saying that 0.3 percent of the shipments coming into your country from a location, from an area, from a company, whatever the case may be, are tainted or unsafe.

So then the other question gets to, if I understood earlier, what kind of goals do you have for your sampling technique? Last comment on this then is, my sense from the Japanese and Hong Kong system is that because they're using a preferential system of determining which shipments to sample, that they anticipate that the incident rate in the subpopulation, sample population is higher than the overall shipment level. So it sets sort of an upper bound of the theoretical number of unsafe shipments coming into Japan and Hong Kong.

Mr. BURGESS. So that is a knowable number, or a range of numbers.

Mr. MARTIN. It's a knowable number for that population.

Mr. BURGESS. For that year?

Mr. MARTIN. For that year and that time.

Mr. BURGESS. That underscores the complexity of all this. And you heard some of my earlier comments. I guess my frustration sitting here as a Member of Congress ostensibly with oversight over the agencies that are responsible for ensuring the safety of the Nation's food supply is we get recall, recall, recall, product safety violation, product safety violation, product safety violation. We don't have the red button on the conveyor belt that we can hit and stop and then go back and do these statistical analyses to find out where the problem is and how to correct the problem. Right now we're just sort of at the receiving end of all this either spoiled, tainted, food, junk, toys, whatever it is. And even from the standpoint of the toys, although that's not the—what we're dealing with today, you've got to imagine that this conveyor belt dumping all these lead-based toys in our country, what are we going to do with them? And Mattel couldn't really answer the question of what they're going to do with them. With spoiled fish it's a little bit different. But it is still the same point, how can we as legislators—and this is what I'm struggling with and I don't think Chairman Dingell's bill has gone quite the direction I would like to see it go. How do we put that stop button on the conveyor belt and say, don't do this anymore until we figure out what's going on?

Mr. MARTIN. I can't comment on the particular specific legislation before you. But what I could say is in the case of Hong Kong and Japan, what they appear to be using is a tiered approach. They try to, to a certain extent if I may, export the issue of monitoring evaluation certification to the exporting entities, the exporting companies as well, to make sure that the products that are coming in are to a certain extent safe. Then they go through a rigorous inspection procedure, again to make sure at a second step that the products are safe. And then in the case of both Hong Kong and Japan, internal to the country you have inspectors that are going

around—there's a recent case in Japan where they pulled some eels off the shelf—and this in my testimony—found out that there was an unsafe level of pesticide in it, and pulled all the fish off the shelf. So the process that seems to be used, the method that's being used in Hong Kong and Japan is, you don't just check once, you check twice, you check three times. And I believe if I may, from the testimony that Mr. Rice is indicating, and also what I tried to indicate in my written testimony, you also have this going on in a parallel process in the private sector. They're checking once, they're checking twice, they're checking three times.

Mr. BURGESS. That brings us to our next point. Mr. Rice, maybe you can weigh in on this as well. If you find at the endpoint, oh, my gosh, there has been a problem, what is the mechanism that you have or that you need, Dr. Martin, to be able to say stop, let's go back to square one and see where the problem is because we definitely have a problem. And not just continually read about it in the Wall Street Journal or the New York Times over and over and over again.

Mr. RICE. Well, in the case of my plan we have traceability. So we keep records of all incoming raw materials and what batches they were made into so we can pull it back.

Mr. BURGESS. If I may interrupt for a second. You can trace it, but can you stop it once that hits the news wires, once that hits the public consciousness that once again we've got a tainted product coming in from the People's Republic of China? Can you stop it?

Mr. RICE. I can't stop the news, but I can stop my product.

Mr. BURGESS. You can stop your product and go back and investigate why the problem occurred?

Mr. RICE. Yes.

Mr. BURGESS. Why do you suppose we're not seeing that process followed? Why are we not seeing the conveyor belt stopped, the inspections done and the problem solved? Why do we have to keep having the same news stories over and over and over again?

Mr. RICE. I don't know. You have to have traceability to some extent so you can trace where your product goes and where it came from.

Mr. STUPAK. [presiding]. Thank you. Mr. Melancon for questions, please.

Mr. MELANCON. Thank you, Mr. Chairman.

Mr. Rice, does Tyson export from the United States foodstuff? Pork, chicken?

Mr. RICE. From the U.S., yes.

Mr. MELANCON. The standards by which they meet, is it that the use for export from the United States to other countries, is it the same that we use for domestic production and sales?

Mr. RICE. Yes. Same plants.

Mr. MELANCON. The imports to other countries from your plants around the world, are they the same standards as you would do in the United States, say, from China to Hong Kong or to Japan?

Mr. RICE. No, they can be different.

Mr. MELANCON. They can be different. Is there some cost differences that makes some tremendous amount of difference that

you couldn't have it uniform across your operations around the world?

Mr. RICE. Well, every country is different. So it is hard. We have specific plants in the U.S. whose products might go to China, in other plants it would go to Russia. So we keep them separate. But you couldn't make one product applicable to the whole world.

Mr. MELANCON. Poultry, are we a net importer or exporter?

Mr. RICE. Exporter.

Mr. MELANCON. And for Japan for poultry?

Mr. RICE. Japan is an importer.

Mr. MELANCON. China?

Mr. RICE. China imports from the United States poultry and exports to Japan poultry.

Mr. MELANCON.So they buy some of our chicken and send it over there.

Mr. RICE. From the United States we export mostly chicken paws and wing tips. And China is exporting leg thighs to Japan.

Mr. MELANCON. I have been to Eastern Market and am still trying to figure out what they do with those chicken paws.

Mr. RICE. I have eaten one and I sell the rest.

Mr. MELANCON. I think I'd grind them all and sell them. I guess what I'm trying to figure out is what complications is there to try and have one standard for a company such as Tyson so that when we know we get product from say Japan or from China coming into this country, poultry product, that it would be the same or the equivalent of what we would ship out of this country or consumed in this country? Is it that complex a problem that it couldn't be standardized to those expectations, because of the nature and the size of your company for instance?

Mr. RICE. Well, the best for us would be the USDA equivalent. That's the product we ship out.

Mr. MELANCON. So USDA basically does keep monitoring pretty well your products?

Mr. RICE. Right.

Mr. MELANCON. But does FDA have any authority or jurisdiction? Or do they monitor or check any of your outgoing or incoming?

Mr. RICE. Not that I know of. But I don't work in the United States.

Mr. MELANCON. But you are glad to be home?

Mr. RICE. Yes.

Mr. MELANCON. Am I'm going looking to see if I have any other questions, Mr. Chairman.

Mr. STUPAK. Thank you, Mr. Melancon. Mr. Rice, besides poultry, any other products you produce in China?

Mr. RICE. We are minority owner of a pork processing plant, but we don't export from there.

Mr. STUPAK. You indicated you use poultry. You obtain them from Japanese certified farms, right?

Mr. RICE. Right.

Mr. STUPAK. Are there other countries that have certified plants or farms in China, Korea or——

Mr. RICE. Korea has certified plants. Singapore has certified plants, so does Malaysia. And I believe the European Union is working on something.

Mr. STUPAK. And the U.S. doesn't have any certified plants?

Mr. RICE. Not that I know of.

Mr. STUPAK. Do you use other certified plants then for poultry or just the Japanese ones?

Mr. RICE. We use just the Japanese ones.

Mr. STUPAK. Have you considered using any other country farms there?

Mr. RICE. Well, I have. But there's less quality control systems in place in those plants. So I would have a higher risk if I did so.

Mr. STUPAK. Is it fair to call them poultry farms?

Mr. RICE. Yes.

Mr. STUPAK. Is the feed used in that poultry farm and all other things used, is it all generated from China internally or do you bring it in from Japan or the United States, the feed and other medicines and things like this you'd use?

Mr. RICE. It's domestically sourced.

Mr. STUPAK. In China?

Mr. RICE. Yes.

Mr. STUPAK. So those sources would also have to be certified then for feed and everything else?

Mr. RICE. Yes. And for Japanese plants, for sure, because they have different requirements on residuals.

Mr. STUPAK. You, Tyson, have been there for how long, 20 years?

Mr. RICE. I have been there 20 years. I think Tyson's been there about 5.

Mr. STUPAK. So this agreement they use with the Japanese for the company of Tyson just came about in the last 5 years?

Mr. RICE. Yes. The Japanese certification process began about 3 or 4 years ago.

Mr. STUPAK. And that's because of an outbreak of illness they had in Japan, right?

Mr. RICE. That's because of China's outbreak of avian influenza.

Mr. STUPAK. They didn't want to give it to Japan, so that's why they used the certification?

Mr. RICE. Right.

Mr. STUPAK. Any reason why that certification would not work with the U.S.? Any reason why the U.S. could not go and certify?

Mr. RICE. I don't believe so. I don't know why it wouldn't work. It's at least a good starting point to consider how to manage that process.

Mr. STUPAK. Mr. Martin, if I may, and Dr. Martin, thanks for being here. How do they determine whether specific farms and production facilities in China meets Japanese safety standards and thus able to export? How do they do that?

Mr. MARTIN. Basically through a process whereby Japanese officials go over to China, meet with Chinese counterparts. They go out to the facilities and inspect it jointly.

Mr. STUPAK. Does Japanese have people permanently stationed in China?

Mr. MARTIN. They don't have people permanently stationed there as far as I understand, but they have people who will go over there and check out facilities.

Mr. STUPAK. When does Japan inspect food shipments from China?

Mr. MARTIN. When do they physically inspect the shipments?

Mr. STUPAK. Right.

Mr. MARTIN. Japanese officials will inspect it when it arrives in Japan at the port. They will make a determination on whether or not that food shipment will be selected for inspection.

Mr. STUPAK. And you said there's three layers of inspections, right?

Mr. MARTIN. Correct.

Mr. STUPAK. First comes in——

Mr. MARTIN. The first is not done by Japanese officials. They're basically relying on the Chinese system. And part of which Mr. Rice explained. The second part is when it comes into port and is clearing customs or is being brought in. If that particular shipment is selected for inspection, it goes to a quarantine center. There's 31 of them I understand in Japan where it will go through a physical inspection. If it passes the inspection, then it's released. The importers can take the shipment and then it goes into the market of Japan. But at that point, municipal authorities are prefectural employees. The equivalent of some state here will then inspect on the shelves on a regular basis.

Mr. STUPAK. In the testimony from our previous panel of our investigators here from the committee, we're talking about China's certification process. Japan doesn't rely on China's certification. They have their own certification process, is that correct?

Mr. RICE. Japan,only for the poultry plants.

Mr. STUPAK. Right.

Mr. RICE. For the 35 poultry plants that ship to Japan, the Japanese have certified their process. But when the product is shipped, AQSIQ is validating that was compliant with the Japanese law.

Mr. STUPAK. The point I was trying to get at, from the testimony, it looked like the Deputy Minister Wei was telling our group that if you just rely upon our system, it would all work. You would not have the problem with the melamine as you had because it wasn't certified by us. It was certified—but it sounds like there's—I wouldn't say a lack of trust but maybe a double checking or a check and balance system. Not only do you rely upon the Chinese system but you have your own certification. Japan has its own certification, or I should say inspection and certification. And even though China may have other certified farms, poultry farms, you rely upon the ones the Japanese have inspected and you inspect. Is that correct?

Mr. RICE. That's correct. If you can understand it as, of all food processors in China, if you rely on that system, your universe of food companies that could be shipped to you is 450,000. So it's this big. If you rely on the AQSIQ system, that shrinks to 12,700. And in the case of the Japanese, they can shrink that to 35.

Mr. STUPAK. And then the premium you said was 30 percent more.

Mr. RICE. It can be 20 to 30 percent more for price.

Mr. STUPAK. What would that mean for the average consumer, do you think? Just use your own product.

Mr. RICE. Because that's not 100 percent of the cost of a product, it could mean a 10 percent to 15 percent increase in pricing.

Mr. STUPAK. Of the product?

Mr. RICE. Right.

Mr. STUPAK. Each country can create its own food safety standards for Chinese imports. My impression is Japan has one set of standards, Hong Kong has another, and Russia has another you mentioned. Everyone has a different standard. You are shaking your head yes, right?

Mr. RICE. Yes. I'm sorry.

Mr. STUPAK. That's all right. I think my time's expired. Mr. Burgess, Mr. Whitfield, questions?

Mr. WHITFIELD. Thank you, Mr. Chairman. I'm sorry I missed you all's testimony a few minutes ago.

But Dr. Martin, let me just ask you, what was your methodology in gathering information about the food safety systems in Japan and Hong Kong?

Mr. MARTIN. Multiple systems. Hong Kong specifically, I lived there for an extended period of time. I continue to have contacts there. I worked there for a number of years. Similarly, I lived in Japan for a period of time and continue to have contacts back there. I also do have the standard contact with the Japanese Embassy here and the Hong Kong Economic and Trade Office here for asking for information, checked out scholarly materials on the information, looked at publications coming from U.S. Government agencies as well as other agencies, the Japanese agencies and the Hong Kong agencies overseas. I also checked the press and the media for information that's available. Basically as wide a search of materials as I could.

Mr. WHITFIELD. And from your knowledge of the Japanese food safety system and the Hong Kong food safety system, are there any lessons that FDA could take from those two systems that could help improve its food safety system?

Mr. MARTIN. I wouldn't use the word "lessons." That would be an issue for them to make the determination of whether they see value or merit in a particular idea. What I tried to indicate in the written report, as well as my oral testimony, is that they seem to have methods that they find—Hong Kong and Japan that is—that they find to be effective in making or getting a reasonable level of surety of the safeness of the food that they're importing from China.

And if you wish, could I specify, basically——

Mr. WHITFIELD. Yes. Just go over a few.

Mr. MARTIN. Well, one of them goes back to a point that I saw or I heard in Mr. Stupak's question, which is when they find an incident, when there is a particular shipment that seems to be problematic, the response both in Japan and Hong Kong is to contact their counterpart in mainland China. And in both systems they are trying to develop a very rigorous traceability process.

For example, all pork coming from mainland China into Hong Kong right now has a radio frequency ID tag on it. So they know exactly where that came from, which farm in mainland China that

came from. What they do is they go back to the mainland authority and say, we have a problem here. It's generally framed in the terms, we have a problem here. How did this happen? How can we prevent it from happening again? So the approach is, we have a shared problem. Go back over. Go back through the system. Find out where it broke down in this three-tiered process and fix it.

Mr. WHITFIELD. Right.

Mr. MARTIN. So that would be one example of an observation of the approach in common in Hong Kong and Japan.

Mr. WHITFIELD. Now Mr. Rice, you indicated that Tyson exports from the U.S. to China poultry product, correct?

Mr. RICE. Yes.

Mr. WHITFIELD. Now is that the whole chicken or is that chicken parts?

Mr. RICE. It's chicken paws and wing tips mostly.

Mr. WHITFIELD. Chicken paws and wing tips. Yet you have facilities in China where you produce chickens as well, is that correct?

Mr. RICE. In China we don't grow chickens but we buy raw chicken meat from other producers and we make further processed products, like nuggets or patties.

Mr. WHITFIELD. And you export that from China to——

Mr. RICE. To Japan and mostly to the domestic market in China.

Mr. WHITFIELD. All right. And based on your experience do you feel that food can safely be imported from China to the U.S.?

Mr. RICE. If the universe of exporters was narrowed down to AQSIQ-certified plants and they're inspected, I believe the Chinese can do it.

Mr. WHITFIELD. And well, Mr. Chairman, I see that my time is just about expired. I want to thank you all for being with us today. We appreciate you taking time to give your expert advice. Thank you.

Mr. STUPAK. Further questions? Mr. Melancon.

Mr. MELANCON. And I'm not sure. But maybe Dr. Martin or Mr. Rice had experience.

I'm hearing that China can monitor its exports when the importing countries require it. But the U.S. obviously doesn't demand this, which kind of makes me wonder, if Hong Kong, Japan and even the European Union don't allow tainted food, where does this tainted food go when they turn it down?

Mr. MARTIN. In the case of Hong Kong and Japan, Japan will destroy tainted food that they capture and is quarantined in the testing process. And Hong Kong, I believe they also destroy the food.

Mr. MELANCON. If it goes to the European Union, do you know?

Mr. MARTIN. I don't know about the European Union.

Mr. MELANCON. I'm of the understanding, at least on seafood, that they just ship it to another country, like the United States, that doesn't have the requirements.

Mr. MARTIN. I couldn't comment on the European Union practice.

Mr. MELANCON. Maybe somebody could look into that. It goes back to that ad that I was shown for a company that's online that says, if you've got FDA-rejected food or if you've got food that's been rejected for importation, contact us, which tells me they're sending it someplace. Sort of like Mr. Burgess. I'm not sure who

got those lead-tainted toys, but I'm sure somebody's going to get them. They're not just going to disappear.

But thank you. I yield back my time.

Mr. STUPAK. Mr. Burgess, anything?

Mr. BURGESS. Thank you, Mr. Chairman. If I could, Mr. Rice. By an accident of marriage, I have family in Arkansas and so from time to time will travel in Arkansas and will see a lot of your company's logos. And the chicken-growing facilities that are licensed by Tyson seem to be pretty secure sites. You can't just wander into one. You have to be there for a reason. There seems to be a lot of reproducibility of the types of chicken houses and how they're constructed. So obviously your company goes to great pains to make sure that the product that is grown in our country meets their standards and presumably that is also product that's available for export now. You mentioned in response to a question that in China you don't grow your own chickens, but you do buy some raw material for export. And in your written testimony you say you practice 100 percent inspection on all raw materials coming into our facility. Can you kind of just give us a quick sketch of what that inspection comprises?

Mr. RICE. Yes. Well, you are talking about our biosecurity, which is keeping the security clear so you can't contaminate your chickens with wild birds or other humans. And that exists in China and in the United States. When I was talking about the raw materials that we use to manufacture our products inside China, inside our plants, are raw chicken meat, flour, breading, oil and these things. And for everything that comes into our facility, we visually inspect it and we also test for residuals and chemicals. So I have eight full-time employees in a plant of 250 that only inspect incoming raw materials. So we want to be sure that 100 percent of what comes in is right before we make our product.

Mr. BURGESS. Now, do you ever find any problems?

Mr. RICE. Yep, we do. That's why we keep that level of inspection.

Mr. BURGESS. When you find a problem, do you communicate that to say the U.S. authorities so that they know to be on the lookout of similar products in other facilities?

Mr. RICE. No, we don't. Because these are local Chinese suppliers, and we are making product mostly for the Chinese market. So we would go straight to our supplier with our quality assurance team and inspect their facility and then look for why that problem came.

Mr. BURGESS. But there would be no dialog with, say, someone else who may be serviced by that same supplier to look out for the bad stuff that's in these chicken wing tips or whatever it is we're selling?

Mr. RICE. No. But Tyson does not source raw materials from China at this time.

Mr. BURGESS. If you see a persistent problem coming from one supplier, what do you do to identify or do you identify that supplier to other companies or to U.S. authorities, to boy, be on the lookout for these guys.

Mr. RICE. No, we would not. But we would stop using that supplier and switch to a new one.

Mr. BURGESS. The only clue that our guys, who are also over there tasked with making sure that products that come into this country are safe is that, hey, Tyson's is giving these guys the cold shoulder. Maybe we ought to look at other stuff coming out of their facility.

Mr. RICE. There is no formal way to notify.

Mr. BURGESS. There is no formal way?

Mr. RICE. No.

Mr. BURGESS. Not even as just an internal company policy, hey, if we find a bad problem, we're going to blow the whistle here and notify others?

Mr. RICE. No. There's no procedure for that.

Mr. BURGESS. Dr. Martin, if I could ask you, I mean, in response to when you elaborated on the answer to Mr. Whitfield's question. You talked a little bit about some of the same issue about Hong Kong and Japan tracking problems if they identify problems. Is that not correct?

Mr. MARTIN. Yes. That's common specifically in the case of the pigs or pork coming in from mainland China, yes.

Mr. BURGESS. So they do, they do keep some track of if there are persistent problems, it heightens their own internal security. But do they communicate with anyone else?

Mr. MARTIN. Outside of Hong Kong, the Hong Kong Government and Japanese Government with mainland counterparts?

Mr. BURGESS. Yes.

Mr. MARTIN. I do not know specific examples where the Hong Kong-Japan Government have contacted a fourth party, that is to say somebody other than mainland China, about the problem.

Mr. BURGESS. So they would not contact another foreign government, say, hey, if you're getting pig's feet from amalgamated pig's feet farm in wherever China, this is a problem for us and it may be a problem for you?

Mr. MARTIN. The example you are giving is of a specific farm and a particular problem. I do not know of any particular case where they would do that. They do hold international meetings where they discuss common problems, we are noticing that a high percentage of this particular food product coming from mainland China is problematic; where is the source of the problem coming from?

Mr. BURGESS. So in general, there is discussion about where the hotspots are, where the problems are, is that correct?

Mr. MARTIN. My sense of it from looking at the proceeds from those meetings, it tends to be at the technical level and on the product level. That is to say, we have a problem product that has this technical problem that comes up time and time again. I suspect on the next panel with USDA and FDA, they can, probably specifically talk about events of that sort because I am sure that they have had some in mainland China and in Hong Kong.

Mr. BURGESS. There would at least be a route for the authorities in this country to be notified of a problem that has occurred and is persistent?

Mr. MARTIN. Yes, there are avenues of communication, sure.

Mr. BURGESS. But there is not a specific obligation to say, hey, this is trouble.

Mr. MARTIN. There's nothing under current Japanese or Hong Kong law that requires those agencies to notify the international community it's a problem.

Mr. BURGESS. Thank you, Mr. Chairman.

Mr. STUPAK. Thank you, Mr. Burgess. Mr. Rice, does Tyson notify the Japanese officials if they find a problem with one of their suppliers, something coming into your plant?

Mr. RICE. No.

Mr. STUPAK. But you receive your product from Japanese-certified suppliers?

Mr. RICE. That's correct.

Mr. STUPAK. Why wouldn't you notify them?

Mr. RICE. Because we're talking about isolated shipments where we might find foreign, foreign objects like hair or a piece of wood or something like that.

Mr. STUPAK. What if it was a chemical that shouldn't be——

Mr. RICE. Then we would notify the AQSIQ. And one process that might help, such a company would end up on the blacklist of the AQSIQ, which would be available publicly to all countries.

Mr. STUPAK. Well, yes, would the AQSIQ, whatever it is there, are they required to pass it down to the Japanese or just publish it?

Mr. RICE. I don't know what the agreement is between AQSIQ and MAFF.

Mr. STUPAK. The growers or suppliers that you use, do they supply exclusively to Tyson and to Japan or can they—other countries or other processors like yourself?

Mr. RICE. They would supply to multiple customers who would be part of their business. In general it's not more than 10 or 20 percent of their business is Japan and the rest would be a domestic market. It could be Southeast Asia or Korea as well.

Mr. STUPAK. We've indicated throughout this testimony that in Japan I think they inspect about 15 percent. U.S., it's less than 1 percent. Is there a number you think would be appropriate, 5 percent, 15 percent, 25 percent of the food products coming into this country should be inspected?

Mr. RICE. I would not know that.

Mr. STUPAK. Dr. Martin, any guess on that?

Mr. MARTIN. I couldn't give you a number. But what I would say is that my anticipation is that a statistician would ask you what's your goal or objective.

Mr. STUPAK. Mr. Rice, you said you have eight lab people or inspectors out of 250. What percentage of your budget is for safety, for inspection, for going to that farm to make sure things are right? Can you give me an estimate?

Mr. RICE. I would guess it's between 3 and 4 percent.

Mr. STUPAK. Does Tyson use carbon monoxide when you ship any of the poultry?

Mr. RICE. No, we do not.

Mr. STUPAK. No further questions. Thank you, Dr. Martin. Thank you, Mr. Rice. Thank you for your testimony. It was very helpful.

We'll dismiss this panel and call up our third panel of witnesses. We have Dr. David Acheson, Assistant Commissioner for Food Pro-

tection at the Food and Drug Administration; Ms. Margaret Glavin, Associate Commissioner for Regulatory Affairs at the Food and Drug Administration. They're accompanied by Mr. Michael Rogers, Director of Field Investigations Division at the FDA; Mr. Domenic Veneziano, Director of Import Operations and Policy at FDA; and Mr. Donald Kraemer, Deputy Director of the Office of Food Safety and the Center for Food Safety and Applied Nutrition at the FDA.

We also have Dr. Richard Raymond, who is the Under Secretary for Food Safety at the U.S. Department of Agriculture. Dr. Raymond is accompanied by Dr. Bill James, who is the Deputy Assistant Administrator for International Affairs at the USDA Food Safety and Inspection Service.

It's a policy of this subcommittee to take all testimony under oath. Please be advised that our witnesses have the right under the rules of the House to be advised by counsel during their testimony. Do any of you wish to be represented by counsel? Everybody indicating they do not, so we will move forward. Please rise and raise your right hand to take the oath.

[Witnesses sworn.]

Mr. STUPAK. Let the record reflect the witnesses have replied in the affirmative. They are now under oath.

We will now hear a 5-minute opening from the witnesses, and they may submit a longer statement for inclusion in the hearing record.

Mr. STUPAK. Dr Acheson, would you like to start for an opening statement?

STATEMENT OF DAVID W.K. ACHESON, M.D., ASSISTANT COMMISSIONER, FOOD PROTECTION, FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. ACHESON. Good morning, Mr. Chairman and members of the subcommittee. I am Dr. David Acheson, Assistant Commissioner for Food Protection at the U.S. Food and Drug Administration. FDA Commissioner Andrew von Eschenbach has appointed me to this new position to provide leadership on strategic and substantive food safety and food defense matters.

Thank you for the opportunity to discuss the important issues relating to the safety of imported food. FDA regulates everything Americans eat except for meat, poultry and processed egg products, which are regulated by our partners at the Department of Agriculture. The agency's committed to ensuring that the Nation's food supply continues to be as safe as possible.

In recent years FDA has done a great deal to detect and prevent both unintentional and deliberate contamination of imported products. But we continue to face many significant challenges to food safety, including changes in consumer expectations, changes in production, manufacturing and processing techniques, increased globalization and terrorism.

One of the major issues we face is the rapidly increasing level of food imports. Currently FDA oversees more than 9 million line entries of imported food annually. Shipments of food represent about 60 percent of FDA regulated imports. We're looking to enhance product safety by broadening our knowledge and applying

enhanced risk-based criteria to the entire life cycle of imported products.

The President is engaged directly in the effort to ensure that FDA and other agencies are doing everything we can to protect Americans from unsafe imports. On July 18, the President issued an Executive order creating a Cabinet level Working Group on Import Safety, which I will discuss in more detail later.

My priority assignment as Assistant Commissioner is to coordinate the development of a new Food Protection Strategy. This will enhance our food safety and food defense systems by addressing the challenges we face. The Food Protection Strategy will be comprised of three fundamental elements: First, a proactive prevention strategy to build safety in from the start; second, risk-based interventions to ensure preventive approaches are effective; and, third, rapid responses when contaminated food is detected or when there's harm to humans or animals. This integrated approach will build on existing partnerships with industry, other regulators and consumers and fully utilizes advances in technology.

FDA's overall goal is to ensure a comprehensive and robust food safety and food defense program that will provide the level of food protection American consumers expect. With regard to imports, we need a fundamental shift from the current model that relies on snapshots at the border to a cost-effective prevention focused model that identifies and targets those steps in the life cycle of imported food where the risks of unsafe products are greatest.

This model is consistent with the President's Interagency Working Group on Import Safety. The working group includes members from 12 Federal departments and agencies, and its mission is to review the procedures, regulations and practices under which we manage the safety of all imported consumer products. The Secretary of Health and Human Services, Michael Leavitt, chairs the working group and FDA plays a key role.

Secretary Leavitt and Commissioner von Eschenbach have traveled extensively throughout the United States during the past few months. The insights that they've gained during their reviews helped shape the strategic framework that was released by the working group on September 10. That report outlines an approach, like FDA's Food Protection Strategy, that's based on the organizing principles of prevention, intervention and response.

With respect to the recent well-publicized issues with regard to the safety of imported products from China, FDA's conducting a series of meetings with Chinese officials to negotiate memoranda of agreements aimed at creating a framework to help assure the safety, quality and effectiveness of products exported from China to the U.S. The agreements also aim to increase cooperation and information sharing between the regulatory bodies of the two nations with a goal of strengthening China's regulatory process. These negotiations are ongoing, with a goal of finalizing the agreements by year's end.

Ensuring the safety of imported foods is a difficult task, but I want to ensure you that FDA is diligently working to efficiently and effectively use the resources and authorities we have been provided by Congress to help protect American consumers.

Thank you for the opportunity to discuss FDA's activities to enhance the safety of imported food. I would be happy to answer any questions you may have.

[The prepared statement of Dr. Acheson follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT OF

DAVID W. K. ACHESON, M.D.

ASSISTANT COMMISSIONER FOR FOOD PROTECTION

AND

MARGARET O'K. GLAVIN

ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON ENERGY AND COMMERCE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

U.S. HOUSE OF REPRESENTATIVES

OCTOBER 11, 2007

For Release Only Upon Delivery

INTRODUCTION

Mr. Chairman and Members of the Committee, I am David W.K. Acheson, Assistant Commissioner for Food Protection at the U.S. Food and Drug Administration (FDA or the Agency). I am joined here today by my colleague, Margaret O'K. Glavin, Associate Commissioner for Regulatory Affairs. Thank you for the opportunity to discuss the important issues relating to the safety of FDA-regulated imported products.

FDA-regulated products include food and animal feed, human and animal drugs, cosmetics, vaccines and other biological products, and medical devices. FDA is committed to ensuring that the nation's supply of these products continues to be among the safest in the world, but in doing so we face significant challenges. One of those challenges is the rapid increase in the volume of imported products.

Each year, approximately $2 trillion of imported products enter the United States. The volume of FDA-regulated imports has doubled in the last five years, and 60 percent of these imported shipments are food. Currently, FDA is overseeing over nine million line entries of imported food annually and most of these entries are large volume commercial shipments. It is estimated that approximately 15 percent of the U.S. food supply is imported, but for some products such as fresh fruits and seafood, imports account for 50 to 60 percent of the supply.

FDA REGULATION OF IMPORTED PRODUCTS

FDA's primary authority over imported food, cosmetics, drugs, biological products, and medical devices, derives from section 801 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Imported radiation emitting products are regulated under section 534 of the FD&C Act. These authorities provide a broad statutory framework to ensure that the products are safe. Imported, as well as domestic, FDA-regulated products are subject to examination by FDA.

When an FDA-regulated product is offered for import into the United States, U.S. Customs and Border Protection (CBP) procedures ensure that FDA is notified. If, based on examination or other information such as the prior history of the product, manufacturer or country, the product appears to be adulterated or misbranded, FDA will give notice advising the owner or consignee of the appearance of a violation and the right to provide evidence (such as a laboratory analysis by an independent laboratory) to rebut the appearance of the violation. In some circumstances, importers may request permission to recondition the product to bring it into compliance with applicable requirements and regulations. If the product is ultimately refused admission, it must be destroyed within 90 days unless re-exported by the owner or consignee.

Imported Food

To better manage the increasing volume of imported products that we regulate, FDA currently screens electronically-submitted information on all incoming shipments, and then uses a risk-based approach that targets our inspectional resources at products having the greatest potential

for causing harm to public health. It is important to note that while FDA is not able to physically inspect a large percentage of import entries, we electronically screen all import entries through the Operational and Administrative System for Import Support (OASIS) for a variety of risk factors. OASIS is an automated system for processing and helping FDA make admissibility determinations for FDA-regulated products offered for import.

In 2002, Congress gave FDA significant new authorities to enhance protection of the food supply in the Public Health Security and Bioterrorism Preparedness and Response Act (the Bioterrorism Act). One of the most important provisions is the requirement that FDA be provided prior notice of food (including animal feed) that is imported or offered for import into the U.S. This advance information enables FDA, working closely with CBP, to more effectively target food that may be intentionally contaminated with a biological or chemical agent or which may pose a significant health risk to the American public. Suspect shipments then can be intercepted before they arrive in the U.S. and held for further examination. Prior notice can be submitted either through CBP's Automated Broker Interface/Automated Commercial System (ABI/ACS) or FDA's Prior Notice System Interface (PNSI). Currently, FDA receives approximately 33,400 prior notice submissions per business day.

Another significant provision of the Bioterrorism Act provides FDA with the authority to commission CBP employees to conduct examinations and investigations. Under a December 2003 Memorandum of Understanding, FDA has commissioned more than 8,000 CBP officers to conduct examinations on FDA's behalf at ports where FDA may not currently have staff. This

inter-agency collaboration significantly strengthens our ability to prevent the introduction of unsafe or insecure imported food into U.S. commerce, while ensuring the movement of legitimate trade.

FDA has numerous other tools and authorities that enable the Agency to take appropriate action regarding imported products. FDA performs routine surveillance examinations of imported goods to check for compliance with U.S. requirements. Although the Agency conducts inspections of food manufacturers overseas, because of the large volume of FDA-regulated foods being exported from a large number of countries, it is not feasible to routinely inspect every shipment of foreign-produced foods at the point of origin. We do, however, work with foreign governments and food producers to help ensure that imported food is produced, processed and packed in accordance with U.S. requirements.

Another key tool for screening imported goods is the Import Alert. Import Alerts are guidance documents that inform FDA field personnel that FDA has sufficient evidence or other information about a particular product, producer, shipper or importer to believe the products do not meet U.S. requirements or is otherwise unsafe. On the basis of that evidence, FDA field personnel may detain the article that is being offered for entry into the U.S. without physically examining the product. When an Import Alert is issued and FDA detains a shipment, the owner or consignee has an opportunity to introduce evidence to demonstrate that the products are not violative. FDA also performs laboratory analysis on a sampling of products offered for import into the U.S. and performs periodic filer evaluations to ensure that import data being provided to

FDA is accurate. In addition, certain violations relating to imported food may lead to civil or criminal charges.

Food Safety Strategy

In May of this year, FDA Commissioner Andrew C. von Eschenbach, M.D., appointed me to fill a newly created position, the Assistant Commissioner for Food Protection, to provide advice and counsel on strategic and substantive food safety and food defense matters. My first priority in this position is to develop a new strategy for the integration of food safety and food defense covering both imported and domestically-produced foods that FDA regulates. The new food protection strategy will identify the Agency's most critical needs, address the changing nature of the global food production system, and provide a framework to address these challenges. The organizing principles of the new strategic framework will be based on prevention, intervention, and response. The plan will apply enhanced risk-based criteria to the entire life-cycle of FDA-regulated imported food. By refining these targeting criteria in a life-cycle approach, we will be able to conduct more rigorous and meaningful reviews of potentially high-risk food entries. The goal is to ensure a comprehensive and robust food safety and food defense program that is tailored to meet the emerging risks posed by the types of foods we regulate.

Interagency Working Group on Import Safety

To promote and enhance the safety of all imported products, the President issued an Executive Order on July 18, 2007, that established the Interagency Working Group on Import Safety. The Working Group, which includes representatives from 12 Federal departments and agencies, is

tasked with reviewing the procedures, regulations, and practices for ensuring that imported food, drugs, and other consumer products are safe. Secretary of Health and Human Services, Michael O. Leavitt, chairs the Working Group and FDA plays a key role. Secretary Leavitt and FDA Commissioner von Eschenbach traveled extensively throughout the country during the past few months visiting ports of entry and reviewing FDA field operations. The insights they gained are helping to shape the conclusions and recommendations of the Working Group.

On September 10, 2007, the Working Group provided the President with an initial report on steps to improve import safety. Their report, "Protecting American Consumers Every Step of the Way: A Strategic Framework for Continual Improvement in Import Safety," outlines an approach that can build upon existing efforts to improve the safety of imported products, while facilitating trade. It recommends that the government work with the importing community in developing methods to address safety risks over the life-cycle of imported products and focus actions and resources to minimize the likelihood of unsafe products reaching our borders. A risk-based, prevention-focused model will help ensure that safety is built into products before they reach consumers.

On October 1, 2007, the Working Group conducted a meeting in Washington to receive input from stakeholders and the general public. By mid-November, an Action Plan based on the Strategic Framework will be provided to the President. The plan will reflect the public comments and recommend specific steps that the Federal government and stakeholders can take to enhance import safety at all levels.

Federal agencies have already begun to implement high-priority recommendations from the interim report. For instance, by November 12, 2007, Federal agencies that rely on Information Technology (IT) systems in their review of imported cargo must develop implementation plans to achieve interoperability of their import data systems with the International Trade Data System managed by CBP. This requirement is consistent with the Security and Accountability for Every (SAFE) Port Act of 2006, and will ensure a single-window system for reporting on imports electronically.

CHINESE IMPORTS

China is a major producer, exporter, and importer of FDA-regulated products and it presents a diverse range of issues for the Agency. China is presently one of the world's largest producers and consumers of agricultural products, and a major supplier to the U.S. of seafood, canned vegetables, fruit juices, honey, and other processed foods. In the past, FDA has encountered compliance problems with several Chinese food exports, including lead and cadmium in ceramic ware used to store and ship food, and staphylococcal contamination of canned mushrooms. While improvements have been made in these products, the safety of food and other products from China as well as other trading partners, remains a concern for FDA, Congress, and American consumers. While these concerns are not unique to China, recent incidents have focused greater attention on these issues. Prominent examples of these concerns are discussed below.

Aquacultured Seafood

Aquacultured seafood is a fast-growing sector of the world food economy, accounting for approximately half of all seafood production worldwide. About 80 percent of the seafood consumed in the U.S. is imported from approximately 130 countries, and over 40 percent of that seafood comes from aquaculture operations. By volume, China is the largest exporter of seafood to the U.S., and the second largest in terms of monetary value. In particular, China exports significant amounts of shrimp and catfish products, which represent two of the ten most consumed seafood products in the U.S.

As the aquaculture industry continues to grow, concern about the use of unapproved drugs and unsafe chemicals in aquaculture operations has increased substantially. There is clear scientific evidence that the use of unapproved antibiotics and other drugs and chemicals such as malachite green, nitrofurans, fluoroquinolones, and gentian violet can result in the presence of residue in the edible portions of aquacultured seafood. Fluoroquinolones have been prohibited from extra-label use in the U.S. and many other parts of the world in aquaculture because of public health concern about the development of antimicrobial resistance. Moreover, prolonged exposure to nitrofurans, malachite green, and gentian violet, or their metabolites, has been shown to induce cancer in humans or animals. From a regulatory perspective, FDA has not approved any of these substances for use as drugs in aquacultured animals, nor are they generally recognized as safe or approved as food additives under section 409 of the FD&C Act.

Since November 2001, FDA has tested shipments of aquacultured seafood products from China and other countries, and when warranted, has placed individual firms on Import Alert. In 2006, FDA broadened these restrictions significantly by issuing an Import Alert providing for the detention without physical examination of eel from anywhere in China due to findings of malachite green. Through increased sampling of imported Chinese aquacultured seafood from October 1, 2006, through May 31, 2007, FDA continued to find residue of unapproved drugs and unsafe chemicals in species including catfish, basa, shrimp, and dace. Because we saw problems from many different companies located in various parts of China, on June 28 of this year, FDA imposed a countrywide Import Alert on all farm-raised catfish, basa, shrimp, dace and eel from China. Under the Import Alert, FDA can detain a shipment, even without physically examining it, unless it is shown to be free of the residue that led to the Import Alert.

Pet Food and Farm Feed

On March 15, 2007, FDA learned that certain pet foods were sickening and killing cats and dogs. Analysis by the Agency's Forensic Chemistry Center revealed melamine and melamine analogues in the pet foods and in the wheat gluten used as ingredients. After FDA traced the suspect wheat gluten to a single supplier in China, we issued an Import Alert focused on this firm and began sampling 100 percent of all wheat gluten from China. In April, FDA launched an investigation into imported rice protein concentrate that also was used as an ingredient in some pet foods and was found to contain melamine and its analogues. The Agency traced the suspect product to another Chinese supplier. We issued an Import Alert focused on this supplier and began sampling 100 percent of all rice protein concentrate from China.

Ultimately, Import Alert No. 99-29 was issued on April 27, 2007, to expand on the previous alerts to cover all vegetable protein products from China. Under the Import Alert, FDA can detain these products unless third party analysis or other evidence demonstrates they are not contaminated with melamine or its analogues. FDA believes that all of the contaminated wheat gluten and rice protein from China used in the manufacture of pet food has been removed from commerce.

During the investigations that traced the distribution of contaminated pet food, it was discovered that byproducts (or scraps) from the manufacture of this pet food were distributed to farms in a limited number of states and added to the feed consumed by swine and poultry. A panel of scientists from five Federal agencies determined that there was unlikely to be a significant risk to human health from consuming food from animals that ate tainted feed, due to the small amounts present and the small amounts that would be consumed.

MEMORANDA OF AGREEMENT

While these concerns are not unique to China, recent incidents have focused greater attention on these issues. FDA and others within the Department of Health and Human Services (HHS) are actively engaged with our Chinese counterparts in negotiating comprehensive Memoranda of Agreement that will include commitments in many areas of food and feed production to increase our confidence in the safety of these Chinese products that are exported to the U.S.

In September 2006, President Bush and Chinese President Hu Jintao agreed to create a Strategic Economic Dialogue between the United States and China. Reflecting the growing relationship between the U.S. and Chinese economies, the Strategic Economic Dialogue is designed to be a forum for discussing ways the United States and China can work together to address economic challenges and opportunities as responsible stakeholders in the international economic system. Last May, in conjunction with the 2nd Strategic Economic Dialogue, HHS initiated discussions regarding the need for stronger agreements with relevant regulatory agencies in China. The agreements are intended to help assure the safety, quality and effectiveness of FDA-regulated products exported from China to the U.S.

The most recent step in this ongoing process occurred two weeks ago when a delegation of senior HHS and FDA officials held a series of initial negotiations with senior officials in Beijing. Represented agencies included the Chinese State Food and Drug Administration; the General Administration of Quality Supervision, Inspection and Quarantine; the Ministries of Health and Agriculture; and the Certification and Accreditation Administration. These sessions initiated formal negotiations on two Agreements, one on the safety of food and feed, and another on the safety of drugs and medical devices. Negotiations will continue next month. FDA believes these talks have yielded significant progress towards achieving two, strong, action-oriented documents.

CONCLUSION

Ensuring the safety of the food supply continues to be a top priority for FDA and we are working hard to ensure the safety of all human food and animal feed, in collaboration with our Federal, state, local, and international food safety partners. FDA is working diligently to efficiently and effectively use the resources and authorities provided by Congress to protect the public health of the U.S. and to help ensure that imported products are safe for American consumers. Despite the challenges which face us, the American food supply continues to be among the safest in the world. Thank you for the opportunity to testify. We look forward to responding to any questions you may have.

Mr. STUPAK. Thank you, Dr Acheson. Ms. Glavin, opening statement, please.

STATEMENT OF MARGARET O'K. GLAVIN, ASSOCIATE COMMISSIONER, REGULATORY AFFAIRS, FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; ACCOMPANIED BY MICHAEL C. ROGERS, DIRECTOR, DIVISION OF FIELD INVESTIGATIONS, OFFICE OF REGULATORY AFFAIRS, FOOD AND DRUG ADMINISTRATION, DOMENIC J. VENEZIANO, DIRECTOR, DIVISION OF IMPORT OPERATIONS AND POLICY, OFFICE OF REGULATORY AFFAIRS, FOOD AND DRUG ADMINISTRATION, AND DONALD W. KRAEMER, DEPUTY DIRECTOR, OFFICE OF FOOD SAFETY, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION

Ms. GLAVIN. Good afternoon, Mr. Chairman and members of the committee. Thank you for inviting me. I'm Margaret Glavin. I'm the Associate Commissioner for Regulatory Affairs at the Food and Drug Administration. The Office of Regulatory Affairs is the lead organization within FDA responsible for enforcing FDA's public health laws and regulations. We're guided in our mission, which is to protect consumers and enhance public health by maximizing compliance of FDA-regulated products and minimizing risks associated with those products. To meet these responsibilities, ORA is staffed with a workforce of approximately 3,200 employees, 2,700 of whom are dispersed geographically throughout the country.

My testimony today will discuss ORA's import operations and the tools we have at our disposal to prevent adulterated or misbranded imported goods from entering domestic commerce. I will also provide an overview of the challenges that confront us and measures that are being contemplated to enhance our coverage of imported goods.

In July, when I testified before this committee, I discussed ORA's proposed Transformation Initiative, a component of which involved consolidating FDA's field laboratories. That effort, including the proposal to close laboratories, is no longer under consideration. What remains as relevant today as it was in July are the challenges that confront ORA in our efforts to fulfill our mission to protect the public health. These challenges have not gone away and are continuing to grow.

For these reasons ORA has undertaken a planning process that examines how we can best meet our future needs and public health mandates. This process, which is drawing on the experience, expertise and input of all ORA employees, will allow us to be more strategic in our efforts to ensure that we invest in the right tools, skill sets and programs to meet the challenges posed by emerging threats, ongoing public health emergencies, increasingly complex technological advances in the industries we regulate and burgeoning imports, one of the topics this committee is addressing today.

The volume of goods offered for entry into the United States is growing exponentially, and these imported products include every type of FDA-regulated product and come from more than 200 countries and more than 300,000 manufacturers worldwide.

As has been said many times this morning, we physically inspect less than 1 percent of the imported food that is offered for entry into the U.S. To better ascertain which food we ought to physically inspect, FDA uses a number of approaches to help us make risk-based decisions. One of these involves having FDA inspectors conduct inspections of foreign manufacturing facilities that export FDA-regulated goods to the U.S. to make certain that they are following good manufacturing processes and other regulatory requirements, such as HACCP for seafood and juice products.

In addition, we conduct outreach to food processors and food producers in foreign countries to enhance their understanding of food safety and good agricultural practices. FDA also works with and provides training to our regulatory counterparts in foreign countries. This training focuses on U.S. public health requirements and methods to improve food safety in order to ensure that exporters are able to meet our requirements, and FDA works with our foreign regulatory counterparts to share information regarding each country's laws, requirements and food safety systems and which also allow for notification to each other when significant violations are found.

In 2002, Congress provided us with significant new authorities to enhance the protection of the food supply through the provisions of the Bioterrorism Act.

FDA utilizes a significant new tool provided under this act that requires us to receive prior notification before food is imported or offered for import into the United States. Advanced notice of imported food shipments allows us, with the support of Customs and Border Protection to electronically screen the shipments for potentially serious threats to health before the food arrives and to target those products flagged by the system as presenting the most significant risk. This allows us to conduct more intensive import security reviews on potentially high-risk entries and to allocate resources for inspections more effectively.

All prior notice data is validated against FDA's OASIS system for completeness to ensure that it meets minimal data submission requirements. Once the data is validated, it is screened against specific food security criteria established in the system to identify and flag high-risk shipments. Prior notice of high-risk screening criteria are based on a number of factors, including risk assessments conducted in accordance with operational risk management and CARVER plus Shock methodologies to identify those food shipments that present the highest food security risk and are most vulnerable. Additional screening criteria are established based upon contemporary intelligence reports.

To conduct intensive, manual high-security reviews, the prior notice staff utilizes information contained in internal FDA data systems, as well as those of other agencies such as CBP and the Treasury Enforcement Communication System to further assess specific risks associated with subject food shipments as well as any links that parties associated with the shipment may have to terrorist organizations or criminal intelligence records. They also consider anomalies in shipping patterns and past shipping histories.

Based on these risk factors, the prior notice center staff makes the determination whether the shipment poses a significant secu-

rity risk to the American people. Those shipments of imported foods that are determined to pose a significant security risk are held upon arrival in the U.S. for joint examination by FDA and CBP personnel. Those shipments that are not deemed to be a security risk are released for an import admissibility review for food safety concerns.

Another significant provision of the BT Act provided FDA with the authority to commission CBP employees to conduct examinations and investigations of imported foods on FDA's behalf so that they can assist us in the examination and investigation of imported food at ports of entry or other facilities and locations in close proximity to such ports. This provides FDA with operational assistance from our CBP colleagues when necessary and has proven to be useful, especially at remote ports of entry.

After prior notice requirements have been met, incoming shipments are subject to an admissibility decision as to whether or not a particular shipment of imported food should be allowed to enter domestic commerce. To make this decision, we often use targeted examinations called physical examinations or field examinations. A field examination is a visual examination of a product to determine whether the product is in compliance with our requirements, and it involves actual physical examination of the product for admissibility factors.

In addition, a field exam can be supplemented with other activities such as sample collections and analyses for microbiological or chemical contamination. When relevant product information is gathered from our domestic surveillance and inspection program, FDA factors this information into its import decisionmaking process.

Another key tool used to screen imports is the import alert. Import alerts are used to provide direction to our field personnel indicating that FDA has sufficient evidence or information about a particular product to refuse admission of that article being offered for entry without physically examining the product. This is a practice that was referred to as detention without physical exam.

Mr. STUPAK. Can you summarize, please.

Ms. GLAVIN. Absolutely.

As I said, we do those things. We also determine if an imported product should be denied. And once we determine that an imported product should be denied entrance into the U.S., a notice of detention and hearing is issued. We detain the goods, and we allow the importer to present evidence supporting the admissibility of the questionable goods. Based upon our review of the evidence, we may release the goods. But if we maintain our position that the goods cannot be allowed admission into the U.S., the goods must either be destroyed or reexported within 90 days.

As I described in my testimony today, we use our available tools and authorities to manage the ever-increasing volume of imported food to achieve the greatest protection possible. And ensuring the safety of the food supply continues to be a top priority of the FDA. As Dr. Acheson has indicated, FDA, including ORA, understands the need to focus our resources to improve consumer protection in the import arena and is committed to moving towards a cost-effective prevention focus model that identifies and targets those steps

in the life cycle of imported products where the risk of unsafe products are the greatest.

Thank you for the opportunity to testify, and I'll be pleased to answer any questions.

Mr. STUPAK. Dr. Raymond, please. Opening statement.

TESTIMONY OF RICHARD RAYMOND, M.D., UNDER SECRETARY, FOOD SAFETY U.S. DEPARTMENT OF AGRICULTURE; ACCOMPANIED BY BILL JAMES, D.V.M., DEPUTY ASSISTANT ADMINISTRATOR FOR INTERNATIONAL AFFAIRS, FOOD SAFETY AND INSPECTION SERVICE

Dr. RAYMOND. Yes, sir.

Mr. Chairman and members of the subcommittee, I'm very pleased to have the opportunity to appear before you here today. I am Dr. Richard Raymond, Under Secretary for Food Safety at the USDA, and I'm here to discuss how the USDA regulates meat, poultry and egg products to protect American consumers.

As the Under Secretary for Food Safety, I do oversee the Food Safety and Inspection Service, FSIS. FSIS is the USDA public health regulatory agency responsible for the administration of laws and regulations that are designed to ensure that the Nation's commercial supply of meat, poultry and egg products is safe, wholesome and properly labeled regardless of whether those products are sold in the United States or imported to or exported from the United States.

In contrast to the rise seen in other imported products, the amount of FSIS-regulated imported meat and poultry products has remained approximately the same in the last 5 years, hovering around 4 billion pounds of meat and poultry from the 33 countries that have equivalent food safety systems. In that time, the amount of imported product that was detained, destroyed or returned has doubled as we have become more effective in what we do.

FSIS employs a comprehensive three-part system for imports that helps to ensure the safety of imported product. This system consists of, one, establishing the initial equivalence of the meat, poultry or egg product inspection system of the country wishing to export to the United States; two, verify and continue equivalence of foreign systems through annual audits; and, three, providing 100 percent reinspection with a few exceptions when products enter the country.

Equivalence is the foundation for our system of imports. It recognizes that an exporting country can provide an appropriate level of food safety even if those measures are different from those applied here in the United States. FSIS begins the process of determining equivalence by analyzing the country's meat or poultry regulatory system with a document analysis to assess whether the country has the laws, the regulations and the infrastructure to support an equivalent system. This document review focuses on a country's practices and five risk areas. They are sanitation, animal diseases, slaughter processing, residues and enforcement.

If the document review is satisfactory, then the process of determining equivalence moves to the on-site review. During an on-site review, an FSIS audit team evaluates all the aspects of a country's inspection program from the headquarters of the inspection system

to regional offices and local offices, and ultimately to individual establishments within the country, and to laboratories that will be testing the product that is destined for the United States.

The second part of our system is to verify continuing equivalence through audits. This means that once a country is determined to have a system equivalent to the United States system, that country is then responsible for ensuring that the entire system that is exporting to the United States employs standards equivalent to those of the United States. To verify that this is happening, FSIS conducts annual audits of foreign food safety systems and procedures through on-site visits by FSIS personnel, including certified establishments, laboratories and review of the government's controls. If a country fails an audit, FSIS can, and we have in the past, suspend imports from that country from individual plants or for specific products.

Finally, the last part of our system for ensuring the safety of FSIS-regulated imports is verifying the continuing equivalence of foreign systems through reinspection of products at the border at our 140 import houses. It is here that the initial checks for proper documentation, evidence of tampering, transportation damage and proper labeling are conducted.

In addition to the initial reinspection of product entering the United States, FSIS then performs intensive random reinspection on approximately 10 percent of the shipments of meat, poultry and egg products. More intensive reinspections are automatically applied to future shipments of product from a foreign establishment when that product fails reinspection.

Access to Customs and Border Protection's Automated Commercial Environment database has provided FSIS with a more targeted approach to identifying and controlling ineligible entry of FSIS-regulated products that did not present to an import house for reinspection as required, and it gets us closer to the entry point rather than chasing it down after its release in commerce. Use of the ACE database is one of our many success stories. While the amounts of imports have been stable, we've markedly increased the amount of detected ineligible product using existing personnel through a collaborative effort with our Federal partners at CBP. In fiscal year 2005, prior to FSIS's use of the ACE system, the amount of ineligible product removed from commerce that did not pass the import houses was a little over 36,000 pounds. In fiscal year 2006, this amount increased to 1.6 million pounds. In the fiscal year 2007, 2.1 million pounds was identified, destroyed or redirected to FSIS for reinspection. That is more than three AirBus 3AD jetliners' worth of product in fiscal year 2007 alone.

Our three-part approach to imports is supplemented by our critical food defense efforts that protect against accidental or intentional food contamination. Dr. Acheson has already mentioned the Interagency Working Group on Import Safety, and I will not repeat many of his comments except to say that I do represent the USDA on that panel, so I do have working knowledge of its products and how it is going about its business.

I'd now like to take just a moment to clarify the current status regarding the importation of FSIS-regulated poultry product from China as they requested in April of 2004. As I mentioned earlier,

any country can apply to be evaluated for equivalence by submitting a request to FSIS. This is exactly what happened when China requested the authority to export poultry to the United States in 2004. After careful study, China's poultry-processing inspection system was determined to be equivalent to our own. In addition, the Animal and Plant Health Inspection Service found no risk to U.S. animal health from import of this type of product if it meets the cooking standards as approved by APHIS.

After the formal rulemaking process was concluded, China was then added to the list of countries eligible to export processed poultry, But the poultry they could process would have to come from either the United States or another country that is approved to export raw poultry products to the United States. In essence, we're talking about processed poultry originating from Canada or the United States, not poultry raised and slaughtered in China. Currently no plants from China are exporting processed poultry originating from the United States or any other country to the United States. In addition, USDA has not published a rule permitting China to export to the United States poultry that is raised and slaughtered in China.

I want to assure everyone that we do have a strong system in place for imported products regulated by the USDA. I believe that our approach to regulating the safety of imported meat, poultry and egg products is one of the best systems in the world. This is due to our rigorous three-part approach determining the initial equivalence, the continuous evaluation of that equivalence through annual audits, and our vigilant surveillance of meat, poultry and egg products entering the country.

Mr. Chairman and all members of this subcommittee, I'd like to thank you for this opportunity to explain the important process that FSIS employs in protecting consumers by ensuring the safety of imported food products. I do look forward to your questions.

Mr. STUPAK. Thank you.

[The prepared statement of Dr. Raymond follows:]

TESTIMONY OF RICHARD RAYMOND, M.D.

Mr. Chairman and Members of the SubCommittee, I am pleased to appear before you today. I am Dr. Richard Raymond, Under Secretary for Food Safety. I am here to discuss how the United States Department of Agriculture (USDA) regulates the importing of meat, poultry and egg products to protect American consumers.

As the Under Secretary for Food Safety, I oversee the Food Safety and Inspection Service (FSIS). FSIS is the USDA public health regulatory agency responsible for the administration of laws and regulations that are designed to ensure that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and properly labeled, regardless of whether those products are sold in the United States or imported to, or exported from, the United States.

The amount of FSIS regulated meat and poultry imported products has remained approximately the same over the past five years, hovering around four billion pounds of meat and poultry from 29 of the 33 eligible countries. However, egg product imports have increased in this past year.

FSIS employs a comprehensive three-part system for imports that helps to ensure the safety of imported product. This system consists of:

- Establishing the initial equivalence of the meat, poultry and egg product inspection system of a country wishing to export to the United States;
- Verifying continuing equivalence of foreign systems through audits; and
- Providing 100 percent re-inspection, with a few exceptions, when products enter the country.

ESTABLISHING EQUIVALENCE

Equivalence is the foundation for our system of imports. It recognizes that an exporting country can provide an appropriate level of food safety, even if those measures are different from those applied here at home.

FSIS has always required an assessment of foreign inspection systems before those nations can export to the United States. This prior review is mandated by our laws, which originally required that a foreign system be "equal to" our system before the foreign product could be admitted. That standard was changed in 1994, to one of equivalency after the United States signed the Final Act of the Uruguay Round of Multilateral Trade Negotiations.

Any country can apply for equivalence by submitting a request to FSIS. An importing country maintains the sovereign right to maintain any level of protection that it deems appropriate to address food safety hazards within its borders. An exporting country has the burden of proving that its system is equivalent to our own if that country wishes to export to the United States.

FSIS begins the process of determining equivalence by analyzing the country's meat or poultry regulatory system with a document analysis to assess whether the country has the laws, regulations, and an infrastructure to support an equivalent system.

This document review focuses on a country's practices in five risk areas: sanitation, animal disease, slaughter and processing, residues, and enforcement. FSIS uses the document review to ensure that the country has in place measures that encompass the standards, activities, resources, and enforcement mechanisms inherent in the US regulatory system for these five areas.

If the document review is satisfactory, the process of determining equivalence then moves to on-site review. During an on-site review, an FSIS audit team evaluates all the aspects of a country's inspection program, from the headquarters of the inspection system to regional offices and local offices, and ultimately to individual establishments within the country and to laboratories that will be testing product destined for the United States. Through these evaluations we seek assurances that the country's inspection program is, in fact, what the documentation claims.

The process for announcing initial equivalence determinations for foreign countries is open and transparent. When FSIS makes an initial equivalence determination, a proposed rule is published in the Federal Register setting forth the determination and our reasoning for it. After a comment period, FSIS reviews all comments submitted on the proposal and, as appropriate, publishes a final rule to add the country as eligible to export meat, poultry or egg products to the United States. This ensures an open and transparent process.

VERIFYING CONTINUING EQUIVALENCE THROUGH AUDITS

The second part of our system is to verify continuing equivalence through audits. This means that once a country is determined to have a system equivalent to the United States, that country is then responsible for ensuring that the entire system exporting to the United States employ standards equivalent to those contained in the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act. FSIS conducts annual audits of foreign food safety systems and procedures to verify that this is taking place. This process includes on-site visits by FSIS personnel, including certified establishments, laboratories and a review of government controls. There is a particular focus on implementation of any new requirements we have put forth since the last audit. For fiscal year 2007, FSIS visited 145 establishments, 39 laboratories, and 86 government offices in the process of auditing all countries actively exporting to the United States. The final audit reports of these countries are posted on the FSIS Web site. If a country fails and audit, FSIS can, and has in the past, suspend imports from that country, from individual plants, or specific products.

VERIFYING CONTINUING EQUIVALENCE THROUGH RE-INSPECTION AT THE BORDER

Finally, the last part of our system for ensuring the safety of FSIS-regulated imports is verifying the continuing equivalence of foreign systems through re-inspection of products at the border. Every shipment of meat, poultry, or egg products that enters the United States must be presented to an FSIS inspector at one of the approximately 140 official FSIS import establishments strategically located at major ocean ports of entry and land border crossings. It is here that the initial checks for proper documentation, evidence of tampering, transportation damage, and proper labeling are conducted. This process is currently assisted by FSIS' Automated Import

Information System (AIIS). AIIS is a database that schedules re-inspection tasks and stores the results of the re-inspection from each point in the process.

In addition to the initial re-inspection of product entering the United States, FSIS performs intensive random re-inspection on approximately 10 percent of the shipments of meat, poultry, and egg products. These re-inspection tasks include product examinations, microbiological analysis for pathogens, and/or a test for chemical residues. Acceptable products are marked as "Inspected and Passed" and released into commerce. Non-compliant products are rejected, marked as "Refused Entry," and either destroyed or returned to the originating country. More intensive re-inspection is automatically applied to future shipments of product from the foreign establishment when product fails re-inspection.

I would like to take a moment to discuss the laboratory system that FSIS relies on to carry out these more intensive inspections. Depending on where the samples are taken, they are shipped to the Eastern, Midwestern, or Western laboratories. These three laboratories are operated by FSIS and are staffed with FSIS personnel. We are constantly working to enhance the capacity of these labs so they are prepared to respond to food emergencies that can be caused by a vast array of contaminants. Indeed, in recognition of our interest in keeping these laboratories up-to-date, we requested $2.5 million in fiscal year 2008 to enhance these important labs.

The important work carried out by import re-inspection personnel I described earlier is supplemented by the twenty-three Import Surveillance Liaison Officers (ISLOs) currently employed by FSIS. These ISLOs are charged with identifying, tracking, and detaining ineligible, illegal, or smuggled product. Like our import re-inspection personnel, they work regularly with other agencies, including Customs and Border Protection (CBP), USDA's Animal and Plant Health Inspection Service (APHIS), the Food and Drug Administration (FDA), and the U.S. Fish and Wildlife Service, as well as brokers and importers at U.S. ports of entry. Access to CBP's Automated Commercial Environment (ACE) database has provided FSIS a more targeted approach to identifying and controlling ineligible entries of FSIS-regulated product closer to the entry point, rather than after its release into commerce. In fiscal year 2005, prior to FSIS' use of the ACE system, the amount of ineligible product removed from commerce that did not pass through import houses was a little over 36 thousand pounds. In fiscal year 2006, this amount increased to 1.6 million pounds, and in fiscal year 2007, 2.1 million pounds was identified, destroyed, or redirected to FSIS for re-inspection.

The Agency and other key Federal partners are working to become fully integrated with CBP's ACE system. This effort will eventually lead to a linkage of all inspection and border control data systems, known as International Trade Data System (ITDS), across all Federal agencies involved in imports.

FOOD DEFENSE

Our three-part approach to imports is supplemented by our critical food defense efforts to protect against accidental or intentional food contamination.

To this end, the Agency performs vulnerability assessments for imported food and, potentially, for food that has illegally entered the U.S. market. These vulnerability assessments help us to strengthen our food import system. Armed with these vulnerability assessments, the Agency conducts ongoing training to increase awareness of food defense issues among our international trading partners.

FSIS inspectors also engage in ongoing and comprehensive training and education efforts that assist them in preventing and responding to any potential threat to the food supply. Coordinated food defense awareness training is conducted in locations nationwide in conjunction with our food defense partners throughout government. They include the Department of Homeland Security (DHS), the Department of Health and Human Services (HHS), other USDA agencies, as well as State and local food defense partners.

FSIS is working jointly with FDA on the continued development of the Food Emergency Response Network (FERN) with other national, State, and local laboratories to provide ongoing surveillance and monitoring of food and to prepare for emergency response stemming from a food illness outbreak, intentional contamination, or even a hoax.

In addition, FSIS is participating in a consortium of lab networks developed by DHS. This integrated consortium will improve coordination among Federal and State partners that are focused on food and agriculture issues. In the process, it will ensure consistency of methods development and the reporting and sharing of lab results between Federal and State partners.

FSIS has also developed and distributed model food security plans for use in import establishments. These plans help the importers develop a personalized Food

Defense Plan that takes into account the unique characteristics of the establishment.

Finally, while import inspectors conduct their regular re-inspection at import facilities, their activities also include efforts aimed at protecting consumers from intentional attacks on the food supply. These activities include facility checks to identify, among other things, suspicious activities in product re-inspection or port areas, evidence of product tampering, or signs that a facility's water supply may have been compromised. The specific procedures performed change according to the threat level.

INTERAGENCY WORKING GROUP ON IMPORT SAFETY

Mr. Chairman, I have gone over how imported meat and poultry products are currently inspected through a systems approach, reviewed our re-inspection procedures at our border and detailed how our food defense efforts improve our effectiveness. USDA is also working closely with the recently formed Interagency Working Group on Import Safety to look at what we can do better. As the USDA representative for the working group, I am speaking from first hand experience.

The President formed this Working Group, which is chaired by Health and Human Services Secretary Michael Leavitt, to ensure that we are doing everything we can to promote the safety of imported products. The mission is critical—and that is to conduct an across-the-board review of import safety by U.S. importers, and by Federal, State, and local governments. It has also been given the task of providing recommendations to the President that will help to further improve the safety of imported products.

In September, the Working Group issued a strategic framework for doing more to ensure the safety of imported products. This framework outlines a risk-based approach that includes the principles of prevention, intervention, and response. The framework supports USDA's long-standing approach to evaluating and verifying the ability of foreign food safety systems to meet food safety requirements for meat, poultry, and egg products exported to the United States.

The next step in advancing the framework will be the Working Group's mid-November release of an implementation action plan. The action plan will provide specific short- and long-term recommendations for import safety improvements and will reflect stakeholder input received through several outreach activities conducted over the past two months, as well as from a public meeting that was held on October 1 at USDA headquarters here in Washington.

I want to assure everyone that we have a strong system in place for imported products regulated by USDA. I believe that our approach to regulating the safety of imported meat, poultry, and egg products is the best system in the world. This is due to our rigorous three-part approach: determining initial equivalence; the continuous evaluation of that equivalence to ensure that it is maintained; and our vigilant surveillance of meat, poultry and egg product entering the country. The safety of our food supply is also due in large part to the work of our food safety partners.

But the state of public health is constantly evolving, and we must be sure we're evolving with it. We cannot afford to let ourselves, our food safety partners, or our nation's food safety systems grow complacent. That is why the Import Safety Working Group is so important. It gives us an opportunity to step back and look at how we can improve our vital import inspection procedures. We all know that we can protect consumers with sensible policies, and together we will do just that.

Mr. Chairman and all Members of the Subcommittee, I would like to thank you for this opportunity to explain the important process that FSIS employs in protecting consumers by assuring the safety of imported food products.

Mr. STUPAK. Dr. Acheson, if I may, I will start questions. We heard Mr. Rice with several countries, in fact even Tyson Foods, that have their own certification process in China. Why doesn't the U.S. have a certification process in China?

Dr. ACHESON. There is a complex answer to that. A lot of the ground has been covered on that already earlier on. But let me try to summarize from the FDA's perspective.

We are able to hold the product, inspect the product at the port of entry if there is an appearance of adulteration. That is a fairly low bar. Right now we do not have the authority at FDA to require certification from a foreign country.

Mr. STUPAK. Are you trying to tell me you need specific requirement from Congress to go certify farms and food producers in China?

Dr. ACHESON. It depends on what you mean by certification. If you are talking about certification as a requirement for entry into the United States, then we would need a specific legal authority to require that as a reason to refuse if it doesn't have the certification.

Mr. STUPAK. So the United States—Russia has one, Japan has one, Hong Kong has one, all of them. Are you saying they all have legislative authority to do that before they can have certification of farms in another country to bring it in?

Dr. ACHESON. I'm not familiar with the laws in Russia or those other countries, but in the United States, my understanding of U.S. Law is, yes, we would require that legal authority to put in place a system whereby we require certification of certain products from particular countries. We don't have that currently.

Mr. STUPAK. You talked about this Import Working Group that is working, and you indicated the President is directly involved in it. Is certification of farms or food-processing plants in other countries part of that discussion you're having in this working group?

Dr. ACHESON. I think certification is part of the general discussion that is being had around—certainly with regard to ensuring the safety of imported products. But again, as it has come out in the earlier panels, one of the things that we need to be certain of at FDA with regard to food safety and food defense is what does that certification mean. Simply having a piece of paper that is a certificate may not be adequate. If we set that system up, we have to verify that that certification system is working to a level that meets the standard that we're comfortable with.

Mr. STUPAK. Well, if we're not certifying, we're only inspecting 1 percent of food coming into this country. We're not keeping the American people very safe then, are we? If you're not certifying the farms, you can't certify the food coming in, you can only certify 1 percent, and 99 percent is not inspected. So how can you assure the American people that the food they're consuming is going to be safe?

Dr. ACHESON. What we're doing is we're reacting when problems occur.

Mr. STUPAK. How can you react? You don't even have recall authority.

Dr. ACHESON. We can undertake recalls voluntarily with firms, and we do that on a regular basis.

Mr. STUPAK. The firm has to voluntarily do it.

Dr. ACHESON. Exactly. But what we recognize is that there is a need to build prevention up front. That is where we're headed.

Mr. STUPAK. For prevention up front, wouldn't you want to certify the farm or the processing plants that are processing the food before it comes here? Isn't that really the first upfront line of defense you could have.

Dr. ACHESON. You certainly need to ensure that the product is being manufactured safely, whether it be domestically or from China or India or wherever. Certainly requiring certification is an option that is under consideration as part of that process.

Mr. STUPAK. Well, let me ask you this. The produce industry has called on the FDA to enact tough new regulations regarding the handling of fresh produce; however, the FDA has not done this. And according to—right there is the exhibit book, exhibit No. 20, an article from the Wall Street Journal in February, Health and Human Services officials rejected the FDA's plan for tough new regulations on the handling of produce. Is it true that the FDA sought mandatory regulations but were overruled by HHS.

Dr. ACHESON. I wasn't part of that particular meeting, but my understanding of that was that the FDA did not take requests for specific mandatory regulations to HHS.

Mr. STUPAK. What did they do with them? The produce industry has been calling for you to do it. According to news reports, the FDA brought it to HHS. So that is not true, they never brought it to HHS.

Dr. ACHESON. Those earlier meetings with HHS were high-level discussions around food safety in general. At that time that was fairly recently after we had had spinach and——

Mr. STUPAK. Most produce——

Dr. ACHESON. Yes. But it was not a specific request for authority that was ultimately turned down.

Mr. STUPAK. So it was ultimately turned down?

Dr. ACHESON. No, I said it was not a specific request for authority that was——

Mr. STUPAK. So you had high-level meetings. What came of the high-level meetings, anything?

Dr. ACHESON. Absolutely. Part of those high-level meetings was a recognition that we needed to step up and do different things to face these new challenges. That's one of the reasons why Commissioner Von Eschenbach created my position and instructed me to develop a food-protection plan, which we're working on, which I anticipate will be launched sometime within the next month or two.

Mr. STUPAK. What can you tell us in this committee that is going to be preventive so we can prevent the action of people getting sick like on *E. coli*? And again, I agree it came from spinach from Salinas Valley, the hearings we have had on it. But what are you doing to prevent that?

Dr. ACHESON. There are a number of things. To put preventive strategies in place, you have to understand what caused the problem in the first place. Again, as has been alluded to earlier, the close proximity of cattle to a spinach field may be——

Mr. STUPAK. That has been going on for 10 years. We've had 20 outbreaks, and the FDA has done nothing to prevent the cattle from polluting the water so it doesn't go on the spinach fields. So where is the preventive action here? You haven't even done an epidemiology study to figure out where it is coming from.

Dr. ACHESON. What you're alluding to there is the need of the basic sciences to put those preventive strategies in place. That is not all there.

Mr. STUPAK. If we don't have basic science, how are we going to have advanced science to inspect food?

Dr. ACHESON. You need the basic science principles to understand how *E. coli* gets on the spinach in the first place. Yes, we

know it is in cattle, but is it coming via the water, via wild animals.

Mr. STUPAK. That's why an epidemiology study would determine that; would it not? Twenty outbreaks in ten years and you still haven't determined that. You haven't even requested an epidemiology study, have you.

Dr. ACHESON. We certainly recognize there is the need for that science, and we have not——

Mr. STUPAK. So are you going to recommend an epidemiology study for Salinas Valley, the Salad Bowl of America.

Dr. ACHESON. What we're going to do is to focus more than on leafy greens in the Salinas Valley. There is a need for more science.

Mr. STUPAK. But are you going to ask for an epidemiology study to try to get down to the source of the *E. coli* bacteria which pollutes the Salinas Valley, which ends up in 20 outbreaks in 10 years?

Dr. ACHESON. You're absolutely right. One of the key questions is to answer that. An epidemiology study is maybe a mechanism to get to that. How does the *E. coli* get from the cattle to the spinach? It is a key question. There is no doubt about that.

Mr. STUPAK. Key question? When are you going to study it or do an epidemiology study.

Dr. ACHESON. The Food and Drug Administration is not a research agency.

Mr. STUPAK. I'm not asking you to do research. Don't you have to have the study be done?

Dr. ACHESON. The FDA doesn't have the resources to require that study, but we certainly put out to our research colleagues——

Mr. STUPAK. You've been the drug czar for some time now. Have you asked for money to do an epidemiology study? Have you asked for more money from the OMB to do inspections?

Dr. ACHESON. As part of the budget process of 2009 and the rolling out of the Food Protection Plan, we've recognized that in order to get where we need to go, we will be needing new resources, yes. That is part of the ongoing process.

Mr. STUPAK. So you haven't asked for it yet, but you think you will in 2009?

Dr. ACHESON. That budget process has to follow its tracks. And we recognize that that is just the way the system is set up.

Mr. STUPAK. I'm over my time. I'll turn to Mr. Whitfield for questions. I'm sure we'll have another round of questions here.

Mr. WHITFIELD. Thank you, Mr. Chairman.

Dr. Acheson, you and Ms. Glavin both have a responsibility for protecting the food supply in the U.S., which is an awesome responsibility. And with your expertise and with your experience and with that responsibility, what concerns you most from your position about guaranteeing the safety of the American food supply? What are two or three things that concern you the most?

Dr. ACHESON. I think the principal concern is to move away from a reactive situation in responding to outbreaks when somebody is sick to building in safety up front, whether that be domestic, as we've just been discussing with regards to spinach, or whether it be from an imported product.

I believe the key to success is to build in preventive strategies at the manufacturing level right up front, wherever that is happening, domestically or foreign.

Mr. WHITFIELD. What kind of progress are we making in doing that?

Dr. ACHESON. The progress that we're making is determining what would be the steps to get there. That is a significant part of the Food Protection Plan that we're talking about, a shifting emphasis into prevention, yet maintaining inspections, focused on risk. Again, the prevention has to be focused on risk and building a more robust response system. We do respond well already, but I would be happier if we were even faster getting a handle on illness quicker, to get it off the shelves faster and protect consumers.

Mr. WHITFIELD. So one thing, then, is going from a reactive to a more preventive method? And we're not there yet. And what is the second thing?

Dr. ACHESON. Well, I've summarized that with the focused, risk-based inspections. We need to continue to inspect, obviously, but those inspections need to be focused in the areas of greatest risk. And as part of that, which is the third point, is the need to integrate that with modern technology; not just information technology, which is critical, especially in the area of imports, of getting better, faster systems to integrate the mountain and the ever-increasing amount of information, but also detection technology. We need to be able to detect problems in foods faster, hopefully in a matter of hours as opposed to days. So we need to build those in as well.

Mr. WHITFIELD. Well, I notice that the largest import refusals come from Mexico, China and India. So how often do we send inspectors to those countries to look at their facilities, or do we?

Dr. ACHESON. I think in the last year—and my colleagues can give you the specific numbers there. It is in the order of 100 to 150 foreign inspections we've done. We can certainly provide you information on which countries that we have——

Mr. WHITFIELD. Are budgetary concerns an issue there or not?

Dr. ACHESON. Certainly the amount of inspections that we do both domestically and foreign are limited by resources.

Mr. WHITFIELD. What is the overall budget for your area of responsibility?

Dr. ACHESON. Within foods, it is about $400 million, I believe. I certainly can get you the exact number.

Mr. WHITFIELD. Four hundred million dollars? That doesn't really seem like very much. And what is the total FDA budget? Do you all know that?

Dr. ACHESON. It is about a billion dollars, the total FDA budget. Two billion. I'm sorry. I'm not familiar with these numbers. We can get them to you for the record.

Mr. WHITFIELD. Let me ask you another question. In February 2006, the FDA had information in hand that other foreign countries, particularly Canada and South Korea, had banned the import of Chinese eel because of the presence of malachite green. Now, that was in February 2006. FDA did not issue an import alert on Chinese eels until around November 2006, some 6, 7, 8 months later. Why did it take so long for FDA to issue an import alert in that situation?

Dr. ACHESON. Again, I have colleagues who can speak more to the specifics of an import alert, But let me try to summarize.

In order to issue an import alert, we have to have the data to show that we can do it, which essentially means demonstrating through a sampling strategy that there is a level of contamination in a certain product of concern, in this case eel, with a certain agent, malachite green, that is of sufficient degree to pose a problem and of sufficient extent to issue a countrywide alert.

What we've done when we see problems with individual companies is we can issue an alert very quickly. We did that with melamine. Two companies were of concern. The import alert for melamine, for protein concentrates was issued in a matter of weeks in that situation. But the malachite green required more testing to get to the point where we could say this is a countrywide issue, it is not just one or two firms that are causing the problem.

Ms. GLAVIN. We also had people from the Center for Food Safety in China trying to gather that information and trying to get information and data on the extent of the problem, which helped us in putting that import alert out.

Mr. WHITFIELD. Let me just ask one other question. My time has expired. But why do you refuse to acknowledge China's certificate of export?

Dr. ACHESON. It is not that we're refusing to acknowledge it. My point is that we cannot require it as a condition of entry into the United States.

Mr. WHITFIELD. So legally you cannot require it?

Dr. ACHESON. Legally we cannot say that that is a requirement and without it we would refuse entry.

Mr. WHITFIELD. Thank you.

Mr. STUPAK. Mr. Melancon with questions.

Mr. MELANCON. Thank you, Mr. Chairman.

Ms. Glavin, you talked about high-risk food shipments. I guess focusing on that, what is a high-risk food shipment? Does somebody have to be critically ill or die?

Ms. GLAVIN. There are a large variety of factors. If we're talking about food safety, the factors would be things such as what is the food. Certain foods are inherently more risky than others. Where is it coming from? Is it coming from a country where we have a history of problems? Is it coming from a manufacturer where we have a history of problems? Do we have any data that shows that there are illnesses connected with that product? So there are a variety of things that—it is not a single piece of information.

A number of you have mentioned a new system that we're piloting at one port right now, and that is the PREDICT system, a system that is designed to take the real-time information we have and make—help us make decisions in real time about what we should look at and what we can let go through without a physical examination.

Mr. MELANCON. You talked about the Department had different authorities, some that may be new, some that you're using. How many times has the Department implemented any of these authorities in recent times?

Ms. GLAVIN. I'm sorry.

Mr. MELANCON. When you were doing your testimony, you talked about these different authorities that the Department had. And I'd have to go back. Both of them were acronyms.

Ms. GLAVIN. I'm sorry. I do use acronyms. I apologize.

There are two issues with respect to food. There are two different kinds of things that we do. The first one is unique to food, and that is we look for—we have a specific responsibility to look for evidence of bioterrorism, intentional adulteration or tampering of food. And that is done in conjunction with CBP. It is done on all food coming into the country. All food coming into the country has to note—we have to be notified before it can enter the country so that we can do that screen.

The second screen is our food safety screen, and that is where we look for food safety problems and look—that is the second set of criteria that are used that are specific to safety, not to the security side. And that would include things like the type of food, where it is sourced, what the company history is, what the history of that importer is, et cetera.

Mr. MELANCON. When you get a product that comes in that has no certificate, shouldn't that be a flag that we ought to be testing that food immediately?

Ms. GLAVIN. Not all countries have certificates. But if a country offers a certificate, we certainly can consider the lack of the certificate if a certificate is available as one of the factors. What Dr. Acheson was saying is that we can't use the lack of a certificate as the sole reason for denying admission.

Mr. MELANCON. Why can't we require a certificate on all food products?

Ms. GLAVIN. We don't have that authority.

Mr. MELANCON. USDA, you have the authority.

Dr. RAYMOND. The Federal Meat Inspection Act and the Poultry Products Inspection Act gives us the authority and requires us to determine if the country has the equivalent food safety system.

Mr. MELANCON. So I guess the question is, has anybody ever asked for that authority over at FDA?

Ms. GLAVIN. I'm not aware that they have.

Mr. MELANCON. We know we have got a problem, and nobody wants to say, maybe you all need to help us give us the tools.

Dr. ACHESON. Let me respond to that. We certainly recognize that we've got challenges. And I have acknowledged in my testimony that part of the Food Protection Plan that we're developing is to address those very challenges that we're discussing today.

Mr. MELANCON. The large quantities of commodities that come in—and, of course, maybe it is easier or harder. I'm not sure. USDA has the ability—maybe FDA needs to be talking to them about how to monitor this stuff and get it done. And somebody needs to say to the Congress, look, we've got a problem, food safety and other issues that are coming in that are creating problems. And in this day and time, I find it difficult, especially after I've been through 2 years of excuses from FEMA and other agencies about why they haven't done anything. As a member of the bureaucracy that is supposed to be trying to protect America, tell us what we need to do. Don't come here and give me an excuse why

we can't do it. I can find excuses not to do it. FEMA has got a great agency for telling me how to do that.

So where I am, and I think where we're trying to come from, is I don't want to continue to see food products coming into this country—and I've said this on many occasions, we've got the dumbest system in the world for negotiating trade deals. It is give them anything they ask for, don't check what comes in, and just go about your business. And it is not a good system. One person negotiates the deal, and then nobody is back here to follow it up.

Shouldn't you be talking with the USTR and saying, we need food safety, we need country of origin, we need labeling, we need certification? If we're going to protect Americans, shouldn't you as the protectorate of the food supply be asking for that authority or that in those trade deals or that of this Congress?

Dr. ACHESON. Again, I find I'm repeating myself. I agree with everything you're saying. Our mission is to protect the public health at FDA. That's what we're about. And part of my job is regards to food safety and food defense. That is critical.

The plan that I keep mentioning is through getting into the throes of clearance, and I would look forward to bringing that to this committee or to you personally and saying here is where we think we need to go, and let's have a dialog and establish a partnership in terms of whether the feeling is that this meets the needs.

We recognize that we have got challenges. We recognize that we need to make changes, we need a new approach. And that is exactly what we're working on. We're just not quite to the point yet where this is out for public viewing.

Mr. MELANCON. My time has run out.

Mr. STUPAK. Thank you, Mr. Melancon.

Mr. Burgess for questions, please.

Mr. BURGESS. Thank you, Mr. Chairman.

Dr. Acheson, thank you for being with us today. Dr. Raymond testified earlier—his written testimony has a much more eloquent definition of equivalence than I used when I spoke a little earlier. Why doesn't the FDA have a similar program of that equivalence concept that the USDA uses?

Dr. ACHESON. There are two answers to that at least, if not more.

Mr. BURGESS. Give me the short answer. And I'm actually going to submit this for a written response because I think it deserves a written response. Let me just ask you to please make that timely. We've been working with—and make no mistake, I love the FDA, I love everything you do, but you guys are slow when it comes to getting responses. So give me the short answer on equivalence and then I really would appreciate a much longer written response.

Dr. ACHESON. The short answer is authority and complexity.

Mr. BURGESS. The authority being you don't have the authority, and you need us to give you the authority legislatively.

Dr. ACHESON. We don't have the same authority that USDA has.

Mr. BURGESS. You need that from us in legislation; is that correct? Are you asking us for that authority?

Dr. ACHESON. I'm not asking you for that authority. I'm answering your question as to why do we not have it.

Mr. BURGESS. I think it would be a good idea if you had it. So if I want you to have it, then we need to write you the legislation that gives you the authority to have it.

Dr. ACHESON. I think that leads into my second answer, which is complexity.

Mr. BURGESS. Before we get into complexity, let me just ask the other question. Would you use it if we gave it to you?

Dr. ACHESON. Within the confines of complexity, you have got to look at whether it is usable.

Mr. BURGESS. I was hoping to stay away from complexity for just a moment.

Dr. ACHESON. You can't disassociate the two.

Mr. BURGESS. Would you use it? Would it be a useful tool? Would it be a part of your armamentarium that you could go forward and provide the protection that Mr. Melancon so eloquently requested of your agency?

Dr. ACHESON. If equivalency was applied uniformly to all countries, to all products that FDA regulates, it would, frankly, be crippling.

Mr. BURGESS. Crippling in the fact that we would have such an enormous bureaucratic burden, we could never surmount it?

Dr. ACHESON. In many ways. We're talking about 200-plus countries, hundreds of products.

Mr. BURGESS. Is there a way to develop a program of equivalency that has the proper safeguards and parameters and boundaries so that it is not crippling, but at the same time provides a base code of safety that we can once again assure the American people that we're doing? Because they don't believe us right now.

Dr. ACHESON. I think with adequate resourcing of both finance and brain power——

Mr. BURGESS. Fast forward. Have you reviewed the legislation that has been put forward by Chairman Dingell? Does the resourcing present in the legislation put forward by Chairman Dingell, does that provide an adequacy of resources for you?

Dr. ACHESON. It is more than just money. To sort out all of these issues of complexity—and I apologize that I keep coming back to that——

Mr. BURGESS. That's where I want your written response because I know that is important.

Dr. ACHESON. That's where it gets complex, because we're not just talking about meat, poultry and egg products. We're talking about hundreds of different regulated commodities with many, many different standards in different countries, and developing that level of equivalency would be unbelievably complicated.

Mr. BURGESS. Again, I do look forward to a timely written response. We'll phrase that as a written question.

Mr. Chairman, I really do want to see the response to that because I think it has to be part of our discussion when we craft this legislation.

Let me just ask you with the little time I have left, were you astounded by the response that if someone is up there checking for their own product in another country, and they find something really bad, they don't feel obligated to disclose that to any of the

regulatory agencies that are also charged with protecting food safety?

Dr. ACHESON. As a person who spent many years in clinical practice as a physician, it worries me that there may be problems out there that we can perhaps do something about and don't hear about it. That is a business decision. Is not a requirement.

Mr. BURGESS. A business decision to be sure, but do you have—with your regulatory authority, do you have the ability to go in and assess the quality-control measures that are being used by a private company that is then importing to the United States? Whether it be an American or foreign company, can you go in and look at their quality assurance methods to make sure they're up to snuff?

We talked about the statistical tests before. Do you have the authority to do that? And if so, would you find such a problem with the analysis of just the quality assurance, or do you need another method of getting that information?

Ms. GLAVIN. With respect to food, sir, we do not have the authority to mandate an inspection of a foreign firm if they choose not to have us come.

Mr. BURGESS. I don't mean to interrupt, But I'm just astounded by that. So if a private company that is importing poultry to this country says, whoa, on this shipment we have got polonium under the chicken wings, we're not going to bring it in, but we just don't say anything about it?

Ms. GLAVIN. Well, poultry is under the USDA, but if it was peaches, yes.

Mr. BURGESS. If it was whatever, shellfish or whatever, if you found a problem to that order or magnitude, which to me means bioterrorism, would you not have authority under the Bioterrorism Act to require that information be given to you?

Ms. GLAVIN. If we had information, absolutely.

Mr. BURGESS. But if they have information, and they just choose not to tell you as a business decision because they don't want to irritate the People's Republic of China, that is OK?

Ms. GLAVIN. I'm not saying it is OK. I'm saying that we don't have the authority to mandate that they give it to us.

Mr. BURGESS. And that would be the situation, that if they said, well, we just don't want to irritate our host, so we're not going to give you that information, that is what would happen?

Ms. GLAVIN. That's right.

Mr. BURGESS. So as we sit up here on this dais attempting to assure the American people we're providing oversight, we've really got no mechanism to go back and check that; is that correct?

This gets back to Mr. Melancon's questions about the trade agreements. And I realize it is out of the purview of this committee and this argument, but clearly that seems to me that is a gaping hole that has got to be closed. Or am I missing something?

Dr. ACHESON. I think in the context of foreign companies, you're correct. And as Ms. Glavin has pointed out, we don't have the authority to do that.

Mr. BURGESS. Do you agree that that is a potential liability for us, a potential vulnerability for us?

Dr. ACHESON. It is one of the areas that we're considering in the Food Protection Plan is what do we need to do to address those kinds of gaps.

Mr. BURGESS. I'm not one that normally eats Chinese eels, and I don't intend to ever begin, but just the whole story with the malachite green stuff is a little disturbing, that you found the problem and it took so long to control the problem. What if it were something much more serious? When I say serious, i.e., involving a food that I might eat.

Dr. ACHESON. If it was food you were eating, we'd be right on it, I can assure you. No. A serious point. We did react very quickly when we had issues with melamine. That was in a matter of days or weeks once we knew there was a problem.

Mr. BURGESS. And I'd submit that I don't know that we really know when that problem began. I have just uncorroborated testimony from veterinarians back in my district, boy, we were losing a lot of pets, and we didn't know why. And that worries me because I don't—again, I don't—and then it comes back to the point that if someone knew that we're grinding up countertops and putting them in our dog food, they've got to tell you that so you know to look for it. Somewhere along the line there has to be some responsibility of the companies that are providing imports into this country or they lose their license, I think. Just my opinion.

Mr. Chairman, I yield back. I know I've gone over.

Mr. STUPAK. Thank you. And I'm sure we'll go another round or two at least with this panel.

You mentioned melamine. That was Customs and Border Patrol that stopped melamine. It wasn't FDA.

Dr. ACHESON. No, it was FDA which issued the——

Mr. STUPAK. We had a hearing. It was Customs and Border Patrol that was stopping melamine before the FDA ever got around to it. Even after the FDA got around to it, it took your lab, like, 48 hours to discover the melamine because it didn't know what it was looking for, right?

Dr. ACHESON. I beg to differ. It was FDA labs who identified that it was indeed melamine. And then it was FDA——

Mr. STUPAK. That was the lab——

Dr. ACHESON. And then it was FDA that set up the import alert. We then worked with Customs and Border Protection to put that into practice.

Mr. STUPAK. When is this plan going to be done? You keep talking about this plan you want. When is it going to be done?

Dr. ACHESON. As soon as possible.

Mr. STUPAK. That means what?

Dr. ACHESON. I would anticipate—and as I've said earlier, it is within high levels of clearance within our Department right now, within HHS.

Mr. STUPAK. When do you anticipate it is going to be done?

Dr. ACHESON. I hope within the next 2 to 3 weeks we'll be able to get this out.

Mr. STUPAK. And are you going to ask for an equivalency standard like the USDA has in this plan?

Dr. ACHESON. The specifics of that plan are still under discussion with our Department. I can't get into the specifics of what may be——

Mr. STUPAK. Why can't you get into the specifics of it?

Dr. ACHESON. Simply because it has not been cleared by my administration.

Mr. STUPAK. Who is the administration, the White House or HHS?

Dr. ACHESON. It is both.

Mr. STUPAK. So you're getting pressure from the White House and HHS to do certain things in this——

Dr. ACHESON. I didn't say we were getting pressure.

Mr. STUPAK. No, I did.

Dr. ACHESON. No, I'm not getting pressure. There is a required process of clearance, and it is just not completed.

Mr. STUPAK. Does the FDA require additional legislative authority to apply HACCP requirements to all domestic food producers, processors like we have for juice and seafood.

Dr. ACHESON. As you have just acknowledged, we have put out HACCP requirements for two products, for juice and seafood.

Mr. STUPAK. Right. So you require further legislative authority to do all domestic food producers and processors is my question. Do you require additional authority, or can you do it underneath the existing HACCP authority since you've done it for juice and seafood?

Dr. ACHESON. I'd have to seek a legal answer to that. I'm not an attorney, but my understanding of that is if we've done it for two, we could potentially do it for more using that same approach.

Mr. STUPAK. Sure. So why wouldn't you do that then, use those requirements to make American consumers safer? You did it for juice and seafood. Why not do it for the rest?

Dr. ACHESON. As I said, I believe that we do need to be seriously looking at putting in preventive controls, and using a HACCP-type approach is potentially a way to do that.

Mr. STUPAK. You indicated to Mr. Burgess that you needed more resources. We indicated that the Dingell-Pallone-Stupak bill which is currently pending, which would generate $500 or almost up to $600 million a year for food. Would that be adequate resources.

Dr. ACHESON. It would certainly help.

Mr. STUPAK. But would it be adequate?

Dr. ACHESON. Adequate to do what?

Mr. STUPAK. To provide food safety, to inspect the 99 percent we're not inspecting.

Dr. ACHESON. No. If the goal is to inspect 100 percent——

Mr. STUPAK. The goal isn't 100 percent. Or is that going to be the goal of your plan, 100 percent?

Dr. ACHESON. No.

Mr. STUPAK. Is there a percentage your plan indicates?

Dr. ACHESON. No. Simply throwing more money at this to do more inspections is not a solution.

Mr. STUPAK. I agree.

Dr. ACHESON. What we've got to do is do smart inspections, and that means the risk—and it gets back to your earlier point——

Mr. STUPAK. Let's go back to the Dingell legislation. Has the FDA taken a position on the Dingell legislation?

Dr. ACHESON. Not that I'm aware of.

Mr. STUPAK. Has the FDA taken any position on any of the bills that have been introduced for the last 10 years on food safety? Have you taken any positions on them.

Dr. ACHESON. I'd have to get back to you on what the official positions are on any of those previous bills that predate my time in this position.

Mr. STUPAK. Ms. Glavin, do you know?

Ms. GLAVIN. I don't know. Sorry.

Mr. STUPAK. I can tell you I wrote the first one in 1998. We're still waiting for an answer. So I hope your plan is not going to be 10 years.

Let me ask you this: What specific requests have you made in terms of resources from the Commissioner or Office of Management and Budget? Have you made requests to them for more money for resources, for inspections, for overseas work?

Dr. ACHESON. We've made requests through the 2008 budget process for an increase——

Mr. STUPAK. And how much was that increase?

Dr. ACHESON. I think it was about $10 million or thereabouts.

Mr. STUPAK. What was the $10 million going to be targeted for? Hopefully not bonuses.

Dr. ACHESON. I know a portion of it was for research, some for foreign inspections. Again, for the record, I could get back to you the breakdown exactly of what the 2008 budget request was.

Mr. STUPAK. Let me ask you this: Do you support recall authority to be given to the FDA, Dr. Acheson?

Dr. ACHESON. We've managed for years without it, and I believe we have an effective system. It is certainly one more tool in the toolbox that could potentially be used in certain situations.

Mr. STUPAK. Do you support recall authority for the FDA?

Dr. ACHESON. Are you asking me personally?

Mr. STUPAK. I'm asking you, first of all, as a drug czar.

Dr. ACHESON. Food czar.

Mr. STUPAK. Food czar. We'll get to drugs next week, November 1.

Dr. ACHESON. As I've said, I believe that it could be a tool in the toolbox that could under certain situations expedite recalls. Since I've been working at FDA in this role for——

Mr. STUPAK. What do you want? Do you want only recall authority for certain types of food or what? I mean, why would you be opposed to a recall authority?

Dr. ACHESON. I'm not opposed to it.

Mr. STUPAK. You are saying only under certain circumstances. You've got to have the authority before you can use it. Just because you have the authority doesn't mean you'll use it. So you'll use it where you want. You can't use it if you don't have it.

Dr. ACHESON. I'm not opposed to us having that authority at all.

Mr. STUPAK. Good.

Let me ask you this: You said that your group is looking at—in proactive, risk-based and rapid response, correct?

Dr. ACHESON. Right.

Mr. STUPAK. Proactive, explain that. In what way are you going to be proactive?

Dr. ACHESON. That is getting back to the prevention issue. What we've got to do is build safety in right up front with the manufacturer, at the processor, so that what is being done at the manufacturing level is building preventative controls up front as opposed to reacting to them when we get illness.

Mr. STUPAK. Sure. I agree with that. So let's go back to certification, let's say like in China, the farms and plants or food processing place. If that is going to be proactive—and even the President is fond of saying we have to fight terrorism overseas so we don't have to fight them on our own shores. So why don't we have that same attitude when we have to fight food safety issues instead of waiting for it to arrive in America? How come we're not being proactive in taking it overseas; instead we allow 99 percent of the food to come in without ever being inspected.

Dr. ACHESON. That's exactly what we're proposing to do.

Mr. STUPAK. How——

Dr. ACHESON. What you're alluding to is pushing the borders out. What we're trying to get away from is this snapshot of the port of entry where we make a determination based on the information that we receive.

Mr. STUPAK. How are you going to get it overseas? How are you going to be proactive overseas? Are you going to assign inspectors overseas in countries?

Dr. ACHESON. There is a number of avenues that we can take. One is to have a greater foreign presence physically from FDA.

Mr. STUPAK. Is that one you recommend?

Dr. ACHESON. It is certainly one of the possibilities that we're looking at.

Second is to develop memorandums of agreement with foreign governments and to work with foreign governments and, as part of that, to get a better insight into the processes and standards that are occurring in foreign countries, particularly in the foreign countries that we have concern about with regards to food safety.

And then the second part is working with the industry in terms of working with them to look at their processes, their data in terms of what they're doing in foreign countries to help determine relative risk of a product coming into the United States.

Mr. STUPAK. All right. My time is up.

Mr. Whitfield for questions.

Mr. WHITFIELD. Just one other question I wanted to ask Dr. Raymond. Dr. Raymond, the Food and Drug Administration has a list of—in their regulations—they have a list of drugs. And they say if one of these drugs is present in an animal that is to be slaughtered for human consumption, then it is disallowed. At a time when they were slaughtering horses in the U.S., even though that meat was being exported to other countries, about four of the listed drugs were specifically used by—in animals that were used in horse racing. And it was a common drug, and a significant number of these horses that were slaughtered were racehorses. How do you ensure that those drugs are not present when the animal is slaughtered?

Dr. RAYMOND. Part of our regular testing is testing for residues. I don't know that I could answer your question that we know—we test them——

Mr. WHITFIELD. I was told that not every animal was tested.

Dr. RAYMOND. That would be correct.

Mr. WHITFIELD. That's correct. So there is a likelihood that—I mean—fortunately, it is not consumed in the U.S., but it was going to Europe and Japan. And these drugs, many of them as a matter of course are given to animals that race. So they are in there. So there is a likelihood that a lot of this meat going abroad had a prohibited substance in it, I would say.

Dr. RAYMOND. I would think that a lot of the drugs that you're referring—I don't know the exact ones, of course, but they were probably things that were used to treat ailments like a tender knee or something like that, like an anti-inflammatory drug that may be in the system for a very short period of time. And most of the horses that would go to slaughter are horses that have long since quit racing, and they may not be taking those drugs, and they are probably not drugs that stay in the meat.

Mr. WHITFIELD. But some of them haven't been off the track long when they're slaughtered. But you've answered the question. So thank you very much.

Mr. STUPAK. Let me just ask a few more questions, if I may.

Ms. Glavin, you made mention of the detain without physical examination alerts, that our food products are actually delivered to the importer premises, correct?

Ms. GLAVIN. That's right.

Mr. STUPAK. And isn't it also true that the importer may obtain a private lab certification that the product is not in violation.

Ms. GLAVIN. Well, when something is detained without physical examination, it is the importer's responsibility to demonstrate that the product should be admitted and——

Mr. STUPAK. The way to do that, they go to a private lab to show that the food——

Ms. GLAVIN. That is one way they can do it, yes, sir.

Mr. STUPAK. May the FDA audit the private laboratory results?

Ms. GLAVIN. We have no regulatory authority over the labs themselves. We certainly look at the lab worksheets in determining whether or not we're going to accept those results.

Mr. STUPAK. So you can't even audit the lab?

Ms. GLAVIN. No. We do some audits, but we have no regulatory authority over those labs.

Mr. STUPAK. Do you want regulatory authority over the labs, certify these labs that are doing the testing.

Ms. GLAVIN. I think that would be something very interesting to look into, yes, sir.

Mr. STUPAK. Not interesting. Would you like that authority as part of the Dingell bill? Certification of these labs? Because there is no certification of these labs, is there?

Ms. GLAVIN. No.

Mr. STUPAK. There is no FDA inspections to make sure they are doing the testing properly?

Ms. GLAVIN. That is right.

Mr. STUPAK. And you have heard testimony today, and we have had it this morning, that basically if you don't get the test result you want, you dump it in the garbage can and get another test until you get the one you want. Isn't that sort of what is being said about these private labs?

Ms. GLAVIN. I have heard that said, yes, sir.

Mr. STUPAK. So wouldn't it appear you would want to certify these labs to make sure that the test results are accurate before we allow this food out in the mainstream commerce?

Ms. GLAVIN. I think that would improve the system. It would also be a resource concern.

Mr. STUPAK. A resource concern. You mean inspection of these labs?

Ms. GLAVIN. Yes, sir.

Mr. STUPAK. And have you ever asked for any money to hire inspectors to inspect the labs or to certify labs?

Ms. GLAVIN. I am not aware that we have ever asked for that.

Mr. STUPAK. Dr. Raymond, if I may, recently the USDA announced recalls of two brands of ground beef. In one of those cases, it took the USDA 18 days to recall the product after learning about its potential health hazard. Why did it take so long?

Dr. RAYMOND. In that case we had one illness, one person. Cultures from that person's stool did grow out *E. coli 0157:H7*. That person had consumed frozen hamburgers from the freezer. We went and got the remaining hamburgers that were in a box that had been opened and tested, 13 tests, and two of them did turn out positive for *E. coli O157:H7*.

At the same time we went out and obtained product that were still in enclosed, sealed boxes, so there would be no risk of having them tampered with, as is routine and normal for us. And all of those samples tested negative.

So we had no rock-solid, concrete proof to say that that contamination of the young lady occurred from a product that was contaminated in the plant. And at that time, with just one case, we didn't feel we had the legal standing to go do a recall.

With the recall, when it did occur 18 days later was because of other illnesses that had eaten product that had been produced prior to that product that we are talking about.

So what I'm trying to say, not defensively, but a recall in 7 days after we found out would not have prevented any of the other illnesses, but it took the other illnesses to line up everything to say beyond a shadow of a doubt it came from that plant on this production date. And that is when the recall was initiated.

Mr. STUPAK. Does USDA have recall authority, or do you have to work with the producer?

Dr. RAYMOND. We work with the producers.

Mr. STUPAK. So you don't have recall authority either?

Dr. RAYMOND. We can seize and detain, but we cannot recall.

Mr. STUPAK. You indicated that on your equivalency standard, you have 33 countries that are allowed to ship food into here because they have an equivalent standard to ours?

Dr. RAYMOND. Yes, sir.

Mr. STUPAK. Does the Department of Agriculture limit the number of ports in which USDA-regulated products can be brought into the country?

Dr. RAYMOND. Mr. Chairman, we don't limit the ports, but all product has to go through one of our import houses. So it can come through a port where we don't have an import house, and it will have to be moved by truck or rail to an import house.

Mr. STUPAK. How many import houses do you have then?

Dr. RAYMOND. There are about 140.

Mr. STUPAK. And I take it they are in close proximity to some of the main shipping ports?

Dr. RAYMOND. They are all either at water ports or on cross-border border crossings, yes.

Mr. STUPAK. Ms. Glavin, how many ports does the FDA allow food to come into?

Ms. GLAVIN. Food can come into any U.S. port. FDA-regulated food can come into any U.S. port.

Mr. STUPAK. Any port?

Ms. GLAVIN. Yes, sir.

Mr. STUPAK. How many ports are there in the United States then?

Ms. GLAVIN. I believe there are in excess of 300.

Mr. STUPAK. Do you have import houses or anything where you limit?

Ms. GLAVIN. No, we have inspectors at approximately 90 of those ports.

Mr. STUPAK. So if there is 300 and some, and there is 90, so one-third at best have inspectors at?

Ms. GLAVIN. Yes, sir.

Mr. STUPAK. And are they limited in what hours they can come into a port, 8:00 to 5:00, or they can come in at any time?

Ms. GLAVIN. That is right.

Mr. STUPAK. Dr. Raymond, how does the USDA decide which ports of entry to designate as eligible to receive the shipments? Again, is it just because they are in close proximity to the——

Dr. RAYMOND. Mr. Chairman, meat and poultry products can come into any port. It cannot enter commerce until they have gone through an import house. So we do not limit the ports. The import houses are located——

Mr. STUPAK. But the import houses, what happens? They come to a port, but they get to an import house. What happens in between there? Do they have to maintain them frozen? How do you maintain the integrity of the product in between the port and your import house?

Dr. RAYMOND. Excellent question. Obviously, one of the things we do look at at the import house is to make certain that it appears that there has been no change in the integrity of the product. For instance, if it is a frozen product, and the box appears to have had moisture on it, we are going to get concerned that perhaps the integrity was not maintained. But obviously these products are going to be shipped under certain conditions, refrigerated trucks, et cetera, depending upon the product.

Mr. STUPAK. How often are the samples of these products collected for testing by a lab? How are often are the samples collected? Is that every box?

Dr. RAYMOND. No, sir. A little over 10 percent of all the lots that come into this country through an import house are opened and are more intensively inspected. Probably about 50 percent of those boxes that are opened are then further tested for pathogens or residues.

Mr. STUPAK. So these lots that come in, you inspect 10 percent, correct?

Dr. RAYMOND. We reinspect all lots, but we open about 10 percent of the boxes.

Mr. STUPAK. Who does your inspection or lab test? Do you have private labs you send this to?

Dr. RAYMOND. No, sir, we have three laboratories that we use.

Mr. STUPAK. All testing is done in-house?

Dr. RAYMOND. In USDA labs staffed by USDA personnel.

Mr. STUPAK. The system you use at USDA, could that be duplicated at the FDA for food?

Dr. RAYMOND. You mean using the import houses, et cetera?

Mr. STUPAK. Yes. Testing with your own labs, not private labs, and——

Ms. GLAVIN. Are you asking me? I am sorry.

Mr. STUPAK. No, I am asking Dr. Raymond. Could your system be duplicated for the FDA?

Dr. RAYMOND. I don't know that I can answer for the FDA. Perhaps portions of our system could be modeled. But I have to point out that it is our authorities that require what we do, and it is our authorities that Congress funds us to have those resources available so we can meet the authorities in the Federal Meat Inspection Act.

Mr. STUPAK. Your resources comes from an inspection fee; do they not?

Dr. RAYMOND. No, sir. Congress gives us a great majority of our resources to do what we do.

Mr. STUPAK. Have you had to come back to Congress to ask for extra resources to do your job, USDA, to do the inspections?

Dr. RAYMOND. We have, and we will continue to do so, I am sure.

Mr. STUPAK. Have you received the resources that you requested from Congress or——

Dr. RAYMOND. Periodically, sir. Sometimes yes, sometimes no.

Mr. STUPAK. Are you short of resources now?

Dr. RAYMOND. I think we have what we need right now to do the job that we are asked to do.

Mr. STUPAK. Thank you. I have nothing further.

Mr. Whitfield?

Hearing no other Members seeking to ask questions, we will dismiss this panel. Thank you all very much for being here. That concludes our questioning. I want to thank all of our witnesses for coming today and their testimony.

I ask for unanimous consent that the hearing record will remain open for 30 days for additional questions for the record. Without objection, the record will remain open.

I ask unanimous consent that the contents of our document binder be entered into the record. Without objection, the documents will be entered into the record.

That concludes our hearing. Without objection, the meeting of the subcommittee is adjourned.

[Whereupon, at 1:32 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

HENRY A. WAXMAN, CALIFORNIA
EDWARD J. MARKEY, MASSACHUSETTS
RICK BOUCHER, VIRGINIA
EDOLPHUS TOWNS, NEW YORK
FRANK PALLONE, JR., NEW JERSEY
BART GORDON, TENNESSEE
BOBBY L. RUSH, ILLINOIS
ANNA G. ESHOO, CALIFORNIA
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DENNIS B. FITZGIBBONS, CHIEF OF STAFF
GREGG A. ROTHSCHILD, CHIEF COUNSEL

ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

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November 20, 2007

David W.K. Acheson, M.D.
Assistant Commissioner for Food Protection
Food and Drug Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Ms. Margaret O'K. Glavin
Associate Commissioner for Regulatory Affairs
Food and Drug Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Acheson and Ms. Glavin:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Thursday, October 11, 2007, at the hearing entitled "Diminished Capacity: Can the FDA Assure the Safety and Security of Our Nation's Food Supply? – Part III." We appreciate the time and effort you gave as a witness before the Subcommittee.

Under the Rules of the Committee on Energy and Commerce, the hearing record remains open to permit Members to submit additional questions to the witnesses. Attached are questions directed to you from certain Members of the Committee. In preparing your answers to these questions, please address your response to the Member who has submitted the questions and include the text of the Member's question along with your response. As you have been asked questions from more than one Member of the Committee, please begin the responses to each Member on a new page.

To facilitate the printing of the hearing record, your responses to these questions should be received no later than the close of business **Monday, December 3, 2007**. Your written responses should be delivered to **316 Ford House Office Building** and faxed to **202-225-5288** to the attention of Kyle Chapman, Legislative Clerk. An electronic version of your response should also be sent by e-mail to Mr. Kyle Chapman at **kyle.chapman@mail.house.gov in** a single Word formatted document.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please contact Kyle Chapman at (202) 226-2424.

Sincerely,

JOHN D. DINGELL
CHAIRMAN

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Bart Stupak, Chairman
Subcommittee on Oversight and Investigations

The Honorable Ed Whitfield, Ranking Member
Subcommittee on Oversight and Investigations

The Honorable Michael C. Burgess, Member
Subcommittee on Oversight and Investigations

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

SEP 1 9 2008

Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

Dear Mr. Chairman:

Thank you for your letter of September 12, 2008, regarding the October 11, 2007, hearing entitled "Diminished Capacity: Can the FDA Assure the Safety and Security of Our Nation's Food Supply? – Part III," and the January 29, 2008, hearing entitled "Science and Mission at Risk: FDA's Self-Assessment." Your letter requested responses to additional questions for the record submitted in two previous letters.

We apologize for the delay in providing these responses. We are now providing the Food and Drug Administration's (FDA or the Agency) responses to the questions from each Member on the "Diminished Capacity: Can the FDA Assure the Safety and Security of Our Nation's Food Supply? – Part III" hearing. We will provide responses to the questions from the "Science and Mission at Risk: FDA's Self-Assessment" hearing as soon as possible.

We have restated each question in bold, followed by our response.

Questions from The Honorable Ed Whitfield

1. **PREDICT has been operating for over 3 years now. Please (a) explain why the Food and Drug Administration (FDA) has not expanded its application and operations to include additional import categories and to operate at more ports of entry and (b) provide FDA's plans for expansion.**

A pilot test of the PREDICT prototype system was conducted by FDA during summer 2007. The prototype system is currently limited to seafood, and the pilot test was limited to seafood imported through a small number of ports in Southern California. FDA is working on expanding the prototype to become a full production application with additional capabilities. The current plan is to include all FDA-regulated products at all ports by 3rd quarter Fiscal Year (FY) 2009, but with a limited screening ruleset. The full risk-based ruleset is scheduled to be implemented by the end of FY 2009. Open-source intelligence activities will be expanded. The PREDICT entry reviewer screens are being integrated into FDA's enterprise-wide import system, with user acceptance testing planned for November 2008.

Considerable work must be done by subject matter experts to develop the extensive risk-based criteria which will be required for PREDICT. FDA's Center for Food Safety and Applied Nutrition (CFSAN) is developing an enhanced method of priority setting, which is a qualitative, relative risk ranking method. It takes into consideration both the likelihood of a product containing the hazard and the severity of that hazard, i.e., physical consequences of consuming the hazard-containing product.

2. How does FDA's June 2007 import alert on Chinese aquaculture products differ from FDA's November 2001 import alert related to drugs in aquaculture products? Did it shift the burden of proof?

Import Alert (IA) 16-124, issued on November 16, 2001, applies to specific aquaculture products from specific foreign firms, including some firms in China. These products are subject to detention without physical examination (DWPE), because FDA had detected residues of unapproved new animal drugs in past shipments of these products from these firms. If detained, to be permitted entry into the United States, information could be provided to show the product meets applicable standards, such as testing by a third-party laboratory for the residues that resulted in the firm's products being placed on the Import Alert. Other aquaculture products from these firms or these or other products from other firms would not be subject to DWPE based on this Import Alert.

IA 16-131, issued on June 28, 2007, is a countrywide DWPE for aquaculture shrimp, catfish, basa, eel, and dace imported only from China. This import alert was based on findings of residues of unapproved new animal drugs during targeted sampling from October 2006 through May 2007, observations made during the FDA inspection mission to China in September 2006, and other information. FDA concluded that the evidence indicates that the use of such drugs is widespread in China in these referenced species, and that continuation of DWPE on a firm-by-firm basis under IA 16-124 was not sufficient to prevent introduction of adulterated product into the United States. As a result, FDA issued IA 16-131 to apply to all Chinese exporters of the specified products, regardless of whether or not their product had previously tested positive for a residue of an unapproved new animal drug.

3. In July 2005, the South Korean FDA found that Chinese eel imports were tainted with a cancer-causing disinfectant called malachite green and moved that summer to block Chinese eel imports. In January 2006, Canada blocked Chinese eel imports for the same reason. In February 2006, FDA had information in hand from PREDICT that other foreign countries, including Canada and South Korea, had banned the import of Chinese eel because of the presence of malachite green. Yet, in your response to questions at the hearing, you said FDA did not act until November 2006 because it had to conduct sufficient testing to determine this was a countrywide issue.

a. Section 801 of the Food, Drug, and Cosmetic Act explicitly authorizes FDA to refuse admission of articles that *appear* to violate the Act. Why did FDA not simply rely on the information from South Korea and

Canada to issue an import alert? Did FDA seek supporting evidence from South Korea, Canada, or any other government?

Although there is sufficient evidence to suggest that the United States and Canada constitute a single market with respect to seafood from China, FDA is not in a position to assert that the same is true with respect to the Republic of South Korea. Such an assertion would be necessary to suggest that Chinese product tested by the government of South Korea and found to have residues of an unapproved new animal drug would have relevance to the likelihood that Chinese product shipped to the United States would have similar residues. It is entirely possible that different suppliers and different practices exist for the South Korean market than exist for the U.S. market.

Because of the similarity between the U.S. and Canadian markets, FDA has engaged in ongoing discussions with the government of Canada on the exchange of data. Canada has been able to supply summary data of samples of aquaculture fish tested for residues of unapproved new animal drugs and these have been very useful to help FDA target problems, such as malachite green in eels, of which FDA was not aware. However, because of legal constraints, the government of Canada was not able to provide the individual laboratory analytical worksheets that would enable FDA to ensure that suitable analytical methods were used, that the methods were properly applied, and that the analytical conclusions are sound. Because of this, FDA developed its own data upon which to support an import alert.

b. **In 1999, FDA detained egg imports from France, Belgium, and the Netherlands based on reports from Europe about polychlorinated biphenyls and dioxin contamination. Why was FDA able to issue an import alert in this case, but not rely on other country information in the case of Chinese eel imports?**

FDA has not been able to find any information on a 1999 import alert on eggs for polychlorinated biphenyls or dioxin contamination.

c. **Why did it take 5 months for FDA to test Chinese eel samples in which FDA continued to find unapproved drugs? Did FDA issue an Import Bulletin while it was testing Chinese eel samples and, if so, when was the Bulletin issued?**

The Canadian Food Inspection Agency (CFIA) issued a countrywide Import Alert for eel from China in January 2006. Based on that information, FDA revised Import Bulletin 16B05 on February 3, 2006, to include eel from China. From that time forward, FDA's field staff began collecting samples of aquacultured eel from China. When samples were found to contain residues of an unapproved new animal drug, e.g., malachite green, FDA placed the Chinese exporter on IA 16-124. By November 2006, FDA had sufficient evidence to support an assertion that the problem of malachite green use in Chinese eel aquaculture was widespread and that continuation of DWPE on a firm-by-firm basis under IA 16-124 was not sufficient to prevent introduction of adulterated product into the United States. As a result, IA 16-130 was issued on November 14, 2006, to apply to all Chinese exporters of

aquacultured eel, regardless of whether or not their product had previously tested positive for residues of malachite green.

d. According to the testimony of Dr. Murray Lumpkin before the Senate in July 2007, violative eel product continued to be shipped, even after the 2006 import alert. Why did the import alert fail?

The import alert did not fail. Shipments of eel from China, *offered* for entry into the United States after November 14, 2006, were detained based on the import alert and refused admission, either because testing showed the presence of illegal residues of malachite green or other chemicals, or information was not submitted to show that the product was admissible.

e. In terms of Chinese eels, how did the June 2007 import alert differ from the 2006 import alert?

IA 16-130, the 2006 import alert that applied only to eel, was canceled when IA 16-131 was issued, because the latter import alert applied to a group of five species that included eel. For eel, it covers not only illegal residues of malachite green, but also of gentian violet. Otherwise, with respect to eel, the two import alerts are essentially the same.

f. Why did the June 28, 2007 import alert not include tilapia, even though malachite green residue was found in numerous samples of this species?

For approximately two years prior to issuance of IA 16-131, FDA had two out of 86 Chinese tilapia samples test positive for residues of malachite green. FDA determined not to include tilapia with the other named species in IA 16-131 for countrywide DWPE because of this relatively low violation rate. However, individual exporters of tilapia from China are subject to DWPE under IA 16-124.

4. According to information FDA provided to Minority Committee staff the evening before the hearing, FDA has no full-time import inspectors, no full-time import investigators, and 30 full-time import entry reviewers. FDA identified 213 employees who spend the majority of their time on import activities. Why are there no full-time import inspectors or investigators? Does FDA have a plan to have full-time import inspectors? Does FDA have any other plans to increase the number of staff assigned to import operations?

The Agency is increasing the number of staff related to all foods programs, including imports. There may be some positions that are filled in large import locations, where they will be focused on import activities and become essentially full time in that activity. Our hiring plan includes many large import areas, but the job announcements for these positions and locations are the same and the qualifications for either an import or domestic position are the same.

As part of a total increase in field investigators, FDA will increase the number of staff that will have import responsibilities.

Overall, our food protection investments for FY 2008 and FY 2009 will allow FDA to increase our professional staff by at least 500 Full Time Employees (FTEs) across all public health programs, including at least 375 FTEs to support FDA's Office of Regulatory Affairs' (ORA) domestic and foreign inspection program. By the end of FY 2010, when the ORA investigators—hired with FY 2008 and proposed FY 2009 increases—are trained and deployed, the increased inspection program resources will give FDA the capacity to conduct an additional 850 foreign food inspections, an increase of at least 2,000 domestic food inspections, and an additional 40,000 import food field exams.

5. **The prior notice center receives 33,000 notices of food imports daily, and FDA claims it inspects 1 percent of all food imports; does FDA conduct over 330 food inspections daily?**

The 1 percent number is an average that relates to the admissibility of all FDA-regulated products entering the United States, not just food. In FY 2007, FDA physically examined 1.28 percent of the approximately 9.4 million food import entry lines. "Physically examined" means that FDA either conducted an import field examination or a laboratory analysis on an import sample of an individual import entry line. To clarify, this percentage is calculated by taking the total number of import food field examinations, plus the total number of import laboratory samples analyzed and dividing that by the total number of import entry line decisions. The number of prior notice reviews is not part of the calculation.

It is important to note that while FDA is not able to physically inspect a large percentage of import entries, it does electronically screen all import entries for a variety of risk factors. This screening helps FDA personnel identify which shipments meet identified criteria for physical examination, sampling and analysis, or other review. With the FY 2008 supplemental funding, we expect to perform an additional 20,000 imported food field examinations in FY 2009.

6. **How often do FDA employees inspect foreign establishments involved in the production or distribution of food set for export to the U.S.?**

Up to 230 countries export food products to the United States each year, and 210,785 foreign food and feed firms had registered with FDA as of September 11, 2008. To use its resources wisely, FDA determines specific firms to inspect, using a risk-based selection method.

Planning for foreign inspections is begun one fiscal year prior to the target fiscal year of the inspection. CFSAN management, in conjunction with ORA, identifies the number of inspections that will take place in the fiscal year. Numerous factors are used to determine firms for inspection, and the following are examples of criteria used for the selection of:

- Countries – major food exporters to the United States; compliance problems as determined by detention information; recent development of a particular industry; credible information from foreign governments, international agencies, or organizations raising safety or quality concerns with the country's exports.

- Products – Products identified in CFSAN's current high-risk definition for domestic coverage; current foodborne illness outbreaks; compliance problems; credible information raising safety or quality concerns; import alerts/bulletins; industrywide compliance problems as determined by detentions, refusals, Establishment Inspection Reports (EIRs), Warning Letters, untitled letters, foreign or domestic recalls, or consumer complaints.

- Firms – Processors of high-risk products; current illness outbreaks or product defects; new technology or processes that raise safety concerns; focus on firms producing and shipping large quantities into the United States, or smaller quantities intended for vulnerable populations; findings of audits or verifications of firms covered by Memorandums Of Agreement or Memorandums Of Understanding; travel efficiencies, e.g., geographically situated close to other firms in the same trip.

Foreign inspections are just one component of FDA's approach to make informed decisions about the admissibility of products. At the border, FDA conducts routine surveillance inspections of imported goods to check for compliance with U.S. requirements. Although FDA is not able to physically inspect a large percentage of import entries, all import entries are electronically screened through OASIS for a variety of risk factors. OASIS is an automated system for processing FDA-regulated products offered for import and helping FDA make admissibility determinations. It includes criteria designed to identify those products posing the greatest safety risk and to determine if the shipment meets identified criteria for physical examination or sampling and analysis or warrants other review by FDA personnel.

FDA also uses information submitted under the Prior Notice requirements to target food that may be intentionally contaminated or otherwise pose a significant health risk. This advance notice of imported food enables FDA to determine which shipments pose such a significant risk that they should be inspected at the border.

To manage the increasing volume of imports, FDA is refining its targeting ability to utilize data from a much wider range of sources to better inform entry decisions. By improving its use of information technology (IT) systems and other systems in FDA, the Agency can better identify products on which to perform additional sampling for likely contaminants.

FDA also works on food safety priorities through its diplomatic relationships and provides technical assistance to foreign regulatory entities. As we have done with China, we are entering into formal agreements with foreign governments. FDA's Beyond Our Borders Initiative is a cornerstone of the Action Plan for Import Safety, and includes establishing offices in China, India, Latin America, Europe, and the Middle East.

In addition to FDA foreign inspections and import exams, this initiative also relies on greater collaboration with foreign regulators, use of third-parties to provide information about the

compliance of regulated industry with FDA standards, and greater FDA direction to regulated industry to ensure their global activities meet FDA standards.

The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires all food products distributed in the United States—whether produced domestically or abroad—to meet the same standards. In the Import Safety Action Plan and the Food Protection Plan, we are proposing additional measures to supplement current authorities that would enhance FDA's ability to determine whether a food product imported from another country meets the same safety standards as those required of foods in the United States.

Specifically, we propose to:

- Accredit highly qualified third parties for voluntary food inspections.
- Refuse admission of food if FDA's efforts to conduct a foreign inspection are unduly delayed, limited, or denied at a facility where the product was manufactured, processed, packed or held.
- Require electronic import certificates for shipments of designated high-risk products.

A. Are these routine surveillance inspections "for cause"?

The food and cosmetic inspections in FY 2007 were surveillance inspections of firms that were targeted using the Agency's risk-based approach or were in direct follow-up to information or emergencies that suggested a firm is making an adulterated product.

B. How many foreign inspections of food-related facilities did FDA perform last year?

In FY 2007, FDA conducted 96 foreign food inspections. With the FY 2008 supplemental funding and the proposed increases for FY 2009, FDA will be able to conduct an additional 850 foreign food inspections by the end of FY 2010.

<u>Questions from The Honorable Michael C. Burgess</u>

1. **Equivalence is the foundation for the United States Department of Agriculture's (USDA's) system of imports, which has produced safe imports of meat, poultry, and egg products.**

   a. **Aside from statutory limitations, please explain why FDA does not have a similar system of equivalence in place for its own import system?**

   b. **Assuming it had statutory authority to implement such a system, what would be the practical issues FDA would have to confront should it seek to implement an equivalence standard?**

c. What parts of USDA's equivalence system could be reasonably applied to FDA's own import system?

FDA does not believe equivalence determinations can be used as a routine mechanism to ensure that imported foods are equally as safe as U.S. produced foods. Equivalence determinations are technically complex activities which are very resource intensive. Usually all or major portions of a food safety system, including infrastructure, program design, and actual control measures, need to be evaluated. Where relatively few products and countries are involved (such as for meat and poultry whose responsibilities fall to the United States Department of Agriculture's Food Safety Inspection Service), routine equivalence determinations can be done. For situations involving many foods (thousands) and a large number of countries (more than 200), as is the case for FDA, using equivalence routinely as a significant means to help ensure food safety has not proved to be feasible. Establishing equivalence with so many countries on so many commodities would be a massive undertaking that would take many years and vast resources to accomplish.

It should be noted that FDA does establish agreements and arrangements with countries relating to food safety, particularly with respect to such areas as information sharing and lists of approved establishments. FDA also participates in the Codex Alimentarius Commission to harmonize international standards. FDA will continue to work on food safety priorities through its diplomatic relationships and provide technical assistance to foreign regulatory entities. As we have done with China, we are entering into formal agreements with foreign governments.

The FD&C Act requires all food products distributed in the United States—whether produced domestically or abroad—to meet the same standards. In the Import Safety Action Plan and the Food Protection Plan, we are proposing additional measures to supplement current authorities that would enhance FDA's ability to determine whether a food product imported from another country meets the same safety standards as those required of foods in the United States.

Specifically, we propose to:

- Accredit highly qualified third parties for voluntary food inspections.
- Refuse admission of food if FDA's efforts to conduct a foreign inspection are unduly delayed, limited, or denied at a facility where the product was manufactured, processed, packed or held.
- Require electronic import certificates for shipments of designated high-risk products.

Together, these steps will help to elevate the standards of imported goods.

2. What obligations do companies have to inform FDA authorities of a problem they earn about or detect with imports.

Under certain circumstances, companies are obligated to inform FDA of problems they learn about or detect. In general, these requirements are applicable regardless of whether the

product was produced domestically or was imported. The statutes and regulations governing the primary reporting requirements, by product area, are:

Drugs

21 CFR 310.305 -- Records and reports concerning adverse drug experiences on marketed prescription drugs for human use without approved new drug applications.

21 CFR 312.32 -- Investigational new drug safety reports.

21 CFR 314.80 -- Postmarketing reporting of adverse drug experiences.

21 CFR 314.81 -- Other postmarketing reports.

Section 760 of the FD&C Act -- Serious adverse event reporting for nonprescription drugs.

21 CFR 514.80 -- Records and reports concerning experience with approved new animal drugs.

Biologics

Section 2125 of the Public Health Service Act -- Reporting of childhood vaccine adverse events.

21 CFR 600.80 -- Postmarketing reporting of adverse experiences.

21 CFR 1271.350 -- Human cells, tissues, and cellular and tissue-based product reporting.

Devices

21 CFR part 803 -- Medical device reporting.

21 CFR part 806 -- Medical Devices; Reports of Corrections and Removals.

Radiation-emitting Products

21 CFR 1002.20 -- Reporting of accidental radiation occurrences.

21 CFR part 1003 -- Notification of defects or failure to comply.

Food

Section 761 of the FD&C Act -- Serious adverse event reporting for dietary supplements.

Section 417 of the FD&C Act -- Reportable food registry.

21 CFR 106.120 -- Infant formula; New formulations and reformulations.

a. Should companies have a specific obligation to inform authorities of problems, perhaps through a safe harbor mechanism to encourage reporting?

FDA is interested in learning of issues that may affect the quality of imported products. As noted above, there are a number of existing reporting requirements.

Thank you for your interest in this matter. Please let us know if there are further questions.

Sincerely,

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

Ex. #	Description	Date
1	Subcommittee on Oversight and Investigations Witness List	10/11/07
2	O&I Hearing Memo; subject: "Diminished Capacity: Can the FDA Assure the Safety and Security of Our Nation's Food Supply? - Part III."	10/10/07
	Congressional Research Service Reports	
3	CRS Report by Geoffrey Becker, Specialist in Agricultural Policy, subject: "Food and Agricultural Imports from China."	07/17/07
4	CRS Report by Geoffrey Becker, Specialist in Agricultural Policy, subject: "U.S. Food and Agricultural Imports: Safeguards and Selected Issues."	10/03/07
	E&C Committee Correspondence on Chinese Imports	
5	Letter to FDA Commissioner Andrew von Eschenbach from Reps. Dingell, Stupak, Melancon and Ross regarding safety of food imports from China.	6/5/2007
6	Letter from Commissioner von Eschenbach (Stephen Mason) responding to E&C Committee 6/5/07 letter regarding safety of food imports from China.	7/9/2007
7	Letter to USDA Under Secretary for Food Safety Richard Raymond from Reps. Dingell and Stupak regarding safety of food imports from China.	6/6/2007
8	Letter from USDA responding to E&C Committee 6/6/07 letter regarding safety of food imports from China.	10/9/2007
	U.S. Department of Agriculture Documents	
9	USDA Foreign Agricultural Service Global Agriculture Information Network report, subject: "People's Republic of China Agricultural Situation, The 11th Five-Year Plan on Food and Drug Safety 2007."	07/16/07
10	USDA Foreign Agricultural Service Global Agriculture Information Network report, subject: "People's Republic of China Sanitary/ Phytosanitary/ Food Safety, China to Attach Inspection and Quarantine Labels for Food Exports 2007."	07/23/07
11	USDA Food Safety and Inspection Service webpage, subject: "Regulations & Policies, Import Information, Eligible Foreign Establishments."	10/10/07
	Chinese Documents	
12	Information Office of the State Council of the People's Republic of China report (www.china.org.cn), subject: "The Quality and Safety of Food in China."	08/17/07

13	Chinese Government document, re: "Chinese Government Attaches Importance to Food and Drug Safety."	07/18/07
14	Chinese news article, "Beijing Promises Greater Efforts to Ensure Food Safety."	07/24/07
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23	Associated Press article by Audra Ang, subject: "China, U.S. to Discuss Seafood Exports."	07/18/07
24	Bloomberg News article by Laurie Burkitt, subject: "China Scares Open Hong Kong Organic Food, Vegetable Tracking."	07/27/07
25	Bloomberg News article by Emily Brown, subject: "China Must Meet U.S. Safety Standards, Leavitt Says (Update 2)."	08/06/07
26	Associated Press article, subject: "Safety-Net Holes Let Chinese Seafood into U.S. Without Testing."	08/07/07
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28	Reuters article, subject: "Most Americans Concerns with China Imports."	09/19/07
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CRS Report for Congress

Food and Agricultural Imports from China

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Prepared for Members and
Committees of Congress

Congressional
Research
Service

Food and Agricultural Imports from China

Summary

U.S. food and agricultural imports have increased significantly in recent years, causing some in Congress to question whether the U.S. food safety system can keep pace. A series of recent incidents have raised safety concerns about the many foods, medicines, and other products from China in particular. For example, in early 2007, evidence began to emerge that adulterated pet food ingredients from China had caused the deaths of an unknown number of dogs and cats. In late June 2007, the U.S. Food and Drug Administration (FDA) announced that it was detaining all imports of farm-raised seafood from China (specifically, shrimp, catfish, basa, dace, and eel) until the shippers of these products could confirm they are free of unapproved drug residues.

U.S. imports of all Chinese food, agricultural, and seafood products have increased from nearly 0.411 million metric tons (MMT) in 1996 to 1.833 MMT in 2006, a 346% rise. The increase by value was 375%, from $880 million in 1996 to $4.2 billion in 2006. China was the sixth leading foreign supplier of agricultural products to the United States and the second leading seafood supplier in 2006. When seafood values are combined with food and agricultural products, China was the third leading foreign supplier, after Canada and Mexico.

Two federal agencies — FDA and the U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) — are primarily responsible for the government's food regulatory system, although a number of other federal, state, and local agencies also have important roles. For imports, FSIS (which has oversight over most meat and poultry) relies on a very different regulatory system than FDA (which has oversight over other foods). Although all imported food products must meet the same safety standards as domestically produced foods, international trade rules permit a foreign country to apply its own, differing, regulatory authorities and institutional systems in meeting such standards, under an internationally recognized concept known as "equivalence."

Despite recent statements by China that it is moving aggressively to improve its food safety system and close unsafe plants, some Members of Congress have expressed sharp criticism of both China's food safety record and U.S. efforts to insure the safety of imports. Congressional committees have held, or are planning, hearings on food safety concerns generally and on the China situation particularly. On May 2, 2007, Senator Durbin won unanimous approval of an amendment to the Senate-passed FDA Revitalization Act (S. 1082) that would require domestic and foreign facilities to notify FDA of food safety problems, and would require FDA to establish a central registry for collecting information and notifying the public about adulterated foods, and for notifying the public about adulterated human or animal foods. The amendment includes elements of his proposed Human and Pet Food Safety Act of 2007 (S. 1274), introduced as H.R. 2108 by Representative DeLauro. Separate bills (S. 1776 and H.R. 2997) would, among other things, impose new user fees on food imports to help cover the cost of their screening. More comprehensive bills (H.R. 1148/S. 654) would combine current federal food safety oversight under a new food safety administration.

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Food and Agricultural Imports from China

Introduction

Food and agricultural imports have increased significantly in recent years, causing some in Congress to question whether the U.S. food safety system can keep pace. Analysts point out that domestically sourced foods also can pose safety problems, as evidenced by recent outbreaks of illness linked to consumption of raw produce and by continuing recalls of meat and poultry products due to bacterial contamination.[1]

However, a series of recent incidents have raised safety concerns about the many foods, medicines and other products from China in particular. For example, in early 2007, evidence began to emerge that adulterated pet food ingredients from China had caused the deaths of an unknown number of dogs and cats. Furthermore, some ingredients also were fed to U.S. food animals, although federal officials claimed that humans were not at risk. In late June 2007, the U.S. Food and Drug Administration (FDA) announced that it was detaining all imports of farm-raised seafood from China (specifically, shrimp, catfish, basa, dace, and eel) until the shippers of these products could confirm that they are free of unapproved drug residues.

Although it has strongly defended its record, the Chinese government also has announced a variety of steps to improve the safety of its food and drug exports, including planned major revisions in its regulations, new inspections, and the closure of nearly 200 problem plants.

These and other developments have greatly heightened public and congressional scrutiny not only of China's own food safety regime, but also of the adequacy of U.S. import safeguards. In the 110th Congress, a number of congressional committees have held hearings on or launched investigations of food imports from China and elsewhere and the U.S. laws and regulations designed to ensure their safety. Bills also have been introduced aimed at clarifying and expanding federal authorities and/or reorganizing agency responsibilities. FDA officials claim that they are examining how best to determine relative risks among products (imported and domestically produced) and among exporting countries. Underlying all of these efforts is the question of whether the agency has sufficient money and staff to address these risks.

Import Trends

U.S. imports of agricultural and seafood products from all countries increased from 32.9 million metric tons (MMT) in calendar year 1996 to 46.7 MMT in 2006, or by 42%. The increase by value was 98%, from $40.1 billion in 1996 to $78.5

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[1] See CRS Report RL32922, *Meat and Poultry Inspection: Background and Selected Issues*, by Geoffrey S. Becker; and CRS Report RL33722, *Food Safety: Federal and State Response to the Spinach E. coli Outbreak*, by Donna V. Porter.

billion in 2006. Among the product categories that at least doubled in volume during the period were live animals, wine/beer, fruit/vegetable juices, wheat, coffee, snack foods, and various seafood products.[2]

Not all agricultural imports enter the human food supply; some products are used as ingredients in pet food and animal feed, in manufactured goods (e.g., rubber), and in the nursery plant trade. Nonetheless, consumers are obtaining a growing portion of their diets from overseas. In 2005, nearly 15% of the overall volume of U.S. food consumption was imported, compared with 11%-12% in 1995. The proportions (volume) for some food product categories are much higher: in 2005 as much as 84% of all U.S. fish and shellfish was imported (55% in 1995); 43% of all noncitrus fresh fruits (34% in 1995); 37% of all processed fruits (20% in 1995); and 54% of all tree nuts (40% in 1995).[3]

U.S. imports of Chinese agricultural and seafood products have increased far more rapidly than the global increase, from nearly 0.411 MMT in1996 to 1.833 MMT in 2006, a 346% rise. The increase by value was 375%, from $880 million in 1996 to $4.2 billion in 2006.

In 2006, China was the sixth leading foreign supplier of agricultural products to the United States (after Canada, Mexico, Italy, Australia, and Ireland, in that order) and the second leading seafood supplier (after Canada). When seafood values are combined with agricultural products, China was the third leading foreign supplier, after Canada and Mexico (see **Table 1**, below).

Table 1. Leading Suppliers of U.S. Agricultural and Seafood Imports, CY2006
(value in billion U.S. dollars)

Country	Agricultural	Seafood	Total
Canada	$13.433	$2.184	$15.617
Mexico	9.390	0.454	9.844
China	2.262	1.922	4.184
Thailand	1.812	1.334	3.146
Italy	2.802	.009	2.811
Indonesia	2.023	0.778	2.801
Chile	1.774	.952	2.726
Australia	2.487	.091	2.578
Brazil	2.237	.130	2.367
Ireland	2.354	.008	2.362
World Total	65.333	13.143	78.475

Source: USDA, Foreign Agricultural Service (FAS), BICO Import Commodity Aggregations.

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[2] U.S. Department of Agriculture (USDA), Foreign Agricultural Service (FAS), U.S. Trade Internet System, BICO (Bulk, Intermediate, and Consumer-Oriented) data.

[3] USDA, Economic Research Service (ERS), unpublished data, obtained May 11, 2007. Other data including that provided by FDA indicate that the current percentage for seafood is somewhat lower than 84%.

Table 2, below, shows the major types of food and agricultural imports from China in 2006. Seafood products, including shrimp, other shellfish (mollusks), and salmon, were the leading food-related (i.e., agricultural and seafood) imports. Fruits, fruit juices, vegetables, tree nuts, teas, and spices also were high on the list.

Table 2. Selected Agricultural and Seafood Imports from China, CY2006

Import	Value (*$1,000*)	(*metric tons unless specified*)
Other fish & products (not listed below)	$1,076,631	332,714
Shrimp & prawns	331,935	68,364
Mollusks	245,607	62,727
Misc. horticultural products	226,047	109,910
Fruit, processed	207,427	247,554
Fruit juices *(kiloliters)*	201,935	933,566
Other crustaceans	159,352	22,051
Feed, ingredients & fodders	147,850	59,988
Misc. industrial use	143,780	12,574
Vegetables, prepared or preserved	122,854	131,002
Poultry, misc.[a]	120,765	15,436
Sugar & related products	104,611	46,429
Salmon	97,792	26,482
Vegetables, dried/dehydrated	93,254	68,516
Edible tree nuts	80,853	10,070
Fresh vegetables, excluding potatoes	77,555	76,296
Other oilseeds products, nonagricultural	75,645	27,857
Grains and feed, misc.	75,495	46,422
Misc. meat products[a]	69,673	15,672
Tea, excluding herbal	68,174	24,007
Misc. hair, industrial use	59,781	13,513
Vegetables, frozen	54,513	67,893
Spices	49,929	43,156
Cocoa & cocoa prods.	48,278	11,661
Misc. sugar and tropical	46,606	13,433
Essential oils	40,249	3,896
Fruit, dried	39,766	7,349
Rice	36,428	104,894

Source: USDA, FAS, FAS Import Commodity Aggregations. Not all products listed.

a. Primarily species not subject to FSIS inspection. (FSIS coverage is of the major commercial red meat and poultry species and their products, while FDA has jurisdiction over any meat and poultry not inspected by FSIS.)

The broader categories in **Table 2** mask some specific products that the United States imports from China. For example, The United States received $941 million in various types of fish fillets. Mushrooms accounted for at least $37 million of the dried vegetable category in 2006.

A recent report by Food and Water Watch, a consumer advocacy organization, noted that China became the leading exporter of seafood to the United States in 2004. Aquaculture has facilitated this growth in exports, particularly of shrimp and tilapia. Catfish, eel, and crab imports also have risen significantly.[4]

U.S. Import Safeguards

Overview

Although all food products imported into the United States must meet the same safety standards as domestically produced foods, international trade rules permit a foreign country to apply its own, differing, regulatory authorities and institutional systems in meeting such standards, under an internationally recognized concept known as "equivalence."[5]

Two federal agencies — the U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) and the U.S. Department of Health and Human Services' Food and Drug Administration (FDA) — are primarily responsible for the government's food regulatory system, although a number of other federal, state, and local agencies also have important roles. For imports, FSIS relies on a very different regulatory system than FDA, including a different approach to addressing equivalence, as described in the following sections.[6]

FSIS

Under Section 20 of the Federal Meat Inspection Act (FMIA) as amended (21 U.S.C. 601 et seq.) and Section 466 of the Poultry Products Inspection Act (PPIA) as amended (21 U.S.C. 451 et seq.), FSIS is responsible for determining the equivalence of other countries' meat and poultry safeguards.[7] A foreign plant cannot

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[4] *Import Alert: Government Fails Consumers, Falls Short on Seafood Inspections*. Food and Water Watch, May 2007. Accessed on the Internet on June 5, 2007, at [http://www.foodandwaterwatch.org/press/publications/reports/import-alert].

[5] This concept is embodied in Article 4 of the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement), which entered into force January 1, 1995, for member nations of the World Trade Organization (WTO). For a more detailed explanation, see CRS Report RL33472, *Sanitary and Phytosanitary (SPS) Concerns in Agricultural Trade*, and the WTO website at [http://www.wto.org/english/tratop_e/sps_e/sps_e.htm].

[6] The two systems are described in more detail in CRS Report RS22664, *U.S. Food and Agricultural Imports: Safeguards and Selected Issues*, from which this section is adapted.

[7] FSIS coverage is of the major commercial red meat and poultry species and their products,

(continued...)

refusals).[15] The refusals for each month can be searched by country or by product category, but not by both at the same time. Data for only 12 months, from May 2006 through April 2007, appeared on the website as of May 2007, and the months were not aggregated into annual figures.[16]

For each line (shipment), the system provides the name of the source company and the reason for refusal. As noted earlier, the size of each shipment in the OASIS database varies. Therefore, it is not possible to calculate the volumes of products being rejected, either as an absolute quantity or as a proportion of total imports. Also, the types or categories of imports do not necessarily correspond to the categories reported through the FAS trade databases (see **Tables 1** and **2**, above).

Mindful of these caveats, CRS prepared a tabulation of the refusals, focusing on nearly 40 categories of FDA-regulated food and food-related products.[17] For the one-year period available at the time of this CRS tabulation (May 2006-April 2007), FDA logged a total of approximately 8,200 refusals. Of these, more than 700 separate shipments were from China. Two other countries had more shipments refused: Mexico with nearly 1,300 and India with more than 1,100 (see **Table 3**).[18]

It is important to note that a higher relative number does not necessarily indicate that one country's products are less safe, or its food safety system less rigorous, than another country's. The country simply might be a more important source of U.S. agricultural and/or seafood imports. On the other hand, Canada, which imports much more to the United States than any other country, had far fewer refusals than either China or Mexico, the second most important U.S. importer in dollar value. India had the second highest number of refusals, even though it is not among the top 10 exporters of food, agricultural, and seafood products to the United States.[19]

Because of technical problems with OASIS at the time this report was prepared, FDA officials said they could not immediately respond in detail to CRS questions about the database that might have shed additional light on the significance, if any, of the numbers in **Table 3**. For example, the information published on the FDA website does not include the overall number of shipments. Thus, CRS could not calculate for this report the percentage of overall shipments that had been refused for

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[15] FDA website, accessed May 31, 2007, at [http://www.fda.gov/ora/oasis/ora_oasis_ref.html].

[16] CRS did not examine FSIS import refusals. China currently is not certified by FSIS to export meat or poultry products to the United States. A proposed rule in the November 23, 2005, *Federal Register* to permit some types of processed poultry is pending.

[17] Also listed in the OASIS refusal reports, but not examined here, are other FDA-regulated products, e.g., human and animal drugs, medical devices, and vitamins.

[18] *The New York Times* reportedly compiled a more recent 12-month tabulation (July 2006 to June 2007), which indicated that refusals were higher during the period: 1,763 for India, 1,480 for Mexico, and 1,368 for China. See "China Not Sole Source of Dubious Food," *New York Times*, July 12, 2007.

[19] Nonetheless, India's exports to the United States were valued at a significant $1.4 billion in calendar 2006.

a given month, country, or product. However, FDA did receive a total of nearly 15 million import shipments of all types of FDA-regulated products, including but not limited to foods, during FY2006, or an average of approximately 1.25 million shipments per month.[20]

Table 3. Number of Import Refusals by Country, May 2006-April 2007

Argentina	59	Guatemala	97	Peru	39
Australia	34	Honduras	113	Philippines	153
Bangladesh	54	Hong Kong	52	Poland	76
Brazil	123	India (2)	1,109	Russia	26
Canada	193	Indonesia (5)	334	South Africa	42
Chile	35	Iran	26	Spain	75
China (3)	720	Italy (8)	228	Sri Lanka	72
Colombia	45	Jamaica	36	Syria	70
Costa Rica	35	Japan (7)	295	Taiwan	165
Dominican Republic (4)	593	Korea (South)	111	Thailand (9)	218
Ecuador	56	Lebanon	26	Turkey	81
Egypt	47	Malaysia	35	Ukraine	25
El Salvador	25	Mexico (1)	1,271	United Kingdom (10)	206
France	178	Netherlands	54	Vietnam (6)	335
Ghana	49	Pakistan	140		

Source: FDA Import Refusal Reports for OASIS. See text for caveats on use of data. Countries with fewer than 25 refusals are omitted here.
Note: Numbers in parentheses indicate top ten countries by rank of number of import refusals.

Reviewing refusals by industry, vegetables/vegetable products and seafood products appear to have been the most frequently refused products (at approximately 1,700 shipments from all countries for each of these two product types). Fruits/fruit products from all countries accounted for nearly 900 refusals. Candy products accounted for nearly 600, and spices/flavors/salts for more than 500. Many fruit and vegetable product refusals originated in the Dominican Republic, Mexico, and several other Latin American and Caribbean nations; a frequently cited reason was pesticide contamination. Bacterial contamination (e.g., Salmonella) or filthy condition was cited numerous times.

Fish and shellfish were refused for a variety of reasons, often bacterial contamination, filthy condition, and/or veterinary drug residues. These products most frequently appear to have originated in Asian countries, not only China but also Vietnam, India, Bangladesh, and others. The recent report by Food and Water Watch analyzed the FDA OASIS refusals of seafood in more detail, and for all calendar

[20] FDA e-mail communication to CRS, June 6, 2007.

years from 2002 to 2006. Among its findings were that more than 70% of all imported seafood products were processed. More than 20% of all seafood refusals were due to Salmonella, of which 40% were shrimp. It also observed that more seafood is being refused for veterinary drug residues.[21]

Many refusals of foods of all types also appear to be due to concerns about mislabeling, failure to register, or failure to document that the product had complied with safe manufacturing practices (e.g., HACCP for low acid canned foods or seafoods).[22]

Refusals of Imports from China

Of the 720 refused shipments from China, nearly half (340) were seafood products, and approximately one-third of these products were eel. The most frequently cited reason for rejecting the eel shipments was a concern about adulteration by unsafe levels of veterinary drug residues. Catfish products also were often refused, usually because of concerns about veterinary drug residues. A wide variety of other types of finfish, from tilapia fillets to cod and salmon products, was refused for numerous apparent concerns, including veterinary drug residues, filthy appearance, and Salmonella contamination. More than three dozen separate shrimp shipments were refused because of filthy appearance, the presence of nitrofuran (a banned antibiotic), or Salmonella. Other examples of refused seafoods were scallops, crawfish, and squid.

FDA also refused a total of 221 shipments of various fruits and vegetables from China, including processed products. Approximately one-fourth of these shipments were of mushrooms, often in dried form; these were most frequently rejected for filthy appearance. Other reasons for refusing fruit and vegetable product shipments ranged from concerns about the presence of violative levels of pesticides or other unacceptable ingredients, including unsafe color additives, to the lack of proper documentation and/or labeling.

Seafood products and fruit and vegetable products together constituted the majority of refused shipments from China. Examples of other types of food products that were refused, although in fewer numbers, were certain candies, bean curd and bean paste, teas, and various nuts and spices.

Chinese officials strongly defend their safety record. One official asserted at a May 31, 2007, news conference that U.S. inspectors had approved "99 percent" of all Chinese food and medical shipments over the last three years and that recent reports of rejected Chinese shipments had been sensationalized. He further argued that most of those that had been rejected were unauthorized shipments that had skirted Chinese controls.[23] Other Chinese officials have declared that U.S. importing

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[21] *Import Alert: Government Fails Consumers, Falls Short on Seafood Inspections.*

[22] The FDA website defines each of these terms, which are among approximately 180 possible specific reasons for refusal.

[23] Li Yuanping, director general of the Chinese Import and Export Food Safety Bureau, as (continued...)

companies need to look beyond their emphasis on low prices and communicate more clearly what their standards are.[24]

FDA officials said they could not immediately respond to a CRS request for the number of food and agricultural shipments from China during the period examined (May 2006-April 2007). They did state that in FY2006, the overall refusal rate for shipments from China (food and all other types of FDA-regulated shipments) was 0.15%. They cautioned that the 99.85% of shipments were not necessarily in compliance, because the agency only has the resources to examine 1% of all line entries (shipments) into the country (see discussion above).[25]

William Hubbard, a former FDA deputy commissioner, recently told National Public Radio (NPR) that total "individual shipments of food and ingredient exports from China to the United States have gone from 82,000 in 2002 to 199,000 in 2006. And I'm told by FDA officials that they're rapidly reaching up to 300,000 this year."[26] However, the same NPR report said that FDA inspectors had blocked 257 food imports from China in April 2007 alone; that number actually represented refused shipments of all FDA-regulated food, drug, and medical products, not foods alone.

Chinese Food Safety Challenges

As noted, the FDA OASIS database does not provide answers as to whether Chinese imports are any less safe than those from other countries. Nonetheless, the country has come under intense criticism in the wake of several widely publicized incidents involving adulterated food, agricultural, and medical exports. For example, in early 2007 pet food ingredients from China that contained the chemical melamine — apparently added to boost the ingredients' protein levels — sickened or killed an unknown number of dogs and cats in North America. The ingredients subsequently were found in some hog, chicken, and fish feed. A risk assessment indicated the problem posed virtually no risk to humans, USDA and FDA officials asserted. Another incident attracted attention in early May 2007, when the Mississippi Commissioner of Agriculture ordered a number of stores there to stop selling catfish from China after samples tested positive for antibiotics banned in the United States.

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[23] (...continued)
quoted in various news reports including "China Says Food Export Inspections Are Effective," *Washington Post*, June 1, 2007. Also see "China Confronts Crisis Over Food Safety," *Wall Street Journal*, May 30, 2007.

[24] "U.S., Chinese leaders try to advance trade, food safety issues," *Agri-Pulse*, May 30, 2007.

[25] FDA e-mail communication to CRS, June 6, 2007.

[26] "Q&A: Why China Tops the FDA Import Refusal List," accessed May 25, 2007, at [http://www.npr.org/templates/story/story.php?storyID=10410111].

Such concerns are not new. An FDA import inspector was quoted in 1991: "Some countries we almost never have problems with.... But others, such as India, Thailand, China, Korea, and many countries in Africa, require constant vigilance."[27]

A number of analysts has examined the food safety challenges China faces as it becomes a major agricultural exporter. USDA economists recently wrote:

> China emerged in the 1990s as a low-cost exporter of food products such as vegetables, apples, seafood, and poultry. But in recent years, China's exports slowed when shipments of vegetables, poultry and shrimp were rejected for failing to meet stringent standards in Japan, Europe, and other countries, revealing a gap between Chinese and international food safety standards.[28]

Some analysts contend that China's problems in complying with other — usually more developed — countries' safety requirements are typical of those faced by most developing countries. They point to a number of specific obstacles the Chinese have encountered in upgrading their safeguards, including:

- the difficulty of standardizing and monitoring production practices at the farm production level, to which many safety problems can be traced due to widespread noncompliance with existing regulations such as environmental rules, and which is composed of 200 million households typically farming on plots of one to two noncontiguous acres;
- heavy use of fertilizers and pesticides to counteract intensively cultivated soils and large pest pressures;
- wide use of antibiotics to control diseases in intensive livestock, poultry, and aquaculture systems;
- industrialization, lax environmental controls, and untreated human and animal waste in fields and waters, which raise concerns about toxic, metal, and microbial contaminants in food;
- a fragmented marketing system dominated by millions of small firms handling small volumes, often on a cash basis with no documentation or ability to trace products;
- a fragmented regulatory and oversight structure involving 10 national government ministries and little coordination with lower levels of government, which often have their own, differing standards for food products; and

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[27] Sharon Snider, "From Psyllium Seeds to Stoneware: FDA Insures the Quality of Imports," *FDA Consumer Magazine*, March 1991.

[28] Linda Calvin et al., "Food Safety Improvements Underway in China," *Amber Waves*, November 2006, USDA, ERS. The Codex Alimentarius Commission is the major international body for encouraging international trade in food while promoting the health and economic interest of consumers. Codex is a subsidiary of the Food and Agriculture Organization and the World Health Organization. One of its key functions is to develop standards, codes of practice, and guidelines for the safety of foods, in accordance with the SPS Agreement. The Codex website is at [http://www.codexalimentarius.net].

- for many commodities and industries, outdated or nonexistent standards, or standards that are inconsistent with internationally accepted ones.[29]

Chinese Efforts to Address Food Safety

To overcome such obstacles, the Chinese government announced it has undertaken a number of major initiatives to bolster its food safety system. For example, officials announced their intention to update a 1995 consumer food law, and in 2006 the Chinese legislature adopted a national framework for building an agricultural product safety system. The Chinese say they now require registration of all land and processing facilities used for exported products, and exporters must have facilities that can test for pesticide residues. The government also samples and tests products for export to help ensure they meet foreign buyers' standards.[30]

China also has been encouraging investment, including foreign direct investment, in production and processing to improve technology, marketing and management skills, and transportation and infrastructure. Six types of processed foods — canned food, aquatic products, meat and meat products, frozen vegetables, fruit/vegetable juice, and some frozen convenience foods — reportedly are to be manufactured under HACCP (hazard analysis and critical control point) standards.[31] HACCP is a system of assessing risks, determining the points at which they might occur during production, and instituting measures to prevent them.[32]

China announced that it will unveil, by the end of 2007, national regulations for recalling adulterated food. At a May 31, 2007, news conference, a Chinese official also pointed to the death sentence handed down to the former head of the government's food and drug safety agency, as an example of its determination to improve product oversight. The agency head had been convicted of taking bribes for approving potentially dangerous drugs. He reportedly was executed on July 10, 2007.[33]

In late June, one Chinese government agency reportedly announced the closure of 180 food manufacturers that it said had been using industrial materials such as dyes, mineral oils, hydrochloric acid, paraffin, and formaldehyde in a variety of food products, including flour, candies, seafood, pickles, and biscuits. Another agency reportedly claimed to have closed 152,000 unlicensed food manufacturers and retailers in 2006 for making counterfeit or low-quality products.

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[29] Calvin. Also, Fengxia Dong and Helen H. Jensen, "Challenges for China's Agricultural Exports: Compliance with Sanitary and Phytosanitary Measures," *Choices*, 1st quarter 2007.

[30] Calvin.

[31] Dong.

[32] FDA information on HACCP is at [http://www.cfsan.fda.gov/~lrd/haccp.html].

[33] "China Executes Former Head of Food Safety Agency," *Wall Street Journal*, July 10, 2007.

The Chinese also are seeking to demonstrate that they are protecting their own consumers from unsafe products, whether domestic or imported. On July 13, 2007, for example, they announced that meat and poultry imports shipped by some U.S. companies were being suspended. These include chicken products that they assert contained *Salmonella* bacteria (although U.S. interests have long noted that proper cooking destroys the bacteria), and pork products that contained an unapproved feed additive (which appears to be legal in the United States).[34]

U.S. Efforts to Improve Import Compliance

At May 15 and May 17, 2007, media briefings on adulteration of plant proteins from China, FDA Assistant Commissioner for Food Protection Acheson reported that he was currently reviewing all aspects of the U.S. food safety system, including imports from all countries. At the time, he and other FDA officials declined to provide specifics on ongoing efforts to secure food safety agreements of any kind with China but did point out that, after shipments of Mexican cantaloupes with Salmonella contamination several years ago, the U.S. and Mexican governments had developed an agreement to improve agricultural practices in Mexico.

Dr. Acheson reportedly stated in a July 11, 2007 conference call that FDA officials were working on a proposed memorandum of understanding (MOU) with China that could include such elements as improving training for Chinese food safety officials and more data sharing on problems.[35]

FDA's Center for Food Safety and Nutrition (CFSAN) website indicates that it is aggressively pursuing both formal and informal agreements with foreign government counterparts to achieve mutual recognition of equivalence of regulatory systems. Another FDA website lists more than 90 "International Arrangements" with approximately 30 separate foreign entities, of which 36 appear to be directly food-related. Roughly a third of these address aspects of shellfish or other seafood safety.[36] FDA's agreements with China apparently do not include any for food, but are in place for lead in tableware.

During a May 22-24, 2007, economic summit with China, the U.S. government requested a meeting soon, possibly in the fall, specifically on food safety. It asked the Chinese to respond to the following specific requests:

- to provide detailed information on Chinese food safety control measures, including the procedures, methodology, and technology for testing and quarantine of suspect products;
- to provide raw data from the testing the Chinese government has conducted on regulated products;

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[34] Various news reports, including *Food Chemical News*, July 2, 2007; *The Wall Street Journal*, July 16, 200; and Reuters, July 15, 2007.

[35] "FDA in talks with China over food safety MOU, says Acheson," *Food Chemical News*, July 16, 2007.

[36] Both websites accessed May 15, 2007, at [http://www.cfsan.fda.gov/~comm/intl-toc.html].

- to provide the ongoing results of all tests for melamine in ingredients destined for humans or animals;
- to impose a registration requirement for all Chinese firms intending to export food and feed products to the United States, and to prohibit exports from unregistered firms;
- to publish a regularly updated list of the registered Chinese firms;
- to issue necessary clearances including multi-year and multi-entry visas for FDA personnel to conduct health-related inspections in China and to audit systems confirming that Chinese firms are meeting U.S. requirements.[37]

In perhaps the most significant move to date, the FDA on June 28, 2007, issued an import alert ordering the "Detention Without Physical Examination" of all of the following aquacultured products from China: catfish, basa (related to catfish), shrimp, dace (related to carp), and eel.[38] FDA said it issued the notice after targeted sampling during October 2006 through May 2007 "repeatedly found that farm-raised seafood imported from China were contaminated with antimicrobial agents that are not approved for this use in the United States." The agents are nitrofuran, malachite green, and gentian velvet, which have been found to be carcinogenic to laboratory animals; and fluoroquinolones, which when used in food animals may increase antibiotic resistance in humans, the agency said.

Under such an import alert, FDA will detain all covered products until the importing firm demonstrates, through testing by an independent laboratory, that a representative sample of their product is free of these contaminants. Although the FDA has long issued these types of alerts for various imports, they generally are more limited in scope, for example, to a particular firm or product.

The import alert reiterates that approximately 80% of U.S. seafood consumption is from imports and that over 40% of these imports come from aquaculture operations. Shrimp and catfish are two of the top 10 most frequently consumed seafood products. China is the largest aquaculture producer in the world, with 70% of total production, and the third largest exporter to the United States. The alert observes: "As the aquaculture industry continues to grow and compete with wild-caught seafood products, concerns regarding the use of unapproved animal drugs and unsafe chemicals and the misuse of animal drugs in aquaculture operations have increased substantially."

Congressional Consideration

Some Members of Congress have expressed sharp criticism both of China's food safety record and of U.S. efforts to insure the safety of that country's imports. The House Agriculture Committee held a hearing on May 9, 2007, to take testimony

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[37] "Actions Requested of the People's Republic of China by the U.S. Government to Address the Safety of Food and Feed," USDA Fact Sheet accessed May 25, 2007, at [http://www.usda.gov].

[38] FDA Import Alert #16-13, which may be viewed at [http://www.fda.gov/ora//fiars/ora_import_ia16131.html]

on the topic from FDA and FSIS officials. Several other panels have held hearings on China import concerns and/or the broader topic of U.S. food safety efforts, most recently the House Energy and Commerce Oversight and Investigations Subcommittee and the Senate Commerce Committee (both during the week of July 17, 2007). Additional hearings on the China situation and on food safety generally are anticipated in both chambers during the 110th Congress.

On May 2, 2007, Senator Durbin won unanimous approval of an amendment to the Senate-passed FDA Revitalization Act (S. 1082) that would require domestic and foreign facilities to notify FDA of food safety problems; would require FDA to establish a central registry for collecting information on adulterated foods, and for notifying the public about adulterated human or animal foods; and would require FDA to implement uniform national standards and labeling for pet foods. The amendment includes elements of his proposed Human and Pet Food Safety Act of 2007 (S. 1274), introduced as H.R. 2108 by Representative DeLauro. The two lawmakers also have introduced more comprehensive bills (H.R. 1148/S. 654) to combine current federal food safety oversight under a new food safety administration.

Senator Durbin in July also introduced S. 1776, which would impose new user fees of $20 per line item of imports to help defray the costs of inspections, increase the number of inspectors, and pay for research into new testing methods. Further, the measure would require foreign governments or firms that want to import food into the United States to be certified by FDA as having equivalent food safety programs. The certifications would be valid for five years, among other provisions. A similar House bill (H.R. 2997) was introduced by Representative Kaptur.

Recent developments with food imports also have spurred calls for speedier implementation of mandatory country-of-origin labeling (COOL) for fresh meats, produce and peanuts, now scheduled to take effect on September 30, 2008. H.R. 357 and S. 404 would mandate COOL by September 30, 2007. A provision in the draft USDA appropriation for FY2008, pending in the House Appropriations Committee the week of July 16, 2007, would set a timeline aimed at ensuring USDA implementation by the currently legislated deadline. (For further information on COOL, see CRS Report 97-508, *Country-of-Origin Labeling for Foods*).

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CRS Report for Congress

U.S. Food and Agricultural Imports: Safeguards and Selected Issues

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Service

U.S. Food and Agricultural Imports: Safeguards and Selected Issues

Summary

U.S. officials continue to assert that the U.S. food supply, including the portion provided through imports, is among the safest in the world. One challenge has been how to keep it safe in the face of rapidly rising imports, a result of globalization and consumer desire for a wider variety of nutritious and inexpensive foods year-round.

Two federal agencies — USDA's Food Safety and Inspection Service (FSIS) and the U.S. Department of Health and Human Services' Food and Drug Administration (FDA) — are responsible for the majority of the total funding and staffing of the government's food regulatory system. For imports, FSIS relies on a very different regulatory system than FDA, including a differing approach to addressing equivalence, as described in this report.

Do U.S. safeguards, generally created at a time when most Americans obtained their foods domestically, remain sufficient to protect public health? What, if any, changes should be made to enhance the safety of food imports? Critics argue that major reforms are necessary because the present programs are both poorly designed and inadequately funded to meet today's challenges. Those who oppose major changes assert that imported foods already are subject to the same safety standards as — and pose no greater hazards than — domestically produced foods. They also contend that smarter allocation of existing resources, and the food industry's own controls, can and should be capable of addressing any problems that arise.

Section 1009 in the Food Safety title (X) of the Food and Drug Administration Amendments Act of 2007 (H.R. 3580; P.L. 110-85), passed in September 2007, requires an annual report to Congress on the number and amount of FDA-regulated food products imported by country and type of food, the number of inspectors and inspections performed, and aggregated data on inspection findings, including violations and enforcement actions. Nearly a dozen other food safety bills pending as of October 2007 contain provisions addressing some aspect of food import safety. Several focus almost exclusively on the issue. Many of these bills (including H.R. 2997, S. 1776, H.R. 1148/S. 654, H.R. 2108/S. 1274, H.R. 3610, and H.R. 3624) propose that importing establishments, and/or the foreign countries in which they are located, first receive formal certification from U.S. authorities that their food safety systems demonstrably provide at least the same level of safety assurances as the U.S. system. Under some of these bills, certification could be denied or revoked if foreign safeguards are found to be insufficient, unsafe imports are discovered, or foodborne illnesses are linked to such products. A number of the bills also propose the collection of user fees from importers to cover the costs of inspecting foreign products at the borders.

Some bills seek to require more physical inspections and testing by FDA at the border or within other countries, to authorize more research into inspection and testing technologies, or to restrict imports to specific ports. H.R. 3100 is another measure with import safety provisions. (This report supersedes CRS Report RS22664.)

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U.S. Food and Agricultural Imports: Safeguards and Selected Issues

Introduction[1]

U.S. officials continue to assert that the U.S. food supply, including the portion provided through imports, is among the safest in the world. One challenge has been the rapid increase in imports, a result of globalization and consumer desire for a wider variety of nutritious and inexpensive foods year-round.[2] With this growth have come new concerns about whether current federal programs sufficiently ensure the safety of these imports. Import alerts in 2007 targeting both adulterated pet food ingredients and farmed seafood from China are among the incidents that have heightened interest in the issue in the 110th Congress.

Do U.S. safeguards, which generally were created at a time when most Americans obtained their foods domestically, remain sufficient to protect public health? What, if any, changes should be made to enhance the safety of food imports? Critics argue that major reforms are necessary because the present programs are both poorly designed and inadequately funded to meet today's challenges. Those who oppose major changes assert that imported foods already are subject to the same safety standards as — and pose no greater hazards than — domestically produced foods. They also contend that smarter allocation of existing resources, and the food industry's own controls, can and should be capable of addressing any problems that arise.

The issue has been explored at a number of congressional hearings in 2007, and several Members of Congress have introduced bills to change the current system.

Food and Agricultural Imports Increasing

U.S. imports of agricultural and seafood products from all countries increased from 32.9 million metric tons (MMT) in calendar year 1996 to 46.7 MMT in 2006, or by 42%. The increase by value was 98%, from $40.1 billion in 1996 to $78.5 billion in 2006. Among the product categories that at least doubled in volume during

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[1] This report supersedes CRS Report RS22664 of the same title. Portions of the previous report were originally derived from information in out-of-print CRS Report 98-850, *The Safety of Imported Foods: The Federal Role and Issues Before Congress.*

[2] David Acheson, Assistant Commissioner for Food Protection, U.S. Food and Drug Administration, testimony before the House Agriculture Committee, May 9, 2007.

the period were live animals, wine/beer, fruit/vegetable juices, wheat, coffee, snack foods, and various seafood products.[3]

Not all agricultural imports enter the human food supply; some products are used as ingredients in pet food and animal feed, in manufactured goods (e.g., rubber), and in the nursery plant trade. Nonetheless, many consumers are obtaining a growing portion of their diets from overseas. In 2005, nearly 15% of the overall volume of U.S. food consumption was imported, compared with 11%-12% in 1995. The proportions (volume) for some food product categories are much higher: in 2005 as much as 84% of all U.S. fish and shellfish was imported (55% in 1995); 43% of all noncitrus fresh fruits (34% in 1995); 37% of all processed fruits (20% in 1995); and 54% of all tree nuts (40% in 1995).[4] **Table 1**, below, shows that the United States' NAFTA (North American Free Trade Agreement) partners, Canada and Mexico, were the largest suppliers of food, agricultural, and seafood imports in 2006.

Table 1. Leading Suppliers of U.S. Agricultural and Seafood Imports, CY2006
(value in billion U.S. dollars)

Country	Agricultural	Seafood	Total
Canada	$13.433	$2.184	$15.617
Mexico	9.390	0.454	9.844
China	2.262	1.922	4.184
Thailand	1.812	1.334	3.146
Italy	2.802	.009	2.811
Indonesia	2.023	0.778	2.801
Chile	1.774	.952	2.726
Australia	2.487	.091	2.578
Brazil	2.237	.130	2.367
Ireland	2.354	.008	2.362
World Total	65.333	13.143	78.475

Source: USDA, Foreign Agricultural Service (FAS), BICO Import Commodity Aggregations.

[3] U.S. Department of Agriculture (USDA), Foreign Agricultural Service (FAS), U.S. Trade Internet System, BICO (Bulk, Intermediate, and Consumer-Oriented) data.

[4] USDA, Economic Research Service (ERS), unpublished data, obtained May 11, 2007. Other data including that provided by FDA indicate that the current percentage for seafood is somewhat lower than 84%.

Federal Oversight Responsibilities

Two federal agencies — USDA's Food Safety and Inspection Service (FSIS) and the U.S. Department of Health and Human Services' Food and Drug Administration (FDA) — are responsible for the majority of the total funding and staffing of the government's food regulatory system. For imports, FSIS relies on a very different regulatory system than FDA, including a differing approach to addressing equivalence, as described below.

Also important are USDA's Animal and Plant Health Inspection Service (APHIS), which is responsible for protecting plant and animal resources from domestic and foreign pests and diseases, and the Department of Homeland Security (DHS), which is responsible for coordinating agencies' food security activities, including border inspections by DHS's U.S. Customs and Border Protection (CBP).[5]

FDA Role

The FDA's food regulatory authority comes chiefly from the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended (21 U.S.C. 301 *et seq.*).[6] This authority makes the agency responsible for the safety of virtually all domestic and imported articles used for food and drink, except meat and poultry (see "FSIS Role," below); these include animal as well as human foods. FDA-regulated foods may be deemed adulterated or misbranded for a variety of statutorily prescribed reasons. For example, food may be deemed adulterated if it contains an added poisonous or deleterious substance or an unsafe food additive or if the food was prepared, packed, or held under insanitary conditions whereby it may have become contaminated or may have been rendered injurious to health.[7] Of a total of approximately 58,000 food establishments (such as manufacturers, warehouses, and shippers), FDA designates about 7,000 as "high risk," based on the types of foods they handle and/or past performance. In general, FDA attempts to conduct annual inspections of these facilities; non-high risk establishments are inspected, on average, once every 3.7 years.[8]

Section 801 of the FFDCA empowers the FDA to refuse entry to any food import if it "appears," based on a physical examination or otherwise, to be

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[5] In total, as many as 15 federal agencies administer at least 30 laws related to food safety. See also CRS Report RS22600, *The Federal Food Safety System: A Primer*.

[6] Portions of this section and the following section are based on Olsson, Frank and Weeda, P.C., and The Food Institute, *Importing Food into the United States: A Regulatory Guide*, 2007. Data sources for this section, unless noted: Acheson, May 9, 2007, testimony, and House Appropriations Committee hearings on Agriculture Appropriations for various years.

[7] 21 U.S.C. § 342(a)(2).

[8] All domestic and foreign food manufacturing facilities must adhere to FDA's Good Manufacturing Practices (21 C.F.R. part 110), which address safe handling and plant sanitation. Exempt are establishments such as farms engaged solely in harvesting, storing, or distributing raw agricultural commodities normally cleaned or otherwise treated before consumption.

adulterated, misbranded, or in violation of the law.[9] In exercising its oversight, the agency relies on a system of prior notifications by importers and document reviews at points of entry (ports). Importers must have an entry bond and file a notification for every shipment. Import information is entered into FDA's database, the Operational and Administrative System for Import Support (OASIS). This system is to help inspectors to determine a shipment's relative risk and whether it needs closer scrutiny (i.e., a wharf or physical examination, and/or testing). FDA inspectors are to work closely with CBP officials on these tasks.[10]

If closer examination is not deemed necessary, FDA allows the product to enter U.S. commerce. A shipment found to be noncompliant is subject to a number of corrective actions, such as relabeling or reconditioning to bring it into compliance, refused entry, or even seizure and destruction. Sometimes, the agency subjects an import to "detention without physical examination,"[11] based on past history or other information indicating that it may be violative. Such detention compels the importer to demonstrate to FDA that the product is safe before it can enter U.S. commerce. Examples in 2007 were the detention of all Chinese plant protein products (including wheat gluten and rice gluten, destined for pet foods) after some were found to contain melamine, an unapproved substance; and of all farm-raised seafood from China (specifically, shrimp, catfish, basa, dace, and eel) until the shippers of these products could demonstrate that they are free of unapproved drug residues.

The volume of FDA-regulated imports has more than tripled in the past decade. The agency received more than 10 million imported food entries in FY2006 compared with fewer than 2.8 million entries in FY1996. Approximately 1% of these shipments were physically examined in FY2006, compared with 1.7% in FY1996.

FDA's ability to operate within other countries appears to be limited. FDA can and does periodically visit foreign facilities to inspect their operations, but usually in response to a concern and only with the permission of the foreign government. Further, FDA asserts that it lacks the staff and funding to increase its presence overseas, regardless of whether it might have the legal authority to do so.[12] FDA's Center for Food Safety and Applied Nutrition (CFSAN) had a budget of $450 million

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[9] 21 U.S.C. § 381(a); see also [http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9auto.html].

[10] The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) greatly expands the prior notification requirements for FDA-regulated imported foods. It also now requires any imported or domestic facility that manufactures, processes, packs, or holds food for U.S. consumption to register with the FDA; farms and retail establishments are among those exempted. Further, the act requires records sufficient to identify the immediate supplier as well as the subsequent recipient of the product, among other provisions.

[11] FDA's authority to detain without physically inspecting an article derives from 21 U.S.C. § 381(a), which states that FDA must refuse admission of certain imports into the United States "[i]f it appears from the examination of such samples *or otherwise*" that such samples are adulterated, misbranded, or otherwise in violation of the law (emphasis added).

[12] An FDA website notes that "[f]ull equity in foreign inspections is far beyond the resources of FDA." Accessed May 15, 2007, at [http://www.cfsan.fda.gov/~comm/intl-toc.html].

and staff of 2,843 (full-time equivalent or FTE) in FY2006, of which $285 million and 1,962 FTEs were in the field.[13]

In a hearing before the House Agriculture Committee, FDA's chief food officer, David Acheson, testified that the agency theoretically has the authority to require equivalency for imports but that FDA's situation is significantly more complex than USDA's (the latter regulates fewer types of food products; see below). An equivalence-type approach is one possible option for the future, he added.[14] At various hearings and media briefings, FDA officials have stated that the agency is reviewing all aspects of the U.S. food safety system including imports, and intends to complete a food protection strategy by mid-November 2007. This time frame also is when the President's cabinet-level working group is to release its "action plan" aimed at enhancing import safety for all imported foods, drugs and other consumer products. The working group unveiled in September 2007 a "strategic plan" which broadly recommends that safety oversight be shifted from border interdiction to risk-based prevention activities throughout the "import life cycle" of products.[15]

CFSAN has stated on its website that it is "aggressively pursuing both informal and formal agreements with foreign government counterpart officials including Memoranda of Understanding for mutual recognition of equivalence of regulatory systems." Another FDA website lists more than 90 "International Arrangements" with approximately 30 separate foreign entities, of which 36 appear to be directly food-related. Roughly a third of these address aspects of shellfish or other seafood safety.[16]

FSIS Role

FSIS regulates the safety and labeling of most domestic and imported meat and poultry, under the Federal Meat Inspection Act (FMIA) as amended (21 U.S.C. 601 et seq.) and the Poultry Products Inspection Act (PPIA) as amended (21 U.S.C. 451

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[13] Although a further breakdown of field staff involved with imported foods was not immediately available, witnesses have testified that 450 inspectors cover between 300 and 400 ports of entry. The hearings were held before subcommittees of the House Committee on Energy and Commerce, July 17 and September 26, 2007. (Other congressional panels, including the House Appropriations subcommittee on agriculture, also have held food import hearings in 2007.)

[14] "Officials defend federal response to melamine contamination," *Food Chemical News*, May 14, 2007. GAO, however, had suggested in 1998 that border inspections alone were ineffective, but that FDA lacks the authority to mandate equivalency (RCED-98-103, *Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable*, April 1998).

[15] Interagency Working Group on Import Safety, *Protecting American Consumers Every Step of the Way: A strategic framework for continued improvement in import safety*, September 10, 2007, accessed at [http://www.importsafety.gov/report/report.pdf]. Also see the September 26, 2007, testimony of Randall Lutter, FDA Deputy Commissioner for Policy before the House Energy and Commerce Subcommittee on Health.

[16] Both websites accessed at [http://www.cfsan.fda.gov/~comm/intl-toc.html].

et seq.).[17] Inspectors are to be present at all times in slaughter plants and for at least part of each day in establishments that further process meat and poultry products. They are to examine all animals destined for human food both before and after slaughter, and to ensure that plants are operating in a sanitary manner, under an FSIS-approved safety plan.

Under Section 20 of the FMIA and Section 466 of the PPIA, FSIS also is responsible for determining the equivalence of other countries' meat and poultry safeguards. A foreign plant cannot ship products to the United States unless FSIS has determined that its country has a program that provides a level of protection that is at least equivalent to the U.S. system.[18] FSIS visits the exporting country to review its rules and regulations, meets with foreign officials, and accompanies them on visits to establishments. When a foreign program is approved, FSIS relies on that government to certify eligibility of, and to inspect, the establishments. FSIS periodically reviews foreign government documents and conducts on-site audits at least annually to verify continuing equivalence.

In addition, FSIS operates a reinspection program at 150 import houses located near approximately 35 border entry points. Agency inspectors review all import records, aided by a computerized sampling program, the Automated Import Information System (AIIS). This system generates inspectors' actual examination assignments based on what the agency believes to be the relative risks of particular product types and/or countries. It also can identify shipments that are to be denied reinspection because, for example, the foreign country or particular plant is not eligible to ship to the United States, or the product has not been certified to enter. Inspectors next are responsible for ensuring that all other imports are in acceptable condition, properly labeled, and accurately counted. This can include opening and physically examining boxes for physical defects, and collecting samples for laboratory testing for contaminants. FSIS can take a number of actions when violative products are found. Products that pass are released into interstate commerce; most are bulk products for further processing at U.S. plants, which are under continuous FSIS inspection.[19]

Meat and poultry imports have increased significantly, from nearly 2.3 billion pounds presented for inspection in FY1996 to 3.9 billion pounds in FY2006. FSIS has estimated that it physically examined approximately 20% of all such imports in FY1996, compared with approximately 10% in more recent years (after implementation of the AIIS in the early 2000s).

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[17] FSIS inspects the major red meat and poultry species and their products, while FDA has jurisdiction over all meat and poultry not inspected by FSIS. The agencies share responsibility for egg safety, under the Egg Products Inspection Act, as amended (21 U.S.C. § 1031 *et seq.*). FSIS covers processed egg products; FDA covers most whole eggs.

[18] A list of the 38 current agreements can be accessed on the FSIS website at [http://www.fsis.usda.gov/regulations_%26_policies/Eligible_Foreign_Establishments/index.asp].

[19] See CRS Report RL32922, *Meat and Poultry Inspection: Background and Selected Issues*, by Geoffrey S. Becker.

In FY2006, FSIS had a total budget of approximately $950 million (appropriated and user fees) and a staff of 9,400, of which 8,000 were in about 6,300 meat and poultry plants nationwide. The agency's international food safety budget that year was $19.355 million, of which $11.75 million went for border reinspections. Other portions were devoted to evaluating foreign programs and to facilitating U.S. exports. The total international staff numbered 165, although a significant number were assigned to non-border duties.[20]

APHIS Role

Most meat and poultry imports also must be accompanied by a veterinary permit, which APHIS administers under authority of the Animal Health Protection Act (AHPA; 7 U.S.C. 8301 *et seq.*). Under the Plant Protection Act (7 U.S.C. 7701 *et seq.*), APHIS also requires phytosanitary certificates for many plants and plant product imports, and more detailed import permits for most foreign fruits and vegetables. Both laws are intended to ensure that imports are free of foreign diseases or pests that would threaten U.S. animal or plant resources. APHIS's border inspection function was transferred to DHS by the Homeland Security Act of 2002 (P.L. 107-296).

International Trade Considerations

U.S. food safety programs operate within the basic constraints of internationally accepted trade rules. Any newly adopted measures, such as those discussed below, under "Issues in Congress," would likely be closely scrutinized by U.S. trading partners for their adherence to such agreements. More specifically, the United States is a signatory to multilateral trade rules which allow governments to adopt, unilaterally, any measures to protect human, animal, or plant life or health. In doing so, however, they are not to be discriminatory or used as disguised protectionism.

This principle was clarified in 1994 when most major trading nations including the United States adopted, along with other so-called Uruguay Round Agreements, the "Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures." This document sets out the basic rules for ensuring that each country's food safety and animal and plant health laws and regulations are transparent, scientifically defensible, and fair. The United States also has signed, or is negotiating, numerous regional and bilateral free trade agreements (FTAs) that may contain SPS language. (Such language in most of the FTAs generally reference the signing parties' rights and obligations under the multilateral SPS agreement.)

The United States also participates actively in the three major international scientific bodies designated by the WTO to deal with SPS matters. One, the Codex Alimentarius Commission focuses on human food safety. (The others are the Office of International Epizootics (OIE) for animal health and diseases, and the International Plant Protection Convention (IPPC) for plant health.) These bodies meet often to discuss threats to human and agricultural health, evaluate SPS-related disputes, and

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[20] House Appropriations Committee hearings on agriculture appropriations for various years.

develop common, scientifically based SPS standards. Such standards can provide guidance for countries formulating their own national SPS measures and help resolve trade disputes.

Although U.S. and World Trade Organization (WTO) officials frequently cite the benefits of SPS cooperation under trade agreements, some, among them food safety and environmental advocacy organizations, have been skeptical. They have argued that implementation of the agreements can result in "downward harmonization" rather than upgraded health and safety standards. Defenders counter that trade rules explicitly recognize the right of individual nations to enact stronger protections than international guidelines if they believe they are appropriate and are justified by scientific risk assessment.[21]

FDA Import Refusals

Overview and Limitations of Analysis

Using the OASIS data (see page 4), the FDA compiles a monthly "Import Refusal Report" for food shipments that it rejects. Such products have to be either re-exported or destroyed by the importer. The agency posts these monthly refusal reports on its website, but only for the most recent 12 months (i.e., only one year's worth of refusals).[22] The refusals for each month can be searched by country or by product category, but not by both at the same time. CRS examined the data for the one-year period from May 2006 through April 2007, and the months were not aggregated into annual figures.

For each line (shipment), the system provides the name of the source company and the reason for refusal. As noted earlier, the size of each shipment in the OASIS database varies. Therefore, it is not possible to calculate the volumes of products being rejected, either as an absolute quantity or as a proportion of total imports. Also, the types or categories of imports do not necessarily correspond to the categories reported through the USDA trade databases (see **Table 1**, above).

Mindful of these caveats, CRS prepared a tabulation of the refusals, focusing on nearly 40 categories of FDA-regulated food and food-related products.[23] For the one-year period available at the time of this CRS tabulation (May 2006-April 2007), FDA logged a total of approximately 8,200 refusals. Of these, the leaders were Mexico with nearly 1,300, India with more than 1,100, and China with more than 700 (see **Table 2**).[24]

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[21] These arguments are covered in more detail in CRS Report RL33472, *Sanitary and Phytosanitary (SPS) Concerns in Agricultural Trade*, by Geoffrey S. Becker.

[22] FDA website, accessed May 31, 2007, at [http://www.fda.gov/ora/oasis/ora_oasis_ref.html].

[23] Also listed in the OASIS refusal reports, but not examined here, are other FDA-regulated products, e.g., human and animal drugs, medical devices, and vitamins.

[24] *The New York Times* reportedly compiled a more recent 12-month tabulation (July 2006

(continued...)

Table 2. Number of Food Import Refusals by Country, May 2006-April 2007

Argentina	59	Guatemala	97	Peru	39
Australia	34	Honduras	113	Philippines	153
Bangladesh	54	Hong Kong	52	Poland	76
Brazil	123	India (2)	1,109	Russia	26
Canada	193	Indonesia (5)	334	South Africa	42
Chile	35	Iran	26	Spain	75
China (3)	720	Italy (8)	228	Sri Lanka	72
Colombia	45	Jamaica	36	Syria	70
Costa Rica	35	Japan (7)	295	Taiwan	165
Dominican Republic (4)	593	Korea (South)	111	Thailand (9)	218
Ecuador	56	Lebanon	26	Turkey	81
Egypt	47	Malaysia	35	Ukraine	25
El Salvador	25	Mexico (1)	1,271	United Kingdom (10)	206
France	178	Netherlands	54	Vietnam (6)	335
Ghana	49	Pakistan	140		

Source: FDA Import Refusal Reports for OASIS. See text for caveats on use of data. Countries with fewer than 25 refusals are omitted here.
Note: Numbers in parentheses indicate top ten countries by rank of number of import refusals.

It is important to note that a higher relative number does not necessarily indicate that one country's products are less safe, or its food safety system less rigorous than that of another country. The country simply might be a more important source of U.S. agricultural and/or seafood imports. On the other hand, Canada, which imports much more to the United States than any other country, had far fewer refusals than either Mexico or China, the second and third most important U.S. importers in dollar value. India had the second highest number of refusals, even though it is not among the top 10 foreign sources of food, agricultural, and seafood products for the United States.[25]

Because of technical problems with OASIS at the time **Table 2** was prepared, FDA officials said they could not immediately respond in detail to CRS questions about the database that might have shed additional light on the significance, if any, of the numbers in the table. For example, the information published on the FDA website does not include the overall number of shipments. Thus, CRS could not

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[24] (...continued)
to June 2007), which indicated that refusals were higher during the period: 1,763 for India, 1,480 for Mexico and 1,368 for China. See "China Not Sole Source of Dubious Food," *New York Times*, July 12, 2007.

[25] Nonetheless, India's exports to the United States were valued at a significant $1.4 billion in calendar 2006.

calculate for this report the percentage of overall shipments that had been refused for a given month, country, or product. However, FDA did receive a total of nearly 15 million import shipments of all types of FDA-regulated products, including but not limited to foods, during FY2006, or an average of approximately 1.25 million shipments per month.[26]

Reviewing refusals by industry, vegetables/vegetable products and seafood products appear to have been the most frequently refused products (at approximately 1,700 shipments from all countries for each of these two product types). Fruits/fruit products from all countries accounted for nearly 900 refusals. Candy products accounted for nearly 600, and spices/flavors/salts for more than 500. Many fruit and vegetable product refusals originated in the Dominican Republic, Mexico, and several other Latin American and Caribbean nations; a frequently cited reason was pesticide contamination. Bacterial contamination (e.g., Salmonella) or filthy condition was cited numerous times.

Fish and shellfish were refused for a variety of reasons, often bacterial contamination, filthy condition, and/or veterinary drug residues. These products most frequently appear to have originated in Asian countries, not only China but also Vietnam, India, Bangladesh, and others. A 2007 report by Food and Water Watch analyzed the FDA OASIS refusals of seafood in more detail, and for all calendar years from 2002 to 2006. Among its findings were that more than 70% of all imported seafood products were processed. More than 20% of all seafood refusals were due to Salmonella, of which 40% were shrimp. It also observed that more seafood is being refused for veterinary drug residues.[27]

Many refusals of foods of all types also appear to be due to concerns about mislabeling, failure to register, or failure to document that the product complied with safe manufacturing practices (e.g., using a system of hazard analysis and critical control points, or HACCP, for low acid canned foods or seafoods).[28]

FSIS Import Refusals

FSIS makes available through its website quarterly enforcement reports summarizing the actions it has taken to ensure that unsafe, unwholesome, and improperly labeled products do not reach consumers. **Table 3** shows the total volume of meat and poultry products presented for import reinspection and how much was refused entry into the country for several recent fiscal years — approximately one-third of one percent of total shipments.

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[26] FDA e-mail communication to CRS, June 6, 2007.

[27] Food and Water Watch, *Import Alert: Government Fails Consumers, Falls Short on Seafood Inspections*, May 2007. Accessed on the Internet on June 5, 2007, at [http://www.foodandwaterwatch.org/press/publications/reports/import-alert].

[28] The FDA website defines each of these terms, which are among approximately 180 possible specific reasons for refusal.

Table 3. Imported Meat and Poultry Products Presented for Inspection and Refused Entry, Selected Years
(thousands of pounds)

Fiscal Year	Presented	Refused Entry	Pct. Refused
2005	4,303,345	14,081	0.33
2006	3,888,188	12,312	0.32
2007 (9 months)	2,949,449	7,596	0.26

Source: USDA/FSIS, various *Quarterly Enforcement Reports*, accessed at [http://www.fsis.usda.gov/Regulations_&_Policies/Quarterly_Enforcement_Reports/].
Note: The figures are based on an entirely different database and inspection regimen than the figures for FDA in Table 2 and therefore are not comparable.

Issues in Congress

U.S. food import safeguards drew renewed attention in 2007 when adulterated pet food ingredients imported from China sickened or killed an unknown number of dogs and cats and subsequently were found in some food animal feed, and after FDA flagged all farmed seafood from China over concerns about unapproved drug residues. One concern has been the adequacy of China's own safeguards and how the United States might encourage improvements. China's emergence as a world agricultural exporter reportedly has been hampered by difficulties in satisfying importing countries' SPS standards.[29]

Others argue that China should not be singled out as the only source of concern. They assert that food imports from other countries also have potentially serious safety risks (see "FDA Import Refusals," above). Furthermore, they contend, domestic foods also can pose safety problems, as evidenced by recent outbreaks of illness linked to consumption of raw produce and by continuing recalls of meat and poultry products due to bacterial contamination. Nonetheless, many of the food safety bills offered in the 110th Congress have focused on proposals to increase scrutiny of imported foods.[30]

Scope of Legislation

As of October 1, 2007, nearly a dozen food safety bills were pending which contain provisions addressing some aspect of food import safety. One (H.R. 3580) has passed Congress; see below. Several of the pending bills focus almost exclusively on the import issue. Many of these bills propose that importing establishments, and/or the foreign countries in which they are located, first receive

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[29] Fengxia Dong and Helen H. Jensen, "Challenges for China's Agricultural Exports: Compliance with Sanitary and Phytosanitary Measures," *Choices*, 1st quarter 2007. See also CRS Report RL34080, *Food and Agricultural Imports from China*, by Geoffrey S. Becker.

[30] For a broader overview of the legislation see CRS Report RL34152, *Food Safety: Selected Issues and Bills in the 110th Congress*, by Geoffrey S. Becker.

formal certification from U.S. authorities that their food safety systems demonstrably provide at least the same level of safety assurances as the U.S. system. Under some of these bills, certification could be denied or revoked if foreign safeguards are found to be insufficient, unsafe imports are discovered, or foodborne illnesses are linked to such products.

A number of the bills also propose the collection of user fees from importers to cover the costs of inspecting foreign products at the borders. These and other bills seek to require more physical inspections and testing by FDA at the border or within other countries, to authorize more research into inspection and testing technologies, or to restrict imports to specific ports. Still other bills call for more extensive mandatory country of origin labeling (COOL), so that consumers can determine where food products originate.[31]

Food and Drug Administration Amendments Act of 2007 (H.R. 3580; P.L. 110-85)

Section 1009 in the Food Safety title (X) of this new law requires an annual report to Congress on the number and amount of FDA-regulated food products imported by country and type of food, the number of inspectors and inspections performed, and aggregated data on inspection findings, including violations and enforcement actions. A similar food safety title (Title VI) was in the Senate-passed version (S. 1082), the Food and Drug Administration Revitalization Act. The House FDA bill (H.R. 2900) lacked the food safety title. H.R. 3580 was the measure which emerged from House-Senate negotiations and replaced the earlier versions. It was cleared by both the House and Senate and signed into law (P.L. 110-85) on September 27, 2007.[32]

Assured Food Safety Act of 2007 (H.R. 2997)

Introduced in July 2007 by Representative Kaptur, H.R. 2997 would require USDA and FDA jointly to establish a program requiring all imported food items to be accompanied by a certificate of safety issued by the government of the exporting country. (The bill does not reference existing food safety authorities.) Items could be excepted if they were from a country that has not been the source of a contaminated food item involved in a health or safety recall in the preceding five years.

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[31] This report does not cover COOL proposals, although recent developments with food imports also have spurred calls for implementation of the (COOL) law for fresh meats, produce and peanuts, now scheduled to take effect on September 30, 2008, or for extension of such requirements to more types of currently uncovered products. See CRS Report 97-508, *Country-of-Origin Labeling for Foods*, by Geoffrey S. Becker.

[32] See also CRS Report RL34102, *FDA Legislation in the 110th Congress: A Side-by-Side Comparison of S. 1082 and H.R. 2900*, by Erin D. Williams, Susan Thaul, Sarah A. Lister, Donna V. Porter, and C. Stephen Redhead. Also see CRS Report RL34089, *FDA Legislation in the 110th Congress: A Guide to S. 1082 and H.R. 2900*, by Erin D. Williams, Susan Thaul, and Donna V. Porter.

If a certified item is found to be unsafe, imports would be prohibited until U.S. officials receive an opportunity to inspect the production facility to assess whether corrections have been made, and determine that the country has taken adequate corrective actions. Another provision would require USDA and FDA to prepare a report on, and implement, the minimum amount of inspection necessary to assure the safety of imports.

A key provision in the bill would require the collection of user fees to defray the increased costs of such inspections, including the costs of hiring additional inspectors. The fees would be assessed beginning in FY2008 on each line item of food imported, up to $20 per line (USDA and FDA would define the meaning of this). The bill also provides for fee adjustments, including for inflation.

Imported Food Safety Act of 2007 (S. 1776)

Also introduced in July 2007, S. 1776 by Senator Durbin is similar in intent to H.R. 2997. However, it amends the FFDCA and applies only to FDA-regulated food imports with regard to certifications and user fees. The bill would require HHS to establish a certification system within two years of enactment, which would apply to a foreign government or foreign food establishment seeking to import food to the United States. Before granting a certificate to a foreign government, HHS would have to review, audit, and certify that its food safety program is at least equivalent to the U.S. program. Before granting a certificate to a foreign establishment, HHS would have to certify, based on an onsite inspection, that the establishment has equivalent food safety programs and procedures.[33]

Certifications would be valid for no more than five years; HHS would be required to audit foreign governments and establishments at least every five years to determine their continued compliance. S. 1776 would authorize HHS to withdraw certification of a food if it is linked to an outbreak of a human illness, if the foreign program is no longer equivalent to the U.S. program, or if U.S. officials are not permitted to conduct an audit or investigation.

Like H.R. 2997, S. 1776 would set a user fee of up to $20 per line item with adjustments for inflation, among other similarities. Unlike H.R. 2997, the Senate bill provides more detail on how the fees will be used. S. 1776 directs that not less than 50% be used for border inspections and not more than 50% be used for a newly authorized research program under the bill. Such research would focus on improved testing and sampling techniques to check for adulteration of imported foods.

Safe Food Act of 2007 (H.R. 1148/S. 654)

The primary thrust of these companion bills, introduced by Representative DeLauro and Senator Durbin in February 2007, is to consolidate federal food safety responsibilities under a new, independent Food Safety Administration (FSA).

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[33] Establishments generally are defined here as any place that processes, holds, or transports food or food ingredients, with the explicit exceptions of farms, and of restaurants and other retailers.

Section 208 of the bills would require foreign governments or foreign establishments that want to export food to the United States to be certified by the new FSA. Such certification would be granted to a foreign government and/or establishment if it could demonstrate that its food safety programs are at least equivalent to the U.S. program; certification of a foreign establishment would have to be based on an onsite inspection. Certifications would be valid for no more than five years. Certification of a food establishment could be revoked any time if it is linked to a foodborne illness, if the country's or establishment's safeguards are found to be no longer equivalent, or if U.S. officials are refused permission to conduct an audit or investigation.

FSA also is to "routinely inspect" food and food animals via a physical examination before they enter the United States to ensure they are safe and properly labeled. Section 402 of the bills provides for holding a food at ports of entry for up to 24 hours if there is reason to believe it is unsafe or misbranded.

Human and Pet Food Safety Act of 2007 (H.R. 2108/S. 1274)

Section 419 of these companion bills, introduced in May 2007 by Representative DeLauro and Senator Durbin respectively, contain certification and auditing requirements similar to those in S. 1776, including the five-year limit on approvals and a requirement to routinely inspect imports (see above). Another provision in H.R. 2108/S. 1274 would require importers to give HHS representatives access to inspection-related records.

Import Safety Act of 2007 (H.R. 3100)

This bill was introduced in July 2007 by Representative Kirk. The measure would amend the FFDCA to significantly increase civil penalties for violations of the act and also would increase the authorization of appropriations for FDA inspection of imported processed foods (and toothpaste) by $20 million annually through FY2012.

Food and Drug Import Safety Act of 2007 (H.R. 3610)

Representative Dingell, Chairman of the House Energy and Commerce Committee, in August 2007 began circulating a "discussion draft" of his legislation to reform and fund food import inspections, among other provisions, most of which would be amendments to the FFDCA. The draft bill was introduced in September 2007 as H.R. 3610. It would require the collection of user fees on imported foods, beginning in FY2008. As in other proposed bills, the fees would be based on the number of entry lines of food, but HHS-FDA could set them as high as $50 per line, with provisions for inflation adjustments. At least 90% of the fee revenue would have to be used to carry out import inspection activities, with priority on inspections at ports of entry and on detection of intentionally adulterated food. The funds also could be used to pay for FDA inspections overseas. Not more than 10% of the

revenue could be used for the bill's newly authorized research into testing techniques for use in import inspections.[34]

H.R. 3610 reiterates that all imported foods must meet the same standards as U.S.-produced foods; entry would be denied to foods even if they appear not to meet them. No foods would be permitted entry unless they are from a foreign facility holding a certificate issued by HHS, or are from a foreign country that has been certified by HHS as having food safety standards at least as protective as those in the United States. Failure to do so could result in revocation of the certificate. HHS would be charged with enforcing the provision through random inspections, sampling and testing.

Another proposed amendment would require HHS-FDA to restrict imports of all foods to ports of entry located in a metropolitan area that has an FDA laboratory capable of testing such foods, although waivers could be granted allowing other ports to be used if the food in question poses no increased likelihood of adverse health consequences. At a July 17, 2007 hearing before the House Energy and Commerce Subcommittee on Oversight and Investigations, the panel's investigators testified that FDA border inspectors currently had to cover 326 ports of entry, greatly straining the existing workforce. Another topic of the hearing was FDA's tentative decision to close a number of its 13 field testing laboratories, which many subcommittee members strongly criticized. H.R. 3610 would prohibit HHS from closing any of these laboratories, as well as any of the 20 FDA district offices.

The Dingell bill also would require labeling of all foods to identify the country of origin, with implementation details left to HHS; and require the department to establish a voluntary "Safe and Secure Food Importation Program" under which food importing companies could receive expedited movement of their products in exchange for abiding by HHS-developed food safety and security guidelines.

Consumer Food Safety Act of 2007 (H.R. 3624)

H.R. 3624 was introduced in September 2007 by Representative Pallone. It would require the establishment, within two years, of a comprehensive import food safety system involving routine HHS inspections of foreign processing facilities and of imports at ports of entry. It authorizes (but does not appear to require) HHS to enter into an agreement with any foreign country desiring to export food to the United States, provided that HHS determines that the foreign food safety system provides at least the same level of protection. Any such agreement would have to: provide for a foreign system which ensures safe food that is not adulterated or misbranded under the FFDCA; enable HHS to undertake activities to verify that the foreign system has at least the same level of safety; and provide for reciprocity in the treatment of U.S. imports. HHS would have to certify the specific types of food products covered by the foreign safety system, and to review each foreign certification at least once every three years.

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[34] H.R. 3610 also would implement a similar fee system for imported drugs.

Fresh Produce Safety Act (S. 2077)

Introduced by Senator Harkin in September 2007, S. 2077 includes in Title III a requirement that HHS, in consultation with USDA, establish by regulation equivalency procedures to ensure that foreign countries exporting produce to the United States meet the criteria set forth for U.S. produce growers.

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ONE HUNDRED TENTH CONGRESS

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June 5, 2007

The Honorable Andrew C. von Eschenbach, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. von Eschenbach:

Under Rules X and XI of the Rules of the United States House of Representatives, the Committee on Energy and Commerce and the Subcommittee on Oversight and Investigations are investigating the adequacy of the efforts of the Food and Drug Administration (FDA) to protect the safety of the Nation's food supply.

The Committee is particularly concerned about the safety of food imports from China. In the last decade, the number of Chinese food imports has increased three fold. Along with this increase in imports, the amount of tainted food from China has also increased. Some recent examples of tainted food from China include mislabeled wheat flour contaminated with melamine, filthy juices and fruits, dried apples preserved with a carcinogen, and mushrooms laced with illegal pesticides. It is quite disturbing to consider that China lacks effective controls to ensure that their exported foods are safe.

The Committee is specifically concerned about the safety of fish and seafood from China. For example, it was recently discovered that catfish imported from China contained two antibiotics banned by FDA. Further, there have been numerous examples brought to the Committee's attention of imported fish and seafood containing contaminants such as salmonella, antibiotics, bacteria, and nitrofuran (a cancer-causing chemical).

In order to assist the Committee in its investigation of the safety of the Nation's food supply, we request that you provide us with the following information for each of the last six years (2001-2006) by no later than close of business on June 12, 2007:

1. The number of food imports from China. Please include both the number of entries and the number of lines;

2. The declared value of all food imports from China;

3. The number of imports from China that were detained pending laboratory examination;

4. The number of Chinese food samples analyzed by private laboratories;

5. The number of Chinese food samples analyzed by FDA laboratories;

6. The number of Chinese food samples determined to be violative;

7. The number of violative Chinese food shipments that were reexported;

8. The number of violative Chinese food shipments that were destroyed;

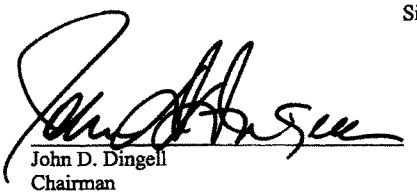
9. The percentage of Chinese food samples found to be violative in each district and each laboratory; and

10. The number of FDA personnel (by full-time equivalent) conducting Chinese food import work for each district, each laboratory, and at headquarters.

If the Food and Drug Administration is unable to assure the safety of Chinese food imports, then the Administration should consider a complete ban of all food imports from China until such time that FDA can assure the American consumer of the safety of these imports.

Your assistance with this request is appreciated. If you have any questions, please contact us or have your staff contact Kevin Barstow or David Nelson with the Committee on Energy and Commerce staff at (202) 226-2424.

Sincerely,



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Chairman

Bart Stupak
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Subcommittee on Oversight and Investigations

Charlie Melancon
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Mike Ross
Member
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07/09/07 MON 17:14 FAX 301 443 2007 DHHS FDA OL 002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

JUL 0 9 2007

Dear Mr. Chairman:

Thank you for the letter of June 5, 2007, co-signed by three of your colleagues, requesting information related to the adequacy of the efforts of the Food and Drug Administration (FDA) to ensure the safety of food imported from China.

We have re-stated each of your requests in bold type, followed by FDA's response. Supporting documents are enclosed as noted. The tables provide data on both human food and animal food and feed. We note that your letter requested import information going back to 2001. However, as discussed with your staff, prior to 2002, FDA's importation records are not readily accessible within FDA's automated import tracking system, the Operational and Administrative System for Import Support (OASIS). Therefore, the information we are providing goes back only to 2002.

1. **"The number of food imports from China. Please include both the number of entries and the number of lines."**

Response: A table providing information responsive to this request is enclosed at Tab A. Because the only meaningful way to report import data categorized by country of origin or by product category is at the line level, we are providing data for line entries (lines) only.

We note that import entries are not product or country of origin specific. Entries often include a combination of foods, drugs, cosmetics, devices and other FDA-regulated products, as well as products not regulated by FDA, and they can include products from a number of different countries of origin. A line entry, however, refers to each portion of an import entry that is listed as a separate item on an entry document. Line entries do contain data elements for country of origin as well as product category.

2. **"The declared value of all food imports from China."**

Response: Information responsive to this request is included in the table enclosed at Tab A.

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3. "The number of imports from China that were detained pending laboratory examination."

Response: A table providing information responsive to this request is enclosed at Tab B. The table provides information on line entries in product categories related to human and animal food that were held under Detention Without Physical Examination (DWPE).

It is important to note that detentions are undertaken pending the refusal or release of an import line entry. We detain shipments offered for import based on an appearance of a violation under 801(a) of the Federal Food, Drug, and Cosmetic Act. Laboratory analysis is only one of many ways to overcome the appearance of a violation and may not be sufficient standing alone in many instances.

4. "The number of Chinese food samples analyzed by private laboratories."

Response: Enclosed at Tab C is a table that details the number and types of analytical packages received by FDA from outside laboratories that include an analysis of Chinese food samples.

5. "The number of Chinese food samples analyzed by FDA laboratories."

Response: The following two tables represent the number of Chinese food samples analyzed by FDA laboratories for fiscal years 2002 – 2006.

The table below tabulates import samples, which are samples of a commodity collected from a shipment made by a foreign firm into the U.S. before they are released into commerce.

Number of Import Chinese Food Samples Analyzed			
FISCAL YEAR	*IMPORTED HUMAN FOOD*	*IMPORTED ANIMAL FOOD AND FEED*	GRAND TOTAL
FY 2002	1,343	13	1,356
FY 2003	2,354	17	2,371
FY 2004	2,295	35	2,330
FY 2005	2,538	44	2,582
FY 2006	2,452	44	2,496
GRAND TOTAL	10,982	153	11,135

The following table tabulates domestic import samples, which are samples of an imported article collected after release from import status.

Number of Domestic Import Chinese Food Samples Analyzed			
FISCAL YEAR	IMPORTED HUMAN FOOD	IMPORTED ANIMAL FOOD AND FEED	GRAND TOTAL
FY 2002	158		158
FY 2003	124	4	128
FY 2004	110		110
FY 2005	105		105
FY 2006	91		91
GRAND TOTAL	588	4	592

6. "The number of Chinese food samples determined to be violative."

Response: The following two tables represent the number of Chinese food samples determined to be violative for fiscal years 2002 – 2006.

Number of Violative Import Chinese Food Samples Analyzed			
FISCAL YEAR	IMPORTED HUMAN FOOD	IMPORTED ANIMAL FOOD AND FEED	GRAND TOTAL
FY 2002	161	3	164
FY 2003	239		239
FY 2004	204		204
FY 2005	175	1	176
FY 2006	148	1	149
GRAND TOTAL	927	5	932

(Collected before release into commerce).

Number of Violative Domestic Import Chinese Food Samples Analyzed			
FISCAL YEAR	IMPORTED HUMAN FOOD	IMPORTED ANIMAL FOOD AND FEED	GRAND TOTAL
FY 2002	66		66
FY 2003	16	1	17
FY 2004	18		18
FY 2005	9		9
FY 2006	25		25
GRAND TOTAL	134	1	135

(Collected after release into commerce).

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7. "The number of violative Chinese food shipments that were reexported."

8. "The number of violative Chinese food shipments that were destroyed."

Response (to both questions): Under the FD&C Act, an import shipment refused admission must be exported or destroyed within 90 days. Enforcement of this requirement is handled by U.S. Customs and Border Protection. FDA does not systematically collect or compile numerical data on the disposition of refused shipments.

9. "The percentage of Chinese food samples found to be violative in each district and each laboratory."

Response: Enclosed at Tab D are five tables that are responsive to your request. These tables represent the percentage of Chinese food samples found to be violative in fiscal years 2002 through 2006. The tables are divided into Analyzing Laboratory and Collecting District. Within each laboratory or district, the data is further divided between human food and animal food and feed. Finally, the data is divided between those samples collected in import status and those samples collected in domestic commerce after having been imported and released into commerce in the United States.

10. "The number of FDA personnel (by full-time equivalent) conducting Chinese food import work for each district, each laboratory, and at headquarters."

Response: We are unable to provide a breakdown of full-time equivalents performing Chinese food import work. FDA does not assign work or hire staff to specifically conduct work based upon the country of origin of regulated products. The duties of FDA staff are assigned by management based upon the yearly work plan, emergencies, and other needs that arise during any given year.

Thank you for your interest in this matter. If you have any further questions or concerns, please let us know. A similar response has been sent to the co-signers of your letter.

Sincerely,

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

Enclosures

TAB A

Entry-Lines from Hong Kong & China by Fiscal Year - Human & Animal Food Related General Product Categories

[redacted]	$30,065,017	3,197	$30,846,603	2,878	$86,546,728	4,466	$117,738,886	7,266	$171,207,359	9,301
	$862,038	116	$764,528	57	$2,692,772	130	$4,569,654	204	$4,599,067	236
	$325,704,740	19,362	$412,128,505	23,998	$559,506,837	28,767	$729,650,840	34,117	$718,797,325	35,604
	$70,730,815	2,999	$79,854,306	5,364	$122,444,812	4,739	$182,766,890	6,116	$246,981,005	7,594
	$16,099,436	2,129	$19,319,114	2,784	$18,023,625	4,876	$19,415,030	5,596	$17,566,680	2,837
	$1,455,027,130	92,343	$2,052,993,972	130,921	$2,455,328,144	158,636	$3,971,932,992	178,178	$3,476,597,186	205,575
	$4,676,612	602	$5,773,778	841	$23,025,947	2,171	$27,716,797	2,025	$29,738,990	1,580
	$4,875,456	38	$5,825,091	43	$11,158,660	65	$27,919,558	80	$37,464,759	126

[redacted]

Note: Value is based on what has been entered by the Customs Broker.
Unless we are examining the shipment, missing value or errors are not routinely corrected by FDA.
Value is not a mandatory data element.

TAB B

China & Hong Kong Detentions without Physical Exam by Fiscal Year
Human & Animal Food Related General Product Categories (entry lines)

	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	Sum:
[illegible]	61	99			1,815	1	2	1,978
[illegible]	18	129	3		1,975		2	2,127
[illegible]	30	181			1,474		1	1,686
[illegible]	9	142	6	1	1,937			2,095
[illegible]	34	75	3	2	1,627		1	1,742
Sum:	161	626	12	3	8,828	1	6	9,637

Source: ORADSS Activities Data Mart

TAB C

Non FDA Analytical Packages by Fiscal Year; Human & Animal Food received from Hong Kong & China General Product Categories

	Animal Foods	Pet Supplies	Human Foods	Sum:
[redacted]	23	16	559	598
[redacted]	5	21	742	768
[redacted]	43	24	1,011	1,078
[redacted]	4	43	1,186	1,233
[redacted]	50	24	1,091	1,165
Sum:	125	128	4,589	4,842

TAB D

FY 2002

Percentage of Violative Chloramphenicol Found Food Samples
Presented By Analyzing Laboratory and by Collecting District/Region
Broken Down By Imported Human Food and by Imported Animal Food and Feed
Further Subdivided By Samples Collected in Import Status and Samples Collected in Domestic Commerce
As reported on June 15, 2001

ANALYZING LABORATORY	Imported Human Food Collected in Import Status			Imported Human Food Collected in Domestic Commerce			Imported Human Food Total			Imported Animal Food and Feed Collected in Import Status			Imported Animal Food and Feed Collected in Domestic Commerce			Imported Animal Food and Feed Total		
	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative
Atlanta Regional Laboratory	38	11	29%	14	3	21%	49	14	29%	2	2	100%				2	2	100%
Midwest Forensic Chemistry Center																		
Northeast Regional Laboratory	413	31	8%	31	10	32%	444	41	9%	2	1	50%				2	1	50%
Pacific Regional Lab Northwest	238	14	6%	6	1	17%	243	15	6%	1	0	0%				1	0	0%
Pacific Regional Lab Southwest	288	37	13%				288	37	13%	4	0	0%				4	0	0%
Southwest Regional Laboratory	165	12	7%	11	1	9%	180	13	7%	3	0	0%				3	0	0%
Winchester Engineering & Analytical Center																		
Denver District Laboratory	24	6	25%	37	23	62%	61	34	56%	2	2	100%				2	2	100%
Detroit District Laboratory	7	0	0%				7	0	0%									
Kansas City District Laboratory	12	0	0%	4	2	50%	16	2	13%									
Philadelphia District Laboratory																		
San Francisco District Laboratory	67	21	32%	8	4	50%	180	25	14%	1	0	0%				1	0	0%
San Jose District Laboratory																		
TOTAL	1,274	134	10%	111	44	40%	1,385	178	13%	16	5	31%				16	5	31%

COLLECTING DISTRICT/ REGIONAL OFFICE	Imported Human Food Collected in Import Status			Imported Human Food Collected in Domestic Commerce			Imported Human Food Total			Imported Animal Food and Feed Collected in Import Status			Imported Animal Food and Feed Collected in Domestic Commerce			Imported Animal Food and Feed Total		
	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative
Midwest Regional Office	2	0	0%				2	0	0%									
Central Regional Office																		
Southeast Regional Office																		
Southwest Regional Office																		
Pacific Regional Office																		
Atlanta District Office	23	4	13%	1	0	0%	24	5	22%	1	0	0%				1	0	0%
Baltimore District Office	28	1	3%	7	2	29%	43	3	7%	2	0	0%				2	0	0%
Chicago District Office	43	8	19%	4	4	100%	47	12	26%									
Cincinnati District Office	16	0	0%	2	0	0%	18	0	0%									
Dallas District Office				6	2	33%	9	3	33%									
Denver District Office	1	0	0%				1	0	0%									
Detroit District Office	23	4	17%	4	0	0%	27	4	15%									
Florida District Office	57	2	4%	2	1	50%	59	3	5%									
Kansas City District Office																		
Los Angeles District Office	274	60	22%	20	4	20%	294	64	22%	6	2	33%				6	2	33%
Minneapolis District Office	9	0	0%	1	1	100%	10	1	10%									
New England District Office	172	2	1%	16	0	0%	188	2	1%	2	1	50%				2	1	50%
New Jersey District Office				1	0	0%	1	0	0%									
New Orleans District Office	14	1	7%	40	34	77%	54	35	65%									
New York District Office	232	26	11%	19	6	32%	251	32	13%									
Philadelphia District Office	13	1	8%	6	5	83%	19	6	32%									
San Francisco District Office	148	27	18%	5	5	100%	153	32	21%	1	0	0%				1	0	0%
San Jose District Office	9	0	0%				9	0	0%									
Seattle District Office	191	35	18%	10	1	10%	201	36	18%	1	0	0%				1	0	0%
Southwest Regional Office	72	11	15%	2	0	0%	74	11	15%									
TOTAL	1,308	191	15%	138	58	42%	1,446	249	17%	13	3	23%				13	3	23%

Data Reported in NACTS and OASIS as of 6/11/2001
The number of samples analyzed may be greater than the number of samples collected because a single sample could be sent to one or more laboratories for analysis. Each analyzing laboratory's result is reported under the Analyzing Laboratory section, but only the highest tab classification is reported for a sample with multiple analyses in the Collecting District/Region section.
No data indicates that there were no Samples Collected or Analyzed

FY 2003

Percentage of Violative Chloramphenicol Positive Samples
Presented By Analyzing Laboratory and by Collecting District/Region
Ranked Down By Imported Human Food and by Imported Animal Food and Feed
Further Subdivided By Samples Collected In Import Status and Samples Collected In Domestic Commerce
As reported on June 05, 2007

ANALYZING LABORATORY	Imported Human Food Collected In Import Status			Imported Human Food Collected In Domestic Commerce			Imported Human Food Total			Imported Animal Food and Feed Collected In Import Status			Imported Animal Food and Feed Collected In Domestic Commerce			Imported Animal Food and Feed Total		
	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative
Arkansas Regional Laboratory	[illegible]	39	19%	18	1	6%	[illegible]	37	18%				1	1	100%	1	1	100%
Arkansas Forensic Chemistry Center				3	0	0%	3	0	0%									
Northeast Regional Laboratory	548	27	5%	41	9	22%	[illegible]	36	6%	4	0	0%	3	1	33%	7	1	14%
Pacific Regional Lab Northwest	[illegible]	35	9%	14	3	20%	[illegible]	31	9%	0	0	0%				0	0	0%
Pacific Regional Lab Southwest	[illegible]	65	14%	9	7	80%	[illegible]	69	14%	2	2	100%				2	2	100%
Southeast Regional Laboratory	247	20	8%	28	5	18%	[illegible]	25	9%	2	0	0%				2	0	0%
Winchester Engineering & Analytical Center	9	0	0%				9	0	0%									
Denver District Laboratory	67	22	33%	18	9	50%	115	31	27%	1	1	100%	1	1	100%	2	2	100%
Detroit District Laboratory	2	0	0%				2	0	0%									
Kansas City District Laboratory	30	1	3%	11	6	55%	68	7	10%									
Philadelphia District Laboratory																		
San Francisco District Laboratory	238	38	16%	16	0	0%	254	39	15%	5	0	0%				5	0	0%
San Juan District Laboratory																		
TOTAL	3,341	239	10%	158	37	23%	3,453	260	11%	20	3	15%	5	3	60%	25	6	24%

COLLECTING DISTRICT/ REGIONAL OFFICE	Imported Human Food Collected In Import Status			Imported Human Food Collected In Domestic Commerce			Imported Human Food Total			Imported Animal Food and Feed Collected In Import Status			Imported Animal Food and Feed Collected In Domestic Commerce			Imported Animal Food and Feed Total		
	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative
Northeast Regional Office	9	0	0%				9	0	0%									
Central Regional Office																		
Southeast Regional Office																		
Southwest Regional Office																		
Pacific Regional Office																		
Atlanta District Office	75	3	4%	3	1	33%	78	4	5%									
Baltimore District Office	43	2	5%	16	3	19%	59	5	8%	2	0	0%				2	0	0%
Chicago District Office	33	4	12%				33	4	12%									
Cincinnati District Office	4	0	0%	2	0	0%	6	0	0%									
Dallas District Office				2	0	0%	2	0	0%									
Denver District Office	4	0	0%	1	0	0%	5	0	0%									
Detroit District Office	28	0	0%				28	0	0%									
Florida District Office	82	7	8%	9	4	44%	91	11	12%									
Kansas City District Office	16	2	13%	1	0	0%	17	2	12%									
Los Angeles District Office	712	121	17%	16	0	0%	728	121	17%									
Minneapolis District Office	24	3	13%	2	0	0%	26	3	12%									
New England District Office	230	1	0%	12	0	0%	242	1	0%									
New Jersey District Office				5	0	0%	5	0	0%				3	1	33%	3	1	33%
New Orleans District Office	35	3	8%	7	1	14%	42	4	10%									
New York District Office	343	23	7%	23	7	30%	366	30	8%	5	0	0%				5	0	0%
Philadelphia District Office	22	4	18%	1	0	0%	23	4	17%				1	0	0%	1	0	0%
San Francisco District Office	323	31	10%	2	0	0%	325	31	10%	5	0	0%				5	0	0%
San Juan District Office	12	1	8%				12	1	8%									
Seattle District Office	305	29	9%	10	0	0%	315	29	9%	4	0	0%				4	0	0%
Headquarters Import District	78	4	5%				78	4	5%									
TOTAL	2,335	209	10%	114	16	14%	2,449	225	10%	17	0	0%	4	1	50%	21	1	5%

Data Reported in FACTS and OASIS as of 06/15/07
The number of samples analyzed may be greater than the number of samples collected because a single sample could be sent to one or more laboratories for analysis. Each analyzing laboratory's result is reported under the Analyzing Laboratory section, but only the highest lab classification is reported for a sample with multiple analyses in the Collecting District/Region section.
No data indicates that there were no Samples Collected or Analyzed

FY 2004

Percentage of Violative Chloramphenicol Drug Food Samples
Presented By Analyzing Laboratory and by Collecting District/Region
Broken Down By Imported Human Food and by Imported Animal Food and Feed
Further Subdivided By Samples Collected in Import States and Samples Collected in Domestic Commerce
As reported on June 03, 2007

ANALYZING LABORATORY	Imported Human Food Collected in Import States			Imported Human Food Collected in Domestic Commerce			Imported Human Food Total			Imported Animal Food and Feed Collected in Import States			Imported Animal Food and Feed Collected in Domestic Commerce			Imported Animal Food and Feed Total		
	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative
Arkansas Regional Laboratory	142	10	7%	18	2	11%	160	12	8%	4	0	0%	1	0	0%	5	0	0%
National Forensic Chemistry Center																		
Northeast Regional Laboratory	485	27	6%	15	4	27%	471	31	7%	3	0	0%				3	0	0%
Pacific Regional Lab Northwest	410	42	10%	9	0	0%	420	42	10%	10	0	0%				10	0	0%
Pacific Regional Lab Southwest	640	68	9%	18	3	16%	663	65	10%	3	0	0%				3	0	0%
Southeast Regional Laboratory	288	6	2%	19	7	37%	276	13	5%	5	0	0%				5	0	0%
Winchester Engineering & Analytical Center	107	0	0%				107	0	0%									
Denver District Laboratory	68	14	20%	4	1	25%	72	15	21%									
Detroit District Laboratory	9	0	0%	1	0	0%	8	0	0%									
Kansas City District Laboratory	8	0	0%	3	0	0%	11	0	0%									
Philadelphia District Laboratory																		
San Francisco District Laboratory	200	42	21%	7	0	0%	207	42	20%	4	0	0%				4	0	0%
San Juan District Laboratory																		
TOTAL	2,394	203	9%	80	19	24%	2,387	222	9%	33	0	0%	1	0	0%	34	0	0%

COLLECTING DISTRICT/ REGIONAL OFFICE	Imported Human Food Collected in Import States			Imported Human Food Collected in Domestic Commerce			Imported Human Food Total			Imported Animal Food and Feed Collected in Import States			Imported Animal Food and Feed Collected in Domestic Commerce			Imported Animal Food and Feed Total		
	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative
Northeast Regional Office																		
Central Regional Office																		
Southeast Regional Office																		
Southwest Regional Office																		
Pacific Regional Office																		
Atlanta District Office	41	0	0%	4	0	0%	45	0	0%									
Baltimore District Office	77	4	5%	6	2	33%	83	6	7%	3	0	0%				3	0	0%
Chicago District Office	45	3	7%	2	0	0%	47	3	6%									
Cincinnati District Office	5	1	20%				5	1	20%									
Dallas District Office				9	2	22%	9	2	22%									
Denver District Office																		
Detroit District Office	29	0	0%				29	0	0%	5	0	0%				5	0	0%
Florida District Office	68	3	3%	2	0	0%	70	3	3%									
Kansas City District Office																		
Los Angeles District Office	752	117	15%	44	1	2%	803	118	15%	5	0	0%				5	0	0%
Minneapolis District Office	8	0	0%	2	1	50%	10	1	10%	1	0	0%				1	0	0%
New England District Office	336	4	2%	9	1	11%	347	5	1%									
New Jersey District Office				3	2	67%	3	2	67%									
New Orleans District Office	49	4	8%	2	0	0%	51	4	8%	2	0	0%				2	0	0%
New York District Office	313	11	4%	13	7	54%	326	18	6%	2	0	0%				2	0	0%
Philadelphia District Office	18	2	12%	1	1	50%	17	3	18%	1	0	0%				1	0	0%
San Francisco District Office	220	19	9%	6	1	17%	226	20	9%	4	0	0%				4	0	0%
San Juan District Office	17	1	6%				17	1	6%									
Seattle District Office	302	32	11%	5	0	0%	307	32	11%	6	0	0%				6	0	0%
Southeast Import District	52	3	5%				52	3	5%	2	0	0%				2	0	0%
TOTAL	2,387	204	9%	102	17	17%	2,489	221	9%	33	0	0%				33	0	0%

Data Reported in FACTS and OASIS as of 06/06/07
The number of samples analyzed may be greater than the number of samples collected because a single sample could be sent to one or more laboratories for analysis. Each analyzing laboratory's result is reported under the Analyzing Laboratory section, but only the highest tab classification is reported for a sample with multiple analyses in the Collecting District/Region section.
No data indicates that there were no Samples Collected or Analyzed

FY 2005

Percentage of Violative Chloramphenicol Kong Feed Samples
Presented By Analyzing Laboratory and By Collecting District/Region
Broken Down By Imported Human Food and by Imported Animal Food and Feed
Further Subdivided By Samples Collected in Import Status and Samples Collected in Domestic Commerce
As reported on June 19, 2007

ANALYZING LABORATORY	Imported Human Food Collected in Import Status			Imported Human Food Collected in Domestic Commerce			Imported Human Food Total			Imported Animal Food and Feed Collected in Import Status			Imported Animal Food and Feed Collected in Domestic Commerce			Imported Animal Food and Feed Total		
	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	#	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative
Alabama Regional Laboratory	234	12	5%	13	1	8%	247	13	5%	3	0	0%				3	0	0%
National Forensic Chemistry Center																		
Northeast Regional Laboratory	391	21	5%	23	2	8%	414	23	6%	7	0	0%				7	0	0%
Pacific Regional Lab Northwest	348	20	5%	6	0	0%	354	20	5%	10	0	0%				10	0	0%
Pacific Regional Lab Southwest	652	69	11%	13	0	0%	665	69	10%	1	0	0%				1	0	0%
Southeast Regional Laboratory	239	6	3%	18	3	17%	257	9	4%	5	0	0%				5	0	0%
Winchester Engineering & Analytical Center	189	1	1%				189	1	1%									
Denver District Laboratory	63	12	19%	3	0	0%	66	12	18%	4	1	25%				4	1	25%
Detroit District Laboratory	6	0	0%				6	0	0%									
Kansas City District Laboratory	60	1	10%	7	0	0%	67	1	0%									
Philadelphia District Laboratory																		
San Francisco District Laboratory	228	28	12%	44	4	9%	272	32	12%	1	0	0%				1	0	0%
San Juan District Laboratory																		
TOTAL	2,010	150	7%	129	10	8%	2,071	160	7%	31	1	3%				31	1	3%

COLLECTING DISTRICT/ REGIONAL OFFICE	Imported Human Food Collected in Import Status			Imported Human Food Collected in Domestic Commerce			Imported Human Food Total			Imported Animal Food and Feed Collected in Import Status			Imported Animal Food and Feed Collected in Domestic Commerce			Imported Animal Food and Feed Total		
	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	#	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative
Northeast Regional Office																		
Central Regional Office																		
Southeast Regional Office				2	2	100%	2	2	100%									
Southwest Regional Office																		
Pacific Regional Office				2	0	0%	2	0	0%									
Atlanta District Office	34	0	0%	1	0	0%	35	0	0%									
Baltimore District Office	108	3	3%	7	0	0%	115	3	3%	3	0	0%				3	0	0%
Chicago District Office	86	1	1%	2	0	0%	88	1	1%	1	0	0%				1	0	0%
Cincinnati District Office	3	0	0%				3	0	0%									
Dallas District Office																		
Denver District Office																		
Detroit District Office	73	5	7%				73	5	7%	1	1	100%				1	1	100%
Florida District Office	33	1	3%	4	0	0%	37	1	3%									
Kansas City District Office	3	0	0%				3	0	0%									
Los Angeles District Office	743	87	12%	20	2	10%	763	89	12%									
Minneapolis District Office	11	0	0%	1	0	0%	12	0	0%									
New England District Office	256	4	1%	51	0	0%	307	4	1%	1	0	0%				1	0	0%
New Jersey District Office				4	0	0%	4	0	0%									
New Orleans District Office	13	0	0%	10	0	0%	23	0	0%	2	0	0%				2	0	0%
New York District Office	365	23	6%	18	3	20%	383	26	7%	7	0	0%				7	0	0%
Philadelphia District Office	23	0	0%				23	0	0%	1	0	0%				1	0	0%
San Francisco District Office	291	19	6%	6	2	33%	297	19	7%	2	0	0%				2	0	0%
San Juan District Office	24	0	0%				24	0	0%									
Seattle District Office	274	30	11%	16	0	0%	290	30	11%	16	0	0%				16	0	0%
Southwest Import District	78	5	7%				78	5	7%	3	0	0%				3	0	0%
TOTAL	2,010	150	7%	97	8	8%	2,083	158	7%	37	1	3%				37	1	3%

Data Reported in FACTS and OASIS as of 06/19/07
The number of samples analyzed may be greater than the number of samples collected because a single sample could be sent to one or more laboratories for analysis. Each analyzing laboratory's result is reported under the Analyzing Laboratory section, but only the highest lab classification is reported for a sample with multiple analyses in the Collecting District/Region section.
An date indicates that there were no Samples Collected or Analyzed

FY 2006

Percentage of Violative Chinese/Hong Kong Food Samples
Presented By Analyzing Laboratory and by Collecting District/Region
Broken Down By Imported Human Food and by Imported Animal Food and Feed
Further Subdivided By Samples Collected in Import States and Samples Collected in Domestic Commerce
As reported on June 05, 2007

ANALYZING LABORATORY	Imported Human Food Collected in Import States			Imported Human Food Collected in Domestic Commerce			Imported Human Food Total			Imported Animal Food and Feed Collected in Import States			Imported Animal Food and Feed Collected in Domestic Commerce			Imported Animal Food and Feed Total		
	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative
Arkansas Regional Laboratory	241	68	7%	18	8	42%	259	76	8%	9	0	0%				9	0	0%
National Forensic Chemistry Center																		
Northeast Regional Laboratory	594	32	0%	15	4	27%	609	36	6%	6	1	17%				6	1	17%
Pacific Regional Lab Northwest	297	34	0%	4	0	0%	301	34	11%	10	0	0%				10	0	0%
Pacific Regional Lab Southwest	371	27	3%	6	1	20%	378	28	8%	5	0	0%				5	0	0%
Southeast Regional Laboratory	329	6	2%	18	2	11%	347	18	5%	3	0	0%				3	0	0%
Winchester Engineering & Analytical Center	342	3	2%				342	3	2%	1	0	0%				1	0	0%
Denver District Laboratory	198	36	24%	9	5	56%	162	41	33%	3	0	0%				3	0	0%
Detroit District Laboratory	1	0	0%				1	0	0%									
Kansas City District Laboratory	8	0	0%	9	0	0%	17	0	0%	2	0	0%				2	0	0%
Philadelphia District Laboratory																		
San Francisco District Laboratory	111	11	10%	25	3	12%	136	14	10%	3	1	33%				3	1	33%
San Jose District Laboratory	1	0	0%				1	0	0%									
TOTAL	2,098	150	7%	104	28	26%	2,202	178	7%	41	2	5%				41	2	5%

COLLECTING DISTRICT/ REGIONAL OFFICE	Imported Human Food Collected in Import States			Imported Human Food Collected in Domestic Commerce			Imported Human Food Total			Imported Animal Food and Feed Collected in Import States			Imported Animal Food and Feed Collected in Domestic Commerce			Imported Animal Food and Feed Total		
	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative	# of Samples	# Violative	% Violative
Midwest Regional Office																		
Central Regional Office																		
Southeast Regional Office																		
Southwest Regional Office																		
Pacific Regional Office																		
Atlanta District Office	26	1	4%	8	0	0%	34	1	3%									
Baltimore District Office	126	5	4%	4	0	0%	143	5	4%	3	0	0%				3	0	0%
Chicago District Office	104	10	10%	4	4	100%	108	14	13%	4	0	0%				4	0	0%
Cincinnati District Office	8	1	13%	3	0	0%	11	1	9%	1	0	0%				1	0	0%
Dallas District Office				3	0	0%	3	0	0%									
Denver District Office	2	0	0%				2	0	0%									
Detroit District Office	68	3	5%	3	1	33%	83	4	5%									
Florida District Office	42	2	5%	5	0	0%	48	2	4%									
Kansas City District Office																		
Los Angeles District Office	510	72	0%	27	4	15%	537	76	0%									
Minneapolis District Office	13	1	0%	3	3	100%	16	4	25%	4	0	0%				4	0	0%
New England District Office	546	19	3%	6	2	33%	552	21	3%	3	0	0%				3	0	0%
New Jersey District Office																		
New Orleans District Office	18	0	0%				18	0	0%									
New York District Office	288	12	0%	21	3	27%	374	15	4%	3	0	0%				3	0	0%
Philadelphia District Office	54	3	13%	3	0	0%	57	3	10%	1	0	0%				1	0	0%
San Francisco District Office	137	7	5%	8	0	0%	145	10	07%	0	0	0%				0	0	0%
San Jose District Office	15	0	0%	1	0	0%	16	0	0%									
Seattle District Office	212	18	0%				212	18	0%	9	1	11%				9	1	11%
Southwest Import District	118	5	4%				118	5	0%	4	0	0%				4	0	0%
TOTAL	2,098	150	0%	91	20	21%	2,221	170	7%	41	1	2%				41	1	2%

Data Reported in FACTS and CARDS as of 06/15/07
The number of samples analyzed may be greater than the number of samples collected because a single sample could be sent to one or more laboratories for analysis. Each analyzing laboratory's result is reported under the Analyzing Laboratory section, but only the highest hit classification is reported for a sample with multiple analyses in the Collecting District/Region section.
An asterisk indicates that there were no Samples Collected or Analyzed

HENRY A. WAXMAN, CALIFORNIA
EDWARD J. MARKEY, MASSACHUSETTS
RICK BOUCHER, VIRGINIA
EDOLPHUS TOWNS, NEW YORK
FRANK PALLONE, Jr., NEW JERSEY
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GREGG A. ROTHSCHILD, CHIEF COUNSEL

ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

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MARSHA BLACKBURN, TENNESSEE

June 6, 2007

Richard A. Raymond, M.D.
Under Secretary for Food Safety
Food Safety and Inspection Service
U.S. Department of Agriculture
1400 Independence Avenue, S.W.
Washington, D.C. 20250

Dear Dr. Raymond:

Under Rules X and XI of the Rules of the United States House of Representatives, the Committee on Energy and Commerce and the Subcommittee on Oversight and Investigations are currently investigating the safety of the Nation's food supply. While the initial focus of the investigation has been on the adequacy of the efforts of the Food and Drug Administration (FDA) to protect the Nation's food supply, a food safety matter of deep concern involving the U.S. Department of Agriculture (USDA) has recently been brought to our attention. We are writing to request your assistance in providing the Committee with more information regarding this matter

On Sunday, May 20, 2007, *The Washington Post* ran an article entitled, "Tainted Chinese Imports Common." This article raised several concerns about the safety of food imports from China. According to the article, USDA has a rule that allows China to export chickens to the United States if the chickens were grown and slaughtered in North America and then processed in China. The *Post* article reports that this rule was promulgated last year "under high-level pressure from China" after quickly passing through multiple levels of reviews. Additionally, according to the article, you have stated that a rule "is in the works" to allow China to export its own homegrown birds to the United States. You further stated "that permission for China to sell poultry is moving ahead because recent USDA audits found China's poultry slaughterhouses to be equivalent to those here." The *Post* article, however, reports that others who have seen the audits disagree with this assertion. One advocacy group called USDA's findings "unbelievable."

In order to assist the Committee with its investigation of the safety of the Nation's food supply, we request that you provide the Committee with the following information:

1. Any documents or communications relating to the decision to allow China to export chickens to the United States that were grown and slaughtered in North America and then processed in China;

2. Any documents or communications relating to the proposed rule that would allow China to export its own homegrown birds to the United States; and

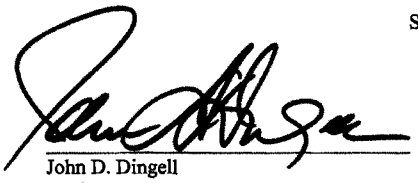
3. Any documents or communications relating to the audits of Chinese poultry slaughterhouses.

Please note, for the purpose of responding to the above request, the terms "documents," "communications," and "relating" should be interpreted in accordance with the attachment to this letter. After reviewing the documents, we may request additional documents and/or staff interviews with USDA/Food Safety Inspection Service personnel.

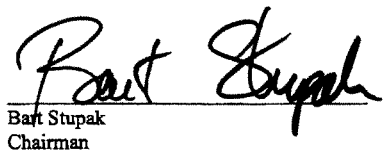
We ask that you supply all requested documents by no later than the close of business two weeks from the date of this letter.

If you have any questions relating to this request, please contact us or have your staff contact Kevin Barstow or David Nelson with the Committee on Energy and Commerce staff at (202) 226-2424.

Sincerely,



John D. Dingell
Chairman



Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Ed Whitfield, Ranking Member
Subcommittee on Oversight and Investigations

ATTACHMENT

1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.

2. The terms "relating," or "relate" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.

United States Department of Agriculture
Office of the General Counsel
Washington, D.C. 20250-1400

October 9, 2007

OCT 09 2007

The Honorable John D. Dingell
Chairman, Committee on Energy and Commerce
United States House of Representatives
Washington, D.C. 20515-6115

The Honorable Bart Stupak
Chairman, Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
United States House of Representatives
Washington, D.C. 20515-6115

Dear Chairmen Dingell and Stupak:

I write in response to your June 6, 2007, letter to Dr. Richard A. Raymond, Under Secretary for Food Safety, United States Department of Agriculture ("USDA"), in which you requested various documents and communications related to the decision to allow China to export poultry products to the United States.

USDA is committed to assisting the Committee and the Subcommittee (collectively the "Committee") in this request for information in a manner that accommodates both the Committee's legitimate oversight interests and the interests of the Executive Branch.

The Committee's letter included three separate inquiries (processing, slaughter, and audit) and has therefore required a substantial amount of work on the part of the Department. In response to your request, FSIS officials promptly commenced a search of the records of the immediate office of the Under Secretary for Food Safety, as well as of the Food Safety and Inspection Service ("FSIS"). Due to the extremely broad scope of the request, we devoted a substantial amount of personnel hours, effort, and resources to this undertaking.

In response to your request, we are providing you with 7,147 pages of responsive materials (Bates stamped 1 – 7147), which are enclosed herewith. The documents responsive to your request are organized chronologically into categories in accordance with the three requests specified in your June 6, 2007, letter.

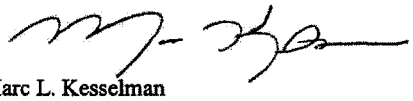
Among the documents being produced are a number of documents of a deliberative character that would not normally be shared outside of the Executive Branch. We are nonetheless providing them in an effort to accommodate the Committee. Please be advised that we have identified some additional documents that are of a distinct character

due to their highly deliberative nature reflecting internal Executive Office of the President decision-making processes. In light of the extraordinary accommodation and in-depth insight being provided regarding each of the Committee's three subject matter inquiries, these additional documents have not been included in the attached production. Should the Committee wish to discuss this matter, we would be willing to explore the possibility of further accommodation.

Regarding the extensive number of documents provided today, we are concerned that disclosure of USDA's internal deliberative documents outside the Congress would have a potential chilling effect on the candor and quality of future Executive Branch deliberations regarding matters of public health, and would hamper our ability to assert applicable exemptions and privileges under the Freedom of Information Act and other disclosure statutes. We request that the Committee use these documents for Committee purposes only and strictly maintain their confidentiality. Accordingly, should the Committee determine that public disclosure is necessary in the exercise of the Committee's responsibilities, we request an opportunity to discuss our concerns with you before the documents are released.

Thank you very much for your consideration. If members of your staff would like to discuss this matter further, please ask them to contact John Golden, Associate General Counsel, at 202-720-3155, or Job Serebrov, Senior Counselor to the General Counsel, at 202-205-4725.

Sincerely,



Marc L. Kesselman
General Counsel

Enclosures

cc: The Honorable Joe Barton
Ranking Member, Committee on Energy and Commerce

The Honorable Ed Whitfield
Ranking Member, Subcommittee on Oversight and Investigations
Committee on Energy and Commerce

The Honorable Richard Raymond
Under Secretary for Food Safety
United States Department of Agriculture

USDA Foreign Agricultural Service
GAIN Report
Global Agriculture Information Network

Template Version 2.09

Voluntary Report - public distribution

Date: 7/16/2007

GAIN Report Number: CH7058

China, Peoples Republic of

Agricultural Situation

The 11th Five-Year Plan on Food and Drug Safety

2007

Approved by:
Maurice House
U.S. Embassy

Prepared by:
Mark Petry, Owen Wagner, and Wu Bugang

Report Highlights:
This is an UNOFFICIAL translation of the 11th Five-Year Plan on Food and Drug Safety as published by the State Council of China. The plan outlines targets for the administration and surveillance of food and drug safety in 2006-2010.

Includes PSD Changes: No
Includes Trade Matrix: No
Unscheduled Report
Beijing [CH1]
[CH]

Executive summary

The State Council of China published the 11th Five-Year Plan on Food and Drug Safety in April 2007. In an effort to step up supervision and administration on the safety of food, drug and food-service industries, the plan outlines the targets and major tasks for the government during the period from 2006-2010.

Special thanks go to the Embassies of Argentina, Brazil, and Canada in China for their assistance in translating this document.

BEGIN TRANSLATION

The Eleventh Five-Year National Plan for Food and Drug Safety

In order to further strengthen the supervision on food, drugs and hygiene of food and beverage services, to constantly enhance the safety of food, beverage and drug use for the public and to promote social harmony and stability, this Plan is formulated in accordance with the "Outline of the 11th Five-Year Plan for National Economic and Social Development of the People's Republic of China" and the relevant guidelines and policies of the Communist Party of China (CPC) Central Committee and the State Council.

Part One Guiding Thoughts and Basic Principles

I. Guiding Thoughts

Guided by Deng Xiaoping's theory and the important thoughts of the "Three Representatives", to earnestly implement the scientific concept of development, fully perform the government duties in social administration and public service, strengthen facility construction for the supervision on food and drugs, improve the technical standard system, vigorously uplift the technical level of inspection and testing, innovate the supervision mechanism, standardize supervisory behavior, enhance the capability and level of supervision, safeguard the safety of food, beverage and drug use for the public, and make due contribution to building a well-off society in a comprehensive way and constructing a harmonious socialist society.

II. Basic Principles

Firstly, we shall adhere to the people-based principle, in order to serve the overall interests of the country. We must take the protection of the safety of food, beverage and drug use for the public as the starting point and the end result of all our work, and ensure that the supervision on food and drug safety is compatible with the economic and social development, with the overall goal of building a well-off society in a comprehensive way, and with the structural reform of the national administrative management system.

Secondly, we shall adhere to scientific supervision and innovative mechanism. We must establish the concept of scientific supervision, improve the supporting technology system, enhance the capability and level of supervision on food and drug safety, innovate the supervision system and build a new supervision mechanism that suits the national conditions and meets the requirements of a socialist market economy system.

Thirdly, we shall adhere to full-process supervision and administration according to law. We must strengthen food and drug safety supervision in accordance with law, continuously improve the laws and regulations pertaining to food and drug safety supervision, ensure stringent law enforcement, standardize supervisory behavior, and achieve the full-process of standardized and effective supervision on all aspects relating to food and drugs.

Fourthly, we shall adhere to an all-round, well-coordinated approach and integrated resource management. We must aim to take full advantage of the available resources, optimize resource deployment, bring into full play the functions of each area and aspect in food and drug safety supervision, establish a food and drug safety supervision mechanism

demonstrating coordinated efforts of joint administration, and utilize effective resources to maximize efficiency.

Fifthly, we shall adhere to strengthening grass-root and basic-level supervision. We must take grass-root and basic-level supervision on food and drug safety as a high priority, organize and mobilize sufficient financial, technical and human resources to better equip grass-root and basic-level units, and considerably reinforce grass-root development and basic work on food and drug safety supervision.

Part Two Development Objectives

Through efforts made over an estimated period of five years, the food and drug supervision system and mechanism will be gradually improved; the law and regulatory system will become more perfect; the quality of supervisory forces will be improved; the capability to exercise administration according to law will be further enhanced; infrastructure construction will be strengthened; technical equipment will be further upgraded; the development of food and drug safety standards and the level of testing technology will be notably advanced; the manufacturing and distribution of food and drugs shall be conducted in a markedly improved and more orderly manner; illegal and criminal activities in manufacturing and distributing fake and inferior food and drugs will be effectively curbed; and the number of food and drug safety incidents will be significantly reduced.

I. By the end of the 11th Five-Year Plan period, a safeguard system for food safety to be basically established

- The food safety information monitoring network will cover 90% of the country;
- The quality safety qualification rate of fresh/live agricultural products in whole-sale markets, large-scale farmers' trading markets and chained supermarkets in large and medium-sized cities will reach 95% based on spot checks;
- 100% of major food safety incidents will be dealt with;
- The food recall system will cover 80% of the country;
- National specific inspections on food manufacturers will cover 90% of the country

II. By the end of the 11th Five-Year Plan period, the level of drug supervision to be substantially upgraded

- The rural drug supervision network will attain a 100% coverage rate, and that of the rural drug supply network will remain at 80% or above;
- In terms of independent capabilities to carry out full-scope inspections against the existing national drug standards, the drug inspection institutes at the provincial and port levels will have the capability to conduct 100% of such inspections, while the drug inspection institutes at the municipal (prefecture) level will have the capability for 80%;
- The state-level medical devices inspection institutes will have the capability to inspect 100% of the products under their jurisdiction, while provincial medical devices inspection institutes will have the capability to inspect over 95% of conventional products in the market;
- The coverage rate of drug supervision spot inspections will be increased from the current 30% to 80%.

Part Three Major Tasks

I. Food Safety

1. To strengthen food safety monitoring

Regionalize the production areas of edible agriculture products. Establish environmental safety monitoring systems for the production areas of agricultural products, to systematically

investigate pollution in the production areas and carry out environmental and quality safety monitoring on key regions and production areas of representative agricultural products. Strengthen the quality and environmental safety management of agricultural inputs. Establish a national system of monitoring and control on pesticide and veterinary drug residues, and expand the network of routine monitoring of quality and safety of agricultural products from coverage of the current 37 cities to all the large and medium-sized cities across the country. Establish a system of monitoring and control on the pollution of raw grain, monitor the quality, safety and hygiene of raw grain and build a network of monitoring of the grain quality and safety and the hygiene of raw grain. Carry out risk monitoring on non-food raw materials, systematically investigate pollution of non-food raw materials, establish a national special inspection system on compulsory standards of key food, implement an electronic labelling management system, and establish and standardize a food recall supervision and management system. Improve the spot check and routine monitoring system for food safety, hygiene and quality, set up food quality monitoring and direct-reporting points. Improve the national monitoring network on food contaminants and food borne diseases.

Column 1: Food Safety Monitoring

Environmental monitoring and control
Reinforce the environmental monitoring and control of the "vegetable basket" production bases in key cities across the country, carry forward environmental safety regionalization and monitoring of key pollution sources in the production areas of agricultural products around Bohai Region, Pearl River Delta and Changjiang River Delta. Establish monitoring points interlinked through network to survey the environment in the production areas of agricultural products in key cities, build a data sharing platform on environmental quality in the production areas of agricultural products across the country.

Market quality monitoring and control
Improve the routine market monitoring system, and establish monitoring and control points to survey the quality of fresh/live agriculture products in wholesale markets, large-scale farmers' trading markets and chain supermarkets in large and medium-sized cities.

Food contaminants and food borne diseases monitoring
Improve the food contaminants and food borne diseases monitoring network, which consists of provinces (regions, municipalities) as the monitoring and control units down to cities and counties as the monitoring points.

Construction of bases
Establish agricultural products and food demonstration bases under the circular economy model; accelerate the construction of bases for pollution-free food (agricultural products), good agricultural practice (GAP), green food and organic food.

Non-food raw material monitoring and food recall
Improve the pollution monitoring network on non-food raw materials at three levels – provincial, municipal and county level; carry out risk monitoring of non-food raw materials in key regions, of key products and key substances. Implement food recall work for high-risk food products such as meat products, dairy products, beverage, processed grain products, and edible vegetable oil.

2. To upgrade the level of food safety inspection and testing

Integrate and take full advantage of the available food inspection and testing resources, tighten up laboratory qualification management, preliminarily establish a coordinated, consistent and effective operational food safety inspection and testing system, achieve the sharing of testing resources, meet the demands for safety supervision on the full process of food production, distribution and consumption, strive to bring the technology of the state-level food safety testing institutes up to par with advanced international level. Promote the socialization of inspection and testing institutes, and vigorously encourage and develop third-party testing institutes.

Column 2: Key Aspects in Building Food Safety Testing Capacity

Inspection and testing on the quality and safety of agricultural products
On the basis of an integration of available resources, establish state-level centres of research on quality standard and testing technology for agricultural products, specialized quality inspection centres for agricultural products, regional quality inspection centres, provincial integrative quality inspection centres for agricultural products and county-level testing stations for agricultural products.

Food quality and safety testing
Enhance the capacity building for state-level food quality supervision and inspection centers and municipal/county-level product quality inspection institutes to carry out food quality and safety testing.

Testing on food contaminants and food borne diseases
Promote testing technology against common hazard elements in the food and beverage industry; improve rapid testing technology against 10 types of common chemical and biological contaminant elements in the food and beverage industry.

Rapid testing
Depending on needs, gradually equip food safety supervision and administrative departments with necessary rapid testing facilities and rapid testing vehicles.

3. To improve standards pertaining to food safety
Further strengthen the efforts in formulating and revising food safety standards and basically establish a unified and scientific food safety standard system. Advance the process of adopting international and foreign advanced standards into China's food safety standards, and actively participate in the formulation and revision of international standards. Formulate feasible transitional or classification standards in accordance with China's specific conditions associated with food production, processing and distribution.

Column 3: Key Aspects in the Formulation of Standards Pertaining to Food Safety

Environmental pollution control standards
Formulate environmental pollution control standards targeting mainly at the environment of the production areas of grain crops, vegetable, animal and aquatic products.

Standards pertaining to food safety
Formulate the production area environmental standards required for certification and surveillance of pollution-free products, good agricultural practice (GAP), organic and green food, standards for grain and major agricultural products, rational standards on the use of pesticides and chemical fertilizers, GM biological safety standards, and standards for prevention and control of animal diseases; complete the formulation and revision of about 500 standards concerning residues and inspection methods of pesticides, veterinary drugs and toxic heavy metal elements; complete the formulation and revision of standards concerning residues and inspection methods of biological toxin and harmful micro-organisms; complete the formulation and revision of the hygiene standards for nutrition labeling, food containers and packaging materials, basic hygiene standards and inspection methods for food contaminants, and hygiene standards for food products and hygiene standards for the use of food additives; formulate standards concerning storage, transport and circulation safety such as the temperature and operational rules on cold chain logistics for fresh/live food.

Demonstration of standardization
Build a demonstration system of quality and safety standardization for bulk fresh/live agricultural products, superior agricultural products and agricultural products for export, and establish state-level agricultural standardization demonstration parks.

4. To build a food safety information system
Take full advantage of the available information sources and infrastructure, build a national food safety information platform and form a food safety information network composed of the following four levels – national, provincial, city and county level, as well as a national direct-reporting network targeting at food safety elements of the key enterprises; build a food safety dynamic information database with high capacity, manageability and enhanced security; establish a national food safety basic information sharing system and create a coordinated network working environment serving for food safety monitoring and analysis, information notification, contingency early warning, emergency response, scientific research on food safety as well as providing social and public service. Accelerate the establishment of a unified food safety public notification system.

Column 4: Key Projects in Systematizing Food Safety Information

Food safety information monitoring network
Build and improve the food safety information-monitoring network, and gradually form a unified and scientific food safety information evaluation and early warning system.

Electronic surveillance
Gradually build an electronic surveillance network to monitor food production, processing and distribution, and achieve electronic surveillance of food production and processing, qualification of operating businesses and product quality.

Food safety information centre
Based on the food safety information network and the integration of the available resources, build a food safety information centre to classify, filter, comprehensively analyze and monitor food safety information, make assessments on the food safety situation and perform early warning.

5. Enhance the science and technology supporting capability for food safety
Carry out basic research, high-tech research, establish key technology research on food safety and a platform for sharing food safety research statistics, and strengthen research of application technology and relevant strategies. Monitor standards of Codex Alimentarius Commission, supervision measures on food safety of major trading countries, and evaluation announcements of WTO's Agreement on the Application of Sanitary and Phytosanitary Measures and Agreement on Technical Barriers to Trade. Strengthen capacity building of food safety technology, and set up preliminarily an open food safety research system, which has autonomous and innovative capability and is internationally compatible. Enhance quality team building and subject building of food safety.

Column 5: Key Points in Food Safety Scientific Research

Monitoring research
Including Codex Alimentarius Commission, and food safety management system, policies, laws and regulations, standards, safety guarantee techniques, key testing methods of major trading countries.

Research of evaluation technology
Involving novel material for food, novel technology and genetically modified foods, food additives and food contact materials.

Research of risk assessment technology
Involving pathogenic microorganisms, pesticide and veterinary drug residue, novel foods, chemical (including biological toxins) hazardous material; set up hazard assessment model and methods for food-borne hazards; put forward high-risk food lists and hazard control measures.

Research of application technology
Including tracing technique for characteristics of food varieties, mapping technique for food production areas, labelling of food production areas and bar coding tracing technique, quality safety tracing technique for agricultural products, and inspection and testing technique, testing methods in food processing and distribution, testing methods of producing and selling forged products, quick testing of food safety, laboratory confirmation technique, standardization of testing methods and safety certification, early warning of food safety emergencies, and food safety control measures and research in food production, processing

and transportation.

6. Strengthen the building of emergency response system for food safety emergencies and major incidents
Improve emergency response system of food safety, and set up food safety quick response connecting mechanism. Improve emergency direction and decision-making system, emergency surveillance, reporting and early warning system, technical supporting system for emergency testing, system for emergency response team and material assurance, and improve the bases for training and exercises, establish on site treatment capability, and enhance government emergency treatment capability. Enhance comprehensively the supervision of investigation on major food safety incidents, improve punishment system, set up system for the return visits by emergency supervisors and gradually complete a national system of specialized food safety supervisors.

Column 6: Key Points in Building A Food Safety Emergency Response System

Emergency response and treatment
Gradually establish a coordinated network and platform for food safety emergencies and major incidents, strengthen the building of a direction and decision-making system.

Quick response of food poisoning
Establish a reporting and response system in restaurant industry regarding food poisoning. Improve capability of treatment and tracing of food poison sources.

Quick response in food processing, distribution
Establish emergency response and treatment system in food processing and distribution.

7. Establish food safety evaluation and assessment system
Establish risk analysis and evaluation system, investigate potential threats of foods and consequences and possibilities of danger, and rank the risk of foods accordingly. The result of risk assessment is provided as the basis for government to make decision and management for food safety.

Column 7: Food Safety Evaluation and Assessment System

Investigation and evaluation
Investigate and evaluate the establishment and implementation of food safety system by enterprises, as well as the safety of livestock, vegetables and fruits, aquatic products, alcoholic products, dairy products, baby products, grain and oil and their products, seasoning, instant food, bean-made products, drinking water, food additives and food packaging materials.

Risk assessment
Conduct food safety risk assessment on pesticide and veterinary drug residues, contamination of harmful and noxious substances, food additives, food packaging materials, food processing techniques and facilities.

Special inspection of key foods
Launch nationwide inspection of 15 key categories of food, and annual compulsory inspection on production and processing enterprises.

8. Improve food safety credibility system
Improve public awareness of credibility, build up an environment of credibility and develop a culture of credibility. Establish preliminarily a system to utilize food safety credibility, comprehensively promote food safety credibility system in its ability to regulate, guide and supervise food safety work. Gradually establish food safety credibility records of enterprises and execute supervision by categorization of food safety credibility. Improve the system of "local governments bare the full responsibility for food safety work, enterprises are the first responsible parties for food safety", enhance self-discipline of enterprises and establish red and black list of enterprises.

Column 8: Food Safety Credibility

Supervision by categorization of food safety credibility
Establish information system for registration records of main food production trading enterprises, and categorization database for main food producers and traders, collect widely access information of main food producers and traders, food safety supervision information, consumer complaint and report information, improve a credibility categorization supervisory system for main food producers and traders

Quantitative classification management
Carry out quantitative classification management of food inspection and strengthen health certification and supervision of food sanitation.

9. Carry on special campaigns on food safety
Severely crack down forgery of food production and trade, prioritize crackdown on high safety risk foods. Improve food safety level of production, processing, transportation and consumption of grain, meat, vegetables, fruits, dairy products, bean products and aquatic products which are closely related to people's daily life. Improve regional food safety supervision system, enhance and improve regular supervision measures of food producers, explore supervision models for rural small-sized food production, processing and trading enterprises. Effectively stop the illegal uses of non-food raw materials, abuse of food additives and food production and trade by unlicensed enterprises. Strengthen supervision of food markets, regulate food advertising, especially advertising in small and medium-sized cities. Enhance supervision of rural food safety, direct the inspection and set up modern distribution and supervision network in rural areas, to comprehensively enhance the food safety assurance capability in rural areas.

Column 9: Special Food Safety Activities

Special programs for food safety in rural areas
Strengthen special controls on pesticide and veterinary drug residues, abuse of prohibited drugs for animal and poultry products, and special controls of drug residue in aquatic products. Gradually establish a comprehensive supervisory network for rural food safety. Establish and popularize quality safety control system in small rural processing enterprises. Carry out special controls on urban-rural connecting food markets. Strengthen supervision and management of small rural restaurants and group dining places and establish reporting systems.

Special control of livestock slaughtering and processing enterprises
Severely crack down illegal slaughtering and set up guarantee system for harmless treatment of disease-affected meat.

Special control of high safety risk food processing industry
Set priorities every year to carry out comprehensive inspection and testing and implement

special controls on production and processing industry of high-risk foods.

Administration of marking and labelling
Strengthen administration of marking and labelling of food, food additives and food packaging materials.

Safety assurance
Implement food safety assurance projects for 2008 Beijing Olympics and 2010 Shanghai World Expo.

Demonstration programs Conduct special inspection on production and processing quality and set up model small enterprises and workshops. Launch self-discipline model food market, supply chains and meat producers. Establish "food safety supply chain demonstration programs", training programs for "hundred household safe meat demonstration factory", and "hundred household green food market".

10. Improve food safety accreditation
Establish a unified "from field to table" national food accreditation system. Promote accreditation of organic and green foods, as well as non-polluted agricultural products and feed. Conduct accreditation of management of agricultural product makers and processing companies. Improve regulation in production, storage and transportation, and self-management of companies. Boost the mutual recognition of food accreditation system of China and the world.

11. Strengthen import-export food safety management
Establish and improve quality safety access system of imported food and launch access procedures that are science based and in accordance with international practice. Manage imported food in categories based on risk assessment and improve the effectiveness of quarantine and inspection of imported food. Improve inspection system for imported food, especially inspection of pesticide, food additive, pathogenic micro-organisms, harmful and noxious substances and labelling. Establish and improve "one model, ten systems" food safety management system for export foods (i.e. "company + base + standardization" management model, and the ten registered management systems for growing and cultivating bases). Utilize to the most extent possible, the stipulations of the WTO "Agreement on Technical Barriers to Trade" and "Implementation of the Agreement on Sanitary and Phytosanitary Measures", establish a good food safety technical trade implementation system. Establish import-export food quality and safety control framework, establish and revise industry standards for inspection and quarantine relating to food safety testing.

Column 10 Key Points for Import & Export Food Safety Administration

Improve import and export food safety quality administration system
Carry out risk assessment, establish and improve inspection and quarantine access procedures for imported foods and market access requirements for all kinds of foodstuffs; implement import and export food quality safety monitoring plan. Establish epidemic, disease, pesticide and veterinary drug residue monitoring system for exported foods, and carry out electronic supervision on export food production and processing enterprises. Carry out export food quality traceability and recall systems, construct risk forecast and quick response systems and release red and black lists of import and export enterprises.

Enhance technical assurance capability in import and export food inspection and quarantine
Reinforce the import and export food testing capability and the building of expert team and

improve import and export food safety information system.

12. Carry out advocacy, education and training on food safety
Formulate the outline for food safety advocacy and education. Reinforce advocacy reporting on laws, regulations, policies and standards for food safety, popularize basic knowledge of food safety, enhance social awareness of food safety and strengthen consumer capabilities of self-protection, participation and surveillance. Accelerate the construction of food safety training system and hold food safety education and training programs of various forms and through various channels to government officials, law enforcers, enterprise managers and staff, journalists and consumers.

Column 11: Food Safety Advocacy, Education and Training

Food safety advocacy and education
Conduct activities like "Bring food safety to the countryside", "Bring Food Safety to the Community" and "Bring Food Safety to the Campus". Develop the concept of "green consumption" and popularize education on food safety knowledge.

Project on upgrading the qualities of food safety supervisors
Carry out trainings on relevant food safety knowledge to law enforcers and professional technical personnel responsible for food safety supervision, raise their awareness of food safety knowledge and enhance their supervision capabilities.

Project on upgrading the qualities of first-line responsible persons for food safety
Strengthen training and education on legal representatives and managers of food production and business enterprises, raise their awareness of food safety knowledge and improve their food security assurance capability.

II Drug Safety
13. Improve the level of drug safety supervision
(1) Establish scientific drug assessment system.
Strengthen the construction of administrative regulations on drug registration and formulate the principles of guidance on drug research and technological development. Integrate administrative resources of drug registration, push forward the reform on drug registration and evaluation systems, control rigorously the registration and approval procedures for drugs and establish efficient turn-around and economical drug registration administrative system. Reinforce supervision and inspection on drug clinical research and the process prior to clinical practices and fully realize the conduct of drug non-clinical and clinical experiments under the supervision of Good Laboratory Practice (GLP) and Good Clinical Practice (GCP). Develop the research on drug evaluation technical methods, enhance and standardize safety evaluation techniques on innovative drugs and drugs imported into our country and encourage innovative drug research and development. Reinforce drug standards administration and implement "Activity Plan of Improving National Drug Standards". Establish the improved scientific assessment system of biotechnology products. Improve the national standards systems for pharmaceutical supplements and packaging materials and containers, which are in direct, contact with medicines. Establish an improved evaluation system of health food registration and inspection.

(2) Reinforce supervision on drug production quality.
Further improve the accreditation system of Good Drug Manufacture Practice (GDMP), revise the GDMP, enhance the implementation level of GDMP, and gradually meet the standards of GDMP in developed countries; strengthen dynamic supervision on pharmaceutical production,

ensure the quality of pharmaceutical production and promote the healthy development of pharmaceutical industry; push forward the implementation of Good Preparation Practice (GPP); strengthen supervision on the sources of Chinese medicines, improve the administrative system for Good Chinese Medicine Production Practice (GCMP), push forward the implementation of GCMP and ensure the production quality of Chinese herbal medicines; and strengthen supervision on pharmaceutical supplements and packaging materials and containers which are in direct contact with medicines.

(3) Improve the supervision system for drugs approved into the market
Improve the monitoring network for adverse drug reaction, standardize adverse drug reaction and reporting monitoring systems, and strengthen the responsibilities of reporting adverse drug reaction. Formulate and implement Drug Re-evaluation Management Measures, put in place the supporting technical specifications and guidelines and carry out periodic and in batches the re-evaluation of drugs approved into the market. Establish and improve long-term risk management mechanisms on monitoring, early warning, emergency response, withdrawal from shelves and elimination of drugs approved into the market. Strengthen the construction of adverse drug reaction monitoring bodies, improve the monitoring system for adverse drug reactions, and enhance the adverse drug reaction monitoring capabilities at the city (prefecture) and county levels. Further improve the classification management system of prescription and non-prescription drugs, consistent with the medical system reform, fully implement the classification management of prescription and non-prescription drugs and push forward the legislation on the classification management of prescription and non-prescription drugs. Further standardize drug packaging and usage directions. Amend the accreditation standards of Good Supply Practice (GSP), improve the accreditation management measures of GSP and traceability system, formulate and implement Good Distribution Practice (GDP) and promote the development of modern logistics. Establish and improve drug abuse monitoring network and supervision network of special medicines and monitor the movement of each needle and each pill of special medicines. Establish monitoring reporting and early warning system for abuse and misuse accidents of narcotic drugs and psychotropic drugs, and improve the evaluation methodology and criteria of drug dependency and abuse potential of narcotic and psychotropic drugs.

(4) Improve the construction of drug testing system.
Standardize the functions of drug testing agencies at all levels; rational allotment of drug testing resources; strengthen the studies on drug testing and inspection methods, establish technical platform for drug testing system and popularize rapid testing techniques; establish and improve information and data exchange systems of national drug testing techniques; improve drug testing system integrated with submission, sampling and approval, reform drug supervision sampling system and enhance the efficiency of the use of funds for drug sampling.

(5) Establish and improve Chinese medicine standards and technical evaluation system.
Establish and improve Chinese medicine classification system and formulate management and technical evaluation criteria; construct the fundamental framework for Chinese medicine standards and technical evaluation system with Chinese characteristics and in conformity to the law of Chinese medicines, formulate and improve standards of Chinese herbal medicine, Chinese herbal medicine pills and Chinese traditional patent medicine, and establish the technical standards for Chinese herb germplasm collection and breeding, and appraisal technical specifications for characteristics of genuine traditional Chinese medicines; further improve the standards and specifications for the production and processing of Chinese medicine, Chinese herbal medicine pill and the procedure for Chinese formulated medicines; establish the quality assurance system for genuine traditional Chinese medicine; formulate technical evaluation standards before the Chinese medicine appear in the market and re-evaluation standards after the Chinese medicine appears in the market; formulate research

guiding principles of reference materials for Chinese medicines and establish Chinese medicine library for standard materials. Reinforce national support and supervision of national drugs. Actively advocate the establishment of international coordination mechanism for traditional medicines.

Column 12: Drug Supervision and Control

Activity plan for upgrading the national drug standards
Upgrade the standards of 4,000 varieties of Chinese traditional patent medicine, 500 varieties of chemical drugs and rectify the standards for 300 varieties of early stage new drugs, formulate standards of 223 varieties of common pharmaceutical supplements and complete formulation and revision of national standards for 1,000 Chinese herbs and 500 Chinese medicine pills.

Key projects for drug re-evaluation after market entry
Establish drug re-evaluation database and information exchange platform, provide safety information of drugs approved for the market, and conduct re-evaluation on key varieties like injection Chinese medicines.

Projects for technology innovation and personnel training
Promote technology innovation projects focused on studies of biotechnology products, Chinese medicine quality standardization, tissue engineering and stem cell medical products and quality control standards, new technologies and models of safety evaluation as well as the studies of testing technologies. Develop distance education system, carry out medical device management, technical and professional training, and complete demonstration training programs for leaders of pharmaceutical regulatory bodies at the provincial, city (prefecture) and county levels.

14. Standardize safety supervision on medical devices.
(1) Establish an improved medical device regulatory system.
Improve the regulatory system for medical device, timely amend Regulations for the Supervision and Administration of Medical Devices, formulate and implement Regulations for the Supervision and Administration of the Distribution of Medical Devices, formulate and revise the following regulations: Administration of Medical Devices Registration, Administration of the Registration of In Vitro Diagnostic Reagents, Administrative of Standards of Medical Devices, Classification Catalogue of Medical Devices, Stipulations on Medical Device Clinical Test, etc.

(2) Strengthen the construction of a medical device standards system.
Improve the medical device standards system, formulate and revise 500 national and industry standards, reinforce collaboration with international standardization organizations and enhance the adoption rate of international standards; and establish research and verification mechanism on medical device-related standard materials.

(3) Strengthen capacity building of medical device testing system.
Strengthen testing capacity building of national and provincial medical device. Make full use of societal resources and expand accreditation of testing agencies; improve the testing capacities for electrical safety, electromagnetic safety and bio-safety of medical devices; and strengthen the testing of high-risk medical devices. Establish working mechanism and system for the supervision of test sampling of medical devices and appraisal test sampling, expand testing items and scopes, standardize test sampling activities and strengthen test sampling efforts.

(4) Strengthen the construction of medical device appraisal and approval system.

Establish and improve national and provincial medical device technical appraisal system, establish teams of appraisal experts, and set up platform for the exchange and communication of medical device technology appraisal; establish and improve integrated technological appraisal standards; and standardize registration and approval procedures of medical devices. Improve medical device clinical test agencies, and carry out the qualification accreditation of clinical test agencies in line with the characteristics of medical devices profession. Establish clinical test appraisal and approval system for modern medical devices and high-risk medical devices.

(5) Strengthen quality control system of medical devices.
Formulate and implement step-by-step the general principles of quality control of medical devices and sterile medical devices, application guidelines of implantable medical devices, active medical devices, passive medical devices, active non-contact medical devices and in vitro diagnostic reagents and working guidelines for inspectors. Conduct quality management training programs on medical devices and strengthen the team building of inspectors. Gradually inspect the second and third category of medical device manufacturers on implementation of quality control system and urge the manufacturers to meet the requirements of the standards.

(6) Strengthen the construction of monitoring and re-evaluation system for adverse events of medical devices.
Formulate and implement Measures on Monitoring and Re-evaluation Management on Medical Device Adverse Events and Medical Device Recall Measures, formulate corresponding technical guidelines and standards, establish and improve the reporting system and strengthen the reporting responsibilities and obligations of the enterprises. Establish a technical platform for risk assessment of medical device approved for entry into the market, and establish early warning and recall systems.

(7) Strengthen supervision on the use of medical devices.
Reinforce research on the use of medical devices, and establish the supervision system on the use of medical devices. Strengthen technical research on medical device service life and product discard standards, establish supervisory evaluation methods for the use of medical devices, and enhance the efficiency of supervision on the use of medical devices.

Column 13: Supervision of Medical Device

Medical device standards
The adoption rate of international standards is to reach 80%. Complete 200 standards for medical-use electric devices, 200 standards for medical-used passive products, 100 standards for diagnostic reagent products, accomplish the formulation and amendment of general safety standards for medical-use electric devices (the 2nd Version) and basic standards for electromagnetic compatibility.

Project of Capacity Building of the Testing of Medical Devices
Reinforce construction of national laboratory for biological functions of medical devices and improve medical devices testing system.

15. Strengthen supervision on pharmaceutical and medical devices market.
(1) Severely crack down on making and selling of fake and shoddy medicines and medical devices. Focus on key investigations of major cases of making and selling fake and shoddy medicines and medical devices with extensive coverage, high-impact, and strong reaction by the public, any activity which constitutes a crime should be timely transferred to the judiciary to legally place the responsibility for the crime. Strengthen supervision on Chinese herbal

medicine market, Chinese herbal medicine and Chinese herbal medicine pills, and strongly rectify and standardize market order.

(2) Continue to rectify and standardize the advertisement of medicine and medical devices. Strengthen the building of qualities of people responsible for reviewing and approving advertisements. Review the contents of the advertisements strictly in accordance with relevant standards, establish an advertisement-monitoring network and intensify monitoring. Strengthen publicity of laws and regulations related to the advertisement of medicines and medical devices, increase the public's ability to distinguish unlawful advertisements and actively promote the effect of supervision by the society. Guide advertisers, advertising companies and advertisement disseminators to advertise in accordance with the laws, and block illegal advertising channels. Severely punish the manufacturers and traders of medicines and medical devices who seriously violate the laws. Gradually establish a comprehensive management and rectification system.

(3) Promote the building of a credibility system for medicines and medical devices. Improve credibility classification management of medicine, establish a integral credibility filing system from administration to people. Establish a credibility management system of medical device manufacturers, strengthen the construction of credibility evaluation quality system and credibility public information system, establish and improve the credibility monitoring files of medical device manufacturers and build medical device credibility operation mechanism. Establish "reputation files" for experts and departments involved in the evaluation of medicines and medical device products, approval of enterprises and accreditation inspection.

(4) Push forward the in-depth building of rural medicine supervision networks and supply networks. Collect experience in building rural medicine supervision networks and supply networks and establish a healthy operational mechanism. The building of rural medicine supervision networks and supply networks should be integrated with the construction of new socialist countryside, especially with that of new rural cooperative medical system. Formulate the guidance policy and supervision measures in accordance with the reality of rural medicine supply, encourage and guide the construction of medicine supply network in line with the development of modern logistics, support and provide guidance to self-collection, self-growing and self-application of Chinese herbal medicines by the rural basic medical institutes and ensure that farmers can access medicines safely, effectively, conveniently and timely.

Column 14: Drug Safety Supervision in Rural Areas

Building Drug Supervision Network and Drug Supply Network in Rural Areas: Guide, support and encourage legally operating drug enterprises to collect and supply to villages through the guidance of policies, to establish rural drug stores that are adapted to needs. Provide assistance to staff working on supervision and information, reinforce the drug supervision efforts in rural areas, disseminate basic drug use knowledge to farmers, establish "well functioning and effectively supervised" drug supervision networks and drug supply networks, to ensure drug use safety in rural areas through supervision efforts on various links from sources, through circulation to usage. To realize 100% coverage for drug supervision network, and 80% coverage for drug supply network.

16. Re-enforce emergency response capacity building towards group accidents caused by drugs and medical devices.
In order to accelerate the construction of monitoring and alert networks over unexpected group accidents associated with drugs and medical devices, so as to improve the

coordination and control as well as the rapid response capability in face of such accidents; to strengthen the emergency response capability of drugs and medical devices inspection institutions in key areas. To strengthen the efforts to render harmless fake drugs and medical devices according to the principle of "treatment on site or in close areas". To actively investigate a compensation system for harms caused by drugs.

Column 15 Building of Emergency Response Capability for Drug and Medical Device Safety

Key Points for Building Emergency Response
Reinforce the construction of national training and exercise bases for emergency response and treatment of drug and medical device accidents, improve the quality of emergency response teams, install equipment and apparatus necessary for emergency treatment, develop training courses on emergency response knowledge and capability and organize regular emergency response exercises, to enhance emergency treatment capability.

17. Promote the Advance of Systematization of Drug and Medical Device Supervision Information
To implement the "3511" Program, designed to promote inter-connection, communication and information sharing so as to attain the synergy amongst governmental departments and improve the efficiency and level of supervision. To accelerate the construction of various core business systems in drug and medical device registration, assessment, enterprise accreditation and verification, *inter-alia*. To expand and perfect the public service system, to accelerate the steps to open up the administration and supervision of drug and medical device, to continuously raise the level of services for enterprises and the general public.

Column 16: Systematization of Drug and Medical Device Supervision Information

The "3511" Program, on the basis of the existing integral administration network, is designed to establish and improve drug supervision information systems at national, provincial and municipal (regional) levels. To build on the basis of integrating existing resources, three information platforms (information infrastructure platform, information security platform and application supporting platform), five application systems (administrative access management system, integrated law enforcement administration system, rapid response system to major incidents, drug and medical device inspection and testing system and public service system), one center (Drug Supervision Information Resource Center) and one standard system (Construct a standardized system of State Food and Drug Administration information).

18. Improve drug and medical device supervision infrastructure
Overall plans must be worked out in order to improve working and equipment conditions by constructing office buildings and furnishing with necessary enforcement equipment within law enforcement institutions, so that in five years from now their office and enforcement equipment capacity will basically meet the demand arising from the enforcement activities, while regions economically more advanced are allowed to lead the move in an appropriate way. Integrate existing inspection and testing resources, establish reasonable schemes, improve experimental conditions, provide equipment and apparatus, to totally raise the hardware standard supported by high technology.

Column 17: Infrastructure for Drug and Medical Device Supervision

Infrastructure construction program

To aim at strengthening the building of infrastructure of enforcement units of local drug and medical device supervision authorities; to reform provincial and municipal drug inspection and testing institutions; and to provide them with basic equipment, facilities and apparatus for enforcement. Meanwhile, it is necessary to speed up the construction of the drug adverse reaction-monitoring network and implement the Project for the Relocation and Reconstruction of China Drug and Bio-products Assay Institute.

PART Four Assurance Measures

I. Establish Scientifically Sound Concepts on Supervision and Renovate Supervision Institutes and Mechanisms

According to the scientific concept of development and the specific requirements of institutional reform of the administration system of the state, actively probe, and renovate supervision institutions and mechanisms. With regard to food safety supervision, strengthen institutional construction, progress further to rationalize the responsibilities of relevant supervision departments, gradually establish a set of highly effective supervision institutes which are compatible with the requirements of scientific concept of development where responsibilities are clearly defined; avoid gaps in supervision; strengthen integrated law enforcement and combined law enforcement of related departments; actively probe, renovate and perfect the institutes of food safety supervision, gradually establish the lasting effective institutions for food safety supervision. On the aspect of drug supervision, institutional reform is to be advanced and the supervision mechanism to be improved by centralized decision-making, unified coordination and supervision exercised by administrative regions. Drug examination, approval and random inspection mechanism must be improved, the reform of administrative law enforcement system to be deepened so as to regulate enforcement activities of administrative laws, to renovate supervision mechanisms at various levels and to ensure enforcement can be well targeted. Problems newly found in the development should be properly handled and resolved, supervision capacity and capability must be enhanced.

II. Improve Safety Responsibility System, Reinforce Sense of Responsibility of Enterprises

In accordance with the requirements of "the local governments take overall responsibilities, supervision departments shoulder their respective responsibilities and enterprises be the first responsible persons", food and drug safety responsibility systems should be established. Local governments are to strengthen organizing and leading efforts, periodically carry out analysis on local food and drug safety situation, establish supervision measures, reinforce supervision and inspection, and effectively handle food and drug safety incidents. All governmental departments are to collaborate and link up with each other to form a complete supervision chain. Production and marketing enterprises are to strengthen the awareness of self-discipline and fulfillment of responsibility, to build and complete corporate responsibility system and self-discipline system, to perfect internal management, enhance corporate credibility and to actively comply with and shoulder food and drug safety responsibility.

III. Complete Law and Regulatory System, Vigorously Promote Administration According to Law

Advances in food sanitation law legislation and revisions should be attained in a timely manner, organizing efforts focused on implementing the Law of Agricultural Products Quality and Safety of the People's Republic of China should be carried out and the regulatory system related to food safety shall be established and perfected; Drug Administration Law of the People's Republic of China and the Rules for the Implementation of the Drug Administration Law of the People's Republic of China should be strictly complied with and a regulatory system related to food and drug safety shall be preliminarily put in place during the Eleventh Five Year Plan period. Deepen the reform of the administrative examination and approval

system, renovate the examination and approval methods, normalize examination and approval procedures, and advance the practice of making governmental affairs public. Establish public hearing and verification system for significant policy making in food and drug supervision, strengthen the administrative case review system. Renovate the mechanisms of supervision on administrative law enforcement, strengthen the supervision on the enforcement of administrative laws, establish and improve the responsibility tracking system, enhance the effectiveness on the supervision of the implementation of administrative laws. Enforce training activities on laws and regulations for grass root enforcement staff, in order to improve their overall quality and enforcement capability of administrative laws.

IV. Increase Government Input, Provide Required Financial Assurance

All levels of government must increase their input into all planned programs to which necessary support and financial assurance based on full utilization and reasonable allocation of existing resources shall be granted while taking into consideration specific situations of each case and following the principal of "being realistic and practical and behaving according to each one's own capabilities", so as to support food and drug safety infrastructure construction, improve food and drug safety supervision capabilities and ensure successful supervision enforcement.

V. Promote the Effectiveness of Societal Supervision, Cultivate Favorable Atmosphere for Public Opinions

Fully promote the effectiveness of the roles of food and drug related industry associations, institutes and intermediate organizations in credibility building, industry self-discipline as well as food and drug safety promotion. Encourage the establishment of various specialized food and drug safety organizations so as to fully make use of their advisory functions in the policy making process. Strengthen the publicity and dissemination of laws and regulations on food and drug safety, strengthen positive media reports on food and drug safety, timely publicize information on food and drug safety, guide public consumption choices, encourage media to supervise public opinions according to law, create favorable conditions for governmental supervision and regulation. Fully promote the effectiveness of consumer supervision, further improve the information collection channels of consumer complaints, build a system of supervision and regulation for market circulation with ample public participation, and complete the communication mechanism between government and consumers in the area of food and drug safety.

VI. Strengthen the Exchange of International Cooperation, Accelerate the Raising of Supervision Level

Through external exchanges and governmental cooperation, actively publicize the laws, regulations and policies for food and drug safety supervision of our country, to enlarge the international influence of our food and drug safety supervision, and to enhance our international standing in this field. Improve the professional quality and internationalization level of public servants through various means of exchange. Actively participate in related activities of the WTO, improve international food and drug safety cooperation and consultation mechanisms, maintain and develop cooperation and work exchange with relevant international organizations, food and drug safety supervision institutions of developed countries, study the advanced concepts and models of food and drug supervision, scientific standards system, advanced inspection and testing methods as well as safety management methods, so as to continuously improve our food and drug safety supervision level.

VII. Establish Mechanism for the Implementation of the Plan, Ensure the Realization of the Planned Goals

This plan is a guiding document for the work on food and drug safety supervision activities for the nation during the period of the 11th Five-Year Plan, the smooth implementation of

this plan will be a concrete demonstration for the proper execution of government responsibilities. The food and drug supervision departments are in charge of the overall coordination, individual related governmental departments are required to elaborate work plans for relevant areas within their respective responsibilities and organize their implementation. During the implementation of those plans, all relevant departments are to effectively strengthen their leadership, to be farsighted based on the current situation, to advance fully the supervision tasks, and to make key breakthroughs. Meanwhile, do well on the details of the work, analyze by item the work according to the goals of the plan, and match them closely with the corresponding annual work arrangement, propose the requirements, in order to carry out concrete implementations. Strengthen supervision, monitoring and evaluation, make timely suggestions for responsive adjustments to the plan, carry out linkage and supplementary work for the implementation of the plan, in order to ensure the due realization of the plan.

END TRANSLATION

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China to attach inspection and quarantine labels for food exports

2007

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Report Highlights:
This is an unofficial translation of an announcement by China's General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ) stating that the quarantine agency will be affixing inspection and quarantine labels to packages of all food products destined for export beginning September 1, 2007.

Includes PSD Changes: No
Includes Trade Matrix: No
Unscheduled Report
Beijing [CH1]
[CH]

Executive Summary

China's quarantine agency AQSIQ recently announced that the entry-exit inspection and quarantine bureaus (CIQs) will begin affixing inspection and quarantine labels to packages for sale of all food products destined for export after being inspected as of September 1, 2007. According to AQSIQ, the move is aimed at ensuring export food quality and safety and cracking down on illegal (unlicensed) food exports. The recent uncovering of food safety problems has been an issue of great concern as other countries have come to question China's food safety and export control system and enforcement.

BEGIN TRANSLATION

Announcement of Affixing Inspection and Quarantine Labels on Exported Food Products

AQSIQ No. 85 (2007)
June 1, 2007

In an effort to ensure exported food quality and safety, crack down on illegal food exports and safeguard the reputation of exported food, AQSIQ has decided that all exported food products which have been inspected by exit-entry inspection and quarantine agencies shall be affixed with an inspection and quarantine label as of September 1, 2007. Details are as follows:

1) All food products that have been inspected by exit-entry inspection and quarantine agencies shall be affixed with an inspection and quarantine label on their packages for sale. The scope of food products subject to this requirement can be found in the appendix.
2) Along with the inspection and quarantine labels, all food products that have been inspected by exit-entry inspection and quarantine agencies should indicate the manufacturer, hygiene registration number, product name, production serial number and production date on their packages during transportation. The exit-entry inspection and quarantine agencies should indicate the above information on the documents and certificates they produce in order to make sure that the products conform to the documents and are easy to trace back.
3) In case the exit-entry inspection and quarantine agencies find that an exported food fails to conform to the documents or is missing an inspection and quarantine label, the product will not be allowed for export.
4) Other procedures pertaining to affixing inspection and quarantine labels shall be implemented in accordance with *Administrative Measures on Exit-entry Inspection and Quarantine Labels* (AQSIQ Decree No. 23 of 2000).

Appendix:

Scope of exported foods subject to inspection and quarantine labels:

Aquatic products, poultry and livestock, wild animal meat and products, casings, egg and products, edible animal tallow, and other animal-origin foods; rice, coarse grain (beans), vegetable and products, wheat flour and grain products, pickled products, peanuts, tea, cocoa, coffee beans, malt, hop, edible seeds, dry (fried) nuts, edible vegetable oil, oilseeds, condiments, milk and dairy products, health food, wine and spirits, canned food, beverage, candies and confectionary, cakes and biscuits, preserved fruit, honey products, fast-frozen food, and food additives.

The above food products must affix (inspection and quarantine) labels on packages for sale; no need to affix labels on packages such as baskets or jute bags during transportation; food in bulk is free from labeling.

END TRANSLATION

Regulations & Policies

Import Information

Eligible Foreign Establishments

Receive Eligible Foreign Establishment updates by email

Recent Updates
Denmark (Oct 8, 2007; PDF Only)
Canada (Oct 3, 2007; PDF Only)
Mexico (Oct 2, 2007; PDF Only)

Countries listed below are recognized as eligible to export to the United States. Select a country below for a complete listing of foreign establishments certified to export meat, poultry or egg products to the United States.

Contact the foreign country's inspection system (or their embassy) for additional information related to the eligible foreign establishments.

Eligible Foreign Meat and Poultry Establishments

Eligible Countries	Type of Product
Argentina (Aug 22, 2006; PDF Only)	Meat
Australia (Jul 9, 2007; PDF Only)	Meat; Poultry (Ratites only)
Belgium (Jun 8, 2005; PDF Only)	Meat
Brazil (Aug 10, 2007; PDF Only)	Meat
Canada (Oct 3, 2007; PDF Only)	Meat; Poultry
Canada (Aug 28, 2006; PDF Only)	Egg Products
Chile (Jul 12, 2007; PDF Only)	Meat
China (Feb 9, 2007; PDF Only)	Poultry
Costa Rica (Feb 7, 2006; PDF Only)	Meat
Croatia (Jun 8, 2005; PDF Only)	Meat
Czech Republic (Jun 8, 2005; PDF Only)	Meat
Denmark (Oct 8, 2007; PDF Only)	Meat
Finland (Feb 6, 2007; PDF Only)	Meat
France (Feb 22, 2007; PDF Only)	Meat; Poultry
Germany (Mar 2, 2007; PDF Only)	Meat
Honduras (Jun 8, 2005; PDF Only)	Meat
Hungary (Aug 27, 2007; PDF Only)	Meat

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To view PDF files you must have Adobe Reader installed on your computer.

Iceland (Jun 8, 2005; PDF Only)	Meat
Ireland (Nov 18, 2005; PDF Only)	Meat
Israel (Feb 2, 2007; PDF Only)	Poultry
Italy (Sep 25, 2007; PDF Only)	Meat
Japan (Jun 9, 2005; PDF Only)	Meat
Mexico (Oct 2, 2007; PDF Only)	Meat; Poultry*
Netherlands (Apr 20, 2007; PDF Only)	Meat
New Zealand (Sep 24, 2007; PDF Only)	Meat; Poultry (Ratites only)
Nicaragua (Dec 17, 2005; PDF Only)	Meat
Northern Ireland (Jun 8, 2005; PDF Only)	Meat
Poland (May 22, 2007; PDF Only)	Meat
Romania (Jan 22, 2007; PDF Only)	Meat
San Marino (Apr 17, 2007; PDF Only)	Meat
Spain (Sep 24, 2007; PDF Only)	Meat
Sweden (Jun 8, 2005; PDF Only)	Meat
United Kingdom (Jun 8, 2005; PDF Only)	Meat; Poultry
Uruguay (Jan 11, 2007; PDF Only)	Meat

*Mexico approved to export only processed poultry products slaughtered under Federal inspection in the United States or in a country eligible to export slaughtered poultry to the United States.

Last Modified: October 8, 2007

The Quality and Safety of Food in China

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Information Office of the State Council
of the People's Republic of China

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I. Food Production and Food Quality

The quality and safety of food is a major benchmark of the economic development and people's living conditions of a country. Adhering to the people-oriented approach, the Chinese government has always attached great importance to food quality and safety. Moreover, sticking to the principle of nipping problems in the bud, it has built and improved a supervisory system and mechanism for food safety, strengthened legislation and the setting of relevant standards, exercised strict quality control regarding food, actively promoted international exchanges and cooperation in this respect, and has greatly raised public awareness of food safety. Thanks to such efforts, the overall level of food quality in China is being steadily enhanced, the situation of food safety is continuously improving, and the order in food production and operation have markedly turned for the better.

I. Food Production and Food Quality

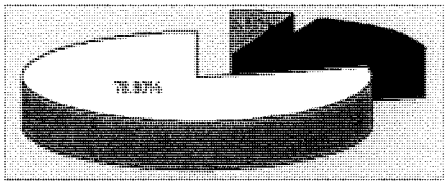
1. The Quality and Safety Level of Processed Food Is Steadily Improving

(1) Rapid and Sound Development of the Food-processing Industry

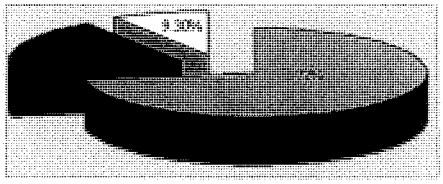
In recent years, China's food industry has maintained fast and sound growth, with a steady increase in economic benefits. Foodstuffs can be classified by their raw materials and processing techniques into 525 kinds in 28 categories: processed grain products; edible oil, fat and fat products; seasonings; meat products; dairy products; soft drinks; convenient food; biscuits; canned food; iced drinks; fast-frozen food; potato and dilated food; candies (including chocolate and chocolate products); tea; alcoholic beverages; vegetable products; fruit products; roasted seeds and nuts; egg products; cocoa and bakery coffee products; sugar; processed aquatic products; starch and starch products; pastries; bean products; bee products; special diet food, and others. At present, China has 448,000 enterprises engaged in foodstuff production and processing. Among them, 26,000 enterprises of designated scale 1 occupy 72 percent of the market, taking the leading role in terms of output and sales revenue; 69,000 are enterprises not up to the designated scale and those with more than ten employees, taking up a market share of 18.7 percent; and 353,000 are small businesses or workshops with fewer than ten employees, with a market share of 9.3 percent. (See Table 1)

1 Refering to private industrial enterprises with annual revenue of two million yuan or more and all state-owned industrial enterprises, as well as private commercial enterprises with annual revenue of five million yuan or more and all state-owned commercial enterprises. — *Tr.*

Table 1 Chinese food enterprises of different types and their respective market shares



- Enterprises of designated scale
- Enterprises not up to the designated scale and those with more than ten employees
- Small businesses and workshops with fewer than ten employees



□ Market share of enterprises of designated scale

■ Market share of enterprises not up to the designated scale and those with more than ten employees

□ Market share of small businesses and workshops with fewer than ten employees

Statistics show that, in 2006, industrial food enterprises of designated scale generated 2,158.695 billion yuan of output value (excluding tobacco), accounting for 6.8 percent of the national industrial output value, and up 23.5 percent year on year. The average annual industrial added value and profit of processing enterprises of grain, oil, meat and dairy products all exceeded 20 percent. The output of major foodstuffs in 2006 were: wheat flour, 51.93 million tons; edible vegetable oil, 19.855 million tons; fresh frozen meat, 11.125 million tons; dairy products, 14.596 million tons; beer, 35.152 million kl; and soft drinks, 42.198 million tons. These figures show rises of 28.2 percent, 17.5 percent, 24.0 percent, 23.5 percent, 14.7 percent and 21.5 percent year on year, respectively. In the first six months of 2007, the accumulated output value of the food industry amounted to 1,281.62 billion yuan, up 29.9 percent as compared with the corresponding period last year. The output of beer, edible oil, soft drinks and gourmet powder led the world.

At present, the development of China's food industry displays the following features:

One, the processing techniques and equipment of some food enterprises reach or approach the advanced international level. Large meat, dairy product, beverage and beer producers all have world first-class production and testing facilities, which guarantees the quality of their products. The development and application of such key processing techniques as membrane-separation technology, physical property modification, cold-aseptic filling, concentration and cold processing has narrowed China's gap with the world advanced level in terms of processing technology and equipment.

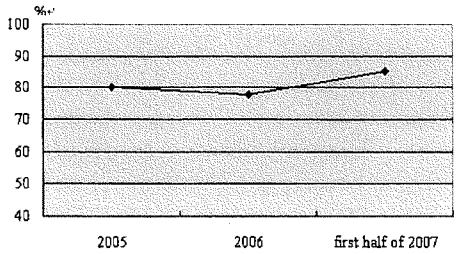
Two, quality control of the enterprises has become more scientific and standard. So far, 107,000 food producers have obtained market access permits regarding quality and safety, and 2,675 have been granted hazard analysis and critical control point (HACCP) certificates.

Three, the structure of products is being improved to cater to the increasingly diverse demands of consumers. The proportion of intensively or deeply processed foodstuffs to the total output of foodstuffs keeps increasing. For instance, liquid dairies now account for more than 85 percent of the total output of dairy products; colas no longer dominate the market, as a result of the mushrooming of packed drinking water and fruit, vegetable and tea drinks; special flour above second grade accounts for 65 percent of the total output of wheat flour; standard rice above first grade accounts for 88 percent of the total output of rice, and special rice for 33.9 percent of the total output of rice; and Grades I and II oil (salad oil and quality culinary oil according to previous national standards) accounts for 58.5 percent of the total output of edible vegetable oil.

(2) Continuous Improvement of Food Quality

One, the acceptance rate of foodstuffs on the whole is steadily rising. The rate was 77.9 percent in the 2006 national foodstuffs sample survey, and it rose to 85.1 percent in a similar survey in the first half of 2007. The level of food quality and safety remains stable, with a gradual upturn. (See Table 2)

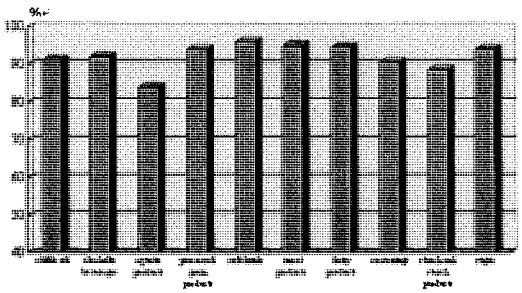
Table 2 Acceptance rate of foodstuffs in sample surveys from 2005 to June 2007



Two, the quality of food produced nationwide is improving. In the first half of 2007, the 31 provinces, autonomous regions and municipalities directly under the Central Government on the mainland of China reported an average 89.2-percent acceptance rate of foodstuffs, and the figure in 14 of them surpassed 90 percent.

Three, the quality of food in key sectors is fairly high. Thanks to the country's endeavors to improve the work of food producers and processors, the quality of 525 kinds of foodstuffs in 28 categories has been enhanced to various degrees, with remarkable progress in the quality of food with a large daily consumption. According to statistics, the ten foodstuffs with the largest consumption are edible oil, fat and fat products; alcoholic beverages; aquatic products; processed grain products; soft drinks; meat products; dairy products; seasonings; starch and starch products; and sugar. In the first half of 2007, sample surveys showed a 90-percent or higher acceptance rate of all the above ten foodstuffs except aquatic products, whose acceptance rate was 85 percent. That of meat products was 97.6 percent. (See Table 3)

Table 3 Acceptance rate of the ten most-consumed foodstuffs in the first half of 2007



(3) Quality Food Dominating the Market

Along with the development of the food industry, the scale of food producers keeps growing, production is becoming more concentrated, and the quality of foodstuffs of large and medium-sized producers is sound. In 2006, the top 100 revenue earners held 24.9 percent of the total sales of the food industry; the top ten dairy producers generated 54.7 percent of the total revenue of the dairy industry; the top ten soft-drink producers generated 39.5 percent of the total output of that industry; the top ten sugar makers produced 43.6 percent of the total output of the sugar industry; the top 50 meat producers accounted for 70 percent of that industry in terms of production capacity and sales; the eight beer brewery groups, each with a production capacity of over one million kl, produced 57 percent of the national beer output; the ten largest wineries produced 62.1 percent of the national output; and the three largest instant noodle producers occupied 76 percent of the Chinese market.

2. The Quality and Safety of Agricultural Products Is Steadily Improving

(1) Fast Growth of High-quality and Safe Brands

Quality agricultural products are steadily expanding their market. Agricultural standardization has been notably enhanced, which increases farmers' income and changes their farming patterns. Hazard-free, green and organic products make up 90 percent of all agricultural-product exports. Over the past five years, the export of green food has shot up 40 percent annually, and has been accepted by over 40 of China's trading partners. So far, China has developed 28,600 kinds of hazard-free agricultural products, and set up 24,600 hazard-free production bases with a total area of 21.07 million hectares. Five thousand three hundred and fifteen Chinese enterprises use the green food logo on their 14,339 kinds of products totaling 72 million tons and grown on 10 million hectares of land. In addition, 600 producers use the organic food logo on their 2,647 kinds of products totaling 19.56 million tons and grown on 3.11 million hectares of land. Altogether, there are 539 state-level agricultural demonstration zones, 100 demonstration counties (farms) and nearly 3,500 provincial-level demonstration zones, with a combined growing area exceeding 33.33 million hectares.

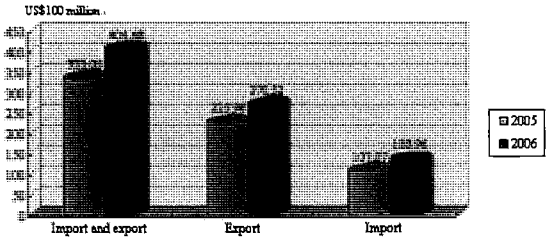
(2) Acceptance Rate of Agricultural Products Rising Continuously

Inspections in the first half of 2007 showed that the average acceptance rate regarding pesticide residues in vegetables was 93.6 percent; those regarding clenbuterol hydrochloride contamination and sulfa drug residues in livestock products was 98.8 percent and 99.0 percent respectively; and that regarding chloromycetin in aquatic products was 99.6 percent, of nitrofuran 91.4 percent, and of pesticide residue over 95 percent in sample surveys done at production bases.

3. The Quality of Imported and Exported Foodstuffs Stays High

China is a large importer and exporter of foodstuffs, with the amount of each growing steadily in recent years. The import and export volume in 2006 totaled US$40.448 billion-worth (excluding wheat, corn and soybean, same below), up 21.45 percent year on year. (See Table 4)

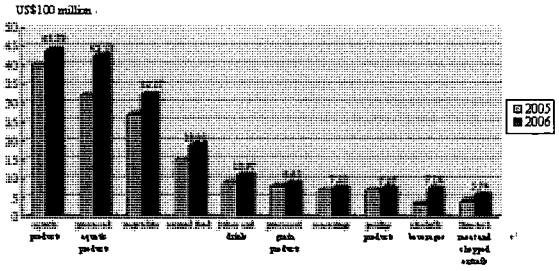
Table 4 China's food import and export volumes in 2005 and 2006



(1) Safety of Export Food Guaranteed

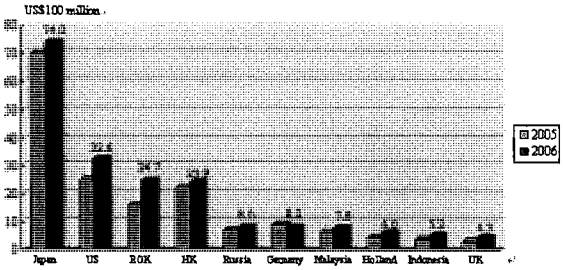
In 2006, China exported 24.173 million tons of food, worth US$26.659 billion, up 13.29 percent and 16.0 percent year on year, respectively. The top ten varieties in terms of export value were aquatic products, processed aquatic products, vegetables, canned food, juices and drinks, processed grain products, seasonings, poultry products, alcoholic beverages, and livestock meat and chopped entrails. (See Table 5)

Table 5 Top ten food varieties in terms of export value in 2006 as compared with 2005



Foodstuffs of the mainland of China have been exported to more than 200 countries and regions, of which the top ten in terms of trade volume are Japan, the US, the ROK, Hong Kong, Russia, Germany, Malaysia, Holland, Indonesia and the UK. (See Table 6)

Table 6 Top ten countries and region in terms of China's export value of food in 2006 as compared with 2005

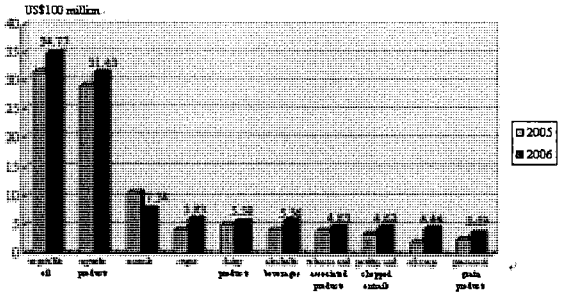


For many years, over 99 percent of China's exported foodstuffs have been up to standard. In 2006 and the first half of 2007, China exported to the US some 94,000 batches and 55,000 batches of foodstuffs, respectively, and 752 batches and 477 batches of each were found by the US to be substandard, making the acceptance rate 99.2 percent and 99.1 percent, respectively. In the case of the EU, the figures were 91,000 batches and 62,000 batches, with 91 batches and 135 batches found by the EU to be substandard, making the acceptance rate 99.9 percent and 99.8 percent, respectively. On July 20, 2007, the Ministry of Health, Labor and Welfare of Japan, the largest importer of Chinese food, released an examination report on food imported from China in 2006, which showed that Japan conducted more sample surveys on Chinese food (15.7 percent) than on food from anywhere else, but Chinese food had the highest acceptance rate (99.42 percent), followed by that imported from the EU (99.38 percent) and the US (98.69 percent). The mainland of China is a major supplier of food for the Hong Kong Special Administrative Region. Two large food sample surveys conducted by Hong Kong's Food and Environmental Hygiene Department in the first half of 2007 showed that the acceptance rate stood at 99.2 percent and 99.6 percent, respectively.

(2) Quality of Imported Food Stable

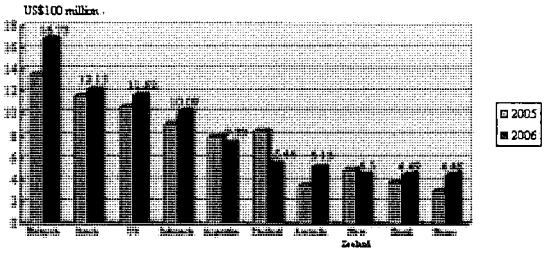
In 2006, China imported 20.273 million tons of food, worth US$13.396 billion, up 37.94 percent and 25.11 percent year on year, respectively. The top ten varieties in terms of import value were vegetable oil, aquatic products, cereals, sugar, dairy products, alcoholic beverages, tobacco and associated products, poultry and chopped entrails, oil crops, and processed grain products. (See Table 7)

Table 7 Top ten food varieties in terms of import value in 2006 as compared with 2005



China imports foodstuffs from 143 countries and regions, and the top ten in terms of trade value are Malaysia, Russia, the US, Indonesia, Argentina, Thailand, Australia, New Zealand, Brazil and France. (See Table 8)

Table 8 Top ten countries in terms of China's import value of food in 2006 as compared with 2005



For many years, the quality of food China imports has been fairly stable, and no serious hazard has been caused by imported food. During the period from 2004 to the first half of 2007, the acceptance rate of imported food, according to statistics released by the ports of entry, were 99.29 percent (2004), 99.46 percent (2005), 99.11 percent (2006) and 99.29 percent (first half of 2007), respectively.

II. Food Safety Regulatory System and Work

To ensure food safety, the Chinese government adheres to the principle of giving priority to prevention and control at its root by monitoring and controlling the whole process, and has formed a regulatory format in which the local governments take the responsibility, related departments provide guidance and conduct coordination, and different sectors make concerted efforts under the unified national leadership. In response to the circumstances in China, the State Council issued the Decision on Further Strengthening Food Safety Supervision in 2004, according to which one monitoring link is supervised by one department; sectional supervision is adopted as the main means while supervision of different varieties as the supplementary means, making clearer the functions and responsibilities of the food safety supervisory departments. The Decision divided food safety supervision into four links, managed by the departments of agriculture, quality supervision and inspection, industry and commerce, and health, respectively. The production of primary agricultural products is supervised by the agriculture department, the quality and daily hygiene supervision of food processing is overseen by the quality supervision and inspection department, supervision of food circulation and distribution is done by the department of industry and commerce, and that of the catering industry and canteene is taken care of by the health department. The integrated food-safety supervision and coordination, and investigation of and penalties imposed for major incidents in this regard are the responsibility of the department of food and drug administration, while imported and exported agricultural products and other foodstuffs are supervised by the quality supervision and inspection department. In this way, there is a strict, complete regulatory system for food safety supervision in which the departments concerned work in close cooperation, with clearly defined functions and responsibilities.

As it is a prolonged and arduous task to strengthen food safety control, a regulatory system and a lasting efficiency mechanism should be established and improved, and planned with consideration given to both present and future needs to deal with both the symptoms and root causes of food safety problems, especially the latter.

The Chinese government stresses food safety from the source, improvement of the related basic regulatory systems, and strengthening of food safety supervision.

1. Intensifying Supervision on the Quality and Safety of Agricultural Products

In 2001, China started to implement the Hazard-free Food Action Plan, focusing on the control of residua of high-toxic pesticides in vegetables and clenbuterol hydrochloride contamination in livestock products, to address the most concerned problems of illegal use of high-toxic pesticide and veterinary medicines, as well as violations of residue standards. The Plan stipulates a complete supervisory process from farmland to market by emphasizing the three key aspects of materials used in farming, production and market excess. By carrying out regular monitoring and inspection, the Plan aims at enhancing people's awareness of food quality and safety, ensuring management responsibility, and improving the levels of management and quality and safety of agricultural products by means of standardization. Today, the system for securing the quality and safety of agricultural products is improving, with steadily strengthened supervisory capacity and notable progress in agricultural standardization, leading to the formation of a work mechanism integrating service, management, supervision, penalty and emergency response, to ensure the quality and safety of agricultural products.

2. Establishing and Strictly Implementing Market Access Systems for Food Quality and Safety

The food quality and safety market access systems established by the Chinese government in 2001 comprise three major ones. One, the production license system, which requires that food-processing enterprises cannot produce and market their products without having the capability to control the source materials' quality, and the adequate conditions to ensure food quality and safety in terms of production equipment, technological flow, product standardization, testing equipment and capability, environment, quality control, storage and transportation, packaging and labeling, and production staff. Enterprises can produce and sell food only after obtaining a food production license. Two, the compulsory inspection system, which means that enterprises have the legal obligation to ensure that their food products pass quality inspection before entering the market. Three, the market access labeling system, i.e., enterprises are required to put on food products the QS label, guaranteeing their quality and safety. Following the principle of phased implementation, by the end of June 2007, some 107,000 food production licenses had been issued to enterprises, which took up over 90 percent of the market of their trades. Meanwhile, supervision has been strengthened over enterprises with food production licenses. By the end of June 2007, 1,276 food production licenses had been withdrawn, cancelled, revoked or nullified for substandard food products. In pace with the growing number of enterprises obtaining the license, the

General Administration of Quality Supervision, Inspection and Quarantine has released lists of such enterprises, making clear that producers without the license and products without the QS label must not enter the market, and warning consumers not to use such products.

3. Intensifying State Supervision by Sample Survey for Food Quality

The Chinese government carries out a food supervision and inspection system mainly by means of sample survey. Since it was set up in 1985, the system has been strengthened and become more focused to enhance its efficiency. In recent years, daily-consumption food items, such as dairy products, meat products, tea, beverages, grain and edible oil, have become the major targets of sample surveys, especially those produced in workshops and enterprises located in concentrated food-producing areas. Special attention has been given to the hygienic indices of microorganisms, additives and heavy metals in food, and to follow-up inspections of small enterprises with unstable product quality. By increasing sample survey frequency and coverage, the goal of rectifying producers of the same type of food by means of sample survey has been by and large met. The state supervisory sample surveys were carried out on 11,104 batches of foodstuffs produced by 7,880 enterprises from 2006 to June 2007. Meanwhile, greater efforts have been made to rectify and punish enterprises turning out substandard products, and to set things straight by means of the following: First, strictly implementing the public announcement system. Three hundred and fifty-five batches of food with serious quality problems produced by 355 enterprises were found in sample surveys and publicly announced. At the same time, publicity is given to good enterprises, quality products and sound brands. Two hundred and forty products winning the title of "Famous Chinese Brand" and 548 freed-from-inspection products have become popular among consumers. Second, strictly carrying out the rectification system. Enterprises with substandard products are urged to rectify themselves strictly, to be examined again in due course. If problems persist, they will be ordered to stop production for an overhaul. If they still cannot pass the inspection after the overhaul, their business licenses will be revoked. Third, strictly implementing the penalty system. Producers who mix impurities or imitations with their products, or pass fake or defective products off as genuine ones will be ordered to stop production, and their products be confiscated. Legal liabilities will be imposed in serious cases by the judicial organs.

4. Intensifying Rectification of Food Workshops

Regional differences and disparities between urban and rural areas in China make the supervision of food workshops a prolonged and arduous task. At present, food workshops with fewer than ten employees are the ones that pose the most difficult problem for ensuring food quality and safety. For workshops engaged in traditional, low-risk food processing, the government sticks to the principle of supervision and standardization while giving guidance to such workshops for consumers' convenience. On the one hand, the government has tried to upgrade them to the market-access requirements by means of shutdown, stoppage of production, merging or changing line of business; on the other, more stringent supervisory measures have been taken to prevent food safety accidents. In recent years, supervision of workshops and small enterprises has been conducted mainly in four aspects: One, transformation of basic work conditions. Workshops cannot start production without meeting the requirements. Two, restrictions on market scope. Food products processed by such small workshops are not allowed to sell outside the administrative areas of townships or towns in which they are located, not allowed to enter shopping centers and supermarkets. Three, restrictions on food packaging. Before obtaining a market access permit, food products from the workshops are not allowed to have marketing package, so that they cannot enter the market disguised as licensed goods. Four, public undertaking. Food workshops must undertake to the public that they do not use any non-food materials, misuse additives, use recycled food, send their products to shopping centers or supermarkets, or market their products beyond the approved region, and guarantee that their food products meet the basic safety and hygienic standards. After such rectifications, the average acceptance rate in sample surveys of food workshops rose to 70.4 percent in 2006. By the end of June 2007, 5,631 workshops had been closed down, 8,814 had been made to suspend production, and 5,385 had reached the requirements after rectification.

5. Promoting the Responsibility System for Regional Food Safety Control

The responsibility system for regional food safety control mainly comprises the following aspects. First, to have specified persons responsible for specified regions and enterprises. The system requires that food safety inspectors of the quality supervision and inspection department go to the townships to supervise the food-processing enterprises; township government coordinators assist the inspectors in supervising food quality and safety; and local reporters bring to attention anything illegal regarding food quality and safety. The number of inspectors, coordinators and local reporters must be fixed, their duties defined, and their working areas and inspecting enterprises designated. Second, the system requires "three enters" and "four graphs." The former refers to entering villages, households and enterprises to find out their working conditions and set up files of food producers and processors; the latter refers to drawing up a graph showing dynamic changes in enterprises, a graph showing the distribution of food producers and processors, a graph showing the implementation of supervisory duties, and a graph giving food safety precautions, so as to carry out proactive monitoring and

control. Third, the system requires local governments to sign documents of responsibility, enterprises to sign letters of undertaking, and quality supervision end inspection departments to submit regular food safety reports.

By the end of June 2007, a total of 16,030 food-safety supervision regions had been set up, 25,346 full-time food-safety inspectors had been put to work, 72,474 local government coordinators had been appointed, and 106,573 food-safety reporters had been recruited in 31 provinces, autonomous regions and municipalities directly under the Central Government. In 2006, the quality supervision and inspection departments at various levels made 900,000 inspections of food producing and processing enterprises.

6. Stepping up Supervision of the Food Circulation Sector

The "Three Green Projects" have been vigorously promoted in China, advocating "green consumption, green markets and green channels." The government encourages modern modes of organization and management for circulation, positively supports the development of chain management and logistics provision; urges marketing enterprises to examine materials before accepting them, check business licenses, require invoices for purchases, keep accounts of transactions and honor their undertakings for food quality, as well as promotes market managers' food quality responsibility system; implements market inspection system in an all-around way; improves the food quality monitoring system, and strictly implements the system that substandard food must be withdrawn from the market and destroyed and made known to the public; strengthens administration over butchering of livestock and fowls, breaks down regional barriers and encourages the nationwide circulation of high-quality foodstuffs with good credit standing and prestigious brand names; improves food processing, circulation and service systems in communities; strengthens the management of the use of genuine food safety labels and standard packaging, and concentrates efforts to crack down on printing of fake packaging, labels and trademarks.

7. Intensifying Supervision of Food Safety in Catering Industry

Hygiene in the catering industry is vital for food safety. In this regard, the Chinese government has primarily done the following: One, it has intensified supervision on hygiene in the catering industry, promulgated and put into effect the Hygienic Standards for the Catering Industry and Group Food Service Providers, adopted a quantified and classified supervisory system for food hygiene management, and strengthened supervision on each link of the catering industry. Two, it has urged the catering industry and canteens to implement the quantified and classified supervisory system for food hygiene management in an all-around way, improved and strengthened monitoring of food contamination and building of a monitoring system on diseases caused by contaminated food. Three, it has intensified crackdown on activities in violation of food safety law, investigated and dealt with serious cases and timely made them known to the public. In 2006, the health departments inspected 2.04 million catering entities of various types and school canteens, dealt with 45,000 cases of illegal food processing and sale and closed down 25,000 food processors and sellers that had been operating without hygiene permits. Four, it has strengthened efforts on hygienic work in schools, directed and carried out special inspections on food and drinking water hygiene, and prevention and treatment of contagious diseases in schools all over the country, as well as prevention of food poisoning and the spread of communicable intestinal diseases. Five, it has conducted food-related jeopardy assessment end issued early warnings for food safety problems on a scientific basis and provided food assessment information.

8. Carrying out Rectification in Respect of Food Quality and Safety in an All-around Way

In order to crack down on the spread of counterfeit and shoddy foodstuffs in certain regions, special comprehensive rectification campaigns were launched in these regions for food quality and safety. The Chinese government has conducted a special project involving hundreds of regions, thousands of townships and tens of thousands of food producers and processors. Targeting key regions, food processing venues and households and their products, the project has resolved the regional problem of producing and selling fake and inferior goods by establishing a food safety monitoring network, stepping up efforts in building up the technological forces such as standardization and monitoring technology, improving technical services for enterprises, promoting the setting up of food industry associations, and intensifying law enforcement and making more stringent efforts to crack down on the production and sale of counterfeit and faulty food. Meanwhile, the departments of industry and commerce as well as quality supervision and inspection keep intensifying law enforcement and, with focus on food quality and safety, direct and conduct special law enforcement actions against activities in producing and processing counterfeit food-related items at the source, strictly crack down on illegal activities such as production of food with non-food materials and misuse of additives in food, as well as food producers with neither a business license nor food-processing permit. In 2006, the quality supervision and inspection departments handled 49,000 illegal operations in this field, confiscating counterfeit and shoddy foodstuffs worth 450 million yuan. In the same year, the departments of industry and commerce sent 5.6 million person/times for law enforcement and inspected 16,000 key food markets and 10.4 million food operating business/times, closed down 151,600 unlicensed businesses, revoked 4,629 business licenses, investigated

and dealt with 68,000 cases of production and sale of counterfeit and shoddy food, of which 48 cases were referred to the relevant judicial organs, and ordered 15,500 tons of substandard foodstuffs off the market.

9. Beefing up the Construction of a Risk-warning and Emergency-response System

The Chinese government has established a nationwide quick risk warning and responding system in respect of food safety, actively conducted risk monitoring and control in food production, processing, circulation and consumption, and preliminarily realized the early discovery, early warning, early control and early treatment of food-safety problems through efficient collection and analysis of information on food safety. It has also established a rapid and efficient response mechanism covering the collection and analysis of risk-related information, issuing warnings and rapid responses so that it is possible to provide prompt reports, take swift action, make accurate judgment and mete out appropriate measures.

10. Establishing and Improving a Food Recall System

This system comprises two aspects: active recall and instructed recall. The system stipulates that it is the responsibility of food producing and processing enterprises to recall their products if necessary, requires that food producers should instantly put a halt to the production and selling of their products if they suspect any safety risk in their food products, and take the initiative to recall such food products. Producers who purposely conceal food hazards or do not perform their recall obligations, or whose faulty production has extended such hazards or made them recur, will be instructed to recall their products. In recent years, in conducting food sample surveys and law enforcement, the General Administration of Quality Supervision, Inspection and Quarantine has become more stringent in demanding food recall when major food-safety hazards, such as pathogenic bacteria, chemical pollutant or non-food materials, are found in food products. Toward those food producing enterprises causing serious consequences, the Administration has revoked their licenses, thus reducing hazards that might be caused by unsafe food and safeguarding the health and safety of consumers.

11. Improving the Food Safety Credit System

The Chinese government pays great attention to the construction of the credit system for food safety, and has set up the preliminary credit records for food-producing enterprises, as well as a system to publicize the honor rolls and blacklists of food producers and processors. Meanwhile, the functions of chambers of commerce and trade associations have been brought into full play to promote self-discipline in the food industry. By giving backing to excellent and competent enterprises, the government supports and helps good and strong enterprises by legislative, administrative and economic means to create an honest environment for food safety, and to enhance people's awareness of honesty in this regard. It has made great efforts in gradual improvement of this mechanism for food safety, and given full scope to its role in regulating, guiding and supervising food safety. It has built up files of credit records of food safety and promoted classified credit monitoring in the food industry. Emphasis is laid on the establishment of a registration and information system and a classified database of credit records of food producers and sellers, which collects information on food producers' and sellers' market access, food-safety control, and consumers' complaints and reports, to ensure an effective control based on adequate information. In recent years, the latest network technology has been used for this purpose, so that consumers may timely, easily, quickly and effectively distinguish counterfeits from genuine ones, which greatly helps safeguard consumers' interests, discourages the production and sale of fake foodstuffs and promotes honesty among enterprises in this industry.

Over the years, the continuous growth of the food industry in terms of variety and quantity as well as the improvement of quality have helped satisfy the people's ever-increasing consumption demands, raised their living standard and promoted national economic development. However, the Chinese government is well aware that there are still problems with food safety, owing to the country's limited socio-economic development. In the days to come, penalties will be focused on those who produce shoddy products or products containing inferior materials or impurities, palm off counterfeits as genuine ones, process foodstuff with non-food or moldy materials, produce foodstuff in disregard of required standards and misuse additives in foodstuff, so as to continuously guarantee food safety and quality.

III. Supervision of Imported and Exported Food

1. Supervision of Imported Food

Exploration and practice over the years have enabled China to set up a complete framework of food quality and safety supervisory system and guarantee measures to ensure the safety of imported food.

-- Scientific risk management system. According to the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) and common international practice, the Chinese government adopts an inspection and quarantine entry system based on risk management for high-risk imported food, such as meat and vegetable, which includes: making a risk analysis on the high-risk food that the exporting country applies to export to China; signing an inspection and quarantine agreement with the exporting country on food involving acceptable risks; carrying out hygiene registration for foreign food enterprises; and quarantining, examining and approving the imported food of animal and plant origin. If epidemic animal or plant diseases or severe food safety problems occur in the exporting country, China shall take timely risk management measures, including suspending food imports from that country.

-- Strict inspection and quarantine system. When imported food arrives at the port of entry, the entry-exit inspection and quarantine authorities carry out inspection and quarantine in accordance with law, and approve the foodstuffs to be imported only if they meet the required standards; and the customs house clears the imported food upon the strength of the Customs Clearance List of Inward/Outward Goods as issued by the entry-exit inspection and quarantine authorities. Only then can the food be sold in the Chinese market. If safety or hygienic problems are found in the food when inspected and quarantined, corresponding measures are immediately taken. In 2006, Chinese entry-exit inspection and quarantine authorities altogether found 2,458 batches of foodstuffs not meeting the standards at ports of entry. In the first half of 2007, some 896 were found, which were returned, destroyed or used in other ways according to law. Thus is the safety of food imported for the Chinese market assured.

-- Complete quality and safety supervisory system. While carrying out inspection and quarantine in accordance with law, the entry-exit inspection and quarantine authorities pay special attention to higher-risk food and problematic foodstuffs as found in the inspection and quarantine at the ports of entry. The authorities promptly issue early warnings of risks when finding imported food with serious problems or the same type of imported food with repeated problems, and take such measures as increasing the proportion of sample survey, adding more items for inspection, and suspending import.

-- Strict system against illegal import. The General Administration of Quality Supervision, Inspection and Quarantine and the General Administration of Customs have set up a cooperation mechanism to jointly fight illegal food imports. In 2006, China signed with the European Union Commission the Arrangement for Cooperation on Joint Prevention of Illegal Actions in the Import and Export of Food, making it clear that the two sides will crack down on such illegal activities as deception, undeclared carrying, illegal transit and smuggling through exchanges of information, technological cooperation, mutual visits of experts and special joint actions. In 2006 and the first half of 2007, 12,292 tons of illegally imported meat were seized.

2. Supervision of Exported Food

Following the principle of "prevention first, supervision at the source, and control throughout the process," the Chinese government has set up and improved an export-food safety management framework composed of "one pattern and ten systems."

"One pattern" refers to the managerial pattern for the production of export food -- "enterprise + base + standardization." This pattern conforms to China's reality and the actual situation in the field of export food, and thus is an important guarantee for the quality of such food. Besides, it is the only way for enterprises to aim for scale and intensive development in the international market. With unremitting efforts over many years, China has basically put this pattern in place for major export food items, especially high-risk foodstuffs such as meat, aquatic products and vegetable.

The "ten systems" are: three for supervision at the source -- the archiving management system for the inspection and quarantine of planting and breeding bases, the epidemic disease monitoring system, and the supervisory system for pesticide and veterinary medicine residue; three for factory supervision -- the hygiene

registration system, the classified management system for enterprises, and the resident quarantine official system for large enterprises producing high-risk food for export; three for product supervision -- the legal inspection and quarantine system for export food, the system of quality tracing and substandard products recalling, and the early risk warning and quick response system; and one for credit building -- a red list and a blacklist for food export enterprises.

-- Strengthening supervision of planting and breeding at the source. To effectively control the risks of animal epidemics, plant diseases and pesticide and veterinary medicine residue, and guarantee food quality and safety and traceability at the source, the entry-exit inspection and quarantine authorities adopt the archiving management system for the inspection and quarantine of export food material bases with such risks. Only the raw materials of planting and breeding bases with archiving approval can be used in processed export food, and all the raw material bases with archiving approval are publicized on the website of the General Administration of Quality Supervision, Inspection and Quarantine. So far, 6,031 breeding farms and 380,000 hectares of planting bases have obtained such approval. For these bases, the relevant agencies strengthen supervision, prevention and control of epidemic diseases, exercise tight management of agricultural input materials, and enforce a strict supervision system over pesticide and veterinary medicine residue, so that these problems are brought under effective control. In recent years, bird flu has been found in many places around the world, but none at the bases under archiving management in China.

-- Strengthening supervision of food producing enterprises. China has adopted a hygiene registration system for all enterprises producing export food, and an enterprise has to be granted such registration before engaging in the production of export food. So far, 12,714 enterprises have been registered, among which 3,698 have passed the HACCP certification of the entry-exit inspection and quarantine authorities. The local entry-exit inspection and quarantine authorities carry out routine supervision and administration of the registered food producing and processing enterprises in a unified way to ensure that the raw materials come from archived planting and breeding bases, and that the production and processing meet the required standards. As regards large enterprises producing or processing high-risk export food such as meat, the entry-exit inspection and quarantine authorities send resident officials to supervise them when needed. The packaging of export food should be labeled with traceable signs according to requirements, so as to ensure the traceability of the products and recall of substandard products.

-- Strengthening inspection and quarantine before the food is exported. As prescribed by Chinese laws, all food should meet the standards set by the inspection and quarantine authorities before being exported, and the customs houses at the ports of exit should clear the export food upon the strength of the Customs Clearance List of Outward Goods issued by the entry-exit inspection and quarantine authorities. If it is demanded by the importing country, the relevant entry-exit inspection and quarantine authorities should issue a hygiene certificate to prove that the food meets the required standards, and enter on the certificate the name, address, number of hygiene registration of the producing enterprise, date of production, date of export, loading port and destination port. When the goods arrive at the port of exit, the inspection and quarantine authorities at the port should examine the goods again, making sure they are intact and conform to the information on the certificate. All these measures guarantee the traceability of the food.

-- Strengthening the construction of the export enterprise credit system. An export enterprise quality undertaking system and a red list and blacklist system for export enterprises are implemented in a comprehensive way, and efforts are being made to increase the awareness of the persons primarily responsible for product quality and help enterprises to form a mechanism of self-management, self-discipline and consciousness of operation in good faith. Included on the List of Sound Enterprises are those with a complete and effective control system, good faith, effective control over safety risks, and a good reputation in the importing countries. Such enterprises are granted favorable policy treatment. Enterprises with serious quality problems as reported by the importing countries or regions, or which have avoided inspection and quarantine or cheated the inspection and quarantine authorities are punished in accordance with the law and included in the List of Unlawful Enterprises and publicized on the Internet so as to enhance the self-disciplinary awareness of enterprises producing export food. So far, 55 enterprises have been put on the list.

Over the years, the departments of quality supervision and inspection, trade, customs, industry and commerce, and taxation have worked closely to promote the quality and safety level of food exported from China and satisfy numerous Chinese and foreign customers with high-quality, delicious and inexpensive foodstuffs. Yet, there are still a tiny number of enterprises that disregard the law, regulations and standards of China and importing countries and, by deception or fraud, avoid supervision by the inspection and quarantine authorities, or export food by improper channels. Consequently, some adulterated, counterfeit or shoddy foodstuffs have found their way from China into foreign markets. The Chinese government is determined to step up the fight against such activities and prevent substandard foodstuffs from going overseas.

IV. Law Regime and Technological Guarantee System for Food Safety

1. Food Safety Law Regime Gradually Improved

China now has a complete law regime providing a sound foundation and good environment for guaranteeing food safety, improving food quality and regulating food imports and exports.

The specific laws in this regard include the Product Quality Law, Standardization Law, Metrology Law, Law on the Protection of Consumer Rights and Interests, Law on the Quality and Safety of Agricultural Products, Criminal Law, Food Hygiene Law, Law on Import and Export Commodity Inspection, Law on Animal and Plant Entry and Exit Quarantine, Frontier Health and Quarantine Law and Law on Animal Disease Prevention.

The specific administrative regulations in this regard include the Special Regulations of the State Council on Strengthening Safety Supervision and Administration of Food and Other Products, Regulations of the People's Republic of China on the Administration of Production Licenses for Industrial Products, Regulations of the People's Republic of China on Certification and Accreditation, Regulations for the Implementation of the Law of the People's Republic of China on Import and Export Commodity Inspection, Regulations for the Implementation of the Law of the People's Republic of China on Animal and Plant Entry and Exit Quarantine, Administrative Regulations of the People's Republic of China on Veterinary Medicine, Administrative Regulations of the People's Republic of China on Pesticides, Provisions of the People's Republic of China on Place of Origin of Export Goods, Regulations for the Implementation of the Standardization Law of the People's Republic of China, Measures for Investigating, Punishing and Banning Unlicensed Business Operations, Regulations on the Administration of Feedstuffs and Feed Additives, Administrative Regulations on the Safety of Genetically Modified Agricultural Organisms and Regulations of the People's Republic of China on Import and Export of Endangered Wild Fauna and Flora.

The specific departmental rules include the Detailed Rules for the Implementation of the Measures for the Administration of the Supervision of Quality and Safety of Food of Food Producing and Processing Enterprises (Trial), Measures for the Implementation of the Regulations of the People's Republic of China for the Administration of Production Licenses for Industrial Products, Measures for the Administration of Food Hygiene Licenses, Measures for the Hygiene Administration of Food Additives, Measures for the Administration of Inspection and Quarantine of Entry and Exit Meat Products, Measures for the Administration of Inspection and Quarantine of Entry and Exit of Aquatic Products, Measures for the Administration of Food Safety in the Circulation Sector, Measures for the Administration of the Safety of Places of Origin of Agricultural Products, Measures for the Administration of the Packaging and Marks of Agricultural Products and Regulations for the Administration of Hygiene Registration of Export Food Production Enterprises.

2. Construction of Food Quality and Safety Standard System Gradually Strengthened

The Standardization Administration of the People's Republic of China administers the country's food standardization work, while relevant departments under the State Council are in charge of specific food standardization work in respective sectors. The departments concerned are responsible for drafting different national standards for food safety, while the Standardization Administration initiates projects, examines them, marks the serial numbers, gives formal approval and promulgates them. Now, a food quality and safety standard system covering all categories, featuring a relatively rational structure and being fairly complete, has taken initial shape in China. Food safety standards cover the place of origin of agricultural products, quality of irrigation water, rules for the rational use of materials put into agricultura, rules and procedures for animal and plant quarantine, good agricultural practices (GAP), standards of maximum amount of pesticides, veterinary drugs, pollutants and spoilage organisms allowed in food, standards for food additives and their use, hygiene standards for food packaging materials, standards for special dietary food, standards for signs or labels on food packages, standards for the management and control of the safe production of food and standards for testing methods concerning food. These standards apply to edible agricultural products and processed food, such as grain, oil, fruit and vegetable, milk and dairy products, meat, poultry, eggs and related products, aquatic products, soft and alcoholic drinks, condiments and infant food; and cover each sector from food production, processing and distribution to final consumption. So far, China has promulgated over 1,800 national standards concerning food safety, and over 2,900 standards for the food industry, among which 634 national standards ara compulsory.

To solve such problems as food safety standards overlapping each other and poorly organized, China has sorted out the over 1,800 national standards, over 2,500 industrial standards, over 7,000 local standards and over 140,000 enterprise standards, repealing more than 530 national and industrial standards. Meanwhile, it has

speeded up the revision of over 2,460 national and industrial standards, issued over 200 new national standards, and worked out plans to enact over 280 national standards. It also works hard to promote and enforce these standards, and urges food producing enterprises to strictly abide by them.

3. Food Certification and Accreditation System Basically Established

The Certification and Accreditation Administration of the People's Republic of China is responsible for administering, supervising and coordinating certification and accreditation work throughout the country, putting in order the certification market and regulating certification activities. A pattern of uniform administration, standardized operation and common implementation for the certification and accreditation of food and agricultural products has come into being, basically establishing a certification and accreditation system covering the entire process "from the farming field to dining table." The certification categories include certification of feeds, GAP certification, certification of hazard-free agricultural products, certification of organic products, certification of food quality, certification of the HACCP management system, and certification of green markets. At present, China ranks among the top ten countries in the world in this regard, with 2.03 million hectares producing certificated organic products. The country has been experimenting with GAP certification geared to international standards in 286 export enterprises and agricultural standardization demonstration bases in 18 pilot provinces; 2,675 food producing enterprises have received HACCP certificates; 28,600 primary agricultural products have passed the certification tests for hazard-free agricultural products; and continuous progress is being made in the certification of feeds, alcoholic beveragee by quality grade, and green markets. The government continuously strengthens its supervision of certificated products and enterprises, and increases the authoritativeness and effectiveness of certification.

4. Food Safety Inspection and Testing Framework Taken Initial Shape

Regarding the supervision of foodstuffs for the domestic market, China has established a number of qualified food inspection and testing institutions, bringing into initial being a food safety inspection and testing framework with "state-level inspection institutions playing the leading role, provincial- and ministerial-level food inspection institutions forming the main body, and city- and county-level food inspection institutions acting as supplement." With the improvement of their testing capability and level, these institutions can satisfy the demands for quality and safety tests throughout the entire process -- from the environment of place of origin, input materials, production and processing, storage and circulation to consumption, and can basically meet the requirements of national, industrial and relevant international standards for food safety parameters. China adopts the certification management that is in line with the international practice for food laboratories, and strengthens international mutual recognition, information sharing and joint tackling of key scientific and technological problems, ensuring the accuracy and fairness of test results. China has accredited the qualifications of some food inspection and testing institutions. Altogether, 3,913 food testing laboratories have passed the laboratory accreditation (similar to metrology certification) of China National Accreditation Service for Conformity Assessment (CNAS) among which 48 ere state-level quality inspection centers for foodstuffs and 35 are key food laboratories. The testing capability and level of these laboratories have reached a relatively advanced international standard. As regards the supervision of import and export foodstuffs, a technical support system ensuring food safety has taken shape, with the 35 state-level key laboratories playing the leading role. There are 163 inspection and quarantine laboratories for import and export foodstuffs throughout China, possessing more than 10,000 sets of large precision instruments of various types. Altogether, 1,189 professionals are directly engaged in the laboratory testing of import and export foodstuffs in these laboratories, with a rational age structure and allocation of staff according to their specialized fields. These laboratories can detect all kinds of food-borne pathogens and 786 safety or hygienic items, such as residue of pesticides and veterinary medicines, additives and heavy metals. By 2006, China had set up 323 state- and ministerial-level quality inspection centers and 1,780 provincial-, prefecture- and county-level testing institutions concerned with agricultural products. Thus, a quality and safety inspection and testing framework for agricultural products, with these institutions at different levels supplementing each other, has taken shape, providing technical support for strengthening the supervision of the quality and safety of agricultural products.

V. International Exchanges and Cooperation Regarding Food Safety

The Chinese government sets great store by cooperating with other countries, regions and international organizations regarding food safety, as well as by learning advanced management expertise and monitoring technology, to improve the overall quality of its foodstuffs.

1. Strengthening Exchanges and Cooperation Regarding Food Safety Technology

China encourages and supports its technical experts to participate in various food sefety technological training programs, seminars, exchanges and comparative reviews. It also welcomes overseas experts to visit China for study or training. Besides the activities organized by the World Health Organization (WHO), China has, since 2001, conducted many rounds of technological training and exchanges on food safety, especially the implementation of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), with the US, the EU, Italy, Canada, Germany, the UK, Switzerland, Denmark, Australia, New Zealand and Thailand. In August 2006, China sponsored food safety training for people from 14 South Pacific countries. To furnish itself with timely information to ensure the foodstuffs it exports are up to the relevant standards, China has translated the laws on food safety and hygiene of the US, the EU, Russia, the ROK and other countries and regions. It has also invited experts from the US, the EU and Japan to offer training on HACCP application, the National Shellfish Sanitation Program (NSSP), residue control and Positive List System. China's laboratories for import and export food inspection and quarantine have taken part in several comparative experiments, such as the Food Analysis Performance Assessment Scheme (FAPAS) of the UK, and joined on regular intervals the international proficiency testing conducted by established certification agencies, such as the Asia Pacific Laboratory Accreditation Cooperation (APLAC) and the Australia's National Association of Testing Authorities (NATA). The national center for disease control and prevention and a dozen provincial ones have passed the WHO food safety inspection capacity verifications. By November 2006, a total of 22 inspection agencies had been granted by the ROK to be "Acknowledged Oversees Official Inspection Agencies," which means that the food items that pass their checks will be free from entry inspection in that country. The testing results of the laboratories of the 35 quality inspection and quarantine agencies directly under the General Administration of Quality Supervision, Inspection and Quarantine have also won acknowledgement from Japan, and many of the laboratories are open ones and have hosted delegations of experts from the US, Canada, the UK, France, Italy, Germany, Switzerland, Australia, New Zealand, Japan, the ROK, Singapore, Hong Kong, as well as other countries and regions.

2. Actively Participating in International Activities Regarding Food Safety

The Chinese government has always been a keen advocator of and participant in international food safety activities. It has dispatched delegations to the Codex Alimentarius Commission (CAC), the International Plant Protection Convention (IPPC) and other international conferences. Its call for regional cooperation on food safety at a meeting of the Asia-Pacific Economic Cooperation (APEC) has received positive responses from Australia, New Zealand and Southeast Asian countries, as a result of which the APEC Food Safety Cooperation Forum was established, co-chaired by China and Australia. China actively participates in international standardization activities for food safety. It is a member of the Technical Management Board and Committee on Conformity Assessment of International Organization for Standardization (ISO). In May 2007, it formally joined the World Organization for Animal Health (OIE). On October 20-21, 2007, it will host, in Nanning, the China-ASEAN Ministerial Conference on Quality Supervision, Inspection and Quarantine, with the theme of "Strengthening Cooperation on Food Safety Management and Protecting Consumer's Rights." The event will discuss the establishment of a cooperative mechanism on food safety, so as to increase exchanges and cooperation among the relevant departments of China and ASEAN to ensure the quality, safety and sanitation of the foods traded among them.

3. Striving to Promote International Cooperation Regarding Food Safety

While organizing regular and irregular seminars or mutual visits of experts with Japan, the ROK, Australia, New Zealand, Singapore, Norway, Russia, Hong Kong, and other countries and regions, China's General Administration of Quality Supervision, Inspection and Quarantine has signed 33 cooperative agreements or memorandums on food safety and 48 import and export food inspection and quarantine protocols with 30 countries and regions, namely the US, the EU, Russia, Japan, the ROK, Singapore, Thailand, Mongolia, Vietnam, the Philippines, Denmark, France, the Netherlands, Ireland, Hungary, Poland, Italy, Norway, Switzerland, Canada, Brazil, Argentina, Chile, Mexico, Uruguay, Australia, New Zealand, South Africa, Hong Kong and Macao. Thus, a long-term and effective cooperative mechanism between China and its food trade

partners has been established. And, based on this, the General Administration of Quality Supervision, Inspection and Quarantine has built a system of annual meetings with many countries and regions. The second China-EU meeting on safety of food and consumer products at the ministerial level is scheduled to be held on September 12, 2007 in Beijing, and the third China-US food safety meeting at the vice-ministerial level is scheduled on September 11-12, 2007 in the US.

4. Promoting Food Trade

The food safety cooperative mechanisms established between China and other countries have greatly promoted bilateral and multilateral cooperation to ensure the safety of foodstuffs traded among them and ease the wide concerns about food safety. For instance, the Sino-Japanese cooperative mechanism plays a key role in ensuring the safety of Chinese food exported to Japan. After Japan's release of its Positive List System, the Chinese government, through communications and negotiations, persuaded Japan to accept its reasonable proposals and adjust some projects accordingly, and co-sponsored three demonstrations and eight special training workshops to help China's food export enterprises further standardize the use and administration of pesticide and veterinary medicines, improve the quality tracing system and guarantee the quality and safety of food exported to Japan. The China-US food safety cooperative mechanism plays a similar role. Since the end of 2005, China's entry-exit inspection and quarantine authorities have continuously found residues of prohibited medicines, pollutants and pathogenic microbes in US meat products exported to China. Their timely notification of such information let the US learn of China's legal requirements concerning food safety, thus effectively protecting Chinese consumers as well as ensuring healthy development of US export of meat products to China. In 2004 and 2005, the two countries, under this cooperative mechanism, evaluated the safety and sanitation of China's exported cooked poultry products. The China-EU food safety cooperative mechanism also works well in solving problems both sides are concerned about. Through timely communication and on the basis of risk assessment, China has solved problems in the import of pork products from some dioxin-affected EU countries. While continuously improving its own food safety management and epidemic prevention and control work, it has actively cooperated with the EU in undertaking hygienic system inspection and risk appraisal which helps build confidence in China's cooked poultry products. The EU has worked out a timetable to resume imports of China's cooked poultry products in 2007.

Food is the first necessity of man, and it is the most direct and most important consumption product of mankind. China is a responsible country, and the Chinese government is devoted to working for the benefits of the people. Over the years, the Chinese government has endeavored to improve food quality, ensure food safety and protect consumers around the world. But, it must be pointed out that China is still a developing country, and the overall level of food safety, including the standards and the industrialization level of food production, still lags behind that of developed countries. China has a long way to go to improve the quality of foodstuffs. Food quality and safety is a common concern of the human society and a shared duty of the international community. As a large importer and exporter of food, China is keen to strengthen exchanges and cooperation with other countries and make unremitting efforts to ensure the safety of food and promote the healthy growth of the global food trade.

CHINESE GOVERNMENT ATTACHES IMPORTANCE TO FOOD AND DRUG SAFETY(07/18/07)

CHINESE GOVERNMENT ATTACHES IMPORTANCE TO FOOD AND DRUG SAFETY

1. The General Picture

Recently, Chinese food safety and product quality have been widely reported by the U.S. media, raising concerns in the United States. China takes this issue very seriously and wages an on-going campaign to address the problem.

As a result of investigations conducted by AQSIQ and relevant agencies, the quality watchdogs of the Chinese Government, the cases reported so far are isolated cases. China is exporting food to over 200 countries and regions in the world, and over 99% its food exports meet the quality requirements.

Statistics of the inspection authority also show that the percentage of certified food exports from China to the United States are 99% in 2004 and 2005 and 99.2% in 2006. For China's food products entering Japan and EU countries, close to 100% are certified.

2. The Findings of Investigations

a. Pet food

The pet food contamination cases uncovered last March were caused by illegal practice of two Chinese companies. These companies involved and the relevant responsible persons have been penalized according to law. At the same time, the competent authority is now stepping up the supervision over relevant industries.

b. Tooth paste

EX 13

There is no existing definite international standard on the use or maximum amount of DEG in tooth paste, nor any data showing cases where the use of tooth paste containing DEG directly leads to poisoning of the human body. In addition, tests conducted by Chinese experts show that tooth paste product made in China that contain DEG are safe. Despite the above and to ensure scientific application of tooth paste by consumers, the General Administration of Quality Supervision, Inspection and Quarantine of China (AQSIQ) recently announced the prohibition of the use of DEG as an ingredient of tooth paste made in China.

c. Tire safety.

Concerning the U.S. media reports that tires imported from China have potential safety problems and have caused a traffic accident in Pennsylvania, the U.S. sales company of the tire in question, FTS, issued a press release to its sales operators and consumers at the end of last month, correcting the company's previous statements about the tire. According to the press release, tests on the relevant types of tires imported from China show that they meet and exceed all U.S. federal safety standards for motor vehicles, and studies on the van and tire involved in the Pennsylvanian accident have led to the conclusion that the tire made in China could not be confirmed as the cause of the accident.

Apart from that, the specialized agency in China conducted tests on samples that are the same type as the tires exported to the United States. The results show that they fully comply with the U.S. standards.

3. Measures Taken

China's trade with countries including the United States has grown so rapidly and on a scale so large that individual problem in food export becomes hardly avoidable. However, the Chinese Government has NOT turned a blind eye or tried to cover up. We have taken this matter very seriously, acted responsibly and immediately adopted forceful measures to address the problems in the interest of the health and safety of the Chinese public and the consumers of the importing nations.

More importantly, the Chinese Government has emerged from the problems with a host of measures targeting and strengthening export food and drug safety, which testify to the resolve and good faith of the Chinese Government to address food and drug quality and safety. The measures include:

a. Stricter inspection at port of export and increased sampling percentage. Food destined for the U.S. market are now subject to 100% open container inspection by port inspection and quarantine agencies, and all those found with discrepancy between goods and documents, or with quality or safety problems will be withheld from exporting.

b. Establishment of an on-line blacklist to publish the names of export companies with malpractice to the public in addition to legal punishment.

c. Rapid response to briefing on sub-standard products provided by food and drug authorities of importing countries. This includes immediate investigation and timely analysis and settlement.

d. Regular AQSIQ press conference. AQSIQ began holding regular press conference in July to increase media and public supervision over government work in food and drug safety.

On the basis of these measures, the Chinese Government will continue to improve overall supervision from production to export, including production, distribution, import and export as well as legislation, enforcement, supervision and management, so as to upgrade the quality and safety of Chinese products and make them safe for domestic and overseas consumers.

4. U.S. Cooperation Needed

It must be pointed out that food and drug safety problem is a global issue rather than unique to China. Developed countries including the United States and European countries are also faced with this problem to different degrees. For example, there have been successive cases of spinach, lettuce and peanut butter contamination in the United States since the beginning of this year.

Pork and poultry exports from certain U.S. companies were found to contain chemical additives or over-the-mark pathogenic bacteria counts, and the Chinese inspection agency had to announce a suspension on relevant imports. According to a report of the New York Times on July 12th, U.S. FDA data of last year shows that food exported from many countries, including some developed countries in Western European and Asia, were refused entry by U.S. customs and China did not top the list in terms of the total amount of products stopped at the U.S. border. In such context, it is unfair and irresponsible for the U.S. media to single China out, play up China's food safety problems and mislead the U.S. consumer.

The Chinese side hopes that the U.S. side will respect science and treat China's food and drug exports fairly, will not exaggerate or play up individual food safety cases and still less creating "China threat" in the field of food and drugs so as to prevent the misimpression among the U.S. public that all food and drugs imported from China are unsafe. Blowing up, complicating or politicizing a problem are irresponsible actions and do not help in its solution or benefit the sound development of bilateral trade. It is even more unacceptable for some to launch groundless smear attacks on China at the excuse of food and drug safety problems.

The Chinese side is ready to strengthen consultations and cooperation with the U.S. side. China's AQSIQ and State Food and Drug Administration would like to further strengthen the existing close and good working relations with the USFDA so as to work together to ensure food and drug safety and better protect the health and wellbeing of the general public in China and the United States.

Chinese Food Exports Are Safe

I. Safety Conditions of Chinese Food Exports

Chinese food products are exported to more than 200 countries and regions. Among the top ten are Japan, the United States, the Republic of Korea, Hong Kong, Russia, Germany, Malaysia, the Netherlands, Indonesia and Britain.

Statistics show that quality rating of Chinese food exports is very high.

According to statistics of Chinese quality supervision agencies, from 2004 to 2006, the number of batches of food items exported from the US to China was 17222, 22584 and 28398 respectively. Among them 169, 259 and 259 batches were found to fail quality check. The percentage of unqualified items was 0.98%, 1.15% and 0.91%. 89459, 81754 and 94442 batches of food were exported from China to the US. Among them 925, 845 and 756 batches failed the quality check by the US FDA with the rate being 1.03%, 1.03% and 0.80%. In the meantime, 324245, 279156 and 275446 batches of Chinese food were exported to Japan, out of which 492, 395 and 459 batches were not up to the standard set by the Ministry of Health, Labor and Welfare of Japan. The percentage was 0.15%, 0.14% and 0.17% respectively. Chinese food exports to EU were 96988, 87464 and 91322 batches. Among them 98, 71 and 151 batches were declared below quality criteria by EU member states with the rate being 0.10%, 0.08% and 0.17%.

These figures testify to the fact that more than 99% of Chinese food exports meet applicable standards which is in parallel with the rate of US food exports to China, even a little higher.

Data from countries and regions that import Chinese food also show that Chinese food exports are safe.

According to statistics of Australia, from April to September in 2006, the rate of Chinese food exports that passed quality standards was 98%, which averaged the rate of its total food imports.

Food products consumed in Hong Kong are mainly from mainland China. According to the two food safe reports issued this year by the Food Safety Centre of Hong Kong Food and Environment Hygiene Department, who conducted two random tests of food items on a large scale, its overall quality rating of food reached 99.2% and 99.6%.

II. Food safety supervision regime in China

China has a strict regime in place to monitor and supervise food exports. Only

companies that register with quality supervision and quarantine agencies are allowed to provide raw material to companies that manufacture exported foods, which in turn have to go through hygiene registration and are up to standards. The production procedure is monitored by quality supervision and quarantine agencies. Exporters are required to put labels on their products so that they could be traced or recalled for quality check. Before being exported, each and every batch of the products will be checked by Exit and Entry quality supervision and quarantine agencies. Only those who pass the check are given green light. If required by importing countries, official certificates will be issued by Exit and Entry quality supervision and quarantine agencies. In this way food exports safety is effectively ensured. In recent years, delegations from Europe, the US, Japan, Korea and Southeast Asian countries have inspected the food export supervision regime of China and have expressed satisfaction.

China has always attached great importance to opinions and feedbacks from importing countries and regions regarding quality and safety of Chinese food exports. In light of recent incidents, to further strengthen safety of food exports, the Administration for Quality Supervision, Inspection and Quarantine (AQSIQ) in China has taken a series of additional measures. Firstly, checks and tests have been increased. When the exported items fail to match the export certificates, or are found to be problematic, they will be banned from exportation. Warning will be issued on the AQSIQ website so as to increase checks and tests on all food items produced by the company or declared by export agents. Companies that violate regulations will be put on the blacklist and barred from exportation. Secondly, random inspections will be increased of items like toothpaste that are not covered under compulsory checks. Thirdly, starting from September 1, 2007, all food exports that have passed quality inspection and quarantine checks are required to put labels on sale and transportation packages. Fourthly, immediate investigation and timely actions will be taken in response to information from importing countries and regions regarding unsafe food items. Fifthly, a blacklist of companies exporting unsafe products will be set up so as to crack down on illegal exports.

III. Calls for scientific and fair attitude

It is our hope that, on the basis of safeguarding bilateral cooperation and exchanges, governments concerned will properly handle food safety issue and treat Chinese food exports in a scientific and fair manner. Certain isolated cases should not be blown out of proportion to mislead the public into thinking that all food from China is unsafe. A case of Chinese company which violated laws and regulations should not be expanded to be the failure of the food safety regime of the Chinese Government. To exaggerate and complicate the issue is not conducive to healthy growth of bilateral trade, or to the overall bilateral relations. We hope that governments concerned can work together, in scientific and truth-seeking manner, to deal with food safety issue and to ensure health of the public.

Beijing promises greater efforts to ensure food safety(07/24/07)

The Beijing food safety authority has pledged to make greater efforts in inspecting catering businesses and food processing facilities across the city to ensure food safety.

Breakfast stands will be one of the key areas that will be scrutinized and those stands that fail to meet hygienic and quality control standards will be closed down, said a spokesman with the Beijing Food Safety Office.

Wang Xiaojing, an official in charge of publicity with the municipal department for industry and commerce, said her department had listed catering ventures and breakfast stands as industries posing high risks to food safety and would increase daily inspections.

The city's law enforcement departments have concentrated efforts in clamping down on caterers operating without permits.

The municipal department of commerce plans to select a group of "role model" enterprises to help the entire catering trade to improve the level of its management.

There are now more than 45,900 catering businesses, including hotels, restaurants and franchises, in Beijing.

In the first six months of the year, the municipal hygienic department carried out a specialized sanitation inspection of more than 10,000 eating outlets and a group of small and medium-sized enterprises were fined more than 4 million yuan.

According to Wang, the municipal department of industry and commerce received 2,980 complaints about food problems from January to June this year.

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Official: food safety in China better but still imperfect(08/07/07)

China's food safety is improving, but is still imperfect, says Lu Huisheng, deputy director of the State Food and Drug Administration (SFDA).

Lu said China was experiencing a "high risk period" for food safety, when the safety risks that appeared in different phases in developed countries had been intensified.

Lu said food safety awareness among consumers and food producers had improved.

In the first quarter, 92.8 percent of the vegetable samples in 37 cities met standards on pesticide residues; and 98.8 percent of the pork samples passed the check on sulfa drug residues, said Lu.

Sulfa drug residues indicate traces of synthetic antibacterial drugs that can harm human immune functions and hematopoietic - or formation of blood and blood cell -- systems.

Since 2006, the government had invested 94.5 million yuan (12.43 million U.S. dollars) in food safety risk research, said an official with the Ministry of Science and Technology.

The government was actively cooperating with other countries to seek solutions to issues of food safety and product quality.

Officials in charge of food safety and product quality from the EU, Japan and the United States were due to visit China later in the year, followed by the third China-U.S. food safety meeting, the second China-U.S. consumer products safety summit, the China-ASEAN Ministerial Consultation on Quality Supervision, Inspection, and Quarantine.

Ex 15

China, U.S. to strengthen co-op in food, drug supervision(08/08/07)

China and the United States will strengthen cooperation in the supervision on food and drug, said China's food and drug watchdog in Beijing on August 8.

Yan Jiangying, spokeswoman of the State Food and Drug Administration (SFDA) said that "the two sides will increase technical exchanges through seminars and training programs, and boost exchange activities between their working staff."

"The two countries also agreed to jointly fight against counterfeit drugs," she said.

Yan said China and the United States will have regular meetings between high-ranking officials and that the two sides are preparing a memorandum for drug and medical equipment supervision.

China and the United States have had negotiations on food and drug security recently including the latest visit by Rich MeKeown, chief of staff for the U.S. Department of Health and Human Services from Aug. 1 to 3.

MeKeown's visit came after the U.S. and China seized unsafe products from each side this year.

The U.S. said the melamine-tainted wheat protein from China were linked to the deaths of cats and dogs in North America and claimed some of Chinese toothpastes, tires, and seafood unsafe.

Meanwhile, China seized orange pulp and dried apricots from the U.S. that contain excessive bacteria, mildew and sulfur dioxide

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May 16, 2007

PAGE ONE

FDA Stymied In Push to Boost Safety of Produce

Amid Rise in Outbreaks Of Illness, Agency Urged New Rules, Monitoring

By JANE ZHANG
May 16, 2007

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WASHINGTON -- The Food and Drug Administration, under fire for a string of illnesses caused by contaminated vegetables, earlier this year came up with an ambitious, industry-endorsed plan calling for tough new regulations on the handling of fresh produce.

But the plan went nowhere after it got a cold reception from FDA's parent agency, the Department of Health and Human Services. And even today, amid continuing concern about the safety of the nation's food supply, efforts to address the problem remain in limbo.

People close to the FDA say HHS officials led by acting Deputy Secretary Eric Hargan rejected the FDA plan, which was presented in February at HHS headquarters. At the meeting, the FDA warned that its current approach to protecting the safety of fruits and vegetables, which relies on the industry following voluntary guidelines, was failing to stop an increase in foodborne illnesses, according to people familiar with the matter. Those in attendance included Robert Brackett, director of the FDA's Center for Food Safety and Applied Nutrition.

Among other things, the FDA outlined a three-year effort that would pump $76 million into its coffers to monitor produce safety and impose stringent rules on growers and processors to prevent contamination. Such a campaign could cut produce-related outbreaks of illness in half, the FDA officials said.

HHS spokeswoman Christina Pearson said that the February meeting was just a background session, with the FDA presenting "a wide variety of options available to us in our efforts to improve food safety," and didn't require a policy or regulatory decision.

An FDA spokeswoman referred calls seeking comment from Dr. Brackett to David Acheson, who on May 1 assumed the newly created position of FDA assistant commissioner for food protection. Dr. Acheson, who at the time of the meeting was chief medical officer of the FDA's food safety center, didn't attend the gathering but was involved in preparing materials for it.

Businesses often resist new regulations. But in recent months, major food-industry groups,

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including the United Fresh Produce Association and the Grocery Manufacturers Association, have called for new FDA rules to ensure the safety of fruits and vegetables, an approach they think will be more effective than voluntary measures in bolstering consumer confidence.

"The message to HHS, from the industry, from Congress, is there's urgency for the administration to act," says Tom Stenzel, president of the United Fresh Produce Association.

The HHS meeting came in the wake of an E. coli outbreak in bagged spinach in September that killed three people and sickened more than 200. The FDA said environmental factors, such as wild pigs, may have caused the outbreak but it can't say for sure. The spinach was processed by Natural Selection Foods LLC, San Juan Bautista, Calif.

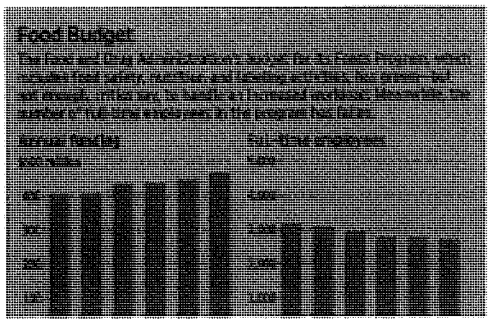
That was followed by two more E. coli outbreaks involving lettuce that sickened more than 150 people who ate at some of **Yum Brands** Inc.'s Taco Bell restaurants and Taco John's International restaurants.

E. coli is a common and ordinarily harmless bacteria found in the digestive tracts of humans and livestock. But, if consumed, it can cause kidney failure and even death, especially among children and the elderly. Cooking can kill E. coli and other bacteria, but food experts say that preventing contamination of fresh produce is crucial because it is eaten raw, and the contaminants can't be washed off.

The FDA's Dr. Acheson said that "nothing was ruled in or out" at the Feb. 6 meeting at HHS. In his new position, he plans to develop a strategic plan to improve food safety, and to meet with HHS officials to discuss a range of issues. On fresh produce, he says it is important "to think about preventive controls," but added that he doesn't believe that the government has enough scientific knowledge to impose new regulations on the handling of fresh produce.

The disclosure of the meeting comes as the FDA is under fire from congressional Democrats and consumer advocates on a range of food-safety problems, which go beyond fresh produce. In February, a salmonella outbreak triggered a recall of the popular Peter Pan and Great Value peanut-butter brands, and more than 400 people became ill.

In March, Ontario-based Menu Foods Inc. recalled more than 60 million cans of contaminated pet food after at least 16 pets died. The FDA has blamed the deaths on the chemical melamine. Melamine has since been found in feed for hogs, chickens and fish.



Some food-safety experts think that in the wake of the pet-food scandal and rising concerns about the safety of imported foods, the Bush administration will have little choice but to take a more aggressive stance on food safety.

A spokeswoman at the White House Office of Management and Budget referred questions to HHS, but says the President's Council on Food Safety, which includes

representatives from agencies dealing with foods, convened last week to discuss how to improve food safety.

Mr. Hargan, the HHS acting deputy secretary, wasn't available for comment, but Ms. Pearson, the HHS spokeswoman, denied that the department was averse to regulation. "We believe in the importance of a strong, science-based regulatory process and take our responsibility to ensure the safety of foods, drugs and other items FDA regulates very seriously," she says. "The FDA is open to suggestions about its regulatory policies at all times."

The only major food-safety regulations that have been issued during the Bush administration are four rules that were mandated by Congress as part of a bioterrorism law. A 2004 proposal aimed at reducing salmonella in eggs hasn't become a final rule, and the FDA isn't sure when it will.

The administration has been "reluctant to make something mandatory until you can prove that it will be something good. You can't prove that it will do something good until you do it," says Lester Crawford, the former FDA commissioner who supported the egg proposal.

The rising number of produce-related outbreaks has been blamed on the centralization of produce distribution, an increase in imports, the growing popularity of prechopped fruits and vegetables, and environmental factors like animal waste on farms. Fruits and vegetables are now responsible for more large-scale outbreaks of foodborne illnesses than meat, poultry or eggs. The number of E. coli cases involving fresh produce increased from six in 1998 to 356 cases in 2006.

Major players in the fresh-produce industry, hurt by sinking sales after the recent outbreaks, support mandatory steps to prevent accidental contamination. Mr. Stenzel, of the United Fresh Produce Association, said the longer the administration waits to issue rules, the more likely Congress is to do the job itself. Given the choice, he added, "the industry would much prefer the scientists at the regulatory agencies to draft the rules, rather than politicians."

Under the Clinton administration, the FDA imposed rules requiring the seafood and juice industries to take steps to prevent contamination. But in 2004, as the number of foodborne illnesses grew, the FDA wrote a voluntary action plan for the produce industry. In the past three years, it has issued warning letters to the industry, including one to California leafy-greens companies, issued advice to growers and processors on how to prevent food-safety risks and launched an investigation into a disproportionately large number of foodborne illness linked to greens in California's Salinas Valley.

A preventive-control regulation, the type proposed by the FDA at the February meeting, is tailored to each industry and company, and the government's cost stems mainly from auditing companies for compliance. For example, a processor would identify the hazards and take measures to reduce them at critical points, such as ensuring the correct chlorine level in washing water.

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Do You Know Who Your Next Meal Is Coming From?

Advertisement

By Joel Achenbach
Washington Post Staff Writer
Sunday, July 15, 2007; D01

"Made in China."

Suddenly, they're the three most alarming words in the English language.

Go to any big box store, supermarket, toy shop: When you weren't paying attention (but enjoying the bargains), everything became Made in China, or made with stuff that's made in China, or made with stuff-that's-made-with-stuff that's made in China.

Nixon shook hands with Mao; deals were cut; investments invested. Beijing got the 2008 Olympics; Shanghai got hundreds of glittering skyscrapers. Now some of our American flags are made in China, and half of our garlic, and something like 40 percent of our apple juice and 19 percent of our honey and 70 percent of our toys and 80 percent of our Vitamin C.

Also, diethylene glycol. That's the industrial antifreeze found in toothpaste imported from China.

And nitrofuran, malachite green, gentian violet -- all three of which are known to be carcinogenic -- and fluoroquinolone. These are antimicrobial agents used by the Chinese aquaculture industry, triggering a ban by the Food and Drug Administration late last month on five types of Chinese seafood.

And of course, melamine. That's C3H6N6for those wanting the molecular makeup. It's an industrial plastic that found its way into canned pet food in the United States earlier this year, triggering the recall of 60 million cans.

"These commodities are flowing in our society essentially unchecked," says former FDA associate commissioner William Hubbard. "We're gambling. Because no one's looking at this stuff!"

Not many people, at least. The FDA says it has 625 field inspectors eyeballing food across the country; they manage to scrutinize about 1 percent of imports. But the number of inspectors has dropped in recent years even as an increasing percentage of our food -- about 13 percent by one recent estimate -- comes from foreign countries, many lacking strict regulation. China has millions of small producers making food and chemicals for the global market. "As a developing country, China's food and drug supervision work began late and its foundations are weak," said Yan Jiangying, the candid spokeswoman for China's food and drug agency. "Therefore, the food and drug safety situation is not something we can be optimistic about."

And now this: Buns stuffed with cardboard.

"A hidden camera followed the man into a ramshackle building where steamers were filled with the fluffy white buns, called baozi, traditionally stuffed with minced pork," reports the Associated Press, summarizing a Chinese television news program. "It showed how cardboard [!!!!!] was first soaked to a pulp in a plastic basin of caustic soda -- a chemical base commonly used in manufacturing paper and soap -- then chopped into tiny morsels with a cleaver. Fatty pork and powdered seasoning were stirred in as flavoring and the concoction was stuffed into the buns."

The Chinese government has vowed to crack down on shady operators. It has to salvage the image of the China brand. The public relations strategy includes both defense and offense: Just yesterday, China banned meat imports from seven American companies, citing contamination by salmonella and chemical additives.

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One might detect the pungent scent of a trade war brewing.

The former head of the State Food and Drug Administration, Zheng Xiaoyu, discovered last week that it's an extremely bad time to get blamed for any of China's food and drug safety problems. He had been convicted of taking bribes in exchange for helping drug companies evade regulation. Sentenced to death in May, he confessed his crimes in a written statement, vowed to return the bribe money, and pleaded for leniency. He proved unpersuasive; the government announced Tuesday that he had been executed. We can only imagine what he was given for his last meal.

Now, pull way back for the panoramic shot: This is a complexifying world in which no single person can grasp more than a tiny scrap of the economic and social systems that sustain us. We can no longer read the code. We don't know the origin of the thing we hold in our hand. We know only that it has a funny aftertaste.

We have become end users of stuff we don't understand that comes from factories we've never seen in cities we've never heard of full of people whose language we don't speak and whose names we can't pronounce.

"There's a world below our level of awareness that affects everything we do -- the quality of food we eat, the water we drink, the clothes on our back," says Robert Clark , a professor emeritus of government at George Mason University. "They're delivered by systems that are so complex, most of the people who are actually in the system don't understand them."

Consider the pet food calamity. One of the country's biggest pet food companies, Menu Foods, decided it needed a new supplier of a single ingredient: wheat gluten. It turned to a Las Vegas company named ChemNutra that specializes in importing food and drug ingredients from China -- stuff like potassium sorbate, L-Cysteine USP29 and L-Glycine USP28 .

ChemNutra bought wheat gluten from something called Xuzhou Anying Biologic Technology Development Co. Ltd., in Jiangsu province. The gluten from Xuzhou Anying was contaminated with melamine, the industrial plastic that ChemNutra believes was intentionally put into the wheat gluten to make it appear to be higher in protein. By the time U.S. inspectors reached the manufacturing plant in China, it had been closed and scrubbed clean. The melamine played a role in sickening or killing an unknown number of pets across the United States.

"There but for the grace of God go people," says Hubbard, the former FDA official. "That same kind of contamination could have killed 4,000 or 5,000 people."

More bad news for the China brand: A New Jersey company recently recalled 450,000 potentially defective Chinese tires. And fireworks made in China reportedly malfunctioned at half a dozen different Independence Day events in Northern Virginia, with one errant shell injuring 11 people in Vienna. There's obviously the danger here of consumer jingoism: The demonization of "Orientals" has a long history. In the post-World War II era, "Made in Japan" meant, for a long time, cheap merchandise. It was a pejorative term, until the Japanese started cranking out cars and televisions and consumer gadgets that were flat-out better than ours.

Merchandise from mainland China didn't start arriving until 1980. The country has recently seen an economic boom built on exports. But many of us do not know much about China other than that it's where our shirt came from, and that it has a Great Wall. Historians will say that China invented paper and gunpowder and the compass and fireworks and a bunch of other cool stuff, but many Americans think of the Chinese inventing ways to counterfeit Hollywood
movies. We know that there are something like 1.3 billion Chinese, but we'd be hard-pressed to name a single one of them. Who among us, today, can name China's president, or prime minister, or Supreme Leader, or whatever he's called? Here's a stumper: *Is China still communist*?

Of course there are people who are highly informed, such as George Mason University government professor Frances Harbour, who was so disgusted by the working conditions in Chinese factories that she tried to boycott

anything made in China. Her boycott lasted about a year before she gave up. She realized that China wasn't the only country with sweatshops. And she found it hard to go without Chinese merchandise.

"I would have had to make my own clothes, practically," she says.

The problems with foreign imports have put a spotlight on the FDA. Democrats in Congress have assailed the FDA for being lax on food safety. "Food safety at the FDA is a stepchild," charges Rep. Rosa DeLauro, a Democrat from Connecticut. "It is nothing about prevention. It is all about after-the-fact."

The FDA has created a new position, the assistant commissioner for food protection. That would be David Acheson, who says he wants to think strategically, identify the biggest risks, try to do more than just play defense.

"Simply putting more inspectors at the ports isn't the answer," he says. "We need to move further upstream, looking at what is euphemistically called the whole life cycle of food."

Acheson points out that several of the biggest food safety scares of the past year were entirely domestic: spinach, then lettuce, then peanut butter.

"Whatever is propped up as the latest crisis is what everybody focuses on," he says. "We can't afford to do that here. We can't afford to say, food safety is all about China."

The ultimate consequences of free trade, of open borders, of the ubiquity of the shipping container that goes right from boat to truck to train to all over the place, remains an unknown. If you're a big-picture guy like Clark, you see the world as a vast petri dish.

"We've been moving around the planet for about 50, 75 thousand years," Clark says. "As we move, we carry with us large animals . . . cattle, horses, pigs, dogs . . . and they all bring their own little companions with them. The horse brought us the common cold. Cattle bring us smallpox. The big difference is the speed with which it all happens now. The speed has increased so fast, and to such a high degree, that it does become a genuinely novel condition on the planet."

The experiment is underway. No one's in charge.

And what you don't know can hurt you.

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MSNBC.com

Poll: 92 percent want 'country of origin' labels

Consumer Reports finds Americans more worried about food safety

Reuters
Updated: 11:07 a.m. ET July 11, 2007

WASHINGTON - U.S. consumers overwhelmingly support stricter food labeling laws, with 92 percent of Americans wanting to know which country produced the food they are buying, a consumer magazine said on Tuesday.

Consumer Reports said recent food scares, including worries about peanut butter and lettuce, have made Americans more interested in knowing not only how their food was produced but where it was made.

"I was definitely shocked at how high these numbers were," said the study's coauthor Dr. Urvashi Rangan, a senior scientist and policy analyst at Consumers Union, the nonprofit organization that publishes Consumer Reports magazine.

"It's much like a nutrition label or an ingredient label in that it needs to be part of the general information coming in about imported foods," she added.

The poll was conducted with 1,004 telephone interviews between June 7 and June 10.

Last month, USDA said it would reopen public comment to its so-called "country-of-origin" labeling measure until August 20.

Congress enacted the meat-labeling requirement as part of a 2002 law but has twice delayed the start date, now set for September 30, 2008.

Campaign issue?

Meatpackers and grocers as well as some farm groups say the labeling law will create an expensive record-keeping headache to track each piece of meat from the slaughter plant to grocery shelf. Other farm groups side with consumer groups in saying shoppers deserve to know if meat is imported or U.S.-grown.

Democratic presidential candidate John Edwards released on Tuesday a package of safety proposals for imported foods, including making country-of-origin labeling mandatory.

"It's time to stop the delays and stop giving in to big agribusiness and food importers," said Edwards.

In recent months, the United States has uncovered safety problems with imports of Chinese seafood, toothpaste and melamine-contaminated wheat gluten that was added into U.S. feed for pets, pigs, chickens and fish.

"It is increased oversight and serious inspections (that) will move us in the right direction," said Democratic Sen. Charles Schumer of New York.

The Consumer Reports study found 86 percent of those surveyed expect the "natural" label to mean that processed foods do not contain artificial ingredients. Still, the group said many manufacturers call their products natural foods even though they contain artificial sugars and oils.

The results also showed that 91 percent of consumers said "organic" fish should be produced without environmental pollution and be low in contaminants such as mercury and PCBs. There currently are no government guidelines in place for organic seafood.

Consumers Union, the Center for Food Safety and Food and Water Watch plan to file a complaint and petition on Wednesday with the U.S. Agriculture Department and Federal Trade Commission to prevent manufacturers

from labeling seafood as organic until a government definition is established.

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1010 WINS - On-Air, Online, On Demand

Posted: Tuesday, 07 August 2007 4:09PM

Safety-Net Holes Let Chinese Seafood into U.S. Without Testing

NEW YORK (AP) -- At least 1 million pounds of suspect Chinese seafood landed on American store shelves and dinner plates despite a Food and Drug Administration order that the shipments first be screened for banned drugs or chemicals, an Associated Press investigation has found.

The frozen shrimp, catfish and eel arrived at U.S. ports under an "import alert," which meant the FDA was supposed to hold every shipment until it had passed a laboratory test.

That was not what happened, according to an AP check of shipments since last fall. One of every four shipments the AP reviewed got through without being stopped and tested. The seafood, valued at $2.5 million, was equal to the amount 66,000 Americans aat in a yaar.

FDA officials stuck the pond-raised seafood on their watch list because of worries it contained suspected carcinogens or antibiotics not approved for seafood.

While no illnesses have been reported, the failings raise serious questions about the FDA's ability to police America's food imports. What's more, the agency is now ralying on the import alert system to screen far more Chinese seafood than ever before.

"The system is outdated and it doesn't work well. They pretend it does, but it doesn't," said Carl R. Nielsen, who oversaw import inspections at the agency until he left in 2005 to start a consulting firm. "You can't make the assumption that these would be isolated instances."

If the system cannot stop known risks, Nielsen said, how can it protect against hidden dangers, such as the ingredients from China that made toothpaste potentially poisonous and killed dozens of pets earlier this year?

China is America's biggest foreign source of seafood, the 1.06 billion pounds it supplied in 2006 accounting for 16 percent of all seafood Americans buy.

President Bush has asked a Cabinet-level panel to recommend better imported food safety safeguards. Chinese officials have promised to inspect fish farms closely for the use of drugs and chemicals, even as they called the FDA's testing mandate illegal under world trade rules.

FDA officials acknowledged that some shipments slip through import alerts, but said overall they work.

"Any time you introduce a human element into something, I don't think you can necessarily guarantee 100 percent," said Michael Chappell, the official responsible for field inspections and labs.

Normally, the FDA inspects just 1 percent of the cargo it oversees. When goods land under an import alert, however, they are considered guilty until proven innocent: All shipments are supposed to be held until private tests that cost importers thousands of dollars show the seafood is clean. Sometimes, the FDA double-checks those tests in its own labs. Products can be detained for months, irking importers who depend on volume to generate profits.

"You can't argue with FDA," said Peter Huh, co-owner of Pacific American Fish Co., a Vernon, Calif. company which paid thousands of dollars for tests on 14 of its eel or catfish shipments. "So there's nothing you can do."

To snag suspects from the torrent of goods entering the ports, the agency uses a web of computer codes and paperwork. The system is complex, and imperfect.

A shipment can escape inspection if, for example, a company uses a name or address not on an import alert, Chappell said. That appears to be what happened in one case the AP found.

Also, FDA workers who must review hundreds of shipments that flash across a computer screen each day may miss some tagged for testing.

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The agency has about 450 budgeted positions for screening approximately 20 million shipments annually of such things as fish, fruit and medical devices. At a congressional hearing last month, FDA employees doubted whether they have the resources to do the job.

The agency is bullish, however, when it targets a product.

Last summer, FDA labs began accumulating evidence that 15 percent of farm-raised shrimp, eel and catfish contained dangerous or unapproved substances. The agency started throwing individual companies on its watch list, and on June 28 issued a sweeping mandate that all shrimp, eel and catfish raised on Chinese farms be stopped and tested.

Federal food safety officials said that while the seafood poses no immediate danger, long-term exposure could increase the risk of cancer or undermine the effectiveness of drugs used to fight outbreaks of disease.

Seafood that clears the ports enters a vast distribution system that includes restaurants, wholesalers and brand-name packagers. The FDA did not tell shoppers to throw away what they had bought; agency officials said they simply had to get control over what China was sending.

The Chinese government and U.S. importers say the FDA overreacted. It would be impossible, importers say, for a person to eat enough seafood to be affected by the trace levels that FDA found of substances such as the antifungal chemical malachite green and Cipro, the antibiotic used to treat victims of the 2001 anthrax attacks.

The AP reviewed 4,300 manifests of seafood shipments from China compiled by Piers Reports, a company that tracks import-export data, and found 211 shipments that arrived under import alert between October and May.

FDA officials refused to identify exactly which shipments were tested, saying they were too busy to do so.

So the AP contacted importers directly, talking to 15 companies responsible for 112 of the 211 shipments. Eleven said their products were tested; four said the FDA did not bother to stop a total of 28 shipments weighing 1.1 million pounds. Virtually all the shipments entered through ports in the Southeast, including Tampa, Fla., Savannah, Ga., and Miami. One entered in Long Beach, which along with the adjacent Port of Los Angeles is the major U.S. gateway for imported seafood.

The importer with the most cases was Florida-based Tampa Bay Fisheries, which brings in 20 million pounds of seafood from China annually, accounting for about one-fifth of sales.

Chief executive Robbie Paterson said 23 shipments of breaded or dusted frozen shrimp delivered between October and May were not inspected. In rare cases, the FDA removes from its watch list companies that have passed five straight tests. Paterson said he assumed that was why Tampa Bay's shipments went through.

Not so: Tampa Bay's shrimp supplier -- the Fuqing City Dongyi Trading Co .-- was on the watch list.

Like many others in the importing business interviewed for this story, Paterson said he believed that import alerts were completely effective and that Chinese seafood poses no health risk.

FDA officials "are diligently doing the inspections as they see fit," Paterson said.

Three other firms said shipments were not stopped and tested.

- A shipment of frozen shrimp brought into Boston by Canada-based Fishery Products International, Ltd. The company says it independently tests imports.

- A shipment of catfish into Savannah by Florida-based Beaver Street Fisheries. The apparent reason: The name and address of the Chinese firm on the paperwork was a slightly different translation than what FDA had on record. The company says it independently tests all imports.

- Two eel shipments into Savannah and one into New York by a Southern California-based importer, which discussed its records on the condition that its name not be published.

The expanded testing mandate has rattled China. U.S. importers said they are being told that the government is holding back shipments until tests show they will pass U.S. muster. The disruption has yet to result in any substantial price increases in the United States.

"I don't really know why they conducted the special test on our products," said a woman who identified herself as Miss Lin, a spokeswoman for Shantou Red Garden Foodstuff, which the FDA placed on its watch list in April after finding its dusted shrimp contained nitrofurans, an antibiotic that may cause cancer. "We've been exporting products to the U.S. for many years and we respect their standards and we meet their standards."

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August 13, 2007

COMMENTARY

Food Fights

By JAMES M. RICE
August 13, 2007

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More and more people are worried about the safety of food coming from China, but what exactly does "safety" mean, anyway? It's no simple question, given that safety standards frequently vary from country to country, and for many reasons. Compounding the problem, "safety standards" aren't always about safety. Standards can become a back door to protectionism. The phenomenon even has a name: technical trade barriers.

Everyone plays this game. The European Union enforces safety regulations that lack support in international science; its standards on hormones prevent the import of U.S. beef, and rules on naturally occurring aflatoxin mold blocks all imports of corn and nut products from Africa. China enforces a zero-tolerance rule on salmonella and the feed-additive ractopamine in meat and animal-feed imports, although the U.S. and EU allow trace amounts, without any accompanying health problems. The U.S. blocked importation of Chinese Ya pears for two years (in 2005 and 2006) based on an alleged fungus that no scientist outside the U.S. Department of Agriculture could ever identify.

It doesn't need to be that way. Despite some safety or sanitary problems with Chinese exports, it's far better to settle these issues through technical discussions on standards rather than through political sparring. Ideally, the end result will be that both countries have the same technical standards for quality and food safety, which will mean products of the same high quality could be sold to consumers in both countries.

The alternative is a climate in which no one can be sure whether import bans are related to genuine safety concerns or politics. My own company, Tyson Foods, and others recently saw some of our processing plants banned from importing into China due to the presence of traces of salmonella that wouldn't survive proper cooking, and would have been acceptable at most other borders. The move followed what was effectively a U.S. ban on imports of several seafood types that may have resulted either from political pressure or concern over trace amount of antibiotics.

More than one year ago, there were some encouraging signs on this topic. The Joint Commission on Commerce and Trade agreed to discuss technical trade barriers. The JCCT is a forum for high-level dialogue on bilateral trade issues between the U.S. and China, and it's co-chaired by the U.S. Secretary of Commerce and China's Minister of Commerce. In their 2006 meeting, both countries agreed to start developing mutually accepted standards to avert disputes over safety regulations. The U.S. Department of Agriculture and China's Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) even signed a memorandum of understanding on this principle.

Then, silence. A dialogue on the issue never materialized. Until, that is, today. Even as the U.S. Food

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and Drug Administration has effectively banned certain types of Chinese seafood and the Chinese have blocked certain meat imports from the U.S., the two sides are finally sitting down together to start discussing standards. Real negotiations about technical food safety and sanitary standards are happening this month in both Beijing and Washington, between the FDA, USDA and AQSIQ. Last week, China's State Food and Drug Administration agreed with the U.S. FDA to increase technical exchanges through seminars and training programs, a process that will certainly increase the technical and scientific skills of Chinese regulators.

As these talks progress, China and the U.S. could turn to world health authorities, who stand a better chance of operating above the fray of national politics. The World Organization for Animal Health (OIE) and the Codex Alimentarius, which literally means the food code, of the Food and Agriculture Organization of the United Nations, provide a base from which to start. Both organizations have standards and guidelines that a member country can adopt, protecting the health of consumers and fair trade practices in our industry.

There is certainly a role for national safety regulators, who can sometimes act more nimbly than a global institution to protect consumers from newly discovered safety threats. To name one example from the pharmaceuticals sphere, U.S. regulators never approved thalidomide for widespread use despite its acceptance elsewhere. But distinguishing between prudence and protectionism requires constant vigilance.

Tyson Foods, Inc. and our industry peers have long sought a set of equal standards for trade of our products between China and the U.S. Only the recent food safety issues inside China and the U.S. have brought both governments back into a discussion. Agreements on scientific quality standards for food will facilitate the trade of food products between producers and consumers, and have the added advantage of bringing universally accepted food standards, and safe food, to all individual consumers, everywhere.

Mr. Rice is Vice President and China country manager for Tyson Foods, Inc.

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Eat Your Spinach, Japan

September 19, 2002

Following the disputes over Japan's imposition last year of provisional safeguard measures on Welsh onions and two other farm products from China, trade frictions between the two countries is once again re-intensifying this year over residual pesticide found in frozen spinach imported from China. Japan has implemented restrictive measures on spinach imports from China, to which Beijing responded with criticism calling the measures non-tariff barriers.

The latest issue surfaced with the Japanese government's announcement in May 2002 to step up inspections of frozen spinach imports from China following the finding of residual agrochemicals exceeding the designated level from the product. On May 21, the Ministry of Health, Labor and Welfare announced a policy that inspection should be carried out on each shipment of frozen spinach declared for import. With more cases of unacceptably high levels of residual agrochemicals unveiled, a series of processed foods containing Chinese frozen spinach have been recalled and a number of retailers have been refraining from selling them. On July 10, the Ministry instructed importers to refrain from importing the products and reinforce inspection. Consequently, the import of frozen spinach from China has been completely stopped since the mid-August. Furthermore, the impact of the reinforced inspections and sales restraint is spreading beyond spinach, depressing Japan's overall vegetable imports from China.

The Chinese are demanding that Japan review its standards for acceptable levels of residual pesticides, insisting that Chinese frozen spinach frequently fails to clear the standards because spinach is subjected to unreasonably strict standards than those applied to other vegetables. Indeed, the acceptable level of chlorpyrifos in spinach is set at 0.01 ppm while komatsuna (Brassica campestris rapifera), a leafy vegetable similar to spinach, is subjected to a 2 ppm limit, 200 times more than the level allowed for spinach. Considering the fact that 99 percent of imported spinach originates in China, Beijing deserves certain sympathy for its account that Japan is trying to restrict imports from China in violation of the non-discrimination principle under the World Trade Organization.

Meanwhile in Japan, the revised Food Sanitation Law was enacted on July 31, paving the way for imposing comprehensive restrictions on the imports and sales of food products produced in a certain country if products from the country are highly likely to violate the law. On August 14, a working-level negotiation on this issue was held in Beijing, in which the Japanese explained the possibility of applying the new measure to frozen spinach produced in China. The newly enacted law is directly linked to the protection of domestic growers as it enables the government to implement a comprehensive import ban on a specific foot product. Indeed, members of the ruling Liberal Democratic Party - particularly those belonging to Agriculture, Forestry and Fisheries Division - had been demanding the enactment of this law. The recent fuss over Chinese frozen spinach gave them a perfect excuse for implementing import barriers on agricultural products.

When the Japanese government invoked provisional safeguard measures last year, it provoked substantial opposition from those viewing the move as a vote-garnering attempt by politicians supported by farmers. The latest series of moves, however, have hardly met with critical voices as they have been implemented under the name of consumer protection. Protecting consumers is surely necessary. But protecting farmers under the guise of consumer protection is no different from the invocation of provisional safeguard measures last year, and will further delay Japan's structural reform and distort resource distribution in the Japanese economy. Not only the regulatory authorities but also the Japanese general public should recognize this.

Related articles:
"Can Japan be a Free Trader and a Protectionist at the Same Time?" (China in Transition column dated April 5, 2002)
"Turning Trade Friction between Japan and China into a Win-Win Game" (RIETI column dated May 29, 2001)

Author, C.H. Kwan
Senior Fellow
Research Institute of Economy, Trade and Industry (RIETI)

Editor-in-Chief, Ichiro Araki
Director of Research

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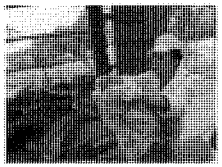
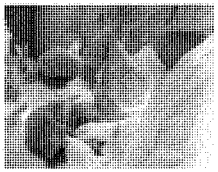
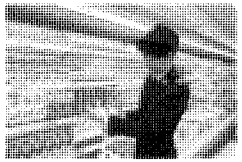
Food Safety Control in Hong Kong

Dr. Constance CHAN
Acting Controller

Centre for Food Safety

Food and Environmental Hygiene Department
The Government of the Hong Kong Special Administrative Region

Ex 33

27 August 2007

Outline

- Basics of Centre for Food Safety
- CFS' Major Areas of Work
  - Partnership
  - Import Control
  - Food Surveillance
  - Communication

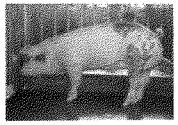
Global Changes

- Rising living standard
- Globalization of food trade
- Advancement in food technology
- Rapid information flow – food incidents, new/re-emerging hazards
- Increasing public expectation on safety of food
- Restructuring of food control framework

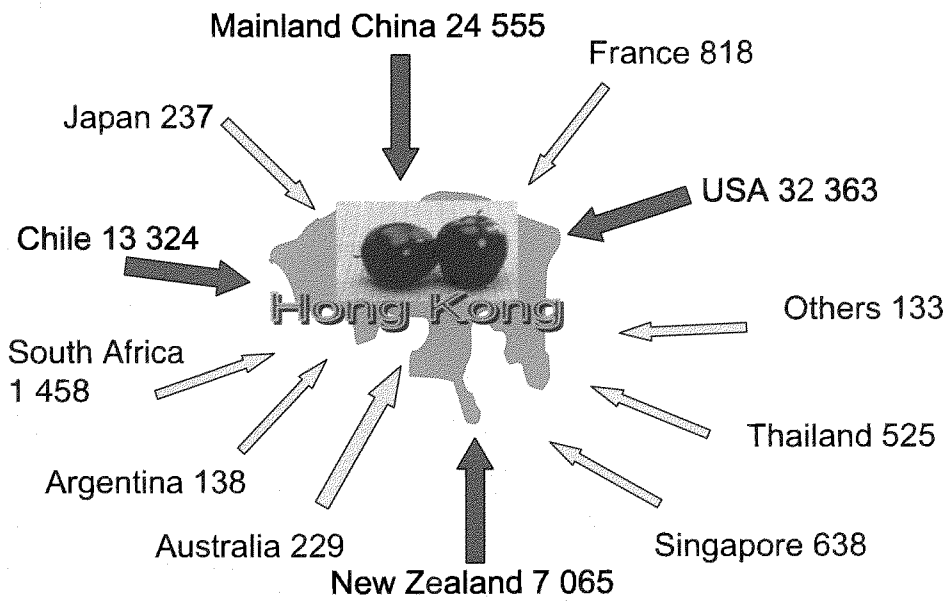
Hong Kong: A Gastronomic Melting Pot for 7 Million People

- Free port
- Densely populated international city
- Little local food production
- Over 95% of food consumed is imported
- Large volume and variety of food from around the world

In 2006, each day we consumed:

1,620 tonnes of fruits	1,440 tonnes of vegetables
Over 30,000 heads of live poultry	Over 4 million eggs
100 tonnes of freshwater fish	280 tonnes of marine fish
130 heads of live cattle	5,400 heads of live pig 

WHERE DO OUR APPLES COME FROM?



Being in a free port, the Hong Kong population is able to enjoy gourmet from around the world (Figures for 2006, in tonnes)

The Centre for Food Safety (CFS)

- Established on 2 May 2006
- Currently about 470 staff
- Multi-disciplinary team of professionals –
  - Public health physicians and nurses
  - Veterinarians
  - Health inspectors
  - Food chemists, nutritionists, food toxicologists, food biotechnologists, food scientists and others

Vision and Mission

- To protect the health of people in Hong Kong through the development and implementation of effective food safety control measures

- To enhance food safety through proactive tripartite collaboration among the Government, food trade and consumers to ensure that food available for sale in Hong Kong is safe, wholesome and fit for human consumption

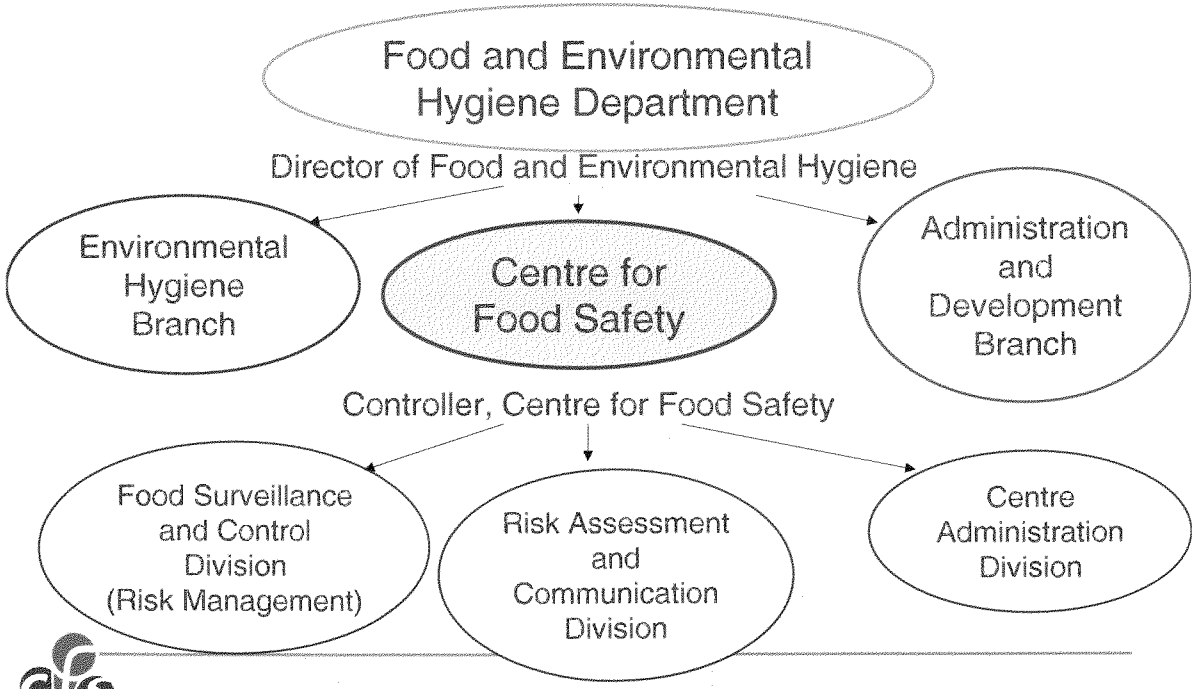
Core Values

- Integrity
- Fairness
- Effectiveness
- Professionalism
- Responsiveness
- Transparency

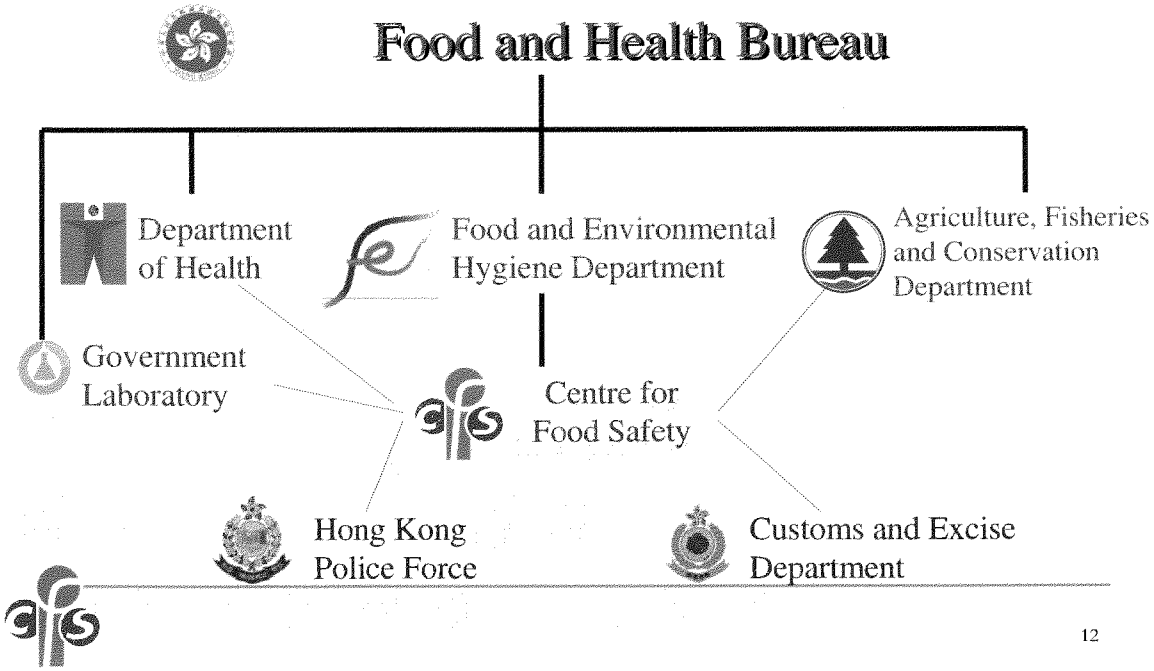
Strategy

- Adopts Integrated Approach
  - From "Farm to Fork"
  - Risk Analysis Framework
- Maintains inter-departmental cooperation
- Emphasizes tripartite collaboration between Government, the trade and consumers
- Enhances networking
  - Global players in food safety
  - Overseas food regulators
  - Experts

Organization of CFS

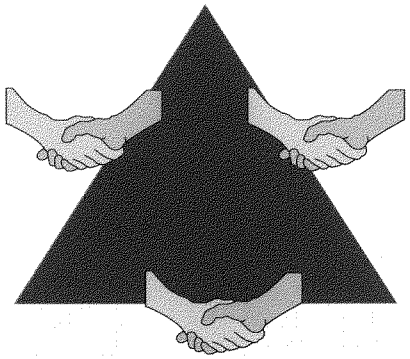


Internal Players



Partnership in Food Safety

Government



Consumers

Trade

Partnership in Food Safety

Government

Consumers

Trade
(Suppliers)

Global Players in Food Safety

- World Health Organization
- Codex Alimentarius Commission
- Food and Agriculture Organization
- World Trade Organization
- World Organization for Animal Health

Ensuring Safety of Imported Food

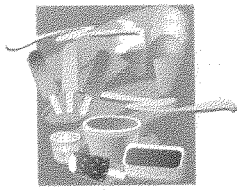
- Collaboration with Mainland and Overseas Authorities

Cooperation Arrangement with AQSIQ in 2003

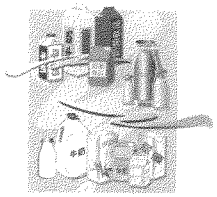
Cooperation Arrangement with GDFDA in 2006

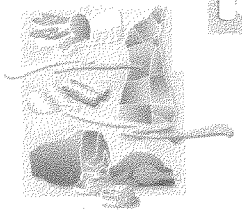
Ensuring Safety of Imported Food

- Import requirements imposed for public health reasons



- High risk foods
  - Game, meat, poultry, milk, milk beverages and frozen confections
  - Import governed by legislation
  - Require prior approval & valid health certificate





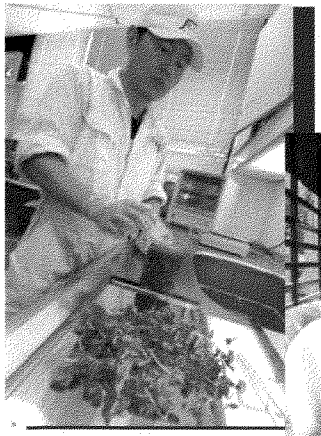
Ensuring Safety of Imported Food

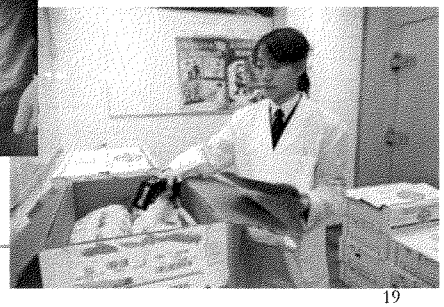
- Administrative Arrangements and Protocols with Mainland and overseas authorities
- Audit Visits
- Voluntary Pre-statutory Notification Scheme
  - egg, meat, live food animals

CFS' veterinarian visiting a fish farm in Guangdong

Ensuring Safety of Imported Food

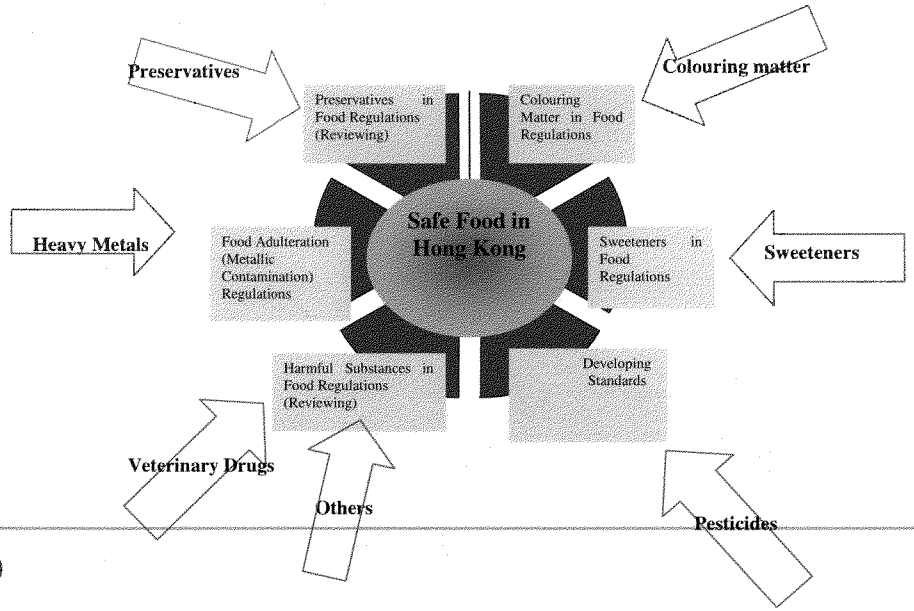
- Inspection at border





Ensuring Safety of Imported Food

- Legislative Control: import permit, health certificates, food standards

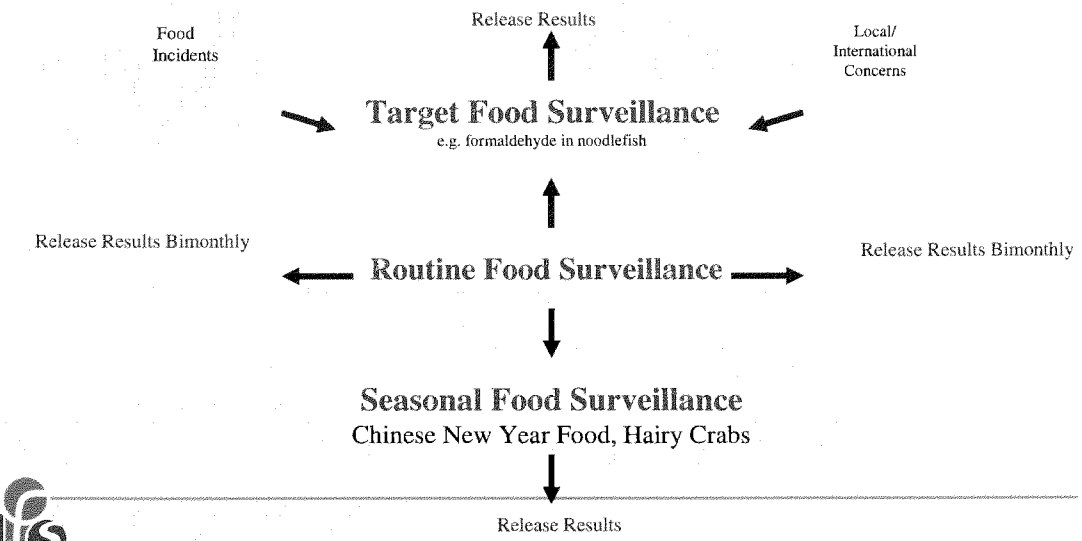


Aligning with International Food Standards

- Setting of Food Standards: Codex Alimentarius Commission, National Authorities, Local Situation (e.g. pesticides, preservatives, veterinary drugs)
- Enhancing risk assessment capacity:
  - Population-based Food Consumption Survey
  - Total Diet Studies

Proactive Food Surveillance and Alert

- Manages a 3-tier food surveillance programme at import, wholesale and retail levels



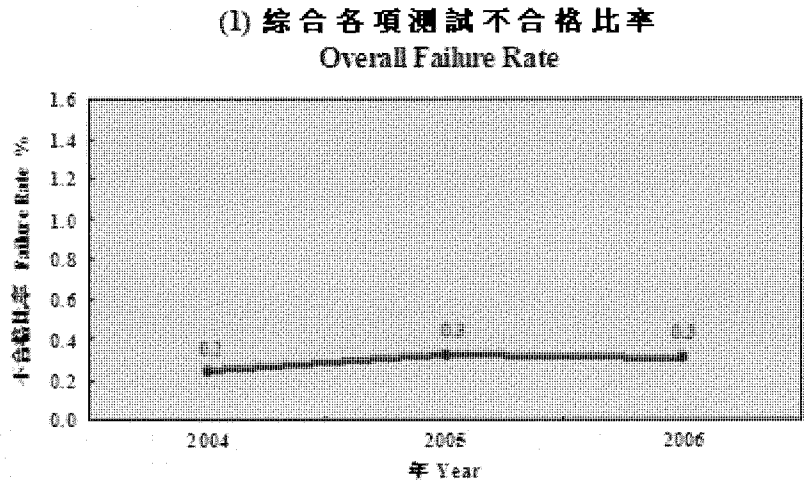
Proactive Food Surveillance and Alert

Update public regularly of results of routine surveillance

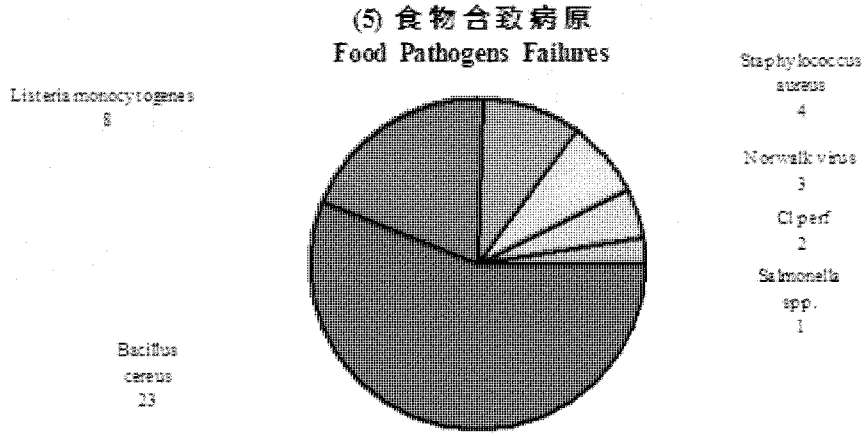
Food Surveillance Results for 2006

- Some 64,000 food samples collected
- Microbiological tests (one-third)
  - Pathogenic bacteria
  - Viruses
- Chemical tests (two-thirds)
  - Food additives
  - Contaminants
  - Natural toxins
- Overall failure rate 0.3%

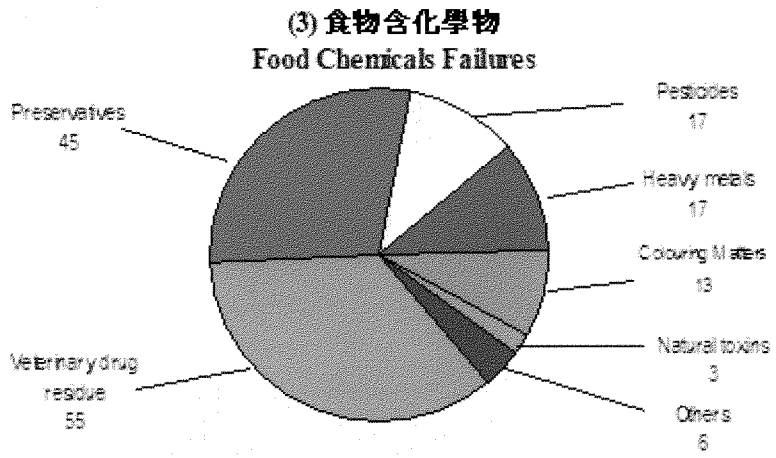
Trend for 2004 - 2006



Food Surveillance Results for 2006 – Microbiological tests



Food Surveillance Results for 2006 – Chemical tests



Managing Food Incidents

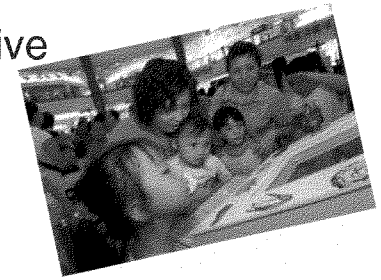
- Manage incidents proactively and efficiently
- Establishing food tracing system
- Expanding legislative power on food recall
- Balance between accuracy and speed in communicating with public and the trade

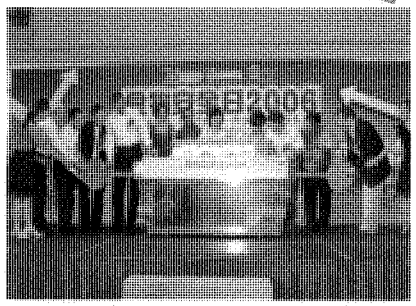
Press conference to update public of important information on food incidents

Communicating with Stakeholders

Communicate to build partnership

- Transparent
- Timely
- Friendly
- Incorporate stakeholders' perspectives
- Multiple channels
- Interactive





Communicating with Stakeholders

- Trade Consultation Forum
- Consumer Liaison Group

Communicating with Stakeholders

- Multiple channels: electronic alerts, TV programmes, newspaper column, online publication, public meetings, press conference

Empowering Stakeholders

- Equip stakeholders for playing their parts in the tripartite collaboration
- Deliver necessary knowledge
- Food labels:
  - Facilitate consumers to make informed choice
  - The trade to be more accountable

Building Networks with Mainland and Overseas Partners

- Global networks: INFOSAN, GEMS/Food network, International Symposium on Food Safety, local workshops with overseas experts

New Initiatives

- Food Safety Bill
  e.g. importer registration, food recall

DIMINISHED CAPACITY: CAN THE FDA ASSURE THE SAFETY AND SECURITY OF THE NATION'S FOOD SUPPLY?—PART IV

DECEPTION IN LABELING

TUESDAY, NOVEMBER 13, 2007

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 11:07 a.m., in room 2123, Rayburn House Office Building, Hon. Bart Stupak (chairman) presiding.

Present: Representatives Schakowsky, Dingell, Whitfield, Burgess, and Blackburn.

Staff present: David Nelson, Kevin Barstow, Richard Wilfong, John Sopko, Scott Schloegel, Kyle Chapman, Alan Slobodin, Peter Spencer, Krista Carpenter.

OPENING STATEMENT OF HON. BART STUPAK, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. STUPAK. This meeting will come to order.

Today we have a hearing on "Diminished Capacity: Can the FDA Assure the Safety and Security of our Nation's Food Supply?—Part IV—Deception in Labeling." Each Member will be recognized for an opening statement. I will begin.

This is the fourth in a series of hearings this subcommittee has held on FDA's ability to assure the safety of our Nation's food supply. Future hearings in this series are expected to include a review of the President's newly announced plan to stiffen the inspection of food imports. Our hearing today, however, will focus on the treatment of the packaging of meat and fish in carbon monoxide.

This recent innovation adopted by some members of the food processing industry is highly deceptive. Carbon monoxide artificially preserves the color of meat, making it appear fresh even after it has spoiled. For that reason, consumers cannot rely on the age-old method of looking at the appearance of meat and fish to gauge its freshness when it has been treated with carbon monoxide. Unfortunately, most consumers are unaware of this fact.

Frankly, I was astonished to learn that carbon monoxide treatment provides no consumer benefit at all. Carbon monoxide does nothing to preserve the freshness of meat and fish; carbon monoxide does nothing to prolong the food's shelf life; and carbon mon-

oxide does not make food safer; carbon monoxide does none of these things.

To put it bluntly, the sole purpose of carbon monoxide packaging is to fool consumers into believing that the meat and fish they buy is fresh no matter how old it is and no matter how decayed it might be. That's because the carbon monoxide keeps the meat looking bright red. It even makes fish look better after treatment.

Over the past few years, some of the largest food processors in the United States have decided to treat their meat with carbon monoxide, both Cargill and Hormel, which our tests find today treat large quantities of meat with carbon monoxide to artificially preserve its color indefinitely. Both companies will say this is not only a safe product, but a safer product because no butcher has touched it. That argument might have some weight if *E. coli* were not still appearing in carbon monoxide-packaged meat in Cargill and in other meat processing plants.

Over the past year, there have been more than 40 meat recalls. Since October, Cargill has had two major recalls, one involving approximately 800,000 pounds of frozen ground beef, and, most recently, more than 1 million pounds of fresh ground beef. It should be pointed out that approximately 11 percent of Cargill's fresh ground beef recall comprising 119,000 pounds had been treated and packaged with carbon monoxide. That recalled meat still looked fresh, red and wholesome, but it contained the deadly *E. coli* bacteria.

Carbon monoxide treatment also disguises rotten fish, something the FDA has known about since at least the mid–1990s. Nevertheless, that didn't stop the FDA from allowing fish importers to treat fish with so-called "tasteless smoke," whose only active ingredient is carbon monoxide. Originally, the carbon monoxide was derived from smoke, but today most fish packers are using carbon monoxide from canisters rather than from the smoking process. This begs the question of whether an FDA-approved label referring to carbon monoxide as "tasteless smoke" isn't further deceiving consumers. The U.S. market has been flooded with fish whose color is preserved or even enhanced by carbon monoxide.

The committee learned from staff visits to several U.S. ports and FDA labs that a high percentage of this carbon monoxide fish is refused entry into the United States because it is decomposing or it contains dangerous levels of histamine. The rejection rate of carbon monoxide fish at the Port of San Francisco, for example, is between 20 and 30 percent. Today we will be hearing from the president of one of the major importers of carbon monoxide-treated fish.

Despite the deceptive nature of the carbon monoxide treatment and the potential health threat, the FDA and USDA have turned a blind eye to this practice. The FDA, for example, has simply ignored Federal law which requires a formal rulemaking with public input and comment for the use of food additives or coloring. Instead, the agency has granted its permission to use carbon monoxide through an odd process in which the FDA announces it has no questions about carbon monoxide's use. I'm looking forward to exploring this matter further with both the FDA and USDA witnesses today, for I and the American people have a number of questions that need to be answered.

Lastly, I would note that soon after we opened this investigation, there were recent letters to a number of prominent food processors and retailers requesting information and records on the blasting of meat and seafood with carbon monoxide. In response, Tyson's Food, Safeway, Giant Food, and Stop & Shop all agreed to stop selling carbon monoxide-treated meat. In addition, Target decided to label all individual meat packages to inform the consumer the meat they are selling is treated with carbon monoxide, and to further caution the consumer that neither the color nor the "use by" or "freeze by" date can be relied upon as an indicator of freshness.

Perhaps we can make additional progress today. If meat and seafood companies want to blast their products with carbon monoxide to artificially enhance the color, the least they should do is label the products and warn consumers not to rely on the color, texture and apparent wholesomeness of their products.

My time is up. I will next turn to the ranking member of the subcommittee, Mr. Whitfield from Kentucky, for an opening statement, please.

OPENING STATEMENT OF HON. ED WHITFIELD, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF KENTUCKY

Mr. WHITFIELD. Chairman Stupak, thank you very much.

We certainly welcome all of the witnesses today for this important hearing. Today's hearing focuses on using modified atmospheric packaging, which uses a mixture of gases, including small amounts of carbon monoxide, nitrogen, oxygen, et cetera, to maintain fresh color and to enhance the shelf life of meat products. I might add that this same technology, in addition to being used in meat, has been used in the packaging of many other products for some time like potato chips, lunch meats, bagged salads, and other products.

Now, the FDA has reviewed the use of modified atmospheric packaging a number of times since the late 1990s, and on every occasion it has agreed that it can be classified as a safe way to package food. In addition, the Food Safety and Inspection Service reviewed scientific data on MAP and decided not to require labeling for atmospheric gases.

Mike Doyle, who is the director of food safety at the University of Georgia, in a study said that the benefits of carbon monoxide, MAP technology, far outweigh arguments against the technique. Scientists at the University of Georgia, for example, contaminated meat samples with *E. coli* and packaged them using MAP. A controlled sample was also packed in traditional packaging tainted with *E. coli*, and when left at an environment of 50 degrees Fahrenheit, the meat packaged without MAP technology had 12 times as many *E. coli* cells. So you can make the argument that this packaging using carbon monoxide provides a safer product.

Another study conducted by Texas Tech University found that the use of carbon monoxide in packaging dramatically decreased the growth of pathenogenics, bacteria, on meat. Of the estimated 100 million packages of carbon monoxide meat that has been sold and consumed in the United States, it's almost negligible of any problems with it.

I know that Chairman Stupak and Chairman Dingell have been focused on this issue for some time and have introduced legislation, and I might say that their legislation, from my understanding, does not ban the use of this technology, but requires a more prominent labeling of its use to provide better notice for consumers.

The use of this technology became an issue in the United States when a company called Calsak began an effort to ban the use of this modified technology. Calsak sells a rosemary extract that meat processors use in traditional packaging that maintains the red coloring of meat; in other words, they have a competing technology with the MAP technology. So is this issue about technology, or is this about safety?

Now, we know that Japan, Singapore and Canada have banned the use of MAP packaging for tuna, and we know that the European Union has banned it for the packaging of meat and tuna. Interestingly enough, in Norway they used it for a period of 17 years with no ill effects, and I might also point out that the European Union Scientific Committee that looked at this technology concluded that there is no health concern associated with the use of 0.3 to 0.5 percent CO and a gas mixture with CO^2 and N2 as a modified atmosphere of packaging gas for fresh meat provided that the temperature during storage and transport does not exceed a certain temperature. So even the EU Scientific Committee has said that this is not a safety issue.

I look forward to the testimony today because all of us are committed to the maximum safety for the consumers in America. I might say, though, that on the second panel of witnesses, unfortunately, our staff did not have an opportunity to interview them, and normally we do have that opportunity.

I would also point out that while a certain percent of seafood coming in through San Francisco—I guess 20 to 30 percent of the imported seafood—treated with carbon monoxide was decomposed, it would be helpful to know what percent coming in without carbon monoxide also had the same problem.

I know that Chairman Stupak and Chairman Dingell issued a letter to all of the health departments in 50 States in the U.S. about a year ago, and it's my understanding that the health departments have replied, but we have not been given access to those studies. So I'm assuming that the replies do not indicate any safety issue from those 50 States.

As I said, we look forward to this testimony on this important consumer safety issue, and I see my time has expired.

Mr. STUPAK. The Chair recognizes Mr. Dingell, the chairman of the full Committee on Energy and Commerce, for any opening statement, please.

OPENING STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. DINGELL. Mr. Chairman, thank you, and thank you for holding this important hearing and also for the excellent series of safety investigations that you have conducted this year. Each of these hearings has not only helped the committee to develop legislation,

but it has also increased Americans' awareness of the risks they face every day in their kitchens or neighborhood restaurants.

Today we turn to the approval of carbon monoxide to disguise the true colors of fish and meat, and to the refusal to disclose to the American consumer the use of this process. This is not to say that sometimes meat and fish treated with carbon monoxide are not perfectly fine when they reach the grocery stores or even the restaurant kitchens, but it concerns us greatly that the treatment with this gas enhances colors, particularly reds, to the point where spoiled meats or fish look fresh as the day they were packaged.

The regulatory agencies responsible for protecting the public health, the Food and Drug Administration—the FDA—and the U.S. Department of Agriculture—have permitted this potentially deceptive practice in the United States even though Canada, Europe and Japan all ban it. In doing so, the FDA and USDA have also refused to require the companies to label their products as treated with carbon monoxide, something that every consumer should know before a purchase.

One of the key factors for consumers in selecting meat or fish is its color, followed by its smell. We have a nice example of meat down on the hearing table. Some of the meat is a year old. I suspect that it is spoiled, although you can't tell so by the color. You probably can't tell by the smell since the packaging is totally sealed, although I suspect that, if the packaging were open, we might find that the contents are not as nice as they look.

Finally, you can't tell by the labeling because the companies have apparently convinced the regulators that consumers might be confused or frightened if they knew they were eating foods which were treated with carbon monoxide. They also might know that the food is packaged in a way which conceals the smell while the color looks good.

One of our USDA witnesses says that the packaging, if it is not bulging, is fine. Committee staff have actually been told by a Hormel scientist that the worst thing that can happen even if a food product is spoiled is that the consumer might have a "unpleasant dining experience." They argue that the spoiled meat won't hurt us. The bacteria that cause the meat to spoil are not pathogens.

Let's test these arguments. I think they are false.

We all know that Cargill, in particular, should know that meat packed in CO can also contain pathogens that can kill or harm us. Last week Cargill recalled more than 1 million pounds of ground beef suspected of containing the dangerous *E. coli* germ. Of that amount, some 119,000 pounds were treated with carbon monoxide and, therefore, would look as fresh and as pleasant as the day they were butchered until some unsuspecting customer purchased it.

Mr. Chairman, I urge you to get to the bottom of how and why these decisions were made by FDA and USDA. I also urge you to lead us to find why the companies still refuse to let the American people know that their meat or fish is being treated with carbon monoxide.

I commend you for your leadership, Mr. Chairman, in this matter and that you are helping us to understand that here we have a problem which may need a legislative fix or which will require, per-

haps, an unpleasant experience by the FDA before this subcommittee, which is so ably chaired by you.

Mr. Chairman, again, thank you for holding this hearing. It is important, and it is important to the safety of the Nation's food supply. I look forward to the testimony of the witnesses today and particularly the response to our questions from both the FDA and USDA.

Mr. Chairman, this committee has a proud record of working to protect the consumers, and I am sure, under your leadership, we will continue to fight for a strong food safety system in this country. Today I hope we will move one step closer to making this necessity a reality.

Thank you, Mr. Chairman. I yield back the balance of my time.

Mr. STUPAK. I thank the gentleman.

Mrs. Blackburn for an opening statement, please.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Mrs. BLACKBURN. Thank you, Mr. Chairman.

I thank you for the hearing that today we are going to use to examine the issue of carbon monoxide technology used in meat packaging, which provides protection against food-borne bacteria and the extended shelf life for fresh meat products. Unfortunately, this technology is being called into question over supposed safety concerns of the packaging format.

Modified atmospheric packaging has been used for over 75 years, Mr. Chairman, to prolong shelf life and to maintain color freshness. Despite situational arguments to the contrary, no conclusive evidence has been presented that links this packaging and this process to increased food-borne illness and/or death. The decomposition of meat products, spoilage alone, does not correlate to food-borne illness such as *E. coli*, and if anyone has ever had a food science class, in fact, they will know that contamination and spoilage are two very distinct issues. They are different issues. According to the University of Minnesota's Center for Infectious Disease Research and Policy, and I'm quoting from them, "There is a major public health difference between food contaminated with pathogens not detectable to human senses and that of spoiled food characterized by changes in food color, taste and texture in such ways as to make consumption unacceptable," end quote.

No packaging format creates *E. coli* or other food-borne bacteria. Instead, packaging is a marketing tool used to manage consumer expectations. If regulation eliminates the use of carbon monoxide packaging, the result will be increased meat handling, leaks and a lack of tamper-resistant packaging, which means there will be more human interaction with the product from the time it is packaged until it moves to its final destination with the consumer. The result would likely lower the quality of meat provided to consumers and would increase the potential for bacteria. This is clearly a step in the wrong direction.

Mr. Chairman, let's give consumers some credit. People eat with their eyes. If they don't trust their eyes, they surely know that they can trust their noses when confronted with rancid meat. In addi-

tion to smell, other obvious signs of spoilage exist. Consumer studies have shown that people rely on the "sell by" date, the smell and the color when determining if meat is fit for consumption.

Those advancing the argument that this carbon monoxide is bad science for meat are misleading the public. There is no need for the Federal Government to implement overzealous regulation that will likely take a step backward and away from safe and efficient meat packaging. Such regulation might open the door for the increased opportunity for further contamination. How many experts have to say that the use of carbon monoxide in meat packaging is not a food safety issue before we believe them? This hearing has nothing to do with food-borne illness. Not one case of human illness has been reported due to the consumption of spoiled food, so the case for public health risk cannot be made.

I hope that we are not participating in a kangaroo court due to certain economic interests and an intra-industry fight. I hope that we will continue to put our focus on food safety issues that have come before us that need our attention, and that we will not participate in a fight under the guise of food and consumer safety.

Thank you, Mr. Chairman, for the hearing, and I yield back my time.

Mr. STUPAK. Ms. Schakowsky for an opening statement, please, for 5 minutes.

OPENING STATEMENT OF HON. JAN SCHAKOWSKY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Ms. SCHAKOWSKY. Thank you, Mr. Chairman. I appreciate your holding this hearing today on deceptive labeling in meat packaging.

As someone who began my career in consumer advocacy by leading a housewives' campaign in 1969 to put freshness dates on food products sold in the supermarkets, this issue is one I care deeply about. It was a package labeled as skirt steak, I think, of a questionable color that led me to ask the butcher at that time in my local supermarket how old the meat was, and I was shocked by his response. He said, "Look, lady, it's fresh, and if you don't like it, you can shop somewhere else." That really launched my campaign with a number of my women friends to seek dates on food, expiration dates.

Consumers expect and deserve as much information as possible about the food they consume even when it comes to questionable packaging practices such as using carbon monoxide to keep meats looking fresh. Some may argue that because carbon monoxide is only used in the packaging, it is not a direct ingredient or a component of the food product, and that, therefore, it doesn't need to be labeled, but when carbon monoxide has the same impact on meat products as red dye or other color additives, this is important information that consumers want to have.

It's no surprise, then, that, according to a recent Consumer Federation of America poll, 78 percent of consumers said that the unlabeled use of carbon monoxide in meat packaging is deceptive, and 68 percent of consumers said they would support a law requiring the mandatory labeling of carbon monoxide.

The city of Chicago, part of which I have the honor of representing, held hearings on this issue in 2006. At that time I joined with

several of my colleagues in sending a letter to the Illinois Department of Public Health, asking that the agency prohibit the sale of meat and fish products treated with carbon monoxide in Illinois.

Businesses are taking notice. Already several major retail stores, such as Safeway and Giant, have announced they will stop selling the product, and Tyson's recently phased out the system in their packaging.

Make no mistake. The practice of treating meat and fish with carbon monoxide gives the product virtually an indefinite red color regardless of the temperature or the storage conditions. Given the fact that the EU, Canada and Japan have all banned the practice due to its misleading nature, I look forward to hearing an explanation from the USDA and from the FDA as to their rationale for approving this practice without at least a labeling requirement.

I am also looking forward to hearing from Nancy Donley, a good friend of mine, who started Safe Tables Our Priority, or S.T.O.P., a Chicago-based organization with a long track record of fighting food-borne illness and raising consumer awareness of important food safety issues that she started after a tragedy affecting her son.

Finally, I want to make sure we think about how this packaging process impacts the elderly and the disabled who may have impaired vision, reduced senses of smell and weakened immune systems. Freshness dates can be difficult to read, and changes in odor brought on by spoilage may not be apparent in the early stages. The bright red color of a meat product may be a key element in their purchasing decision, and I worry about their being misled or, even worse, their purchasing a product that will make them ill.

Mr. Chairman, on the subject of deceptive food labeling, I also look forward to the committee's looking into deceptive practices in labeling chicken infused with salt water as all natural. This practice makes the chicken heavier, and it raises the sodium content substantially, and it has led to consumers spending an additional $2 billion annually on chicken infused with salt water.

I thank you, Mr. Chairman. With that, I yield back.

Mr. STUPAK. Thank you.

Mr. Burgess for an opening statement, please.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. Thank you, Mr. Chairman. As always, I appreciate your holding this series of hearings on the Food and Drug Administration's ability to assure the safety and security of the Nation's food supply.

Throughout the hearings I feel that we have been able to shed some light on some real problems affecting our food supply here in this country. I also think we've been able to identify, perhaps, some real solutions.

It has become apparent that our Federal agencies that are tasked with helping keep Americans safe from harmful foods and harmful products are using 19th or 20th century tools when dealing with a 21st century problem. However, the Food and Drug Administration does not shoulder all of the blame in this situation.

Somehow Congress failed to intuit and to recognize the rapid change that was going to be incurred by globalization, by living in

a global village. There are multiple points to which we can affix responsibility, but it would be sheer fantasy to believe that Congress does not own its own share of the responsibility. Although the change that we can attribute to globalization did not happen quickly, it did not happen overnight. It is now up to Congress to absolve itself for not maintaining situational awareness. I believe that Congress does need to step up and give the Food and Drug Administration the resources and authorities they need to keep Americans safe. This series of hearings on the Food and Drug Administration's ability to assure the safety and security of the Nation's food supply will help us do just that.

For instance, during a hearing this summer, we learned that the Food and Drug Administration lacks the ability and the explicit authority to immediately stop dangerous food and products from coming into this country. For that reason I introduced H.R. 3967, the Imported Food Safety Improvement Act of 2007, to stop countries from sending harmful food and products into the United States. H.R. 3967 will allow us to finally take control of the food that is being sent to America. It will also send a strong message to countries that in the past have allowed harmful products entry into our stream of commerce.

So, when it comes to food safety, I feel just as strongly as many of us profess to feel about terrorism on a broader scale. We need to say to other countries, "You're either with us or against us. Solve the problem on your end, or we'll take measures to solve the problem on ours."

A review of the hearing timeline clearly shows that this legislation came about through a series of important hearings. I continue to believe in the mission we are trying to accomplish today; however, while I realize that today we are only focusing on one single form of food technology, that is the use of low oxygen in meat packing, I do wish we would have observed adherence to the original plan of holding a hearing that focused on a variety of technologies aiming at keeping our food safe. Considering the enormity of the problems we are facing in food safety, I have found the scope of today's hearing to be very narrow in its focus. In fact, it's so narrow that it limits the utility of what we should be about.

Today's hearing involves a controversy about the use of carbon monoxide in modified atmospheric packaging in meat. Fair enough. Industry is responding to demands and is moving much faster than Congress can in this regard, and the controversy is rapidly being addressed by the efforts in the marketplace and, to some degree, in response to letters from the majority.

I do appreciate the efforts of the majority's detailing this to the principal players of the industry. I would be very interested to know if the changes being contemplated in the industry are as a result of rigorous scientific investigation. I hope they are not merely a capitulation to the demands of the majority and of their staff. The majority can be commended for making this a disappearing oversight problem if what they did were to shine a bright light on a real problem; but, again, I do wonder, Mr. Chairman, if we have this response as a result of rigorous scientific investigation and sound science.

Mr. Chairman, very briefly, we have heard from the majority staff about a trip they took to China. I took a trip to China in 1993 with the Association of Aerospace Physicians. Let me tell you, I gained a new appreciation for modern American packaging and cellophane during that trip. One afternoon I took a side trip and walked through what was the equivalent of the Beijing Safeway. It was there I learned that modern American innovation was, indeed, a wonderful thing. In China, they had meat out in the open. Well, let's be honest. They had live snakes in bins, and you don't normally see those in a Safeway even here in DC, but they had meat out in the open with no covering, rendering it pretty unappetizing because of the smell, the sight of flies and the overall color. So flies, discoloration and olfactory assaults were such to make even the most ravenous of appetites vanish.

Mr. Chairman, if you are correct about the use of low oxygen being deceptive, then you are to be commended for making this a disappearing oversight problem; however, I would also like to commend Hormel for trying to make their product better by finding a way to address the issue of long-term color change through new interventions. In Mr. Ettinger's testimony, he mentions that his company has filed a patent on this new technology, so I look forward to hearing more about the technology and how it may remove some of the concerns that the use of the carbon monoxide may be deceptive.

I also look forward to the discussion with the Food and Drug Administration regarding the "generally recognized as safe" determination. I recognize that the majority leadership of this subcommittee is concerned that this process does not include a review or a comment period. I would just briefly point out that it was not during this administration, but during the previous administration that this decision was made. Apparently the Clinton administration did not have a problem that there was no review or comment period allowed.

Again, Mr. Chairman, thank you for holding the hearing. I hope we will be able to hold hearings on a broader array of topics within the entire context of food safety.

I yield back the balance of my time.

Mr. STUPAK. That concludes the opening statements by members of the subcommittee.

Our first panel is before us. On our first panel, we have Mr. Daniel Engeljohn. He is the Deputy Assistant Administrator of the Office of Policy, Program and Employee Development, Food Safety and Inspection Service, the U.S. Department of Agriculture. He is accompanied by Dr. Robert Post, the Deputy Director of the USDA's Center for Nutrition Policy and Promotion.

We have Dr. David Acheson, the Assistant Commissioner for Food Protection at the FDA. He is accompanied by Mr. Lane Highbarger, the Consumer Safety Officer for the FDA's Division of Biotechnology and GRAS Notice Review in the Center for Food Additive Safety and Applied Nutrition; Mr. Philip Spiller, the Senior Advisor for Special Projects in the FDA's Center for Food Safety and Applied Nutrition; Mr. Donald Kraemer, the Deputy Director of the Office of Food Safety at the FDA's Center for Food Safety and Applied Nutrition.

Dr. Tarantino with the Office of Food Additive Safety, the Center for Food Safety and Applied Nutrition, Food and Drug Administration. So, Dr. Tarantino, thank you for being here.

It's the policy of this subcommittee to take all testimony under oath. Please be advised that witnesses have the right under the rules of the House to be advised by counsel during their testimony.

Do any of you wish to be advised by counsel?

Everyone is shaking their heads "no," so I'll take that as a "no." Therefore, I'm going to ask you to rise and to raise your right hands to take the oath.

[Witnesses sworn.]

Mr. STUPAK. Let the record reflect the witnesses replied in the affirmative.

You are now under oath.

We will now hear a 5-minute opening statement from our first panel. You may submit a longer statement for its inclusion in the hearing record.

Dr. Engeljohn, if you'd like to start, please.

TESTIMONY OF DANIEL ENGELJOHN, DEPUTY ASSISTANT ADMINISTRATOR, OFFICE OF POLICY, PROGRAM AND EMPLOYEE DEVELOPMENT, FOOD SAFETY AND INSPECTION SERVICE, U.S. DEPARTMENT OF AGRICULTURE, ACCOMPANIED BY ROBERT POST, DEPUTY DIRECTOR, CENTER FOR NUTRITION POLICY AND PROMOTION, U.S. DEPARTMENT OF AGRICULTURE;

Mr. ENGELJOHN. Mr. Chairman and members of the committee, thank you for inviting me to appear before you today to discuss carbon monoxide in meat packaging.

I am Dr. Daniel Engeljohn of the USDA's Food Safety and Inspection Service. I am a senior executive with the Department, developing food safety policy, where I have been for the last 29 years. My educational background is in animal science, food science and allied health science. I hold a Ph.D. in human nutrition with an emphasis on experimental research methods, and my work experience at the USDA has centered on risk management policies associated with the safety of meat, poultry and processed eggs. I currently serve on the National Advisory Committee on Microbiological Criteria for Foods, whereby the committee provides guidance to the USDA and to the Food and Drug Administration on food safety issues.

The development in new technologies is largely initiated by industry itself as it responds to consumer demands. In 2000, FSIS and the FDA entered into a Memorandum of Understanding, allowing the simultaneous review of new technologies to increase the speed with which useful new technologies could be used. The FDA determines the safety of a food ingredient and its safe levels of use while, simultaneously, FSIS evaluates whether the ingredient has its intended technical effect. Allowing these evaluations to occur at the same time effectively decreases the time any food ingredient spends in review.

Under the Federal Meat Inspection Act, FSIS is responsible for determining the efficacy and suitability for food safety ingredients and additives in meat products as well as for prescribing safe con-

ditions for use. "Suitability" refers to the effectiveness of the ingredient or additive in performing the intended purpose of use, and it refers to the assurance that the conditions of use will not result in an adulterated product or one that would mislead the consumer.

One form of technology used by the meat industry that has received a great deal of attention in recent months is carbon monoxide in packaging. Carbon monoxide is used to stabilize the color pigment of meat when it is red and, therefore, most appealing to consumers. The use of carbon monoxide in packaging does not impart a color to the meat; it simply maintains its naturally occurring color. Carbon monoxide does not become a part of the product and dissipates as soon as the package is opened. This is unlike other ingredients used to stabilize the red color of meat, such as citric acid, sodium ascorbate and rosemary extract, all of which actually do become a part of the product and may have a lasting effect on product color even after packaging is removed.

In 2002, carbon monoxide, for use as a component of modified atmospheric packaging, was accepted by the FDA as being generally recognized as safe, or GRAS. In accordance with our Memorandum of Understanding with the FDA, the USDA in 2004 reviewed the GRAS notice submitted by Precept Foods and wrote two letters to the FDA dated April 28 and June 2, 2004, in response. It is common for FSIS to find data in original GRAS notices to be insufficient for a suitability determination and for us to notify the FDA that we consider the petition to be incomplete. The petitioners then provide additional data, which may result in our accepting the suitability of an ingredient or the acceptance with or without specific use conditions.

On April 28, 2004, we sent the FDA a letter that reflected the preliminary FSIS decision based on the data we were submitted with the original GRAS notice from Precept Foods, the petitioner. As a result of the April 28 letter, the petitioner submitted additional data to address our concerns that the application of carbon monoxide may be misleading to consumers if used as described in the initial GRAS notice.

The June 2, 2004, letter describes that our earlier concerns have been addressed by Precept Foods. Precept provided data evaluating shelf life, the microbiological outgrowth and the color of meat products treated and packaged using various methods, including that proposed in the original GRAS notice. These data are generally described in the third paragraph of the June 2 letter.

As stated in the June response, Precept provided additional information to FSIS, addressing specific suitability concerns raised in the April 28 letter. Based on the spoilage information and use conditions provided by Precept, FSIS reversed its decision and determined that the use of carbon monoxide is suitable in modified atmospheric packaging, but only when a "use by" or a "freeze by" date is applied. "Use by" or "freeze by" dates are required on all systems in which carbon monoxide is in direct contact with meat.

FSIS will continue to make its labeling decisions and its suitability reviews on the basis of the FDA's safety conclusions. Based on the data presented at the time of the letters, FSIS stands by its 2004 decision on suitability for the use of carbon monoxide in meat packaging; however, as always, FSIS would reassess the situation

if new data become available. FSIS has also asked our sister agency at the USDA, the Agricultural Research Service, to conduct research related to packaging systems.

Thank you for the opportunity to testify before you today. I look forward to addressing questions you might have.

[The prepared statement of Mr. Engeljohn follows:]

TESTIMONY OF DANIEL ENGELJOHN

Mr. Chairman and members of the committee, thank you for inviting me to appear before you today to discuss carbon monoxide (CO) in meat packaging. I am Dr. Dan Engeljohn of USDA's Food Safety and Inspection Service (FSIS).

FSIS is the USDA public health regulatory agency responsible for the administration of laws and regulations that are designed to ensure that the Nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and properly labeled, regardless of whether those products are sold in the United States or imported to, or exported from, the United States. FSIS is also responsible for determining that foreign meat and poultry plants operate under an inspection system equivalent to the United States before they can export to the United States.

REVIEWING TECHNOLOGY IN THE MEAT INDUSTRY

The development of new technologies is largely initiated by industry itself, as it responds to consumer demands. There are two different types of technologies that are subject to review: processing technologies and ingredient technologies. Processing technologies are those technologies developed to aid in the production of meat, poultry, and egg products. Examples of processing technologies include carcass washes, the steam vacuum, and steam pasteurization.

Ingredient technologies are those technologies that involve the addition of an ingredient, generally as defined by FDA, to a product or the use of packaging to ensure safety or increase shelf life. Examples of this kind of technology include carbon monoxide packaging and irradiation.

Prior to 2000, the review process for new ingredients was lengthy and cumbersome. FDA was responsible for the initial safety review. This was then followed by a review by FSIS to determine the acceptability or suitability of the technology; that is, to determine whether the ingredient served the purpose for which it was intended. In 2000, FSIS and FDA entered into a Memorandum of Understanding allowing simultaneous review of new technologies to increase the speed with which useful new food ingredients could be used.

FDA determines the safety of a food ingredient and its safe levels of use, while simultaneously FSIS evaluates whether the ingredient has its intended technical effect. Allowing these evaluations to occur at the same time effectively decreases the time any food ingredient spends in review.

Under the Federal Meat Inspection Act (FMIA), FSIS is responsible for determining the efficacy and suitability of food ingredients and additives in meat products as well as prescribing safe conditions of use. Suitability refers to the effectiveness of the ingredient or additive in performing the intended purpose of use and the assurance that the conditions of use will not result in an adulterated product or one that will mislead consumers.

CARBON MONOXIDE IN MEAT PACKAGING

One form of technology used by the meat industry that has received a great deal of attention in recent months is carbon monoxide in packaging. Carbon monoxide is used to stabilize the color pigment of meat, when it is red and, therefore, most appealing to consumers. Use of carbon monoxide in packaging does not impart a color to the meat; it simply maintains its naturally occurring color.

Carbon monoxide does not become a part of the product and dissipates as soon as the package is opened. This is unlike other ingredients used to stabilize the red color of meat, such as citric acid, sodium ascorbate, and rosemary extract, all of which actually do become a part of the product and may have a lasting effect on product color even after packaging is removed.

In 2002, carbon monoxide, for use as a component of modified atmosphere packaging, was accepted by FDA as being "Generally Recognized as Safe," or GRAS. GRAS refers to a chemical or substance that is added to food and is exempt from regulation because its extensive use has produced no known harmful effects. GRAS notifications must be accompanied by scientific data establishing that, under the pro-

posed conditions of use, the substance is safe, and that it will be used at the lowest levels necessary to accomplish the intended functional effects. USDA assesses suitability of use under the proposed conditions after FDA has assessed the ingredient's safety.

In accordance with our Memorandum of Understanding with FDA, USDA in 2004 reviewed the GRAS notice submitted by Precept Foods, and wrote two letters to FDA, dated April 28 and June 2, 2004 in response.

It is common for FSIS to find data in original GRAS Notices to be insufficient for a suitability determination and for us to notify FDA that we consider the petition to be incomplete. The petitioners then provide additional data which may result in our accepting the suitability of the ingredient or substance with or without specific use conditions.

On April 28, 2004, we sent FDA a letter that reflected a preliminary FSIS decision that was based on the data that were submitted with the original GRAS Notice from Precept Foods, LLC, the petitioner. As a result of the April 28 letter, the petitioner submitted additional data to address our concern that the application of carbon monoxide may be misleading to consumers if used as described in the initial GRAS notice.

The June 2, 2004 letter describes that our earlier concerns had been addressed by Precept Foods, LLC. Precept provided data evaluating shelf life, microbial outgrowth, and color of meat products treated and packaged using various methods including that proposed in the original GRAS notice. These data are generally described in the third paragraph of the June 2 letter.

As stated in the June response, Precept provided additional information to FSIS addressing specific suitability concerns raised in the April 28 letter. Based on the spoilage information and use conditions provided by Precept, FSIS reversed its decision and determined that the use of carbon monoxide is suitable in modified atmosphere packaging, but only when a use-by or freeze-by date is applied. Use-by or freeze-by dates are required on all systems in which carbon monoxide is in direct contact with the meat.

In November 2005, FDA received a petition asking it to withdraw its decision that carbon monoxide in meat packaging is Generally Recognized as Safe. FSIS will continue to make its labeling decisions and its suitability reviews on the basis of FDA's safety conclusions. Based on the data presented at the time, FSIS stands by its 2004 decision on the suitability of the use of carbon monoxide in meat packaging. However, as always, FSIS would reassess the situation if new data becomes available. FSIS has also asked USDA's Agricultural Research Service (ARS) to conduct research related to packaging systems.

Thank you for the opportunity to testify before you today. I look forward to addressing any questions you might have.

Mr. STUPAK. Thank you. Dr. Post, I understand you're not going to give an opening, or are you?

Mr. POST. No, I am not.

Mr. STUPAK. OK.

Dr. Acheson, I think you're the next one to give an opening statement then.

TESTIMONY OF DAVID W.K. ACHESON, M.D., ASSISTANT COMMISSIONER FOR FOOD PROTECTION, FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY LANE HIGHBARGER, CONSUMER SAFETY OFFICER, DIVISION OF BIOTECHNOLOGY AND GRAS NOTICE REVIEW, OFFICE OF FOOD ADDITIVE SAFETY, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION

Dr. ACHESON. Good morning, Chairman Stupak and members of the subcommittee. I am Dr. David Acheson, the Assistant Commissioner for Food Protection for the Food and Drug Administration, and I'm joined today by my colleagues at the FDA and the USDA.

The FDA appreciates the opportunity to testify this morning. To start, I'll briefly highlight the recently released Food Protection

Plan and the Import Safety Plan. I will then address your concerns about the use of carbon monoxide in modified atmospheric packaging for meat and as a preservative for fish.

In May 2007, the FDA was charged with developing a comprehensive and integrated food protection plan to keep the Nation's food supply safe from both unintentional and deliberate contamination. The underlying principle of the Food Protection Plan is to build in safety measures across a product's life cycle from production to consumption.

Mr. STUPAK. Doctor, if I may, we will have that hearing in January. So, if you want to go right to carbon monoxide, we could probably expedite it because we do have quite a few people on this panel if we're going to get right to our testimony. So, if you want to go to carbon monoxide and GRAS, we'd appreciate it.

Dr. ACHESON. It would be my pleasure to do that.

Mr. STUPAK. Thank you.

Dr. ACHESON. Turning now to carbon monoxide, the Food, Drug and Cosmetic Act, section 201(s) provides that a substance that is generally recognized among qualified experts as having been shown to be safe under the conditions of its intended use is excluded from the definition of a "food additive." It is therefore not subject to the food additive petition process.

For these substances that are generally recognized as safe, or GRAS, an interested party such as a food manufacturer may notify the FDA of its conclusion that a substance is GRAS under the intended conditions of use. The FDA reviews the GRAS notice to determine whether it provides a sufficient basis to support the party's GRAS self-determination and then responds to the notifier as to whether the agency has any questions.

To show that a substance is generally recognized as safe, the proponent must show that there is a consensus of expert opinion regarding the safety of the specified use of the substance. Unanimity among experts regarding the safety of a substance is not required.

During the period 2000 through 2005, the FDA responded to three GRAS notices for the use of carbon monoxide in modified atmospheric packaging systems for meat and one for notice of the use of tasteless smoke in tuna. The FDA responded by stating that the agency does not question the basis for the GRAS determinations.

The FDA routinely consults with the USDA's Food Safety and Inspection Service to address our related but separate roles in the regulation of ingredients in meat, including the three GRAS notices for meat. The FDA can and does place additional limitations on the use of GRAS substances beyond those specified in the notifications.

We are aware that concerns have been raised about the possible misuse of CO in seafood and the use of CO-containing MAP systems for meat. The FDA has received citizen petitions which challenge the FDA's acceptance of the GRAS status of these products. We continue to receive information submitted for consultation under the citizen petition process, and we are continuing to review and to analyze that information.

In conclusion, ensuring that FDA-regulated products are safe and secure is a vital part of FDA's mission. The Food Protection Plan provides an updated approach to assure that the U.S. food

supply remains one of the safest in the world, and I look forward to presenting that to you later.

We look forward to working with this committee and with the Congress on implementing the Food Protection Plan and the Import Safety Plan. Thank you for the opportunity to discuss the FDA's activities to enhance food safety. I'd be happy to answer any questions.

[The prepared statement of Dr. Acheson follows:]

Statement
Before the Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
United States House of Representatives

Recent Food Safety Activities at the Food and Drug Administration

Statement of
David Acheson, M.D., F.R.C.P.
Assistant Commissioner for Food Protection
Food and Drug Administration
U.S. Department of Health and Human Services

For Release Only Upon Delivery

Tuesday, November 13, 2007

INTRODUCTION

Good morning, Chairman Stupak and Members of the Subcommittee. I am Dr. David Acheson, Assistant Commissioner for Food Protection at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). FDA appreciates the opportunity to discuss our new Food Protection Plan (or the Plan) and the Import Safety Action Plan, which were released last week. You also asked that we address the use of carbon monoxide in modified atmosphere packaging for meat and fish.

In May 2007, Secretary of Health and Human Services Michael O. Leavitt and Commissioner of Food and Drugs Andrew C. von Eschenbach, M.D., charged FDA with developing a comprehensive and integrated FDA Food Protection Plan to keep the nation's food supply safe from both unintentional and deliberate contamination. Driven by science and modern information technology, the Plan aims to identify potential hazards and counteract them before they can do harm. I would now like to share some of the highlights of this plan.

FOOD PROTECTION PLAN

The Plan builds in safety measures that focus on risks across a product's life cycle, from the time a food is produced to the time it is distributed and consumed. FDA's integrated approach within the Food Protection Plan encompasses three core elements: prevention, intervention, and response.

The *prevention* element means promoting increased corporate responsibility, identifying risks and building in mitigation steps so that food problems do not occur in the first place. The *intervention* element focuses on risk-based inspections, sampling, and surveillance at all points in the food supply chain. The *response* element bolsters FDA's emergency response efforts by allowing for increased speed and efficiency and improved communication.

While American consumers enjoy one of the safest food supplies in the world, growing challenges require a new approach to food protection at FDA – an increased emphasis on prevention. Recent outbreaks linked to fresh produce, peanut butter, and pet foods show how FDA responds quickly to contain food safety problems. While this level of response needs to be maintained and even enhanced, there is also a need to focus more on building safety into products right from the start to meet the challenges of today. FDA will work with the private sector to build on the actions of the food industry to ensure product safety. Building safety into products is described in one word: prevention.

Prevention

Prevention is the first essential step for an effective, proactive food safety and defense plan. FDA's plan implements three key prevention steps: (1) promote increased corporate responsibility to prevent foodborne illnesses; (2) identify food vulnerabilities and assess risk; and (3) expand the understanding and use of effective mitigation strategies. The prevention steps are risk-based and will be implemented as appropriate to particular segments of the industry, taking into account that some foods are inherently safer than others.

First, to promote increased corporate responsibility, FDA must strategically place greater emphasis on preventive measures for food safety and food defense. These measures will promote improved food protection capabilities throughout the food supply chain. This will require close interaction with growers, manufacturers, distributors, retailers and food service providers, and importers. FDA will continue to work with industry and state and local governments to further develop the tools and science needed to identify vulnerabilities and determine the most effective approaches. With regard to imports, FDA will also work with foreign governments, which have a greater ability to oversee manufacturers within their borders to ensure compliance with U.S. safety standards

FDA is requesting new authorities to accomplish this first goal. For example, the Food Protection Plan outlines new authorities to require entities in the food supply chain to implement measures *solely* intended to protect against the intentional adulteration of food by terrorists or criminals at points of high vulnerability. FDA is also seeking explicit authority to issue regulations requiring that high-risk foods be prepared, packed, and held under a system of preventive food safety controls for high-risk foods – those that have been associated with repeated instances of serious health problems or death to humans or animals from unintentional contamination.

Second, to identify food vulnerabilities and assess risk, FDA will work with the food industry, consumer groups, and Federal, state, local, and international partners to generate the additional data needed to strengthen our understanding of food safety and food defense risks and vulnerabilities. A comprehensive, risk-based approach allows

FDA to maximize the effectiveness of its available resources by focusing on food products that have the potential to pose the greatest risk to human and animal health. By analyzing data collected throughout the food product life cycle, we are better able to detect risks posed by food products. We are also better able to recognize key junctures where timely intervention can reduce or avoid those risks. Working with HHS's Centers for Disease Control and Prevention (CDC), FDA will also build the capacity to attribute pathogens to specific foods and identify where in the production life cycle the foods became contaminated. When established and emerging risks are identified, assessed, and ranked, we are able to more effectively allocate our available resources to manage these risks.

Third, in order to expand the understanding and use of effective mitigation strategies, FDA will initiate risk-driven research about the sources, spread, and prevention of contamination. We will also develop new mitigation tools and implement appropriate risk management strategies. Building on risk assessments, FDA will initiate basic research to enhance our understanding of sources of contamination, modes of spreading, and how best to prevent contamination. This information will inform FDA's efforts to promote increased corporate responsibility to implement effective preventive steps. Focusing on higher risk foods, FDA will conduct research and leverage relationships with outside organizations. FDA will also research, evaluate, and develop new methods to detect contaminants in foods, and seek to facilitate new technologies that enhance food safety.

Intervention

Because no plan will prevent 100 percent of food contamination, FDA is also focused on having targeted, risk-based interventions to provide further protection. These interventions must ensure that the preventive measures called for are implemented correctly. The Plan includes ways to focus on inspections and sampling based on risk, enhance risk-based surveillance and improve the detection of food system signals that indicate contamination.

However, the universe of domestic and foreign food establishments subject to FDA inspection is immense and continues to increase. Therefore, legislation to authorize FDA to accredit or recognize and use highly qualified independent third parties to evaluate compliance with FDA requirements would allow FDA to allocate resources more effectively. This would be another effective way to further assess the growing universe of food establishments. Use of accredited third parties would be voluntary and might offer more in-depth review and possibly faster review times and expedited entry for imported goods manufactured in facilities inspected by accredited third parties. FDA would not be bound by these third-party inspections in determining compliance with FDA requirements. However, use of accredited third parties may be taken into consideration by FDA when setting inspection and surveillance priorities.

In order to enhance the Agency's risk-based surveillance, FDA plans to focus on improving our ability to target imported foods for inspection based on risk through the use of advanced screening technology at the border and enhanced information sharing

agreements with key foreign countries.

Also, as part of the FY 2008 budget, the Administration proposed a new user fee requiring manufacturers and laboratories to pay the full costs of reinspections and associated follow-up work when FDA reinspects facilities due to failure to meet current Good Manufacturing Practices (cGMPs) or other FDA requirements. Where FDA identifies violations during an inspection or issues a warning letter, FDA conducts follow-up inspections to verify a firm's corrective action. The proposed fee ensures that facilities not complying with health and safety standards bear the cost of reinspection.

Further, FDA should have the option of moving the inspection of high-risk products of concern "upstream" by entering into agreements with the exporting country's regulatory authority for that entity (or an FDA-recognized third party inspector) to certify each shipment or class of shipments for compliance with FDA's standards *prior* to shipment. FDA would apply this requirement to imported products that have been shown to pose a threat to public health for U.S. consumers. While FDA would retain the authority to verify the safety of imported products, this approach shares the burden of ensuring the safety of food products with the exporting country. For such a system to be effective, FDA will have to establish an in-depth collaboration with the relevant foreign government authority to ensure that the standards, processes, and criteria by which the foreign authority or third party is certifying products are consistent with FDA's. The Agency will also have to take several steps to ensure a secure system that prevents counterfeiting of the certificates and takes into

consideration transshipment of products as a way to avoid certification. FDA would use non-discriminatory, scientific, and risk-based criteria to determine the focus of this proposed authority.

As noted earlier, improving the detection of food system "signals" that indicate contamination is an important component of enhancing our intervention capabilities. FDA can better detect and more quickly identify risk "signals" in the food supply chain by deploying new rapid screening tools and methods to identify pathogens and other contaminants and by enhancing its ability to "map" or trace adverse events back to their causes by improving its Adverse Event and Consumer Complaint Reporting System. This additional information will serve as a supplemental warning indicator for trending emerging food protection problems.

The recent pet food recalls showed us that we must continue to focus our efforts on animal food and feed, as well as human food. For example, to provide the information necessary to allow for early detection of, and intervention with, contaminated pet food, FDA will work with the veterinary community, veterinary hospitals, and other private U.S. sources to develop an early warning surveillance and notification system to alert veterinarians and others about problems with the pet food supply.

Response

During the past year, FDA responded to food safety problems with contaminated spinach, lettuce, vegetable proteins, and peanut butter, among other foods. While

FDA's response to these outbreaks was swift and effective, there is always a need to respond faster and communicate more effectively with consumers and other partners.

To improve our immediate response, FDA will work with stakeholders to develop an action plan for implementing more effective trace-back process improvements and technologies to more rapidly and precisely track the origin and destination of contaminated foods, feed, and ingredients. We will also increase collaboration with foreign, Federal, state, and local FDA partners to identify a contamination source, remove contaminated products, and implement corrective actions.

Another key component of improving FDA's response is additional authority for emergency responses. FDA is requesting authority for mandatory recall authority and enhanced access to food records during emergencies. FDA is seeking mandatory recall authority to be used only when the current process of voluntary recalls fails to promptly remove foods that present a threat of serious harm to humans or animals. Although FDA has the authority to seize adulterated or misbranded food, this is not the most efficient option when contaminated product has already been distributed to hundreds or thousands of locations. And while FDA has been able to accomplish most recalls through voluntary actions by product manufacturers or distributors, there have been rare instances in which a firm was unwilling to conduct a recall. In such situations, FDA needs the ability to require a firm to conduct a recall to ensure the prompt and complete removal from distribution channels of food that presents a threat of serious harm to humans or animals. This authority would be limited to foods that the

Secretary has reason to believe are adulterated and present a threat of serious adverse health consequences or death. It would be imposed only if a firm refuses or unduly delays conducting a voluntary recall. An order to recall food could only be issued by the HHS Secretary, Deputy Secretary, or Commissioner of Food and Drugs, and would be accompanied by appropriate due process rights.

FDA is seeking authority that would give the Agency more complete and streamlined access to records necessary to identify the source or cause of foodborne illness and take needed action during food related emergencies. Improved access to information concerning the safety and security of food, including records related to an article of food or related articles of food that may present a threat, will enhance FDA's ability to identify problems, respond quickly and appropriately, and protect public health. The requirement would not impose any new recordkeeping burdens and would maintain the current statutory exclusions for the records of farms and restaurants.

Currently, access to records under section 414 of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act) is limited to instances where, for an article of food, FDA has a reasonable belief that the food is adulterated *and* presents a threat of serious adverse health consequences or death. FDA proposes to expand access to records of *related* articles of food, such as food produced on the same manufacturing line. FDA also proposes, in food-related emergencies, to remove the adulteration requirement to allow its inspectors access to records in emergency situations where FDA has a reasonable belief that an article of food presents a threat of serious adverse health consequences or death.

IMPORT SAFETY ACTION PLAN

The President has engaged directly in the effort to make sure we are doing everything we can to protect Americans from unsafe imports. On July 18, he issued an Executive Order creating a Cabinet-level Working Group on Import Safety to promote the safety of imported products. The working group, which includes representatives from twelve Federal departments and agencies, including FDA, the Department of Agriculture (USDA), and the Department of Commerce, reviewed the procedures, regulations, and practices for ensuring that imported food, drugs, and other consumer products are safe.

On November 6, Secretary Leavitt presented the Import Safety Action Plan to the President. This Action Plan presents broad recommendations and specific short- and long-term action steps, categorized under the organizing principles of prevention, intervention, and response. Each action item is based on the building blocks identified in the Strategic Framework, released in September 2007. That report concluded that the United States must transition from an outdated "snapshot" approach to import safety, in which decisions are made at the border, to a cost-effective, prevention-focused model that identifies and targets critical points in the import life cycle where the risk of the product is greatest, and then verifies the safety of products at those important phases.

This Action Plan follows the organizing principles identified in the Strategic Framework – prevention, intervention, and response. I would like to point out a few key recommendations that affect FDA. Consistent with the Food Protection Plan, the Action Plan recommends that

the Agency have explicit authority to issue regulations requiring preventive food safety controls for high-risk foods and authority to require entities in the food supply chain to implement measures solely intended to protect against the intentional adulteration of food.

The Action Plan recommends that FDA examine food-safety control systems of other countries to determine whether improvements can be made to the operation of FDA's food regulatory program to provide the Agency with comprehensive knowledge of food safety systems of other countries. FDA could identify elements or components of those systems that are recognized as food safety system "best practices" and utilize them to strengthen and enhance FDA's prevention, intervention, and response activities.

Another recommendation is that FDA develops a voluntary certification program based on risk for foreign producers of certain products who export to the U.S. Such requirements would apply to designated high-risk products imported from countries with which FDA has an agreement to establish a certification program that provides levels of safety that are consistent with FDA standards. In order to implement this, FDA would need legislative authority to accredit independent third parties to verify compliance with FDA requirements. The Action Plan also recommends that FDA have the authority to issue a mandatory recall of food products when voluntary recalls are not effective.

GRAS STATUS OF CARBON MONOXIDE AND TASTELESS SMOKE

Under sections 201(s) and 409 of the FD&C Act, any substance, the intended use of which results or may reasonably be expected to result in its becoming a component of food, or otherwise affecting the characteristics of any food, is a food additive subject to premarket review and approval by FDA, unless the substance falls within one of the exclusions from the definition of "food additive" in section 201(s) or meets the exemption for investigational use in section 409(j) of the Act.

Under section 201(s) of the FD&C Act, a substance that is generally recognized among qualified experts as having been adequately shown to be safe under the conditions of its intended use (generally recognized as safe, or GRAS), is excluded from the definition of "food additive" and is not subject to the food additive petition process in section 409. The Act does not provide a process or specific authority for FDA premarket approval of GRAS status, and an interested person need not consult with, or even inform, FDA before or after making its own determination that a substance is GRAS under the intended conditions of use.

FDA has set out the standards for what constitutes general recognition of safety for GRAS status in Title 21, *Code of Federal Regulations*, section 170.30. The same quality and quantity of scientific data that are needed to support a food additive approval are needed to support a GRAS determination; however, there are additional criteria for the use of a GRAS ingredient. These criteria include a general availability of the data and information relied on

to establish the safety of the ingredient, such as publication of scientific literature, and consensus among qualified experts about the safety of the ingredient for the intended use.

A substance must be shown to be "generally recognized as safe" under the conditions of its intended use. Explicitly, GRAS is not an inherent property of a substance, rather, it relates to the specific conditions of use for the substance. The person asserting GRAS status has the burden of proving that the use of the substance is "generally recognized as safe." To establish such recognition, the proponent must show that there is a consensus of expert opinion regarding the safety of the specified use of the substance. Unanimity among experts regarding safety of a substance is not required, and mere conflict among experts is not enough to preclude a finding of general recognition.

Under FDA's voluntary GRAS notification program, an interested party may notify the Agency of its conclusion that a substance is GRAS under the intended conditions of use. FDA reviews the GRAS notice (GRN) to determine whether it provides a sufficient basis to support the party's GRAS self-determination and then responds to the notifier as to whether the Agency has any questions. Information in the notice corresponding to the substance and its conditions of use specified in the GRAS self-determination and FDA's response to the notice are readily available to the public by postings to the Agency's website (*http://www.cfsan.fda.gov/~rdb/opa-gras.html*).

During the period of 2000 through 2005, FDA responded to three GRAS notices for the use of carbon monoxide (CO) in modified atmosphere packaging (MAP) systems for meat products

(GRNs 83, 143, and 167) and one notice for the use of "tasteless smoke," (smoke filtered to remove the taste components), in tuna (GRN 15). FDA responded by stating that the Agency does not question the basis for the GRAS determinations.

FDA routinely consults with USDA's Food Safety and Inspection Service (FSIS) to address our related, but separate, roles in the regulation of ingredients in meat. Consistent with the process established in a Memorandum of Understanding for the review of ingredients used in the production of meat and poultry products, FDA consulted with FSIS on the three GRAS notices for use of CO in MAP systems for meat products. While FDA has authority under the FD&C Act to determine the safety of ingredients used in food, FSIS has separate authority for determining whether the intended use of an ingredient in meat is suitable under the Federal Meat Inspection Act (FMIA). FSIS also has responsibility for the labeling of meat products. FSIS has informed FDA that the use of CO in MAP systems, under the conditions specified in the GRAS notices, complies with the FMIA.

GRAS Notice for Tasteless Smoke

In a revised notice to FDA dated March 11, 1999, Hawaii International, Inc. submitted information that it had determined, based on scientific procedures, that the intended use of tasteless smoke to protect the taste, aroma, and color of seafood at levels sufficient to accomplish this purpose is GRAS (GRN 15). The Agency limited its evaluation of Hawaii International's notice to tuna.

In our March 10, 2000, response stating that the Agency has "no questions" regarding the GRAS status of tasteless smoke, FDA clearly stated that Hawaii International, or any other party who markets tuna that has been preserved with tasteless smoke, is responsible for ensuring that such tuna is neither misbranded under sections 403(a), 403(i)(2) or 403(k) of the FD&C Act, nor adulterated under sections 402(b)(3) or 402(b)(4).

FDA stated that Hawaii International's use of tasteless smoke constitutes use as a preservative, therefore, the ingredient statement on labels of tuna treated with the substance must, among other things, declare that the tuna is treated with tasteless smoke, and that it is used as a preservative. In addition, the treated tuna may not be represented as "smoked," nor identified as "fresh."

FDA's response letter further stated that if the application of tasteless smoke causes the color of tuna flesh to be enhanced, potentially causing consumers to be misled about the true nature or value of the tuna, the product may be adulterated.

FDA is aware of the concerns that the use of tasteless smoke or CO, one of its components, on tuna may prevent detection of potentially dangerous histamine formation in tuna. FDA considered these concerns in responding to the GRAS notice and concluded that they were not scientifically sound. Tasteless smoke and CO are effective in preventing the color change that routinely accompanies the freezing and thawing of tuna; however, color change is not a reliable means of screening out decomposed from non-decomposed fish, or of screening out histamine-containing from non-histamine-containing fish. Color change routinely occurs as a

result of the freezing and thawing process, unassociated with the kinds of abuse conditions that produce either histamine or decomposition.

The most effective means of detecting decomposed fish is by odor. This is a highly effective tool for eliminating fish that are unfit for food because of decomposition. This is the method used by FDA examiners and regulatory examiners around the world. However, it has only limited utility in screening fish, such as tuna, for histamine content. The type of abuse conditions that lead to fish decomposition (e.g., being held at low temperature for extended periods of time) often do not lead to histamine formation in fish, which is associated with high temperature abuse. There is no scientific evidence that tasteless smoke or CO affects either the formation of histamine or the ability to detect histamine formation through sensory analysis.

Given the lack of a reliable relationship between odors of decomposition and levels of histamine, it is understandable that consumers on occasion eat fish that tastes fresh, but still become ill from high levels of histamine. This has been a recognized public health problem for many years. FDA has invested considerable research time and dollars to provide the seafood industry with the best possible guidance on how to prevent the hazard. The seafood industry is required to address these public health issues by instituting Hazard Analysis Critical Control Point (HACCP) principles that help prevent abuse conditions that can lead to histamine formation.

Illnesses can occur as a result of lapses in the implementation of these mandatory controls. FDA takes these lapses seriously and uses its regulatory authorities to address them. Testing of imported tuna, which is highly targeted to suspect lots, reveals elevated histamine levels in both untreated products and products treated with tasteless smoke and CO. Nonetheless, if processors are using tasteless smoke or CO treatment to make decomposed fish look better, they are in violation of the adulteration provisions of the FD&C Act. Enhancing the appearance of decomposed fish, however, does not inhibit FDA from uncovering such adulteration by sensory (odor) examination of lots at the border.

GRAS Notice for Carbon Monoxide

In a notice to FDA (GRN 83) dated August 29, 2001, Pactiv Corporation stated its determination, through scientific procedures, that CO is GRAS for use as a component of a gas mixture in a MAP system. The level of CO in Pactiv's MAP system is 0.4 percent. The other components of the MAP system are carbon dioxide (30 percent) and nitrogen (69.6 percent). The MAP system is used for packaging fresh cuts of case-ready muscle meat and ground case-ready meat to maintain wholesomeness, provide flexibility in distribution, and reduce shrinkage.

In its response dated February 21, 2002, FDA stated that based on the information provided by Pactiv, as well as other available information, the Agency had no questions regarding Pactiv's conclusion that CO is GRAS under the intended conditions of use.

FDA responded to two other GRAS notices for the use of CO in MAP systems for meat, stating that it had no questions regarding the sponsors' GRAS determinations. These notifications, which incorporated the information in the Pactiv notification by reference, were from Precept Foods, LLC (FDA response of July 29, 2004) and Tyson Foods, Inc. (FDA response of September 29, 2005). In its review of each of these GRAS notices, the Agency carefully considered the information provided by the notifier, as well as all other available relevant information in reaching the decision not to challenge the notifiers' determinations that their uses were GRAS.

We are aware that concerns have been raised about the possible misuse of CO in seafood and about the use of CO-containing MAP systems for meat. Agency regulations provide for a mechanism whereby parties seeking reconsideration of FDA decisions can make available to FDA data and information in support of their request. Indeed, FDA has received citizen petitions which challenge FDA's acceptance of the GRAS status of CO-containing MAP systems and of tasteless smoke. We continue to receive information relevant to the citizen petitions and to GRNs 15, 83, 143, and 167, and are currently reviewing that information.

CONCLUSION

Ensuring that FDA-regulated products are safe and secure is a vital part of FDA's mission – to protect and promote public health. Changes in consumer preferences, industry practices, and the rising volume of imports have posed challenges that required us to adapt our current food protection strategies. The Food Protection Plan provides an updated approach to ensure

that the U.S. food supply remains one of the safest in the world. The Plan will help prevent harm before it can occur, will provide enhanced intervention measures, and improve our ability to respond to food safety threats.

FDA remains committed to working closely with all of its partners to implement the Plan's measures to protect the nation's food supply. We look forward to working with the Members of this Committee and the entire Congress to obtain passage of the requested legislative authorities identified in the Food Protection Plan and the Import Safety Action Plan. Thank you for the opportunity to discuss FDA's activities to enhance food safety. I would be happy to answer any questions.

Mr. STUPAK. Thank you, and thank you for your comments on carbon monoxide.

Do any other panelists wish to give an opening statement?

Hearing none, we will begin questions, and I'll begin.

Dr. Acheson, you indicated that the FDA approved carbon monoxide on a GRAS, generally accepted as safe, without any questions, correct?

Dr. ACHESON. There was never a petition submitted for carbon monoxide specifically. It was tasteless smoke for which the GRAS notice was submitted.

Mr. STUPAK. OK. Did the FDA then make any approval of carbon monoxide for the use in packaging?

Dr. ACHESON. The FDA has not been submitted a specific petition on carbon monoxide per se.

Mr. STUPAK. So this is basically a USDA issue?

Dr. ACHESON. The FDA has no concerns about the use of carbon monoxide in modified——

Mr. STUPAK. Right, but you just said that no petition was before you, so you didn't have anything on which to deal with this on carbon monoxide, correct?

Dr. ACHESON. There was no petition submitted. That doesn't mean that the agency didn't review the situation to determine——

Mr. STUPAK. Did the agency review a carbon monoxide petition by Precept Foods?

Dr. ACHESON. The agency has reviewed the safety issue surrounding carbon monoxide.

Mr. STUPAK. Let me try it again.

Did you review the Precept application for the use of carbon monoxide, the matter before us?

Dr. ACHESON. I'll ask——

Mr. STUPAK. Dr. Tarantino is shaking her head "yes."

Ms. TARANTINO. Yes, we did.

Mr. STUPAK. OK. Were you the person who reviewed it then?

Ms. TARANTINO. It was reviewed in my office, in the office I lead.

Mr. STUPAK. OK. Dr. Acheson said the FDA had no questions. Do you agree there are no questions?

Ms. TARANTINO. That was our final determination after the questions that FSIS raised and the information that we received in the final——

Mr. STUPAK. OK. So that was in 2004 that you had no questions?

Ms. TARANTINO. That's right.

Mr. STUPAK. OK. Before you indicated you had no questions, your office—does the European Union allow carbon monoxide in your packaging?

Ms. TARANTINO. The European Union itself does not.

Mr. STUPAK. OK. How about Canada, does it allow?

Ms. TARANTINO. In meat packaging, I'm not sure.

Mr. STUPAK. OK. It does not.

How about Japan, does it allow?

Ms. TARANTINO. I don't know.

Mr. STUPAK. With the fact that these major countries and the European Union do not allow it, did that raise a question with the FDA?

Ms. TARANTINO. We looked at all of the information that was in front of us, all of the information that we are aware of.

Mr. STUPAK. Did you specifically look at the European Union, Japan and Canada?

Ms. TARANTINO. We were aware of the Scientific Committee on Food, which is the risk assessors, and we were aware of the studies that had been done in Norway that supported their use of the technology for about 20 years.

Mr. STUPAK. Correct. Norway is part of the European Union; is it not? Therefore, they no longer use carbon monoxide, correct?

Ms. TARANTINO. Correct.

Mr. STUPAK. So they used it at one time, and now they don't. So, obviously, there were some questions there.

Ms. TARANTINO. Not about safety apparently.

Mr. STUPAK. OK. For what, consumer deception?

Ms. TARANTINO. I don't know.

Mr. STUPAK. So did you ever explore why Norway and the European Union went from using it to not using it?

Ms. TARANTINO. The European Union system is quite different from ours. Our understanding was that another member country or, in fact, a nonmember country petitioned the EU not to permit it in the EU, and they decided not to.

Mr. STUPAK. OK. Dr. Engeljohn, let me ask you this. You indicated that this Memorandum of Understanding between the FDA and the Department of Agriculture was to increase the speed on issues of food safety and packaging and issues like this, correct?

Mr. ENGELJOHN. Yes. The MOU is to make it so that we would do a simultaneous review.

Mr. STUPAK. OK. In your speed to review and to approve things, where does public input come in? When does the public have a chance to comment on your review process here?

Mr. ENGELJOHN. In the review such as the one on carbon monoxide, there was no public review process in that the issue becomes one of our providing input to the FDA about the suitability of the use, and then they make that final determination, but there is no public process on this particular issue.

Mr. STUPAK. OK. So there was no public input.

So the only way someone could really challenge your issue is through a citizen's petition, correct?

Mr. ENGELJOHN. Petitions are one way to do it. The agency does listen in terms of any input that we hear in terms of questions or new data becoming available for which we might re-review the issue.

Mr. STUPAK. In your testimony you also said that one of the purposes when you review it is not to mislead the consumer; is that correct?

Mr. ENGELJOHN. Yes.

Mr. STUPAK. OK. All of the studies we've seen for the last 50 years indicate that consumers purchase their meat or seafood based on appearance; is that correct?

Mr. ENGELJOHN. Appearance is one indicator.

Mr. STUPAK. OK. Has appearance been overturned as one of the indicators that citizens rely upon when they purchase their meat or seafood?

Mr. ENGELJOHN. In this particular case, the agency did put a "use by" "freeze by" date, knowing that that, in fact, would be the best indicator as the appropriate and optimal use of this product for the consumer.

Mr. STUPAK. Well, tell me. How many studies show that people buy meat based on "use by" or "freeze by" dates?

Mr. ENGELJOHN. The agency did contract for a study, which we did receive in 2002, which did identify that an overwhelming majority of consumers relies heavily upon the "use by" or "sell by" date.

Mr. STUPAK. Do they also rely upon color?

Mr. ENGELJOHN. They do rely on other indicators, but the "use by" date is the primary mode for which they rely.

Mr. STUPAK. Will you submit that study to us? We've asked for those documents. You've never provided those to us.

Mr. ENGELJOHN. We did supply that study, but we will make sure that you do have it.

Mr. STUPAK. OK. Turn to exhibit No. 28. It's the 33rd Reciprocal Meat Conference, 1980.

The first page of that study talks about "studies the importance of meat color that was demonstrated by Newman, et al." I'm on the right-hand side, at about the third paragraph. I'm at the last sentence that says, "Certainly, consumers have few, if any, means of estimating the flavor, juiciness, tenderness of a cut of meat while it is in the showcase, so they must base their selection on visual appearance. Color, of course, is much of what the consumer bases his choice on."

You're saying you have a study that contradicts this study?

Mr. ENGELJOHN. We have a study that does indicate that "use by" dates is a predominant means by which a consumer makes that decision, but color also is one of those indicators.

Mr. STUPAK. Let me ask you about the—you talked about the April 28 letter. I believe Dr. Post was the author of that one. In that letter three times he mentions consumers and the deceptive practice that carbon monoxide would add if this process were approved; is that correct? That's exhibit No. 18 in your book. It's exhibit No. 18. It's an April 28 letter that, I think, Dr. Post authored in which you say, "It is our opinion that the use of Precept Foods' MAP system that is described in the GRAS notice for use with case-ready, fresh cuts of meat and ground meat could potentially mislead consumers into believing they are purchasing a product that is fresher or of greater value than it actually is and may increase the potential for masking spoilage"; is that correct?

Mr. POST. That is correct.

Mr. STUPAK. OK. Then the next exhibit, No. 19, is on June 2, 2004. You reversed your opinion in a letter to the FDA, stating that you no longer believe Precept's system could mislead consumers; is that correct?

Mr. POST. Yes.

Mr. STUPAK. OK. Now, Dr. Engeljohn stated, as a result of the letter of April 28, Precept submitted additional data to address your concerns that the use of carbon monoxide could be misleading to consumers; is that correct?

Mr. POST. Yes. Additional data were——

Mr. STUPAK. What additional data did Precept submit to you to get you to reverse your decision?

Mr. POST. Well, the April 28 letter to the FDA indicates that there was a failure in study design, and that the samples of steaks actually contained a solution, including potassium and other ingredients—potassium and sodium diacetate. The results would not be indicative of a spoilage pattern associated with whole muscle cuts of meat not containing any added substances, and those data on whole muscle cuts not containing added ingredients were needed.

Also, it indicated that no samples were tested to establish a spoilage pattern for ground meat products stored under modified atmospheric packaging, and so data were needed there as well.

Mr. STUPAK. So did they ever submit that data to you without the antimicrobial agents so that it would not show spoilage?

Mr. POST. Yes. Those data were received in May 2004.

Mr. STUPAK. All right. Now, Dr. Post, you are a scientist evaluating microbial growth in meats. Would you question a study where the microbial levels started high and ended up low, and where microbial counts correlated inversely with gas formation and odor scores? Would you question that as a scientist?

Mr. POST. Yes, I would.

Mr. STUPAK. OK. Well, go to exhibit 71(e).

That is the data you relied upon. If you look at 71(e), you will see that there is a question where the microbial levels started high and ended up low, and where microbial counts correlated inversely with gas formation and odor scores. Do you see that in exhibit 71(e)? It's on the last three pages. In the columns marked CT/MG, it shows a decline in all microbial counts from day 26 to day 30 and day 41. So, if anything, microbial counts should go up, not down the longer it sits, correct?

Mr. POST. That is correct. However the information that we received did not show the growth of microorganisms in the shelf life of the product.

Mr. STUPAK. Well, this is the information right here. This is the information you received from Precept; is it not? Look at 71. It's from their attorneys. There's a two-page cover letter, then there's the whole study. I just directed you to the last three pages. I'm not a scientist, but even I figured it out that the microbial level should go up, not down, and the gas odors and formation were reversed in this study. That's true, right, in looking at those last three pages?

Mr. POST. Yes. I haven't examined these thoroughly, but I'm understanding what you're saying.

Mr. STUPAK. Well, you would have examined them thoroughly before you approved this process, wouldn't you?

Mr. POST. Yes, and we did.

Mr. STUPAK. Well, then, if that's the case, Dr. Highbarger, Dr. Engeljohn, any of you there, or even Dr. Acheson, you said if new evidence presented which would show that this practice isn't safe, that you would reverse your decision. So, based upon the questions here, would you not reverse your decision because the study you relied upon, to your understanding, is incorrect?

Mr. POST. Well, data that were submitted in May did, in fact, sample steaks, whole muscle cuts—the kind of product data that

we wanted—as well as ground beef data, and no signs of spoilage were detected in any of the samples through 41 days.

Mr. STUPAK. Well, that's your conclusion, but the charts show us differently on those last three pages, don't they? We just went over them. It shows it differently than your conclusion. That's the data.

Let me go a little farther because Precept Foods—which is a joint venture between Cargill and Hormel, right? That's what Precept Foods is, correct?

Mr. POST. I'm not aware.

Mr. STUPAK. OK. Go to the last 2 pages of exhibit 71(e). Because Precept also realized the data they submitted is the opposite of what you concluded, still they submitted the data. Look at the last two pages there, at the last three pages, actually. It's an e-mail, Monday, May 10, 2004. It's to Ann Waylan from it looks like, D. Rusick at *Hormel.com*. 71(d). Go to 71(d). OK. We're talking about this study now.

Do you see this? This is the last 3 pages. It's an e-mail.

Mr. POST. Yes, I found that.

Mr. STUPAK. OK. This is on May 10th that they submitted these documents to you.

It says, "Ann, obviously, you have had other things on your mind recently, but when you get a chance to review this report, please let me know if you see any other funny data in it. I welcome any insights or questions you may have. Quite honestly, this test seems to raise more questions than it answers. Thanks much."

Now, that was at 3 o'clock in afternoon. If you go there, Ann Waylan responds 3 hours later: "I've read the report a couple of times." This is her e-mail response back to Mr. Rusick. "These data do bring some interesting thoughts. Why are the samples with the most off-odor have micro counts that aren't different than the samples that have acceptable odor? The sample with the last date have more desirable odor than the samples without last date. Why are micro counts decreasing as the number of days increase?" That's the inverse that I talked about. "Also, micro counts are decreasing, but odor is increasing." That's reversed. It should be just the opposite. "When the environment has bugs, I think there would be an increase in CO^2, but on the package tested, the CO^2 has decreased. Just a thought. Why put a claims statement in the summary of these data that don't show results that can be patentable? Why not let the patent lawyers determine?"

Would you agree with me that that questions the validity of the study they submitted which you based your approval upon?

Would you agree with me? Is that what that e-mail says?

Mr. POST. Based on this information, I think this leads to some questions, yes.

Mr. STUPAK. Based on this information, don't you think you should reconsider your approval of the use of carbon monoxide until we get these questions answered?

Mr. POST. Well, I suppose my best response is that based on the data that we received in May 2004, no signs of spoilage were detected in any of the samples. The additional data were from studies that were conducted in February 2000——

Mr. STUPAK. By Precept Foods as the data submitted to you on which you based your decision upon, correct?

Mr. POST. Exactly.

Mr. STUPAK. So the questions I raised and the questions raised in this e-mail, would you not want to reconsider it, the use of carbon monoxide in packaging?

Mr. ENGELJOHN. This is Engeljohn on behalf of the Department FSI. So I would say as I said in my opening statement, if in fact we receive new data or information for us to reassess the information that we were previously provided, we certainly will do that. And we have in fact——

Mr. STUPAK. So you'll now reassess your—based upon this e-mail, the information that I pointed out?

Mr. ENGELJOHN. We clearly will look at the data and we have asked our research arm of the Department to actually work with us on the design of a study to actually, in fact, look at this particular issue as well as the broader one.

Mr. STUPAK. Can you assure the American people that based upon this faulty study on which you made your approval, you will suspend the use of carbon monoxide in modified packaging until you get the answers resolved here? This raises some serious issues, does it not?

Mr. ENGELJOHN. I think we would still go back to the issue of the data that we were looking at were specific to the issue of whether or not spoilage would be an indicator here and whether or not we did not look at this from a safety perspective.

Mr. STUPAK. And you also look at deception, whether or not this packaging is deceptive to the American people?

Mr. ENGELJOHN. Again, from our perspective, we did establish a use-by/freeze-by date as the mode in which a consumer would in fact be able to tell if this product were spoiled.

Mr. STUPAK. Let me ask Dr. Highbarger. I had asked you earlier. You've seen these studies. You saw these studies, right?

Mr. HIGHBARGER. I saw them, I don't recall them at all. I can't pull the numbers out of my head. That was 3 years ago.

Mr. STUPAK. All right. You're looking at the book there. Do you agree with me that when the microbial counts should have gone up, they were decreasing? When odor should have gone up, it decreased? That there are problems here as pointed out in those e-mails? Do you agree that there are problems in those studies based upon their own internal e-mails of Cargill and Hormel under Precept Foods? That we have some serious questions here now?

I take it that is a "yes."

Let me ask Dr. Engeljohn. Dr. Engeljohn, you mentioned about the GRAS. Was there ever a GRAS study panel for this carbon monoxide use in the packaging? You usually get a panel together, don't you, to review it on the GRAS?

Mr. ENGELJOHN. Not that I'm aware of, sir.

Mr. STUPAK. You usually do one, don't you?

Dr. Post, you look like you want to answer. You usually do a GRAS review panel, you have a panel to review it before you——

Mr. POST. I'll answer "no" to that, but I'll also defer to my FDA colleagues to answer.

Mr. STUPAK. So there was no outside review, just your internal review of these studies submitted by Precept Foods, correct?

Mr. POST. Yes.

Mr. STUPAK. My time is gone over. I know we talked about going 10 minutes. It looks like I went more than 10 minutes.

Let's go for 10 minutes of questioning by Mr. Whitfield.

Mr. WHITFIELD. Dr. Engeljohn and Dr. Post and Dr. Highbarger, I might say that our side of the aisle did not receive any of these documents that you were being questioned about until last night. And they're very technical documents. There is one aspect in here where it says that microbial growth was acceptable throughout the test for all treatments. We received them last night.

Mr. STUPAK. Excuse me. Mr. Whitfield, if I may. These documents were provided for some time. We found them over the weekend. Our staff worked yesterday. I worked yesterday, even though it was a holiday. We did find them last night. We presented them to your staff last night.

Mr. WHITFIELD. We got them last night.

Mr. STUPAK. Right. They were attached, we believe, erroneous to a different document. And being good investigators that our staff is——

Mr. WHITFIELD. I'm not questioning how it happened. I'm just expressing the fact that we received it last night and these gentlemen were not aware of it until they were questioned about it just a few minutes ago.

Mr. STUPAK. Right. The question was not only on e-mail, but also studies that they've had since 2004.

Mr. WHITFIELD. These were e-mails that Hormel had. These were internal documents, and I doubt that these gentlemen had access to it. But it certainly raises the question that you all can review this and come up with it.

But to suggest that you would be able to give the explicit answers to these questions at this time, I think is unreasonable. Have you seen any of these documents before, any of the three of you?

Mr. POST. No, we haven't.

Mr. WHITFIELD. And so that is the point that I wanted to make on those.

Mr. STUPAK. If you may defer for a moment.

Mr. WHITFIELD. Sure.

Mr. STUPAK. You never saw the e-mails until now. I never saw them until last night. But you've certainly seen the studies since 2004. You're the guys who reviewed it, right?

Mr. POST. We have seen the studies that supported the decision in——

Mr. STUPAK. So the issues I brought up about the converse order here where microbials were going up when they should have been going down, those are things you should have picked up in 2004, correct?

Mr. POST. To my recollection, those were not the kind of results we saw.

Mr. WHITFIELD. So those were not the results that you saw. But from the analysis that you did and from your decision, you made the decision that this using carbon monoxide and modified atmospheric packaging was safe from your standpoint; is that correct?

Mr. ENGELJOHN. FSI has made the determination that the use of this technology and carbon monoxide was suitable for the use of

meat and that a use-by/freeze-by date would be appropriate to identify the product would not be spoiled.

Mr. WHITFIELD. And all packaging that uses it does have a date that it must be used by; is that correct?

Mr. ENGELJOHN. We preapprove labels and all labels in carbon monoxide packaging on meat or poultry products must have a use-by or freeze-by date.

Mr. WHITFIELD. Would it be accurate to say that the consensus of expert opinion and scientific opinion is that there is not a safety issue with using this packaging? Would that be accurate?

Dr. Tarantino, would you agree with that statement?

Ms. TARANTINO. It certainly appears to. We haven't seen any real evidence of a public health issue or safety issue.

Mr. WHITFIELD. Now, there has been some discussion about the European Union. Do you recall, Dr. Tarantino, receiving a letter from a Norwegian scientist at the Norwegian Food Research Institute?

Ms. TARANTINO. I do.

Mr. WHITFIELD. And explaining that the use of CO in meat packing was banned by the EU for safety reasons?

Ms. TARANTINO. He expressed that and also expressed that it wasn't actually banned. It just was not approved in the EU, and it was not for safety reasons.

Mr. WHITFIELD. So from your knowledge, it had nothing to do with safety issues?

Ms. TARANTINO. Not as far as I know.

Mr. WHITFIELD. Dr. Acheson, in your testimony you noted that FDA had received a citizens petition challenging the FDA's acceptance of the GRAS status for carbon monoxide packaging in meat and tasteless smoke; is that correct?

Dr. ACHESON. That's right, yes.

Mr. WHITFIELD. And what individuals or entities filed that petition?

Dr. ACHESON. I'd ask Dr. Tarantino specifically to give you the very specific answer to that, if I may.

Mr. WHITFIELD. Dr. Tarantino?

Ms. TARANTINO. Calsak submitted the citizen petition for challenging our decision on carbon monoxide in meat and EnviroWatch, a group in Hawaii, filed a citizen petition about the decision on tasteless smoke.

Mr. WHITFIELD. Do any of the followers, specifically Calsak have an economic interest in the FDA withdrawing GRAS acceptance for carbon monoxide?

Ms. TARANTINO. I'm aware they have a competing product.

Mr. WHITFIELD. They have a competing product. So they do have an economic interest.

Now, Dr. Acheson, let me ask you. What do you consider your responsibilities that you have at the FDA? What do you consider as the three most important food safety problems or the three biggest public health threats to the U.S. food supply?

Dr. ACHESON. Well, there are two ways that we could answer that. One is to look at the bigger picture of where do we need to go with food safety, which is essentially focused on building strong safety and upfront prevention, appropriate intervention, and rapid

response. If you're going to address specifically what foods do we have the greatest concern about, then the way to approach that is what is causing illness, what is the public health risk? And what we're seeing is a variety of different types of fresh produce where we've seen repeated outbreaks. Issues with eggs is another high priority. So there are a number of them. And this particular issue is not a safety concern even remotely high on our radar screen.

Mr. WHITFIELD. OK. So this carbon monoxide in packaging, as you said, is not remotely an issue?

Dr. ACHESON. From a safety perspective with limited resources, we have to look where the public health risks are.

Mr. WHITFIELD. Now, Dr. Engeljohn, what about from your perspective, do you view this issue as one of your priorities for food safety?

Mr. ENGELJOHN. This is not a priority for the Agency with regard to public health. We have other pathogens and other issues related to that. Labeling is an issue for which we do have statutory requirements to address, and we'd fit all of our labeling issues into a matter of prioritization that we have, with public health being the No. 1 focus.

Mr. WHITFIELD. Now, I know that there are some consumer groups here in the second panel. But as a Member of Congress, I have not received any complaints that I'm aware of from any citizen about this packaging being a problem for consumers in my district. And you all, are you being besieged with letters from consumers expressing concern about packaging using carbon monoxide? Are you all receiving any information about that?

Dr. ACHESON. I'm not aware that we're being bombarded with those kinds of letters, but we recognize that this is clearly a concern for consumers and our committee to think further about it.

Mr. WHITFIELD. Is the USDA at this time restricting competitors from advertising or marketing their products as carbon monoxide-free? Or USDA?

Mr. ENGELJOHN. At USDA and the Food Safety Inspection Service, I'm not aware of any labeling. We would not consider such a label to be appropriate. All of the technologies that we approve labeling for are, in fact, safe; and the issue being whether or not it is suitable.

Mr. WHITFIELD. Would there be any prohibition of a company putting on its label as carbon monoxide-free?

Mr. ENGELJOHN. To my knowledge, we would not allow such a statement.

Mr. WHITFIELD. You would not allow?

Mr. ENGELJOHN. Would not.

Mr. WHITFIELD. Dr. Post?

Mr. POST. We'd allow statements about any technology that are truthful and not misleading, because we have a pre-approval requirement. The word "free" I think is a little problematic, I think, in this case.

Mr. WHITFIELD. OK. All right.

Now, have you all heard of Dr. Michael Osterhome at the University of Minnesota, or Mike Doyle of the University of Georgia? Any of you familiar with them?

Dr. ACHESON. Yes.

Mr. WHITFIELD. And I think both of them and their institutions have conducted some studies on this issue; is that correct?

Dr. ACHESON. I believe so, yes.

Mr. WHITFIELD. And from their studies, they have concluded that safety is not an issue with this packaging; is that correct?

Dr. ACHESON. I believe so, yes.

Mr. WHITFIELD. OK. And both of them are leading experts in this field, with extensive scientific knowledge; is that correct?

Dr. ACHESON. Correct.

Mr. WHITFIELD. OK. I have no further questions. Thank you.

Mr. STUPAK. I thank the gentleman.

Ms. Schakowsky for questions, please. Ten minutes.

Ms. SCHAKOWSKY. First, Mr. Chairman, let me congratulate you and our staff of researchers and investigators for providing us with information that makes it possible to really explore, apparently more fully even than the USDA on some of the information that we have. I've actually been pretty surprised that in preparation for this hearing, that the witnesses have not—for example, Dr. Acheson, you seemed unaware of the FDA's involvement with the issue of carbon monoxide. And I'm looking at your written testimony when it says GRAS, generally recognized as safe, notice for carbon monoxide right here; the notice to the FDA; the response dated February 21, 2002.

I would have imagined that you would have been aware of your own testimony that referred to the involvement of the FDA in this issue. Let me put on my consumer hat; that is where I started in the grocery store, dealing with getting freshness dates on.

Why do you think that this packaging is used? What is the intention of the packaging, Dr. Engeljohn?

Mr. ENGELJOHN. The packaging, as with all packaging, would be in part to ensure that the product doesn't become recontaminated. That is the first issue. And it is the importance of packaging throughout the distribution chain. The use of the gas, in this case carbon monoxide, has a specific purpose which in this case is to remove oxygen and to——

Ms. SCHAKOWSKY. I guess I'm asking, again, from a consumer point of view. Is it not to make the product more acceptable to consumers by making it look fresher?

Mr. ENGELJOHN. I think from the FSI's perspective, is that the use of the technology retains a color that is there in the product naturally within the shelf life that it normally would have for optimal use.

Ms. SCHAKOWSKY. So you would not agree that the—that at least a partial intention of this technique is to make consumers believe—because we do look at color. Go into any meat department of any grocery store and watch people choose a product. And what they're looking for—because you can't put your face on the product and smell it—is looking for color. Is that not true?

Mr. ENGELJOHN. Color is a very important indicator for the freshness of the product, yes.

Ms. SCHAKOWSKY. OK. And so this technology takes away that signal from consumers. Is that not true?

Mr. ENGELJOHN. This technology does not take away the signal entirely. It retains a color that would be there throughout the nor-

mal shelf life and optimal use of this product. And that's what we established the use-by date time.

Ms. SCHAKOWSKY. One of the packages in front of you is 2 years old and it might look OK to consumers. Is that not a problem?

Mr. ENGELJOHN. It is a problem from the perspective that it is critical that the use-by date be adhered to. And that is the reason why we approved the label with the purposeful intent of having a use-by date that is in fact based on the shelf life studies that we were represented.

Ms. SCHAKOWSKY. Target has presented a letter—it is exhibit 76—asking the USDA to approve a label that Target would like to put on its meat packages that are packaged with carbon monoxide.

They are seeking approval to affix a label containing the following information on those meat products. "Consumer notice: Carbon monoxide has been used to preserve the color of this product. Do not rely on the color or the use or freeze-by date alone to judge the freshness of the product. For best results, please follow the safe handling instructions", which I understand are on the product as well.

Will you approve this label and allow Target to label its meat in this manner?

Mr. ENGELJOHN. The Agency did receive that letter late Friday evening and it is under consideration. And our primary objective in evaluating that statement as one being submitted was to ensure it is truthful and not misleading. So we'd look at all aspects of what the statement would say.

Ms. SCHAKOWSKY. And if you approve that language, will you direct that all meat packaged in an atmosphere containing carbon monoxide be labeled with the same language?

Mr. ENGELJOHN. The issue would be making sure that the label is truthful and not misleading in those aspects, and then we'd make some consideration as to whether or not we need to reevaluate our original approval condition, which was solely the use of a use-by/freeze-by date. So it would be a part of the consideration that we would have.

Ms. SCHAKOWSKY. Let me tell you that I think this discussion represents a kind of tone-deaf understanding of what consumers expect and want. Safety is certainly a major consideration, but we have technologies now that can take junk, really old food, and do all kinds of things to it so that if you consumed it, it would not hurt you, it would be OK.

That is not the standard that American consumers want. They want to know that this product—that's why we look at color, so that we bring something home to our family that is fresh for them. Freshness is a concern for families regardless of whether or not it is going to make someone sick or, horribly, perhaps kill a child.

So this is—I really would—if you want to be besieged by letters and phone calls and opposition, I assure you that that could happen if people feel that they are being deceived by a product, because it is not simply the notion of making someone sick. We have enough right now in the way of—I don't even know what you do when you put lights on things and all kinds—to get rid of the bacteria. It is not comforting to me to know that you can take fecal matter and make it not hurt me. I don't want it in my food.

And the same issue, I want to be able to use my senses to decide what is for my family, and I feel that it is deceptive to allow a packaging that would take that away from me, especially since in the grocery store itself I can't literally smell the food, so I don't really have a lot of questions about it.

But I think you ought to question the decision that you're making. I think that consumers do want, as consumers in Europe and other places—and you ought to look at the reasons for their—the decisions that they've made—want not to have something that discolors or artificially colors in some way their food products. I assure you that shoppers across the country will not be simply complacent about this.

Thank you. I yield back.

Mr. STUPAK. Thank you. Mr. Burgess for questions, please.

Mr. BURGESS. Thank you, Mr. Chairman.

Dr. Acheson, let me just ask you a question about the imports of fish and imported tuna that some of your testimony revealed elevated histamine levels, is that correct, in imported tuna?

Dr. ACHESON. [Non-verbal response.]

Mr. BURGESS. Is there any difference between carbon monoxide-treated tuna and noncarbon monoxide-treated tuna as far as the histamine levels are concerned?

Dr. ACHESON. Carbon monoxide really doesn't have anything to do with the formation of histamine. And this is actually a fairly complicated process in that there is a formation of histamine as a process that can occur in fish, and there is also the formation of odors that can form in fish which we'd normally call spoiled fish. These things happen generally in very different tracks. They are not the same thing causing one from the other.

And so I think the complication here is that it would be nice if we could use the odor of fish to tell us whether there was histamine present. As a matter of fact, we can't. It doesn't work that way. And CO doesn't really have any impact on that ability.

Mr. BURGESS. So what is the purpose in using the carbon monoxide in the treatment of fish?

Dr. ACHESON. Either tasteless smoke or carbon monoxide is used principally in frozen fish because with the freezing and thawing, you get a change in color in that fish to something that is fairly unappetizing, you might say. There is nothing wrong with the fish. It is not spoiled, it is not decomposed, it is not dangerous, it is not lower in quality in any way. It has just changed color because of the freezing and thawing process. And as a result, there is difficulty in marketing that kind of product, and the industry has found by treating the fish with either CO or tasteless smoke, they are able to retain that color that it had immediately before freezing, which actually serves some benefit because marketing of frozen fish that can produce histamine is a safer way to market the fish, because it very much reduces the ability of the fish to produce histamine when it is frozen as compared to when it is marketed as refrigerated. So there is actually some health benefit there.

Mr. BURGESS. So the freezing then, the physical activity of freezing the fish, delays the production of histamine in the fish, and the carbon monoxide treatment allows you to market the fish that has been frozen. So indirectly, then, there may well be a benefit to the

consumer of lower levels of histamine in fish that still looks palatable when it is thawed.

Dr. ACHESON. That is fairly possible, yes.

Mr. BURGESS. Have you ever done a study that compares high histamine levels and decomposition in carbon monoxide-treated foods versus those present in noncarbon monoxide-treated seafood and concluded that a higher percentage of decomposition histamine levels are found in seafood treated with carbon monoxide?

Dr. ACHESON. I'm not aware of any study that has done that. We're certainly aware that carbon monoxide-treated fish do sometimes have histamine present. We're also aware that fish that are not carbon monoxide-treated also have some occasions where histamine is present. And, of course, this is something that FDA tries to regulate at the border through testing.

Mr. BURGESS. So are there other products besides tuna that are treated with carbon monoxide, other seafood products?

Dr. ACHESON. We are aware that tilapia might also be treated, and probably is with some regularity.

Mr. BURGESS. Is that OK? Is that within the scope of the regulations? Or is that an adulteration of the product?

Dr. ACHESON. There has been no GRAS notification for the use of CO or tasteless smoke in tilapia. But by the same token, the statute does not require someone using CO or carbon monoxide—a GRAS substance, let me put it that way—does not require someone to notify FDA if they are using a substance they believe to be GRAS. That is just the way the statute is written.

Mr. BURGESS. And it makes no difference whether that tilapia—is any tilapia produced domestically, or does it all come from foreign sources?

Dr. ACHESON. I believe there is some produced domestically, but it is mostly a foreign product.

Mr. BURGESS. And there would be equal treatment of that product with carbon monoxide whether it is produced domestically or imported?

Dr. ACHESON. Yes.

Mr. BURGESS. OK. If FDA did make a determination that the use of carbon monoxide was resulting in an adulterated product, you would stop that at the border; is that correct?

Dr. ACHESON. The difficulty here is that, as you have heard the discussion before, is that with limited resources we try to focus our resources on food safety issues.

Mr. BURGESS. But if you thought it was dangerous——

Dr. ACHESON. If we thought it was dangerous, we'd certainly stop it at the border. That's absolutely correct.

Mr. BURGESS. Is this just enforcement discretion or does this speak to the benign nature of carbon monoxide treatment of seafood products?

Dr. ACHESON. I think it is enforcement discretion. The issue of—first of all, tilapia doesn't produce histamines. So that issue isn't even an issue for tilapia. So that takes out even the discussion of that issue associated with tilapia. But the fact that it may in fact constitute an economic adulteration, arguably that could be the case. But FDA does need to decide where we need to put our resources. So I think this is, in fact, enforcement discretion and put-

ting our recourses on the food safety issues that Dr. Acheson mentioned a few minutes ago.

Mr. BURGESS. Would you restrict competitors who were selling this competing seafood product that didn't use carbon monoxide, would you restrict them from mentioning in advertising or marketing that competing imports are using carbon monoxide without FDA notification or acceptance?

Dr. ACHESON. In their advertising?

Mr. BURGESS. Yes.

Dr. ACHESON. I'm not aware that that is a prohibition.

Mr. BURGESS. Again, does that speak to a problem with the laws in that arena, or does it speak to the fact that carbon monoxide treatment is again a real—regarded as a relatively benign process?

Dr. ACHESON. Because if competitors felt it was an advantage, they'd be—they'd be advertising in that way?

Mr. BURGESS. Yes.

Dr. ACHESON. I'm assuming that they made the decision that it is not worth their while to market in that way.

Mr. BURGESS. We all recall the tuna advertising plans that dealt with the—I forget whether it was the capture of tuna or sea turtles in the nets that captured the tuna. Was it walruses? It was dolphins.

Obviously there was a competitive advantage to advertising dolphin-friendly tuna. I know that's what I always look for. I would never buy dolphin-unfriendly tuna knowingly. What does the—in your opinion, what does the FDA believe would be the public health impact from requiring notice and comment for all of the generally regarded-as-safe petitions? Is there any concern that this would stifle advances in innovation that might in fact, if not stifled, improve food safety?

Dr. ACHESON. I think Dr. Tarantino is probably better able to answer that question.

Ms. TARANTINO. Sure. First of all, I think as Don mentioned as well, if something is GRAS, you don't have to notify us or come to us at all. Notice and comment rulemaking certainly takes a very long time and there are situations when you have to do it.

Mr. BURGESS. How long a period of time?

Dr. ACHESON. It depends on what the issues are. It does require a publishing proposal, taking comments and then doing rulemaking.

Mr. BURGESS. Days, weeks, months or years?

Ms. TARANTINO. Years. And I think what is also true is the process. The GRAS notification process is about as transparent as the food additive petition process. In both cases—in one case we put the notice on the Web, and in the other case we put a notice in the Federal Register. And in neither case do we go out and actively solicit comments, but people have an opportunity to comment and give information as much as possible. So we try to make the GRAS notice process as transparent as is possible, while keeping it a fairly efficient process, because we want to encourage people to come to us, because we get much more information about what is in the food supply and can stop it if we know about it.

Mr. BURGESS. I see. Let me just ask anyone on the panel who can answer the question. I've been primarily talking about seafood

products, but this would apply to beef products as well that are treated with carbon monoxide.

What happens to the carbon monoxide when the food is cooked? Does the hemoglobin molecule denature and break apart and the carbon monoxide is then released? And since we're talking about concentrations of four-tenths of 1 percent, that obviously would not pose a hazard to someone inhaling carbon monoxide, would it?

Mr. HIGHBARGER. I can't give you any numbers, but the majority of the carbon monoxide would be just blown off from cooking. So you'd be eating almost nothing. I can't give you numbers.

Mr. BURGESS. The exposure to carbon monoxide to temperatures normally involved in cooking would not create any new compound or substance which might in turn be harmful to the consumer?

Mr. HIGHBARGER. There is no chemistry there that could happen, no.

Mr. BURGESS. Thank you, Mr. Chairman. I will yield back.

Mr. STUPAK. Thank you. We will go for another round of questions.

Mr. Kraemer, Mr. Burgess had asked you about the treatment of fish with either tasteless smoke or carbon monoxide, correct?

Dr. ACHESON. Yes.

Mr. STUPAK. And you said they treated it with using either one, tasteless smoke or carbon monoxide, correct?

Dr. ACHESON. Yes. I referred to—I responded to both, yes.

Mr. STUPAK. Does the FDA decipher between the two for labeling purposes?

Dr. ACHESON. Yes. The labeling would be different depending upon what was being used.

Mr. STUPAK. What is the label for tasteless smoke?

Dr. ACHESON. Tasteless smoke would need to say "preserved with tasteless smoke," I think is the correct terminology.

Mr. STUPAK. Tasteless smoke is really carbon monoxide, is it not?

Dr. ACHESON. One of the components of tasteless smoke is carbon monoxide.

Mr. STUPAK. OK. What is the label for carbon monoxide, then?

Dr. ACHESON. Presumably, it would need to say "preserved with carbon monoxide."

Mr. STUPAK. OK. Let me show this picture up there. The person is wearing a respirator, spraying seafood. Would that be tasteless smoke or carbon monoxide?

Dr. ACHESON. I can't tell from the photograph. I don't know. I've not seen the operation of either process.

Mr. STUPAK. All right. If tasteless smoke is the same as carbon monoxide, then why not just label truthfully as carbon monoxide and not tasteless smoke?

Mr. BURGESS. Mr. Chairman, I'm going to object. How can he possibly know what that individual would be spraying? No one can tell just from a picture like that. We don't see a canister, we don't see a label, we don't see a skull and crossbones, a biohazard label. It is illustrative only for the purposes of inflaming the rhetoric. I see nothing to be gained by showing us that picture. I yield back.

Mr. STUPAK. We'll get to the picture with the second panel. We'll lay the proper foundation, OK? So if tasteless smoke is the same

as carbon monoxide, then why not just label it truthfully as carbon monoxide and not tasteless smoke?

Dr. ACHESON. They are not the same. One of the components of tasteless smoke is carbon monoxide, but there are other components as well.

Mr. STUPAK. What else do you get with tasteless smoke other than carbon monoxide on your seafood?

Dr. ACHESON. What else is in tasteless smoke? I believe nitrogen is one of the components.

Mr. STUPAK. Does that adhere to the fish, then, when you're using tasteless smoke?

Dr. ACHESON. No. I don't think it has any effect on the fish. It is essentially inert.

Mr. STUPAK. So the only thing that reapplies into the fish when using tasteless smoke is carbon monoxide, right?

Dr. ACHESON. The component that causes the effect of color-fixing is carbon monoxide.

Mr. STUPAK. So why don't you just call it carbon monoxide and not tasteless smoke?

Dr. ACHESON. I think it is a truthful statement to call it tasteless smoke, because in fact that is what it is.

Mr. STUPAK. But there is no smoke, there is no taste because it is tasteless. It is carbon monoxide.

Dr. ACHESON. It is tasteless.

Mr. STUPAK. You take tasteless smoke and put all the impurities, what do you have left, carbon monoxide, correct? And a little nitrogen? Same as CO carbon monoxide, right? When you use carbon monoxide, you have a little nitrogen left over too?

Mr. KRAEMER. The active ingredient, if you will, is carbon monoxide.

Mr. STUPAK. OK.

Let's go back to Dr. Post. Mr. Whitfield sort of indicated like we sort of sprung a surprise on you, even though you're the guy that did the study 3 or 4 years ago.

Let's go back to your document binder, 71(d) and 71(e); 71(d), I'll grant you, is the document we found in our files that we received from Hormel with the e-mail.

And in 71(d), pages 3, 4 and 5, are the data that I referred to when I said that the microbial levels start out high and ended low, and where the microbial counts correlated inversely to gas formation and odor scores. So those are the three labels.

If you go to 71(e), exhibit 71(e), which is—starts off, first two pages, from the law firm of Hogan & Hartson. Then inside, page 3 is Excel, the use of carbon monoxide in lid stock on ground beef. And that is the study they submitted in which you based your approval and—am I correct?

Mr. POST. I would need more time to look at this and the original submission. I can't tell from the complexity of the data.

Mr. STUPAK. That is a copy we got from you, from FDA and from the Department of Agriculture.

Well, let's go to the last three pages of exhibit E and exhibit D, they are the same. The data is the same, is it not? It shouldn't take a lot of time to figure that one out. It is pretty clear that the last three pages in E, the data submitted to you, the last three pages

in exhibit D, the internal memo with the e-mail that questions the validity of the study, those are the same three pages, the data, whether it is the e-mail or your study was based on those three pages of data—is that correct—where the microbial levels started off high and ended up low and where microbial levels correlated inversely to gas formation in the overall score; is that correct?

Mr. POST. They appear to be the same, yes.

Mr. STUPAK. OK. Thank you.

Let me ask this question. Dr. Acheson, you said there has been no complaints at the FDA about carbon monoxide. Has the FDA done any studies to determine if consumers are aware, in fact, that carbon monoxide is being used to treat their meat?

Dr. ACHESON. No, the FDA hasn't. But we're considering undertaking some.

Mr. STUPAK. So if no one knows about it, they can't really complain, can they?

Dr. ACHESON. I think people know about it.

Mr. STUPAK. No.

Dr. Tarantino, let me ask you this. You mentioned the Norway study in questions, I believe, with Mr. Whitfield. And you said Norway—in fact, it is exhibit No—if you want to look in the exhibit book, I believe it is exhibit No. 30. That is the Norway study I believe you were referring to, correct?

Ms. TARANTINO. My No. 30 is a publication from the University of——

Mr. STUPAK. Go to the next one, 31. Mr. Whitfield asked you about Minnesota, too. So I'll ask about that later.

Ms. TARANTINO. That is one publication from their data.

Mr. STUPAK. Right. Is that the Norway study you're talking about, where you thought they had no concerns about carbon monoxide?

Ms. TARANTINO. It is not the only one, but we have the raw data from their studies. But this is one publication.

Mr. STUPAK. Sure. That starts with page 201. Go to page 218 of that study. Page 18 right in there. Lower right-hand corner, last sentence says "and the safety of MAP," or modified packaging, "products are mostly threatened by temperature abuse." Would you agree with that statement?

Ms. TARANTINO. The author of this study I think has written to say his words have been misinterpreted. What he was saying was that safety of meat is threatened by temperature abuse of any kind, including this modified atmosphere packaging and any other packaging.

Mr. STUPAK. Sure. So let's go to exhibit 30, then, the first one I asked you to refer to. And this is our University of Minnesota, Department of Food Science and Nutrition, where both Cargill and Hormel are located in Minnesota. And it starts off that the abstract basically says that the temperature abuse's main concern is for chilled and/or MAP meat and poultry products, since it is not the only cause of economic loss, but also made to food-borne illness hazardous, correct?

Ms. TARANTINO. I don't see the terms, but OK.

Mr. STUPAK. OK. Let's go to page 218 of that study. It starts on page 201 and goes to page 218. And let me just ask you this based

upon your knowledge—or maybe Dr. Post or one of the others would like to comment on it.

It says in the middle of the page that the microbial population of fresh meat is affected by many factors such as the number and distribution of microbial species present at the start; health and handling of the live animal; slaughtering practice; chilling of the carcass; sanitation; type of packaging and handling throughout distribution and storage; is that correct?

Ms. TARANTINO. I see the line, yes.

Mr. STUPAK. Would you agree with that, all of those factors go to microbial?

Ms. TARANTINO. It certainly sounds like it, yes. But I would defer to the USDA, too.

Mr. STUPAK. OK, thanks.

Mr. Highbarger, in the letters from Dr. Post or to you to Dr. Post, back and forth, on approving this process here, did you look at the data that was submitted by Precept Foods in response to the April 28 letter? Did you look at that data?

Mr. HIGHBARGER. I don't believe so on that one.

Mr. STUPAK. OK.

Mr. HIGHBARGER. That was not submitted to us.

Mr. STUPAK. The letters going back and forth were to you, correct?

Mr. HIGHBARGER. That's correct.

Mr. STUPAK. From "Mr. Post developed this," and on the April 28, 2004 letter he brought up again three times, on top of page 2, bottom of page 2, about the deception that may cause or mislead consumers into believing the product they are purchasing is fresher than it actually is, correct?

Mr. HIGHBARGER. Yes.

Mr. STUPAK. It is exhibit No. 18 if you want to look at it.

Then on exhibit 19, when he apparently goes through the study and comes up with the wrong conclusions of the study based on the data, he never mentions the deception to the consumer.

Did you ever ask him why—if that was—you raised it three times in your initial letter, the deception to the consumer. How come before you gave final approval you never discussed the deception to the consumer? What happened in the next 6 weeks or so? No one cared about the deception to the consumer, or you didn't have any concerns about it? Because he was addressing the letter to you. You see, he never mentions deception. The first letter, he mentioned it three times. The second letter to get the approval from you, he never mentioned deception. What happened?

Mr. HIGHBARGER. Well, I would interpret to say—because I haven't seen this letter for 3 years, obviously. Under the proposed conditions of use, the scores and subjective evaluations were shown to be acceptable during a shelf life of 20 save days under the proposed conditions——

Mr. STUPAK. Correct. But you never mentioned deception to the consumer. I guess that is the part that bothered me.

Mr. HIGHBARGER. That is inherent in it.

Mr. STUPAK. That is inherent in it. OK. Dr. Post wrote to you. So you're the person who then finally approved the carbon monoxide in the packaging to be used?

Mr. HIGHBARGER. I'm a member of the team who evaluates all the information, yes. I'm the point of contact. All the communication comes through me.

Mr. STUPAK. You said you didn't see the studies then. How did you evaluate to reach your conclusion it was OK to do this, to put carbon monoxide in packaging, if you never reviewed the studies, those three pages I talked about in exhibit 71(d) and 71(e)?

Mr. HIGHBARGER. I obviously deferred to the USDA.

Mr. STUPAK. To whom at the USDA would you have deferred to; to Mr. Engeljohn?

Mr. HIGHBARGER. Through the memos that they sent us saying that it was acceptable under the proposed conditions of use.

Mr. STUPAK. OK. You're a scientist, right?

Mr. HIGHBARGER. Yes, I am.

Mr. STUPAK. So if you had seen where the microbial levels started high and ended low and where microbial counts correlated inversely with gas formations and odor scores, you would have caught that and you would have rejected that study?

Mr. HIGHBARGER. I would have to look at it before I could say anything.

Mr. STUPAK. OK. So will you look at it now? Because if my statement is correct, then in the study you based your decision upon, the microbial levels started high and ended low and where microbial levels correlated inversely with gas formation odors. If that is true, as in exhibit 71(d) and 71(e), you've got to reverse your decision then, right?

Mr. HIGHBARGER. I'll certainly look at it.

Mr. STUPAK. When can you do that? This is a matter of importance to this committee. That's why we're having this hearing. When can you convene your GRAS panel and review this data? Dr. Tarantino?

Ms. TARANTINO. We'll talk to FSIS and look at the data and look at the study. But remember, our decision on whether we do something on the pending matter of the citizen petition or overturn the GRAS will depend on everything we see, including this study and including looking at what these numbers say.

Mr. STUPAK. But if your initial decision was wrong based on this study, shouldn't you suspend the GRAS then until—is there a procedure to suspend the GRAS while you study this further? Is there a procedure? Can you do that?

Ms. TARANTINO. The procedure would be that we'd have to say that we no longer agree that it is GRAS, that it is an unapproved food additive, and build a record and a case that supports that.

Mr. STUPAK. An unapproved food additive. Why wasn't it considered a food additive when it was first considered?

Ms. TARANTINO. Because, as was said earlier in the testimony, that GRAS substances are exempt from the definition of a food additive. They do not require premarket approval.

Mr. STUPAK. Well, we look forward to you convening your GRAS review panel and review this study in depth, and I hope you have all the raw material, not just the flow charts given to us.

Mr. Whitfield with questions.

Mr. WHITFIELD. Thank you, Chairman Stupak. We focused a lot with this panel on safety issues of which the general consensus

seems to be there are no safety issues. And then we also focused on deception. And there has been a lot of discussion about deceiving the consumer to believe that meat is more fresh than it really is because of the use of carbon monoxide.

From a legal standpoint, what legal responsibility does FSIS at USDA have about food deception, of policing food deception?

Mr. ENGELJOHN. Our statutory authority requires us to ensure that product is not misbranded, mislabeled, and so it is an issue which we'd take into consideration in our determination of whether it is——

Mr. WHITFIELD. Could you give us an example of something that has been referred to as deception from your jurisdiction in the last couple of years?

Mr. ENGELJOHN. Well, one issue that is probably easier to understand in terms of a deception and why we don't allow it in meat products to begin with would be paprika. It is a compound that—or spice—when used has a red color. And although it does cause the lean tissue to turn red or stay red, it also causes the fat to turn red and stay red. So the product appears to be more lean than it is. So that is a determination of perhaps an economic adulteration situation. So we do not allow it for that reason.

Mr. WHITFIELD. But on this particular issue from the perspective, the official position of USDA, is that you do not view this as deception by the use of carbon monoxide; you do not view that as a deception, do you?

Mr. ENGELJOHN. We do not view the use of carbon monoxide as a deception when there is a use-by/freeze-by date on the package which is, in fact, the determinant for whether the product is optimal.

Mr. WHITFIELD. And I don't know if you've seen all these samples that are out there, but I'm assuming that all these sample packages have use-by dates on them; is that correct?

Mr. ENGELJOHN. If they are treated with carbon monoxide, they must have it on there, or they are improperly labeled, and that would be a violation of our requirements.

Mr. WHITFIELD. But if they do not use carbon monoxide, they do not have to have a use-by date on there?

Mr. ENGELJOHN. That is true. If they do not use carbon monoxide in the packaging, and use other gases including oxygen or any series of other combinations of gases, there is no use-by or freeze-by date, and they do in fact have a tendency to cause the color to be retained as long as the product is in the package. So virtually any product in a package is going to have delayed spoilage in terms of changes with microbiological content as well as color and other indicators.

Mr. WHITFIELD. Were you going to say something, Dr. Post?

Mr. POST. I'm just agreeing with him.

Mr. WHITFIELD. OK. I yield back.

Mr. STUPAK. Ms. Schakowsky, questions?

Ms. SCHAKOWSKY. I do. Let me see if I understand about the imported fish that we have. About 80 percent of the fish that we have is imported; is that correct?

Dr. ACHESON. That is correct.

Ms. SCHAKOWSKY. Would you say that almost all of it is packaged with CO?

Dr. ACHESON. I'll ask Mr. Kraemer to try to give you an estimate as to what percentage of that is packaged with CO.

Mr. KRAEMER. I would say for all fish, it is a very small percentage. But for tuna, we don't know what the exact percentage is. But I would say it is a significant percentage.

Ms. SCHAKOWSKY. And what percent of FDA tests show that the fish is actually decomposed or may have histamines—or do we know—of the inspected fish?

Dr. ACHESON. What I do know is that between 2001 and 2005 we had about 4,800 samples of decomposed fish. But what I don't know—if we can find for the record—is what the denominator is for that.

Ms. SCHAKOWSKY. Apparently we've been asking this question on this committee since May, and we really would like to get that information from you.

Dr. ACHESON. OK. Sure.

Ms. SCHAKOWSKY. Dr. Tarantino, isn't it true that under FDA, that any substance that is a component or otherwise affects the characteristics of any food is considered a food additive?

Ms. TARANTINO. Yes, unless it is subject to one of the exemptions in that definition.

Ms. SCHAKOWSKY. Isn't it also true that as a food additive the substance is then subject to premarket review and approved by FDA unless it falls within one of those definitions?

Ms. TARANTINO. That's right.

Ms. SCHAKOWSKY. One of the major exclusions is GRAS are generally recognized as safe under the conditions of its intended use, correct?

Ms. TARANTINO. Correct.

Ms. SCHAKOWSKY. So today we're discussing meat packaged in an atmosphere containing carbon monoxide and the exposure of seafood to carbon monoxide before freezing. And these processes were determined to be GRAS. That's correct, right?

Ms. TARANTINO. Yes.

Ms. SCHAKOWSKY. Under 21 CFR, paragraph 170.35, the affirmation of GRAS status must occur through the notice and comment rulemaking process in which FDA publishes a notice in the Federal Register, allows 60 days for comments, evaluates the comments and then determines whether the substance is GRAS—Generally Recognized As Safe—is that correct?

Ms. TARANTINO. Or FDA to affirm that something is GRAS, that's correct. We did not do that in this case.

Ms. SCHAKOWSKY. Well, that's really where I'm going. It says, however, GRAS notice 015, which allows tuna to be exposed to tasteless smoke, and GRAS notice No. 143, which allows meat to be packaged in an atmosphere containing carbon monoxide were both determined to be GRAS without following the notice and comment rulemaking process; isn't that true?

Ms. TARANTINO. The GRAS exemption does not require FDA to participate in the GRAS determination at all. So in those cases, it was the party, the manufacturer, who made the determination that it was GRAS, and then voluntarily notified us of both its deter-

mination and all of the information and studies on which it based that determination, and gave us an opportunity to react to that and to see whether we had any questions or not.

Ms. SCHAKOWSKY. So in other words, you're saying that it is on the say-so—I'm trying to understand this process and how it differs from 21 CFR that the GRAS status must occur through the notice and comment rulemaking process which FDA publishes in the Federal Register, comment period, et cetera.

Ms. TARANTINO. The regulation that you're referring to is that if—how we do it if the FDA decides to make a statement that something is GRAS and to affirm the GRAS status. That is the current regulation for how to do that. As I say, people can determine GRAS status without coming to us, without notifying us, without coming to us at all. The GRAS notification procedure gives them an opportunity to voluntarily come to us and gives us an opportunity to know better about what is in the food supply so that if there are safety issues or are issues about the GRAS status, we can raise questions about it.

Ms. SCHAKOWSKY. OK. Well, forgive me, then. Are you saying that for something to be determined generally recognized as safe, who is the arbiter, then, of that?

Ms. TARANTINO. Experts, experts. The definition says generally recognized to be safe by experts who are qualified by training and experience to judge the safety of food.

Ms. SCHAKOWSKY. And who can be those experts? Can these be experts that work for or are hired by the company seeking this GRAS——

Ms. TARANTINO. They can be. But the information on which a GRAS determination is based is not just a company doing its own studies in its own laboratory and then submitting it to the Agency. That information needs to be generally known. So, often that is through publications in the peer-reviewed literature. It can be in many different ways. It can be through principles in chemistry as part of the reason for carbon monoxide. It can be a lot of different ways that the information is publicly known so those experts, wherever they are in the world, can see whether the information does support the safety or does not.

Ms. SCHAKOWSKY. We are hearing today that there is some difference among experts. And the GRAS notices that we're talking about today were determined under a proposed rule dating back to 1997. The proposed rule would replace the GRAS petition process, create a new GRAS notification procedure under the proposed rule, no notice, no comment process. And as you said, the FDA doesn't perform its own research, but instead only looks at what the notifier has supplied in support of its GRAS determination. So essentially this is an ex parte process where FDA only considers the information that the notifier wants it to.

Ms. TARANTINO. We also look at other data that is out in the public arena. We look at any information available to us in our files or available to us through the literature and the scientific basis.

Ms. SCHAKOWSKY. It looks to me like this is just another example where the FDA has filed proposed rules instead of its own regulations. Under Federal law it is a well-settled rule that an agency

has to file its own regulations. So it looks to me like the FDA violates the law by not doing this.

Ms. TARANTINO. If we were to affirm the GRAS status of a compound on our own, we would use notice and comment rulemaking. The regulation you are reading was a regulation we proposed to give a mechanism for those who wanted to get an opinion from us as to whether their GRAS determination was correct. That was one mechanism that we put in the regulations.

The GRAS notification is a mechanism that we have also proposed and are using, which does the same thing. It allows people who have made a GRAS determination to come to us, to let us know what they are doing, what they're selling, what they're marketing, and gives us the opportunity to object if we see a problem with it.

In many cases, when the process was very burdensome, people just didn't come to us at all. So one of the big advantages of the notification process is it encourages people to come in with some regularity, we do object to their GRAS determination.

Ms. SCHAKOWSKY. When something is determined to be generally recognized as safe, it is pretty hands-off then.

Ms. TARANTINO. No. There are processes by which we can go back and revisit those decisions and we——

Ms. SCHAKOWSKY. Like we think maybe today's hearing might prompt——

Ms. TARANTINO. No. The citizen petitions that have been filed are processes that have been developed specifically for that purpose.

Ms. SCHAKOWSKY. Did you say some petitions? Oh, yes. The petition on this, I was just told, is 2 years old. So how promptly is——

Ms. TARANTINO. Well, I think everyone here has said we're interested in new information, and there has been a lot of information submitted to that docket on that petition up until quite recently that we are very interested in looking at.

Ms. SCHAKOWSKY. And wouldn't a notification and comment period make it easier to solicit other expert testimony as well as consumer input? Whether or not the FDA actually does its own testing?

Ms. TARANTINO. It would be one way, I suppose. But I think we've tried to accommodate that by making sure the people have notice that the notification is in and with the agency who submitted it, what it is for, as promptly as is feasible.

Ms. SCHAKOWSKY. Dr. Acheson, I think, said that people know that meat is treated with CO. Wrong. I think that's absolutely not true that most people think when they're at the grocery store that the reason for that bright red color is because it has been treated. Hopefully, that word will get out more and will help people in their decision-making, but I don't think at this point that is true.

Thank you.

Mr. STUPAK. Thank you.

Mr. Burgess, questions?

Mr. BURGESS. Thank you, Mr. Chairman.

Dr. Tarantino, maybe you could expand or provide a little context for the answers to the questions you just gave Ms. Schakowsky. What would be the effect of expanding the comment process for determining whether a process was generally regarded as safe?

Ms. TARANTINO. I'm not entirely clear how one would do that, but I suppose you could say that we could, in a final rule, for the GRAS notice process or in some part of the process, go out and explicitly seek comments. We do get comments on GRAS notices pretty regularly.

Mr. BURGESS. But expanding the notice and comment process, would that have the net effect of slowing things down?

Ms. TARANTINO. Oh, sure.

Mr. BURGESS. Well, we keep talking about 1997. I referenced it in my opening statement, and we heard it mentioned here again just a minute ago. What happened in 1997?

Ms. TARANTINO. In 1997, I think there was a general recognition—no pun intended—that the process that we were using for doing petitions to look at whether something is GRAS was kind of an unusual situation. We had set up a petition process for people to ask us whether they need to petition us as a food additive, and we would say no, but it would take a long time because it was a very cumbersome rulemaking process. And the end result of that is that most people made their own GRAS determinations, went to market, and then depended on us to make a postmarket finding. If we disagreed with them, we'd have to take an enforcement action.

Mr. BURGESS. We already talked about the timelines to some degree. Again, are we talking about days, weeks, months, years or decades?

Ms. TARANTINO. Years. It was years. So it was a big disincentive for people to come to us and tell us about what they were planning to market.

As to the process we did, one of the main reasons was to make it a more efficient process while encouraging people to come to us so we would have a much better view of what was in the marketplace, what was being developed, what the new technologies were, and that if we did have an issue, we could review what was sent. We could review the information that was out there publicly, and if we had an issue or a concern, we could express that concern right away.

Mr. BURGESS. So, in other words, the agency made the decision, rather than to be punitive, they'd try to be helpful?

Ms. TARANTINO. That certainly was a better way of going about it to do it ahead of time so that we wouldn't need to use enforcement resources, but have the review done before it went to market.

Mr. BURGESS. Well, since it seems to be the object of a lot of discussion—I've got to tell you, I'm kind of mystified as to why we're having this hearing. There are a lot of other things we could be talking about—salmonella, *E. coli*, you name it—but we're talking about bugs that I can hardly pronounce.

What would be required just to simply close up this process—close up the rulemaking process and get a determination on the rulemaking process? From 1997 to 2007, that's a decade. Even for a slow-moving Federal agency, that seems like a reasonable amount of time.

Ms. TARANTINO. We are all very interested in closing that out and in writing a final rule to put this process in the regulations.

Mr. BURGESS. So, as a practical matter, what is left to do?

Ms. TARANTINO. To make sure that, in the intervening years, nothing has changed. And we may look for additional comments to see if anything has changed, but we want to get that final rule out as much as anyone does.

Mr. BURGESS. Well, in the intervening decade a lot has changed. We're getting much more of our foods from—we've already heard in other panels before this committee that we're getting an enormous number of our foodstocks imported from overseas. It seems to me that the American public would be better served if we were to allow the agency to be a little bit more flexible, a little bit more agile about responding to these new threats that are coming in, and we, yet, seem to be mired in the 1997s and not able to move forward.

Ms. TARANTINO. The process we are operating under now is operating under that proposal because it was a voluntary process.

Mr. BURGESS. Do you feel like it's working?

Ms. TARANTINO. I do very much. I think it works quite well.

Mr. BURGESS. Would you be in favor of our turning the clock back and going back to 1997 or prior to 1997?

Ms. TARANTINO. Before? Personally, no.

Mr. BURGESS. You don't think that American public safety would be greatly enhanced by doing that?

Ms. TARANTINO. No. I believe the current processes are very protective of public health.

Mr. BURGESS. Would it be detrimental to go back to the type of processes that we had prior to 1997?

Ms. TARANTINO. I think it would be much more resource-intensive, and it would be hard to know whether you would get very much benefit from it.

Mr. BURGESS. OK. Thank you. You've been very candid with your answers, and I appreciate that.

We've got a lot of doctors on the panel. Do we have a lawyer? Someone needs to help me with this term "ex parte" because it keeps coming up. Being a simple country doctor, is that like a unilateral comment that's made? Let me just ask anyone on the panel, either the FDA or the USDA. Does it violate some process, or is it in any way illegal to have these *ex parte* comments on regulation or guidance?

Dr. ACHESON. I personally cannot answer your question. I don't know. Maybe one of my FDA colleagues can. I would have to get back to you with an answer for that.

Mr. BURGESS. OK. It keeps coming up. We saw it in the majority's report to the committee.

Mr. BURGESS. Kind of going back to carbon monoxide for just a moment, either Dr. Acheson or Mr. Kraemer, does the FDA have any concerns about the safety and the use of the 0.4 percent atmospheric carbon monoxide in packaging?

Dr. ACHESON. From a safety perspective, we do not.

Mr. BURGESS. Can we regard it as simply a packaging material? We've already heard in the last round of questioning I had that it's volatile; it goes away when the food is cooked. So, from the consumer's perspective, is it any different from the cellophane that helps to keep the food fresh?

Dr. ACHESON. It's considered by us to be a fixative, a preservative of color. It has got nothing to do with freshness per se. It's color.

Mr. BURGESS. It's coloration. So is it bound by the same rules that other coloration agents are held to?

Dr. ACHESON. Well, my understanding—and I'll ask Dr. Tarantino to clarify—is that it's bound by preservative approaches as opposed to that it's not considered to be a color additive.

Mr. BURGESS. Oh, it's not a color additive.

Ms. TARANTINO. Right. It is a color fixative, which is different from a color additive. A color additive imparts new color.

Mr. BURGESS. So, as a scientific matter, there is a difference between a fixative and an additive?

Dr. ACHESON. Yes. A fixative maintains color as is. An additive is, by definition, an addition.

Mr. BURGESS. Is there any difference in the use of carbon monoxide in seafood products as opposed to meat products?

Dr. ACHESON. Well, what do you mean?

Mr. BURGESS. Does the FDA have a view as to the carbon monoxide used in seafood, in fish products? Is it identical in all respects as a fixative in fish products as it is in meat products?

Dr. ACHESON. Yes.

Mr. BURGESS. OK. Thank you, Mr. Chairman. I yield back a minute and a half.

Mr. STUPAK. Thank you, Mr. Burgess.

Mr. Dingell for questions, please.

Mr. DINGELL. Mr. Chairman, thank you.

This question is to Dr. Tarantino.

Doctor, what record was completed by the FDA in connection with the issuance of whatever rule was issued by Food and Drug with regard to the CO insertion into the packaging? Was there any record established at all by Food and Drug on this matter?

Ms. TARANTINO. There is an administrative file for each of the GRAS notices.

Mr. DINGELL. Was there any action taken by Food and Drug which would comply with the requirements of the Administrative Procedures Act? If so, what? Was there a finding made that the actions of Food and Drug were in compliance with the Administrative Procedures Act?

Ms. TARANTINO. The notification to the agency was made voluntarily by companies who chose to notify us——

Mr. DINGELL. What about consumer groups? Was there ever notice given to the public?

Ms. TARANTINO. The——

Mr. DINGELL. Yes or no? Was there notice given to the public? Was notice filed in the Federal Register?

Ms. TARANTINO. The notices were put on the Web.

Mr. DINGELL. On the Web. They were not printed in the Federal Register?

Ms. TARANTINO. No. We were using the Web.

Mr. DINGELL. What responses were received? How many?

Ms. TARANTINO. On the notices for the meat, I do not believe we got any comments between the time that we put the notice on the

Web and when we made the final decision. On tuna, we may have. I think we did, but I'd have to check.

Mr. DINGELL. So the answer is you don't know?

Ms. TARANTINO. As I said, I think we did for tuna.

Mr. DINGELL. Does anybody at Food and Drug know?

Ms. TARANTINO. We can find out and get back to you.

Mr. DINGELL. Don't you think you ought to be able to answer that question when you're appearing here to discuss these matters? It would seem so to me.

Dr. ACHESON. Sir, we try to be as prepared as we can, but certainly there are times when we just don't have all the information. We'd be happy to get back to you for the record on that.

Mr. DINGELL. I find myself surprised.

Now, Dr. Tarantino, why are there no e-mails, drafts or like documents that would indicate your thinking as the carbon monoxide questions were under consideration that have been produced to this committee? Are there such documents? Are there such e-mails? Are there such drafts in the records of Food and Drug?

Ms. TARANTINO. We have made an attempt to be responsive to your——

Mr. DINGELL. All right. I'm going to ask you to submit them to the committee, all of them.

I'm going to ask unanimous consent, Mr. Chairman, that the record remain open so that they may be submitted and may be included.

Now, why have several documents regarding communications with the Office of Chief Counsel regarding seafood been produced from the Office of Seafood files, but there's nothing regarding the meat decisions? Can you answer that question?

Ms. TARANTINO. We have produced everything we have found thus far, and we are continuing to look.

Mr. DINGELL. So you don't have anything with regard to the meat decisions?

Ms. TARANTINO. Only the things that have been produced thus far are what we've found so far.

Mr. DINGELL. Now, were the lawyers consulted on this matter?

Ms. TARANTINO. No, not that I recall.

Mr. DINGELL. So they were not consulted.

Mr. Highbarger, why were no e-mails or other documents from your office produced until last week when the Office of Legislation was attempting to have you removed from the witness list?

Mr. HIGHBARGER. I just found those e-mails. I don't have a better answer.

Mr. DINGELL. When were you first asked to search for documents relative to this committee's request? When did you deliver the e-mails and to whom? Please answer the question.

Mr. HIGHBARGER. Early August.

Mr. DINGELL. Mr. Chairman, we will submit a letter to the witness requesting more specific answers as to when, what was submitted and why.

Now, Mr. Highbarger, since you were charged with the responsibility of analyzing the submissions relative to the question of carbon monoxide meat, why do none of your e-mails reflect any analyt-

ical work from you or the colleagues that were asked to also opine on the submissions? Please tell me why.

Mr. HIGHBARGER. Because there was no analysis to discuss. It was simply do you have any questions about the validity of the studies, and does it cover the entire—does it encompass it.

Mr. DINGELL. So you're saying you did no analysis; is that what you're telling me?

Mr. HIGHBARGER. My scientific reviewers reviewed the data submitted.

Mr. DINGELL. I find myself curious. How do you come to a decision at Food and Drug if you don't analyze those questions?

Mr. HIGHBARGER. It's not me, personally, who is doing the analysis. We have a team of scientists who are reviewing the data. At the end of the period of time, they tell us. We have no questions about the submission.

Mr. DINGELL. All right. Let me ask you this: You have produced no records whatsoever from that group to this committee, have you?

Mr. HIGHBARGER. Just e-mails that I sent you.

Mr. DINGELL. Are there such records?

Mr. HIGHBARGER. I would have to talk to my reviewers to see if they have any. I don't know.

Mr. DINGELL. You have been requested to deliver those records; have you not?

Mr. HIGHBARGER. I've delivered everything that I have found so far.

Mr. DINGELL. You have delivered everything that you have found so far. Is this to have us believe, then, that we have everything that is in Food and Drug's files, and, if you submit nothing more, that there is nothing more to support the decision of Food and Drug? Is that right?

Mr. HIGHBARGER. We are continuing to look for additional data.

Mr. DINGELL. You're continuing to look. OK.

Now, kind of inform me. Has Food and Drug ever come to a decision on the application with regard to the carbon monoxide and its use in the packaging of meat and fish products? Is there a formal ruling or some action that has been taken, Dr. Tarantino, by Food and Drug?

Ms. TARANTINO. There is not a formal ruling or action. What we did was respond to those who made their own GRAS determination as to whether we had a concern.

Mr. DINGELL. So you essentially took no action; is that right?

Ms. TARANTINO. That's right.

Mr. DINGELL. And the folks in the industry are now out busy using this device without any formal ruling by Food and Drug; is that right?

Ms. TARANTINO. That's correct.

Mr. DINGELL. That's rather curious, isn't it? Is that the regular practice at Food and Drug just to hold a proceeding, arrive at no decision, and then let everybody do what they want to do?

Ms. TARANTINO. If a substance is GRAS under its conditions of use, they may use it without a formal ruling from FDA. That is correct.

Mr. DINGELL. Do you have any opinions by the lawyers at the Food and Drug or at the Department of Health and Human Services saying that this is the proper procedure for Food and Drug to take in this matter?

Ms. TARANTINO. The GRAS notice procedure has been reviewed by attorneys, yes.

Mr. DINGELL. What rulings do you have from the lawyers saying that this is a proper procedure for Food and Drug to take?

Ms. TARANTINO. Well, the attorneys reviewed the proposal that we published in 1997.

Mr. DINGELL. The attorneys reviewed the proposal, but the attorneys, what did they do after they had reviewed the proposal? Did they say this is proper or not proper?

Ms. TARANTINO. We published the proposal, so it was with their concurrence, yes.

Mr. DINGELL. Did they say it was proper?

Ms. TARANTINO. Yes.

Mr. DINGELL. Do you have a written opinion on that from the attorneys?

Ms. TARANTINO. We have their sign-off on the proposal from 1997.

Mr. DINGELL. The sign-off. What does that mean?

Ms. TARANTINO. They concurred.

Mr. DINGELL. Why did the attorneys not come forward with a written finding on this? They did not come forward with any written finding. They just signed off. What does that mean?

Ms. TARANTINO. The proposal laid out what we were planning to do as to how we would run a program for doing GRAS notices, for reading GRAS determinations.

Mr. DINGELL. Has this matter ever been finalized? Has there ever been a final order by Food and Drug on this matter?

Ms. TARANTINO. We're working on that.

Mr. DINGELL. Now, how long has it been that you have been working on it?

Ms. TARANTINO. Too long. The proposal was issued in 1997.

Mr. DINGELL. How long has it been that this process has been used?

Ms. TARANTINO. Almost 10 years.

Mr. DINGELL. Ten years. You're still working on it?

Ms. TARANTINO. We're working on finalizing the regulations that would underpin the proposal.

Mr. DINGELL. When do you expect to have the matter finalized?

Ms. TARANTINO. I can't answer that.

Mr. DINGELL. What comments have you received from consumer groups on this matter?

Ms. TARANTINO. We certainly received comments. I don't know. I would have to go back and look at the comments from consumer groups.

Mr. DINGELL. Do you have a formal record to support the findings?

Ms. TARANTINO. We have an open docket with the comments, and we have a record that supports the proposal.

Mr. DINGELL. Do you have an opinion from your attorneys that this complies with the requirements of the Administrative Procedures Act?

Ms. TARANTINO. The GRAS proposal? Yes.

Mr. DINGELL. Do you have an opinion that says that it's proper for them to proceed, to continue, under the process they have with regard to the carbon monoxide gas being used in packaging without formal approval by the Food and Drug?

Ms. TARANTINO. Not specifically about the meat packaging, no.

Mr. DINGELL. Well, Mr. Chairman, it looks like Food and Drug is in need of reform, and I guess we're going to have to give it. Thank you, Mr. Chairman.

Mr. STUPAK. Thank you, Mr. Dingell.

Mr. WHITFIELD. May I just do a quick follow-up here.

Mr. STUPAK. Sure.

Mr. WHITFIELD. Dr. Tarantino, just to make sure I understand this, in 1997, the Congress passed the Food and Drug Administration Modernization Act of 1997, which created a notification procedure for food contact substances; is that correct?

Ms. TARANTINO. That's correct.

Mr. WHITFIELD. Under that law, the FDA has three methods to adopt a substance as GRAS. One, you can list the substance in your own regulations; is that correct?

Ms. TARANTINO. Yes. That has nothing to do with the food contact substance part, but go ahead.

Mr. WHITFIELD. OK. All right.

Well, on the approval of the GRAS substances, let me talk about that. You can adopt that yourself in your own regulations?

Ms. TARANTINO. Right.

Mr. WHITFIELD. Or you can rely on industry self-determination of the substance.

Ms. TARANTINO. Correct.

Mr. WHITFIELD. Or you can make this substance the subject of a GRAS notice.

Ms. TARANTINO. Correct.

Mr. WHITFIELD. Those are the three options available; is that correct?

Ms. TARANTINO. Correct.

Mr. WHITFIELD. OK. I have no further questions. Thank you.

Mr. STUPAK. Hearing nothing further from the Members, this panel will be dismissed. Thank you.

Mr. STUPAK. Our second panel of witnesses will be Mr. Mike Picchietti, the president of Regal Springs Trading Company and a member of the American Coalition for Tilapia; Ms. Nancy Donley, president of the S.T.O.P. Organization, which stands for Safe Tables Our Priority; and Ms. Wenonah Hauter, executive director of the organization of Food & Water Watch.

It is the policy of this subcommittee to take all testimony under oath. Please be advised that witnesses have the right, under the rules of the House, to be advised by counsel during your testimony.

Do any of you wish to have counsel?

The witnesses have indicated not. Therefore, I will ask you to please stand and to raise your right hands to take the oath.

[Witnesses sworn.]

Mr. STUPAK. Let the record reflect all witnesses answered in the affirmative. They are now under oath, including with their opening statements.

We will go with Mr. Picchietti for your opening statement for 5 minutes. Your full statement will be part of the record.

STATEMENT OF MIKE PICCHIETTI, PRESIDENT, REGAL SPRINGS TRADING COMPANY MEMBER, AMERICAN COALITION FOR TILAPIA, BRADENTON, FL

Mr. PICCHIETTI. Thank you, Chairman Stupak, Ranking Member Whitfield and members of the subcommittee, for the opportunity to testify regarding the consumer deception with tilapia fish that have been artificially colored using carbon monoxide.

Throughout the United States, frozen carbon monoxide-gassed tilapia fillets are routinely being removed from import packaging and placed into fresh seafood counters to be thawed out and sold as refreshed or previously frozen or simply, unethically, as fresh tilapia fillets. The misidentification and the total lack of identification of carbon monoxide as an ingredient is now widespread for tilapia, and from what I've learned today, there is no "use by" date in the fresh counters at all.

The issue that unites this group of competitors, our ad hoc coalition, that produces approximately 80 percent of fresh tilapia fillets for the U.S. market is the impact that carbon monoxide-gassed tilapia is having on our businesses and on the potential of long-lasting harm on the current positive image that tilapia has on the market.

We are here today because of our concern in losing the trust and confidence for tilapia with the American consumer because of this disguised practice of keeping the knowledge of carbon monoxide as an ingredient from the consumer. What concerns us is that the American consumer is not aware of what they are buying and eating. How could they be if it is not labeled? Most Americans realize that carbon monoxide is a very common poison, and therefore, using it as an ingredient is alarming.

According to the current United States National Marine Fishery Service import statistics, 125 million pounds of frozen tilapia fillets have been imported from China into the United States through August of this year. Members of the American Coalition for Tilapia estimate that at least 70 percent of this volume of product is gassed with carbon monoxide. Therefore, that's about 88 million pounds of frozen carbon monoxide-gassed fillets that have been consumed by Americans so far. That's approximately 176 million meals of carbon monoxide-gassed tilapia that have been consumed in the first 8 months of this year.

To illustrate industrywide uneasiness surrounding this trade in carbon monoxide seafood products, buyers and sellers use a kind of code terminology to identify trade of the product. Names like "cold-smoked," "izumidai," "sashimi grade," and "CO" are all used to identify carbon monoxide-treated product rather than using the correct name to identify carbon monoxide. At the consumer level every attempt is made to keep the identification disguised at the point of purchase. Given all the exotic names, the ingredient is nothing more than the carbon monoxide molecule.

Without using CO, frozen tilapia fillets turn brown when thawed out just like fresh fillets do in the natural aging process. From a competitive standpoint, frozen tilapia fillets produced in China are much cheaper than fresh tilapia fillets produced in the Americas, frequently by as much as 75 percent less. Thawing out CO-gassed Chinese frozen tilapia fillets for sale in the fresh counter has become one of the most profitable seafood items in the category.

Fresh fillets from our coalition cost more to produce and to deliver because we deliver by expensive airfreight, rushing to beat the negative impact of time and temperature on the shelf life of our product. Our products are untreated and more perishable because they are never frozen. We have to rush to maintain the red and natural fresh colors without the aid of preservatives like carbon monoxide treatments. If a vendor can simply use carbon monoxide on a cheaper product without the risk of a consumer's asking questions about the ingredient because there is no label, why buy true, fresh tilapia?

We understand the right of choice and the effort of the vendors to provide value to the consumer. The cost advantage of frozen product will provide ongoing sales for Chinese tilapia. We feel Chinese frozen tilapia sales will continue to find a healthy growth without the need for using carbon monoxide. We have no problem with that. America needs low-cost fish to meet the demands of a healthy diet and the decreasing wild catch.

What we find objectionable is competing on an uneven playing field against a product that is chemically enhanced and then unlabeled so the consumer will misperceive the ingredient-enhanced bright pink or red color as a sign of freshness, which is far from the truth.

This deceptive practice has been going on for 10 years. The American Tilapia Association visited the Food and Drug Administration in the spring of 1998 to protest this carbon monoxide fraud. During the meeting with the FDA's Office of Seafood, arranged by the National Fishery Institute, the FDA indicated that it did not consider carbon monoxide in seafood a public health risk, but they understood that economic fraud could take place. They concluded that they did not have the manpower to enforce the law, and so the issue was one that producers would have to deal with. I was personally present at the meeting and have witnessed the development of this issue for the last 10 years. It has taken 10 years for someone inside the Government to finally ask the same questions about carbon monoxide in seafood.

Following the FDA's recommendation of nearly 10 years ago, we made repeated attempts to address the issue from within the industry. In our opinion, it's clear the problem will not be solved voluntarily from within the industry. The market has grown so large and so profitable that producers using carbon monoxide are unwilling to voluntarily forego these easy profits. There is no risk since there is no enforcement or clarity on the labeling laws. It has been a domino effect. Vendors are pressured to sell these CO products to remain competitive.

We believe the best way to protect the American consumer is either to legislate effective labeling or to ban this carbon monoxide use in tilapia, because enforcement has proved impossible. We fear

the worst case, that the American consumer will place a blanket of distrust over all tilapia products if this carbon monoxide issue continues its disguised status. The consumer would be justified in seeking revenge against an industry that was unable to control such massive fraud.

The bottom line is that this carbon monoxide GRAS approval is a passport for fraud. The wholesome image we worked so hard to establish for tilapia could be destroyed by this deceptive practice. We hope the investigations will shed light on this practice so we can find a solution before it's too late.

Thank you.

[The prepared statement of Mr. Picchietti follows:]

Testimony of

Mr. Michael Picchietti

President
Regal Springs Trading Company

On behalf of

The American Coalition for Tilapia (ACT)
Tropical Aquaculture, Rainforest Aquaculture, Regal Springs

before the

Subcommittee on Oversight and Investigations
of the
House Committee on Energy and Commerce
110th Congress, 1st Session

for Hearings on

"Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation's Food Supply? – Part IV – Deception in Labeling"

November 13, 2007

Thank you Chairman Stupak, Ranking Member Whitfield, and Members of the Subcommittee for the opportunity to testify today regarding consumer deception with Tilapia fish that have been artificially colored using carbon monoxide.

I am testifying on behalf of the American Coalition for Tilapia (ACT), an ad hoc coalition comprised of three of the largest fresh tilapia producers, who represent at least 80% of the fresh tilapia fillets being produced for the North American Market. The

concern that unites this group of competitors is the adverse impact that carbon monoxide adulterated Tilapia had on our businesses, the United States market, and the American consumer.

Several members of the American Coalition for Tilapia were industry pioneers from the early 1990's and played key roles in developing the market for fresh Tilapia. All ACT members have been unified in their drive to consistently deliver a high quality, unadulterated, additive-free, wholesome, fresh and never frozen Tilapia fillet to every American consumer. The longstanding efforts of all ACT producers have been admirable; Tilapia has gone from an unknown product to a widely recognized and healthy source of nutrition for all Americans.

Pioneering American Coalition for Tilapia members took on significant risks in the early 1990's, investing in emerging democracies in Latin America and in an industry that barely existed and was considered highly risky. In spite of these challenges, we have succeeded and are now able to consistently deliver sustainable supplies of fresh Tilapia to the American market. It is a tremendous success story, not only from a business point of view, but also from a social and environmentally sustainable perspective. The Tilapia farming industry has created tens of thousands of low skilled jobs in some of the poorest areas in Latin America. We are also considered a "green industry." For the past two years, American Coalition for Tilapia members has been actively engaged with the World Wildlife Fund to certify our sustainable farming practices. Our operations are transparent, our products do not use preservatives, and we follow the laws of our host countries and the United States of America. Most importantly of all, we have earned the trust of the

American consumer, which has made tilapia the fastest growing seafood choice in America.

We are here today because of our concern in loosing the trust and confidence for tilapia with the American consumer. The American Coalition for Tilapia members are facing significant financial challenges and public relations risks that are directly linked to the economic deception caused by the staggering number of imports of carbon monoxide-treated frozen Tilapia fillets from China and other Asian countries. What concerns ACT the most is that the American consumer is being deceived. Every month, millions of pounds of carbon monoxide-treated frozen Tilapia fillets are entering the United States. These chemically enhanced products are being sold to, and consumed by, the average American consumer, without complete knowledge that carbon monoxide is an ingredient.

According to current United States National Marine Fisheries import statistics (*See Table NMFS*); 125,000,000 pounds (57,181,343 kilos) of frozen tilapia fillets have been imported from China into the United States through August of this year (2007). Members of the American Coalition for Tilapia estimate that at least 70% of this volume of product is gassed with carbon monoxide. We therefore estimate that 88,000,000 pounds of frozen carbon monoxide-gassed tilapia fillets have been consumed by Americans so far this year. Working with the assumption that an average meal size is around one-half pound, a total of 176 million meals of carbon monoxide-gassed Tilapia have been consumed through the first eight months of this year. The observation we have made is that a majority of this volume is consumed without the knowledge that carbon monoxide was used as an ingredient.

The decision of the American Coalition for Tilapia to come forward has not been an easy one. Many members have customers who buy these carbon monoxide-treated products as well as our own. However we have received enough support to urge us on in trying to find clarity on this FDA oversight. Many of our collogues and customers within the seafood industry continue to be surprised, frustrated and morally challenged trying to work within the challenges this generally regarded as safe (GRAS) approval has imposed on them. Many industry colleagues expected the FDA to rescind the GRAS approvals, at least for industrial carbon monoxide.

The Food and Drug Administration of the United States has previously determined that carbon monoxide in seafood is GRAS and therefore does not pose a health risk to the American consumer. While we dispute this finding, the fact remains carbon monoxide is being added to the product and is therefore, by law, considered an ingredient. According to FDA requirement 21 CFR 101, any ingredient must be labeled at point of purchase to make the consumer aware it has been used on the product. At the import level, we believe a lot of the product is in fact being labeled according to or close to FDA requirements. However, at multiple distribution levels within the United States, carbon monoxide ingredient identity is being misrepresented or simply removed altogether. In fairness to FDA we think their GRAS approval for Hawaii International for tasteless smoke on Tuna never anticipated the widespread use of CO on so many species of fish at such massive volumes. For this reason, our logic is if the FDA is unable to manage or enforce the labeling laws they should rescind the GRAS approvals until it can be managed.

To demonstrate the deceptive ambience surrounding this trade in carbon monoxide products, buyers and sellers use a kind of code terminology to identify trade of this product. Names like "Cold Smoked," "Izumi Dai," "Sashimi Grade" and "CO" are all used within the trade to identify carbon monoxide treated product. Even when labeling attempts are made using the scientific acronym for the carbon monoxide molecule "CO" does not identify the common name understood by most consumers for carbon monoxide. In this day and age of "Buyer Beware," one should become very suspicious when deceptive terms or exotic-sounding names are used to identify what is nothing short of chemically treated seafood. We believe the American consumer deserves better.

Throughout the United States, frozen carbon monoxide-gassed Tilapia fillets are routinely being removed from import packaging and placed into fresh seafood counters, to be thawed out and sold as refreshed, or previously frozen, or simply and unethically as fresh Tilapia fillets. Misidentification and total lack of any identification of carbon monoxide as an ingredient is now widespread.

From a competitive standpoint, frozen Tilapia fillets produced in China are much cheaper than fresh Tilapia fillets produced in the Americas, frequently by at least 75%. It has become one of the most profitable seafood items in the grocery counter. The Chinese product is cheaper from a production and distribution standpoint. Fresh fillets from American Coalition for Tilapia cost more to produce and deliver, especially because we charge to deliver quicker since our true fresh fillets are all natural and more perishable. We also have to maintain the red and natural flesh colors without the aide of preservatives like carbon monoxide treatments. True fresh fillet have to be flown into the United States and moved quickly to maintain quality and shelf life. Frozen product, on

the other hand, can be transported and stored more economically and with fewer losses at the store level. Vendors can simply unwrap the frozen fillet packaging and put the fillets into the fresh case, thaw them out over a few hours time and with carbon monoxide in the blood of the fillet, the adulterated products will maintain their heightened red fresh looking blood colors for weeks on end.

The cost advantage alone will provide on-going sales for the Chinese tilapia. We feel Chinese frozen tilapia sales will still find healthy growth without the need for using carbon monoxide. What we find objectionable is competing on an uneven playing field. While many experienced industry insiders will avoid buying these artificial looking fillets, the average American consumer will misperceive the bright pink or red color as a sign of freshness. Nothing could be further from the truth. We feel it is hard enough competing with low cost Chinese production on price, having to do so with deceptive labeling in addition is unacceptable.

This deceptive practice has been going on for ten years. The American Tilapia Association visited the Food and Drug Administration in the spring of 1998 to protest this carbon monoxide fraud. During a meeting with the FDA's Office of Seafood that was arranged by the National Fisheries Institute, the FDA indicated that it did not consider carbon monoxide in seafood a public health risk but they understood that economic fraud could take place. They concluded that they did not have the manpower to enforce the law and so the issue was one that producers would have to deal with. I was personally present at that meeting and have witnessed the developments of this issue for the last ten years. It has taken ten years for someone inside our government to finally ask these same questions about carbon monoxide in seafood.

Following the FDA's recommendation of nearly ten years ago, repeated attempts have been made to address this issue from within the industry. Our concerns have been voiced within the industry and published in trade magazines (*GoogleIntrafish carbon monoxide*), yet the practice continues and expands every year. We have also tried to influence our trade organizations about the potentially severe consumer public relations risks associated with this issue coming before the public eye. The indirect association of a poisonous gas with carefully crafted wholesome image of our members' fresh farmed-raised Tilapia remains at the forefront of our concern. While many companies in the foodservice and grocery sectors have removed or never used carbon monoxide-treated Tilapia, confusion continues to reign in the market. Well intentioned buyers and sellers are under pressure to use this product to compete in their marketplace. Carbon monoxide use has become common knowledge and routine for everyone except the end user i.e., the American consumer.

In our opinion, it's clear the issue will not be solved from within the industry because it has gotten so big and so profitable that it's simply too valuable to volunteer to give up the profits. We firmly believe the only effective solution is through legislation.

Our position is that the consumer should be made aware of the choice they are making in their purchase, the law says so. This especially holds true when it is a choice being unduly influenced by the purposeful manipulation of the appearance of the fish with an artificial ingredient. Our conclusion is that there are consumers that may not want to eat carbon monoxide fish even at the cheaper price and even if our very own FDA is telling them it is "generally regarded as safe." The majority of consumers right now simply have no clue they are buying tilapia saturated with carbon monoxide gas.

Members of the American Coalition for Tilapia believe it is not unreasonable to demand that the ingredient label law be applied and enforced industry-wide. Furthermore, we feel the consumer should be permitted to see natural spoilage rates of fresh Tilapia rather than viewing artificially enhanced and preserved Tilapia products.

Our nightmare is when Mr. and Mrs. America goes home, looks up carbon monoxide in Webster's dictionary, and finds it defined as: a colorless, odorless, highly poisoness gas - and then seeks revenge on all Tilapia producers. We are afraid those that are trying to do the right thing will be punished and the sustainability of our industry compromised. The image and "marketability" of carbon monoxide as a legitimate ingredient is somehow hard to swallow. (*See photo's of gassing process*) We fear the American consumer will place a blanket of distrust over all Tilapia products if this carbon monoxide issue enters the public media mainstream. Frankly, the consumer would be justified in seeking revenge against an industry that was unable to control such a massive fraud. The bottom line is that this carbon monoxide issue is a passport for fraud in our food industry.

We hope you consider this bill as we feel the FDA GRAS approval for Tuna has had an impact far greater than it was intended. I would be pleased to answer any questions from the Committee.

THANK YOU

Key Points – Carbon Monoxide Treated Tilapia Fillets

1. ACT (American Coaltion for Tilapia) is an ad hoc group of American companies engaged in the business of production and import of tilapia (fish) in Central and South America.
2. ACT members were pioneers in the development of tilapia in the US market and their sales currently represent about 95% of the fresh tilapia fillets sold in the United States.
3. The underlying purpose of our coalition is to create consumer awareness of the food safety issues and potential consumer fraud as it relates to the common practice of treating tilapia fillets with carbon monoxide.
4. The vast majority of carbon monoxide treated tilapia fillets enter the US market as frozen fillets imported from China.
5. American consumers have purchased 88,000,000 lbs. of Carbon Monoxide treated tilapia fillets imported from China YTD in 2007
6. The US Food and Drug Administration has granted Carbon Monoxide treated seafood GRAS (Generally Regarded as Safe) status as a preservative. (CO treated seafood is banned in the EU, Japan and Canada)
7. The FDA requires Carbon Monoxide to be labeled as an ingredient but lacks enforcement capabilities.
8. Carbon Monoxide intensifies the red color of fish flesh and disguises the natural aging (browning) process of fish fillets. This opens the door to consumer fraud.
9. Many American consumers routinely purchase CO treated "thawed" tilapia fillets (fraudulently) sold as fresh fillets at retail seafood counters. Fillets they think are fresh could be months old.
10. Great quantities of unlabeled or mislabeled Carbon Monoxide treated tilapia fillets are sold regularly to American consumers at both the retail and foodservice level.
11. The quality of frozen tilapia fillets from China fillets vary greatly in quality and the practice of thawing CO treated fillets presents a serious risk to the image of tilapia to the American consumer.
12. The American consumer has a right to know the fish they are buying at retail or eating in a restaurant has been treated with Carbon Monoxide so they can make an informed buying decision.
13. The FDA should consider an outright ban on the use of Carbon Monoxide on fish fillets.

Tilapia Fillet
$2.98 lb.
Farm Raised
product of
China
previously
frozen

National Marine Fisheries Service
Fisheries Statistics and Economics Division

You asked for the following

Trade Type: IMPORTS

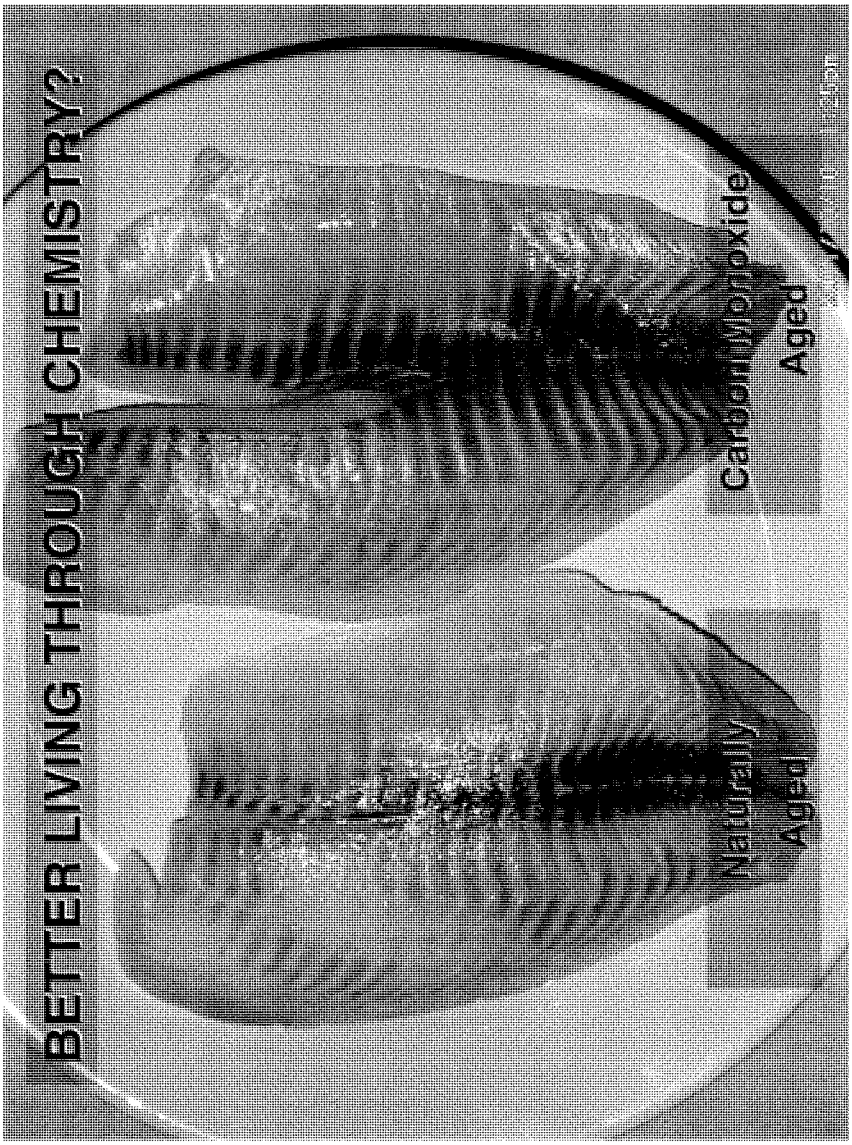
Month: August *Data is cumulative from January through August.*

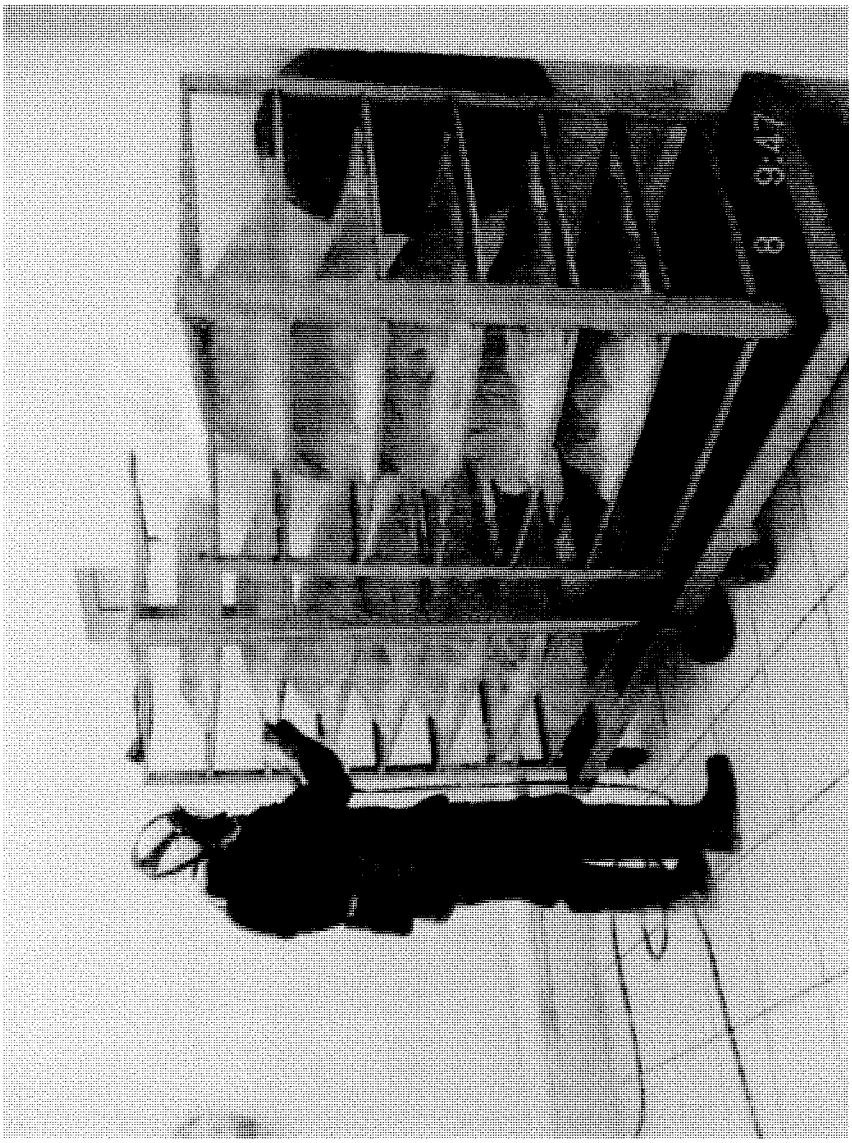
Year: 2007

Product: TILAPIA

Current data through September, 2007.

Product	Country	2006 Kilos	2006 Value	2007 Kilos	2007 Value
TILAPIA FILLET FRESH	BELIZE	25,762	167,492	22,576	141,717
TILAPIA FILLET FRESH	BRAZIL	905,315	4,935,326	158,562	1,003,887
TILAPIA FILLET FRESH	CANADA	0	0	1,459	6,063
TILAPIA FILLET FRESH	CHILE	19,771	131,464	17,298	116,137
TILAPIA FILLET FRESH	CHINA	0	0	17,400	51,672
TILAPIA FILLET FRESH	COLOMBIA	286,668	1,966,374	410,467	2,896,887
TILAPIA FILLET FRESH	COSTA RICA	1,594,638	9,420,932	3,000,442	19,416,721
TILAPIA FILLET FRESH	ECUADOR	7,394,137	47,607,946	8,412,590	52,710,596
TILAPIA FILLET FRESH	EL SALVADOR	140,780	863,742	189,880	1,173,456
TILAPIA FILLET FRESH	HONDURAS	4,769,960	31,544,775	5,400,494	35,256,055
TILAPIA FILLET FRESH	JAMAICA	164,910	1,114,362	136,255	865,33
TILAPIA FILLET FRESH	MEXICO	2,217	15,899	1,970	14,50
TILAPIA FILLET FRESH	NICARAGUA	2,448	15,092	16,054	101,07
TILAPIA FILLET FRESH	PANAMA	108,341	657,275	21,858	110,60
TILAPIA FILLET FRESH	PERU	0	0	5,556	38,55
TILAPIA FILLET FRESH	SPAIN	0	0	422	3,38
Subtotal		**15,414,947**	**98,440,679**	**17,813,283**	**113,906,65**
TILAPIA FILLET FROZEN	ARGENTINA	0	0	27,216	67,37
TILAPIA FILLET FROZEN	CAMEROON	0	0	19,964	44,20
TILAPIA FILLET FROZEN	CANADA	0	0	22,012	151,47
TILAPIA FILLET FROZEN	CHILE	17,373	55,104	19,051	61,81
TILAPIA FILLET FROZEN	CHINA	38,967,704	119,085,526	57,181,343	177,483,14
TILAPIA FILLET FROZEN	CHINA - HONG KONG	38,102	125,540	74,521	128,42
TILAPIA FILLET FROZEN	CHINA - TAIPEI	2,108,454	7,899,045	1,487,158	6,293,59
TILAPIA FILLET FROZEN	COSTA RICA	0	0	119,544	676,95
TILAPIA FILLET FROZEN	ECUADOR	163,571	785,866	133,275	698,03
TILAPIA FILLET FROZEN	HONDURAS	0	0	383,450	2,190,35
TILAPIA FILLET FROZEN	INDONESIA	4,725,878	23,779,819	5,255,895	26,327,02
TILAPIA FILLET FROZEN	JAMAICA	615	5,318	21,833	143,70
TILAPIA FILLET FROZEN	JAPAN	36,286	208,542	19,958	57,20
TILAPIA FILLET FROZEN	PANAMA	143,974	458,660	121,860	519,79
TILAPIA FILLET FROZEN	PERU	0	0	19,958	113,28
TILAPIA FILLET FROZEN	PHILIPPINES	19,737	75,135	0	
TILAPIA FILLET FROZEN	SOUTH KOREA	2,660	22,067	0	
TILAPIA FILLET FROZEN	THAILAND	170,999	748,307	11,300	116,67
TILAPIA FILLET FROZEN	VIET NAM	37,920	100,320	0	
Subtotal		**46,433,273**	**153,349,249**	**64,918,338**	**215,073,05**


BETTER LIVING THROUGH CHEMISTRY?
Naturally Aged
Carbon Monoxide Aged



Mr. STUPAK. Thank you.

Ms. Donley, your opening statement, please.

STATEMENT OF NANCY DONLEY, PRESIDENT, SAFE TABLES OUR PRIORITY, NORTHBROOK, IL

Ms. DONLEY. I would like to thank you, Chairman Stupak and members of the subcommittee, for giving consumers an opportunity to weigh in on a subject that is critical to our very existence, and that is the safety of our food.

My name is Nancy Donley, and I am the president of S.T.O.P., Safe Tables Our Priority. S.T.O.P. Is a national grassroots, nonprofit organization whose mission is to prevent illness and death from pathogens in the food supply. Our work involves sound policy advocacy, building awareness of food-borne risk and its management, and providing victim assistance. I personally became involved in food safety after the death of my 6-year-old son Alex from *E. coli O157:H7* poisoning in 1993.

It is very important to emphasize that modified atmospheric packaging systems, or MAPs, have been used for years. The traditional MAP system for meat includes the use of carbon dioxide and nitrogen, which provides an antimicrobial benefit. The current debate centers on the addition of small amounts of carbon monoxide into this mix. Adding carbon monoxide creates a chemical reaction that changes the color of the meat to a very bright red. That color change is maintained indefinitely until the package is opened. This unnatural but appealing color change is the sole purpose for adding carbon monoxide into the process. The addition of carbon monoxide does not contribute any additional antimicrobial properties to its traditional MAP system using carbon dioxide and nitrogen.

Meat packaged with carbon monoxide might be very unsafe, but the consumer would never question this because of its artificial bright red color. Microorganisms, including deadly pathogens, breed whenever there is a breach in the cold chain. Meat will turn brown or gray if it has been temperature-abused, something that consumers know to look for. However, meat packaged with carbon monoxide will still appear bright red and safe even after extreme temperature abuse. High pathogen levels could be present, putting the consumer at risk of serious food-borne illness.

A change in color also keeps the entire food system honest. Meat processors, storage facilities, transportation carriers, and retail establishments have strong incentives to maintain the cold chain because otherwise the product is easily identified as compromised, rendering it unsalable. That safety check disappears with meat that always remains red regardless of extreme temperature abuse.

Proponents of using carbon monoxide argue that consumers would be warned via an odor if the product were spoiled. We have two concerns with this. There are people with compromised olfactory senses who may not notice an off-order. Seniors often experience this, and they are one of the populations most at risk of contracting the most severe forms of food-borne illness. Odors are only detectable once the package is open, which doesn't occur until the purchaser has brought it home. The customer has the choice to return it, which is a hassle, or to throw it away. In each case the customer has been cheated.

These and other factors all point to the need for labeling any meat that has been packaged using carbon monoxide. Consumers have the right to know what processes and additives have been used in the food they purchase. Full disclosure is necessary. In this case the label would need to state that carbon monoxide was used in packaging, which causes meat to artificially maintain a bright red color. It should also state that the customer must heed the "use by" or "freeze by" date listed and not rely on color, and that to do so is unsafe.

Color is a tool heavily used by consumers to judge if their meat is fresh and safe. We are concerned that people will choose to eat meat that has been packaged using carbon monoxide after the "use by" date because they don't want to throw out what appears to be a perfectly fine-looking $10 steak; hence the need for clearly worded information to minimize this risk from happening.

Lastly, I want to comment on the process used by the FDA and the USDA to grant GRAS status to meat packaged with carbon monoxide. First and foremost, we believe that this is a color additive issue that should have gone through a general rulemaking process, but, obviously, this did not happen. Regardless, the way that our regulatory agencies handle these GRAS petitions cause us deep concerns. I am neither a scientist nor a statistician, but even I can tell after looking at this study submitted to the FDA and to the USDA by the companies in support of their petitions that sound science was not used.

The number of samples of ground beef used was extraordinarily small. For instance, they only used six in one study and 15 in the other. In each study all of the samples were taken from one plant at a single point in time. The temperature abuse study was done at 50 degrees Fahrenheit, which is far colder than even room temperature, and last is that the sampling was done at the point of production rather than on retail product that had passed through the cold chain.

The FDA itself has acknowledged that temperature abuse is common throughout distribution and retail markets. As a consumer who relies on our Government to evaluate processes used on the foods I feed my family, I'm appalled. The FDA and the USDA need to revisit these GRAS approvals and also need to reevaluate how they accept the science of companies seeking to use new additive and food technologies.

Thank you for your attention. I'll be happy to answer any questions.

[The prepared statement of Ms. Donley follows:]

Testimony of Nancy Donley
President of S.T.O.P.—Safe Tables Our Priority
before the
Subcommittee on Oversight and Investigations
of the Committee on Energy and Commerce
U.S. House of Representatives

November 13, 2007

I'd like to thank Chairman Stupak and members of the Subcommittee on Oversight & Investigations for giving consumers an opportunity to weigh in on a subject that is critical to our very existence—the safety of our food.

My name is Nancy Donley and I am the president of S.T.O.P.—Safe Tables Our Priority. S.T.O.P. is a national, grassroots, non-profit organization whose mission is to prevent illness and death from pathogens in the food supply. Our work involves sound policy advocacy, building awareness of foodborne risk and its management, and providing victim assistance. Our members include families who have suffered illness and loss from a broad spectrum of food types including contaminated meat and poultry, produce, juice and RTE processed foods. I personally became involved in the issue of food safety after the death of my 6-year-old son, Alex, from *E. coli* O157:H7 poisoning from contaminated meat in 1993.

S.T.O.P. has been engaged in the debate over the use of carbon monoxide (CO) in modified atmosphere packaging, or MAP, for the past several years. I'd like to state at the onset that our concern does not stem from a belief that human exposure to the trace

amounts of carbon monoxide used in this process are a cause for concern. Rather, our concerns center on the following three areas:

1. The change in appearance of meat when it undergoes a MAP with CO and the safety issues that this poses for consumers.

2. The lack of labeling requirements for meat that is packaged in this manner.

3. The process used by FDA and USDA to grant GRAS status to meat packaged with CO as part of a MAP system.

1. Safety Issues

I think that it is important to emphasize that the MAP systems that use carbon dioxide (CO2) and nitrogen (N) have been used for years. One of the benefits resulting from this combination of gases produces an antimicrobial component. The current debate centers around the addition of small amounts of carbon monoxide to this process. Adding CO causes a chemical reaction to occur that changes the color of the meat to a very bright red, and it maintains that color indefinitely until the package is opened. This unnatural but appealing color change is the sole purpose for adding CO into the process and we consider it to be deceptive. The addition of CO to the MAP process does not contribute any additional antimicrobial properties that the traditional MAP system using CO2 and N doesn't already possess. Proponents are disingenuously suggesting otherwise.

Our concern is that the safety of the meat packaged in this manner might be severely compromised and the consumer would never know it because it would still look completely fresh. Microorganisms, including deadly pathogens, breed whenever there is a breach in the cold chain. Meat will turn brown or grey if it has been temperature abused, signaling that its freshness and safety have been compromised. However, meat produced in a MAP system with CO, will still appear fresh and safe even after extreme temperature abuse, because its color will remain bright red. High pathogenic levels could be present, putting the consumer at risk of serious foodborne illness.

The fact that meat that has been packaged in the more traditional method undergoes a readily-apparent color change helps keep the production, distribution and retail system honest. Meat processors, storage facilities, transportation carriers and retail establishments have strong incentives to maintain the cold chain because otherwise the product is easily identified as compromised and becomes un-saleable. That built-in safety check disappears when CO is used as part of a MAP process because temperature abuse is not apparent. Unsafe meat will make it through the distribution system, into retail stores and ultimately into consumers' homes because it looks completely fresh. While color is not the only factor used for determining freshness, it is a tool heavily relied upon by consumers.

One of the arguments put forward by proponents of this technology is that a spoiled product, even though appearing fresh, would produce an 'odor'—a highly subjective term—once opened. We take exception on two counts.

1. There are people with compromised olfactory senses who may not notice an off odor. Studies show that this is a common effect of aging, so seniors, one of the populations most at risk of contracting the most severe forms of foodborne illness, are put at increased risk.[1]

2. Odors are only detectable once the package is opened, which is after the purchase has been made and the meat is in the customer's home. There certainly are economic concerns here. People live very busy lives and often find it easier just to toss out the spoiled item than to take the time to return it to the grocery store and put up with the hassle. People lose or throw out their store receipt and can't return it. Maybe they froze the product and months go by before they finally take it out to use it, only to discover that the product is spoiled. In all of these instances, the customer has been cheated.

2. <u>The Need for Labeling</u>

[1] Charles J. Wysocki & Marcia L. Pelchat, *The Effects of Aging on the Human Sense of Smell and Its Relationship to Food Choice,* 33(1) Crit. Rev. Food Sci. Nutr. 63,63 (1993). Charles J. Wysocki & Avery N. Gilbert, *National Geographic Smell Survey: Effects of Age Are Heterogenous,* 561Ann. N.T. Acad. Sci. 12 (1989).

These and other factors all point to the need for labeling to identify any meat that has been packaged with a MAP system using CO. Consumers have the right to know what processes and additives have been used in the food they purchase. This means full disclosure with all pertinent information. In this case the label would need to state that CO was used in the packaging causing the meat to maintain a bright red color which should not be considered an indicator of freshness. It should also state that the customer must heed the use/freeze by date listed and that to do otherwise is not safe. A lack of full disclosure in labeling is equally as deceptive as no disclosure at all.

It is only with the inclusion of complete information in labeling that consumers can make informed purchasing and consumption decisions. I mentioned earlier that color is a tool heavily used by consumers to judge if their meat is fresh and safe. We are concerned that people will choose to eat the meat packaged with CO as part of the MAP system after the use-by date because they won't want to throw out what appears to be a perfectly fine-looking $10.00 steak. Hence the need for clearly-worded information.

3. FDA and USDA's GRAS Approval process

Lastly, I want to comment on the process used by FDA and USDA, in 2002 and 2004, to grant GRAS status to meat packaged with CO as a part of a MAP system.

First and foremost, we believe that the use of CO as part of a MAP system should have been considered a color additive and gone through a general rule-making process. Obviously, that did not happen.

Regardless, the way that our regulatory agencies handled these GRAS petitions, and one can only surmise that they handle others in a similar fashion, causes us deep concern.

I am neither a scientist nor a statistician, but even I can tell after looking at the studies submitted to FDA and USDA by companies in support of their petitions, that the science was not sound.

1. The numbers of samples taken of ground beef were extraordinarily small (6 in one study and 15 in the other).

2. In each study, all samples were taken from one plant at a single point in time.

3. The temperature abuse study was done at 50 degrees Fahrenheit, colder even than room termperature.

4. The sampling was done at the point of production rather than on retail product that had passed through the cold chain. FDA has acknowledged that temperature abuse is common throughout distribution and retail markets.[2]

[2] FDA Food Code, supra note 68 at 547.

As a consumer who relies on our government to evaluate processes used on the foods I feed my family, I'm appalled. FDA and USDA need to revisit these GRAS approvals and re-evaluate how they accept the science of companies seeking to use new additive and food technologies.

Thank you for your attention and I will be happy to answer any questions.

Mr. STUPAK. Thank you.

Ms. Hauter, your opening statement, please.

STATEMENT OF WENONAH HAUTER, EXECUTIVE DIRECTOR, FOOD & WATER WATCH, WASHINGTON, DC

Ms. HAUTER. Good morning, Chairman Stupak, Ranking Member Whitfield and members of the subcommittee.

I am Wenonah Hauter, executive director of Food & Water Watch. We're a consumer advocacy group located here in Washington, DC. Regrettably, we're spending more and more of our time watchdogging the Federal agencies that are supposed to be protecting our food safety.

I appreciate the opportunity to participate in this hearing because we are outraged that the FDA is putting the economic interests of the industry before the health and safety of consumers. We expect industry to maximize profits. We expect the Federal agencies to protect the citizens of this Nation.

Color is one of the most important factors for a consumer in determining that meat is fit to eat. In 2003, a study was prepared by the National Cattlemen's Beef Association showing that U.S. retailers lose about $1 billion each year in fresh beef sales because of discoloration, and that's what this is all about. Let's be honest. This is about making sure that consumers will buy old meat that may be contaminated. At worst, it's dangerous; at best, it's a consumer rip-off.

Now, I've brought my own package of meat today, and we sat here this morning and heard that it's OK that the meat is still pink even though this meat was purchased on October 27, had a "sell by" date of October 31 and has been sitting out for 2 days, but we heard it was OK because there is a "sell by" date. This "sell by" date is so small that I can hardly see it with my progressive lenses, and an elderly person would not be able to see it. This is deceptive packaging.

Meat that's processed within a store butcher shop and that is wrapped for display in meat cases normally has a shelf life of 4 to 5 days. Case-ready meat that's packaged with modified atmospheric packaging that doesn't have carbon monoxide has a shelf life of 10 to 12 days, but the U.S. Department of Agriculture has approved a "use by" date of 28 days for ground beef and 35 days for muscle cut beef that's treated with carbon monoxide. Month-old meat is not fresh, in my opinion.

Now, we've heard extensively about GRAS this morning, and we agree with the other speakers on this panel. This process needs to be reviewed and changed.

Second, since carbon monoxide imparts a new color to the meat that's treated, we believe that the FDA should have considered this technology to be a color additive under the Federal Food, Drug and Cosmetic Act.

Third, we believe that the use of carbon monoxide for red meat products is a violation of the Federal Meat Inspection Act because the USDA is allowing adulterated products into commerce since they have not been properly approved and with the use of a color additive, and it makes the product look better or of a greater value than untreated products.

Fourth, the FDA did not conduct any consumer research to determine whether there would be any issue with deception from this technology.

Fifth, the USDA inexplicably reversed its position on allowing this process to be used on red meat products, which we've heard about this morning.

Now, consumer organizations have done research about how consumers feel about the carbon monoxide treating of meat. The Consumer Federation of America used a public opinion research firm, Opinion Research Corporation, and they found three out of four consumers, or 75 percent, are very concerned or are somewhat concerned about the practice of adding CO to meat to make the meat appear bright red. Over three-fourths of consumers, 78 percent, said that the practice of treating red meat with CO is deceptive.

In the July 2006 issue of Consumer Reports, the Consumers Union reported findings on red meat that had been treated with carbon monoxide. The Consumers Union scientists tested 10 packages of ground beef and steaks that had been treated with CO, and they found that even though the meat appeared to be red, some of the meat samples had spoiled or had bacterial counts that were close to indicating spoilage. By their "use by" or "freeze by" dates, seven samples were fresh, but two packages of ground beef from one company were spoiled.

We have attached this information to our testimony, and we hope that this committee will continue investigating this. We believe that this practice should be banned.

Thank you.

[The prepared statement of Ms. Hauter follows:]

Testimony of
Wenonah Hauter, Executive Director
Food & Water Watch
Before
U.S. House of Representatives
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce

November 13, 2007

Good morning Chairman Stapak, Ranking Member Whitfield and members of the subcommittee. My name is Wenonah Hauter and I am executive director of Food & Water Watch. We are a non-profit consumer organization that works on food policy and water infrastructure issues. We were founded in November 2005 and we are based here in Washington, D.C.

I welcome this opportunity to testify today on an issue that is very important to my organization – the consumer's right to know what we are feeding our families. Our organization has been in the forefront of such labeling issues as the implementation of country-of-origin labeling for meat and seafood. We are currently fighting an attempt by the Food and Drug Administration (FDA) to eliminate the labeling requirements for foods that have been treated with irradiation. And, last but not least, we have been working with other consumer organizations, such as the Consumer Federation of America, Safe Tables Our Priority, the Government Accountability Project, and Consumers Union, among others, to shed light on the issue that the subcommittee is examining today – the use of carbon monoxide in modified atmosphere packaging for meat, poultry and seafood. I believe that today will be the first time that a congressional committee has invited all of the stakeholders to testify at one hearing on this issue and I commend your leadership for organizing today's discussion.

We view the use of carbon monoxide in modified atmosphere packaging as a consumer deception issue, so Food & Water Watch wholeheartedly supports H.R. 3115, the "Carbon Monoxide Treated Meat, Poultry, and Seafood Safe Handling, Labeling, and Consumer Protection Act" introduced by Chairman Stupak, Congressman Edward Markey and Congresswoman Rosa DeLauro, that would require all meat, poultry and seafood products

packaged with carbon monoxide to carry a safety notice informing consumers that the products have been treated as such and that the products' freshness should not be judged by its color.

As a direct result of that proposed legislation and the subcommittee's inquiries of various major supermarket chains and meat and poultry processors about their use of carbon monoxide in the foods they sell, we have seen a marked change in the use of this questionable technology. For example, supermarket chains such as Giant Foods, Stop & Shop, and Safeway have recently announced that they would stop carrying meat products that have been packaged in modified atmosphere containers with carbon monoxide. Most significant was the announcement by Tyson Foods – that largest protein processor in the country – that it would stop using carbon monoxide in its modified atmosphere packaging systems because demand for such products from its customers had dropped.

While these voluntary actions should be commended, we believe that Congress needs to enact legislation to prevent some of these companies from reneging on their current policies.

As I stated earlier, we view the use of carbon monoxide in food packaging as a consumer deception issue. Why do we say that? I have brought with me a package of ground beef that was purchased on October 27, 2007 from a local supermarket. The label on the package states that the product had a sell-by date of October 31, 2007 and a "use by/freeze by" date of November 15, 2007 – two days from now. The meat looks perfectly fine by looking at it. What you do not know is that we left this meat out at room temperature for 48-hours. We re-refrigerated the meat. But this meat is spoiled. One would not be able to tell that by looking at it because the color of the meat – the primary indicator of spoilage to the average consumer – has not changed from the red color it had the day it was purchased. This package is not giving off any odor at this point. The meat inside this package was treated with carbon monoxide. If I opened this package right now, I am sure that the odor would indicate that the product was spoiled. Ironically, the slogan for the supermarket chain where this meat was purchased is "Where Freshness Matters." This meat – whether it had been intentionally abused or stored under ideal conditions – is not fresh by any stretch of the imagination.

While we intentionally caused this meat to spoil, it may not be uncommon for spoiled meat to reach supermarkets because of improper refrigeration en route between the meat processor and the store. On November 5, 2007, an investigative report by the CBS News affiliate in Chicago revealed several instances in recent months of improperly refrigerated meat and poultry products that made their way to restaurants and grocery stores. Some of the meat products were exposed to 95-degree heat for several hours.[1] Trucks break down, truck refrigeration units malfunction, there are traffic accidents, and the refrigeration units of in-store meat cases may not work properly. Meat that is not treated with carbon monoxide and subject to temperature abuse will begin to oxidize and turn brown. Meat that is treated with carbon monoxide will retain its color and mask spoilage even when improperly stored.

Meat that is processed within store butcher shops and wrapped for display in meat cases normally has a shelf life of about 4 to five days. Case ready meat that is packaged with modified atmosphere packaging without carbon monoxide has a shelf life of 10 to 12 days. But the United States Department of Agriculture (USDA) has approved a use by date of 28-days for ground beef and 35-days for muscle cut beef that is treated with carbon monoxide. Month old meat is not fresh in my opinion and I do not think most consumers perceive it that way.

We believe that both the FDA and USDA have let consumers down in a number of ways on this issue.

First, FDA permitted the use of carbon monoxide in food packaging through the less-than-transparent process called GRAS – Generally Recognized as Safe – by which industry can file notices on processes it intends to use and if there are no objections by FDA, the company can proceed with the new process. FDA usually reviews these notices with the information filed by the company that wants to use the new process. There is no formal notice and comment period. Unless one actively peruses the FDA website on GRAS notices, they generally go unnoticed by the average consumer. And, if one were interested in finding out what the GRAS notification

[1] CBS Channel 2, Chicago. "Filthy Food: Serious Meat Safety Violations," November 5, 2007, see http://cbs2chicago.com/investigations/filthy.food.violations.2.489781.html.

contained, it would require filing a Freedom of Information Act request to obtain the information.

Second, since carbon monoxide imparts a new color to the meat that is treated, we believe that FDA should have considered this technology to be a color additive under the Federal Food Drug and Cosmetic Act {21 U.S.C. 321 (t) (1)}. If FDA had done that, it would have opened the process to formal notice and rulemaking.

Third, the FDA failed to conduct any consumer research to determine whether there would any issue with deception with this technology. There have been some in industry who have argued that there is consumer satisfaction with food products treated with this technology. The problem is that consumers do not know that their meat, poultry or seafood may have been treated with carbon monoxide. If consumers knew that up-front, it could impact their purchasing decisions.

Fourth, USDA inexplicably reversed its position on allowing this process to be used on red meat products. In an April 28, 2004 letter to FDA, Dr. Robert Post, Director of the Labeling and Consumer Protection Staff for the Food Safety and Inspection Service at USDA, expressed serious reservations about using carbon monoxide in modified atmosphere packaging for red meat because it "...could potentially mislead consumers into believing they are purchasing product that is fresher or of greater value than it actually is and may increase the potential for masking spoilage."[2] Six weeks later, however, Dr. Post changed his mind. Again, neither Dr. Post nor anyone else at USDA offered any consumer research to support the change in position.

Fifth, we believe that the use of carbon monoxide for red meat products is a violation of the Federal Meat Inspection Act because USDA is allowing adulterated products into commerce since there has not been proper approval of this technology as a color additive and it makes the product look better or of a greater value than untreated products.[3]

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[2] Letter from Dr. Robert Post, Director of Labeling and Consumer Protection, Food Safety and Inspection Service, United States Department of Agriculture to Dr. Lane Highbarger, Office of Food Additive Safety, Food and Drug Administration, April 28, 2004.
[3] See 21 U.S.C. 601 (m)(8) and 9 C.F.R. 301 (2) (8), 424.23(A).

Since the agencies charged with protecting our food supply have not conducted the proper research into this issue, I offer the results of some research conducted by consumer organizations that shows that is technology is perceived to be deceptive by consumers and that meat processed with carbon monoxide in modified atmosphere packaging can mask spoilage even if a consumer opens the package within the use by date listed on the package.

In a national poll conducted among 1019 adults in September 2006 for the Consumer Federation of America, the public opinion research firm Opinion Research Corporation found the following:

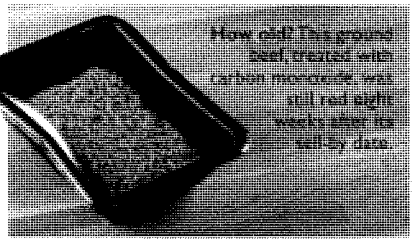
- Most consumers are concerned about the practice of adding CO to color meat and believe this practice to be deceptive, according to the survey.
- Sixty-three percent (63%) agreed with the statement that "the freshness of meat is directly related to the color of the meat." By extending the bright red color of meat for several weeks longer than untreated meat, carbon monoxide masks the true color of the meat and consumers are unable to accurately determine if the meat is fresh.
- Three out of four consumers (75%) are very concerned or somewhat concerned about the practice of adding CO to meat to make the meat appear bright red for up to several weeks longer than untreated meat.
- Three out of four consumers (74%) also replied that CO-treated meat such as ground beef should not be allowed to have a 28-day shelf life, as required by the Federal government. The typical shelf life for prepackaged meat that has not been treated with CO is 10 to 12 days.
- Over three-fourths of consumers (78%) said that the practice of treating red meat with CO is deceptive.
- Moreover, 68% of consumers would strongly support a law to make it mandatory that meat treated with CO be labeled.[4]

In the July 2006 issue of *Consumer Reports*, Consumers Union reported findings on red meat that had been treated with carbon monoxide. Consumers Union scientists tested 10 packages of

[4] Consumer Federation of America. "Most Consumers Are Concerned About Practice of Adding Carbon Monoxide to Meat, New Survey Finds," September 25, 2006, see http://www.consumerfed.org/pdfs/CO_Meat_Consumer_Press_Release_9.25.06.pdf

Seeing red Spoiled meat may look fresh

Attention, meat shoppers: Your supermarket may be selling ground beef and steaks packaged with gas that keeps it looking red for a month or longer. Our tests found that meat packaged using that method stayed red even if it was spoiled.



How old? This ground beef, treated with carbon monoxide, was still red eight weeks after its sell-by date.

The process, used in factory-wrapped (or case-ready) meat, replaces most of the oxygen in the package with other gases. Those include tiny amounts of carbon monoxide, which react with the pigment in meat, producing a red color. The shelf life for ground beef sealed in that mix of gases can be extended from about 14 days to 28 days, and about 10 days to 35 days for whole cuts.

Some supermarket chains, including Kroger and Publix, refuse to carry meat packaged with carbon-monoxide, citing concerns about appearance and freshness or quality.

Bacterial counts that indicate spoilage in meat may make it taste and smell bad, but food safety experts say that it is generally not a health hazard. Thorough cooking will kill bacteria that cause foodborne illness, though it won't necessarily undo spoilage odors or bad taste.

The U.S. Food and Drug Administration determined as recently as July 2004 that it had no objections to the use of carbon-monoxide packaging for fresh meat. In November 2005, Kalsec, a company in Kalamazoo, Mich., that uses a different meat packaging process, petitioned the FDA to ban carbon monoxide for that use. The company argued that federal regulations prohibited substances that "make food appear better or of greater value than it is." At press time, the FDA was still reviewing the company's petition.

Consumer Reports decided to do limited testing to check whether carbon-monoxide-packaged meat can stay red even when spoiled. Since there's no requirement that the process be listed on meat labels, we called manufacturers to verify that the brands purchased were packed with carbon monoxide. We tested 10 samples of locally purchased ground beef and steaks from three companies. We found that the meat appeared red even if it was spoiled or had bacterial counts that were close to indicating spoilage.

By their use- or freeze-by date, seven samples were fresh but two packages of ground beef from one company were spoiled; an additional sample was on the brink of spoilage a day before the stamped date.

WHAT YOU CAN DO

Ask whether your grocer sells meat packed with carbon monoxide. If so, don't use color as the only guide to freshness. Check the package and buy meat whose stamped date is a couple of weeks away. With all meat, check for signs of spoilage, such as surface slime, and discard meat that smells bad.

Did you know?

A painful lower leg can indicate high cholesterol

People with pain in the Achilles tendon, which connects the muscles of the calf to the heel, should consider getting their cholesterol checked. In research involving 200 people, those with a common form of hereditary high cholesterol were nearly seven times more likely than those without to report tendon pain lasting three days or more, researchers report in the March 2006 issue of Annals of the Rheumatic Diseases. Cholesterol builds up in the tendons, as well as the arteries, causing pain and swelling.

names&claims

COCOAVIA: CHOCOLATE THAT HELPS THE HEART?

Packages of CocoaVia Original Chocolate Bars claim they contain "natural plant extracts which have been proven to reduce bad cholesterol (LDL) by up to 8 percent," and "high levels of naturally occurring cocoa flavanols to help promote healthy circulation." But does snacking on CocoaVia chocolates really promote a healthy heart, as the package claims? Possibly, but there are less caloric ways to get your flavanols.

When we asked for scientific evidence to support CocoaVia's claims, the manufacturer, Mars, sent us published articles on the cardiovascular benefits of cocoa rich in flavanols and studies suggesting that flavanol-rich cocoa either improved vascular function or inhibited clotting in clinical trials. Support for the cholesterol-lowering claim included an abstract that, at press time, had not yet been published. Most of the studies were done with Mars collaboration or funding.

Nutritional experts we consulted said the studies that Mars sent were not definitive. Adding two 100-calorie CocoaVia bars a day to your diet "for maximum benefit," as the packaging suggests, could result in a weight gain of about 20 pounds in a year unless other foods are reduced or exercise is increased. And at a cost of $4.99 for a box of five bars, you'd spend nearly $730 a year. Our expert tasters found that CocoaVia bars had an intense dark-chocolate flavor and a fairly smooth melt.

CR's take: It makes more sense to focus on consuming flavanols from foods such as apples, grapes, and tea.

Mr. STUPAK. Thank you.

We will go to questions. Let me start with you, Ms. Hauter. You indicated you had your study done, but did you ever hear of a study where they considered consumers and how they purchase their meat products or seafood by a "use by" date? Are you aware of any study like that?

Ms. HAUTER. No, I've never heard of such a study.

Mr. STUPAK. Thank you.

In your study, did you have any baseline to see what the respondent's knowledge was of carbon monoxide used in meat before your survey?

Ms. HAUTER. No. This was a Consumer Federation of America study, and as far as I know, they didn't look at this issue. In fact, I think that the reason Members of Congress are not hearing from their constituents is, I would bet, that almost no one knows about this.

Mr. STUPAK. In your study what was the significance of your findings? You mentioned your meat there, and on the far left—my far left, your far right—there is actually hamburger that was just purchased here on November 10 with an expiration date of yesterday. So give me the significance of your findings of your study there.

Ms. HAUTER. Well, people don't want this kind of deceptive packaging, and it's by a very large percentage.

Mr. STUPAK. OK. Ms. Donley, you used the words "cold chain" in your testimony. Is that the temperature of meat and how it's processed? Do you want to explain that a little further?

Ms. DONLEY. The cold chain is the various points along the route from production all the way through to the retailer where there has to be a cold enough temperature maintained to keep bacteria from breeding. So the chain would include warehouses and trucking companies where we're counting on all of those points to maintain that temperature, that safe temperature.

Mr. STUPAK. You also indicated the "use by" date. Do you believe that's a valid notification to consumers?

Ms. DONLEY. No, I don't, because consumers really use their eyes to make their decisions, and there is going to be the person who is going to say, "Hey, there must be something wrong with the date. This looks perfectly fine. I'm going to go ahead and eat it," who can put himself or herself at serious risk of food-borne illness.

Mr. STUPAK. OK.

Mr. Picchietti, if I may, you were talking about tasteless smoke in your testimony, but you gave it other words. What were the other names you were using?

Mr. PICCHIETTI. Well, I wasn't talking about tasteless smoke. I was talking about industrial carbon monoxide. The other names I mentioned are——

Mr. STUPAK. So are these names that have to be on packages of tilapia, these other names?

Mr. PICCHIETTI. Some of them are.

Mr. STUPAK. What are they?

Mr. PICCHIETTI. Izumidai, which is a Japanese word used in Japan, I guess. It signifies CO. Everyone knows.

Mr. STUPAK. All right.

Mr. PICCHIETTI. Cold-smoked—of which that's something else; actually, that's done to salmon, I believe, but the main thing is that's just not mentioned is "carbon monoxide."

Mr. STUPAK. Nor would it trigger the thought in a consumer's mind that this is carbon monoxide.

Mr. PICCHIETTI. Yes. Exactly.

Mr. STUPAK. Let me ask them to put those pictures up.

Do you want to explain the pictures that we were talking about earlier? I actually had one up, and Mr. Burgess sort of objected to it. It was the guy with the respirator who was spraying the fish.

Mr. PICCHIETTI. Well, that's just how it's done.

Mr. STUPAK. Let's see if we can get one of these pictures up. If you can get those up for us, because I want to ask you a couple of questions about it. OK. Here is the picture I had up before it was objected to.

Could you explain what that is and what's going on there?

Mr. PICCHIETTI. Well, when the fish is filleted, they are put in like a cookie tray, and then a big plastic bag is put around it, and it's like filling up a balloon. You put the pure carbon monoxide gas, industrial gas, into the bag for an hour or so, and the hemoglobin has an affinity to it. It gets inside the hemoglobin, and it turns the fish red, actually a different color than the actual red normally.

Mr. STUPAK. I think we have a picture of that. We have a picture of the fish side by side. One is red and the other is——

Mr. PICCHIETTI. Carbon monoxide is poisonous, so it's dangerous for the workers. In the early days——

Mr. STUPAK. That's why the respirator?

Mr. PICCHIETTI. Yes, that's why the respirator.

Mr. STUPAK. Right here, is this—no. There's carbon monoxide, and there's naturally aged.

Mr. PICCHIETTI. Right. That would be both frozen products, the same age thawed out, and one looks like that, and that's what normal frozen would look like.

Mr. STUPAK. But the redness, that's brought out by the carbon monoxide?

Mr. PICCHIETTI. Yes. And you can see it's actually not even natural red; it's very heightened. So, with the discussion earlier about additive/fixative, it seems like an additive.

Mr. STUPAK. Now, you and your companies go with the fresh tilapia. You say that it is more expensive, of course, because you get the fish, and you've got to fly it, right, air express?

Mr. PICCHIETTI. Yes.

Mr. STUPAK. Where is most of your fish produced, grown?

Mr. PICCHIETTI. The coalition's fish is all from Latin and Central America.

Mr. STUPAK. OK.

Mr. PICCHIETTI. It's fresh because it's closer. Asia, at least now, can't fly it over.

Mr. STUPAK. How long would you consider the product to be fresh? How long will it last?

Mr. PICCHIETTI. Oh, 10 to 14 days from harvest.

Mr. STUPAK. OK. You come in from Latin America or Central America, you said. What ports do you have to bring your tilapia into?

Mr. PICCHIETTI. Miami, Boston, Los Angeles. Mostly Miami.

Our farm is only an hour and a half from Miami.

Mr. STUPAK. I have no further questions at this time.

Mr. Whitfield for questions.

Mr. WHITFIELD. Thank you, Mr. Chairman.

I want to thank this panel for your time and for being with us this afternoon.

Mr. Picchietti, in your testimony, you talked about 125 million pounds of tilapia that's imported into the country; is that correct?

Mr. PICCHIETTI. Well, as of August.

Mr. WHITFIELD. Now, is that coming in from China, or does that include the tilapia that you all bring in from Central America.

Mr. PICCHIETTI. No, it doesn't include that. I had a graph up there which showed what we all brought in.

Mr. WHITFIELD. OK. So the 125 million pounds is coming from Asia.

Mr. PICCHIETTI. That's just China which is about 85 to 90 percent of——

Mr. WHITFIELD. Do you have any idea how many millions of pounds of tilapia is consumed in the United States in a year?

Mr. PICCHIETTI. Yes. One pound per person. We surpassed cod and catfish in 2006, 350 million pounds.

Mr. WHITFIELD. Now, to make sure that I understand, are you claiming that using carbon monoxide is a safety issue, or is it basically an unfair trading practice and deception.

Mr. PICCHIETTI. Well, I don't have all kinds of scientific data about the safety issue.

Mr. WHITFIELD. Yes.

Mr. PICCHIETTI. What I do know is it's not labeled, and the fellow today said it has to be labeled, and it's not being labeled in the fresh case.

Mr. WHITFIELD. When you say "not labeled," do you mean used by a certain date?

Mr. PICCHIETTI. Well, basically the FDA fellow said you can use the CO tilapia as long as it has a "use by" date on it.

Mr. WHITFIELD. Right.

Mr. PICCHIETTI. The other thing is at the fresh seafood counters in grocery stores, there's no ingredient label either. So those are the two issues we're objecting to, which is that we feel it should be labeled in the fresh seafood case. We never thought of the "use by" date.

Mr. WHITFIELD. Yes. So, from your perspective, it's really an unfair situation because of the issues that you discuss in your testimony primarily.

Mr. PICCHIETTI. Well, it's illegal, right? That's what this fellow said today.

Mr. WHITFIELD. Yes, it is illegal. It's on the books. So, if that's occurring, then it needs to be enforced in some way. It's an enforcement issue, right.

Now, Ms. Hauter, you're the executive director of Food & Water Watch. How old is Food & Water Watch?

Ms. HAUTER. We're 2 years old, but we're a spin-off from Public Citizens where, for 10 years, we ran a food safety program.

Mr. WHITFIELD. Do you have dues-paying members?

Ms. HAUTER. Yes, we have dues-paying members.

Mr. WHITFIELD. Would those be companies, or would those be individuals.

Ms. HAUTER. We take no corporate money, just public support.

Mr. WHITFIELD. Just donations from individuals.

Ms. HAUTER. Donations and foundation money.

Mr. WHITFIELD. Yes. OK.

Now, back in September 2006, in tab 26 of the booklet there, which you can look at if you want to—you don't have to—the Consumer Federation of America did a survey, and they asked consumers what are some of the issues that they used to decide which products to purchase, and the No. 1 item that they looked at in making a decision to purchase was the "use by" or the "sell by" date; No. 2 was packaging/appearance; No. 3 was smell; No. 4 was color; No. 5 was texture; No. 6 was taste. I know there has been some testimony today that the one item that consumers look at most is color, yet according to this survey conducted in September, the No. 1 issue that they looked at was the "sell by" date.

Would you disagree with that, or are you aware of that?

Ms. HAUTER. I think that a "sell by" date is different on different kinds of products. When you, for instance, purchase milk, the "sell by" date is kind of up there at the top. It's large. Everybody looks at it. I think it—I know that you can't see this, but if you look at a "sell by" date that is so small that it's under all of the information about safe handling, people would not notice this when you pick up a——

Mr. WHITFIELD. So, if the "sell by" date would be larger, that would make it easier for you to accept?

Ms. HAUTER. I think it's important to have a "sell by" date——

Mr. WHITFIELD. Oh, I do, too, absolutely.

Ms. HAUTER. But I think it's also, for meat, that traditionally people look at the color, and I think if you were going to actually do research on this, you would have to look product by product to see how people purchase items.

Mr. WHITFIELD. Now, in your *ConsumerReports.org* that you submitted earlier in tab 41, I guess, you reported that you all did limited tests on carbon monoxide-packaged meat, and you found that three out of 10 samples had gone bad within the "use by" date. I'm assuming you've seen this report. I would ask: Do you know if Consumer Reports tested traditionally packaged meats as well?

Ms. HAUTER. I'm not sure if they did or not. I can't answer that.

Mr. WHITFIELD. Now, I understand that the shelf life of traditionally packaged meat is shorter than the carbon monoxide MAP-packaged meat. So, if that's true for the MAP carbon monoxide-packaged meat, I would think it would also, maybe, even be a worse case for the traditional package. Do you have any thoughts on that?

Ms. HAUTER. Could you restate that? I didn't understand.

Mr. WHITFIELD. Well, what I said was in your report, you all point out that three out of the 10 samples of carbon monoxide-packaged meat had become contaminated prior to the "use" date's expiring.

Ms. HAUTER. Right.

Mr. WHITFIELD. They evidently did not do any testing of traditionally packaged meat, which most studies indicate does not last as long in the shelf life as the carbon monoxide meat. So I would say that if they had been fair on this test and had tested both samples, it's more than likely that the traditionally packaged may have turned out worse than the carbon monoxide meat.

Ms. HAUTER. But I think, sir, with all due respect, the point is that with regular packaged meat, there will be discoloration, but with carbon monoxide-treated meat, there will not be discoloration, and so consumers won't realize that there may be contamination. The longer meat sits, and when there's bacteria on it, which there almost always is, the bacteria continues to multiply, but a consumer would not be aware of it or is likely be aware of it when the meat is still pink and pretty like this.

Mr. WHITFIELD. Now, let me ask both you and Ms. Donley, because I know that you both are committed to this issue, and all of us are very much concerned about food safety, obviously. Do you have the names of anyone who has been sickened by spoiled meat that was masked by carbon monoxide?

Ms. HAUTER. Well, I think it's very difficult to determine when or how people get sick from meat, and I think we would have to go to the CDC and see if they have been able to—in the information they collect, if that's one of the questions they ask, because I'm not sure that we would be aware, when people do get sick, that it was because of carbon monoxide.

Mr. WHITFIELD. But you're not aware of anything specifically?

Ms. HAUTER. I'm not aware of anything specifically.

Mr. WHITFIELD. What about you, Ms. Donley?

Ms. DONLEY. I'm not aware of anything specifically either, but then again, someone who had become sickened probably would not be aware either that it was from the packaging, the process by which it had been packaged, because there is no requirement even to say how it was processed, so a person wouldn't know.

Mr. WHITFIELD. Do you all have the names of any companies or supermarkets that purposely have sold bad or spoiled meat to consumers?

Ms. DONLEY. I can't imagine any supermarket's wanting to intentionally sell spoiled meat. It may have unknowingly sold spoiled meat, but I can't imagine anyone doing that intentionally.

Mr. WHITFIELD. But you do feel like, if they're using carbon monoxide, that it is a deceptive practice?

Ms. DONLEY. Definitely.

Mr. WHITFIELD. OK. Ms. Donley, you testified about breaking the chain of refrigeration, warning that a consumer will not know by color or by the "use by" date whether meat has been temperature-abused at the store or elsewhere.

How does a consumer know that opaque packages, such as sealed hamburger packs or wrapped sausage, have not been temperature-abused?

Ms. DONLEY. They don't. You bring up an excellent point, and I wish that the technology would be used that shows that the temperature has been compromised. There are—I can't come up with the term right now—devices that can be used in a package that

would show it. So I think it's an excellent idea that all meat contain that.

Mr. WHITFIELD. Now, you all heard testimony earlier today about scientific studies conducted at the University of Georgia, the University of Minnesota, and Texas Tech in which the consensus was, in scientific opinion, that MAP packaging using carbon monoxide was not a safety hazard.

Do you all have any scientific studies indicating that those studies are inaccurate?

Ms. DONLEY. I don't have any studies that my organization has done of their own.

I would like to say, though, that it's important to take a look at what is being compared in those studies. For instance, I know that some of the referrals that have been made to Dr. Doyle, who is a very good scientist from the University of Georgia, that what he reported on—and it's not even a published study, to my knowledge—but what he took a look at in his research centered on looking at meat that—at samples that had been wrapped in just the regular overwrap process, and he compared that to meat that had been in the MAP process using the CO. So it's really an apples-and-oranges comparison.

Mr. WHITFIELD. But the consensus of scientific opinion is that this is not a safety hazard, and you all are not aware of any additional scientific studies that would refute that is I think what you testified to.

Ms. DONLEY. I think we need to define here what I'm talking about as far as safety. And what I'm referring to that is that I think it—pretty much it seems to be the general consensus among the scientists that this is not an issue that is going to do something to render the meat itself unsafe. But the safety factor enters into it is how it appears to people when temperature abuse could have happened, but the act in and of itself or the process in and of itself is not unsafe.

Mr. WHITFIELD. Mr. Chairman, I think my time has expired.

Mr. STUPAK. Thank you.

There is a company that has labels that will turn colors if the temperature is abused.

Ms. Schakowsky for questions, please.

Ms. SCHAKOWSKY. I just wanted to comment on that. It is not that the CO necessarily is the defect, but that it masks other problems that may exist and may present a safety hazard. So I can't imagine a study that would show in and of itself that the CO was the problem, and that's the problem.

I wanted also to mention—I wanted to respond to something Mr. Whitfield said about the "sell by" date or a date on a product. I think that—I'm very proud of those dates. I feel like in 1969 our little group of housewives helped to get that on there. But you look at those dates primarily when you don't have other indicators. If you're going through the meat case, and you see something that looks fine, you may be prone to buy it. When you look at the date, it is because it doesn't look right, or you can't see through it, like milk or something, I think.

I wanted to—there are a couple of things. One, I wanted to comment—Mr. Picchietti—sashimi grade was another. I love sashimi,

and if I saw sashimi grade—I think I have seen sashimi grade on something. I think that is a good thing because I didn't know that, that it meant that it was treated. I think those names are really deceptive. And for me, particularly sashimi grade, I had no idea. I thought it was a positive because I like sashimi. I just wanted to let you know that. So I'm agreeing with your testimony.

Mr. PICCHIETTI. I'd just like to clarify that it is a real term used for real sashimi grade products. But as in the trade and among buyers and sellers, when you say is your tilapia sashimi grade, it is usually understood that it has got industrial carbon monoxide in it.

Ms. SCHAKOWSKY. Not being in the industry, in the business, I certainly wouldn't know that.

I wanted to ask Ms. Donley a question. You were saying that you thought that the process was faulty, but also that had it—were it called a color additive, that the process would be entirely different. Could you explain that?

Ms. DONLEY. Sure. First of all, it is great to see you again, Congresswoman.

If this had been determined, which we think it should have been determined, that this was a color additive, it never would have been subject to GRAS approval. It would have gone through a formal rulemaking process, and it would have been open for public comment, and that a lot—all of this—it would have fleshed out additional science. It would have fleshed out consumer concerns and been a much better process than what actually happened here.

Ms. SCHAKOWSKY. In any case, I think that there ought to have been a regular rulemaking process so that there was a comment period. And I agree with you, Ms. Hauter, that people don't know—I don't know. Maybe it is a lot of men who don't shop, frankly, who are making these comments. Excuse me, guys who go to the store and actually shop. But, I think most people actually are unaware that—and I wanted to ask you about relying on industry data. If you could expand on your comments on that.

Ms. HAUTER. We just generally have a concern when industry data is used because they have a bias, and the questions that are asked may be different than the questions that we would ask. We think that it is generally a problem——

Ms. SCHAKOWSKY. Were you satisfied—were you here when the FDA was testifying?

Ms. HAUTER. I was here, and I thought that they were not able to answer the questions that they should have been able to answer. And I know from our experience—we just did a very extensive report on imported fish that we had to wait over a year to get our Freedom of Information Act request answered, and when the data came to us, it was in such poor shape that we couldn't use it and had to have it manipulated to——

Ms. SCHAKOWSKY. When it is old, it gets decomposed.

Ms. HAUTER. So I was not surprised. And that has been our experience and our concern about the FDA.

Ms. SCHAKOWSKY. Well, this committee has asked for information. You have asked for information. The FDA has failed to act for over 10 years. So timeliness in dealing with all of these is a problem.

And I also recognize the competitive issues as well. I want fresh fish. I don't want fresh-appearing fish. And you would know the difference in colors, but I wouldn't know that it is too red or not too red.

I think we have to resolve this for safety and for deceptive—consumer deception reasons. Thank you.

Mr. STUPAK. Thank you.

Ms. Donley, you were asked—Mr. Whitfield and others asked about the studies in temperature. In the exhibit book, they are exhibit 30 and 31. I had asked—and you have it right in front of you there. I asked the FDA about these studies. One was from Minnesota, the other one was Norway. The Norwegian study on page 218 says the safety of the modified atmospheric packaging, products are mostly threatened by temperature abuse. And if you go to exhibit No. 30, again that study, which is out of the University of Minnesota, says temperature abuse is a main concern for chilled and/or modified atmosphere packaging, meat and poultry products, since it will not likely cause economic loss, but may also lead to food-borne illness hazard. A major question of such products is whether spoilage due to microbial or chemical action will occur before pathogen numbers or toxic levels become a risk when a product undergoes abuse temperatures.

So is that the temperature or the code part that you were talking about?

Ms. DONLEY. Right. That is the cold chain process. And anywhere along those points, if the temperature is raised higher than what it should be to keep bacterial growth from occurring, bacteria has a way of multiplying very, very rapidly.

Mr. STUPAK. Let me ask this question. Ms. Hauter, you have your package there. Right there we have samples E, F and G on your extreme left and my right. Take a look at those samples. What do they look—appear to you, E, F and G?

Ms. DONLEY. These three?

Mr. STUPAK. Yes, the three on the end.

Ms. DONLEY. They look very, very fresh to me. And I think—if I might, when we talk about these "use by" or "freeze by" or "sell by" dates, I think consumers look at those dates when they are making their purchase. When I go to the 7-Eleven next to my office and I buy my sandwich, I look to see when it was prepared on so I'll buy the one that was prepared most recently. The consumer buys this package of meat, sticks it in the refrigerator. When they go to use it and it looks that color, they're not even going to—it is not going to occur to them to even look to see that "use by" date because it looks perfectly fresh.

Mr. STUPAK. Ms. Hauter, do you think E, F and G look fairly fresh?

Ms. HAUTER. They look perfectly——

Mr. STUPAK. Mr. Picchietti?

Ms. HAUTER. They look like they were just cut.

Mr. STUPAK. OK. Well, E was purchased on January 12, 2007. That is, what, 10 months ago. F was purchased 1 year and 8 months ago, and G nearly 2 years ago. Needless to say, they are temperature-abused, I take it, sitting here, and yet they are staying fresh-looking.

I have no further questions. Anyone else?

With that I'll thank and dismiss this panel. Thank you.

I call up our third and final panel if we will for today. The panel consists of Mr. Gregory Page, CEO of Cargill, Incorporated; Mr. Jeffery Ettinger, chairman, president and CEO of Hormel Foods Corporation; Mr. Doug Brinsmade of the Anova Food, Incorporated.

It is a policy of this subcommittee to take all testimony under oath.

Pleased be advised that witnesses have the right under the rules of the House to be advised by counsel during your testimony. Do any of you wish to be represented by counsel?

Everyone indicated no. Therefore, I ask you to stand and raise your right hand. Please take the oath.

[Witnesses sworn.]

Mr. STUPAK. Let the record reflect that all three gentlemen indicated they are under oath.

We will begin with opening statements. Who would like to begin?

Mr. Page, you're on my right. If you want to start, please.

STATEMENT OF GREGORY PAGE, CHIEF EXECUTIVE OFFICER, CARGILL, INCORPORATED

Mr. PAGE. Thank you, Mr. Chairman and subcommittee members. You have requested as the chief executive officer of Cargill I speak to you today about the production of meat products and Modified Atmosphere Packaging, otherwise and often referred to as MAP. We in the food science community consider this packaging to be one of the most important food safety innovations ever.

Packaging innovations have a long history of improving food safety. Many advances now seem simple, canned goods, pasteurization, vacuum packaging and tamper-resistant fresh food packaging to name just a few. There was a time when the salt curing of meat was the most advanced technology available, and it performed fairly well as a critical health protection for a thousand years or more.

We now know a lot more about food safety and have many, many more technologies available to help make food as safe and as accessible to consumers in ways we never imagined. Basic food science and food safety principles have evolved. And these principles direct some of the most critical research and innovation of our product offerings. We know the importance, for instance, in prohibiting cross-contamination. We know about the importance of controlling temperature and moisture, of controlling the oxygen and the interior atmosphere of a package, and of controlling the pH. We also know that processing technology, preservatives and additives play a critical role in consumer protection.

Consumer demands and scientific knowledge also direct research and innovation. Today's consumers want a wide variety of perishable items, including produce, fish and meat. They often want products that can be labeled as natural or organic. And they want these items to be available at their local stores year round, 24 hours a day for their convenience. It is this drive to safely satisfy consumer demand that leads us to the technologies of today.

Scientists have long known the importance of controlling the interior atmosphere of food packages, and one of the earliest applications of modified atmosphere packaging was in 1927 when storing

apples in an atmosphere of reduced oxygen and increased carbon dioxide resulted in increased shelf life.

The early understanding and use of gas mixtures led us to the case-ready systems available today. Beef is typically delivered to a grocery store in one of three ways, as a box product sealed in a vacuum package, or as individual packages with high oxygen or low oxygen-modified atmosphere packages ready for display in the meat case for consumer purchase. Boxed, vacuum-packaged product is opened at the grocery store and cut into steaks or roasts and then wrapped in the store for retail display. Case-ready products come completely packaged and labeled and can be taken from a line box and placed immediately in the retail display. The case-ready system eliminates the need to open, handle and repackage the product in the store and greatly reduces the chance of cross-contamination.

We want consumers to have all the benefits of these advanced packaging systems. We believe it unfortunate that there has been misinformation about low-oxygen MAP. We have seen some retail customers who have found this technology serves them and their customers best find the need to back away from it because of public pressure.

We recently had the opportunity to host investigators from this committee at one of our case-ready plants. We as a company learned clearly from our guests the important issue concerning the committee members was the potential that a consumer may not fully understand that color is not the only indicator of freshness. For this reason we will be adding wording to our labeling, pending, of course, USDA approval, to include the following statement: "Color is not an indicator of freshness. Please refer to 'use' or 'freeze by' dates." We believe this effectively addresses the concerns expressed by the committee visitors to our plants regarding the protection of public health, while not undermining the adoption of the safety and the convenience afforded through this case-ready packaging technology.

We stand firmly by our previous statements that color is not a proper indicator of freshness or safety, and we support the FDA's and the USDA's decisionmaking. While there are many foods like eggs, ketchup, salad dressing and carrots that all maintain their coloration, only observing freshness dates will tell you when the products are past their peak of flavor or quality.

My point is this: science should guide our regulatory decisions. Consumers suffer a great disservice when competitive pressures drive a debate that leads consumers away from the superior food safety and freshness performance inherent in the packing we are discussing today.

I'm sure the individuals in the salted meat industry were discouraged when new innovations led to canning and ultimately packaging, and I'd relate a story specific to meat. In 1904, a guild of more than 600 butchers in San Francisco formed the Butchers Board of Trade, And the purpose of their organization was to oppose the adoption of ammonia-based mechanical refrigeration, which was newly being introduced at that time. Their self-serving opposition would have prolonged the continued unsanitary use of block ice to chill meat. In fact, at that time people resisted this

pressure, and the adoption of mechanical, rapid refrigeration of meat was adopted, to the great benefit of consumers.

Cargill is deeply committed to serving the needs of our customers. The low-oxygen technology that we've discussed today is an important evolution in packaging and is but one example of our commitment.

I'd like to thank this committee for its commitment and leadership in the area of food safety. I want to recognize the work of the committee staff and would be pleased to answer any of your questions to the best of my ability. Thank you.

[The prepared statement of Mr. Page follows:]

TESTIMONY OF GREGORY PAGE

Thank you Chairman Stupak and subcommittee members.

You have requested that as the chief executive officer of Cargill I speak to you today about the production of meat products in Modified Atmosphere Packaging—known as MAP. We, and the food science community consider this packaging to be one of the most important food safety innovations ever.

My testimony today has been crafted with a great deal of input from our research and development leaders, and since I am not a scientist, I will be relying on their expertise for any questions of a scientific nature.

FOOD PACKAGING INNOVATIONS

Packaging innovations have a long history of improving food safety. Many advances now seem simple—canned goods, pasteurization, vacuum packages, and tamper resistant fresh food packaging, just to name a few. There was a time when the salt curing of meat was the most advanced package available, and it performed fairly well as a critical health protection for a thousand years or so. We now know a lot more about food safety and have many, many more technologies available to help make food as safe and accessible to consumers in ways never before imagined.

Basic food science and food safety principles have evolved, and these principles direct some of the most critical research and innovation of our product offerings. We know the importance of prohibiting cross contamination. We know about the importance of controlling temperature and moisture, of controlling the oxygen and interior atmosphere of a package, and controlling pH. We also know that processing technology, preservatives and additives play a critical role in consumer protection.

Consumer demands and scientific knowledge also direct research and innovation. Today's consumers want a fresh and wide variety of perishable items including produce, fish and meat. They often want products that can be labeled as natural or organic. And, they want these items to be available at their local stores, year-round, for their convenience.

It is this drive to safely satisfy consumer demand that leads us to the technologies of today.

PACKAGING GASES, FOOD PRODUCTS, AND FOOD SAFETY

Scientists have long known the importance of controlling the interior atmosphere of food packages. One of the earliest applications of Modified Atmospheric Packaging (MAP) was in 1927, when storing apples in an atmosphere of reduced oxygen and increased carbon dioxide resulted in increased shelf life.

In the 1930s a modified atmosphere was used in the storage and transportation of fruit in the holds of ships, and increasing the carbon dioxide concentration surrounding beef carcasses transported long distances was shown to increase shelf life by up to 100%.

Today, nitrogen is probably the most widely used gas in food packaging. Nitrogen is often used as the principle gas to flush oxygen out of packages that will be vacuum packed. The Food and Drug Administration and the United States Department of Agriculture have long accepted the safe use of nitrogen as a packaging gas.

As previously mentioned, carbon dioxide has also been utilized as a key packaging gas. Fresh fruits and vegetables are often shipped in a mixture of gases, where the carbon dioxide level plays a key role in both suppressing microbial activity as well as helping regulate the ripening process which in turn greatly extends shelf life, and helps guarantee product safety.

The careful use and application of this gas has long benefited consumers by helping the produce industry manage supplies and meet consumer demands. For perishable items, like bananas, we in the U.S. do not have the climate to produce adequate quantities to meet demand. Carbon dioxide and other packaging gases allow the American consumer to become accustomed to a perpetual supply of fresh fruits and vegetables. Without Modified Atmosphere Packaging, we would not have fresh bananas, berries or apples in winter, and packaged or organic salad greens.

Much like carbon dioxide, gas mixtures containing ethylene are critical for a wide number of fresh fruits and vegetables. Ethylene promotes the ripening of apples, avocados, bananas, citrus, dates, mangos, melons, papayas, pears, pineapples and tomatoes.

In the context of historical innovations, the use of carbon monoxide is relatively new. The Food and Drug Administration approved the use of this gas in 2002. It is used in combination with carbon dioxide and nitrogen, all of which have important food safety and freshness properties. Unique to the FDA approval is that we asked for, and FDA supported, the mandate that foods packaged in this format must include tamper-proof freshness dating.

Modified Atmosphere Packaging and Case Ready MeatsThrough a MAP system, meat is packaged at a central processing plant and is then delivered to the retail grocery store in a tray covered with a protective film. This helps eliminate the potential for cross contamination that can come from human handling both at the retail store and in the home. The package is both leak-proof and tamper proof, adding additional consumer protections.

Mr. Chairman, you have recently raised the question that MAP packaging containing CO may allow meat to retain its characteristic red coloration for too long, potentially masking spoilage. I appreciate the opportunity to help ensure that this technology is more fully understood and to convey our deep commitment to consumer protection.

Today beef is typically delivered to a grocery store in one of three ways—as boxed product sealed in a vacuum packaged bag, or as individual packages with high oxygen or low oxygen modified atmosphere packages, ready for display in the meat case for consumer purchase. Boxed, vacuum-packaged product is opened at the grocery store and cut into steaks or roasts and then wrapped for retail display. Case ready products come completely packaged and labeled, and can be taken from a lined box and placed in the retail display. The case ready system eliminates the need to open, handle, and re-package the product in the store, greatly reducing the chances of cross contamination.

Meat products in a vacuum bag have a shelf life of about 35 days. The shelf life of case ready products will vary depending on the packaging technology used.

There are two types of case ready MAP product offerings—those packaged in a high oxygen (high-ox) format and those in a low oxygen (low-ox) format. We believe that both are good formats, but the low-ox format, in many respects, has significantly better functionality, especially in the area of ensuring freshness and convenience for the consumer.

Steaks and roasts that are packaged in a low-ox environment have a shelf life roughly equivalent to the 35 days of the vacuum bag. Steaks and roasts in high-ox packaging have a shorter shelf life of only 14 or 15 days. You can observe this shelf life concern not only in meat packaging but also in produce. As a point of reference, note that the spoilage of a head of lettuce accelerates rapidly after the packaging is removed.

The technology in MAP produces a shelf life similar to packages using vacuum technology. And, it achieves this equivalent shelf life in a manner that is much more convenient and appealing to consumers.

Protecting freshness and shelf life are indeed critical. Beyond preserving freshness and reducing microbial activity, low-ox packaging also protects against flavor degradation. High levels of oxygen in a high-ox packaging such as a traditional tray wrap will deteriorate the flavor of meat. Many university studies have shown that meat in a high ox package can look acceptable, but will have a significantly less acceptable flavor than low oxygen products. Low oxygen packaging helps to maintain the natural flavor of meat.

There are additional benefits of low-ox packaging. By giving retailers the shelf life similar to vacuum packages in a direct to consumer format, small retail stores in both rural and very urban areas have the opportunity to offer diverse product lines. The packaging reduces waste, because retailers can make more efficient purchasing decisions. The packaging is also more tamper-proof, through the use of imprinted use-by or freeze-by instructions that cannot be removed.

OXYGEN AND PRODUCT COLOR

Let me cover just a little bit about the science of our packaging technology as outlined by our R&D team.

One of the challenges with low oxygen packaging is that the removal of oxygen has a visual impact on meat coloration. As you may recall from high school biology, blood appears bluish when it has not been exposed to oxygen. Once exposed to oxygen, blood becomes red. This same principle also applies to meat coloration and MAP packaging.

While substantial food safety benefits are attained in low oxygen packaging, a dull red to almost purplish discoloration of the product would make the product unattractive to the consumer. In contrast, the traditional grocery tray is more exposed to oxygen, and therefore it appears red.

To gain the functional and appearance performance for low-ox packaging, we substitute the oxygen with other acceptable and safe gasses. One of these gasses we use involves a trace amount of carbon monoxide (0.4 percent). As previously noted, this is fully approved by the FDA, based on volumes of scientific study.

As the committee is no doubt aware, many of the leading food scientists have submitted papers and testimony that show the superior freshness and food safety performance of this packaging. I want to note that with all MAP products, the packaging gas dissipates immediately once the package is opened. Once the package is opened, product degradation continues in a manner similar with other opened packaging systems.

CONTINUAL INNOVATIONS IN FOOD SAFETY AND PACKAGING TECHNOLOGY

We want consumers to have all the benefits of MAP. But to do so, the package must be as attractive as competing products in the case. We believe it unfortunate that there has been misinformation about low oxygen MAP. We have seen some retail customers who have found this technology serves them and their customers best, find the need to back away from it because of public pressure campaigns led by a Michigan-based competitor offering a different technology. As advertised, this competing technology uses a different method to inhibit oxidation, and includes a masking effect for flavor. Our technology has no such feature. We are hopeful that greater understanding of the facts will help to abate this pressure.

We recently had the opportunity to host investigators from the House Committee on Energy and Commerce at one of our case ready plants. We learned clearly that the most important issue concerning committee members was the potential that a consumer may not fully understand that color is not the only indicator of freshness. For this reason, we will add wording to our labeling, pending USDA approval, to include the statement, "Color is not an indicator of freshness. Please refer to use or freeze by dates." We believe this effectively addresses the concerns of the Committee in protecting public health, while not undermining the adoption of the safety and convenience offered through case ready packaging.

We stand firmly by our previous statements that color is not a proper indicator of freshness or safety, and we support the FDA's and the USDA's decisionmaking. While there are many foods like eggs, ketchup, salad dressing, and carrots that all maintain their coloration, only observing freshness dates will tell you when the products are past their peak of flavor or quality.

My point is this—science should guide our food regulatory decisions. A well orchestrated, but non-science based press campaign, should not. Consumers suffer a great disservice when competitive pressures drive a debate that leads consumers away from the superior food safety and freshness performance inherent in this particular packaging.

I'm sure the individuals in the salted meat industry were discouraged when new innovations led to canning and ultimately vacuum packaging. However, consumers were better off, and most importantly, more safely served as innovations in food safety and preservation continued.

The need for continual food safety innovations and product marketing is recognized by all of us. We want our competitors to continue to innovate. We are going to continue to innovate. We encourage our suppliers to innovate. Consumers demand it; food safety demands it; it raises the bar for everyone; and it's the right thing to do.

Cargill is deeply committed to serving the needs of our customers. The low oxygen technology that we have discussed today is an important evolution in packaging technology and is but one example of our commitment.

I want to thank this committee for its commitment and leadership in the area of food safety. I want to recognize the work of the committee staff. I would be pleased

to answer any questions to the best of my ability, and ask that the committee allow my colleague Dr. Eilert to answer questions of science that are beyond my expertise.

Mr. STUPAK. Thank you.

Mr. Ettinger, please.

STATEMENT OF JEFFREY M. ETTINGER, CHAIRMAN, PRESIDENT, AND CHIEF EXECUTIVE OFFICER, HORMEL FOODS CORPORATION

Mr. ETTINGER. Thank you, Mr. Chairman, for the opportunity to testify today.

There appear to be many misconceptions about our modified atmosphere packaging technology, so we appreciate the chance to explain why we believe so strongly in this product line.

Our company, Hormel Foods, was founded 116 years ago on the twin principles of innovation and quality. Indeed, our reputation for quality and wholesomeness is really our most important company asset. For the past 20 years, we've dedicated considerable research to the fresh meat case for both pork and beef. As a result of this research, we contributed to the design of a low-oxygen packaging system that provides a fresher, safer product to consumers.

Oxygen is the enemy of many food products, including meat, because it accelerates spoilage. Grocery stores are replete with examples of the use of modified atmosphere packaging to keep products fresh. These include potato chips, cereals, bag salads, lunch meats and shredded cheese.

In the case of fresh beef and pork, our process controls the atmosphere in the package to a ratio of 64.6 percent nitrogen, 35 percent carbon dioxide and four-tenths of a percent of carbon monoxide. In our GRAS petition, we provided clear evidence that meat packed in this matter maintains freshness for up to 35 days. This technology was found acceptable by the FDA and approved by the Food Safety and Inspection Service.

Our low-oxygen packaging system has received overwhelming support from the scientific community because it is both safe and beneficial to consumers. Mr. Chairman, I have 10 letters from leading scientists supporting the safety of the technology. And with your permission, I'd like to submit them for the record.

Mr. STUPAK. Without objection.

Mr. ETTINGER. Thank you, Mr. Chairman.

I would like to speak now to the benefits provided to consumers by this product line. First off, it puts much more of the available shelf life in the hands of the consumer, providing the consumer with a fresher, better eating experience. Second, it is leak-proof, preventing possible contamination from raw meat in a grocery basket or the consumer's refrigerator. Third, it eliminates the potential of cross-contamination at the store. Fourth, it allows for the packaging and code dating of meat in a temperature-controlled environment under USDA inspection. And fifth, the packaging is tamper-resistant.

The main area of inquiry I've heard today relates to the question are consumers being deceived by the red color. Let me first lay to rest the notion that we'd deliberately attempt to deceive consumers by, in essence, coloring bad meat to look good. All the products sold

in this joint venture is branded with our Hormel brand. The last thing we would do is enter a category with new product, put our brand on it, and endanger our overall company reputation by selling bad product.

We do recognize that the inclusion of carbon monoxide in the package stabilizes the color of the meat. This is why we put a "use by" date on the front of this product in type three times larger than normal and put another "use by" statement on the back. Given the extensive testing we performed, we were confident that the packaging system would be beneficial to consumers, and indeed this has been the case. This product has been in the market now for 3 years, and we've sold nearly 23 million packages of it. Every package has our 800 number on it. Every package contains a guarantee of satisfaction. This product has enjoyed one of the highest levels of consumer acceptance of any product we have recorded, and we have no documented cases of food-borne illness associated with this package. So the concern about potential color confusion is really unsupported by our real-life experience.

The U.S. Government labeling authority for these products has determined that our current labeling with its prominent "use" or "freeze by" freshness date is truthful and not misleading. Nonetheless, in an effort to address the concerns about color expressed by subcommittee staff, we have offered language to modifying the proposed bill that we'd be willing to adopt, the same language Mr. Page mentioned, and that is, "Color is not an accurate indicator of freshness. Refer to the 'use' or 'freeze by' date." In addition, we have informed the subcommittee staff about ongoing efforts we are making to improve this packaging and address long-term color change.

We appreciate what the subcommittee is ultimately trying to do, protecting consumers from harm, and as a trusted American brand for 116 years, that has always been and will remain our goal as well. I would be pleased to answer any questions to the best of my ability. Thank you.

Mr. STUPAK. Thank you.

[The prepared statement of Mr. Ettinger follows:]

Testimony of Jeffrey M. Ettinger,
Chairman, President and Chief Executive Officer,
Hormel Foods Corporation
November 13, 2007
Subcommittee on Oversight and Investigations,
Committee on Energy and Commerce

Mr. Chairman, Members of the Subcommittee, thank you for the invitation to testify today on the modified air packaging technology Hormel uses for its branded case-ready meat products. We appreciate and share the purpose of the Committee's investigation of this issue – to ensure consumer protection.

Our experience with the lid-stock packaging technology under consideration by the committee today is this – it is the most recent advancement in food packaging technology for fresh meats that reduces food safety risks and delivers a high quality product to our consumer. This packaging system has among the highest consumer satisfaction ratings, and is one of the most accepted products in our company's 116-year history.

Hormel is headquartered in rural Minnesota. We have over 18,500 employees working in operations in Minnesota, Iowa, Nebraska, Wisconsin, Kansas, California, Georgia, Ohio, Wyoming, Colorado, Arizona, Pennsylvania, and in field sales throughout the country. Our company was founded on principles of innovation and quality, and our reputation for quality and wholesomeness is our most important company asset. We always seek to improve quality, safety and convenience for our consumers. Our mission

is to provide consumers of our products with a great eating experience. We have introduced many packaging innovations over the course of our history that have improved product safety, widened the range of consumer choice, and responded to new challenges in food marketing and distribution.

Throughout our history we have dedicated research efforts to the fresh meat case, for both pork and beef. By studying other research in the field, and by conducting our own, we designed a low oxygen packaging system that provides a fresher, safer product to consumers. Oxygen is the enemy of many food products, including meat, because it accelerates spoilage. It discolors the product, first making it unappetizing in appearance, and later causing spoilage. Our grocery stores are replete with examples of the use of modified atmosphere packaging to keep product fresher. These include potato chips, cereals, bagged salads, lunch meats, and shredded cheese. By controlling the atmosphere in the package to a ratio of 64.6% nitrogen, 35% carbon dioxide, and 0.4% carbon monoxide, we can keep meat in a fresh and high quality condition for a longer period of time than traditional overwrapped meat.

We proved freshness up to 35 days and submitted this data to the Food and Drug Administration under the GRAS notification process used for several hundred food ingredients. The technology was found acceptable by FDA, and approved by the Food Safety and Inspection Authority for use in packaging red meat cuts and ground meat. We ultimately chose a 24-day shelf life in order to insure an optimal eating experience for our consumers.

CO MAP technology has received overwhelming support from the scientific community, because it is both safe and beneficial to consumers. Supporters of this technology include individuals such as Dr. Michael Doyle, the Director of the Center for Food Safety at University of Georgia; Dr. Alden Booren, Michigan State University; Dr. Joseph Sebranek, Iowa State University; Dr. Mindy Brashears, Texas Tech University; and many others.

In addition to providing consumers a larger access window to fresh meat products, there are a number of other benefits to this packaging and technology:

- It is leak-proof, preventing possible contamination from raw meat to other items in a grocery basket, or in a consumer's refrigerator;
- It eliminates the potential of back-room cross-contamination at the store;
- It allows for the packaging and code-dating of meat in a temperature controlled, HAACP-regulated environment; and
- The packaging is tamper-resistant.

In sum, we feel we have advanced food safety and improved on the quality of the eating experience for our consumers.

We have been pleased to accompany committee staff on a tour of the production facility using this packaging technology, and to answer questions that have been raised. We

believe that there are two main areas of inquiry from the committee and would like to address both in our testimony today:

(1) *Are consumers being deceived by the red color?*

NO.

Let us first put to rest the notion that we are attempting to deceive consumers by in essence "coloring" bad meat to look good. This product is BRANDED with our Hormel brand. The last thing we would do is enter a category with a new product, put our brand on it, and expect that people would have a bad experience.

The inclusion of carbon monoxide in the package does stabilize the color of meat. If improperly handled or used well beyond the sell or use by date, it is possible that it could be spoiled in the package, yet still look red. We put sell by dates on the front of this product in type three times larger than normal to address this. We put another sell by date on the back of the product. There are other further signs of spoilage that would alert a consumer that the product has gone bad, even if it still looks red. If the customer somehow misses the visible signs and sell by date, and brings the spoiled product home, spoilage will be obvious when he or she opens the product. At that time the customer may return the product. This is true of meat or any other grocery item that may go bad before it is sold to the consumer.

We don't have to rely upon an academic debate as to whether consumers are likely to have a bad experience with this product. It has been in the market for three years, and we have sold 23 million packages, and 190 million servings. Every package has our 800 telephone number on it. Every package contains a guarantee of satisfaction. Indeed, this product has enjoyed one of the highest levels of consumer acceptance of any product we've recorded in our long history. We have no documented cases of foodborne illnesses associated with this packaging.

(2) Why don't we just mention the use of CO on the label?

Hormel will comply with any labeling of this product that is determined to be necessary and fair through the legislative or regulatory process.

FSIS, the U.S. government labeling authority for these products, has determined that the current labeling of this product – with the prominent "use or freeze by" label is truthful, and not misleading. As a U.S. business it is essential for us to continue to rely on an orderly, well-defined path to market, and on the regulatory review and authorization processes that exist, in order to continue to innovate and provide improved products to the American consumer.

Notwithstanding this, in an effort to address the concerns expressed by Subcommittee staff and consumer groups, we have offered to add additional language to our label to address the color issue and expressly inform consumers that-- "Color is not an

accurate indicator of freshness. Refer to use or freeze-by date." We also offered to add language reminding consumers of the right temperature setting for home refrigeration – a key point of concern that has been expressed by Subcommittee staff. Finally, we are committed to ongoing technological innovation to improve this packaging and address long-term color change. A patent has been filed on this technology.

We appreciate what this Subcommittee is ultimately trying to do—protect consumers from harm. As a trusted American brand for 116 years that has always been and will remain our goal, along with delivering a quality product to the consumer that is convenient for him or her to enjoy. Low-oxygen modified atmospheric lid-stock packaging is safe and beneficial to the consumer, and our customers have strongly embraced the technology and welcomed the benefits it provides.

I would be pleased to answer any questions to the best of my ability, and hope the committee will allow my colleague Dr. Phillip Minerich to answer questions of science that are beyond my expertise.

Mr. STUPAK. Mr. Brinsmade.

STATEMENT OF DOUG BRINSMADE, PRESIDENT AND CHIEF EXECUTIVE OFFICER, ANOVA FOOD, INCORPORATED

Mr. BRINSMADE. Good afternoon, Mr. Chairman and members of the subcommittee. My name is Doug Brinsmade, and I'm the president and CEO of Anova Food, Incorporated. We are a division of the Anova Food Group. The Anova Food Group is a global seafood company specializing in sourcing, processing and distributing the seafood products from worldwide sources. We supply frozen seafood products to a majority of retailers, food service distributors and restaurant chains across America under our patented process called Clearsmoke, of which Blane Olson, president of Clearsmoke, and I are the patent holders.

Mr. Chairman, I'm here today as a representative of the seafood industry with 20 years of involvement in the industry and over 12 years of experience in the use of filtered wood smoke technology of which natural-occurring carbon monoxide is part of the wood-burning process. We have utilized filtered wood smoke technology under full consumer labeling mandated by the FDA since 1999. We also utilize the U.S. Department of Commerce NOAA Seafood Inspection Program. These two combined items with an outstanding corporate quality assurance program has allowed Anova to sell over 150 million portions without a single food safety issue. That is over 1,200 container shipments.

The goal of filtered wood smoke technology is to produce a frozen-at-source seafood product which is then delivered safely through frozen distribution to the food service distributor, supermarket chain, restaurant chain or consumer with a level of quality that comes as close as possible to the quality of the seafood item when it is caught.

Filtered wood smoke technology is considered GRAS by the U.S. Food and Drug Administration because of the longstanding food safety record of smoked food products. Our Clearsmoke branded seafood products, as well as other competitors' products, have maintained an impeccable safety record for the 9 years since the inception of the technology. Since 1999, under the FDA Import Bulletin 16B–95, the seafood industry has been mandated to label all seafood products with filtered wood smoke as processed with filtered wood smoke as a preservative for color retention. We put this label on each individual package of our fish and on our primary box the fillets come out of.

We also explain the Clearsmoke filtered wood smoke process on our retail bags so that the consumer is fully aware of the process. I have brought a retail bag that fully explains our process, and I'd like to submit our retail bag and our label to this subcommittee.

Industrial carbon monoxide is also used by the frozen seafood industry. It is not the choice of Anova to utilize CO, but after my 12 years of industry experience, I am willing to state that if CO is used properly, in moderation and with integrity, it can be successful. Some of the largest seafood companies in the United States successfully use industrial carbon monoxide in their seafood programs. The use of industrial carbon monoxide is also considered GRAS by the FDA. All packed seafood items containing CO must

be labeled "processed with carbon monoxide as a preservative for color retention."

Both filtered wood smoke and CO have increased the consumption of seafood since the processes have opened up new menu and retail opportunities. This has increased the consumption of seafood which is healthy and a very important part of one's diet.

We feel that the labeling that we have used in the last 9 years mandated by the FDA is consistent and in line with our food safety record. We continue to work with the FDA and the USDC to guarantee that our seafood is processed under HACCP and all labeling requirements.

I'd like to clarify to the subcommittee that the term "tasteless smoke" is a patented process. Both Clearsmoke and tasteless smoke are filtered wood smoke processes.

I want to thank the chairman and the committee for allowing Anova Food to come up and present the history of our filtered wood smoke process. Please let me know if I can answer any questions you might have.

[The prepared statement of Mr. Brinsmade follows:]

TESTIMONY OF DOUG BRINSMADE

Good Morning Mr. Chairman and Members of the subcommittee. My name is Doug Brinsmade and I am the President and CEO of Anova Food, Inc. The Anova Food Group is a global seafood company specializing in sourcing, processing, and distributing seafood products from worldwide sources. Anova maintains buying offices, plants, and operating partnerships in 15 different countries within Africa, Asia, and South America. We supply fresh and frozen seafood products to a majority of retailers, foodservice distributors, and restaurant chains across Europe and America. Anova has over 100 employees worldwide and handles approximately 60 million pounds of fish a year.

Mr. Chairman, I am here today to discuss a food preservation technology know as Clearsmoke. Clearsmoke is a patented, filtered wood smoke generation process used for over 8 years to preserve seafood. The goal of Clearsmoke and the Anova Food Group is to continue to provide safe, healthy seafood products to our customers. We deliver frozen-at-source seafood products to the consumer which exhibit ninety percent of the quality characteristics of a fish that's just been caught. Because of the many questions and concerns about the use of carbon monoxide and filtered smoke in seafood, I would like to start off by making the distinction that Clearsmoke is not an additive. Clearsmoke is a smoking process that incorporates only one ingredient to preserve seafood: filtered wood smoke. Filtered wood smoking is a food preservation process based on the centuries old process of wood smoking, created specifically to extend or preserve the shelf life of fresh and frozen seafood products. A naturally occurring component of all wood smoke is carbon monoxide, and as with all smoked foods, it has an effect of preventing the oxidation of colors in the seafood products we process and freeze.

Filtered wood smoke (as is all wood smoke) is considered GRAS or "Generally Recognized As Safe" by the FDA because of the long standing food safety record of smoked products. Our technology does not use industrial carbon monoxide or commercially mixed carbon monoxide. We only use natural hickory wood chips to create smoke. Hickory is chosen because of its ability to produce a very clean smoke with lower tar output compared to softer woods. The wood chips are burned in a conventional off-the-shelf smoke generator. The resultant smoke is scrubbed and cooled to 80—F using existing standard smoke industry techniques. The smoke that is generated is first passed through a primary filter which removes all of the particulate components of the smoke, including tar, ash, and soot. This process is done by a purely passive filtration means and does not concentrate or chemically alter the natural composition of the smoke. The smoke is then passed through the secondary filter which reduces, but does not eliminate, the odor and color components of the smoke. The smoke is accumulated in an accumulation chamber and then either pumped directly to the "smoke house" and applied directly to the product or compressed into storage containers for later use. Warm smoke is applied to the product before it is sent into the chiller for "sleep over" at 0—C to 3—C. The smoking step

is followed by an ozone step for bacterial and smoke odor reduction. Finally, the product is vacuum packed and quick frozen, preventing spoilage and the potential for forming histamine.

The action of the smoke in this process is that of smoke preservation and not of a flavoring or color additive. There are no added chemicals, additives or preservatives of any kind used in the Clearsmoke process. What remains are the natural preservation gasses and standard phenolic compounds that are present in all natural wood smoke. As the wood smoke is applied, naturally occurring carbon monoxide (CO) in the preservation gasses is responsible for the "locking in" of the existing color of the product, which is maintained through the freezing process.

The Clearsmoke process is similar to grilling a steak at home. If you barbeque on the grill with wood, the smoke contains, among many things, carbon monoxide. The Clearsmoke process does not increase or adulterate the color or quality of the product in any way; it simply retains the existing quality and color of the product at the time of processing and subsequent freezing.

Since the development of the Clearsmoke technology preservation process, Anova Food Group has provided over 150 million portions using this technique without a single report of a food safety incident. Our Clearsmoke products are sold in some of the largest restaurant and supermarket retail accounts in the USA. One of the most important points of the process is that it allows us to deliver a frozen seafood item that is very close in quality to fresh seafood items at a fraction of the cost and with impeccable food safety. We have avoided the rigors and high risks associated with global fresh seafood transportation.

As an example of the success of the utilization of Clearsmoke products by supermarket accounts, in 2004 a major supermarket, using Clearsmoke frozen tuna, planned a tuna advertisement for a summer weekend. The commercial benefits were as follows:

- They were able to plan the ad 3 months in advance with a guaranteed price since the product was frozen.
- The product was stocked in the stores a week prior to the sales, with backup in the local warehouse.
- An advertisement for $5.99 per pound was placed in the local newspaper. The ad stated "Clearsmoked Tuna Loins" and the words "previously frozen."
- Over 40,000 lbs of tuna was sold in 5 days and a further order of 8,000 lbs was given for the next week.
- There were zero complaints, zero returns, and two calls from consumers asking what "Clearsmoke" was.
- This ad was considered extremely successful by the supermarket and there were over 100,000 happy customers.

In 1999, the FDA issued an "Import Bulletin" No. 16B–95 to explain its policy concerning the appropriate legal status of filtered smoke and carbon monoxide to its inspectors. The bulletin indicates that when fish are treated with either compound, the fish can no longer be labeled as "fresh." The use of carbon monoxide or filtered smoke is allowed to be used to preserve the color of fresh fish, but not allowed to make bad fish look good. Therefore, all imported filtered wood smoke products and carbon monoxide processed products must be labeled since filtered wood smoke and carbon monoxide are considered by the FDA to be ingredients. In addition, it states that the labeling must disclose the presence of tasteless smoke or carbon monoxide as an ingredient of the fish on the package label along with a description of its technical function.

Anova Food labels all of our products and we've done so since the very beginning. We've not missed one label since 1999, when FDA issued the import bulletin. Our label reads, "Ingredients: Tuna processed with filtered wood smoke as a preservative for color retention." Since our products are vacuum packaged, the labels must also state "Remove from Vacuum Packaging before Defrosting" and includes other handling instructions. Our consumers understand our clearly labeled products, but because FDA is concerned that the use of filtered smoke or carbon monoxide could mask the visual signs of decomposition, new laws are being introduced to protect against this. The law states that "a food shall be deemed to be adulterated if damage or inferiority has been concealed in any manner." In addition, it states that "a food shall be deemed to be adulterated if any substance has been added thereto or packed therewith so as to make it appear better or of greater value than it is."

We oppose the use of carbon monoxide to mask any decomposition in fish. The use of carbon monoxide can be an effective means to provide the consumer with a safe product, but we agree that it must be labeled properly. We also strongly oppose any company that uses carbon monoxide to retain color, freeze the product, unfreeze

the product and then claim that it's fresh. We believe if a product has been frozen, then thawed, it must be labeled as "previously frozen."

Clearsmoke technology is 100% safe and has been fully tested at the University of Florida. The process is FDA and USDC approved. Anova Food has embraced the inspection of all of its processing plants by the United States Department of Commerce NOAA Fisheries Inspection Program since 1999. The USDC sends competent inspectors to each of our processing plants around the world, twice per year, to verify the use of Good Manufacturing Processes, HACCP and general food safety. Over the last 5 years the USDC has built an extensive database on fish 'color' in order to specifically verify that no color adulteration is taking place under FD&C section 401(b&c). These inspectors do an excellent job for us as well as protecting the US consumer.

The Clearsmoke method of preserving seafood continues to be a safe and innovative way to provide fish to millions of Americans at a time when the Federal Government is encouraging us to consume seafood at least twice a week for its many health benefits. We continue to work towards making heart-healthy seafood products more readily available. Because of the global nature of our industry, the seafood community places exceptional emphasis on the safety of the international seafood supply. Our seafood products are some of the safest items on restaurant menus and grocery store shelves today. There have been no reported illnesses of Clearsmoke imported seafood because we take pride in what we do to ensure that our products have been properly handled, stored and prepared.

Thank you Chairman Stupak. I appreciate the opportunity to testify today. I look forward to answering any questions you may have.

Mr. STUPAK. Thank you all for your testimony.

Mr. Page, Precept Foods that we've been talking about, or Precept, that is a common partnership between you—by you, I mean Cargill and Hormel, right?

Mr. PAGE. That's correct.

Mr. STUPAK. And you said that science should be a controlling factor here. Should science be allowed to deceive the consumer of the product that they're about to purchase?

Mr. PAGE. I think it has been said by Mr. Ettinger very clearly that it is no one's intention to do that. And I think the purpose of the technology clearly is to enhance food safety and the consumer's experience, both the quality of the food they eat and also the safety of it.

Mr. STUPAK. But it also deceives the consumer, right?

Mr. PAGE. I don't believe—I think that is a matter of intention or motive, and it is clearly not the case.

Mr. STUPAK. Then why don't you tell the consumer, then, that you use carbon monoxide in your packaging; if it is not to deceive the consumer, why won't you tell them?

Mr. PAGE. I think it is important—first of all, in the regulatory environment, that has not been the requirement. The labels have been approved.

Mr. STUPAK. So you're only going to do it if you're required, not if it is for the best interest of the consumer?

Mr. PAGE. I was going to finish my answer. I think the risk in a lot of cases—there are other gases that play an important part of food safety.

Mr. STUPAK. But we're talking about carbon monoxide right now. My question is about carbon monoxide.

Mr. PAGE. I understand. But I think the issue is relevant in the sense that what consumers would like to know and have is great faith in the regulatory environment that surrounds the product, not necessarily to become chemists or to be faced with packages that are cluttered with all of the information surrounding the prod-

uct in agonizing detail. The important issue is around the healthfulness——

Mr. STUPAK. Don't you think the consumer would want to know how the food is treated or prepared, any food? Don't you think they want to know that?

Mr. PAGE. I don't.

Mr. STUPAK. You don't think they want to know that?

Mr. PAGE. I don't think that people want to be distracted by information that is not helpful to their purchasing decision. I think we could go over a variety of things. I talked about the fact that chlorine, for instance, forms a very important part of our food safety environment. If we had brochures——

Mr. STUPAK. How is not knowing——

Mr. PAGE. If we had a big sign over every product in the grocery store where chlorine was part of the food safety chain, it would have a detrimental effect on people——

Mr. STUPAK. We're talking about carbon monoxide. How would the consumer be helped by not knowing? How is that helpful? If I don't know something, how is that helpful to me?

Mr. PAGE. OK. If the standard is to be helped——

Mr. STUPAK. You said it is helpful to the consumer. How is it helpful if I don't know what it is?

Mr. PAGE. Do they have the context for it? It is not to disparage anybody's judgment.

Mr. STUPAK. So you think consumers are not sophisticated enough to make a decision?

Mr. PAGE. I said not to disparage that, but I think from a clarification standpoint, if it does not become part of the product, I think——

Mr. STUPAK. One of your customers is Target; is it not?

Mr. PAGE. They are.

Mr. STUPAK. And they're willing to put on there it is carbon monoxide-treated, the "sell" date. Do you think they don't understand their consumers, Target consumers, are not sophisticated? What is it?

Mr. PAGE. At this moment we're not dealing directly with Target on this specific issue. And I may want to defer to Jeff for the specific answer with regard to Target, but we have other customers where we are having the discussion about what they'd like included on the packaging that goes into their stores.

Mr. STUPAK. Mr. Ettinger, you wanted to put in those 10 documents there from your experts, and we accepted them. Did you ask in those experts how people chose their food, what factors went into consideration under food?

Mr. ETTINGER. The testimony within the letters really focuses on the food safety of the technology.

Mr. STUPAK. So you didn't ask them about carbon monoxide and if consumers should know?

Mr. ETTINGER. No, sir. That was not part of those letters.

Mr. STUPAK. Mr. Whitfield asked questions here from Hormel, and consumers used the following to determine wholesomeness: "sell by" date, packaging, smell. He went through it. Did you tell your consumers in the survey that you package your meat in carbon monoxide?

Mr. ETTINGER. I'm not sure that that was our survey that you're referring to.

Mr. WHITFIELD. Mr. Chairman, actually that was a Consumer Federation——

Mr. STUPAK. You're Hormel, right?

Mr. ETTINGER. Yes, sir. It is in a document we submitted, but it was not our survey that was conducted.

Mr. STUPAK. But this is what you submitted, right, to the——

Mr. ETTINGER. Yes.

Mr. STUPAK. Did you tell the consumers you have carbon monoxide meat here?

Mr. ETTINGER. No, sir.

Mr. STUPAK. Do you tell your customers that you have carbon monoxide in your meat? Do you think your survey would be different if they people knew there was carbon monoxide in the meat?

Mr. ETTINGER. I don't know that it would. I think that the survey goes to the priority that consumers place on information that is useful for them to make decisions.

Mr. STUPAK. Were you here when the last panel testified?

Mr. ETTINGER. Yes, I was.

Mr. STUPAK. And they said that 75 percent of the consumers stated that they were very concerned about the practice of adding carbon monoxide to meat. Do you dispute that?

Mr. ETTINGER. No. I heard that testimony.

Mr. STUPAK. OK. Let me go to exhibit 30, which I think is right there in front of you. I've referred to it throughout.

Mr. PAGE. Is it in this book, sir?

Mr. STUPAK. Yes. I'm not sure that is the right one. There are two books there.

In those 10 letters you submitted, did your experts take in the microbial population of fresh meat as affected by many factors, such as the number and distribution of microbial species present at the start of the health and handling of live animals, slaughtering practices, chilling of the carcasses, sanitation, type of packaging, handling throughout distribution and storage; or were they just talking strictly about carbon monoxide?

Mr. ETTINGER. I don't know that they specifically looked at that, but clearly, as experts within the field of food science, they would recognize, yes, that there are varying conditions that need to be monitored.

Mr. STUPAK. And every one of those can affect the safety of the food, correct?

Mr. ETTINGER. That's correct.

Mr. STUPAK. And you don't feel that if anything is wrong with the handling of the food, like, say, sample G there that looks quite fresh, that your carbon monoxide doesn't mask over any microbial pathogens or agents in that fish—or, excuse me, that meat that has been sitting there for 2 years?

Mr. ETTINGER. You reference that that package was over 2 years old. Yes, we would have a problem with that. We would hold the companies with whom we do business on this product line. We have a contract with each one of them that they will pull products at code date. We recognized that testimony earlier today from the Government indicated that that was a critical element of this

project—of this packaging being approved was that the code date had to be prominent.

Mr. STUPAK. Do you think that is deceptive to the consumer?

Mr. ETTINGER. I think that they shouldn't be consuming a product that is 2 years old.

Mr. STUPAK. Would you consume it?

Mr. ETTINGER. Absolutely not.

Mr. STUPAK. But yet you think adding carbon monoxide to keep it fresh-looking is OK?

Mr. ETTINGER. We don't add carbon monoxide to make product look fresh beyond its code date. I can explain more thoroughly——

Mr. STUPAK. So why isn't that turning all brown and nasty then if it has been 2 years if it is past the code date? It has got carbon monoxide, E, F, G.

Mr. ETTINGER. The carbon monoxide does have a tendency to stabilize color in the meat.

Mr. STUPAK. That may not be the purpose of carbon monoxide, but as we can see there—it may not be your purpose when you add it, but it is the end result, is it not, in E, F and G? It looks fresh well past the code date?

Mr. ETTINGER. Those aren't our packages.

Mr. STUPAK. I know. So therefore it would appear at least to be deceptive to the average person.

Mr. ETTINGER. We'd be concerned if consumers are eating that product beyond the code date.

Mr. STUPAK. OK. Thanks.

Mr. Brinsmade, you stated that you supply seafood products to retailers, distributors and restaurants across the United States and Europe. Do you sell any of your products to Europe that have been exposed to your Clearsmoke technology?

Mr. BRINSMADE. Yes, sir. Up until December of this prior year, we were selling Clearsmoke products in the EU.

Mr. STUPAK. So until December 2006? What happened? You don't anymore?

Mr. BRINSMADE. Yes, sir. So what occurred is that we are actually a Dutch corporation, and we had won five suits with the Dutch health authorities and proved through science that this process was actually a valid process. What then occurred was that some of the member states, specifically some of the southern states who rely on specifically tuna for their economy, felt that this was deceptive. So there was a bit of economic issues; therefore they changed legislations. We are now currently still fighting this battle in the EU.

Mr. STUPAK. OK. So they thought it was deceptive. So since December of last year, you can't bring it into the EU. Do you still sell your products over there without Clearsmoke?

Mr. BRINSMADE. Yes, we do sell fish products without Clearsmoke.

Mr. STUPAK. So in order to economically—economic—it is not an economic thing then. You can still make a profit and all that by selling to the EU even though you don't have Clearsmoke on your fish products, right?

Mr. BRINSMADE. Yes, sir. We diversified into other species of fish.

Mr. STUPAK. OK. What is in your Clearsmoke besides carbon monoxide that affects fish?

Mr. BRINSMADE. Yes, sir. You asked this question before, so I'm glad I've had the opportunity to answer this. In smoked processes, be it tasteless smoke or Clearsmoke, it is a wood-smoking process, which means we burn hickory wood. The attributes of the wood, such as phenols, which is the No. 1 ingredient that retards bacteria—you have hydrogen, you have phenols, you have nitrogen, carbon dioxide—all of those are used for the preservation of the product. And it is a process that has been going on, as we all know, for hundreds and hundreds of years. So we are smoking the product.

Mr. STUPAK. OK. So when I asked Mr. Kraemer the same question, you were right, when he said it was just carbon monoxide and nitrogen, there is more to it than that?

Mr. BRINSMADE. Much more to it, sir.

Mr. STUPAK. Is that what helps enhance the color, then, of the seafood? I think we have had some slides in the last testimony where the tilapia side by side, one was enhanced and much brighter. Was it the pathogens that do that, the nitrogen? What is it that——

Mr. BRINSMADE. The actual—what fixes the color is the carbon monoxide component of the smoke in our smoke process. But you receive the same amount of carbon monoxide when you throw a T-bone on the grill through our process. Any time you burn anything on a grill or when you burn a table, you're getting the same levels of carbon monoxide.

Mr. STUPAK. OK. Mr. Whitfield for questions.

Mr. WHITFIELD. Thank you, Chairman Stupak.

Thank you all very much for being with us today and testifying on this important issue.

I would like to ask this question to, I guess, Mr. Ettinger. In the first panel, Chairman Stupak referred to e-mails among employees of Hormel, and it related to an April 2004 FDA letter requesting more information. And the documents indicated that internal Hormel employees had some concerns about the samples' microbacterial counts, the stats of the studies conducted by David Rusack. And I was wondering, Mr. Ettinger, if you can tell me, were those concerns addressed, and, if so, how?

Mr. ETTINGER. Mr. Whitfield, that is the first I had heard of that. However Dr. Phillip Minerich, who is the head of our research and development facility, and who Mr. Rusack works for, is here today. And if the committee would like to take testimony from Mr. Minerich on that topic, he'd be very welcome to provide that.

Mr. WHITFIELD. We appreciate that very much. Thank you.

I've been a little bit perplexed about this hearing, truthfully, even though I recognize that everyone is certainly acting with the very best of motives. But we have a situation here where a process, a packaging process, using carbon monoxide has been approved by the Department of Agriculture. They have a Memorandum of Understanding with the FDA. We have a consensus of expert scientific opinion that this is a safe process. We have a package that has a date on it that it must be used by a date certain. You all have contracts with the people who purchase your meat and sell it in grocery stores that they must agree to not keep it past the "best use" date. And I know that being a publicly traded company, you're al-

ways obviously concerned about legal liability and everything else. And you, too, Mr. Ettinger, and Mr. Page, all of you chief executive officers are responsible for taking care of your stockholders and the public as well with the very best of products.

So I would just ask you, do you have any concern whatsoever about the safety of this product for your consumers? Mr. Page?

Mr. PAGE. I think, as I've said, the technology enhances safety. It clearly inhibits the growth of bacteria and of pathogens if they're present; that it affords the consumer the opportunity to carry products home in their shopping cart or their grocery bag into their refrigerator without the risk of cross-contamination. It enhances food safety not just in the store by eliminating this by doing it in the back room, but in the home by avoiding the cross-contamination that can take place with other packaging technologies.

I think clearly it would be our intention to encourage the adoption of technologies that allow consumers to buy these products, to use them safely in their homes.

Mr. STUPAK. Mr. Ettinger?

Mr. ETTINGER. What I would add to that is we have the added benefit 3 years later of having had actual experience in the marketplace, and as I mentioned in my testimony, we've sold nearly 23 million packages of this case-ready lid-stock product. We have our 800 number on every package. It is all branded Hormel. It tends to be a high-ticket item. These are beef and pork whole muscle items in the case of the joint venture, and so if consumers have a bad experience with it, we're going to hear about it.

During that entire timeframe, we've received 48 consumer calls relating to flavor or off condition of any type. We are very open to trying to address to knock the No. 48 down, and that is part of the discussions we've had with subcommittee staff where we're open to adding language to the package talking about color to see if we can make that number even lower. But clearly the experience has been that consumers are not eating bad product and are not being deceived by this technology.

Mr. WHITFIELD. Mr. Brinsmade, did you want to make a comment?

Mr. BRINSMADE. No, sir. Listening to these gentlemen, I have nothing more to state.

Mr. WHITFIELD. Now, it has been referred to a sample there is 2 years old. I'm assuming if we opened that package up, there would be a little bit of an odor. Would there? Would there be an odor in this package that is over 2 years old?

Mr. ETTINGER. There should be a very significant odor.

Mr. WHITFIELD. Now, we have heard a lot today about consumer deception, and certainly there is a distinction between consumer deception and consumer acceptance. And I think your goal was to facilitate the consumer, give them an attractive product. Anybody in the business of selling food products wants an attractive package. And so your intent here was not to deceive anyone, but was to help provide consumer acceptance, I'm assuming. Was that correct?

Mr. ETTINGER. I think that is an element of this packaging system that is really not understood. What we're trying to do with this packaging is provide the available freshness to the consumer.

I can give you an illustration of this. Our company is headquartered in Austin, MN, a small town in rural Minnesota, south Minneapolis. We basically have two major grocery stores in the town. I went to both stores on Saturday to look at what was available in terms of the fresh meat offerings in those cases. One of the stores uses the traditional overwrap method done in the store, and the typical product life left that would be available to the consumer in that store was 2 to 3 days. The other store in town sells the product line that utilizes our low-oxygen-modified packaging, and the typical available freshness to consumers in that store was 10 to 11 days. The consumer then has the opportunity to bring that product home and doesn't have to decide the first night, gee, do I grill this up now, or do I have to put it in the freezer? This provides them with the available freshness that prior to this technology was often in the back room of the store and not available to them.

Mr. WHITFIELD. Now, one last question. I know that a petition has been filed at the FDA asking them to review the GRAS determination relating to this packaging. It was filed by a Calsak Company. Are you all familiar with Calsak Company?

Mr. PAGE. Not intimately, but in preparing for today, I was made aware——

Mr. WHITFIELD. And you are aware that they use rosemary extract, and it is competing with your technology; is that correct?

Mr. PAGE. That's what I was told, yes.

Mr. WHITFIELD. I yield back. I have no time left.

Mr. STUPAK. Mr. Dingell for questions.

Mr. DINGELL. Thank you.

Gentlemen, your testimony today has been very helpful, and I want to express to you my appreciation for your presence.

First of all, I note here in the comments made by you, Mr. Ettinger, you said this

> Inclusion of carbon monoxide in a package does stabilize the color of meat. If improperly handled or used well beyond the "sell" or "use by" date, it is possible that it could be spoiled in the package, yet still look red. We put sell by the dates—"sell by" dates on the front of this product in type three times larger than normal to address this. We put another "sell by" date on the back of the product.

Then you said this

> Hormel will comply with any labeling of the product that is determined to be necessary and fair through the legislative or regulatory process.

Then in your rather helpful comments, Mr. Brinsmade, I note you said this on behalf of yourself and your company

> We oppose the use of carbon monoxide to mask any decomposition in fish. The use of carbon monoxide can be an effective means to provide the consumer with a safe product, but we agree that it must be labeled properly.

Gentlemen, do you all agree with those statements? Is there any disagreement on the part of anyone with those three statements? Yes or no?

Mr. ETTINGER. Mr. Dingell, there were quite a few statements, and I think I would be in agreement with all of them, except if you're incorporating by reference Mr. Brinsmade's statement that carbon monoxide should be on the label, I would respectfully disagree with that.

Mr. DINGELL. OK. Now, gentlemen, we have a little problem here. We have a situation where it is possible that if the labeling doesn't warn the consumer, that consumer is libeled by a product where decomposition or overage or the safety of the meat product is masked by the presence of the carbon monoxide treatment; is that right?

Mr. ETTINGER. Well, two things would have to happen for that to occur.

Mr. DINGELL. That is a possibility; is it not?

Mr. ETTINGER. Well, the consumer would have to not notice the code by date, and the store would have to violate our contract and not pull the product prior to the code by date. But it is certainly conceivable that both of those things could happen.

Mr. DINGELL. Hormel says this here: The inclusion of carbon monoxide in the package does not stabilize the color of meat. If improperly used or used well beyond the "sell" or "use by" date, it is possible it could be spoiled in the package and still look red.

So we have then here a problem, don't we? We can—the consumer, if this is not properly labeled, can be buying overaged meat which is unsafe, which looks good, but which, when he gets it home, he'll find either it smells bad, is unpleasant to eat, or can, in fact, be unsafe. Isn't that a true statement?

Mr. ETTINGER. We feel that the product line provides——

Mr. DINGELL. Just yes or no.

Mr. ETTINGER. It is possible that a consumer could bring the product home, and it would be——

Mr. DINGELL. And there is no disagreement there, I think, at the table there.

Now, tell me, what do we do to see to it that this is properly labeled so that the consumer gets the warning he needs, industry gets the ability they need to properly process the food, and at the same time see to it that the public interest and the public are safe because the regulation is adequate to ensure proper protection of the consumer? How do we do that?

Mr. ETTINGER. Due to helpful discussions we've had with subcommittee staff and a third meeting where they actually flew out to the facility at Cargill, we've had an opportunity to at least engage in dialog about some of the possible ways to address that, and we really have kind of proposed two of them. One is the additional label language that both Mr. Page and I referred to, that color and freshness—color is not—excuse me—an accurate indicator of freshness, that the consumer should refer to the "use" or "freeze by" date.

Mr. DINGELL. The Food and Drug—Food and Drug does not require anything be done with regard to a "sell by" date, do they?

Mr. ETTINGER. My understanding is it is not required under——

Mr. DINGELL. Under regulation. And yet some of the companies, I think Hormel, has put a "sell by" date on there, don't you?

Mr. ETTINGER. Yes. All the products sold——

Mr. DINGELL. And that is done out of concern for the safety of your consumer?

Mr. ETTINGER. That's correct.

Mr. DINGELL. Because you believe that that is necessary to protect them.

Now, there are other companies that do not do that, aren't there?

Mr. ETTINGER. I know on the products that we sell through Hormel, both the joint venture and on a regular basis——

Mr. DINGELL. So if that is not done, the consumer then is not protected, is he? The consumer doesn't know what the "sell by" date is. He buys himself a nice-looking red meat, and he finds that that consumer is perhaps put at risk because he didn't know when that had to be used or sold or frozen; isn't that right?

Mr. PAGE. The USDA made it a condition of their approval of the use of this technology that there be a "sell by" date. So you said the FDA, and I think Mr. Ettinger answered correctly to that question. With the USDA the Government——

Mr. DINGELL. But Food and Drug doesn't require a "sell by" date, nor does the Department of Agriculture, do they?

Mr. PAGE. No. As a requirement of this technology, we're obliged to put a "use by" date——

Mr. DINGELL. Are you required to do that?

Mr. PAGE. It is a condition——

Mr. DINGELL. Where is that in the regulation?

Mr. PAGE. It is a condition of our approval.

Mr. DINGELL. I am of the view, read correctly, that there is no regulation on this, that the regulation has never been promulgated. Am I in error on that point?

Mr. PAGE. I won't speak technically or legally to the issue of the regulation, but I do know we're not allowed to produce this product with this technology in our facility without a USDA-approved label.

Mr. DINGELL. This is a very good answer, sir, but it doesn't answer the question. Food and Drug does not have in place any regulation with regard to labeling or a "sell by" date, do they? They simply permit you to do this. And there is no published regulation. The regulation, if such has been put forward, has never had either the comments of consumers or anybody other than the industry groups; isn't that right?

Mr. PAGE. Not to restrike a dead horse, but the letter we received back from the USDA authorizing the implementation of this packing technology excludes the specific requirement that the label must show a "use by" date.

Mr. DINGELL. See, here is my concern. The consumer is not protected. You folks don't have a clear regulation. Honest folks like the three of you sitting there at the table, you don't have a regulation you can point to. And on top of that, rascals in the industry don't have to pay to heed any regulation because there is no regulation in place. And I'm not sure how we prosecute them from misbehavior or how we protect the consumers or how we protect you from unfair competition by rascals who aren't troubled about these matters.

I think we have a bad situation on our hands. Are you here to defend that situation? I find myself hard put to defend it. I think you're at risk. I think the consumer is at risk. And I think Food and Drug is not doing its job. Am I in error in my thesis on these matters?

Mr. ETTINGER. I really wouldn't have a comment as to the entire regulatory ambit, but we know in terms——

Mr. DINGELL. Well, we have got rascals out there that are able to disregard this. They make their meat look red, they sell rotten meat, and you three, who I think are interested in doing an honest job, find yourself in a position where you're competing with folks who don't feel themselves pressured to do us right. I think that is a bad situation. So we've got you folks getting badly treated and the consumer shabbily treated.

This is a bad situation. Something has got to be done. How is it that I can defend it, or, even more importantly, how is it, gentlemen, that you can defend it?

Mr. ETTINGER. I guess we can only rely on the regulatory experience we have had with this product.

Mr. DINGELL. And we have already talked about the regulatory system. And we are going to have a nice letter off to Food and Drug asking them to explain how they've complied with the requirements of the administrative procedure. And I have to say that if somebody—some reasonably intelligent lawyer were to sue Food and Drug, Food and Drug would all the sudden have a very large problem on its hands.

But you, marketing your foods, if somebody gets bad meat, which is colored to be a nice pink—are going to have a very fine lawsuit on your hands. And I think this is something that we've got to address here in this committee, see to it that Food and Drug does its job, see to it that Food and Drug protects you, see that you are protected, see that the consumers are protected and that everybody is treated in a proper and decent fashion. And I don't see that today. And I wonder how it is that you're so comfortable appearing here before the committee when you're confronting a situation of this kind.

Mr. PAGE. I want to address the regulatory environment, and certainly some of the testimony regarding the processes surrounding GRAS are not clear. But I do believe that both of our companies or all three of our companies have spent a great deal of time with our technical staff and are very comfortable with the science surrounding this packaging.

Mr. DINGELL. I'm not attacking your company. I'm just saying, fellows, I think you have a problem on your hands, and I think the consumer has got a problem on his hands. And I think Food and Drug is the architect of this misery, and I think we've got to see to it that Food and Drug does a better job. And we're going to dissect Food and Drug in a very nice communication in which we are going to ask them about how it is they are doing it and why it is that they are doing this.

So, gentlemen, thank you for your patience with me.

Mr. Chairman, members of the committee, I thank you for your courtesy to me, and I yield back the balance of my time.

Mr. STUPAK. Thank you, Mr. Chairman.

Mr. Burgess for questions, please.

Mr. BURGESS. Thank you, Mr. Chairman.

Let's just follow up on that for just a moment because the chairman of the full committee has said that the FDA was the architect of this misery. Let me ask you each in turn, how many cases of illness are we talking about having been caused by this type of packaging?

Mr. ETTINGER. Well, the packaging involved in the Precept venture all carries the Hormel brand. It carries our Hormel Foods 800 line, and we've received no documented cases of food-borne illness out of 22-plus million packages sold.

Mr. BURGESS. And either Mr. Page or Mr. Brinsmade, either one of you recorded any instances of illness?

Mr. BRINSMADE. No, sir. Out of the seafood side of the 150 million portions that we have supplied the U.S. market, we have zero food-borne illnesses.

Mr. BURGESS. And I'm going to assume there are no deaths that are directly attributed to this type of packaging and this technology. Is that a correct assumption?

Mr. BRINSMADE. Yes, sir.

Mr. BURGESS. What about the number of complaints? People didn't die. How many complaints have you had that people have been misled or deceived by what the focus of this investigation has been today?

Mr. BRINSMADE. As far as our company is concerned, we've had zero.

Mr. BURGESS. Mr. Ettinger?

Mr. ETTINGER. As I mentioned earlier to Chairman Stupak, we do have 800-line consumer information on the package, and we do get calls from our consumers on this product line and a lot of our other product lines as well. Out of the entirety of the 3 years we've been selling the product and the over 22 million packages sold, we tallied up that there had been 48 comments from consumers relating to flavor or off-condition complaints for this product line. That is a very low ratio in terms of what would be typical in the food industry. But we also recognize that we'd like that number to be zero. We'd be looking for ways to make that happen.

Mr. BURGESS. So 44 out of 22 million?

Mr. ETTINGER. That's correct. Forty-eight.

Mr. BURGESS. Forty-eight.

And, Mr. Page?

Mr. PAGE. None that I'm aware of.

Mr. BURGESS. So the architect of the misery has really not got much to show for their architecture.

How do you measure—how do you measure the likelihood of deception? If deception is the issue here, Mr. Chairman, I have got to assume that is the issue here because, for the life of me, we have got no illness, no death, no complaints. We have got plenty of problems with salmonella in peanut butter and *E. coli* in lettuce leafs, things we legitimately should be focusing on. But how do you measure the likelihood of deception from this packaging? Has anyone done an audit to see if the consumer is, in fact, misled by the color of the food that they purchased or misled by the "use by" or "freeze by" date?

Mr. ETTINGER. We are not aware of any consumers that have stated specifically that they feel they were misled by it, but I think it goes beyond that. I think there has just been a general confusion about the purpose of carbon monoxide in this packaging system to the notion that the reason we're utilizing it is we are attempting, in essence, to color bad meat and make it look good.

That is not the purpose of carbon monoxide in this overall packaging system. This system was introduced as a food safety enhancement. It allows us to pack case-ready product in our plant, and provide maximum available shelf life to consumers, and provide them with a tamper-proof, leak-proof package that they then can rely on in their own homes.

Mr. BURGESS. I appreciate the leak-proof aspect of it.

Let me just ask, do you audit the store shelves to make certain that food that is beyond the "use by" or "freeze by" date is not appearing or is not maintained on the grocery shelves?

Mr. ETTINGER. The retailer is obviously a different company than ours. In this case and this particular product line, we do have very specific contracts in place with each retailer with whom we partner, and this has really been very significant to them. They don't typically turn over their entire meat case to a case-ready program unless we maintain certain obligations in our facilities as well.

One of the other aspects that was not talked about in terms of preserving the freshness and protecting the consumer is when our product goes from our production—the production plant of the venture to the retailer, it goes in a truck that has temperature indicators in the truck to make sure that it is maintained at the proper temperature during that whole time, and then the cold chain then becomes the responsibility of the retailer. We train them in that, we audit them in that, and we make sure that that is being maintained for the consumer's protection.

Mr. BURGESS. So you do provide audits on the maintenance of temperature. And those trucks that you talked about that have the temperature-sensing devices, do those go to some type of recording device so that that information is maintained over time?

Mr. ETTINGER. Yes, we do.

Mr. BURGESS. Thank you.

And let me just ask, Mr. Ettinger, and I apologize for not being here when you gave your oral testimony, but in your written testimony you elaborate on a new technology that Hormel is developing to address the issue of long-term color change. Can you tell us a little bit about what the technology is and how it would address some of the concerns raised by the witnesses on the consumer panel?

Mr. ETTINGER. One of the things I mentioned in the testimony and I have spoken to in a couple of times during the question and answers, we really feel that this product line provides many benefits to consumers, the product safety, the additional available shelf life.

We recognize through our discussions with the subcommittee and the subcommittee staff that the lack of color has been a potential downside. We felt we were addressing that by putting code dating on it in three-times-larger type. And I know that in testimony earlier, they were looking at a package where they couldn't see it. I think if you look at our package, it is really very clear on both the front and the back of the package. But in addition to that, we stand ready to try to eliminate even the 48 complaints that we have received related to flavor. We want to make sure that people are not having a bad experience with this product.

So we have offered to include the language relating to color, and we are working on a technology that would allow the meat, when it goes beyond code date, to turn a brown color that would be more typical of overwrapped meat in the grocery store. If we can accomplish that without compromising any of these other advantages on food safety, then we will be happy to roll that out, and we are working earnestly in that regard.

Mr. BURGESS. It almost brings to mind the old Mission Impossible thing. You could have a product that self-eliminated after the expiration date, but I guess that would be hard on a grocer's shelves.

The chairman brought up that there was no actual rule you were following, Mr. Page. I think you tried to speak to that when you said that the USDA has made a suitability determination that is based on the labeling; is that not correct? So there actually are rules in place that you follow, rules put forward by the U.S. Department of Agriculture.

Mr. PAGE. There was a process that was outlined to us, which we followed, to gain consensus from prominent scientists, to take that body of evidence and bring it forward. I understand from this hearing that that evidence passed back and forth between the FDA and the USDA. The outcome of their effort following some requests for additional information were a letter to our company and to our joint venture company, allowing us to begin to utilize this technology provided that we had prominent "use by" information for the consumer on the retail-ready package. So we experienced the regulatory administrative process and the science focusing to be quite intense.

Mr. BURGESS. And I appreciate the large-print edition of the "use by" dates that you have on there so that I don't inadvertently bring home something that's close to its expiration, because it does cause domestic problems.

Mr. Ettinger, let me ask you just to finish up here—and I wasn't here when Mr. Whitfield did his questioning. Apparently, the issue came up that there was a study that Hormel had submitted to the U.S. Department of Agriculture where there were some problems with the study; is that correct?

Mr. ETTINGER. That is correct.

Mr. BURGESS. And that the U.S. Department of Agriculture relied upon this study to make their determination?

Mr. ETTINGER. Yes. What I testified to Mr. Whitfield was—he brought up the e-mail exchange that was in the evidence Chairman Stupak had referred to, and I stated that I really had not been familiar with that e-mail prior to hearing it in the testimony today but that along with me today is Dr. Phillip Minerich, who is the head of our Research and Development facility and whom Mr. Rusick, who was the author of that one e-mail, worked for, and that he could explain what's going on in that e-mail if the committee would like to have that testimony.

Mr. BURGESS. I think it would be beneficial to the committee if we were to hear that explanation, because it was kind of left as an unresolved question.

Mr. STUPAK. OK. You have to stand and be sworn in. If you're going to testify, you have to be sworn in. Do you not want to be sworn in? Do you want to testify? You have to do it for the record.

State your name first, please.

Mr. MINERICH. Phillip Minerich.

Mr. STUPAK. Spell it, please.

Mr. MINERICH. M-I-N-E-R-I-C-H.

[Witness sworn.]

Mr. STUPAK. OK. The record should reflect the witness has been sworn in.

Mr. BURGESS. And I appreciate your willingness to provide us additional information. I just feel like the question was left out there not fully answered, and if you can provide us some additional information, I think that would be helpful to the committee.

Mr. MINERICH. Yes. I think there was some discussion about some data that was submitted to the FDA. I know Dr. Post was trying to recall a few years back what that data was, and then there was an e-mail correspondence.

What this, in essence, boils downs to is the suppression of microbial growth, that this data demonstrates, really supports the agency's determination that this packaging system is safe and does not mask spoilage or odor. The data indicate that a low-oxygen, high-carbon dioxide packaging system actually does control microbial growth, and this result was later confirmed and replicated and validated through the work of Dr. Mike Doyle at the Center of Food Safety at the University of Georgia.

We see this as a good thing, that this high CO^2 environment, low oxygen environment does suppress microbial growth, not only from a spoilage perspective but also from the food safety perspective; and of all of the packaging systems that we want to deliver our products to the consumers in, we want to choose the one that delivers the most safety to the consumer with an adequate product for an enjoyable eating experience.

Mr. BURGESS. So your data——

Mr. STUPAK. Your time has expired, Mr. Burgess. We'll go around for a second round if you want to ask more questions.

Mr. BURGESS. Your data would support the fact that a micro atmosphere high in carbon dioxide would, in fact, suppress that type of microbial growth?

Mr. MINERICH. Yes. This data did a very good job in two types of bacteria—the total plate count, which is a general microbial count, and then also in psycrophiles, which are bacteria that specifically grow under refrigerated conditions—and our data supported that.

Mr. BURGESS. I thank the witness for his testimony.

Mr. Chairman, I yield back. I'll have no further questions.

Mr. STUPAK. Mr. Minerich, let me ask you this question then, and these are questions I put forth.

The microbial levels started high and ended low in your study, and the microbial counts correlated, virtually, gas formation and odor scores; is that true? Yes or no?

Mr. MINERICH. Looking at the data, the microbial growth really is almost stabilized.

Mr. STUPAK. Well, it started high, and it ended up lower. It should go up high, should it not, after time?

Mr. MINERICH. No, sir. This packaging system, because of its low oxygen atmosphere and its high CO^2 atmosphere, suppresses microbial growth.

Mr. STUPAK. Let me ask you this then. Let's go to 71(d) if you want to go there.

Now, you are actually listed on the copy list, are you not, in 71(d)? You are the "Phil Minerich;" is that correct?

Mr. MINERICH. Yes, sir.

Mr. STUPAK. You're Research and Development; is that right?

Mr. MINERICH. Yes, sir.

Mr. STUPAK. Who is Dave Rusick then?

Mr. MINERICH. Dave Rusick is a development leader who works in my department.

Mr. STUPAK. OK. So you're his boss.

Mr. MINERICH. Yes, sir.

Mr. STUPAK. All right. As to this e-mail we've been talking about, had you seen that e-mail before today?

Mr. MINERICH. I don't recall seeing this e-mail before today.

Mr. STUPAK. All right. I'm looking at 71(d). I'm in the e-mail now.

Mr. MINERICH. What page is that?

Mr. STUPAK. Well, it's the last two pages of the exhibit.

Mr. MINERICH. Yes, sir.

Mr. STUPAK. OK. I read earlier about Mr. Rusick's and Ms. Ann Waylan's going back and forth. Then Mr. Rusick says

> Thanks for the response, Ann. Believe me. We are also puzzled by the data.

So he is puzzled by the data, but you are not.

> But this is the second time it has happened regarding micro counts, gas and color. The first time is when we made samples for the FSIS.

That would be the Department of Agriculture

> there is something going on. I don't have the answers.

It goes on, and he lays out the questions.

> There doesn't appear to be a clear correlation between micro counts, gas and odor. You would think the counts would be highest in packages with the most gas and odor, but that's not necessarily the case . . . Basically, however, there is a difference in the micro counts between the four treatments, which was a real surprise. I would have thought the lactate would have further retarded the bacterial growth therein.

Now, "lactate" is an antibacterial agent, right, to keep it down?

Mr. MINERICH. Yes.

Mr. STUPAK. Then if you go on, you say

> It appears to me that the micro counts that you talked about remain relatively constant, as you said, across the four treatments during the three sampling periods. I could see the micro counts eventually dying off after they reached the multi millions, but data didn't come close to that. Regarding odor, we may not be checking for the right bug.

Then it goes on to say

> I think we have to at least determine what the data tells us before we send it to lawyers, but it was forwarded on.

So are you disputing Mr. Rusick then?

Mr. MINERICH. No. I think this is a really good example of what happens in a company such as ours where innovation is just ingrained. Ann Waylan initiated the dialog. Dave Rusick responded, saying this was very early in this technology. He has repeated a study that shows some interesting data that this is really suppressing microbial growth, and the concern with the attorneys is really—the question was at that time: Is there potential that between lactate and high CO^2 and low CO and low oxygen that there might be some discoverable or patentable opportunity here? That's what this discussion was really around.

Mr. STUPAK. But it said that he had already discussed it with the USDA, that Forest Dryden may have used these—Forest Dryden is one of your workers, one of your employees?

Mr. MINERICH. Forest Dryden was the vice president of Research and Development before he retired.

Mr. STUPAK. He used the tables to discuss it with Dr. Post, who we know is with the USDA.

The part that bothers us is you had questions about the studies—that's what this e-mail indicates—and this data, which is in 71(d), is the same evidence or the same data in 71(e), the next exhibit which was submitted to the USDA for your approval. That's what bothers us.

The other part that bothers me is you extol the virtues of modified atmospheric packaging. And I'm not here to attack that type of packaging, and there is no doubt that there may be many benefits associated with it, but our concern is in using carbon monoxide in this type of packaging.

Your testimony is that—Mr. Ettinger and Mr. Page both indicated you stated that the modified atmosphere that you use in your packaging suppresses microbial activity. However, isn't it true that the addition of carbon monoxide to this packaging process does not contribute any additional antimicrobial properties? Carbon monoxide doesn't give you any antimicrobial properties.

Mr. MINERICH. At the time of this study, it was unknown. That's why the curiosity.

Mr. STUPAK. But we know that today, in sworn testimony by Mr. Page and Mr. Ettinger, they said that it did suppress microbial activity.

Mr. MINERICH. Correct.

Mr. STUPAK. So we didn't know when we did the study, even though we submitted it to the USDA. Today, we know it doesn't provide microbial activity. Yet we testified it does produce antimicrobial activity. So who is telling whom the truth here?

Mr. ETTINGER. I don't know, from my testimony at least, that the carbon monoxide had anything to do with that. Carbon monoxide is used as part of the total MAP packaging system as a substitute for oxygen so that the product will turn red, just as meat products naturally turn red when they're exposed to oxygen in the back room of a retail establishment.

Mr. STUPAK. But carbon dioxide is chiefly responsible for antimicrobial activity, isn't it, for suppressing it?

Mr. ETTINGER. Yes.

Mr. STUPAK. Nitrogen is basically a filler to replace the oxygen, correct?

Mr. ETTINGER. That would be my understanding.

Mr. STUPAK. So then why, in your testimony, did you mention that modified atmospheric packaging here that you ought to use would suppress microbial activity?

Mr. ETTINGER. We believe that the complete packaging system used in a case-ready environment versus a store overwrapped product have many food safety benefits. It's all of it put together.

Mr. STUPAK. Then why couldn't you have just used carbon dioxide with the nitrogen and not use carbon monoxide?

Mr. ETTINGER. Because the product that we would then put into the retail case would be purple, and the consumer doesn't want to buy purple meat.

Mr. STUPAK. So what is more deceptive, the purple meat or bright red meat?

Mr. ETTINGER. Meat is purple in its natural state unless it's exposed to oxygen. In a regular opportunity at a grocery store, meat is shipped in a vacuum-packed package that is purple; and when it's held—it's perfectly fresh as long as it's held in a refrigerated environment, and it isn't until that product is cut open and then put into cases and exposed to oxygen that it turns red.

Mr. STUPAK. So let's go back to the purpose of the hearing. As I said in my opening statement, carbon monoxide does nothing to preserve the freshness of the meat or fish, true? It does nothing to preserve the freshness?

Mr. ETTINGER. Not by itself.

Mr. STUPAK. OK. Carbon monoxide does nothing to prolong the food's shelf life, does it?

Mr. ETTINGER. No.

Mr. STUPAK. Carbon monoxide doesn't make food safer, does it?

Mr. ETTINGER. No, not by itself.

Mr. STUPAK. Then what's the purpose of using carbon monoxide other than to deceive the consumer?

Mr. ETTINGER. Because it allows us, in combination with the packaging technology itself and the carbon dioxide in nitrogen, to provide consumers with fresher products and with enhanced food safety.

Mr. STUPAK. What is your 800 number? You mentioned your 800 number that consumers can call. What is it?

Mr. ETTINGER. It's a number that's on every package or product.

Mr. STUPAK. Yes. What is it? What is the number?

Mr. ETTINGER. Oh. Let me see if it——

Mr. STUPAK. I know it's hard to read. It's so small.

Mr. ETTINGER. Yes, that would be my difficulty.

Mr. STUPAK. It's not deceptive, but——

Mr. ETTINGER. I would need to borrow some glasses.

Mr. STUPAK. OK. You don't know it off the top of your head.

Mr. ETTINGER. No, I don't.

Mr. STUPAK. Mr. Page, do you know your 800 number?

Mr. PAGE. I do not.

Mr. STUPAK. How about you, Mr. Brinsmade?

Mr. BRINSMADE. Yes, I do.

Mr. STUPAK. It's on your package, probably.

Mr. BRINSMADE. Could I look at it?

Mr. STUPAK. Sure, if it's on your iPod. I carry your 800 number on my BlackBerry.

Mr. BRINSMADE. I do have it, sir. I don't know it off the top of my head.

Mr. PAGE. I'll give Hormel's, while he's looking, with your permission.

Mr. STUPAK. Hormel's is 1–800.

Mr. PAGE. 523–4635.

Mr. STUPAK. 4635. OK.

Mr. BRINSMADE. I will submit my 800 number to you in a second, sir.

Mr. STUPAK. It's probably on your package there. It might be quicker than modern technology.

Mr. BRINSMADE. Actually, our 800 number is not on this package, sir.

Mr. STUPAK. OK. Well, just submit it.

Mr. Ettinger, you indicated you had 48 complaints over thousands and thousands, but none of those people knew or complained about carbon monoxide in your meat, did they?

Mr. ETTINGER. No.

Mr. STUPAK. Because you never told them there was carbon monoxide there.

Mr. ETTINGER. No, but the complaints I was referring to are related to flavor or an off-condition.

Mr. STUPAK. Right, but now, once we know your 800 number, people can now call, who might be watching this, and voice their opinions on carbon monoxide. Would that be fair?

Mr. ETTINGER. Yes.

Mr. STUPAK. OK. Mr. Page, would that be fair if they called your 1–800–523–4635 to express their concerns?

Mr. PAGE. Yes.

Mr. STUPAK. Because you guys have said you have never done any kind of studies to determine how consumers feel about it, right?

Mr. ETTINGER. No. That's correct. This would be an excellent environment for consumers to learn all about the advantages of the technology.

Mr. STUPAK. OK. Let me ask you another question, if I may, Mr. Ettinger.

Mr. ETTINGER. Yes.

Mr. STUPAK. Let me ask you this question. In your testimony and in Precept's letter to the committee, dated August 11, you stated that using carbon monoxide does not mask spoilage. "Spoilage is manifested by changes in meat color, flavor or appearance. We know that packaged meat in atmosphere containing carbon monoxide will appear red indefinitely even if spoiled."

In your testimony and in your letter, you stated that other spoilage indicators like odor will alert consumers that a product is spoiled even if it does not look like it. Please explain to me how the consumer can detect off-odors in sealed packages at the point of purchase.

Mr. ETTINGER. They would not be able to. That is one of the trade-offs of having a tamperproof/leakproof packaging, is it would diminish the amount of odor. However, it also has the added effect

that, if a consumer were to take it home and open it, it has trapped in any potential spoilage odors, and so they would actually experience them much more strongly than traditional meat items.

Mr. STUPAK. But the point of deception is when I purchased the meat. If it's spoiled because it's hermetically sealed, I can't smell it if I wanted to in the store.

Mr. ETTINGER. Not at the point of purchase, but then our expectation is we would have heard about it from our consumers.

Mr. STUPAK. In fact, when you talked about the samples in your answers, you said you had one here, and in about 2 years, that would have a significant odor, but you can't smell it right there, can you?

Mr. ETTINGER. That is correct.

Mr. STUPAK. OK.

Mr. Page, Mr. Burgess asked you about the safety and all that of carbon monoxide, but, just recently, Cargill recalled over 1 million pounds of ground beef in November, right?

Mr. PAGE. That is correct.

Mr. STUPAK. Isn't it true that the last recall was for *E. coli O157:H7,* a particularly dangerous pathogen? Right?

Mr. PAGE. It was.

Mr. STUPAK. Eleven percent of that recall, 119,000 pounds, was shipped to grocers in packages that contained carbon monoxide; isn't that correct?

Mr. PAGE. Yes.

Mr. STUPAK. OK. I have no further questions.

Mr. Burgess.

Mr. BURGESS. Yes, but just to follow up on that, the product that was shipped that had the toxigenic *E. coli* that also concomitantly had carbon monoxide, those two facts are true and not related. Like the carbon monoxide did not cause the *E. coli*. It didn't cause it to be more toxigenic. It didn't cause it to be more virulent than it would have been under normal circumstances. We really should be having this hearing about toxigenic *E. coli* and how it finds its way into the ground beef products that are sold in our stores.

Mr. STUPAK. I agree.

Mr. BURGESS. Instead, we're talking about a packaging component where realistically—again, I'll reiterate, there have been no illnesses, no deaths, no complaints or 48 complaints out of 22 million items sold.

I agree with Mr. Ettinger completely. If you open a package that has been sealed against leakage and the micro atmosphere is escaping and you open it up and it's a bad product, you're going to know about it pretty quickly, and if you're in my family, you'd probably take it back to the grocery store and get reimbursed or an additional product dispensed.

Would that not be the case, Mr. Ettinger?

Mr. ETTINGER. Yes, sir.

Mr. BURGESS. So he's familiar with my family.

Look, as to this line of questioning that we've just heard, there's a lot of things that I could say.

To any one of you, is it deceptive that you put nitrogen in the micro atmosphere of those packages before you seal them up in those leakproof containers? Do you feel it's deceptive to the con-

sumer that you're not disclosing that there is nitrogen in those packages?

Mr. ETTINGER. No, we don't believe so. We think it has been fairly common practice to have modified atmosphere for a number of food products to enhance freshness and safety.

Mr. BURGESS. Well, of course, nitrogen occurs—it's ubiquitous in our atmosphere, and it's generally an inert gas as far as human and plant life is concerned and as far as the process of respiration is concerned, but carbon dioxide is not, so you're putting in 40 percent carbon dioxide. That would probably be a lethal partial pressure of carbon dioxide for any one of us if we were to breathe 40 percent carbon dioxide for any period of time.

Do you disclose that?

Mr. ETTINGER. No, sir, because it is just in the package, and it dissipates upon opening.

Mr. BURGESS. Exactly. So the issue of the carbon monoxide, again, is to extend the shelf life of the product, which is clearly defined and delineated on the product that you sell on the shelves.

I would be interested if there has been any type of audit done to show whether or not the product is in a timely fashion removed from the grocery shelves if it extends beyond its "use by" or "freeze by" date. There is no way that this Congress, that this committee, can ever, ever prevent a consumer from mishandling a product. That's going to happen from time to time, and it's regrettable, but we can't go into every refrigerator and every home and make certain that all the food that has a "use by" or a "sell by" date is disposed of in a proper manner.

I support and encourage Mr. Ettinger to continue with that technology that would, perhaps, be an additional visual cue to the consumer that maybe this stuff has gone beyond its date. Again, short of self-inhalation or some type of warning buzzer on the package of bacon, I don't know how you would get that accomplished.

Again, I'll just tell you, Mr. Chairman, that I'm a little disappointed with the hearing. There are plenty of things—we've devoted a whole day to this. There are plenty of other things we could have done. For heaven sakes, we never had a hearing in subcommittee on SCHIP, and we've devoted a whole day to this. I'm, frankly, mystified by the behavior of the majority.

I yield back the balance of my time.

Mr. STUPAK. Obviously, you missed the hearing on SCHIP. It was on Medicare Advantage, which we did have a very good hearing on.

So this hearing is necessary for a number of reasons. Last week, Agriculture had their hearing, and they did not have very balanced panels, shall we say, when the consumer groups were not invited. Here, we've had both sides.

Second, legislation pending before our committee does call for the labeling of carbon monoxide-treated packaging in meat. That's our food safety bill. We've done most of our work on inspections, all of our food safety. Seafood especially we did some hearings on earlier this year. So we've had about three or four hearings. This is right up the line, and it's an appropriate hearing.

With that, let me dismiss and thank this panel for coming. Thank you for adding your testimony today.

Mr. Ettinger, we'll need those 10 letters or letters you said you had by scientists, because we agreed to put that in the record. We would like to do that, please.

Mr. ETTINGER. Yes, sir.

Mr. STUPAK. So I want to thank all of our witnesses for coming today and for your testimony.

I ask unanimous consent that the hearing record will remain open for 30 days for additional questions for the record. Without objection, the record will remain open.

I ask unanimous consent that the contents of our document binder be entered into the record. Without objection, the documents will be entered into the record.

That concludes our hearing. Without objection, this hearing of the subcommittee is adjourned.

[Whereupon, at 3:30 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

HENRY A. WAXMAN, CALIFORNIA
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January 16, 2008

Daniel Engeljohn, Ph.D.
Deputy Assistant Administrator
Office of Policy, Program, and Employee Development
Food Safety and Inspection Service
U. S. Department of Agriculture
1400 Independence Avenue, S.W., Room 340 JW
Washington, D.C. 20250–3700

Dear Dr. Engeljohn:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Tuesday, November 13, 2007, at the hearing entitled "Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation's Food Supply? – Part IV – Deception in Labeling." We appreciate the time and effort you gave as a witness before the Subcommittee.

Under the Rules of the Committee on Energy and Commerce, the hearing record remains open to permit Members to submit additional questions to the witnesses. Attached are questions directed to you from a Member of the Subcommittee. In preparing your answers to these questions, please address your response to the Member who has submitted the questions and include the text of the Member's question along with your response.

In order to facilitate the printing of the hearing record, your responses to these questions should be received no later than the close of business **Wednesday, January 30, 2008**. Your written responses should be delivered to **316 Ford House Office Building** and faxed to **202-225-5288** to the attention of Kyle Chapman, Legislative Clerk. An electronic version of your response should also be sent by e-mail to Mr. Kyle Chapman at **kyle.chapman@mail.house.gov** in a single Word formatted document.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please contact Kyle Chapman at (202) 226-2424.

Sincerely,

JOHN D. DINGELL
CHAIRMAN

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Bart Stupak, Chairman
Subcommittee on Oversight and Investigations

The Honorable John Shimkus, Ranking Member
Subcommittee on Oversight and Investigations

Responses to Questions for the Record
from the House Committee on Energy and Commerce by
Dr. Daniel Engeljohn
Director of the Food Safety and Inspection Service's
Regulations and Directives Development Staff

February 7, 2008

Q 1A: Has FSIS changed its position with respect to the adequacy of date labeling to signal freshness and safety to consumers? If so please describe the reasons for this change and any data that supports this change, including evidence addressing the issue of temperature control as a necessary predicate to meaningful date labeling.

A: The Food Safety and Inspection Service (FSIS) has not changed its position on date labeling. To ensure that consumers are not misled, FSIS requires a use-by or freeze-by date be included on meat products that use carbon monoxide packaging. This is to ensure that the shelf life of the product ends before spoilage occurs. Use-by or freeze-by dates are required on all systems where CO is in direct contact with the meat. These dates are an indicator of spoilage and therefore reflect if the product is fit for consumption. FSIS has published several compliance policy guides on date labeling on its website: (http://www.fsis.usda.gov/Fact_Sheets/Food_Product_Dating/index.asp

Q 1B: Did data submitted by Precept in support of its proposed "use-or-freeze by" dates for carbon monoxide-treated meat include studies of meat handling under real-world conditions, such as during storage, at retail display, and in the hands of consumers? Or were the "use-or-freeze-by" dates set based upon laboratory studies?

A: The data the Agency relied upon was for laboratory conditions designed to mimic abusive conditions expected in cold-chain management through retail distribution and holding.

In this case, Precept provided data to support a shelf life of 28 days for ground beef and 41 days for whole muscle cuts. These data were used by Precept to establish its "use or freeze by" dates and is consistent with how industry determines the shelf life of other meat products.

Precept also evaluated meat packaged in three types of modified atmosphere packaging (MAP) systems that are currently used by industry today under temperature abuse conditions (e.g., in situations where the packaged meat is held for some period of time above 40°F). That study showed that meat packaged in all three MAP systems, including Precept and Cryovac's MAP system that are packaged with CO, will show signs of spoilage when subjected to temperature abuse conditions.

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MARSHA BLACKBURN, TENNESSEE

January 16, 2008

Robert Post, Ph.D.
Deputy Director
Center for Nutrition Policy and Promotion
U.S. Department of Agriculture
3101 Park Center Drive, Suite 1034
Alexandria, VA 22302

Dear Dr. Post:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Tuesday, November 13, 2007, at the hearing entitled "Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation's Food Supply? Part IV – Deception in Labeling." We appreciate the time and effort you gave as a witness before the Subcommittee.

Under the Rules of the Committee on Energy and Commerce, the hearing record remains open to permit Members to submit additional questions to the witnesses. Attached are questions directed to you from a Member of the Subcommittee. In preparing your answers to these questions, please address your response to the Member who has submitted the questions and include the text of the Member's question along with your response.

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Thank you for your prompt attention to this request. If you need additional information or have other questions, please contact Kyle Chapman at (202) 226-2424.

Sincerely,

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Subcommittee on Oversight and Investigations

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

MAR 1 0 2008

Dear Mr. Chairman:

Thank you for providing an opportunity for the Food and Drug Administration (FDA or the Agency) to testify at the November 13, 2007, hearing before the Subcommittee on Oversight and Investigations, which examined the use of carbon monoxide for the treatment of fish and in modified atmosphere packaging for meat. This letter provides responses for the record to questions posed by Subcommittee Chairman Bart Stupak in your letter of January 16, 2008.

We have restated each question below, in bold type, followed by FDA's response. We have grouped questions 9 and 10 together and provided a consolidated response.

1. The Food and Drug Administration's (FDA) Generally Recognized As Safe (GRAS) notification proposed rule states that GRAS status based on scientific procedures, such as that asserted for carbon monoxide-treated meat, must be based upon data that are ordinarily published, and that unpublished studies may help corroborate GRAS status. Please identify and describe the published studies—not private industry data—that support the GRAS status of carbon monoxide-treated meat under actual conditions of use (not laboratory conditions).

FDA has set out what constitutes general recognition of safety for generally recognized as safe (GRAS) status in Title 21, *Code of Federal Regulations* (CFR) 170.30. Importantly, the same quality and quantity of scientific data are needed to support a GRAS determination as are needed to support a food additive approval. However, there are additional criteria for the use of a GRAS ingredient. These criteria include a general availability (such as through publication in the scientific literature) of the data and information relied on to establish the safety of the ingredient and consensus among qualified experts about the safety of the ingredient for the intended use. These two facets (i.e., general availability and consensus) are necessary to establish general recognition.

As discussed in the preamble to the proposed rule to establish the GRAS notification program,

"studies" would be one of several types of scientific "data and information" that could support the technical element of a scientific procedures GRAS determination (see 62 *Federal Register* 18938). Other types would include generally available and accepted scientific data, information, methods, or principles, which ordinarily are published. Depending on the circumstances, other scientific data and scientific information such as that relating to chemical identity or characteristic properties of a substance, as well as methods of manufacture, could support, and in some cases be sufficient to satisfy that element. Thus, "studies" is a type of generally available "data and information."

The mechanism by which carbon monoxide (CO) acts to stabilize the natural red color of myoglobin in muscle (meat) is well-known and described in the scientific literature (for example, "The storage life of beef and pork packaged in an atmosphere with low carbon monoxide and high carbon dioxide;" Meat Science; Sorheim, O., Nissen, H., and Nesbakken, T.; 52(157 - 164); 1999).

In its GRAS notice 143 on meats that are shipped in modified atmosphere packaging (MAP) systems, Precept relied on the data and information in GRAS notice 83. Thus, published studies considered in the context of the Agency's review of GRAS notice 143 included "Food Microbiology and Food Safety Into The Next Millennium;" Proceedings Of The Seventeenth International Conference Of The International Committee On Food Microbiology And Hygiene (ICFMH), Veldholven, the Netherlands, 13-17 Sept. 1999 – Packaging of Ground Beef in an Atmosphere with Low Carbon Monoxide and High Carbon Dioxide Restrains Growth of *Escherichia coli* O157:H7, *Listeria monocytogenes, Yersinia enterocolitica* and *Salmonella diarizonae*; Nissen, H., Alvseike O., Bredholt S., Nesbakken T. Collectively, these published studies describe the technical effects (microbial growth profiles and odor) of CO in packaged meat.

2. At the hearing, serious flaws were exposed in the privately-generated data submitted by Precept in support of the GRAS status of the use of carbon monoxide in fresh meat. It was revealed that, in the study submitted to show that antimicrobial agents used in an earlier-submitted study had no effect on the microbial growth profile of steaks packaged with carbon monoxide, microbial counts decreased over time in both treated and control samples, which was contrary to the expected pattern. Further, odor scores and gas formation were not correlated with microbial counts. Did FDA observe these flaws in the data? If so, did FDA address these issues with Precept or with the Food Safety and Inspection Service (FSIS)? If FDA did not observe the apparent flaws in the report submitted to support GRAS status, why not?

We believe that you are asking about the data Precept submitted to the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) on May 12 and May 28, 2004. At this time, we cannot comment on any apparent flaws in the data because we are currently reviewing materials provided to us by Precept on November 20, 2007. We understand that these data were originally provided to FSIS by Precept on May 12 and May 28, 2004, to address questions raised by FSIS related to the suitability of the MAP system in the packaging of fresh meat. As you are aware, FSIS has authority for determining whether the intended use of an ingredient in meat is suitable under the Federal Meat Inspection Act (FMIA). Suitability

relates to the effectiveness of an ingredient for its intended use and the assurance that the conditions of use will not result in an adulterated product or one that misleads consumers. It is our understanding that FSIS reviewed the data submitted by Precept on May 12 and May 28, 2004. Subsequent to their review, FSIS informed FDA that the use of CO in MAP systems, under the conditions specified in the GRAS notice, complies with the FMIA.

Subsequent to the November 13, 2007, hearing, representatives of Precept Foods, Cargill, and Hormel, met with USDA and FDA on November 20, 2007. FDA received materials from Precept at that meeting, including data that Precept indicated were the same as those previously submitted to FSIS on May 12 and May 28, 2004. As noted above, FDA is currently reviewing those materials.

3. Does FDA consider the fact that carbon monoxide can mask spoilage to be a safety risk?

FDA has concluded that CO does not mask signs of spoilage. FDA carefully considered the safety of using CO in MAP systems for meat. Our analysis of the GRAS notices considered microbiological safety (i.e., level of contamination) and the data submitted assured us that use of CO in MAP systems would not result in an increased risk of foodborne illness to the consumer.

The color of meat is <u>not</u> a reliable indicator of microbiological safety; contamination of meat by pathogenic bacteria is not, in general, something that a consumer could visually detect. Additionally, CO-containing MAP systems (CO is used only up to 0.4 percent) will behave as other MAP systems do and will <u>not</u> mask signs of spoilage, such as off-odor, meat that is slimy or tacky to the touch, or packaging that is bulging because of gas formation from spoilage bacteria.

4. Did FDA consider the effect of consuming spoiled meat on persons with compromised immune systems such as children, the elderly, persons undergoing cancer treatment, or AIDS patients?

When FDA does a safety analysis of ingredients added to foods, we look at potential effects across the entire population. Our conclusion that the use of CO in MAP systems would not result in increased risk of foodborne illness applies to all consumers because we have concluded that CO does not mask signs of spoilage.

5. How does date labeling safeguard consumers if the meat has been temperature abused, yet still looks red and fresh regardless of its age or condition?

FDA and FSIS considered the issue of temperature and concluded that under the conditions of use described in the GRAS notices, even at abusive temperatures, whether color is maintained or not, off-odors and slime will persist as indicators of spoilage in meat products.

FSIS regulates the labeling of meat under the FMIA, including "use or freeze by" date labeling. For additional information about the labeling of meat, we defer to FSIS.

6. The fact that meat turns brown if temperature-abused has been a market incentive for processors, transporters, and retailers to ensure adequate temperature control throughout the chain of distribution. With carbon monoxide treatment, however, the meat will stay red and fresh-looking regardless of how it has been handled or how long it has taken to get to market. Is FDA concerned about the loss of this safe handling incentive?

FDA is committed to ensuring the safety and wholesomeness of the nation's food supply. As noted earlier, FDA and FSIS considered the issue of temperature and concluded that under the conditions of use described in the GRAS notices, even at abusive temperatures, whether color is maintained or not, off-odors and slime will persist as indicators of spoilage in meat products. Also, we note that the proper storage and transport of foods is a requirement that all food producers must comply with under U.S. law.

7. Similarly, FDA has recognized that home refrigerators are frequently well above appropriate temperatures. Does this pose a safety risk when carbon monoxide-treated meat may spoil yet still looks fresh?

As noted above, the color of meat is not a reliable indicator of microbiological safety; contamination of meat by pathogenic bacteria is not, in general, something that a consumer could visually detect. Additionally, CO-containing MAP systems (CO is used only up to 0.4 percent) will behave as other MAP systems do, and will not mask signs of spoilage, such as off-odor, meat that is slimy or tacky to the touch, or packaging that is bulging because of gas formation from spoilage bacteria.

8. At the hearing, Dr. Acheson stated that FDA is considering undertaking studies about consumer understanding or awareness of carbon monoxide use in fresh meat and poultry. Please report on the status of those studies, including the types of studies considered, the nature of the questions to be explored, and the timeline for conducting those studies.

The studies about consumer understanding or awareness of CO use that Dr. Acheson referred to at the November 13, 2007, hearing would be for fish. To date, FDA has not started any such studies, but remains committed to considering their usefulness, in light of other obligations and priorities.

We defer any questions on studies about consumer understanding or awareness of carbon monoxide use in fresh meat and poultry to FSIS under their authority under the FMIA.

9. Despite the evidence that carbon monoxide in meat packaging is a color additive, Dr. Acheson testified at the hearing that "It's considered by us to be a fixative, a preservative of color." Why did FDA not require foods treated with carbon monoxide to be labeled as a condition of its safe use, in accordance with the requirement in section 403(k) of the Food, Drug, and Cosmetic Act that all chemical preservatives be identified in the product's labeling?

10. At the hearing, Dr. Acheson testified that the use of carbon monoxide is identical in all respects as a fixative in fish products as it is in meat products. Donald Kraemer, Deputy Director of FDA's Office of Food Safety in the Center for Food Safety and Applied Nutrition, testified that the label of fish treated with carbon monoxide would need to say, "Preserved with carbon monoxide." Why did FDA not require, as a condition of safe use of carbon monoxide in fresh meat, the same label statement it requires on carbon monoxide-treated fish, where carbon monoxide serves the same color function in both products? Did FDA discuss the labeling of carbon monoxide-treated meat with FSIS?

We do not agree with the premise in question 9 that the evidence shows that CO in meat packaging is a color additive. As we stated in our letter to you of September 28, 2007, FDA has previously concluded that substances used to fix the natural color of meats are considered to be color fixatives and not color additives. In 1982, a Federal district court agreed with FDA that nitrites fix rather than impart color in bacon and therefore are not color additives in bacon.

The mechanism by which CO acts to stabilize the natural red color of myoglobin in muscle (meat) is well-known and described in the scientific literature. FDA concluded that the use of CO, as described in the GRAS notices, is not a color additive because it does not impart color, but rather fixes the natural red color of myoglobin, the color that consumers associate with meat products.

Questions 9 and 10 relate to why the labeling of tuna is different from the labeling of meat. With respect to the Agency's review of the use of filtered smoke containing CO (tasteless smoke), FDA reviewed the data presented in GRAS notice 15 and found no reason to disagree with the conclusion that the use of tasteless smoke on raw tuna before it is frozen to preserve its taste, aroma, texture, and color is GRAS. In our response letter, we stated that if someone were to use tasteless smoke (or any other preservative) on partially decomposed fish, the fish would be adulterated. Additionally, the sale of contaminated fish, whether treated with tasteless smoke or not, is illegal because the product is adulterated. As you noted, at the hearing Mr. Kraemer pointed out that the use of tasteless smoke on raw tuna, before it is frozen, must be indicated in labeling in accordance with the Federal Food, Drug, and Cosmetic (FD&C) Act. However, under the FMIA, FSIS has authority to determine the appropriate labeling of meat products. FSIS has informed FDA that the use of CO in MAP systems, under the conditions specified in the GRAS notices, complies with the FMIA.

Thank you again for your interest in this matter. We hope this information is helpful. Please do not hesitate to contact us if we can provide assistance in the future.

Sincerely,

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

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January 16, 2008

Laura Tarantino, Ph.D.
Director
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration
U.S. Department of Health and Human Services
5100 Paint Branch Parkway (HFS–200)
College Park, MD 20740

Dear Dr. Tarantino:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Tuesday, November 13, 2007, at the hearing entitled "Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation's Food Supply? – Part IV – Deception in Labeling." We appreciate the time and effort you gave as a witness before the Subcommittee.

Under the Rules of the Committee on Energy and Commerce, the hearing record remains open to permit Members to submit additional questions to the witnesses. Attached are questions directed to you from a Member of the Subcommittee. In preparing your answers to these questions, please address your response to the Member who has submitted the questions and include the text of the Member's question along with your response.

In order to facilitate the printing of the hearing record, your responses to these questions should be received no later than the close of business **Wednesday, January 30, 2008.** Your written responses should be delivered to **316 Ford House Office Building** and faxed to **202-225-5288** to the attention of Kyle Chapman, Legislative Clerk. An electronic version of your response should also be sent by e-mail to Mr. Kyle Chapman at **kyle.chapman@mail.house.gov** in a single Word formatted document.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please contact Kyle Chapman at (202) 226-2424.

Sincerely,

JOHN D. DINGELL
CHAIRMAN

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Bart Stupak, Chairman
Subcommittee on Oversight and Investigations

The Honorable John Shimkus, Ranking Member
Subcommittee on Oversight and Investigations

	Description	Date
1	Subcommittee on Oversight and Investigations Witness List	11/13/07
2	O&I Hearing Memo; subject: "Diminished Capacity: Can the FDA Assure the Safety and Security of Our Nation's Food Supply? - Part IV - Deception in Labeling."	11/09/07
	Congressional Research Service Products	
3	GRAS Notifications Graph	
4	CRS Report (excerpt) by Richard Rowberg, et al; subject: "Food and Drug Administration Modernization Act of 1997 - The Provisions."	03/13/98
	E&C Committee Correspondence	
5	Letter to Andrew von Eschenbach, FDA Commissioner, from Reps. Dingell and Stupak, re: Decisions by the Center for Food Safety and Applied Nutrition (CFSAN) to permit the use of carbon monoxide on meat and fish.	2/9/2006
6	Letter to Secretary Michael Leavitt, Department of Health and Human Services, from Rep. Dingell, et al; re: ordering FDA to rescind its GRAS determinations regarding the use of carbon monoxide to color meat and fish.	3/30/2006
7	Letter to Jeffrey Ettinger, Chairman of Hormel Foods, and Warren Staley, Chairman of Cargill, from Chairmen Dingell and Stupak, re: Meat Packaged in Atmosphere Containing Carbon Monoxide.	6/26/2007
7A	Response to June 26, 2007 Letter.	8/10/2007
8	Letter to Steven Burd, Chairman of Safeway, from Rep. Dingell, et al, re: Meat Packaged in Atmosphere Containing Carbon Monoxide.	6/26/2007
8A	Response to June 26, 2007 Letter.	7/16/2007
9	Letter to Richard Bond, President of Tyson Foods, from Chairmen Dingell and Stupak, re: Meat Packaged in Atmosphere Containing Carbon Monoxide.	6/26/2007
9A	Response to June 26, 2007 Letter.	8/9/2007
10	Letter to FDA Commisioner Andrew von Eschenbach from Chairmen Dingell and Stupak, re: Decisions by the Center for Food Safety and Applied Nutrition (CFSAN) to permit the use of carbon monoxide on meat and fish.	7/27/2007
10A	Response (1) to July 27, 2007 Letter	9/28/2007
10B	Response (2) to July 27, 2007 Letter	11/6/2007
10C	Response (3) to July 27, 2007 Letter	11/8/2007
11	Letter to Jose Alvarez, Chairman of Giant Food, from Chairmen Dingell and Stupak, re: Meat Packaged in Atmosphere Containing Carbon Monoxide. **October 11, 2007 Response Included.	9/13/2007
11A	Response to September 13, 2007 Letter	10/11/2007

12	Letter to Robert Ulrich, Chairman of Target Corporation, from Chairmen Dingell and Stupak, re: Meat Packaged in Atmosphere Containing Carbon Monoxide.	9/13/2007
12A	Response to September 13, 2007 Letter	10/4/2007
	FDA GRAS (Generally Recognized as Safe) Materials	
13	FDA Talk Paper, subject: "FDA Proposes Simplified GRAS Notification System."	04/17/97
14	USDA Center for Food Safety & Applied Nutrition, et al, Memorandum of Understanding, subject: "Regarding the Listing or Approval of Food Ingredients and Sources of Radiation Used in the Production of Meat and Poultry Products."	January 2000
15	GRAS Notice No. GRN 000015, responding to the notice submitted on behalf of Hawaii International Seafood, Inc.; subject: Tasteless Smoke.	03/10/00
16	GRAS Notice No. GRN 000083, responding to the notice submitted on behalf of Pactiv Corporation; subject: Carbon Monoxide.	02/21/02
17	GRAS Notice No. GRN 000143, responding to the notice submitted on behalf of Precept Foods, LLC; subject: Carbon Monoxide.	07/29/04
18	Letter to Lane Highbarger (FDA) from Robert Post (USDA-FSIS), re: GRAS Notice No. GRN 000143.	04/28/04
19	Follow up letter to Lane Highbarger from Robert Post, re: April 28, 2004 letter on GRAS Notice No. GRN 000143.	06/02/04
20	21 CFR Section 170 - Food Additives (Selected Excerpts).	
	Import Warnings	
21	FDA Import Bulletin #16-B95, "Tuna Processed with Tasteless Smoke and/or Carbon Monoxide."	5/27/99
22	Cancellation of FDA Import Bulletin #16-B95	6/17/03
	Consumer Issues	
23	Letter to FDA, re: CFA support of the Nov. 15, 2005 Citizen Petition submitted by Kalsec, Inc requesting FDA prohibit use of carbon monoxide in packaging of meat.	01/17/06
24	CFA Press Release, subject: "Leading Supermarket Chains Refuse to Sell Carbon Monoxide-Treated Meat."	04/05/06
25	CFA Press Release, subject: "Most Consumers Are Concerned About Practice of Adding Carbon Monoxide to Meat, New Survey Finds."	09/25/06
26	CFA Survey	Sep-06
~~27~~	~~CFA Survey Methodology~~	~~Sep-06~~
	Meat Studies	

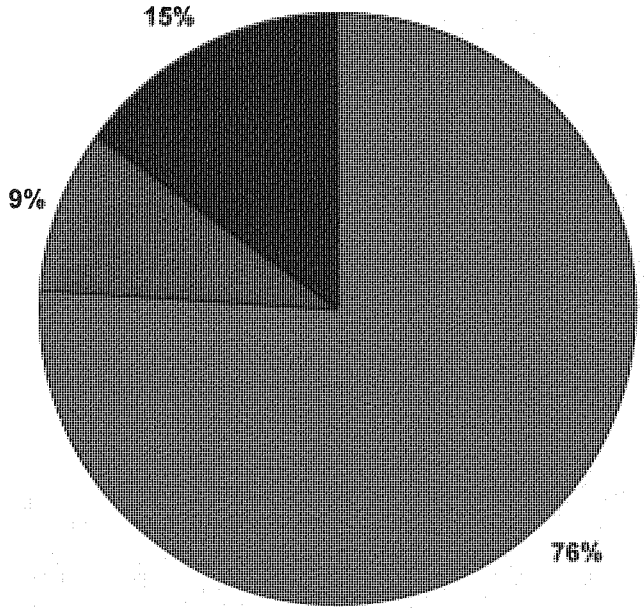
28	33rd Reciprocal Meat Conference Report by Donald Kropf (pp. 15-32); subject: "Effects of Retail Display Conditions on Meat Color."	1980
29	Food Research International article (Volume 27, pp. 371-377) by G.G. Greer, et al, subject: "Evaluation of the Bacteriological Consequences of the Temperature Regimes Experienced by Fresh Chilled Meat During Retail Display."	1994
30	Journal of Food Safety article (Volume 15, pp. 201-227) by Theodore Labuza and Bin Fu, subject: "Use of Time/Temperature Integrators, Predictive Microbiology, and Related Technologies for Assessing the Extent and Impact of Temperature Abuse on Meat and Poultry Products."	6/15/1995
31	International Journal of Food Microbiology article (Volume 59, pp. 211-220) by H. Nissen, et al, subject: "Comparison Between the Growth of Yersinia enterocolitica, Listeria monocytogenes, Escherichia coli O157:H7 and Salmonella spp. In Ground Beef Packed by Three Commercially Used Packaging Techniques."	2000
32	European Commission Scientific Committee on Food report, subject: "Opinion of the Scientific Committee on Food on the Use of Carbon Monoxide as Component of Packaging Gases in Modified Atmosphere Packaging for Fresh Meat."	12/18/01
	Tuna Documents	
33	Canadian Food Inspection Agency Communique to All Importers of Fish, re: "Fish Treated with Carbon Monoxide."	06/17/99
34	Letter to the Directors of Public Protection Wales (United Kingdom) from the Food Standards Agency of Wales, re: "Carbon Monoxide and Smoked Tuna."	08/09/04
35	Agri-Food and Veterinary Authority of Singapore announcement, re: "Carbon Monoxide Treated Tuna."	07/21/05
	News Articles	
36	New York Times article by Julia Moskin, subject: "Tuna's Red Glare? It Could be Carbon Monoxide."	10/06/04
37	Washington Post article by Rick Weiss, subject: "FDA is Urged to Ban Carbon Monoxide-Treated Meat."	02/20/06
38	Consumer Affairs article, subject: "FDA Asked to Prohibit Use of Carbon Monoxide in Red Meat."	02/21/06
39	New York Times article by Marian Burros, subject: "Which Cut is Older? (It's a Trick Question.)"	02/21/06
40	Consumer Affairs article, subject: "Supermarket Chains Refuse to Sell Carbon Monoxide-Treated Meat."	04/06/06
41	Consumer Reports article, subject: "Seeing Red: Spoiled Meat May Look Fresh."	July 2006
42	New York Times article by Harold McGee, subject: "Red-Meat Miracle, and Other Tales from the Butcher Case."	04/04/07
43	USA Today opinion article, subject: "Our View on Food Safety: When You Buy Red Meat, Looks Can Be Deceiving."	10/01/07
44	Washington Post article by Rick Weiss, subject: "Hearing on Beef Packaging Fails Activists' Smell Test."	10/30/07

45	~~Post Bulletin.com editorial, subject: "Hormel Meats Don't Need Carbon Monoxide."~~	~~11/03/07~~
46	Associated Press article, subject: "Company Recalls Tainted Beef."	11/04/07
47	Associated Press article, subject: "Company Recalls Million Pounds of Ground Beef."	11/03/07
~~48~~	~~The Globe and Mail article by Bertrand Marotte, subject: "Producers Slam Tougher U.S. Tests for Canadian Meat, Poultry."~~	~~11/06/07~~
	Additional Documents	
49	Email Correspondence between John Keating of Cargill and David Nelson, E&C Committee Senior Investigator, re: Cargill Hamburger Recall.	11/06/07
50	Publix Sign	
~~51~~	~~Kennet District Council (United Kingdom) report, re: "Scombrotoxic Food Poisoning," http://services.kennet.gov.uk/environment~~	~~08/13/07~~
52	2007 Meat Recalls	11/03/07
53	Fish Producer Treating Product with Carbon Monoxide - photo	
54	National Geographic article by Avery Gilbert and Charles Wysocki, subject: "The Smell Survey."	10/01/87
55	Fish Comparison Photo	
	Internal FDA Documents Discussing CO in Fish (Located in Supplementary Binder)	
56	Letter from Martha Peiperl (CFSN) to Eugene Lambert, re: "exclusion of fresh meats under § 173.350."	05/24/95
57	Letter from Kim Young, Office of Seafood (CFSN) to Glenn Kiel, National Marine Fisheries Service, re, "use of CO for purpose of enhancing the color of tuna loins."	08/09/96
58	Letter from Melvin Drozen, of Keller and Heckman, to Mary Snyder, Office of Seafood, re: "status of a technique for processing frozen tuna."	07/17/97
59	Letter from Anthony Brunetti (CFSN) to Melvin Drozen, re: "use of CO to enhance the red color of imported tuna steaks."	08/14/97
60	Letter to Phillip Spiller, Office of Seafood, from Melvin Drozen, re: "to discuss the Agency's response to the marketing of tuna treated with CO."	09/05/97
61	Report: "Carbon Monoxide Treated Seafood: A Recommendation for Compliance Action."	1998
62	FDA Email Correspondence Chain from Tony Brunetti to Paulette Gaynor, re: "CO/Tuna."	06/10/98
63	"Draft Comments on the GRAS Premarket Notice for the Use of Tasteless Smoke in the Preservation of Seafood."	06/11/98
64	Letter to Lisa Bogard (Praxair) from Robert Martin (Office of Premarket Approval), re: "approval of a modified atmosphere gas mixture for use in packaging meat."	07/02/98

65	Facsimile to Paulette Gaynor from Rodney Hoffman containing 8-14-97 letter from Melvin Drozen and 12-9-97 letter from Philip Spiller regarding Tasteless Smoke (redacted).	07/02/98
66	FDA Email Correspondence Chain from Linda Kahl to Paulette Gaynor, et al, re: CO in Tuna	09/10/98
67	FDA Email Correspondence from George Hoskin to Linda Kahl, et al, re: "Processing frozen tuna…"	09/11/98
68	FDA Email Correspondence from Linda Kahl to Paulette Gaynor, re: "CO as a color fixative."	10/26/99
69	Office of Premarket Approval Routing and Transmittal Slip from Linda Kahl to Kitty Bailey and Janice Oliver, re "Letter from Janice Oliver regarding the GRAS notice for Tasteless Smoke."	03/08/00
70	Office of Seafood document, subject: "CO/TS-Treated Fish - Enforcement Strategies Meeting - Issues Outline."	03/20/02
	Precept Foods Materials regarding CO in Meat (Located in Supplementary Binder)	
71	Letter to Robert Post (FSIS) from Precept Foods, re: "Use of Carbon Monoxide in Modified Atmosphere Packaging Systems for Fresh Meat."	07/02/03
71A	Excel/Cargill Study, subject: "Ground Beef Abuse Study in Peelable, Low Oxygen and Carbon Monoxide Lidstock Tray."	05/13/03
71B	Excel/Cargill Study, subject: "Use of Carbon Monoxide in Lid Stock on Ground Beef."	02/14/03
71C	Hormel Foods Resarch Report, subject: "To determine the shelf-life of boneless beef strip steaks and top round steaks packaged in a barrier plastic tray, lid-sealed with a barrier film and backflushed with a gas mixture of 35% carbon dioxide/ 0.4% carbon monoxide/ balance nitrogen."	06/06/03
71D	Hormel Foods Research Report, subject: "Always Tender/ Barrier Lid Stock Test."	05/05/04
71E	Letter to Robert Post (FSIS) from Precept Foods w/ attached report, "Use of Carbon Monoxide in Lid Stock on Ground Beef."	05/12/04
71F	Letter to Robert Post (FSIS) from Precept Foods, re: "suitability considerations related to GRAS Notice No. 000143."	05/28/04
18	Letter to Lane Highbarger (FDA) from Robert Post (USDA-FSIS), re: GRAS Notice No. GRN 000143. *Duplicate Entry*	04/28/04
19	Follow up letter to Lane Highbarger from Robert Post, re: April 28, 2004 letter on GRAS Notice No. GRN 000143. *Duplicate Entry)	06/02/04
	USDA Recall Notices (Located in Supplementary Binder)	
72	USDA Recall Notice, subject: "Wisconsin Firm Recalls Ground Beef Products Due to Possible E. coli o157:h7 Contamination."	10/06/07
73	USDA Recall Notice, subject: "Pennsylvania Firm Recalls Ground Beef Products Due to Possible E. coli o157:h7 Contamination."	11/08/07

	Additional Materials (Located in Supplementary Binder)	
74	Letter to Precept Foods from Laura Tarantino (FDA), re" GRAS Notice No. GRN 000143."	07/29/04
75	Letter to Robert Post (FSIS) from Lane Highbarger (CFSN), re: Post's 7-18-03 Letter to FDA, re: Precept's MAP system and GRAS Notice No. GRN 000083.	09/11/03
76	Letter to FSIS from Venable LLP (on behalf of Target Corporation), re: Target seeking approval to affix a label containing a consumer notice on certain meat products.	11/09/07
77	Chart, "A Comparison of Bacterial Contamination: Commercially Available Ground Beef."	
~~78~~	~~Cargill Meat Solutions Final Report, subject: "#24032 New Laura's Lean Offerings Shelf Life."~~	~~September 2006~~

GRAS Notifications



- FDA Had No Questions
- Notice Does Not Provide a Basis for a GRAS Determination
- Notifier Stopped the Process

*Presentation by Mitchell Cheeseman, Deputy Director of FDA's Office of Food Additive Safety, at the Food Law and Regulation Conference on Oct. 1-2, 2007

98-263 STM

CRS Report for Congress

Received through the CRS Web

Food and Drug Administration Modernization Act of 1997 — The Provisions

March 13, 1998

Richard Rowberg, B. Randall, Donna Porter,
Bernice Reyes-Akinbileje, and Donna Vogt
Science, Technology, and Medicine Division
and
Diane Duffy
American Law Division

Ex.4

Sec. 308. Glass and Ceramic Ware

Previous Policy or Law. Under the existing regulation, if lead has been used in the glazes and decorative decals of ornamental and decorative ceramic ware, the containers must provide adequate information that they are not to be used for food-handling purposes. In 1979, the FDA and several other agencies entered into a voluntary agreement with the industry to end-test the lead content of glass containers in acetic acid solution. In 1997, newly identified problems related to lead paint led the agencies to decide that the old voluntary agreement was not stringent enough given advances in understanding the effects of lead in children. As a result, the agencies convened a meeting with industry and announced that the voluntary agreement was revoked.

FDAMA97. The Act prohibits the Secretary from implementing any requirement that would ban, as an unapproved food additive, lead and cadmium-based paints in the lip and rim area of glass and ceramic ware before one year after the regulation is published. Lead and cadmium-based paint may not be banned as an unapproved food additive, if the paint is on glass or ceramic ware that has less then 60 millimeters of decoration below the external rim, or is on an object that is not intended for use by children, unless the Secretary determines that it is unsafe. The Secretary may not take any action before January 1, 2003, to ban lead and cadmium-based enamel on glass and ceramic ware. Any action taken after that date to ban such enamel on those containers must be done by regulation and cannot be prohibited on those products before one year after the final regulation is published.

Sec. 309. Food Contact Substances

Previous Policy or Law. Since passage of the Food Additive Amendment of 1958, food contact substances (FCS) have been regulated in the same manner as food additives. The manufacturer wishing to use the FCS was required to submit a petition to the FDA for approval, if the FCS migration into the food was at a high level. Alternatively, the substance could be classified as "generally recognized as safe", "prior sanctioned" or used under an existing regulation.

FDAMA97. The Act allows an FCS to be used in food products under either a regulation or a notification, and the substance cannot be considered to be adulterated while either is in effect. Under the notification process, at least 120 days prior to its introduction into interstate commerce, the manufacturer or supplier of an FCS may notify the Secretary of the name of the person, identity, and intended use of the FCS, and the determination that it is safe. The notification must contain the basis of the "safe" determination and all the information required to be submitted, as outlined in regulations promulgated by the Secretary.

The notification will become effective 120 days after it is submitted, and the substance may then be introduced into interstate commerce, unless within that period the Secretary has determined that, based on the information submitted, its use is unsafe. The manufacturer or supplier must be informed of an "unsafe" determination. A decision by the Secretary to object to a notification would constitute final agency action for purposes of judicial review. The term 'food contact

substance' means the substance that is the subject of a notification, and does not include similar or identical substances manufactured or prepared by someone else.

The notification process can be used for marketing authorization for an FCS, except where the Secretary determines that submission and review of a petition is necessary for adequate assurance of safety, or the Secretary and any manufacturer or supplier agree that a petition should be submitted. The Secretary is authorized to promulgate regulations to identify the circumstances in which a petition is to be filed, including such criteria as the probable consumption and potential toxicity of the FCS.

For 120 days after receipt, the Secretary is to keep confidential any information provided in a notification. Except for any trade secrets or confidential commercial information, the material may then be made available to interested parties.

The notification program will not operate in any fiscal year, unless an appropriation of at least $3 million is specifically made for that program that fiscal year. In addition, the Secretary is to certify that the amount appropriated for the FDA's Center for Food Safety and Applied Nutrition for each fiscal year is the same as or greater than the amount appropriated for the Center for FY1997. By April 1, 1999, the Secretary is to begin accepting and reviewing notifications, if a specific appropriation is made for the last six months of FY1999 and certified by the Secretary. The necessary sums are to be appropriated for each fiscal year from 1999 through 2003. Authorization of these appropriations, however, cannot be made for a fiscal year for any amount below that specified by the Act. Not later than April 1 of FY1998 and February 1 of each subsequent fiscal year, the Secretary must provide an estimate of the costs of operating the notification program for the next fiscal year to the House and Senate Committees on Appropriations, the House Committee on Commerce, and the Senate Committee on Labor and Human Resources.

The term "food contact substance" means any substance used in manufacturing, packing, packaging, transporting or holding food if such use is not intended to have any technical effect in the foods. The Secretary is to prescribe the procedure by which a notification is no longer to be in effect.

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February 9, 2006

Andrew C. von Eschenbach, M.D.
Acting Commissioner
Food and Drug Administration
5600 Fisher Lane, Room 1555
Rockville, Maryland 20857

Dear Dr. von Eschenbach:

We understand that a series of related decisions by the Center for Food Safety and Applied Nutrition (CFSAN) apparently permits the use of carbon monoxide to alter the color of meat and fish to make those substances appear edible beyond the time when they may decompose sufficiently to be contaminated by one or more dangerous toxins.

A review of Food and Drug Administration (FDA) responses to GRAS (generally recognized as safe) notices by interested companies indicates that the FDA has apparently decided that (1) it can ignore its own regulations, (2) that it can issue potentially dangerous determinations without public hearings or any form of notice and comment procedure, and (3) that it will accede to the requests of meat and fish packers and packaging manufacturers seeking to extend the shelf life appeal of meat and fish regardless of a potential impact on the public health.

Our review of the very limited public documents and other materials (obtained by interested parties under the Freedom of Information Act (FOIA) and provided to us) raises serious questions that require your prompt attention:

1. What is the reason to believe that this artificial coloration of meat and fish will not fool consumers to their detriment? The data attached to GRN 000083 ("Pactiv" notification) and GRN 000143 ("Precept Foods" notification) reveal no arguments, much less definitive science, to suggest that consumers will not be fooled by artificial coloring of meat products. In fact, that is the stated purpose of their petitions. The FDA response to GRN 000167 (Tyson notification) suggests that CFSAN reviewed no data in that case that would show that consumers can distinguish meat colored to look fresh but of potentially dangerous age from meat that is in fact fresh.

Ex. 5

2. The Precept Foods notice argues that end dating will be sufficient notice to consumers of meat in danger of spoiling. None of the documents obtained under FOIA associated with that notice, however, purport to have measured the extent to which consumers are guided by end dating when purchasing meat, a commodity that has typically been purchased based on appearance. Nor is there any indication in the FDA response to any of the notices of an FDA requirement regarding the type, size, color, or placement of "use or freeze by" information on the package. Does the FDA possess and did it consider scientific studies on how consumers distinguish good meat from that which is going bad? If not, why not? Does the FDA have requirements that specify how prominent critical safety information such as the end date must be displayed on packaged meat and fish? If not, why not?

3. Your CFSAN scientists apparently think there is no danger to the public health in permitting the packagers to disguise the degradation of meat and fish. What is the basis for that belief? Please provide all relevant documentation including all internal notes or other memorandum where the issue of disguising the appearance of meat and fish was considered.

4. A plain reading of 21 CFR 173.350(c) appears to categorically prohibit the use of carbon monoxide on "fresh meat products." Is this prohibition no longer operative? Please explain whether the FDA now disagrees with its own regulation and, if so, why it has not addressed the matter through notice and comment rulemaking.

5. Given that the European Union has banned the use of carbon monoxide on meat and fish products, why does the FDA maintain that such use is "generally recognized as safe"?

6. In a Citizen's petition filed November 15, 2005, Kalsec argues that neither FDA nor the Food Safety and Inspection Service (FSIS) has ever before approved a color additive for meat precisely because it promotes deception by making meat appear fresher than it is, thus violating Section 721 (b)(6) of the Act and 21 CFR 379e (b)(6). What is the basis for CFSAN's disregard of both the statutory and regulatory prohibition of disguising meat by artificial coloration with carbon monoxide?

7. Please provide all documents including notes and memoranda relating to all contacts with FSIS personnel regarding GRN000143.

8. The use of carbon monoxide on fish is discussed in GRN 000015. Carbon monoxide is used as an ingredient in "tasteless smoke" which has alleged preservative properties for treating tuna before freezing and thus is not purely employed for its ability to disguise degradation. But the potential for such disguised spoilage in a food that is often eaten raw is of concern. What steps has the FDA taken to assure that fish sellers have not relied on its GRAS notice responses to treat packaged fish with carbon monoxide to make it appear to be fresher than it is?

9. Should the FDA require that the presence and purpose of carbon monoxide be prominently labeled so consumers can be aware of what they are buying?

FDA is first and foremost charged by Congress with protecting the public health and the safety of the food supply. But the FDA's decisions to not object to GRAS notices regarding the use of carbon monoxide on meat or fish products ignore those mandates. Given the lack of discernible consumer benefit and the obvious increase in risk to consumers of meat and fish from these decisions, we request that you withdraw the FDA response to GRAS notices GRN 000167, GRN 000143, and GRN 000083. And if the FDA believes that it can demonstrate a favorable risk/benefit ratio on the question of the application of carbon monoxide to color fresh meat and/or fish, then the FDA should go to notice and comment rulemaking to acquire the authority to permit such usage.

Thank you for your attention to this public health matter and to our concerns. With regard to questions and related document requests made in this letter, we would appreciate your responses no later than the close of business, Thursday, February 23, 2006. If you have any questions regarding this request, please have your staff contact David Nelson, Minority Investigator/Economist with the Committee on Energy and Commerce, at (202) 226-3400.

Sincerely,

JOHN D. DINGELL
RANKING MEMBER

BART STUPAK
RANKING MEMBER
SUBCOMMITTEE ON OVERSIGHT
AND INVESTIGATIONS

CC: The Honorable Joe Barton, Chairman
Committee on Energy and Commerce

The Honorable Ed Whitfield, Chairman
Subcommittee on Oversight and Investigations

Dr. Richard Raymond, Under Secretary for Food Safety
Department of Agriculture

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ONE HUNDRED NINTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

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March 30, 2006

The Honorable Michael O. Leavitt
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Leavitt:

We ask you to order the Food and Drug Administration (FDA) to rescind its GRAS (generally regarded as safe) determinations regarding the use of carbon monoxide to color meat and fish until such time as notice and comment rulemaking can determine whether such practices, under existing conditions of refrigeration and labeling and existing consumer practices, are safe for American consumers. If you choose not to order the FDA to take immediate action, we ask that you undertake an immediate public information campaign to inform consumers that they cannot rely on color to ascertain the safety of meat and fish. Such a campaign should contain cautions such as never under any circumstance consume meat or fish that exceeds its "use by" date; never remove meat and fish from their dated packaging before use; and, if consumers have problems with reading the packages or smelling the contents, to seek help before consuming such products.

On February 9, 2006, Representatives Dingell and Stupak sent the attached letter to FDA Commissioner von Eschenbach detailing concerns regarding the decisions to permit meat of unknown age and safety to be displayed as red and therefore wholesome. While FDA has not found time to respond to the concerns raised in the February 9 letter, it did find time on February 27, 2006, to hold a press conference to address public indignation over the FDA decision. Unfortunately, several statements by the two FDA representatives, Dr. Laura Tarantino, Director of the Office of Food Additive Safety, and Ms. Susan Bro, a public relations official assigned to the Commissioner's Office, were helpful to the meat industry, but not helpful to consumers.

Meat that is packaged with the CO captured within the packaging until it is opened will retain a fresh, appetizing appearance indefinitely under almost any storage conditions. The attached pictures are of meat whose "use by" date was in October, and meat packaged with and without CO and left at room temperature for 27 hours. Clearly the coloring of each package that contains CO is deceptive in that the meat appears safe yet is entirely spoiled.

EX.6

At the February 27th press conference, Dr. Tarantino plainly stated: "I think one of the issues is that color probably is not a major or particularly good indicator of spoiled meat." That is certainly the case after FDA's decision. But what most every American consumer knows and Dr. Tarantino knew or should have known is that color has been the principal basis for consumer determinations of the quality and safety of meat. Not only is this fact recognized by multiple marketing studies by the meat industry itself, it is clearly the only reason that the industry sought the GRAS determination. Nowhere is it alleged that placing meat in a sealed atmosphere containing CO has any purpose other than to assure that the meat appears fresh regardless of its age.

This could have significant consequences. The industry presentations to FDA and the U.S. Department of Agriculture Food Safety and Inspection Service (FSIS) were made on an *ex parte* basis behind closed doors. It appears from FDA and FSIS statements that the industry presented evidence that toxins would not attach to meat kept at 38-42 degrees F during an interval of 28 to 42 days depending on the cut. What Dr. Tarantino should have known, however, (at least by the time of the news conference because it is referenced in petitions before the FDA) is that meat is not stored at a constant 38-42 degrees. Most people understand this from common experience. One study stated: "Temperature abuse is common throughout the distribution and retail markets, with temperature in 21% of household refrigerators often higher than 10 degrees (C) (50 degrees F). Recent data suggested that 33% of retail refrigerated foods were held in display cases above 7 degrees C (45 degrees F) and 5% were held above 13 degrees C (55 degrees F). Temperatures were even higher in southern market regions. Serious microbial stability problems exist because of the frequency of temperature abuse."

Further, whatever incentive existed to assure adequate refrigeration of meat because of the fear of economic loss associated with "browning" was diminished by the FDA decision. Now that the consequences of poor handling of meat will not be obvious, such mishandling can be expected to increase.

Who might be hurt? The population least able to protect itself against this FDA-approved deception is the most vulnerable to the potential illnesses from bad food. The Centers for Disease Control and Prevention has identified the elderly (along with infants and the immunocompromised) as at the highest risk for illness and death from foodborne illness. It is precisely this group that is mostly likely to be losing a meaningful sense of smell, and is least able to read the often obscure labeling.

Dr. Tarantino advises that smell is a better indicator than color of spoilage in meat. But the National Geographic Survey (NGS), in a seminal work involving 1.2 million subjects, found that chemical exposure, pregnancy, and head injury as well as colds and flu can cause permanent loss of smell but overwhelmingly such loss occurs as we age. As one article by prominent nutritionists noted after reviewing the NGS findings, "the decline in sensitivity to the odor with age is large enough to render the odor useless as a warning for about half of the elderly population."

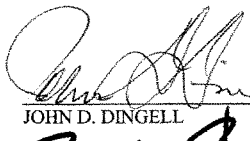
Also, because some deterioration of eyesight is virtually universal after age 40, it is precisely those Americans that are least able to rely on a sense of smell that are also likely to be victimized by the lack of meaningful labeling standards. Both Dr. Tarantino and Ms. Susan Bro dismissed press conference questions regarding inadequate labeling by noting that it is the Department of Agriculture's responsibility to assure that meat is properly labeled. Apparently, they believe the legibility of the labeling was not their problem even though FDA's decision made prominent "use by" labeling the consumer's only defense against unsafe meat.

This is no idle concern. A trip to any supermarket reveals that the labeling on meat products often appears to be deliberately illegible. Certain of the pre-packaged products use low-resolution ink jet printing on the film packaging itself to "inform" the consumer of the end date. Such printing is not visible to someone with 20/20 vision unless the light hits it at a certain angle. Other packages print the "use by" in 8-point type or less combined with other information that is not relevant to product safety such as weight.

Given these facts, we urge you to order FDA to rescind its acceptance of the use of carbon monoxide to color meat and fish until a full and public process can be undertaken and, if CO is ultimately allowed, until labeling is strengthened and clarified. If you refuse, you should at least order an aggressive public campaign to tell consumers they can no longer trust what their eyes are telling them about the suitability and safety of packaged meat and fish.

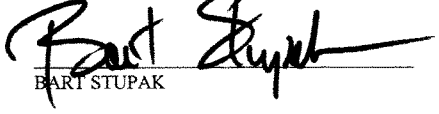
Because the misleading use of carbon monoxide continues, we ask that you examine these matters and respond to us by Wednesday, April 12, 2006. If you have any questions regarding these requests please contact one of us, or have your staff contact David Nelson of the Committee Democratic staff at (202) 226-3400.

Sincerely,

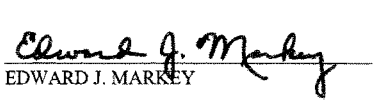


JOHN D. DINGELL

HENRY A. WAXMAN



BART STUPAK



EDWARD J. MARKEY

Attachments

cc: The Honorable Joe Barton, Chairman
Committee on Energy and Commerce

The Honorable Nathan Deal, Chairman
Subcommittee on Health

The Honorable Mike Johanns, Secretary
Department of Agriculture

HENRY A. WAXMAN, CALIFORNIA
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ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

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MICHAEL C. BURGESS, TEXAS
MARSHA BLACKBURN, TENNESSEE

June 26, 2007

Mr. Jeffrey M. Ettinger
Chairman, President, and CEO
Hormel Foods Corporation
1 Hormel Place
Austin, MN 55912

Mr. Warren R. Staley
Chairman and CEO
Cargill, Incorporated
15407 McGinty Road West
Wayzata, MN 55391

Dear Messrs. Ettinger and Staley:

Under Rules X and XI of the Rules of the United States House of Representatives, the Committee on Energy and Commerce and the Subcommittee on Oversight and Investigations are investigating the adequacy of the efforts of the Food and Drug Administration (FDA) and the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) to protect Americans from contaminated or otherwise unsafe food. It is our understanding that Precept Foods, LLC (Precept), a joint venture between Hormel Foods Corporation and Excel Corporation (a wholly-owned subsidiary of Cargill, Incorporated), markets fresh meat that is packaged in an atmosphere containing carbon monoxide, designed to alter the color of the meat indefinitely. For the purposes of this letter, the use of "Precept" refers to the joint venture and to each of your firms individually, as well as any subsidiaries of your firms.

Beyond any consumer deception that may be involved, the Committee has concerns about the public health consequences of this packaging and the *ex parte* decisions by FDA and FSIS that made such packaging lawful. We have questions regarding the conditions under which these rulings have come about, as well as how Precept chooses to market prepackaged fresh meats that appear to have been deceptively colored. Accordingly, we request responses to the following inquiries and make the following record requests:

1. **Scientific Evidence:** We are interested in the scope and quality of the studies Precept submitted to FDA and FSIS to support its GRAS (Generally Recognized As Safe) notification (GRN 000143) for the use of carbon monoxide in meat packaged in which carbon monoxide remains in contact with the meat until the package is opened by the consumer. We are aware of three studies that were submitted by Precept in support of its GRAS notification. These are:

Ex. 7

- Excel Report: Use of Carbon Monoxide in Lid Stock on Ground Beef. Project # 23034, February 14, 2003, Authors: Nancy Rathje and Graciel Catano;

- Excel Report: Ground beef abuse study in peelable, low oxygen and carbon monoxide lidstock tray, May 13, 2003, Authors: Liza John, Barney Wilborn and Graciel Catano; and

- Hormel Report: Precept Foods / MAP Packaging, R&D Project # PF002.00, June 6, 2003, Author: Dave Ruzek

(a) Does Precept consider these reports, as submitted to FDA and FSIS, to meet standards for publication in a reputable, peer-reviewed scientific journal?

(b) Does Precept intend to publish these reports? If not, why not?

(c) How does Precept respond to the allegation that some of the above reports fail to include all data, report only mean values—without a measure of variability, fail to include replicate results, or fail to support conclusions with data?

(d) Were other studies provided to FDA or FSIS in support of GRN 000143 to address these issues?

(e) We were told that the food industry practice for firms seeking a GRAS determination by FDA is to generally convene an independent GRAS panel and submit the panel's report as part of their GRAS notification. Apparently, Pactiv Corporation convened a GRAS panel to support its GRAS notification for the use of carbon monoxide in its fresh meat packaging system. Did Hormel and/or Cargill convene an independent GRAS panel? If not, why not?

Please provide the following:

(f) Curricula vitae for the authors of the reports listed above;

(g) Names and curricula vitae of any experts Precept consulted, and copies of any reports they supplied; and

(h) Copies of all reports submitted by Precept to FDA or FSIS related to GRN 000143.

2. **Consumer Reliance on Meat Color as an Indicator of Freshness and Safety:** It is apparently well documented in published scientific and industry literature that consumers rely heavily upon meat color in selecting fresh meat for purchase and consumption. By reacting with the meat to create a red color that simulates the look of fresh meat—regardless of the age of the meat or whether it has been temperature abused—carbon monoxide can mask signs of microbial spoilage, aging, and deterioration. We are interested in any special labeling or educational means that Precept employs to inform the consumer that meat has been treated with carbon monoxide to make it appear red indefinitely, and that its color should not be used

to judge freshness or safety, since the packaged meat can appear to be edible well beyond the point of microbial spoilage.

Has Precept conducted studies that demonstrate consumers are able to recognize meat that is aged, spoiled, or temperature abused in the face of contradictory visual cues that they have historically relied upon? Please provide to the Committee any studies or other documents Precept has prepared or relied upon relating to the ability of consumers to detect spoilage where meat appears red and fresh looking.

3. **Odor and Package Bulging as Purported Indicators of Spoilage:** Does Precept allege that consumers can adequately detect spoilage in red, fresh-looking carbon monoxide-treated meat by aroma or by the presence of a bulging package?

   (a) Please explain how the consumer can detect off-odors in hermetically sealed packages at the point of purchase—the point at which consumer deception occurs.

   (b) Have Precept done any studies on what percentage of the population may have difficulty detecting the spoilage odors associated with carbon monoxide-packaged meat?

   (c) Did Precept discuss with FDA the special risks facing anosmic individuals, especially the elderly, who are also at high risk for food-borne illness? If not, why not?

   (d) Does Precept have data describing the percentage of packages that bulge as a result of over-filling during manufacture, changes in elevation during transport, changes in weather or any other factors that would tend to make sealed packages bulge? If not, why not?

   Please provide all documents relating to your responses to the questions listed above.

4. Labeled Shelf Life: We understand that Precept proposed, and FDA and FSIS accepted, "use or freeze by" dates on packages of carbon monoxide-treated meat of up to 28 days from packaging for ground beef and up to 35 days for whole muscle cuts. We are informed that the Opinion of the European Commission's Scientific Committee on Food (EC Opinion) on the use of carbon monoxide as component of packaging gases in modified atmosphere packaging for fresh meat, adopted 13 December 2001, determined that the shelf life of the treated meat was 11 days for ground beef and 14 days for beef loin steaks (at 4° C or 39.2° F). The EC Opinion also states that raising the temperature to 8° C (46.4° F) reduced the shelf life of carbon monoxide-treated ground beef by about one half. According to published scientific reports, 21 percent of the refrigerators in the U.S. operate at temperatures around 50° F and temperature abuse in other parts of the chill chain is well documented.

   (a) Please provide the data upon which Precept proposed the 28- and 35-day shelf lives noted above.

(b) Were these periods of shelf life established under ideal laboratory conditions or under conditions reflecting the actual conditions of distribution, storage, and retail and consumer handling that the treated meat is likely to encounter? If these periods were established based upon ideal laboratory conditions, please explain why actual conditions were not considered when Precept originally submitted its GRAS notification to FDA.

(c) Was Precept aware of the EC Opinion prior to the submission of GRN 000143? If so, why was this opinion not provided to FDA as part of the GRAS notification—consistent with FDA's requirement that GRAS notifications must include a "comprehensive discussion of any reports of investigations or other information that may appear to be inconsistent with the GRAS determination?"

(d) How does Precept reconcile the substantial difference between the shelf lives of 11 and 14 days (for ground beef and beef loin steaks, respectively) reported in the EC Opinion and the 28- and 35-day shelf lives proposed by Precept? Was this difference discussed with FDA? If not, why not?

(e) We are aware that Precept has stated that, in light of "actual conditions," Precept is using "more conservative dates" reflecting a shorter shelf life. What labeled shelf life is Precept currently using on its carbon monoxide-treated meat? Please explain the "actual conditions" that prompted this change. Please provide all tests and/or other documents that were used to establish the "more conservative dates" Precept has said it currently uses.

5. Legibility and Effectiveness of Date Labeling:

(a) Does Precept use any special labeling to assure that consumers can read the "use or freeze by" dates on the packages?

(b) Has Precept gathered data regarding the prominence of the "use or freeze by" date labeling required to allow persons with compromised vision—particularly the elderly, who have a long history of relying on color as their primary indicator of meat quality, and who may have difficulty smelling the odors associated with spoiled meat—to be able to read the "use or freeze by" date on the package? If not, why not?

(c) If meat has been temperature abused during manufacture, distribution, at retail or in the possession of the consumer, the "use or freeze by" date becomes worthless as an indicator of meat quality and questionable with regard to food safety. Under temperature abuse conditions, neither the color of carbon monoxide-treated meat nor "use or freeze by" date labeling provide consumers with accurate information as to the product's fitness for consumption.

(d) Has Precept taken any steps to inform the customer of these facts, through product labeling or other means? If not, why not?

Please provide any data or other information Precept has generated or relied upon relating to the effectiveness of "use or freeze by" date labeling to positively affect consumer purchasing practices.

6. Temperature Abuse Concerns: The discoloration of meat packaged in air or in high oxygen modified atmospheres that occurs as a result of temperature abuse is an enormous financial incentive driving meat production and transportation activities to maintain rigorous and proper control of temperature. If the temperature is not controlled, the meat turns brown and becomes unsaleable.

   (a) Since the color of carbon monoxide-treated meat is completely insensitive to temperature abuse, what contracted conditions or other additional controls has Precept put in place to insure adequate temperature control during manufacture, storage and distribution?

   (b) What steps has Precept taken to educate meat retailers about the different way this meat product will behave when temperature abused?

   Please provide all documents relating the responses to questions listed above.

7. Retail Practices:

   (a) What is average loss to spoilage of ground meat, and other cuts that have been prepackaged in atmospheres containing carbon monoxide? Please provide the related documentation.

   (b) How does this loss compare to meat that is not treated with carbon monoxide? Please provide the related documentation.

   (c) When such losses occur at the retail level, does the retailer absorb the loss or does Precept reimburse the retail stores for spoiled meat?

   (d) Do the same commercial terms apply to carbon monoxide-treated meat and meat that has not been so treated?

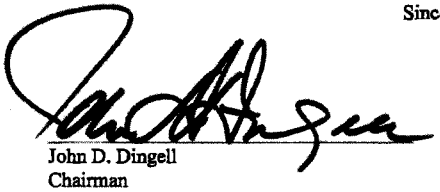
   (e) Does Precept have any systems in place that are capable of documenting customer complaints relating to carbon monoxide-treated meat? If so, please describe these systems.

The Committee hereby requests all records relating to Precept's decision to market fresh meat products treated with carbon monoxide. This request includes, but is not limited to, all studies that Precept—including its component firms as noted earlier—has commissioned or performed in-house regarding the use of carbon monoxide in the packaging of fresh meat, the due diligence that Precept performs on such fresh meat products regarding temperature controls in the processing and transport of these products, any studies or focus groups regarding the criteria for consumer selection of fresh meat products, consumer acceptance of meat whose color is

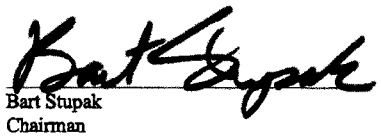
preserved by carbon monoxide, consumer ability to smell or otherwise detect spoiling meat, and the ability and actual experience of consumers reading "use or freeze by" dates on packages.

Please provide Precept's responses and the requested records to the Committee offices in room 316 Ford House Office Building no later than 30 days from the date of this letter. Please provide all records requested in an electronic sortable format. The words "records" and "relating to" are defined in an attachment to this letter. If this request is interpreted to require production of documents that would constitute an unreasonable burden, it may be modified upon agreement with Committee staff. If you have any questions regarding this request, please contact us or have your staff contact David Nelson, Kevin Barstow, or John Arlington of the Committee staff at (202) 226-2424.

Sincerely,



John D. Dingell
Chairman



Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Ed Whitfield, Ranking Member
Subcommittee on Oversight and Investigations

ATTACHMENT

1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.

2. The terms "relating," or "relate" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.

HOGAN & HARTSON

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August 10, 2007

Martin J. Hahn
Partner
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The Honorable John D. Dingell
Chairman
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Bart Stupak
Chairman
Subcommittee on Oversight and Investigations
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Re: Response to June 26, 2007 Inquiry

Dear Chairman Dingell and Chairman Stupak:

We are writing this letter on behalf of our client, Precept Foods, LLC (Precept Foods), in response to your letter dated June 26, 2007 requesting answers to seven categories of questions regarding the generally recognized as safe (GRAS) status of carbon monoxide (CO) when used as a component in the modified atmosphere packaging (MAP) system for certain meat products. Precept Foods is a joint venture between Hormel Foods Corporation and Cargill Meat Solutions, a wholly-owned subsidiary of Cargill, Incorporated. The Precept Foods case ready pork and beef products are sold under the HORMEL® brand name. We note at the outset that we appreciate the Committee's willingness to extend the response deadline until August 10th.

By way of brief background, Precept Foods enhanced the use of CO in MAP, specifically in barrier lidstock trays, to provide an alternative and improved system for case ready meats. One of the challenges long facing the meat industry is the color change that naturally takes place with the pigments in fresh meat. The pigment in meat, myoglobin, has a purplish-red color before it is exposed to oxygen. When meat is first cut (such as a steak) or ground (such as hamburger), the meat will "bloom" and form a bright red color because the myoglobin will react with the oxygen

Ex. 7a

in the atmosphere and form oxymyoglobin. After about three days of exposure to the air, oxymyoglobin will break down into metmyoglobin, which has a brownish color.

One of the growing trends in the retail industry is the use of case ready meats. These products are cut (or ground) and packaged at a USDA-inspected facility that is operating under a Hazard Analysis Critical Control Point (HACCP) system. The USDA-inspected facility places the meat in the package that will be purchased by the consumer, eliminating the need for the retailer to handle the meat again where it would be exposed to the environment and could come in contact with physical, chemical, and microbiological contaminants. Case ready meats must be transported from the USDA-inspected facility to the retailer using a packaging technology that will minimize the formation of metmyoglobin.

Numerous packaging systems have been developed over the years to maintain a desirable natural color of packaged meats. Vacuum packaging maintains meat color by excluding oxygen and has been used for over 30 years. The meat in vacuum packages will have the purplish-red color of myoglobin. Vacuum packaged meat has a typical shelf life of about 35 days in the package and three days when removed from the package, for a total of 38 days. Another technology involves packaging meat in a high oxygen modified atmosphere. The high oxygen helps maintain the stability of the oxymyoglobin and the bright red color for up to 11 days but can result in a rancid odor and flavor due to oxidation of fat. These high oxygen and vacuum packaging systems are designed for the specific purpose of minimizing the formation of metmyoglobin and enabling the true shelf life of the meat to be realized.

The industry developed a MAP system that uses CO because it shares the strengths of the vacuum and high oxygen systems without the shortcomings. CO binds with myoglobin and forms carboxymyoglobin, which naturally has a bright red color and is relatively stable. Meat in the CO MAP system has a target shelf life of 28 days for ground beef and 35 days for whole muscle cuts, which is slightly less than the typical shelf life for vacuum packaged meat. The meat color is stabilized in the CO MAP and vacuum packaging system, but the CO MAP system maintains a bright red color rather than the purple red color in vacuum packaging. The CO MAP system does not result in an appreciable change in shelf life or color stability over the vacuum packaging systems on the market; it merely combines the shelf life benefits of the vacuum packaged product with the preferred color of the high oxygen MAP systems.

Importantly, meat color is not a reliable indicator of product safety or spoilage. Metmyoglobin can form on meat that is safe, wholesome and delicious, and meat that is bright red due to its oxymyoglobin content can be spoiled and unfit for consumption. Regardless, consumers have an aversion to meat with metmyoglobin in much the same way they avoid apples and other fruit with minor blemishes. While the blemished fruit and metmyoglobin meat may be delicious and nutritious, consumers gravitate toward products with the preferred color. The industry developed the CO MAP systems in large part to address this consumer preference for meat with a stable, bright red color.

Pactiv Corporation (Pactiv) was the first company to submit a GRAS notification for the use of CO in a modified atmosphere system for meat. Pactiv submitted its GRAS notification in September 2001 and FDA completed a favorable review of the notification in February 2002.

Two years later, in January 2004, Precept Foods filed its GRAS notification for a modified atmosphere packaging using 0.4% CO in a slightly different packaging system.

In addition to demonstrating the GRAS status of CO, the GRAS notification also contained extensive data and information establishing the technology is suitable for use in meat. These data specifically evaluated the effect of CO on meat color and whether this technology would mask signs of spoilage. While carboxymyoglobin will maintain its color after meat is spoiled, the data convincingly demonstrate the CO MAP system does not mask odor or other signs of spoilage. Moreover, each case ready product is packaged with a clear and conspicuous "use or freeze by" date. Consumer surveys establish consumers place a heavy reliance on such "use or freeze by" dates when making purchasing decisions for perishable products such as meat.

Precept Foods has taken a responsible approach regarding the implementation of the technology by making it available only to those retailers that have received training and that have passed a cold chain audit confirming the store can effectively maintain temperature control during receiving, holding and retail display. Precept Foods transports the case ready products in trailers with temperature recording devices to ensure temperature is maintained during transit. Precept Foods also has established receiving guidelines instructing the retailers to check the temperature recording devices and record the temperature of the shipped product when it arrives at the retailer. These and other programs are designed to minimize the possibility that the case ready products will be subject to temperature abuse.

In the unlikely event a package is subject to temperature abuse and the product spoils before its "use or freeze by" date, the technology does not present any issues unique to a packaged perishable product. The data convincingly establish that CO does not mask odor, one of the primary signs of spoilage used by consumers. Consumers, therefore, will have the same clues of spoilage that are present when milk, yogurt, meat packaged in vacuum packaging, and countless other packaged perishable products are subject to temperature abuse and spoil before the expiration of their "use-by" dates.

The data summarized in the GRAS notification and found in this submission convincingly establish the low level of CO found in the MAP system does not present any toxicological concerns that would present a safety issue. Indeed, there is consensus among scientific experts that there are sufficient data to support the safety of these low levels of CO. In addition, the data convincingly establish CO MAP systems are suitable for use in meat. After reviewing the information submitted, FDA, in consultation with USDA's Food Safety and Inspection Service, completed a favorable review of the GRAS notification and did not object to the Precept Foods finding that there are sufficient data to support the GRAS status of CO on the basis of scientific procedures. The agencies also found persuasive the data and information demonstrating the suitability of a MAP system containing CO in meat.

Since the agencies completed their review, there have been additional data and information further demonstrating that the technology is not used to mask decomposition and that consumers have the information they need to avoid consumption of spoiled products. After reviewing the extensive data and information in this response, we trust your Committee similarly will agree

there are sufficient data to support the GRAS status of CO and that the technology is suitable for use in packaging meat.

Below, we address each of the seven general sets of questions asked in the order presented in the June 26th letter. For your convenience, we provide background information when it is useful to place the question in the proper context and we repeat each question in its entirety before providing our response. Attached to this letter are copies of the numerous documents that support the responses to each of the questions.

A. Question 1: Scientific Evidence

1. General Background on the GRAS Process

The concept of GRAS substances is firmly embedded in the Federal Food, Drug, and Cosmetic Act (FFDCA). In 1958, the United States Congress enacted the Food Additive Amendments to the FFDCA. In essence, the 1958 amendments require that before a new additive can be used in food, its producer must demonstrate the safety of the additive to FDA. The goal of the 1958 amendments, as defined by Congress is two-fold – first, "to protect the health of consumers by requiring manufacturers of food additives and food processors to pretest any potentially unsafe substances which are to be added to food; and second, to advance food technology by permitting the use of food additives at safe levels." 1/

When enacting the 1958 amendments, Congress also recognized that many substances should not require formal premarket review to ensure their safety because their safety had been established by either scientific procedures or common use in foods prior to 1958. The 1958 amendments provide an exemption from the food additive definition (and premarket review and approval) for those substances that are generally recognized, among experts qualified by scientific training, as having been adequately shown through scientific procedures to be safe under the conditions of their intended use. 2/ Therefore, Congress specifically provided that a substance that is generally recognized as safe (GRAS) for a particular use may be marketed for that use without further FDA review and approval.

Despite the lack of mandated premarket review and approval for GRAS substances, over the years FDA has sought to assist the food industry in determining whether a given substance is GRAS for a particular use. For example, the agency's regulations in 21 C.F.R. Part 182 contain a list established by FDA shortly after the 1958 amendments identifying substances that when used for the indicated purpose are GRAS. In the 1970s, FDA undertook a systematic review of the data supporting the safety of the GRAS substances listed in Part 182. In instances when the review confirmed sufficient data support the GRAS status of the substance, FDA would affirm the GRAS status and publish the substance in Part 184. At that time, the agency also created a GRAS petition process whereby an individual could on a voluntary basis petition FDA to review

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1/ Cong. Rec. 17413 (daily ed. Aug. 13, 1958) *reprinted in* Legislative History of the Federal Food, Drug, and Cosmetic Act and Its Amendments, vol. XIV at 865.

2/ Federal Food Drug and Cosmetic Act Section 201(s).

and affirm the GRAS status of a substance though rulemaking. 3/ The petition process was "designed as a voluntary administrative process whose purpose was to provide a mechanism for official recognition of lawfully made GRAS determinations." 4/

The GRAS affirmation petition process was slow and cumbersome with some GRAS affirmation petitions taking over 20 years for the agency to review and issue an affirmation regulation in Part 184. In 1997, FDA decided to streamline the GRAS petition process and issued a proposed rule that would replace the petition process with a notification process. FDA concluded the petition process, due to the resource intensive rulemaking component, "deter[red] many persons from petitioning the agency to affirm their independent GRAS determinations." 5/ In the preamble to the proposed rule creating the notification process, FDA explained that the notification process would "provide an incentive for manufacturers to inform FDA of their GRAS determinations. This would result in increased agency awareness of the composition of the food supply and the cumulative dietary exposure to GRAS substances." 6/ The GRAS notification process, therefore, replaced one voluntary process with another – one designed to provide greater transparency to independent GRAS determinations.

While FDA has not yet finalized the GRAS proposed rule, the agency has been accepting and successfully reviewing GRAS notifications since shortly after publishing the proposed rule. FDA received its first GRAS notification on November 2, 1998 7/ and as of the date of this letter has received 227 GRAS notifications. 8/ The notification process has successfully resulted in the review of these GRAS notifications, reviews that would have been less likely to occur under the old GRAS affirmation petition process.

When proposing the notification procedure, FDA set forth the required contents of a GRAS notification and clarified the criteria for a GRAS determination. FDA stated that as a general matter, "a determination that a particular use of a substance is GRAS requires both technical evidence of safety and a basis to conclude that this technical evidence of safety is generally known and accepted." 9/ FDA has defined "safe" as "a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use." 10/ Establishing general knowledge and acceptance of safety has two components: (1) the data and information relied upon to establish safety must be generally available, and (2) there must be a basis to conclude that there is consensus among qualified experts about the safety of the substance for its intended use. 11/ FDA has explained that "consensus does not require

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3/ 62 Fed. Reg. 18937, 18940 (April 17, 1997).
4/ *Id.* at 18941.
5/ *Id.*
6/ *Id.*
7/ GRN 000001, copy accessed on Aug. 6, 2007 at http://www.cfsan.fda.gov/~rdb/opa-g001.html.
8/ GRN 000227, copy accessed on Aug. 10, 2007 at http://www.cfsan.fda.gov/~rdb/opa-grsn.html.
9/ 62 Fed. Reg. at 18940.
10/ 21 C.F.R. § 170.3(i).
11/ 62 Fed. Reg. at 18940.

unanimity among qualified experts." 12/ Thus, although the existence of "a severe conflict among experts regarding the safety of the use of a substance precludes a finding of general recognition, . . . mere conflict" will not. 13/

2. The Precept Foods GRAS Determination

Almost two years before Precept Foods filed its GRAS notification, FDA had completed a favorable review of a GRAS notification filed by Pactiv Corporation for the use of CO in a MAP system. 14/ The Pactiv GRAS notification, GRN 000083 (hereinafter GRN 83), involved the use of a modified atmosphere containing 0.4% CO, 30% carbon dioxide and 69.6% nitrogen. The technology involves the packaging of case ready meats in a larger package or "mother bag" that would contain the modified atmosphere. When the "mother bag" arrives at the retailer, the case ready meats are removed from the MAP system and placed on the retail shelf. The Pactiv system involves the use of permeable packaging film surrounding the trayed meat, which allows the CO, carbon dioxide and nitrogen in the atmosphere surrounding the meat in the mother bag to dissipate over time. Prior to the Pactiv GRAS notification, FDA also completed a favorable review of a GRAS notification for tasteless smoke, which contains CO, to protect the taste, aroma and color of seafood. 15/ FDA and FSIS, therefore, had a familiarity with the underlying data supporting the GRAS status of CO containing systems in the processing of foods.

The Precept Foods technology involved a similar application of CO as the Pactiv system with an atmosphere of 0.4% CO, with the balance being approximately 35% CO_2 and 65% N_2. The Precept Foods system differed from the Pactiv system in that the modified atmosphere containing CO remains in contact with the meat until the package is opened by the consumer. The technology also differs in that Precept Foods, rather than the retailer, applies the "use or freeze by" date. Given the similarities with the GRAS notification submitted by Pactiv, Precept Foods initially thought its packaging system would be covered by GRN 83. Relying upon the scientific data summarized in GRN 83 and its own corroborating studies, Precept Foods contacted FSIS and asked the agency to recognize the safety and suitability of its new low oxygen system with CO. 16/ FSIS decided the slight differences in the technology warranted the filing of a separate GRAS notification by Precept Foods. 17/

12/ *Id.* at 18941.
13/ *Id.*
14/ GRN 83, Document 100568-100829.
15/ GRN 000013, Letter to Martin J. Hahn from Ms. Janice F. Oliver, Deputy Director, CFSAN, FDA (March 10, 2000) (copy accessed Aug. 9, 2007 at http://www.cfsan.fda.gov/~rdb/opa-g015.html).
16/ Letter to Robert Post, Labeling and Consumer Protection Staff, FSIS, USDA, from Gary Kushner and Ann Boeckman, Hogan & Hartson LLP (July 2, 2003), Document 10001-100061.
17/ Letter to Robert Post, Labeling and Consumer Protection Staff, FSIS, USDA, from Lane A. Highbarger, Division of Biotechnology and GRAS Notice Review, CFSAN, FDA (Sept. 11, 2003), Document 100062-100064.

Precept Foods filed a GRAS notification with FDA on January 6, 2004 providing the data and information supporting the GRAS status of CO when used as a component in a MAP system. 18/ Given the similarities between the Precept Foods and Pactiv systems, the Precept Foods GRAS notification incorporated by reference all of the data submitted by Pactiv in GRN 83. Stated differently, Precept Foods did not resubmit data and information that already had been covered in GRN 83. Precept Foods also used the same approach to assess the safety of its MAP system containing CO as other modified atmosphere systems. Precept Foods compared CO intake estimated to result from the specific modified atmosphere of interest to national health-based standards for acceptable exposure to CO in ambient air. 19/ Based on national, health-based standards for CO exposure, Precept Foods concluded that the use of CO at 0.4% in a MAP system for fresh meats poses no health or safety concern and is not reasonably expected to result in any measurable levels of carboxymyoglobin in the blood of those who consume treated meat or who are nearby when one or more packages of case ready meat are opened. This conclusion is consistent with the conclusion of Sorheim, et al. (1997) in the published literature that "it is highly improbable that CO exposure from meat packaged in an atmosphere containing up to 0.5% will represent a toxic threat to consumers through the formation of COHb [carboxyhemoglobin]." 20/

Precept Foods concluded that the intended use of CO is GRAS on the basis of scientific procedures at the trace concentrations used in the MAP system on the basis of the published data, including toxicology studies evaluating the safety of CO. As the basis for its GRAS determination, Precept Foods relied on conclusions in the published literature and generally accepted scientific data, and incorporated by reference GRN 83, including the finding of the panel of experts convened by Pactiv that issued an opinion supporting the GRAS status of CO. Moreover, the use of CO in retail packages has an established safety record in Norway. A system widely and safely used for nearly twenty years in a country such as Norway clearly meets the "reasonable certainty of no harm" standard.

In addition to demonstrating there are no toxicological concerns under the intended conditions of use and the proposed use of CO is GRAS, Precept Foods also submitted information addressing the suitability of using a CO MAP system in meat products. As part of any GRAS notification for use on meat or poultry products, FSIS consistently asks companies to submit information demonstrating the suitability of the substances intended for use in meat products or processing.

18/ GRN 143, Document 100081-100110.

19/ In its GRAS notification, Precept Foods estimated that exposure to CO would be 0.054 mg CO per meal of cooked meat, assuming meat absorbs 30% of the CO in the package, an 85% reduction in CO exposure due to cooking of the meat, and 100% absorption by the consumer. Alternatively, if 100% of the CO in the package were absorbed and 100% of the CO is consumed, Precept Foods estimated that a consumer would be exposed to 1.2 mg of CO. Further, if the consumer were exposed to 100% of the CO in the package, the consumer would only be exposed to 2.18 mg of CO. These exposure amounts are well below the safety limits set by the Environmental Protection Agency (EPA) and OSHA. EPA's National Ambient Air Quality Standard is 9 ppm CO in air, resulting in the inhalation of 52 mg of CO in 8 hours. The OSHA Permissible Exposure Limit is 50 ppm in air, resulting in the inhalation of 290 mg CO in 8 hours.

20/ Sorheim, et al., (1997), Document 100845-100850.

The suitability analysis relates to the effectiveness of the GRAS substance in performing the intended purpose of use and assurance that the conditions of use will not result in an adulterated product or one that misleads consumers. 21/ For purposes of its suitability analysis, FSIS asked for data demonstrating that CO does not significantly change key meat characteristics and does not mask spoilage.

Precept Foods commissioned three studies to substantiate the suitability of the planned MAP system. The first study evaluated the effects of temperature abuse on ground beef stored in different atmospheres and concluded that meat stored in a CO atmosphere (0.4%) does spoil and emanate a noticeable odor. 22/ The second study examined shelf life, bloom, and cooked color of ground beef packaged in varying levels of CO. 23/ The third study examined the shelf life of boneless beef strip steaks and top round steaks packaged in a barrier lid stock back-flushed with 0.4% CO, 35% CO_2, and the balance as N_2. In this study samples were found to maintain acceptable quality for at least 42 days. Microbiological, chemistry, color, odor, and cooked evaluations showed no signs of spoilage over this period of time. 24/

These studies confirmed that the use of CO in the Precept Foods system will not mask spoilage and will perform in a manner comparable to similar systems, including other CO packaging systems that FDA and FSIS previously deemed acceptable. Specifically, a CO-containing environment will allow meat to maintain a desirable color but will neither inhibit microbial growth nor affect the characteristic odor or other indicators (e.g., gas or slime formation) of meat spoilage. The ability of meat packaged in CO to spoil and to emanate off-odors has been reported in the published literature (Sorheim et al., 1999). 25/

Thus, the data submitted to FDA and FSIS convincingly established that the proposed use of CO in a MAP system is GRAS and does not present any unique toxicological or safety concerns. The extensive published information on the safety of CO establish there is general recognition among experts qualified by scientific training and experience to evaluate safety and that the proposed use of CO presents a "reasonable certainty of no harm," which is the safety standard required for GRAS substances. The data also demonstrated the suitability of CO in the MAP system. Perhaps most important, the scientific experts reviewing the GRAS notification within FDA, in consultation with the individuals at FSIS with extensive expertise on reviewing the

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21/ Letter to Dr. Lane Highbarger, Office of Food Additive Safety, CFSAN, FDA, from Dr. Robert Post, Labeling and Consumer Protection Staff, FSIS, USDA (Apr. 28, 2004), Document 100114-100116.

22/ John, Wilborn and Catano, Excel Report: "Ground beef abuse study in peelable, low oxygen and carbon monoxide lid stock tray," (May 13, 2003), Document 100012-100015.

23/ Rathje and Catano, Excel Report: "Use of Carbon Monoxide in Lid Stock on Ground Beef. Project #23034" (Feb. 14, 2003), Document 100016-100024.

24/ Ruzek, Hormel Report: "Precept Foods/MAP Packaging, R&D Project #PF002.00," (June 6, 2003), Document 100025-100061.

25/ Sorheim, et al., (1999), Document 100851-100858.

suitability of substances for use in meat and poultry, completed a favorable review of the Precept Foods GRAS notification. 26/

3. Response to Questions

Question 1(a): Does Precept consider these reports [referring to three internal studies conducted by Precept] submitted to FDA and FSIS, to meet standards for publication in a reputable, peer-reviewed scientific journal?

Precept Foods used methodologically valid practices and conducted the studies in a manner that would meet the standards for a reputable peer-reviewed journal. The quality of research done within the research and development departments of individual companies is often of the same quality as that done by universities, but industry research is generally not published because it usually contains sensitive and proprietary information that is used to develop and differentiate products within a very competitive marketplace. Precept Foods did not conduct these studies with the intent of seeking publication in peer-reviewed journals. Nor is Precept Foods required to do so under the applicable GRAS standard.

It is well recognized that GRAS notifications can be corroborated by unpublished data. The FDA position is clear. The safety of GRAS substances must be established through "generally available and accepted scientific data, information, methods, or principles which ordinarily are published and may be corroborated by unpublished scientific data, information, or methods." 27/ The Precept Foods GRAS notification satisfied this requirement. GRN 143 and GRN 83 summarize the extensive published safety data supporting the GRAS status of CO in MAP systems. The Precept Foods notification established that the use of CO in MAP systems met the reasonable certainty of no harm standard by demonstrating, using established scientific principles and data, that the use of CO at 0.4% in a MAP system for fresh meats poses no health or safety concern and is not reasonably expected to result in any measurable levels of carboxymyoglobin in the blood of those who consume treated meat or who are nearby when one or more packages of case ready meat are opened. A similar conclusion is reached in GRN 83 and by the published literature.

The three studies mentioned by the Committee corroborated information in the published literature regarding the suitability of CO-containing systems by evaluating the effect of such systems on color. One of the studies specifically focused on whether the CO-containing system would mask spoilage under abusive conditions. These three studies established the effective concentration of CO in a modified atmosphere, establish a suitable shelf life, and confirm that the systems will not adversely affect meat characteristics, including the signs of spoilage. Precept Foods designed the studies primarily to address issues that could be raised by FSIS as it conducted its suitability analysis. After reviewing the data submitted in the GRAS notification, FSIS concluded the proposed use of CO was suitable for application on meat products.

26/ Letter to Gary Jay Kushner and Anne M. Boeckman from Laura Tarantino, Director, Office of Food Additive Safety, CFSAN, FDA (July 29, 2004), Document 100148-100150.
27/ Proposed 21 C.F.R. § 170.30(b); 62 Fed. Reg. at 18960.

Question 1(b): Does Precept intend to publish these reports? If not, why not?

No. As explained above and in GRN 143, the published literature supports the GRAS determination that CO is safe for the intended conditions of use, raises no material questions about the safety of CO and reflects no significant conflict of expert opinion regarding key safety factors.

Question 1(c): How does Precept respond to the allegation that some of the above reports fail to include all data, report only mean values – without a measure of variability, fail to include replicate results, or fail to support conclusions with data?

Precept Foods used methodologically valid practices and procedures when developing and conducting the studies. Precept Foods shared with FSIS and FDA the information the agencies needed to evaluate the suitability of the MAP system containing 0.4% CO. The studies supported the proposed shelf life for products in CO MAP systems and confirmed conclusions in the published literature that meat packaged in a CO containing environment will produce noticeable signs of spoilage.

Although the studies primarily reported Mean values, these values were statistically analyzed to include Standard Error, Median, Standard Deviation, Sample Variance and Range. The Hormel study also involved replications of the primals. 28/ Dr. Bruce Paterson and Dr. Forrest Dryden helped design the Hormel test protocol and interpret the data. Moreover, the study results are consistent with earlier exploratory studies conducted by Hormel R&D and Cargill and discussed in response to question 4(a), below, and with studies reported in the Precept Foods patent application, which included a statistical analysis of the odor scores. 29/ These studies further corroborate the data submitted to FSIS establishing that the Precept Foods MAP system will perform in a manner comparable to similar systems deemed safe and suitable.

Any potential concern regarding the reporting of only mean values was addressed in a follow-up submission to FSIS. In a May 12, 2004 letter to Dr. Robert Post, Director of the FSIS Labeling and Consumer Protection Staff, Precept Foods submitted additional studies supporting the

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28/ The rigor that went into designing this test, as outlined in Table 1 attached to the study, is further emphasized. Two different beef sub-primals (strip loins and top rounds (were evaluated – each one was replicated six times (six different strip loins, six different top rounds). A total of 252 packaged samples (tests and control) were manufactured and analyzed. The test was designed to evaluate the samples after spending a specified period of time in storage and in the display case. As shown in table 1, C1-10-13 means this control sample was held in boxed storage for 10 days and then placed in the display case for 3 days before being sent to the lab for micro/chem. analysis (day 13). T1-20-38 means this test sample was held in boxed storage for 20 days prior to being placed in the display case and was then held in the display case for 18 days before being sent to the lab (day 38); See *infra* note 79 for study and data, Document 400015-400412.

29/ Patent Application, "A Method of Using Lactate and Carbon Monoxide to Improve the Quality of Fresh Meat," Document 100833-100844.

conclusions drawn from these initial suitability studies. 30/ Specifically, Precept Foods provided FSIS with a revised copy of the ground beef study (Use of Carbon Monoxide in Lid Stock on Ground Beef; Project #23034). Precept Foods expanded this revised study to include additional data points collected through 27 days in support of a shelf life of 28 days for ground beef products packaged in the Precept Foods system. In addition, Precept Foods provided FSIS with information regarding the relationship between subjective color assessments and "a* values" used in the ground beef study. 31/

Precept Foods designed the studies for purposes of assessing the suitability of CO in the MAP system using standard protocols that typically are conducted for these type of studies. The final reports contained the data and information that FSIS needed to complete its analysis. Regardless of the accuracy of the Committee's characterization of the "issues" with the submitted data, FSIS – the agency with extensive expertise in reviewing the suitability of substances in meat and poultry products – found the studies sufficiently designed and the information appropriately robust to support the agency's suitability analysis.

Question 1(d): Were other studies provided to FDA or FSIS in support of GRN 000143 to address these issues?

Precept Foods provided FSIS with additional information confirming that spoilage occurs in untreated meats packaged in the Precept Foods system. In particular, Precept Foods provided a study that sought to compare the effects of different combinations of injection treatments (including untreated controls) and atmosphere on the shelf life of strip steaks packaged in barrier lid stock trays. 32/ The study confirmed that untreated steaks packaged in the planned MAP system do not have significantly different spoilage patterns from steaks treated with antimicrobial agents in the time periods examined (26, 30, and 41 days). The results further confirmed that untreated products packaged in a modified atmosphere containing 0.4% CO, 35% CO_2, and 65% N_2 have an acceptable microbiological profile and may reasonably be expected to be sound and wholesome throughout a 35-day shelf life. Precept Foods also provided FSIS with information explaining the criteria used in this study to determine that the products were acceptable and that spoilage had not occurred. Specifically, Precept Foods provided FSIS with the range of the typical count of psychotropic bacteria found after 41 days. 33/

Furthermore, Precept Foods met with FSIS and FDA in September 2006 and discussed two additional studies regarding the impact of CO on the microbiological quality and safety of ground beef. 34/ These studies showed that the spoilage characteristics of meat packaged in

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30/ Letter to Robert Post, Labeling and Consumer Protection Staff, FSIS, USDA, from Gary Kushner and Ann Boeckman, Hogan & Hartson LLP (May 12, 2004), Document 100117-100133.
31/ Letter to Robert Post, Labeling and Consumer Protection Staff, FSIS, USDA, from Gary Kushner and Ann Boeckman, Hogan & Hartson LLP (May 28, 2004), Document 100135-100141.
32/ See *supra* note 30.
33/ See *supra* note 31.
34/ Power Point Presentation by Mindy Brashears, Ph.D., Texas Tech University (Sept. 29, 2006), Document 100527-100560; See, Brooks, C. et al., Reciprocal Meat Conf. Proceedings (2006), Document 200062-200069.

different atmospheres (traditional overwrap, high-oxygen, and CO) are similar when factors such as age, temperature and source are controlled.

Precept Foods also referenced or submitted the studies, below, in its correspondence with FDA and FSIS regarding GRN 143.

> O. Sørheim et al., *Technological, hygienic, and toxicological aspects of carbon monoxide used in modified-atmosphere packaging of meat*, 8 Trends in Food Sc. & Tech. 307, 311 (1997). 35/
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> O. Sørheim et al., *The storage life of beef and pork packaged in an atmosphere with low carbon monoxide and high carbon dioxide*, 52 Meat Sci. 157-164 (1999). 36/
>
> D.H. Kropf, *Effect of Retail Display Conditions on Meat Color*, 33 Reciprocal Meat Conf. Proceedings 15, 29 (1980). 37/
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> Gamage, S. D., J. B. Luchansky and S. C. Ingham, *Pulsed-field gel electrophoresis typing of Hafnia alvei isolated from chub-packed and retail ground beef*, Letters in Appl. Microbiol. 26 (1998). 38/
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> H. Nissen, et al., *Comparison between the growth of Yersinia enterocolitica, Listeria monocytogenes, Escherichia coli O157:H7 and Salmonella spp. in ground beef packed by three commercially used packaging techniques*, Int. J. Food Micro., Vol. 59, 211-220 (2000). 39/
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> J.H. Silliker and S.K. Wolfe, *Microbiological Safety Considerations in Controlled-Atmosphere Storage of Meats*, Food Tech. 59-63 (Mar. 1980). 40/
>
> Watts, D.A. et al., 1978. *Fate of [^{14}C] Carbon monoxide in Cooked or Stored Ground Beef Samples. J. Agric.* Food Chem. 26, 210-214. 41/

Finally, the Precept Foods GRAS notification incorporated by reference GRN 83 and thereby all studies provided in association with that GRAS notification were also provided to FDA in support of the Precept Foods GRAS notification.

> *Question 1(e): We were told that the food industry practice for firms seeking a GRAS determination by FDA is to generally convene an independent GRAS panel and submit the panel's report as part of their GRAS notification. Apparently*

35/ Document 100845-100850.
36/ Document 100851-100858.
37/ Document 100859-100876.
38/ Document 100887-100891.
39/ Document 100877-100886.
40/ Document 100892-100896.
41/ Document 100897-100903.

Pactiv Corporation convened a GRAS panel to support its GRAS notification for the use of carbon monoxide in its fresh meat packaging system. Did Hormel and/or Cargill convene an independent GRAS panel? If not, why not?

A GRAS panel is not a requirement for a GRAS determination – the requirement is expert consensus regarding safety. There is no genuine scientific dispute regarding the underlying toxicological and other studies supporting the safety of a 0.4% concentration of CO in a MAP system for fresh meat under the intended conditions of use. Moreover, at least two expert panels have reviewed the data on CO and issued opinions supporting its GRAS status. As recognized by this Committee, Pactiv convened an expert panel for its GRAS notification, which Precept Foods incorporated by reference. Dr. Sørheim, Dr. Hunt, and Dr. Cornforth are the three experts on the Pactiv Expert Panel, all of whom support the safety of CO in retail packages. 42/ A GRAS notification for CO submitted by Tysons Foods, which is currently under consideration by FDA and FSIS as GRN 000188, also contains the findings of an expert panel recognizing the GRAS status of the CO in that system. 43/

In addition, several experts have publicly stated their conclusion that low oxygen systems with CO are safe. For example, in a perspective published in *Food Technology,* Professors Joseph Sebranek, Melvin Hunt, Daren Cornforth, and Susan Brewer stated that –

> The claim that CO packaging will result in unsafe products is not scientifically sound. There is no greater risk of pathogenic bacteria associated with CO packaging than with any other packaging system currently used for fresh meat. In fact, a valid argument can be made that CO packaging creates opportunities to increase safety. It is important to realize that the presence or absence of bacteria of public health significance on meat is independent of meat color. 44/

Finally, Dr. Hunt, Dr. Brashears, and Dr. Sørheim have submitted letters to FDA supporting the use of CO in the Precept Foods system. 45/ In addition, other competent and reliable scientific

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42/ See *supra* note 14, Document 100773-100829.

43/ GRAS Notification No. GRN 000188, GRAS Claim for the Use of Carbon Monoxide in Modified Atmosphere Packaging for Red Meat Products 20 (Dec. 22, 2005), Document 101163-101184.

44/ J.G. Sebranek, M.C. Hunt, D.P. Cornforth, and M.S. Brewer, *Carbon Monoxide Packaging of Fresh Meat,* 60 J. Food Tech., No. 5, 184 (May 2006), Document 100904.

45/ Letter to Dr. Laura Tarantino, Office of Food Additive Safety, CFSAN, FDA from Dr. Melvin Hunt, Professor of Meat Science (Jul. 26, 2006), Document 100905-100907; Letter to Dr. Laura Tarantino, Office of Food Additive Safety, CFSAN, FDA from Dr. Mindy Brashears, Texas Tech University (Aug. 23, 2006), (accessed on Aug. 10, 2007 at http://www.fda.gov/ohrms/dockets/dockets/05p0459/05p-0459-c000009-01-vol2.pdf), Document 101191-101215; Letter to Dr. Laura Tarantino, Office of Food Additive Safety, CFSAN, FDA from Dr. Oddvin Sørheim (Sept. 6, 2006) (accessed Aug, 10, 2007 at http://www.fda.gov/ohrms/dockets/dockets/05p0459/05p-0459-c000011-01-vol7.pdf), Document 101216-101218.

experts, such as those in 1(g), below, have expressed their support for the safety of CO-systems. Clearly there is a firm basis for finding consensus among qualified experts regarding the safety of CO packaging in the Precept Foods system.

Question 1(f): Please provide CV for the authors of the reports listed above

A copy of the CV for each of the following authors is attached.

- Graciel R. Catano 46/
- Liza John 47/
- Nancy M. Rathje 48/
- David C. Ruzek 49/
- Barney S. Wilbom 50/

Question 1(g): Please provide names and CV of any experts Precept consulted, and copies of any reports supplied.

The individuals identified below have been instrumental in the development of the data and information supporting the GRAS status and suitability of CO in a MAP system. Some of these individuals are employees of Precept Foods, Cargill or Hormel while others are outside experts. In instances when the individual has prepared an expert report or opinion, we are attaching copies of such reports. The CVs for these individuals also are attached, if available.

- April A. Archer, Cargill, study investigator (CV provided) 51/
- Dr. Alden M. Booren, Michigan State University, food science researcher (opinion regarding CO MAP systems provided) 52/
- Dr. Mindy Brashears, Texas Tech University, food science researcher (CV and various presentations to FDA and USDA regarding CO MAP systems provided) 53/
- Dr. Daren P. Cornforth, Utah State University, food science researcher (CVs and opinion and presentation regarding CO MAP systems provided) 54/

46/ Document 100911.
47/ Document 100912.
48/ Document 100913-100914.
49/ Document 100915.
50/ Document 100916-100917.
51/ Document 100918-100919.
52/ Document 100920-100921.
53/ Document 100922-100989.
54/ Document 100990-101018.

- Dr. Forrest Dryden, former Vice President, Research and Development, Hormel (Retired, CV not provided)
- Curtis J. Cundith, Cargill, research and development (CV provided) 55/
- Dr. Scott J. Eilert, Cargill, research and development (CV provided) 56/
- Dr. Vasilios H. Frankos, ENVIRON Corporation (currently at FDA), (CV and opinion regarding CO MAP systems provided) 57/
- Dr. Melvin C. Hunt, Kansas State University, food science researcher (CV and opinions and presentation regarding CO MAP systems provided) 58/
- Dr. Bruce Paterson, Development Leader, Hormel Foods Corp. (now with Schwan's) (CV not provided)
- Dr. Oddvin Sørheim, MATFORSK – Norwegian Food Research Institute, food science researcher (CVs and opinions and presentations regarding CO MAP systems and presentation 59/

We also are providing the Committee with scientific publications, presentations, and other information in the Precept Foods files that are supportive of the GRAS status of CO.

- T. Aune, *Fresh meat in consumer packaging – a toxicological evaluation of the use of up to 0.5% CO in a gas mixture*, (reference not identified). 60/
- R. Huffman, American Meat Institute Foundation, "Current Events in Case ready Packaging: The Challenge of Managing Meat Color," presented at Meat Industry Research Conference, Hollywood, FL (Oct. 3, 2006). 61/
- H. Nissen et al., *Packaging of ground beef in an atmosphere with low carbon monoxide and high carbon dioxide restrains growth of Escherichia coli O157:H7, Listeria monocytogenes, Yersinia enterocolitica and Salmonella diarizone*, in Food Microbiol. and Food Safety Into the Next Millennium: Proceedings of the 17th Int'l Comm. on Food Microbiol. and Hygiene, Veldhoven, The Netherlands (13-17 Sept. 1999). 62/

55/ Document 101019.
56/ Document 101185-101190.
57/ Document 101020-101035.
58/ Document 101036-101083.
59/ Document 101084-101101.
60/ Document 101102-101106.
61/ Document 101107-101141.
62/ Document 101142-101144.

- R. Solheim, "Consumer purchase probability of beef and pork packaged in different atmospheres," English summary of report O-7224 for MATFORSK, Norwegian Food Research Institute (11 July 1996). 63/
- O. Sørheim, "Discoloration of meat as an indicator of leakages in packages containing a CO gas mixture," English summary of report O-7224.col for MATFORSK, Norwegian Food Research Institute (28 Nov. 1996). 64/

Question 1(h): Please provide copies of all reports submitted by Precept to FDA or FSIS related to GRN 000143.

We are attaching a copy of all reports and correspondence submitted by Precept Foods to FDA or FSIS relating to GRN 143 as Documents 100000-100567.

B. Question 2: Consumer Reliance on Meat Color as an Indicator of Freshness and Safety

1. Background on Spoilage

Meat spoilage has been defined as "any single symptom or group of symptoms of overt microbial activity, manifested by changes in meat odor, flavor or appearance." 65/ Spoilage is highly dependent on the specific type of bacteria present and determining an exact numerical enumeration for spoilage is not absolute. Generally, products will exhibit signs of spoilage with total plate counts in the range of 10^7 to 10^8. Depending on the bacteria present, however, there could be evidence of spoilage with significantly lower plate counts such as 10^4 or with significantly higher plate counts reaching 10^9. 66/ The total plate count by itself, therefore, is not a particularly reliable indicator of spoilage.

In an anaerobic environment such as that in the CO MAP system, lactic acid bacteria will predominate, displacing pseudomonads and other aerobic bacteria. 67/ Although lactic acid bacteria typically produce fewer malodorous compounds than the more aerobic bacteria, this does not mean that spoilage is "masked;" it simply means that good quality shelf life is extended because off-odors may not develop as rapidly. In addition to lactic acid bacteria, low oxygen

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63/ Document 101145-101157.

64/ Document 101158-101162.

65/ Gill, C.O. The control of microbial spoilage in fresh meats. *In* Advances in Meat Research, vol. 2, Meat and Poultry Microbiology. Pp. 49-88 A.M. Pearson and T. R. Dutson (Eds.) AVI Publishing Company Inc: Westport, CT. (1986), Document 200011-200032.

66/ Lund, BM, Baird-Parker, TC, Gould, GW, "The Microbiological safety and Quality of Food," Aspen Publishers, Inc., Gaithersburg, MD (2000), pg 376, Document 200000-2000001; Doyle, PD, Beuchat, LR, Montville, TJ, "Food Microbiology Fundamentals and Frontiers," ASM Press, Washington DC, pg 95, Document 200002-200004; Jay, MJ, "Modern Food Microbiology" (6th Ed), Aspen Publishers, Inc., Gaithersburg, MD (2000), pg 71-75; Document 200005-200010.

67/ Gill (1986) at 283-84, 286, 288-89, Document 200011-200052.

environments with CO may contain facultative anaerobes such as *Hafnia alvei* and *Serratia liquefaciens*. These microorganisms produce putrescine and cadaverine, which are very malodorous compounds. *Heterofermentative lactics* and *enterics* can also produce copious amounts of gas, causing swelled packages. 68/ At the end of shelf life or after extended temperature abuse, spoilage odors and gassy packages will develop in product packaged in a low oxygen CO-containing atmosphere. Sørheim et al. (1997) noted that "consumers will be able to detect spoilage by the presence of off-odours." 69/

Microbial shelf life will continue to be determined, as it always has been, on such considerations as anticipated microbial growth, product composition, and distribution conditions, including storage temperatures. Product shelf life is not a static issue that is addressed with one or two studies and then forgotten. Responsible companies, such as Precept Foods, maintain aggressive quality control programs in which product shelf life is continually monitored at the retail level and adjusted on a case-by-case basis. As discussed in detail below, the data and information submitted as part of GRN 143 supported a targeted shelf life of 28 days for ground beef and 35 days for whole muscle meats. At present, Precept Foods is currently using more conservative dates, such as 24 days for most whole muscle cuts of beef and pork.

Shelf life determinations are based primarily on quality factors. The safety of any meat product is based on an absence of pathogens, the control of spoilage organisms, and adequate handling, including cooking. CO is not reasonably expected to stimulate or otherwise affect pathogen growth. CO does not affect the ability of a MAP system to slow the growth of microorganisms, nor does it affect the characteristic odor of meat spoilage. The only impact of CO is stabilization of the product color. While consumers do consider the color of meat in assessing product quality, it is only one – and not necessarily the primary one – of many factors.

2. Response to Questions

"2(a)" We are interested in any special labeling or educational means that Precept employs to inform the consumer that meat has been treated with carbon monoxide to make it appear red indefinitely, and that its color should not be used to judge freshness or safety, since the packaged meat can appear to be edible well beyond the point of microbial spoilage.

The label on all Precept Foods case ready meats has a clear and prominent "use or freeze by" date. The attached pictures show the prominence of the date code statement and its placement on both the top and bottom of the meat package. 70/ While FSIS does not require the "use or freeze by" dates on fresh meat, Precept Foods includes a prominent date on each of its packages. As

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68/ Gamage, S. D., J. B. Luchansky and S. C. Ingham, *Pulsed-field gel electrophoresis typing of Hafnia alvei isolated from chub-packed and retail ground beef*, Letters in Appl. Microbiol. 26 (1998), Document 100887-100891.

69/ O. Sørheim, et al., *Technological, hygienic, and toxicological aspects of carbon monoxide used in modified atmosphere packaging of meat*, 8 Trends in Food Sci. & Tech. 307, 311 (1997), Document 100845-100850.

70/ Product shots showing date codes and labeling generally. Documents 200033-200038.

discussed in more detail below, the data establish that consumers rely on such "use or freeze by" dates when making decisions about whether to purchase or consume a product. Data in the literature as well as that generated by Precept Foods show that CO does not mask spoilage and in the unlikely event of abuse, signs of spoilage (e.g., odor, bulging packages, slime) will be present. Importantly, this scenario is the same with other foods that can spoil when in packaged form such as vacuum-packaged meats and other packaged perishable foods such as milk and yogurt. For most perishable foods, including fresh meat, consumers have a long history of relying upon open code dates along with odor and other signs that the product may not be suitable for consumption.

> *"2(b)" Has Precept conducted studies that demonstrate consumers are able to recognize meat that is aged, spoiled, or temperature abused in the face of contradictory visual cues that they have historically relied upon? Please provide to the Committee any studies or other documents Precept has prepared or relied upon relating to the ability of consumers to detect spoilage where meat appears red and fresh looking.*

Aside from the acknowledged long history of consumers relying upon open code dating and other signs of spoilage, several studies have been conducted on the ability of consumers to detect spoiled meat products through odor and/or bulging packages when the color of the meat is otherwise acceptable.

A study by Excel Corporation, which was submitted as Attachment A of Precept's submission to FSIS, examined the effects of temperature abuse on ground beef stored in different atmospheres. 71/ Three MAP treatments were studied: a CO system with "peelable" trays (containing 0.4% CO, 35% CO_2, and 64.6% N2), a CO lid stock system (containing 0.4% CO, 35% CO_2, and 64.6% N2), and a low oxygen system (containing 35% CO_2 and 65% N2). All trays were stored initially at 35°F for 5 days. After 5 days, trays were stored at 50°F under dark conditions; on day 7, the film on the "peelable" tray was removed and all trays were stored at 50°F under lighted conditions. Microbial analysis, odor analysis, and color scores were performed. Spoilage characteristics were found to be similar for all three atmospheres. On day 7, all trays displayed increased microbial counts but did not have a detectable odor. On day 9, however, the film on all trays was bulging, all samples had a detectable odor, and elevated microbial counts were measured for all treatments. It was concluded that meat stored in a CO atmosphere (0.4%) does spoil and emanate a noticeable odor.

Research conducted by Texas Tech University and presented at the 2006 Reciprocal Meat Conference further confirmed CO did not mask signs of spoilage. 72/ Trained panelists and

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71/ John, L., B. Wilborn, and G. Catano, (May 13, 2003) "Ground beef abuse study in peelable, low oxygen and carbon monoxide lid stock tray," Excel Corp., Document 100012-100015.

72/ J.C. Brooks, M.M. Brashears, M.F. Miller, A.R. Hoyle, J.D. Kellermeier, and J.M. Mehaffey. 2006. "New Developments and Future Needs in Fresh Meat Packaging: The Spoilage Characteristics of Ground Beef Packaged in High-Oxygen and Low-Oxygen Modified

consumers evaluated the interaction of color change, odor scores, and microbial counts in ground beef patties packaged in a variety of MAP systems. The study evaluated five treatments: traditional foam tray with film over-wrap, high oxygen (80% O_2 and 20% CO_2), high oxygen with rosemary extract, low oxygen carbon monoxide (0.4% CO, 30% CO_2, and 69.6% N_2), and low oxygen carbon monoxide with rosemary extract. The trained and consumer panelists evaluated the beef patties for changes in color and odor through 21 days of simulated retail display conditions, including continuous fluorescent lighting. The trained panelists evaluated color and odor on scales of 1-5. Consumer panelists were asked if the patties were of good color, how likely they would be to purchase the product based on color, if the meat smelled fresh, and how likely they were to consume the meat based upon odor. Microbial loads, consisting of total aerobic plate counts (APC), Lactobacilli, and psychrophilic aerobes, were determined using standardized methods.

A majority of trained and consumer panelists detected off odors in ground beef packaged in a low oxygen atmosphere with CO after approximately 14 days of storage, which corresponded to a substantial increase in microbial loads. Though such products are not actually "spoiled" unless the off odors are sufficient to cause product rejection, the results do confirm that anaerobic packaging systems with carbon dioxide will not suppress the formation of off-odors. It should be noted that the conditions of this test kept the product in a display case for the duration of the shelf life, conditions not reflective of normal fresh meat distribution.

Consumer research commissioned by the American Meat Institute supports the favorable experience to date with CO MAP systems. 73/ The research, conducted by the Opinion Dynamics Corporation, asked primary grocery shoppers about willingness to purchase and prepare meat based on appearance and odor. When asked about willingness to purchase meat that appeared bright red but was in packaging that appeared to be excessively bulging, most consumers (88%) said that they would be very unlikely (75%) or somewhat unlikely (13%) to purchase such a product. In terms of willingness to prepare and consume meat products, almost all consumers (95%) said they would be very unlikely (90%) or somewhat unlikely (5%) to prepare and consume a product that was bright red but past its use-by date and accompanied by a detectable odor.

These results comport with portions of the survey recently commissioned by the Consumer Federation of America, in which consumers rated qualities used in purchasing meat. 74/ Overall, consumers identified the "use-or-sell-by date" as the single most important factor in evaluating meat to purchase (with 60% reporting to give it a "great deal" or "a lot" of weight). In comparison, 57% gave smell a "great deal" or "a lot" of weight; 52% gave color a "great deal" or "a lot" of weight; 43% gave price a "great deal" or "a lot" of weight; and 30% gave texture a

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Atmosphere Packages." Proceedings of the Reciprocal Meat Conference, University of Illinois at Urbana-Champaign, pp 61-65, Document 200062-200069.

73/ Memorandum dated Nov. 16, 2006, from Larry Shiman, ODC, to Janet Riley, AMI, entitled "Omnibus Questions on Packaging and Color," Document 200070-200071.

74/ Letter to Laura Tarantino, Ph.D., Director, Office of Food Additive Safety, CFSAN, FDA from Chris Waldrop, Deputy Director, Food Policy Institute, Consumer Federation of America (Oct. 3, 2006), Document 200039-200061.

"great deal" or "a lot" of weight. These results show unambiguously that consumers rely on numerous factors in deciding whether to purchase, prepare, and consume fresh meat products, and that open code dating is of particular importance. Other parts of that survey, however, are of limited use in evaluating consumer perceptions regarding low oxygen systems with CO. Significantly, questions relating to consumer perceptions about the use of CO were asked without adequate context. For instance, the questions did not explain why the CO technology is used, that it has been favorably reviewed by both FDA and USDA, that it offers distinct benefits, that it has a history of favorable use in Norway and this country, or how it compares to other packaging systems that have long been used.

The prominent "use or freeze by" dates on the product label, the development of off odors in spoiled product and the consumer surveys summarized above demonstrating the importance of such "use or freeze by" dates when making purchasing and consumption decisions, establish the ability of consumers to recognize meat that has been spoiled. 75/

C. Question 3: Odor and Package Bulging as Purported Indicators of Spoilage

3. Does Precept allege that consumers can adequately detect spoilage in red, fresh-looking carbon-monoxide treated meat by aroma or by the presence of a bulging package?

Consumers are well versed at detecting spoilage in perishable foods, including that of fresh meat. As discussed in the response to Question 2, above, odor is one of the primary means of spoilage detection, while other signs, such as gas (e.g., bulging packages) and slime formation also are used.

3(a) Please explain how the consumer can detect off-odors in hermetically sealed packages at the point of purchase – the point at which consumer deception occurs.

Consumers cannot detect off-odors in hermetically sealed packages of foods of any type at the point of purchase, regardless of whether it is meat, dairy, produce or other perishable foods in such packaging. There is hardly a regular consumer of milk who has not purchased the product in a sealed container only to discover upon opening that it has soured or "turned." Singling out the point of purchase as the purported point at which consumer deception occurs, however, makes little sense for perishable products in sealed containers. Consumers who discover a spoiled product upon its opening can receive a refund by returning it to the store.

75/ The Committee also asked for focus group testing evaluating consumer acceptance of meat whose color is treated with carbon monoxide. We are attaching the results from focus group testing demonstrating consumer acceptance of raw and cooked meat products that are packaged in CO MAP systems. Levin, Nora, "Report of Meat Preparation Focus Groups and In-Home Qualitative" (Nov/Dec 2002), Document 200072-200111; Sorensen Associates Final Report, "T-Bone Steak Beef Durability HVT," (March 2004), Document 200112-200156.

3(b) Has Precept done any studies on what percentage of the population may have difficulty detecting the spoilage odors associated with carbon monoxide-packaged meat?

Precept has not investigated what percentage of the population may have difficulty detecting spoilage odors of meat packaged in low oxygen atmospheres containing CO. The research conducted by Texas Tech University and discussed in 2(b), above, showed consumers can indeed detect the spoilage of meat packaged in a CO MAP system. Moreover, as discussed previously, the odors associated with spoilage of meat in low oxygen atmospheres containing CO have been found to be similar to those associated with meat spoilage in other MAP systems.

To the extent there is a subset of the population that will be unable to detect spoilage odors, these consumers will have difficulty detecting spoilage in any packaged perishable product such as meat packaged in chub packs, meat in vacuum packaging, milk, and many others. Because color is not a reliable indicator of spoilage, there is no reason to single out low oxygen atmospheres containing CO for this type of evaluation.

3(c) Did Precept discuss with FDA the special risks facing anosmic individuals, especially the elderly, who are also at high risk for food-borne illness? If not, why not?

Precept Foods did not discuss with FDA the purported "special risks" facing anosmic individuals. To the best of our knowledge, neither FDA nor FSIS has required studies of such a unique population of consumers for any perishable foods regardless of the type of packaging employed. The anosmic individual will have difficulty detecting spoilage of any packaged perishable product. Because low oxygen atmospheres containing CO do not mask spoilage in fresh meats, they present no unique risks. Moreover, unlike dairy products and fresh produce that are consumed without further processing, raw meat will be subjected to thermal processing, further mitigating any potential food safety issues.

3(d) Does Precept have data describing the percentage of packages that bulge as a result of over-filling during manufacture, changes in elevation during transport, changes in weather or any factors that would tend to make sealed packages bulge? If not, why not?

Precept Foods controls the volume of gas put into the lid stock packages – and, consequently, the amount of bulge in these products – by measuring the dome height of packages immediately following the sealing step. A written and visual description of the dome appearance on ground beef packages is attached. 76/ The optimal amount of gas, as measured from lip of the tray to the top of the dome using a T-bar rule or plastic cut-out templates for pre-determined tray heights, creates a slight (1/8 to 1/4 inch) dome in the retail case, which aids in wicking any condensation to the corners of the package. Too much gas (anything exceeding 1/2 inch) deforms the package, gives it an hourglass or football shape, and prevents the specified number of packages from

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76/ Cargill Meat Solutions, "REDiFresh™ Ground Beef" (undated), Document 300000-300001.

fitting into a shipping container. Overfilled packages are not purposely distributed to customers, and, therefore, the percentage of such packages has not been measured.

Changes in elevation will affect the degree to which a sealed food container will bulge. This bulging is commonly observed in a variety of food products, including potato chips, grated cheese, processed meats, and low oxygen systems containing CO. Customers living in high altitude areas are well accustomed and familiar with the increased bulge resulting from the differences in atmospheric pressure. Spoiled products will still exhibit off odors and/or slime formation allowing consumers in high altitude areas to detect spoiled product. As a result, the percentage of bulging packages resulting from changes in elevation has not been measured.

D. Question 4: Labeled Shelf Life

1. Background on Date Codes

Date codes are not required on meat products. As explained by FSIS in its consumer guidance on product dating, "Use-by" dates are calendar dates provided by the manufacturer to indicate "the last date recommended for the use of the product while at peak quality." 77/ FSIS has recognized and reiterated for consumers that "'Use-by' dates usually refer to best quality and are not safety dates. But even if the date expires during home storage, a product should be safe, wholesome and of good quality – if handled properly and kept at 40°F or below."

All products packed in the Precept Foods CO MAP system display an open date code or "use or freeze by" date. Application of a validated and controlled "use or freeze by" date addresses a major drawback of traditional meat packaging – lack of consistent code dating because the point at which a product will be prepared and displayed for sale is unknown. Reliance on a centrally applied open date code offers a far more objective means of assessing product age and quality than highly subjective measures such as color.

"Use or freeze by" dates are applied by a centralized packing facility and will not vary depending upon the timing of retail display. The use of a centralized packing facility for the finished retail package eliminates all retailer discretion in the process, adding the consumer benefit of an open dating system that is scientifically established, validated, and controlled. In addition to minimizing any risk of cross contamination that can occur in a retail establishment, the use of such a system substantially reduces any risk that the shelf life will be manipulated inappropriately at the retail level. It also provides some assurance that product labels will not be altered following application of the mark of inspection.

As shown in the studies conducted by Opinion Dynamics Corporation and the Consumer Federation of America discussed in question 2(b) above, consumers rely on date codes when making purchasing decisions for fresh meat. Consumer reliance on date codes is further documented in the annual report of U.S. Grocery Shopper Trends, published by the Food

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77/ FSIS Fact Sheet, "Food Labeling, Food Product Dating;" (copy accessed Aug. 8, 2007 at http://www.fsis.usda.gov/fact_sheets/Food_Product_Dating/index.asp), Document 400000-400004.

Marketing Institute. 78/ According to the Trends report, virtually all consumers (99%) are aware of date codes, with 83% of consumers participating in that survey reporting use of date codes with respect to fresh meat and poultry specifically. When asked about the frequency with which date codes are used, 92% of consumers responded that they checked date codes "every time" or "fairly often" and 77% reported discarding foods past the use-by date "every time" or "fairly often." Most participating consumers tied date codes to some degree of health risk: 25% felt eating a food past the code date would present a "serious" health risk; 37% felt it would present "some" health risk; and 30% felt a "slight" health risk would be presented. Though such views may not be appropriate because codes typically are quality- rather than safety-based, the apparent view of date codes as relevant to health further suggests consumers take date codes seriously.

Consumers rely on code dates in numerous contexts, including hot dogs, deli meats, and dairy products. Fresh meat products such as whole muscle cuts and ground beef are no different. "Use or freeze by" dates are important features of many perishable foods, but are only one aspect of product quality. As with milk, yogurt, hot dogs, luncheon meats, retail chub packs, and numerous other products, a "use-by" date is interpreted in light of other factors, such as signs of spoilage.

2. Responses to Question 4

Question 4(a): Please provide the data upon which Precept Foods proposed the 28 and 35 day shelf lives.

Precept Foods submitted to FSIS and FDA two specific studies in support of the company's request for a 28 day maximum shelf life for ground beef and a 35 day maximum shelf life for whole muscle cuts. The shelf life conditions in GRN 143 are guidelines that reflect potential shelf life. Precept Foods selects the "use or freeze by" dates (not to exceed 28 or 35 days, as applicable) most achievable for any particular product in light of the specific conditions of that particular product. The studies submitted with GRN 143 represent only part of the shelf life picture. Precept Foods collected then, and continues to collect today, data to ensure that product of the highest quality is sold to consumers.

As noted above, two studies were submitted with GRN 143 in support of the Precept Foods request for shelf life as a condition of use for the proposed CO packaging system. In the first study, Hormel Foods examined the shelf life of boneless beef strip steaks and top round steaks packaged in a barrier lid stock back-flushed with 0.4% CO, 35% CO_2 and the balance as N_2. 79/ A treatment simulating the Pactiv master bag concept described in GRN 83 was used as a control. Samples were stored in a 38°F cooler prior to display and placed in a 38-40°F simulated retail display case at designated intervals. Control samples were removed from the master bag prior to display. After 3-5 days in the display case, samples were photographed, opened for odor

78/ Food Marketing Institute, U.S. Grocery Shopper Trends 68-69, 115, 117, 121 (2006), Document 400005-4000014.

79/ David Ruzek, Precept Foods/ MAP Packaging (R&D Project #PF002.00) (June 6, 2003), Document 400015-400412.

evaluation, and sent to the lab for microbiological and chemistry analysis. Some samples were also cooked and evaluated for flavor.

Overall, both test and control samples were found to maintain acceptable quality at least 42 days. Microbiological, chemistry, color, odor, and cooked evaluations showed no signs of spoilage over this period of time. Although total Mesophilic and Psychrophilic bacteria counts increased throughout the study, the counts were deemed acceptable and not indicative of spoilage. The pH and TBA values remained constant, suggesting that no significant microbial spoilage or oxidative rancidity, respectively, had taken place. All samples were judged to be acceptable for odor, and no cooked samples exhibited unacceptable flavors.

Because the steaks in this first study were injected with an antimicrobial solution, Precept Foods submitted additional information to FSIS confirming the spoilage pattern associated with untreated meats packaged in the same modified atmosphere. 80/ The study sought to compare the effects of different combinations of injection treatments (including untreated controls) and found that the untreated steaks did not have significantly different spoilage patterns from those that were treated with antimicrobial agents. After 41 days, the microbial, odor, and chemistry results justified a 35 day shelf life for both untreated and treated steaks packed in a MAP with 0.4% CO.

An additional study provided with GRN 143, conducted by Excel, examined shelf life, bloom, and cooked color of ground beef packaged in varying levels of CO. 81/ Four treatments were studied: three CO treatments at 0.2%, 0.3%, and 0.4% (with 35% as CO_2 and the balance as N_2) in a plastic tray with a barrier film, and one CO treatment at 0.4% in a peelable film tray. Trays were stored in a cooler at 35° F and removed and placed under conditions simulating retail display at designated intervals. Microbial sampling was conducted "pre-display" and "post display," objective and subjective colors were read daily, residual oxygen levels and product off-odors were analyzed daily, cooked color and sensory evaluations were performed, and bloom was assessed. Based on microbial sampling throughout the test, it was concluded that there were no major differences in microbial counts between treatments. On day 20, a greater increase in aerobic plate count was noted for the peelable treatment than the lid stock treatments. This was described as a "trend" and attributed to removal of the product from a high CO_2 environment.

Color was deemed acceptable on the 0.3% CO and 0.4% CO lid stock treatments throughout the test. The 0.2% CO treatment received a lower color score. The peelable treatment received a higher color score than the 0.2% treatment, but a lower score than other CO treatments. Evaluations of cooked colors on days 9 and 16 showed normal cooked colors in all

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80/ Summary of Hormel Foods Research Report, in Letter to Dr. Robert Post, Food Safety and Inspection Service, from Gary Kushner and Ann Boeckman, Hogan & Hartson, LLP (May 12, 2004), Document 100117-100133.

81/ Nancy Rathje and Graciel Catano, Use of Carbon Monoxide in Lid Stock on Ground Beef (Project #23034) (Feb. 14, 2003), Document 400413-400427, 400438-400461; Color photographs for this and studies conducted on Feb. 6, 2003, *infra* note 86, and Feb. 13, 2003, *infra* note 87, are attached in Documents 400553-400602.

concentrations of CO with no pinking at 145°F or 170°F. No off or spoiled odors or flavors were noted for any treatments through day 16.

A revised summary of this study, also submitted to FSIS, provided additional information regarding the microbial count for the ground beef. After 27 days in storage the ground beef had a microbial count of slightly more than 7-log, depending upon whether the product was tested on day 27 or after 3 days of display. Thus, the authors concluded that "on the basis of these data, measured to a total shelf life of 30 days (27 days plus 3 days display), a shelf life of 28 days for ground beef packaged in this format is justified." 82/

In addition to the studies submitted with GRN 143, Hormel Foods conducted for Precept Foods a number of exploratory shelf life studies on intact muscle cuts. Excel/Cargill similarly conducted exploratory shelf life studies examining the shelf life potentially achievable under the Precept Foods packaging system. The following studies were conducted prior to the submission of GRN 143:

- Heidi Edwards, Hormel Foods Research Report R&D Project # PF002.00; Sensory Study #3653; "Always Tender Beef - New York Strip Steak – Various Pump Levels (Sept. 27, 2002). 83/

- Hormel Foods Research Report R&D Project # PF002.00; Sensory Study #3655; Oct. 8, 2002 "Always Tender Beef – Chuck Steak– Various Pump Levels. 84/

- Heidi Edwards, Hormel Foods Research Report R&D Project # PF002.00; Sensory Study #3656; Oct. 9, 2002 "Always Tender Beef – Top Round Steak – Various Pump Levels. 85/

- Nancy Rathje and Graciel Catano, Use of Carbon Monoxide in Lid Stock on Beef Cuts and Grind (Project # 23034) (Feb. 6, 2003). Strip steaks were stored for 3, 10, 17, 24, and 31 days and then were displayed for 5 days. At 22 days (17 days storage and 5 display days) microbial counts for product treated with 0.4% CO were less than log 5 for aerobic plate counts, anaerobic counts, and LAB counts. In addition there were no off or spoiled odors or flavors on any of the product through day 24. This study is significant

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82/ Nancy Rathje and Graciel Catano, Use of Carbon Monoxide in Lid Stock on Ground Beef (Project #23034) (Feb. 14, 2003, Revised May 12, 2004) in Letter to Dr. Robert Post, Food Safety and Inspection Service, from Gary Kushner and Ann Boeckman, Hogan & Hartson, LLP (May 12, 2004), Document 100119-100128.
83/ Document 400428-400437.
84/ Document 400462-400471.
85/ Document 400472-400481.

because it shows the packaging system can achieve acceptable microbial, odor, and flavor profiles throughout the stated shelf life for these products. 86/

- Nancy Rathje and Graciel Catano, Use of Carbon Monoxide in Lid Stock on Beef Cuts (Project # 23034) (Feb. 13, 2003). Inside round steaks were stored for 3, 10, 17, and 24 days and then were displayed for 4 days. At 28 days (24 days storage and 4 days display) microbial counts for product treated with 0.4% CO were less than log 6 for aerobic plate counts, anaerobic counts, and LAB counts. In addition there were no off or spoiled odors or flavors on any of the product through day 27. 87/

- Barney Wilborn, Impact of Tray Footprint on Beef in CO in Barrier Lid stock (Oct. 13, 2003). This study examined the effect of the tray size on the performance of beef packaged in a CO MAP system. The study found that product performed well in the display case from day 7 to day 43; however, off odors did begin to develop at day 35. Microbial counts were found to be acceptable for all cuts throughout the 43 day test and similar to vacuum packaged product approximately the same age. This study shows packaged product can be acceptable past the shelf life established in the GRAS notification. The study also demonstrates microbial load is not the only indicator of spoilage, as odor developed before unacceptable microbial levels were reached. 88/

- Barney Wilborn, Shelf Life Performance of Enhanced Beef, Enhanced Pork and Ground Beef in Various Tray Depths of CO in Lid stock (Oct. 31, 2003). Although the objective of this study was to examine the appropriate tray depth for product in a MAP system containing CO, microbial analysis was also conducted. After 29 days (26 days storage and 3 display days) all microbial cuts for beef counts were approximately log 6 or lower. Microbial counts for pork cuts were approximately log 5 or lower after 35 days (32 days storage and 3 days display). Ground beef samples revealed microbial counts of around log 7.5 after 16 and 20 days. This study does not have associated odor and other sensory data but indicates microbial levels were acceptable for beef and pork cuts. The ground beef microbial levels are in the range typically associated with spoilage, but spoilage cannot be confirmed without odor and other sensory data. 89/

- Dave Ruzek, Hormel Foods Research Report; Precept Foods/MAP Packaging (Dec. 6, 2003). This study examined the shelf life of T-bone steaks cut from different aged raw materials – 7 and 14 day old beef short loins. The steaks were packaged in a MAP system with .35% carbon monoxide. The author of the report concluded that a code date

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86/ Document 400482-400520; Color photographs for this and studies conducted on Feb. 13, 2003, *infra* note 87, and Feb. 14, 2003, *supra* note 81, are attached in Documents 400553-400602.

87/ Document 400521-400552; Color photographs for this and studies conducted on Feb. 6, 2003, *supra* note 86, and Feb. 14, 2003, *supra* note 81, are attached in Documents 400553-400602.

88/ Documents 400603-400681.

89/ Documents 400682-400742.

of 28 days could be recommended for bone-in product packaged in such a system with 0.35% CO. 90/

- Graciel Catano, Enhanced vs. Nonenhanced in CO Lidstock (PRP 23270) (Sept. 19, 2003). This study was conducted to evaluate the impact enhancement may have on the performance of lidstock product packaged in CO. Enhanced product performed as well as non-enhanced in overall color and outperformed in lower microbial counts over 31 days of observation. 91/

Finally, the companies gained a wealth of knowledge through shelf life testing conducted using the Pactiv system described in GRN 83. This system served as the foundation for the Precept Foods system. Notably, the Pactiv system produces a comparable shelf life to that proposed by Precept Foods in GRN 143. Pactiv commissioned a study where meats were packaged in the Pactiv system, then stored at 35°F or 43°F for up to 35 days. In discussing the study results, the authors stated that "this suggests that quality products that have been handled in a sanitary fashion can be stored in the MAP system up to 35 days without compromising microbial quality. 92/ Thus, there is ample evidence that a shelf life of 28 or 35 days can be achieved for most products packaged in a CO MAP system.

> *Question 4(b): Were these periods of shelf life established under ideal laboratory conditions or under conditions reflecting the actual conditions of distribution, storage, and retail and consumer handling that the treated meat is likely to encounter? If these periods were established based upon ideal laboratory conditions, please explain why actual conditions were not considered when Precept Foods originally submitted its GRAS notification to FDA.*

Precept Foods carefully designed the shelf life studies to simulate conditions of centralized production, distribution, and display of retail beef and pork. In other words, most of the Precept Foods shelf-life studies were conducted under laboratory conditions designed to simulate average distribution and retail display case conditions. Specifically, initial or preliminary shelf life studies are conducted using product processed in a pilot plant under conditions similar to those in production facilities. Product is stored at temperatures typically found in retail storage facilities and then displayed in retail display cases that mimic the typical temperature, lighting, and defrost cycle conditions in grocery store display cases.

Thus, the conditions used in the studies submitted with GRN 143 did reflect typical retail temperature controls. This is consistent with the design of shelf life studies in the industry where a *potential* shelf life is established. Moreover, the application of appropriate temperature controls is a fundamental good manufacturing practice (GMP) requirement for all perishable foods. The intended conditions of use on which a GRAS assessment is based necessarily assume GMP compliance. Temperature abuse, therefore, is not part of the intended conditions of use of a GRAS substance.

90/ Documents 400743-400883.
91/ Document 400884-400909.
92/ GRAS Notification No. 83 (attachment 4) at 168, Document 100729-100760.

Nonetheless, to address the potential for temperature fluctuations, Precept Foods tested the performance of the CO MAP system under abusive conditions and confirmed that the system would not mask spoilage. 93/ Precept Foods included this study, which has been discussed previously, as part of its GRAS notification. In addition, GRN 143 also pointed to practical experience with other modified atmosphere packaging systems that present nearly identical issues, as well as almost twenty years of experience in Norway. 94/ This information is direct evidence of actual distribution, retail conditions, and consumer behavior and was included in the Precept Foods GRAS determination.

Finally, in addition to initial or preliminary shelf life determination studies, Precept Foods also conducts routine shelf life verification studies. These studies either adopt or simulate normal production practices. For those studies that adopt normal production practices, product is produced in case ready facilities under normal production, stored in the plant's finished goods cooler, shipped by truck to the product distribution center, and stored in the raw material/ finished goods cooler until the specified display period. Product display and evaluation is then conducted based on the specific protocol for the particular study. Through these shelf life verification studies, as well as through ongoing monitoring, including monitoring of temperature control in retail settings, Precept Foods sets shelf life on a case-by-case basis. Thus, Precept Foods continually takes into consideration actual or simulated conditions of distribution, storage, and retail display when determining the shelf life for its products.

> *Question 4(c): Was Precept Foods aware of the EC opinion prior to the submission of GRN 000143? If so, why was this opinion not provided to FDA as part of the GRAS notification – consistent with FDA's requirement that GRAS notifications must include a "comprehensive discussion of any reports of investigations or other information that may appear inconsistent with the GRAS determination?*

Precept Foods was aware of the Opinion of the European Commission's Scientific Committee on Food prior to the submission of GRN 143. It was unnecessary to specifically address the Scientific Committee on Food opinion in GRN 143 because this opinion views the intended use of CO in a favorable light. Specifically, the Committee reviewed toxicological and microbial aspects of CO, and concluded as follows: "[T]here is no health concern associated with the use of 0.3%-0.5% CO in a gas mixture with CO_2 and N_2 as a modified atmosphere packaging gas for fresh meat provided the temperature during storage and transport does not exceed 4°C." 95/ Precept Foods views the temperature requirement as consistent with the GRAS determination because cold chain management is important for any perishable food, not simply fresh meats marketed in MAP systems.

93/ Liza John, Barney Wilborn, and Graciel Catano, Ground Beef Abuse Study in Peelable, Low Oxygen Carbon Monoxide Lid stock Tray, May 13, 2003, Document 400910-400930.

94/ Scott Eilert, What I learned in Norway ... A Trip Report, July 16, 2002, Document 400931-400938.

95/ Opinion of the Scientific Committee on Food on the use of carbon monoxide as a component of packaging gases in modified atmosphere packaging for fresh meat, SCF/CS/ADD/MSAd/204 Final (18 Dec. 2001), Document 400939-400947.

Equally important is that the legal status of a material in the European Union or any other political system has no bearing on a GRAS assessment in the United States. There are numerous instances in which substances and technologies are deemed safe in the United States but not Europe (and vice-versa), as evidenced by the longstanding disputes over beef hormones, regulation of modern biotechnology, and the so-called "precautionary principle." What matters from the perspective of the "common knowledge" element of a GRAS determination is not the policy of any particular government; the issue is whether qualified experts consider the substance to be "safe" for its intended conditions of use. Governments may reject an additive for reasons other than safety, or they may choose a more conservative position than the scientific evidence would suggest is necessary. In Europe, for example, a food additive may be rejected if a technological need for the additive is not demonstrated. 96/

A letter from the European Commission Health & Consumer Protection Directorate-General provides insight into the distinctive policy approaches taken in the United States and Europe. In addressing whether to recommend changes to the existing authorizations for nisin, a GRAS antimicrobial in the United States, the letter stated that the "Commission agrees with the principle that anti-microbial agents should not be used in the food production chain." Though the Commission was actually contemplating an exception for nisin, the fact remains that such a principle is obviously at odds with U.S. law and policy. U.S. agencies are no more bound to accept EU policy on CO than on antimicrobials, biotechnology, or any other matters in which different points of view are evident.

> *Question 4(d): How does Precept Foods reconcile the substantial difference between the shelf lives of 11 and 14 days (for ground beef and beef loin steaks, respectively) reported in the EC Opinion and the 28- and 35-day self lives proposed by Precept Foods? Was this difference discussed with FDA? If not, why not?*

The Scientific Committee on Food based its shelf life recommendation on the publication by Sorheim (1999), which was cited and discussed in the Norwegian Meat Cooperative and the Norwegian Independent Meat Association application for the assessment of carbon monoxide. 97/ It was not a recommendation on the commercial shelf life for all meat stored in low oxygen atmospheres with CO. The Sorheim study was cited in GRN 143 and in GRN 83. Beyond these references, this difference was not discussed with FDA or FSIS because it was not relevant to the Precept Foods GRAS determination. The focus of a GRAS determination is whether there are sufficient data in the public domain to support the GRAS status of CO on the basis of scientific procedures.

96/ Indeed, the treatment of CO by the European Commission, Health & Consumer Protection Directorate-General appears to have been driven by concerns other than safety – namely, the issue of whether CO misleads the consumer with respect to product freshness. Letter from Robert J. Coleman, European Commission, to Mrs. Caroline F. Jackson, European Parliament, Document 400948-400951.

97/ Application for Assessment of the Food Additive Carbon Monoxide (CO) Prior To Its Authorization, Document 400952-400990.

As a practical matter, the shelf life results obtained by Sorheim (1999) cannot be used to determine the shelf life for product processed and packaged by Precept Foods. The specifics of shelf life are determined on a case-by-case basis, taking into account such factors as raw material quality, the type of meat product, distribution needs, likely temperature variations, and similar conditions. Shelf-life for a particular product is determined by a number of factors. As noted in the Scientific Committee Opinion, "[e]nd-product characteristics affecting the shelf life depend among others on type of product, initial contamination, atmosphere, storage temperature, packaging material and design." 98/ Shelf life can also be influenced by the age of the raw materials, conditions at slaughter, and conditions in the processing facility. In addition, acceptable shelf life is not a universally defined standard. It is based on microbial count, flavors, and odors, and other acceptability factors (such as appearance and purge level) and there is variability within each of these factors. For example, depending upon the type of bacteria present, different microbial counts may be deemed acceptable. Obvious signs of spoilage can occur at 10^4 if certain types of microorganisms predominate, while ground beef that contains 10^7 per gram can be organoleptically acceptable if the predominant flora consists of homofermentative lactic acid bacteria. Because the Sorheim (1999) study was conducted under different conditions from those in the studies conducted by Precept Foods, it is not surprising that different shelf lives were obtained.

Finally, we note that the shelf lives requested by Precept Foods are consistent with modified atmosphere packaging systems in general that extend the shelf life of products. For example, vacuum packaged primals can be stored for 36 days before being ground in a retail facility and put on display. 99/ Vacuum packaged case ready ground beef typically has a shelf life of 23 days and case ready meats in high oxygen systems typically have a shelf life of 11 to 14 days. 100/ Beef and pork that is exported to Asia typically have a shelf life of 45-55 days. Using the Pactiv system described in GRN 83, Precept Foods used a display-by date of approximately 25 days and a recommended display life in the retail case of 3 days, for a total shelf life of 28 days. 101/ Moreover, the National Beef Tenderness Survey found that the average age of raw materials the cold storage facilities of retail stores was 23 days. 102/ Finally, Precept Foods is aware of at least one meat processing company in Norway (a country with considerable experience in CO MAP packaging) that achieved approximately 20-22 days shelf

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98/ Opinion of the Scientific Committee on Food on the use of carbon monoxide as a component of packaging gases in modified atmosphere packaging for fresh meat (adopted on 13 December 2001) at 3. *Supra* note 95.

99/ AMI Foundation, "Ground Beef Shelf Life (Days)," Document 401002.01-401002.02.

100/ *Id.*

101/ Letter to Dr. Robert Post, Food Safety and Inspection Service, from Gary Kushner and Ann Boeckman, Hogan & Hartson LLP (July 2, 2003), Document 100001-100061.

102/ J.W. Savell et al., National Beef Tenderness Survey – 2006, Proceedings of the 59th American Meat Science Association Reciprocal Meat Conference 43, 44 (2006), Document 401021-401029.

life for its consumer-ready meat despite a cold chain management system that is not as rigorous as those used by companies in the United States. 103/

> *Question 4(e): We are aware that Precept Foods has stated that, in light of "actual conditions," Precept Foods is using "more conservative dates" reflecting a shorter shelf life. What labeled shelf life is Precept Foods currently using on its carbon monoxide treated meat? Please explain the "actual conditions" that prompted this change. Please provide all tests and/or other documents that were used to establish the "more conservative dates" Precept Foods has said it currently uses.*

There has been no "change" in the Precept Foods shelf life determinations. Shelf-life determinations do not and should not always be the same as the periods used for "use or freeze by" dates. Significantly, the 28- and 35-day limits for ground products and whole muscle cuts, which are supported by the shelf life studies, serve as guidelines, these values were never intended to apply to all products. Precept Foods is currently using shelf life limits that are more conservative than these targets, to allow for tolerance and temperature variations as well as age of the raw material. For example, Precept Foods currently uses a shelf life of approximately 24 days for most whole muscle cuts. Any reputable company will take the same approach, as a brand cannot survive continual sales of products that spoilage before the expiration of the "use or freeze by" date.

Numerous shelf life studies, which are summarized briefly below and attached to this submission, have been conducted as part of the ongoing shelf life verification program.

- Barney Wilborn, Impact of Residual Oxygen on Meat Packaged in CO in Lidstock (Jan. 29, 2004). This study found residual oxygen in CO lid stock packages as high as 0.5% does not appear to impact visual color, microbial growth or cooked color of ground beef or pork chops. Visual color scores were acceptable for all packages throughout the 27 day shelf life evaluation, although some packages did possess off odors at the end of 27 days. In addition, both the pork chops and the ground beef had microbial counts within acceptable levels throughout most of the study period. At the end of the 27 day study period, log 7 microbial counts were observed and, combined with the development of off odors, resulted in a shortening of the prescribed shelf life. 104/

- Always Tender Barrier Lid stock Test I (Mar./April 2004). This project evaluated the effect of various injection treatments on subjective odor scores of beef strips packaged in the CO MAP system, stored up to 41 days. 105/

- Always Tender Barrier Lid stock Test II (Jun./Jul. 2004). This project evaluated the effect of various injection treatments on subjective odor scores of beef strips packaged in

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103/ Scott Eilert, What I learned in Norway ... A Trip Report, July 16, 2002, Document 400931-400938.
104/ Document 401030-401097.
105/ Document 401098-401179.

the CO MAP system, stored up to 45 days. Microbial data was also collected, summarized and showed a psychrophilic count of less than 10^7 after 45 days (38 days storage and 7 days display). 106/

- Always Tender Barrier Lid stock Test III (Aug./Sept. 2004). This project evaluated the effect of various injection treatments on subjective odor scores of beef strips packaged in the CO MAP system stored up to 47 days. In addition to odor, color, gas, microbial and chemistry data were collected. After 35 days (30 days storage, 5 days display) total plate count was less than log 5 and the psychrophilic count was less than log 6. Similar microbial counts were found after 47 days. The few samples examined for flavor evaluation, however, produced a livery flavor at 35 days. 107/

- Hormel CO Barrier Headspace Test PF 006.02 (Sept. 16, 2004). This study was an exploratory study conducted to evaluate two different tray depths (hence headspace) and compare their respective effect on the color of top round steaks that were cut to two different thicknesses. Psychrophilic bacteria counts also were collected, and the counts were acceptable (less than log 7) at 21 days but reflected some signs of spoilage (greater than log 7) at 40 days. 108/

- Hormel "Gas Mixture Shelf Life Testing" (Oct. 19, 2004). This study was conducted to evaluate the effect of higher levels of CO_2 in the CO MAP system. The study was terminated because the higher levels of CO_2 caused the lidded film to be drawn down onto the meat surface. Microbial analysis was performed, and the psychrophilic counts were found to be less than log 7 at 26 days. No formal study report was written because there was no practical value in increasing CO_2 levels in the barrier lidstock package. 109/

- Carolina Realini and April Archer, Raw Material Age Requirement of Beef Packaged in CO Lid stock (Oct. 2004). As an example of the numerous factors that can influence shelf life, this study examined the effect of raw material age on shelf life. This study found odor for strip steaks, chuck roasts, or inside round steaks can be acceptable through 28 days of finished product shelf life when using 7 or 14 day old raw material but not when using 21 day old raw material. Microbial counts were found to be less than log 7 for strip steaks, chuck roasts, and inside round steaks when using 7, 14, or 21 day old raw material to produce up to 28 day old finished product. 110/

- Hormel Foods Report; PF # 002.30 Enhance vs. Non-Enhance Strip Steaks in CO Lid stock (Nov. 9, 2004). This study examined the effect of enhancement on strip steak performance in CO lid stock packaging. Steaks were examined for color, odor, wetness,

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106/ Document 401180-401288.
107/ Document 401289-401517.
108/ Document 401518-401549.
109/ Document 401550-401583.
110/ Document 401584-401609.

and microbial counts after 14, 21, and 28 days. Enhanced steaks had lower microbial counts. 111/

- April Archer, Raw Material Age Requirement of Pork Packaged in CO Lid stock (Jan. 2005). This study examined the effect of raw material age on shelf life for pork. Study results show the odor scores and the microbial counts for various cuts of pork after certain periods of time by raw material age. Microbial results for pork butt steaks, boneless chops, and bone-in chops were less than log 7 for 7, 14, 21, and 28 day old finished products when using 7, 14, or 21 day old raw material. Odor was acceptable for boneless and bone-in butt steaks for 28 day and 21 day finished products when using 7 day old and 14 day old raw material, respectively. Using 21 day old raw material can result in acceptable odor through 14 days for boneless chops and bone-in butt steaks. For bone-in chops, 7 day old and 14 day old raw material will result in acceptable odor through 21 day and 14 day finished products, respectively. Odor was not acceptable for bone-in chops using 21 day raw material. 112/

- Hormel: Modified Atmosphere Gas Comparison Effects on TBA Values for Beef Top Round Steak and Beef Top Sirloin Butt Steaks (March 15, 2005). This study, which was conducted for a marketing presentation, examined the oxidative rancidity for two cuts of beef packaged in two different MAP systems (low O_2/CO v. high O_2) at 11, 14, 17, 25 and 31 days. The study found that meat packaged in a low O_2/CO containing atmosphere has less oxidative rancidity over time than the high O_2 atmosphere. In addition to TBA scores, the study also collected microbial data. 113/

- Hormel: Residual O2 Top Round Evaluation PF 006.002 (Mar. 21, 2005). This study involved a rudimentary test designed to evaluate the effects of varying levels of residual oxygen in the barrier lidstock tray. The study evaluated only one top round, which was at least 14 days old prior to being cut into steaks. This study did show some correlation between the high psychrophilic counts and a sour odor. However, because of its very limited size, no formal study report was written. 114/

- Hormel: Top Round and Top Butt Headspace Evaluation (Mar. 31, 2005). This was another exploratory study conducted to investigate the effect of headspace on the color life of top round and top butt steaks. Product was evaluated after at 1, 5, 9, 19, 20 days for color. Microbial data were collected after 20 days, and it was noted that the psychrophilic bacteria counts were less than log 6. No formal study report was written. 115/

- Dave Ruzek, Headspace vs. Residual O2 in CO Barrier Lid stock Tray (May 12, 2005). This study examined whether there is a correlation between headspace and the level of

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111/ Document 401610-401612.
112/ Document 401613-401672.
113/ Document 401673-401763.
114/ Document 401764-401777.
115/ Document 401778-401825.

residual oxygen on the performance of various cuts of beef packaged in CO containing MAP. This study demonstrates that the overall performance of products over time is dependent upon specific primals and individual muscles. Most samples were evaluated for color acceptability at 3, 14, 21 and 27 days. Some samples were also tested for pH and TBA value after 14 and 27 days. Results showed that, based on a small sampling size (three pieces per primal), headspace and levels of residual oxygen did have short term and long term effects on the performance (depending on the primal) of steaks cut from top rounds, top butts, chuck rolls or strip loins and packaged in CO barrier lidstock trays. 116/

- Hormel: CR Pork Chops/ Barrier Lid High Ox vs. CO (July 14, 2005). This study was conducted primarily to generate TBA values for a marketing presentation. It compared TBA values for products packaged in high O_2 barrier lidstock to those packaged in low O_2/CO barrier lidstock. The high O_2 packages produced significantly higher TBA values. The psychrophilic counts were generally less than log 6. 117/

- April Archer, #23895 Laura's Lean Whole Muscle Shelf Life Verification (Feb. 17, 2006). In this first study, microbial analysis was acceptable through the 21 day shelf life and 5 day display period (26 total days), but odor evaluations indicated that the product would be unacceptable before the end of the 21 day shelf life. Thus, subsequent studies were conducted to validate a 15 day shelf life and 5 day display period (21 total days). 118/

- David Ruzek, Always Tender Case Ready Pork Shelf-Life Studies (Feb. 28, 2006). The objective of this study was to determine if the shelf-life code date could be extended from 24 to 28 days for assorted pork chops, boneless pork sirloin chops, and pork blade steaks packaged primarily in lidstock based on odor, color, TBA, and microbial counts. Although the code date could be increased for certain items, it became apparent that the amount of time the product spends in the display case has a major effect on its shelf life. Due to off odors and microbial counts exceeding log 7, it was concluded that most, if not all, case ready pork items should be rotated out of the display case after 5-7 days to ensure acceptable quality and performance of the product. 119/

- April Archer, #23895 Laura's Lean Whole Muscle Shelf Life Verification II (April 2006). As evidence as to how different cuts of meat can perform differently, in this study strip steaks and stew meat remained acceptable through a 16 day shelf life and 5 day display period (21 total days), according to odor and microbial analysis. Eye of Round steak did not perform through 21 total days; therefore, the study authors recommended both additional testing and a shorter shelf for this cut. This validation study and the one preceding it demonstrate how shelf life is determined and adjusted according to spoilage

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116/ Document 401826-402087.
117/ Document 402088-402136.
118/ Document 402137-402173.
119/ Document 402174-402182.

indicators even though a longer allowable shelf life was established in the GRAS notification. 120/

- Cargill Meat Solutions, #24092 New Laura's Lean Offerings-Shelf Life (Sept. 2006). As part of the shelf life verification program, this study was conducted to validate the shelf life for top blade and cubed steaks. Top blade steaks performed acceptably through 21 total days, but cubed beef did not. Product was stored for 14, 18, and 21 days and then displayed for 3 days. Cubed steaks had aerobic plate count of 7-log at 14 days storage plus 3 days display (17 total days). 121/

E. Question 5: Legibility and Effectiveness of Date Labeling

Question 5(a): Does precept use any special labeling to assure that consumers can read the "use or freeze by" dates on the packages?

Federal regulations do not require the use of date codes on case ready meats. Precept Foods included date codes as a condition of use in its original GRAS submission. These date codes are featured prominently on the package in at least one location. The attached pictures show the prominence of the date code statement and its placement on both the top and bottom of the meat package. 122/

Date codes are commonly used on many food products. In addition to meat packages, these codes routinely appear on perishable commodities such as milk, yogurt, cheese, and bagged vegetables. The studies discussed above establish consumers are aware of and comfortable with date codes such as the Precept Foods "use or freeze by" dates. The consumer of meat is no different than the consumer of these other commodities. Accordingly, there is no reason to believe that date codes on meat packages should be considered any differently than date codes on other food.

Question 5(b): Has Precept gathered data regarding the prominence of the "use or freeze by" date labeling required to allow persons with compromised vision – particularly the elderly, who have a long history of relying on color as their primary indicator of meat quality, and who may have difficulty smelling the odors associated with spoiled meat – to be able to read the "use or freeze by" date on the package? If not, why not?

As evident from the attached photographs, the date codes on the Precept Foods packages are clear and prominent – far more prominent than the codes on many other food packages. The prominence makes it easier for anyone with compromised vision to read the date code.

120/ Document 402183-402218.
121/ Document 402219-402244.
122/ Product Shots, Document 200033-200038. See also, "Hormel Case Ready Pork and Beef Meat Case to Cook Product Shots," Document 500000-500014; "Pork Lidstock," Document 500015-500023; Beef Lidstock Line," Document 500024-500034; "Pork Line," Document 500035-500047.

Individuals with compromised vision and smell will have difficulty reading the date codes on any perishable product and detecting spoilage due to odor. The issues presented by this subset of the population, therefore, are not unique to meat packaged in a CO MAP system.

> *Question 5(c): If meat has been temperature abused during manufacture, distribution, at retail or in the possession of the consumer, the "use or freeze by" date becomes worthless as an indicator of meat quality and questionable with regard to food safety. Under temperature abuse conditions, neither the color of carbon monoxide-treated meat nor "use or freeze by" date labeling provide consumers with accurate information as to the product's fitness for consumption.*

"Use or freeze by" dates are important features of many perishable food packages, but are only one aspect of product quality. As with milk, yogurt, and bagged spinach packages, a "use-by" date is interpreted in light of other factors, such as signs of spoilage. A product that has been temperature abused has not been handled in accordance with the Food Code and with other regulatory requirements. As recognized by FDA in the 2005 Food Code, the fresh meat case has a relatively good record of temperature control as compared to other areas. 123/

The same issues raised by the Committee with temperature abuse are presented by other perishable food products. Milk that has been temperature abused can spoil before its "use-by" date and the consumer will have no indication the milk is spoiled at the point of purchase. The nature of the spoiled product will be evident, however, when the consumer opens the milk and can smell the off odors. The same holds true for meat that has been shipped in vacuum packaged bags, subjected to temperature abuse resulting in spoilage and then ground into hamburger or cut into steaks. These products will exhibit the bright cherry red color and the consumer likely would not discover the product is spoiled until he or she takes the product home and opens the package. Simply stated, when temperature abuse occurs, the consumer frequently will not realize the product is spoiled until the packaged is opened at home. The issues raised by the Committee, therefore, are not unique to meat packaged in a MAP system involving CO. Fortunately, we have one of the most sophisticated retail food systems in the world that will minimize the likelihood for temperature abuse. And in the unlikely event temperature abuse takes place, there will be evidence of spoilage other than color alerting the consumer that the product should not be consumed.

Moreover, the issues raised by the Committee are at odds with the consumer acceptance of case ready meats. The attached graph tracks consumer satisfaction ratings from case ready and primal cuts of fresh pork and beef. 124/ The graph shows that over 99.999% of consumers are satisfied with these products, as measured by the absence of consumer complaints. Case ready meats have out-performed primal cuts by generating fewer consumer complaints in every year of the analysis, which started in 2003.

123/ FDA, 2005 Food Code 547 (Annex 6), (copy accessed Aug. 9, 2007 at http://www.cfsan.fda.gov/~acrobat/fc05-a6.pdf).

124/ Hormel Fresh Pork & Beef Consumer Satisfaction," Document 500048.

Question 5(d): Has Precept taken any steps to inform the customer of these facts, through product labeling or other means? If not, why not?

As discussed above, there is no reason for consumers to treat differently the date codes on the Precept Foods packages than the codes on other food products. As such, there is no reason to believe that the "use or freeze by" dates on meat packages warrant special explanation. In fact, the Precept Foods "use or freeze by" dates are larger and more prominent than the date codes provided on the packages of many other perishable foods.

The efficacy of the date codes on meat packages is further enhanced by FSIS consumer education guidance, which is made available on the FSIS website. 125/ This guidance addresses the importance of good handling practices and signs of spoilage, such as bad odor and a "sticky" feeling on the outside. In its guidance, FSIS says, "even if the date expires during home storage, a product should be safe, wholesome and of good quality – if handled properly and kept at 40°F or below." FSIS goes on to emphasize, "Foods can develop an off odor, flavor or appearance due to spoilage bacteria. If a food has developed such characteristics, you should not use it for quality reasons. If foods are mishandled, however, food borne bacteria can grow and cause food borne illness – before or after the date on the package."

Precept Foods takes great efforts to educate its own customers about its products and their "use or freeze by" dates by providing them with training materials. For example, Precept Foods developed a DVD, which is discussed in 6(b), below, that educates the retail customer about the placement, prominence, and purpose of the "use or freeze by" date and explains that such dates should be used to answer customer questions about when to use the product.

F. Question 6: Temperature Abuse Concerns

1. Background

The risk of temperature abuse, especially any alleged threat of deliberate mishandling in the distribution chain, is speculative and certainly of limited relevance to the intended or likely conditions of use for CO in fresh meat packaging. Indeed, similar allegations could be made with respect to other perishable foods (e.g., milk, eggs, processed and cured meats, fresh-cut fruits and vegetables, and even fresh meat and poultry packaged in high oxygen environments), any of which could theoretically be subject to temperature abuse sufficient to promote spoilage or the growth of pathogens (if any) without a noticeable change in product color. For most perishable foods, including fresh meat, consumers have a long history of relying upon open code dates along with odor and other signs that the product may not be suitable for consumption (e.g., slime).

In the merchandising of any perishable commodity, great care needs to be employed to ensure proper storage and handling that will minimize the potential for spoilage. This discipline, commonly referred to as "cold chain management," is practiced on all meat products today. The application of appropriate temperature controls is a fundamental good manufacturing practice

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125/ FSIS Fact Sheet, *supra* note 77, Document 400000-400004.

(GMP) requirement for all perishable foods. The intended conditions of use on which a GRAS assessment is based necessarily assumes GMP compliance. Temperature abuse, therefore, is not part of the intended conditions of use of a GRAS substance.

2. Responses to Question 6.

Question 6(a): Since the color of carbon monoxide-treated meat is completely insensitive to temperature abuse, what contracted conditions or other additional controls has Precept put in place to insure adequate temperature control during manufacture, storage and distribution?

Case ready packaged meats can be prepared in a central facility under continuous FSIS inspection and in compliance with applicable FSIS requirements. Among these are requirements for Hazard Analysis Critical Control Point (HACCP) 126/ plans for raw meat products, Sanitary Standards Operating Procedures (SSOPs), and Good Manufacturing Practices (GMPs). These HACCP plans, SSOPs, and GMPs all emphasize the importance of temperature control. In addition, use of a central facility eliminates any handling of meat and poultry products after USDA applies its mark of inspection. The Food Code recognizes that post-production handling can present a risk of cross-contamination:

> Even if foods . . . receive adequate thermal processing, a particular concern is present at retail when employees open manufactured products and repackage them. This operation presents the potential for post-processing contamination by pathogens. 127/

In addition to preventing cross-contamination, preparation in a central location also enhances food security by reducing the risk of product tampering.

Temperature control is managed from receiving through shipment and delivery. 128/ Briefly, the product arrives at the establishment typically as a sub-primal of beef, pork, trim, or ground package. The sub-primal is processed into steaks, chops, roasts, ground beef, sausage and other products and then tray packaged and shipped. As described below, control points for

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126/ HACCP involves the systematic identification and management of risks associated with the manufacture and distribution of meat and poultry by identifying potential hazards in the system, monitoring critical control points, and implementing corrective actions when necessary. The HACCP regulations are promulgated at 9 C.F.R. Part 417.

127/ FDA, 2005 Food Code 547 (Annex 6) (copy accessed Aug. 9, 2007 at http://www.cfsan.fda.gov/~acrobat/fc05-a6.pdf).

128/ "Product Category Description" and accompanying documents containing the HACCP and temperature control plans for the Precept Foods seasoned steaks manufactured at its Austin facility, Documents 600000-600017.

temperature occur throughout the process with different temperatures tailored to meet different processes and products. 129/

- Receipt of raw materials: Temperature controls identify the maximum temperature that is acceptable when receiving raw material at the facility (e.g., 40 or 41°F, depending on the product). Measurements typically are taken when the trailer arrives at the facility from the refrigeration unit settings of the trailer, temperature recorders on the trailer during transit, and product temperature at receiving. Temperatures in excess of the specified parameters will cause the load to be rejected and the product will not be processed.

- Holding Cooler: The temperature of the holding coolers will be monitored to ensure they are maintained at an acceptable level. A typical temperature would be between 32-35°F.

- Production Room: Production room temperature is maintained at a specified temperature, such as less than 40°F. The temperature of product throughout the process (saws, injectors, portioning equipment) also can be monitored and maintained at a specified level.

- Finished Product/Box Cooler: Finished product will be stored in a cooler that may have automated temperature recorders. Depending on the nature of the product that is processed, the specified temperature can vary with 32-36°F considered appropriate for some processes and 22-24°F for others.

- Shipping/Trailer temperatures: Trailer temperatures will be specified with 28°F considered typical for many shipments. This temperature can be written on the Bill of Ladings and verified before the trailer leaves the plant. Temperature recorders are placed on each load to ensure ambient air temperature of shipment.

In addition, Precept Foods has established receiving guidelines for customers receiving case ready meats. 130/ The guidelines instruct customers to record the surface temperature of product in each shipment by placing a calibrated, probe-style thermometer between the packages. If the surface temperature is between 28.0 to 40.0°F, the product is acceptable and no further action is necessary. When the surface temperature exceeds 40.1°F, the customer is instructed to obtain one internal temperature and 10 additional surface temperatures. If the internal temperature exceeds 40.0°F, a single surface temperature exceeds 45.0°F, or the average surface temperature exceeds 40.0°F, the customer is instructed to contact Precept Foods for assistance in determining the disposition of the product.

129/ "Temperature Control of Seasoned Steaks" and accompanying documents, Documents 600018-600047; "Product Receiving Log" and accompanying documents, Documents 600048-600050.

130/ "Precept Case Ready Meats Receiving Guidelines," Document 600051.

Precept Foods also uses temperature tracking devices in each shipment of case ready products. If the temperature of the tracking device is between 40.1-50.0°F for less than six hours and the product surface temperature averages less than 40.0°F, the product is considered acceptable. If the temperature of the trailer exceeds 50.0°F or exceeded 40.0°F for more than 6 hours, the retailer is instructed to contact Precept Foods for assistance in determining the disposition of the product.

The temperature controls used by Precept Foods in receiving, processing and shipping the product are designed to ensure the integrity of the cold-chain system and eliminate the potential for temperature abuse.

> *Question 6(b): What steps has Precept taken to educate meat retailers about the different way this meat product will behave when temperature abused?*

Precept Foods has made extensive efforts to educate its retail customers about the importance of cold chain management. Precept Foods conducts an extensive education and audit program before it will allow retailers to carry case ready meats in CO MAP systems. Precept Foods used the process described below, when qualifying the first retailer for use of the CO MAP system. 131/

> Phase I – In the first phase of product roll-out, Precept Foods personnel held meetings with the top four management people for each store in the retailer's distribution regions. These meetings included a detailed presentation. These store managers were also each given reference pocket cards containing information about the case ready system.
>
> Phase II(a) – Before the case ready product was to be rolled out to each store, Precept Foods personnel held a pre-meeting with the stores' meat managers regarding the logistics of testing temperature controls and setting store displays. The information provided in these meetings generally followed the same format as the presentations conducted in Phase I, except Precept Foods conducted live demonstrations in the store rather than a Power Point presentation. Precept Foods also provided each store with a video of the demonstrations for future reference and for the training of new employees. 132/
>
> Phase II(b) – The first step in rolling out case ready product in each store was a cold chain audit. Precept Foods personnel conducted cold chain audits and inspections of each store and distribution facility. These audits and inspections included a comprehensive inspection of distribution, storage, and display facilities to ensure the case ready product would be maintained at proper temperatures throughout the distribution and retail systems. Until a store was able to pass the cold chain audit successfully, it did not receive case ready product.

131/ The attached cold chain audit documents outline the detailed process used for qualifying the retailer, Documents 600052-600278.

132/ "Blue Ribbon Beef Production Overview DVD," Document 600279-600280.

Phase III – Once a store demonstrated that proper temperature control would be provided to the product in its cold chain audit, Precept Foods personnel set each store. Store setting included emptying, cleaning and sanitizing store shelving, ensuring proper air flow and temperature, and setting up store displays and point-of-sale materials. At this time, Precept Foods personnel also met with all the employees in the store's meat department to explain the case ready program and, again, to give the live product demonstration that had been given to the store's meat department management in Phase II(a). Each employee was also given a pocket reference card that explains the case ready program.

Phase IV – After each store was set with case ready product, Precept Foods personnel visited within a week. During these visits, Precept Foods personnel monitored temperature and other product display and storage conditions and answered questions from store employees.

Ongoing – On an ongoing basis, the Precept Foods retail operations teams visit each store on a regular basis and continues to monitor and approve storage and display conditions and educate store employees.

Precept Foods followed a similar approach when rolling out a new case ready product for this same retail customer. 133/ As part of this roll-out, the Precept Foods personnel again went through the entire Phase II and Phase IV steps, including conducting audits of the store's storage and display conditions and interviewing each store's meat manager concerning questions, concerns, education, criteria, and other issues of concern.

In 2005, Precept Foods worked with another retailer to launch that store's case ready product system. The launched paralleled that explained, above, except the roll-out was simultaneous throughout all stores. In addition, the retailer produced their own training materials, based on the Precept Foods information, and conducted mandatory training of all meat department employees and management. 134/

G. Question 7: Retail Practices

Question 7(a): What is average loss to spoilage of ground meat, and other cuts that have been prepackaged in atmosphere containing carbon monoxide? Please provide the related documentation.

Precept Foods does not track the loss that is due to spoilage of its products. Retail stores have historically purchased meat and have been responsible for managing their inventory. When the store-packaged meat turns an unacceptable color, the store can re-cut the meat exposing a "fresh surface" that will again bloom into a bright red color, grind the whole muscle meat into hamburger, process the product and sell it as a prepared food in the deli, or destroy it. Any

133/ "Roll-Out Schedule," Document 600281-600288.
134/ "Receiving Food Products Safely" and accompanying documents, Document 600289-600357.

information regarding the average loss due to spoilage would be considered confidential information by the retailer.

The case ready meats do allow the retail store to maintain better control over their meat inventory. The savings due to better inventory management are not unique to the use of CO containing MAP systems but to the nature of case ready meats. Case ready meats have a validated shelf life providing the retailer with a high degree of assurance that the product will be of an acceptable quality and color. Product that is packaged in the store may be prone to color changes well before the product has "spoiled" and is unacceptable for consumption. The case ready meats also allow the retailer and the processor to track more efficiently how quickly a particular product is selling at the store. Through increased tracking, the retailer can better manage inventory and can minimize the likelihood of stocking meat that will not be sold before its "use or freeze by" date. Confidential information from a retailer and shared with Cargill Meat Solutions demonstrates case ready meats have helped at least one retailer better manage its meat inventory and decrease loss. 135/ The retailer tracked loss due to "shrink," which is a measure of whether a product has to be marked down or removed from the retail meat display. These products, which may be perfectly wholesome and suitable for consumption, are marked down or removed due to their color.

The ability to better manage meat inventory, consumer convenience, and other factors have led to the continued growth of the case ready meat market. According to the 2006 National Meat Case Study published by Jerry Kelly of Cryovac Food Packaging Division, case ready meats now represent 60% of the total self serve meat case packages, which represents an 11% growth since 2002. 136/ The study notes case ready meats experienced a greater in stock position than store wrapped products with over 71% of case ready meats available throughout the day while compared to only 51% for store wrapped products. These findings provide further evidence that it is easier for retailers to manage meat inventory with case ready meats.

We are aware of reports in the literature that the CO MAP systems are saving the meat industry over $1 billion dollars per year. We believe this number is based on a 1995 publication that evaluated the use of vitamin E supplementation of beef cattle for the purpose of improving the color of beef. 137/ These authors report that the supplementation of beef cattle with vitamin E could extend the display life of fresh, ground and frozen beef because the increased levels of vitamin E in the meat blocked the oxidation of myoglobin to metmyoglobin. The authors designed the study to evaluate a scientific, rather than economic, effect of the technology. The

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135/ Cargill Meat Solutions PowerPoint Presentation, "Current Business Environment, What is your ability to manage...." (showing a decrease in average shrink for 93% grind, ground round, and ground chuck since switching to case ready meats of about 4, 5, and 9%, respectively), Document 700034-700046.

136/ Kelly, Jerry, "National Meat Case Study," Published in the Proceedings of the American Meat Science Association 59th Reciprocal Meat Conference, University of Illinois at Urbana-Champaign (June 18-21, 2006). Document 700000-700005.

137/ Liu, Q., Lanari, M.C., Schaefer, D.M., "A Review of Dietary Vitamin E Supplementation for Improvement of Beef Quality," J. Animal Sci 73:3131-3140 (1995), Document 700006-700015.

authors, nonetheless, estimated the technology would save retailers $792 million per year. The authors arrived at this number by identifying the total beef market as $22 billion and "extrapolating that retailers could improve their receipts by 3.6%." The authors do not identify the basis for the 3.6% extrapolation and we are unaware of any data indicating that retailers lose 3.6% of beef each year due to shelf life.

Question 7(b): How does this loss compare to meat that is not treated with carbon monoxide? Please provide the related documentation.

We are aware of reports that the category of case ready meats allows the retailer to better manage inventory and will translate into less loss due to "shrink" as discussed, above. The information, however, does not compare the CO MAP systems with other MAP systems such as vacuum packaging or high oxygen MAP systems.

Question 7(c): When such losses occur at the retail level, does the retailer absorb the loss or does Precept reimburse the retail stores for spoiled meat?

The retailer generally is responsible for managing the meat inventory and will absorb the loss for meat that is not sold before the expiration of its "use or freeze by" date.

Question 7(d): Do the same commercial terms apply to carbon monoxide-treated meat and meat that has not been so treated?

The terms under which a retailer and a manufacturer do business are governed by contract and are unique and confidential between the customer and the manufacturer. The terms under which CO-treated and untreated meat are sold, however, are identical and are governed by the same terms and conditions. A standard Precept Foods invoice, reflecting these standard terms and conditions is provided. 138/

Question 7(e): Does Precept have any systems in place that are capable of documenting customer complaints relating to carbon monoxide-treated meat? If so, please describe these systems.

Precept Foods has a system for receiving and tracking consumer complaints that is able to track complaints on specific products. The system is used for all products and is not limited to those packaged in CO MAP systems.

Consumer complaints are received through the 800 number, e-mail or regular mail. An 800 number appears on each of the Precept Food packages making it easy for consumers to contact the company. All contacts are entered into the Consumer Response System and the following minimum information is collected: reason, product, and initial comment. 139/ We are attaching a print out of the computer screen showing the field codes that are used to collect information on consumer complaints. Category codes also have been established to help track the nature of the

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138/ Standard Invoice, Document 700016-700018.

139/ "Consumer Complaint Display Screens," Document 700019-700026.

complaints. 140/ Examples of the general category codes include consumer inquiries about the formula, labeling, recycling, the appearance, flavor, foreign objects, ingredients, packaging, compliments, and many others. These general categories are then further broken into more specific subcategories. By way of example, the general category of "Off condition" is broken into subcategories such as bad color, freezer burned, off odor, rancid condition, slimy and spoiled. The detailed nature of the system allows for the collection and coding of consumer complaints for the various products marketed by Precept Foods.

H. Conclusion

The information contained in this letter and the extensive documents attached to this submission establish there are sufficient data to support the GRAS status of CO MAP systems and the suitability of these systems for in use in packaged meat. The data in this submission detail the extensive testing that has gone into the development and continued monitoring of the shelf life of these products. These studies form the foundation for the "use or freeze by" dates appearing prominently on the label. The numerous consumer studies referenced in this submission establish consumers rely heavily on "use of freeze by" dates when making purchasing decisions.

We understand the Committee also has expressed concern with potential issues that could be developed when product in the CO MAP system is subject to abusive temperatures. The information in this submission establishes the numerous controls that are in place to ensure the product is manufactured, held, transported, received and displayed at proper refrigerated temperatures. The integrity of the system is further maintained by the detailed training and cold chain audits that take place before a retailer is allowed to receive the case ready products. The comprehensive nature of the program minimizes the possibility that product will be subject to temperature abuse. In those rare instances when temperature abuse does occur and the product spoils before the expiration of its "use or freeze by" date, there will be evidence of spoilage through off odors, bulging packages, and/or the formation of slime. The consumer, therefore, will have the same tools that are available to detect spoiled perishable products such as milk, yogurt, or vacuum packaged meats.

We trust the Committee will concur with our assessment that the data and information submitted to FDA and FSIS and developed since the agencies completed their review of the GRAS notification support the GRAS status of CO and the suitable use of the CO MAP system in meat.

We would like to discuss briefly the documents that we included in this response. For purposes of our response, we focused primarily on those responsive documents that are in the files of the joint venture, Precept Foods. In instances when the questions could not be answered by the documents solely in the files of Precept Foods, Hormel and Cargill have supplemented the response with documents falling outside of the joint venture. The documents attached to this request are representative of the documents that are responsive to each of the seven sets of questions raised by this Committee. Many of the attached documents contain proprietary business information and are marked "confidential." We ask that this Committee respect the proprietary nature of these documents and take the necessary precautions to protect their

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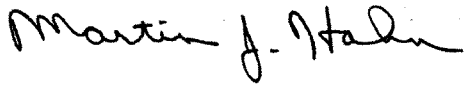
140/ "Consumer Complaint Category Codes," Document 700027-700033.

confidentiality. Finally, we were unable to provide the documents in a searchable electronic format. We received hard copies of many of these documents and they could not be converted easily into an electronic form that is readily searchable.

If you have any questions or comments, please contact us.



Martin J. Hahn
Counsel to Precept Foods

MJH/jgw

Attachments

Volume 1, Documents 100000-100567
Volume 2, Documents 100568-100829
Volume 3, Documents 100833-101218
Volume 4, Documents 200000-300001
Volume 5, Documents 400000-400412
Volume 6, Documents 400413-400938
Volume 7, Documents 400939-401517
Volume 8, Documents 401518-402087
Volume 9, Documents 402088-402244
Volume 10, Documents 500000-600357
Volume 11, Documents 700000-700045

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ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

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June 26, 2007

Mr. Steven A. Burd
Chairman and Chief Executive Officer
Safeway, Inc.
5918 Stoneridge Mall Road
Pleasanton, CA 94588-3229

Dear Mr. Burd:

Under Rules X and XI of the Rules of United States House of Representatives, the Committee on Energy and Commerce and the Subcommittee on Oversight and Investigations are investigating the adequacy of the efforts of the Food and Drug Administration (FDA) to protect Americans from contaminated or otherwise unsafe food. It is our understanding that Safeway, unlike most other supermarket chains, regularly sells its customers fresh meat that is packaged in an atmosphere containing carbon monoxide, designed to alter the color of the meat to make it appear fresh and wholesome indefinitely.

Beyond the consumer deception involved, the Committee has concerns about the public health consequences of this packaging. These concerns are set out in the attached letters to Commissioner von Eschenbach and Secretary Leavitt dated February 9, 2006, and March 30, 2006.

As a large national grocery chain that has chosen to sell meat packaged in an atmosphere containing carbon monoxide, we have questions regarding the company's decision to sell prepackaged fresh meats that have apparently been deceptively colored, and the conditions under which these products are sold. Accordingly, we request your responses to the following questions:

1. Temperature Control

We are interested in any special precautions that Safeway employs to assure that carbon monoxide-treated meats are stored between 34 - 40° F. This is the temperature range that

meatpacking companies used to support the extended "use or freeze by" dates indicated on these treated meat packages in their Generally Recognized As Safe (GRAS) petitions to FDA.

(a) Has Safeway commissioned or performed any in-house studies regarding the temperature of its storage and retail displays that house fresh meat—and fish, if applicable—that have been treated with carbon monoxide?

(b) Does Safeway measure the temperature in its fresh meat display cases? If so, please describe the protocols for measuring the temperature, including where in the display case the temperature is measured, *e.g.*, top, bottom, front, or rear of case. Please also provide the range of variation in temperature for each measurement period from January 1, 2004, forward for the ten largest and ten smallest Safeway stores (measured by value of meat sales, if available). If Safeway does not measure the temperature of its fresh meat display cases, how does Safeway ensure that the meat on display is not spoiled?

(c) Has Safeway received any citations from regulators for inadequate temperature control in meat since January 1, 2004? If so, please provide all documents relating to such citations.

(d) Please describe the due diligence that Safeway performs on the suppliers of such fresh meat products regarding temperature controls in the processing and transport of these products.

2. Consumer Purchasing Behavior

Please provide information and all documents Safeway has generated or examined relating to the following studies or focus groups regarding:

(a) Criteria for consumer selection of fresh meat products;

(b) Consumer acceptance of meat whose color is preserved by carbon monoxide;

(c) Consumer ability to smell or otherwise detect spoiling meat; and

(d) The ability and actual experience of consumers reading "use or freeze by" dates on packages.

3. Labeling/Store Signs

(a) If applicable, please provide any special labeling or store signs that Safeway employs to inform consumers that the meat has been treated with carbon monoxide, including any labeling or signs advising consumers that the color of treated meat should not be used to judge freshness.

(b) Please describe how Safeway assures that consumers, particularly those of declining eyesight, can read the "use or freeze by" dates on packages of carbon monoxide-treated meat, and provide copies of any special labeling Safeway uses to assure readability of those dates.

4. Shelf Life

(a) Upon receipt by Safeway and placement in the retail display case, what is the average shelf life remaining for carbon monoxide-treated meat, that is, days before the labeled "use or freeze by" date? Please provide all related documentation.

(b) On average, how long is fresh meat that has not been treated with carbon monoxide held in the retail display case?

(c) Please describe and provide all documents relating to any protocols Safeway employs to ensure that meat that is past its labeled "use or freeze by" date is pulled from the display case and no longer offered for sale, including steps the company takes to ensure that these protocols are followed. Please provide any disciplinary records regarding store managers that have violated these protocols (names of individuals but not store locations may be redacted).

(d) What does Safeway do with carbon monoxide-treated meat that remains unsold past the labeled "use or freeze by" date?

(e) How does Safeway determine the shelf life of meat not treated with carbon monoxide?

5. Losses Due to Spoilage

(a) What is average loss to spoilage of 1) ground meat, and 2) other cuts that have been prepackaged in atmospheres containing carbon monoxide?

(b) How does this loss compare to meat that is not treated with carbon monoxide?

(c) When such losses occur, does Safeway absorb the loss or does the meat packer reimburse the stores for spoiled meat?

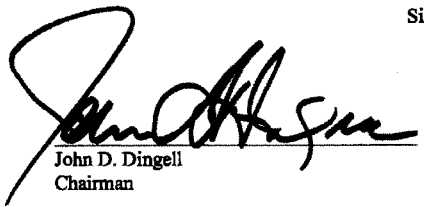
(d) Do the same commercial terms apply to carbon monoxide-packed meat as meat that has not been so treated?

6. Consumer Complaints

Does Safeway have any systems in place that are capable of documenting consumer complaints relating to carbon monoxide-treated meat? If so, please describe such systems and provide any documents relating to such consumer complaints.

Finally, to the extent not otherwise requested, please provide all records relating to Safeway's decision to sell fresh meat products treated with carbon monoxide. Please provide the requested records and other responses to the Committee offices in Room 316 of the Ford House Office Building no later than the close of business three weeks from the date of this letter. The words "records" and "relating to" are defined in an attachment to this letter. If this request is interpreted to require production of documents that would constitute an unreasonable burden on the company, it may be modified upon agreement with Committee staff. If you have any questions regarding this request, please contact us or have your staff contact David Nelson, Kevin Barstow, or John Arlington of the Committee staff at (202) 226-2424.

Sincerely,



John D. Dingell
Chairman

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Ed Whitfield, Ranking Member
Subcommittee on Oversight and Investigations

ATTACHMENT

1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.

2. The terms "relating," or "relate" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.

RALPH M. HALL, TEXAS
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February 9, 2006

Andrew C. von Eschenbach, M.D.
Acting Commissioner
Food and Drug Administration
5600 Fisher Lane, Room 1555
Rockville, Maryland 20857

Dear Dr. von Eschenbach:

We understand that a series of related decisions by the Center for Food Safety and Applied Nutrition (CFSAN) apparently permits the use of carbon monoxide to alter the color of meat and fish to make those substances appear edible beyond the time when they may decompose sufficiently to be contaminated by one or more dangerous toxins.

A review of Food and Drug Administration (FDA) responses to GRAS (generally recognized as safe) notices by interested companies indicates that the FDA has apparently decided that (1) it can ignore its own regulations, (2) that it can issue potentially dangerous determinations without public hearings or any form of notice and comment procedure, and (3) that it will accede to the requests of meat and fish packers and packaging manufacturers seeking to extend the shelf life appeal of meat and fish regardless of a potential impact on the public health.

Our review of the very limited public documents and other materials (obtained by interested parties under the Freedom of Information Act (FOIA) and provided to us) raises serious questions that require your prompt attention:

1. What is the reason to believe that this artificial coloration of meat and fish will not fool consumers to their detriment? The data attached to GRN 000083 ("Pactiv" notification) and GRN 000143 ("Precept Foods" notification) reveal no arguments, much less definitive science, to suggest that consumers will not be fooled by artificial coloring of meat products. In fact, that is the stated purpose of their petitions. The FDA response to GRN 000167 (Tyson notification) suggests that CFSAN reviewed no data in that case that would show that consumers can distinguish meat colored to look fresh but of potentially dangerous age from meat that is in fact fresh.

2. The Precept Foods notice argues that end dating will be sufficient notice to consumers of meat in danger of spoiling. None of the documents obtained under FOIA associated with that notice, however, purport to have measured the extent to which consumers are guided by end dating when purchasing meat, a commodity that has typically been purchased based on appearance. Nor is there any indication in the FDA response to any of the notices of an FDA requirement regarding the type, size, color, or placement of "use or freeze by" information on the package. Does the FDA possess and did it consider scientific studies on how consumers distinguish good meat from that which is going bad? If not, why not? Does the FDA have requirements that specify how prominent critical safety information such as the end date must be displayed on packaged meat and fish? If not, why not?

3. Your CFSAN scientists apparently think there is no danger to the public health in permitting the packagers to disguise the degradation of meat and fish. What is the basis for that belief? Please provide all relevant documentation including all internal notes or other memorandum where the issue of disguising the appearance of meat and fish was considered.

4. A plain reading of 21 CFR 173.350(c) appears to categorically prohibit the use of carbon monoxide on "fresh meat products." Is this prohibition no longer operative? Please explain whether the FDA now disagrees with its own regulation and, if so, why it has not addressed the matter through notice and comment rulemaking.

5. Given that the European Union has banned the use of carbon monoxide on meat and fish products, why does the FDA maintain that such use is "generally recognized as safe"?

6. In a Citizen's petition filed November 15, 2005, Kalsec argues that neither FDA nor the Food Safety and Inspection Service (FSIS) has ever before approved a color additive for meat precisely because it promotes deception by making meat appear fresher than it is, thus violating Section 721 (b)(6) of the Act and 21 CFR 379e (b)(6). What is the basis for CFSAN's disregard of both the statutory and regulatory prohibition of disguising meat by artificial coloration with carbon monoxide?

7. Please provide all documents including notes and memoranda relating to all contacts with FSIS personnel regarding GRN000143.

8. The use of carbon monoxide on fish is discussed in GRN 000015. Carbon monoxide is used as an ingredient in "tasteless smoke" which has alleged preservative properties for treating tuna before freezing and thus is not purely employed for its ability to disguise degradation. But the potential for such disguised spoilage in a food that is often eaten raw is of concern. What steps has the FDA taken to assure that fish sellers have not relied on its GRAS notice responses to treat packaged fish with carbon monoxide to make it appear to be fresher than it is?

9. Should the FDA require that the presence and purpose of carbon monoxide be prominently labeled so consumers can be aware of what they are buying?

FDA is first and foremost charged by Congress with protecting the public health and the safety of the food supply. But the FDA's decisions to not object to GRAS notices regarding the use of carbon monoxide on meat or fish products ignore those mandates. Given the lack of discernible consumer benefit and the obvious increase in risk to consumers of meat and fish from these decisions, we request that you withdraw the FDA response to GRAS notices GRN 000167, GRN 000143, and GRN 000083. And if the FDA believes that it can demonstrate a favorable risk/benefit ratio on the question of the application of carbon monoxide to color fresh meat and/or fish, then the FDA should go to notice and comment rulemaking to acquire the authority to permit such usage.

Thank you for your attention to this public health matter and to our concerns. With regard to questions and related document requests made in this letter, we would appreciate your responses no later than the close of business, Thursday, February 23, 2006. If you have any questions regarding this request, please have your staff contact David Nelson, Minority Investigator/Economist with the Committee on Energy and Commerce, at (202) 226-3400.

Sincerely,

JOHN D. DINGELL
RANKING MEMBER

BART STUPAK
RANKING MEMBER
SUBCOMMITTEE ON OVERSIGHT
AND INVESTIGATIONS

CC: The Honorable Joe Barton, Chairman
Committee on Energy and Commerce

The Honorable Ed Whitfield, Chairman
Subcommittee on Oversight and Investigations

Dr. Richard Raymond, Under Secretary for Food Safety
Department of Agriculture

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March 30, 2006

The Honorable Michael O. Leavitt
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Leavitt:

We ask you to order the Food and Drug Administration (FDA) to rescind its GRAS (generally regarded as safe) determinations regarding the use of carbon monoxide to color meat and fish until such time as notice and comment rulemaking can determine whether such practices, under existing conditions of refrigeration and labeling and existing consumer practices, are safe for American consumers. If you choose not to order the FDA to take immediate action, we ask that you undertake an immediate public information campaign to inform consumers that they cannot rely on color to ascertain the safety of meat and fish. Such a campaign should contain cautions such as never under any circumstance consume meat or fish that exceeds its "use by" date; never remove meat and fish from their dated packaging before use; and, if consumers have problems with reading the packages or smelling the contents, to seek help before consuming such products.

On February 9, 2006, Representatives Dingell and Stupak sent the attached letter to FDA Commissioner von Eschenbach detailing concerns regarding the decisions to permit meat of unknown age and safety to be displayed as red and therefore wholesome. While FDA has not found time to respond to the concerns raised in the February 9 letter, it did find time on February 27, 2006, to hold a press conference to address public indignation over the FDA decision. Unfortunately, several statements by the two FDA representatives, Dr. Laura Tarantino, Director of the Office of Food Additive Safety, and Ms. Susan Bro, a public relations official assigned to the Commissioner's Office, were helpful to the meat industry, but not helpful to consumers.

Meat that is packaged with the CO captured within the packaging until it is opened will retain a fresh, appetizing appearance indefinitely under almost any storage conditions. The attached pictures are of meat whose "use by" date was in October, and meat packaged with and without CO and left at room temperature for 27 hours. Clearly the coloring of each package that contains CO is deceptive in that the meat appears safe yet is entirely spoiled.

At the February 27th press conference, Dr. Tarantino plainly stated: "I think one of the issues is that color probably is not a major or particularly good indicator of spoiled meat." That is certainly the case after FDA's decision. But what most every American consumer knows and Dr. Tarantino knew or should have known is that color has been the principal basis for consumer determinations of the quality and safety of meat. Not only is this fact recognized by multiple marketing studies by the meat industry itself, it is clearly the only reason that the industry sought the GRAS determination. Nowhere is it alleged that placing meat in a sealed atmosphere containing CO has any purpose other than to assure that the meat appears fresh regardless of its age.

This could have significant consequences. The industry presentations to FDA and the U.S. Department of Agriculture Food Safety and Inspection Service (FSIS) were made on an *ex parte* basis behind closed doors. It appears from FDA and FSIS statements that the industry presented evidence that toxins would not attach to meat kept at 38-42 degrees F during an interval of 28 to 42 days depending on the cut. What Dr. Tarantino should have known, however, (at least by the time of the news conference because it is referenced in petitions before the FDA) is that meat is not stored at a constant 38-42 degrees. Most people understand this from common experience. One study stated: "Temperature abuse is common throughout the distribution and retail markets, with temperature in 21% of household refrigerators often higher than 10 degrees (C) (50 degrees F). Recent data suggested that 33% of retail refrigerated foods were held in display cases above 7 degrees C (45 degrees F) and 5% were held above 13 degrees C (55 degrees F). Temperatures were even higher in southern market regions. Serious microbial stability problems exist because of the frequency of temperature abuse."

Further, whatever incentive existed to assure adequate refrigeration of meat because of the fear of economic loss associated with "browning" was diminished by the FDA decision. Now that the consequences of poor handling of meat will not be obvious, such mishandling can be expected to increase.

Who might be hurt? The population least able to protect itself against this FDA-approved deception is the most vulnerable to the potential illnesses from bad food. The Centers for Disease Control and Prevention has identified the elderly (along with infants and the immunocompromised) as at the highest risk for illness and death from foodborne illness. It is precisely this group that is mostly likely to be losing a meaningful sense of smell, and is least able to read the often obscure labeling.

Dr. Tarantino advises that smell is a better indicator than color of spoilage in meat. But the National Geographic Survey (NGS), in a seminal work involving 1.2 million subjects, found that chemical exposure, pregnancy, and head injury as well as colds and flu can cause permanent loss of smell but overwhelmingly such loss occurs as we age. As one article by prominent nutritionists noted after reviewing the NGS findings, "the decline in sensitivity to the odor with age is large enough to render the odor useless as a warning for about half of the elderly population."

Also, because some deterioration of eyesight is virtually universal after age 40, it is precisely those Americans that are least able to rely on a sense of smell that are also likely to be victimized by the lack of meaningful labeling standards. Both Dr. Tarantino and Ms. Susan Bro dismissed press conference questions regarding inadequate labeling by noting that it is the Department of Agriculture's responsibility to assure that meat is properly labeled. Apparently, they believe the legibility of the labeling was not their problem even though FDA's decision made prominent "use by" labeling the consumer's only defense against unsafe meat.

This is no idle concern. A trip to any supermarket reveals that the labeling on meat products often appears to be deliberately illegible. Certain of the pre-packaged products use low-resolution ink jet printing on the film packaging itself to "inform" the consumer of the end date. Such printing is not visible to someone with 20/20 vision unless the light hits it at a certain angle. Other packages print the "use by" in 8-point type or less combined with other information that is not relevant to product safety such as weight.

Given these facts, we urge you to order FDA to rescind its acceptance of the use of carbon monoxide to color meat and fish until a full and public process can be undertaken and, if CO is ultimately allowed, until labeling is strengthened and clarified. If you refuse, you should at least order an aggressive public campaign to tell consumers they can no longer trust what their eyes are telling them about the suitability and safety of packaged meat and fish.

Because the misleading use of carbon monoxide continues, we ask that you examine these matters and respond to us by Wednesday, April 12, 2006. If you have any questions regarding these requests please contact one of us, or have your staff contact David Nelson of the Committee Democratic staff at (202) 226-3400.

Sincerely,

JOHN D. DINGELL

HENRY A. WAXMAN

BART STUPAK

EDWARD J. MARKEY

Attachments

cc: The Honorable Joe Barton, Chairman
Committee on Energy and Commerce

The Honorable Nathan Deal, Chairman
Subcommittee on Health

The Honorable Mike Johanns, Secretary
Department of Agriculture

EXECUTIVE OFFICES
SAFEWAY INC.
5918 STONERIDGE MALL ROAD
PLEASANTON, CA 94588-3229

July 16, 2007

The Honorable John D. Dingell, Chairman
Committee on Energy and Commerce
2125 Rayburn Office Building
Washington, D.C. 20515-6115

The Honorable Bart Stupak, Chairman
Subcommittee on Investigations and Oversight
2125 Rayburn Office Building
Washington, D.C. 20515-6115

Dear Chairmen Dingell and Stupak:

I am writing in response to your June 26, 2007 correspondence inquiring about the sale of pre-packaged meat packaged in an atmosphere containing carbon monoxide (CO). Your letter also expressed your concern with the Food and Drug Administration's (FDA's) review and "generally recognized as safe" (GRAS) designation of this process.

Our customers and their safety are Safeway's highest priority. We pride ourselves on offering our customers the highest in food quality and wholesomeness and the best in product availability and selection. Likewise, we maintain high food safety standards – in many areas exceeding regulatory and industry standards. We also work with reputable and high quality suppliers and require that they meet all legal regulatory requirements, as well as our own.

Only a limited selection of fresh meat products in our stores are supplied to us utilizing carbon monoxide modified atmospheric packaging (CO MAP). Indeed, the vast majority of our fresh meats are not packaged under such conditions. Safeway neither engages in CO MAP processing of meats, nor does it set code dates for said product.

Our fairly recent decision to try a limited selection of CO MAP items, was based in large part on our commitment to food safety. The FDA-approved CO MAP process afforded our customers meat packaging under strict food processing standards and limited additional handling at critical points of contact.

Both Safeway and its customers rely on the expertise of our federal food safety agencies. We also place a high value on our customers' trust. Because the Committee has expressed concerns - and in so doing may have raised concerns with customers who

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Ex. 8a

do not have the benefit of the background on this process and may be confused – we have elected to discontinue the sale of fresh meat products packaged under CO modified atmospheric packaging conditions.

Safeway has notified its CO MAP fresh meat suppliers of its decision. Likewise, we have ceased ordering and receiving CO MAP fresh meats into our distribution system. We no longer carry these types of products in our distribution inventory and are in the process of phasing out any existing inventory in our retail stores. Specifically, with the exception of two lamb and veal cuts, CO MAP fresh meat products will no longer be sold in or stores as of July 17, 2007. The limited lamb and veal cuts packaged in a CO modified atmospheric process will no longer be available in our stores as of July 27.

We hope that this information addresses any concerns you may have as they relate to Safeway.

Very truly yours,

Michael McGinnis
Senior Vice President
Meat & Seafood

cc: Steve A. Burd
Robert A Gordon
Kevin Herglotz
Valerie D. Lewis
Shannon Campagna
Nick Maduros

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June 26, 2007

Mr. Richard L. Bond
President and Chief Executive Officer
Tyson Foods, Inc.
2210 West Oaklawn Drive
Springdale, AR 72762-6999

Dear Mr. Bond:

Under Rules X and XI of the Rules of the United States House of Representatives, the Committee on Energy and Commerce and the Subcommittee on Oversight and Investigations are investigating the adequacy of the efforts of the Food and Drug Administration (FDA) and the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) to protect Americans from contaminated or otherwise unsafe food. It is our understanding that Tyson Foods, Inc. (Tyson) markets fresh meat that is packaged in an atmosphere containing carbon monoxide designed to alter the color of the meat indefinitely.

Beyond any consumer deception that may be involved, the Committee has concerns about the public health consequences of this packaging and the *ex parte* decisions by FDA and FSIS that made such packaging lawful. We have questions regarding the conditions under which these rulings have come about, as well as how Tyson chooses to market prepackaged fresh meats that appear to have been deceptively colored. Accordingly, we request responses to the following inquiries and make the following record requests:

1. ***Scientific Evidence***: We are interested in the scope and quality of the studies Tyson submitted to FDA and FSIS to support its Generally Recognized As Safe (GRAS) notification (GRN 000167) for the use of carbon monoxide in fresh meat packages, in which carbon monoxide remains in contact with the meat until the package is opened by the consumer.

    a. Please identify all studies, reports, and scientific data submitted to FDA and FSIS relating to GRN 000167, including, but not limited to, any studies relating to the

Ex.9

b. ability of carbon monoxide in the Tyson packaging system to mask spoilage of meat and any research addressing consumer perceptions and handling of the carbon monoxide-treated meat.

c. Does Tyson consider any of the studies or reports it submitted to FDA and FSIS to meet standards for publication in a reputable, peer-reviewed scientific journal?

d. Does Tyson intend to publish these reports? If not, why not?

e. We were told that the food industry practice is that firms submitting a GRAS notification to FDA generally convene an independent GRAS panel and submit the panel's report as part of their GRAS notification. Apparently, Pactiv Corporation convened a GRAS panel to support its GRAS notification for the use of carbon monoxide in its fresh meat packaging system. Did Tyson convene an independent GRAS panel? If not, why not?

Please provide the following:

f. Names and curricula vitae of any experts Tyson consulted, and copies of any reports they supplied.

g. Copies of all reports submitted by Tyson to FDA or FSIS related to GRN 000167.

2. ***Consumer Reliance on Meat Color as an Indicator of Freshness and Safety***: It is apparently well documented in published scientific and industry literature that consumers rely heavily upon meat color in selecting fresh meat for purchase and consumption. By reacting with the meat to create a red color that simulates the look of fresh meat—regardless of the age of the meat or whether it has been temperature abused—carbon monoxide can mask signs of microbial spoilage, aging, and deterioration. We are interested in any special labeling or educational means that Tyson employs to inform the consumer that the meat has been treated with carbon monoxide to make it appear red indefinitely, and that its color should not be used to judge freshness or safety because the packaged meat can appear to be edible well beyond the point of microbial spoilage.

   Has Tyson conducted studies that demonstrate consumers are able to recognize meat that is aged, spoiled, or temperature abused in the face of contradictory visual cues that they have historically relied upon? Please provide any studies or other documents Tyson has prepared or relied upon relating to the ability of consumers to detect spoilage where meat appears red and fresh looking.

3. ***Odor and Package Bulging as Purported Indicators of Spoilage***: Does Tyson allege that consumers can adequately detect spoilage in red, fresh-looking carbon monoxide-treated meat by aroma or by the presence of a bulging package?

    a. Please explain how the consumer can detect off-odors in hermetically sealed packages at the point of purchase—the point at which consumer deception occurs.

    b. Has Tyson done any studies on what percentage of the population may have difficulty detecting the spoilage odors associated with carbon monoxide-packaged meat?

    c. Did Tyson discuss with FDA the special risks facing anosmic individuals, especially the elderly, who also are a high risk for food-borne illness? If not, why not?

    d. Does Tyson have data describing the percentage of packages that would bulge as a result of over-filling during manufacture, changes in elevation during transport, changes in weather, or any other factors that would tend to make sealed packages bulge? If not, why not?

    Please provide all documents relating to your response to the questions listed above.

4. ***Labeled Shelf Life***: We understand that Tyson proposed, and FDA and FSIS accepted, "use or freeze by" dates on packages of carbon monoxide-treated meat of up to 28 days from packaging for ground beef and up to 35 days for whole muscle cuts. We are informed that the Opinion of the European Commission's Scientific Committee on Food (EC Opinion) on the use of carbon monoxide as a component of packaging gases in modified atmosphere packaging for fresh meat, adopted 13 December 2001, determined that the shelf life of the treated meat was 11 days for ground beef and 14 days for beef loin steaks (at 4° C or 39.2° F). The EC Opinion also states that raising the temperature to 8° C (46.4° F) reduced the shelf life of carbon monoxide-treated ground beef by about one half. According to published scientific reports, 21 percent of the household refrigerators in the U.S. operate at temperatures of around 50° F and temperature abuse in other parts of the chill chain are well-documented.

    a. Please provide the data upon which Tyson proposed the 28- and 35-day shelf lives noted above.

b. Were these periods of shelf life established under ideal laboratory conditions or under conditions reflecting the actual conditions of distribution, storage, and retail and consumer handling the treated meat was likely to encounter? If these periods were established based upon ideal laboratory conditions, please explain why actual conditions were not considered when Tyson submitted its GRAS notification to FDA.

c. Was Tyson aware of the EC Opinion prior to the submission of GRN 000167? If so, was this opinion provided to FDA as part of the GRAS notification, consistent with FDA's requirement that GRAS notifications must include a "comprehensive discussion of any reports of investigations or other information that may appear to be inconsistent with the GRAS determination?" If not, why not?

d. How does Tyson reconcile the substantial difference between the shelf lives of 11 and 14 days (for ground beef and beef loin steaks, respectively) reported in the EC Opinion and the 28- and 35-day shelf lives proposed by Tyson? Was this difference discussed with FDA? If not, why not?

5. ***Legibility and Effectiveness of Date Labeling***:

a. Does Tyson use any special labeling to assure that consumers can read the "use or freeze by" dates on the packages?

b. Has Tyson gathered data regarding the prominence of the "use or freeze by" date labeling required to allow persons with compromised vision—particularly the elderly, who have a long history of relying on color as their primary indicator of meat quality and who may have difficulty smelling the odors associated with spoiled meat—to be able to read the "use or freeze by" date on the package? If not, why not?

If meat has been temperature abused during manufacture, distribution, at retail, or in the possession of the consumer, the "use or freeze by" date becomes worthless as an indicator of meat quality and questionable in regard to food safety. Under temperature abuse conditions, neither the color of carbon monoxide-treated meat nor "use or freeze by" date labeling provide consumers with accurate information as to the product's fitness for consumption.

Has Tyson taken any steps to inform the customer of these facts, through product labeling or other means? If not, why not?

Please provide any data or other information Tyson has generated or relied upon relating to the effectiveness of "use or freeze by" date labeling to positively affect consumer purchasing practices.

6. ***Temperature Abuse Concerns***: The discoloration of meat packaged in air or in high oxygen modified atmospheres that occurs as a result of temperature abuse is an enormous financial incentive driving meat production and transportation activities to maintain rigorous and proper control of temperature. If the temperature is not controlled, the meat turns brown and becomes un-saleable.

   a. Since the color of carbon monoxide-treated meat is completely insensitive to temperature abuse, what contracted conditions or other additional controls has Tyson put in place to insure adequate temperature control during manufacture, storage, and distribution?

   b. What steps has Tyson taken to educate meat retailers about the different way this meat product will behave when temperature abused?

   Please provide all documents relating the responses to questions listed above.

7. ***Retail Practices***:

   a. What is average loss to spoilage of 1) ground meat, and 2) other cuts that have been prepackaged in atmospheres containing carbon monoxide? Please provide the related documentation.

   b. How does this loss compare to meat that is not treated with carbon monoxide? Please provide the related documentation.

   c. When such losses occur at the retail level, does the retailer absorb the loss or does Tyson reimburse the retail stores for spoiled meat?

   d. Do the same commercial terms apply to carbon monoxide-treated meat and meat that has not been so treated?

   e. Does Tyson have any systems in place that are capable of documenting customer complaints relating to carbon monoxide-treated meat? If so, please describe these systems.

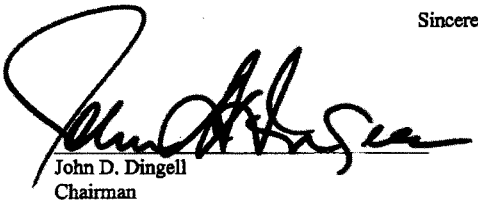
The Committee hereby requests all records relating to Tyson's decision to market fresh meat products treated with carbon monoxide. This request includes, but is not limited to, all studies that Tyson has commissioned or performed in-house regarding the use of carbon

monoxide in the packaging of fresh meat, the due diligence that Tyson performs on such fresh meat products regarding temperature controls in the processing and transport of these products, any studies or focus groups regarding the criteria for consumer selection of fresh meat products, consumer acceptance of meat whose color is preserved by carbon monoxide, consumer ability to smell or otherwise detect spoiling meat, and the ability and actual experience of consumers reading "use or freeze by" dates on packages.

Please provide Tyson's responses and the requested records to the Committee offices in room 316 of the Ford House Office Building no later than 30 days from the date of this letter. Please provide all records requested in an electronic sortable format. The words "records" and "relating to" are defined in an attachment to this letter. If this request is interpreted to require production of documents that would constitute an unreasonable burden, it may be modified upon agreement with committee staff.

If you have any questions regarding this request, please contact us or have your staff contact David Nelson, Kevin Barstow, or John Arlington of the Committee staff at (202) 226-2424.

Sincerely,



John D. Dingell
Chairman

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Ed Whitfield, Ranking Member
Subcommittee on Oversight and Investigations

ATTACHMENT

1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.

2. The terms "relating," or "relate" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.

August 9, 2007

Honorable John D. Dingell
Chairman
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, D.C. 20515

Honorable Bart Stupak
Chairman
House Energy and Commerce
Subcommittee on Oversight and Investigations
2352 Rayburn House Office Building
Washington, D.C. 20515

Re: Tyson Foods, Inc.

Dear Chairmen Dingell and Stupak:

I am writing in response to your letter of June 26, 2007, to Tyson Foods, Inc. ("Tyson") relating to the review by the House Energy and Commerce Committee and the Subcommittee on Oversight and Investigations ("Committee") into the adequacy of efforts of the Food and Drug Administration ("FDA") and the U.S. Department of Agriculture's Food Safety and Inspection Service ("FSIS") to protect Americans from contaminated or otherwise unsafe foods.

The quality and safety of our fresh meat products is a high priority for Tyson. We combine this commitment of excellence toward food quality and safety with state-of-the-art facilities, programs, and processes. This "gold standard" approach enables us to protect consumer health as we remain a leader in the production of meat and meat protein based products.

Tyson's commitment to a "gold standard" means that we implement programs and processes to ensure the quality and safety of our fresh meat products. We have in place a best-in-class Hazard Analysis and Critical Control Point ("HACCP") program. We also have cutting-edge cold chain management programs from slaughter to packaging that include critical control points to ensure that products are safe and wholesome. For example, we carefully monitor and manage temperatures and the packaging, storage, and distribution of our products. We take great pride in these programs, as they represent our

Tyson Foods, Inc. 2210 West Oaklawn Drive Springdale, AR 72762-6999
Phone: 800-643-3410 www.tysonfoodsinc.com

Ex. 9a

complete dedication to food safety and quality assurance. Complementing our efforts for safety are the USDA inspection personnel who carefully monitor our facilities to make sure that our programs are sufficient and properly implemented.

As you know, Tyson representatives have been working with Committee staff to more fully understand and address the Committee's concerns regarding the utilization of carbon monoxide ("CO") in fresh meat packages. Although, the use of CO is approved by FDA and USDA, Tyson has decided to discontinue the use of the barrier tray CO process approved by FDA in GRN 000143.

We estimate that it will take approximately five weeks to phase out the utilization of the barrier tray CO process. As part of this process, customer notification and new packaging should be finalized by August 24, 2007. Thus, we anticipate that by September 7, 2007, Tyson will no longer manufacture products in a CO barrier tray.

Tyson shares the Committee's desire to provide the American consumer with safe and wholesome food. As part of that commitment, Tyson will continue to work with the USDA, FDA, and the Committee to provide the highest quality beef, chicken, and pork products to the American consumer.

Thank you for your consideration.

Sincerely,

Gary Sherneman
Vice President Business Operations
Fresh Meal Solutions

cc: w/ encl. Joe Barton, Ranking Minority Member
Committee on Energy and Commerce

w/o encl. Hon. Ed Whitfield, Ranking Member
Subcommittee on Oversight and Investigations

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August 13, 2007

COMMENTARY

Food Fights

By JAMES M. RICE
August 13, 2007

DOW JONES REPRINTS

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More and more people are worried about the safety of food coming from China, but what exactly does "safety" mean, anyway? It's no simple question, given that safety standards frequently vary from country to country, and for many reasons. Compounding the problem, "safety standards" aren't always about safety. Standards can become a back door to protectionism. The phenomenon even has a name: technical trade barriers.

Everyone plays this game. The European Union enforces safety regulations that lack support in international science; its standards on hormones prevent the import of U.S. beef, and rules on naturally occurring aflatoxin mold blocks all imports of corn and nut products from Africa. China enforces a zero-tolerance rule on salmonella and the feed-additive ractopamine in meat and animal-feed imports, although the U.S. and EU allow trace amounts, without any accompanying health problems. The U.S. blocked importation of Chinese Ya pears for two years (in 2005 and 2006) based on an alleged fungus that no scientist outside the U.S. Department of Agriculture could ever identify.

It doesn't need to be that way. Despite some safety or sanitary problems with Chinese exports, it's far better to settle these issues through technical discussions on standards rather than through political sparring. Ideally, the end result will be that both countries have the same technical standards for quality and food safety, which will mean products of the same high quality could be sold to consumers in both countries.

The alternative is a climate in which no one can be sure whether import bans are related to genuine safety concerns or politics. My own company, Tyson Foods, and others recently saw some of our processing plants banned from importing into China due to the presence of traces of salmonella that wouldn't survive proper cooking, and would have been acceptable at most other borders. The move followed what was effectively a U.S. ban on imports of several seafood types that may have resulted either from political pressure or concern over trace amount of antibiotics.

More than one year ago, there were some encouraging signs on this topic. The Joint Commission on Commerce and Trade agreed to discuss technical trade barriers. The JCCT is a forum for high-level dialogue on bilateral trade issues between the U.S. and China, and it's co-chaired by the U.S. Secretary of Commerce and China's Minister of Commerce. In their 2006 meeting, both countries agreed to start developing mutually accepted standards to avert disputes over safety regulations. The U.S. Department of Agriculture and China's Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) even signed a memorandum of understanding on this principle.

Then, silence. A dialogue on the issue never materialized. Until, that is, today. Even as the U.S. Food

and Drug Administration has effectively banned certain types of Chinese seafood and the Chinese have blocked certain meat imports from the U.S., the two sides are finally sitting down together to start discussing standards. Real negotiations about technical food safety and sanitary standards are happening this month in both Beijing and Washington, between the FDA, USDA and AQSIQ. Last week, China's State Food and Drug Administration agreed with the U.S. FDA to increase technical exchanges through seminars and training programs, a process that will certainly increase the technical and scientific skills of Chinese regulators.

As these talks progress, China and the U.S. could turn to world health authorities, who stand a better chance of operating above the fray of national politics. The World Organization for Animal Health (OIE) and the Codex Alimentarius, which literally means the food code, of the Food and Agriculture Organization of the United Nations, provide a base from which to start. Both organizations have standards and guidelines that a member country can adopt, protecting the health of consumers and fair trade practices in our industry.

There is certainly a role for national safety regulators, who can sometimes act more nimbly than a global institution to protect consumers from newly discovered safety threats. To name one example from the pharmaceuticals sphere, U.S. regulators never approved thalidomide for widespread use despite its acceptance elsewhere. But distinguishing between prudence and protectionism requires constant vigilance.

Tyson Foods, Inc. and our industry peers have long sought a set of equal standards for trade of our products between China and the U.S. Only the recent food safety issues inside China and the U.S. have brought both governments back into a discussion. Agreements on scientific quality standards for food will facilitate the trade of food products between producers and consumers, and have the added advantage of bringing universally accepted food standards, and safe food, to all individual consumers, everywhere.

Mr. Rice is Vice President and China country manager for Tyson Foods, Inc.

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BusinessWeek

DECEMBER 8, 2004

SPECIAL REPORT -- THE CHINA PRICE

"The China Price"

They are the three scariest words in U.S. industry. Cut your price at least 30% or lose your customers. Nearly every manufacturer is vulnerable -- from furniture to networking gear. The result: A massive shift in economic power is under way

From the rich walnut paneling and carved arches to the molded Italian Renaissance patterns on the ceiling, the circa 1925 council chamber room of Akron's municipal hall evokes a time when the America's manufacturing heartland was at the peak of its power. But when the U.S.-China Economic & Security Review Commission, a congressionally appointed panel, convened there on Sept. 23, it was not to discuss power but decline. One after another, economists, union officials, and small manufacturers took the microphone to describe the devestation Chinese competitors are inflicting on U.S. industries, from kitchenware and car tires to electronic circuit boards.

These aren't stories of mundane sunset industries equipped with antiquated technology. David W. Johnson, CEO of 92-year-old Summitville Tiles Inc. in Summitville, Ohio, described how imports forced him to shut a state-of-the-art, $120 million tilemaking plant four football fields long, sending Summitville into Chapter 11 bankruptcy protection. Now, a tenfold surge in high-quality Chinese imports at "below our manufacturing costs" threatens to polish Summitville off. Makers of precision machine tools and plastic molds -- essential supports of America's industrial architecture -- told how their business has shrunk as home-appliance makers have shifted manufacturing from Ohio to China. Despite buying the best computer-controlled gear, Douglas S. Bartlett reported that at his Cary (Ill.)-based Bartlett Manufacturing Co., a maker of high-end circuit boards for aerospace and automotive customers, sales are half the late-1990s level and the workforce is one-third smaller. He waved a board Bartlett makes for a U.S. Navy submarine-detection device. His buyer says he can get the same board overseas for 40% less. "From experience I can only assume this is the Chinese price," Bartlett said. "We have faced competition in the past. What is dramatically different about China is that they are about half the price."

SLIDE SHOW: CHINA PRICES

Where the Jobs Went

"The China price." They are the three scariest words in U.S. industry. In general, it means 30% to 50% less than what you can possibly make something for in the U.S. In the worst cases, it means below your cost of materials. Makers of apparel, footware, electric appliances, and plastics products, which have been shutting U.S. factories for decades, know well the futility of trying to match the China price. It has been a big factor in the loss of 2.7 million manufacturing jobs since 2000. Meanwhile, America's deficit with China keeps soaring to new records. It is likely to pass $150 billion this year.

Now, manufacturers and workers who never thought they had to worry about the China price are confronting the new math of the mainland. These companies had once held their own against imports mostly because their businesses required advanced skills, heavy investment, and proximity to customers. Many of these companies are in the small-to-midsize sector, which makes up 37% of U.S. manufacturing. The China price is even being felt in high tech. Chinese exports of advanced networking gear, still at a low level, are already affecting prices. And there's talk by some that China could eventually become a major car exporter.

Multinationals have accelerated the mainland's industrialization by shifting production there, and midsize companies that can are following suit. The alternative is to stay at home and fight -- and probably lose. Ohio State University business professor Oded Shenkar, author of the new book *The Chinese Century*, hears many war stories from local companies. He gives it to them straight: "If you still make anything labor intensive, get out now rather than bleed to death. Shaving 5% here and there won't work." Chinese producers can make the same adjustments. "You need an entirely new business model to compete."

America has survived import waves before, from Japan, South Korea, and Mexico. And it has lived with China for two decades. But something very different is happening. The assumption has long been that the U.S. and other industrialized nations will keep leading in knowledge-intensive industries while developing nations focus on lower-skill sectors. That's now open to debate. "What is stunning about China is that for the first time we have a huge, poor country that can compete both with very low wages and in high tech," says Harvard University economist Richard B. Freeman. "Combine the two, and America has a problem."

How much of a problem? That's in fierce dispute. On one side, the benefits of the relationship with China are enormous. After years of struggling to crack the mainland market, U.S. multinationals from General Motors (GM) to Proctar & Gamble (PG) and Motorola (MOT) are finally reaping rich profits. They're making cell phones, shampoo, autos, and PCs in China and selling them to its middle class of some 100 million people, a group that should more than double in size by 2010. "Our commercial success in China is important to our competitiveness worldwide," says Motorola China Chairman Gene Delaney.

By outsourcing components and hardware from China, U.S. companies have sharply boosted their return on capital. China's trade barriers continue to come down, part of its agreement to enter the World Trade Organization in 2001. Big new opportunities will emerge for U.S. insurers, banks, and retailers. China's surging demand for raw materials and commodities has driven prices up worldwide, creating a windfall for U.S. steelmakers, miners, and lumber companies. The cheap cost of Chinese goods has kept inflation low in the U.S. and fueled a consumer boom that helped America weather a recession and kept global growth on track.

But there's a huge cost to the China relationship, too. Foremost is the question of America's huge trade deficit, of which China is the largest and fastest-growing part. While U.S. consumers binge on Chinese-made goods, the U.S. balance-of-payments deficit is nearing a record 6% of gross domestic product. The trade shortfall -- coupled with the U.S. budget deficit -- is driving the dollar ever downward, raising fears that cracks will appear in the global financial system. And by keeping its currency pegged to the greenback at a level analysts see as undervalued, China amplifies the problem.

America's Eroding Base

The deficit with China will keep widening under most projections. That raises the issue: Will America's industrial base erode to a dangerous level? So far the hardest-hit industries have been those that were destined to migrate to low-cost nations anyway. But China is ramping up rapidly in more advanced industries where America remains competitive, adding state-of-the-art capacity in cars, specialty steel, petrochemicals, and microchips. These plants are aimed at meeting insatiable demand in China. But the danger is that if China's growth stalls, the resulting glut will turn into another export wave and disrupt whole new strata of American industry. "As producers in China end up with significant unused capacity, they will try to be much more creative in how they deploy it," says Jim Hemerling, a senior vice-president at Boston Consulting Group's Shanghai office.

That's why China is an even thornier trade issue for the U.S. than Japan was in the 1980s. It's clear some Chinese exporters cheat, from intellectual-property theft and dumping to securing unfair subsidies. Washington can get much more aggressive in fighting violations of trade law. But broader protectionism is a nonstarter. On a practical level the U.S. is now so dependent on Chinese suppliers that resurrecting trade barriers would just raise costs and diminish the real benefits that China trade confers. Also, unlike Japan 20 years ago, China is a much more open economy. It continues to lower tariffs and even runs a slight trade deficit with the whole world -- which makes the U.S.'s deficit with China all the more glaring. Hiking the value of the yuan 30% might help. But that's unlikely. For one thing, Beijing fears what such a shift would do to jobs -- and the value of its $515 billion in foreign reserves. The real solution is for the U.S. to reduce its twin deficits on its own -- but that's more America's issue than China's.

Meanwhile, U.S. companies are no longer investing in much new capacity at home, and the ranks of U.S. engineers are thinning. In contrast, China is emerging as the most competitive manufacturing platform ever. Chief among its formidable assets is its cheap labor, from $120-a-month production workers to $2,000-a-month chip designers. Even in sophisticated electronics industries, where direct labor is less than 10% of costs, China's low wages are reflected in the entire supply chain -- components, office workers, cargo handling -- you name it.

China is also propelled by an enormous domestic market that brings economies of scale, feverish local rivalry that keeps prices low, an army of engineers that is growing by 350,000 annually, young workers and managers willing to put in 12-hour days and work weekends, an unparalleled component and material base in electronics and light industry, and an entrepreneurial zeal to do whatever it takes to please big retailers such as Wal-Mart Stores (WMT), Target (TGT), Best Buy (BBY), and J.C. Penney (JCP). "The reason practically all home furnishings are now made in China factories is that they simply are better suppliers," says Janet E. Fox, vice-president for international procurement at J.C. Penny Co. "American manufacturers aren't even in the same game."

Fox's point is important. China's competitive advantages are built on much more than unfair trade practices. Some 70% of exports now come from private companies and foreign ventures mainly owned by Taiwanese, Hong Kong, Japanese, and U.S. companies that have brought access to foreign markets, advanced technology, and managerial knowhow. Aside from cheap land and tax breaks in some areas, private Chinese manufacturers get minimal government help. "The Chinese government cannot afford to offer financial support to the export economy," says business professor Gu Kejian of People's University in Beijing. And as capital floods in and modern plants are built in China, efficiencies improve dramatically. The productivity of private industry in China has grown an astounding 17% annually for five years, according to the U.S. Conference Board.

China needs U.S. imports, though not as much as imagined when Beijing agreed to join the WTO. U.S. exports to China have risen 25% to 35% annually in the past two years. But China's exports still outstrip its imports from the U.S. by 5 to 1. The U.S. sells about $2.4 billion worth of aircraft a year, and its semiconductor exports tripled in three years. Otherwise the U.S. looks like a developing nation. It runs surpluses in commodities such as oil seeds, grains, iron, wood pulp, and raw animal hides.

Meanwhile, the Chinese keep expanding their export base. Chinese competition arrives so fast that it's nearly impossible to adjust through the usual strategies, such as automating or squeezing suppliers. The Japanese, South Koreans, and Europeans often took "four or five years to develop their piece in the market," says Robert B. Cassidy, a former U.S. Trade Representative official who helped negotiate China's entry into the WTO and now works for Washington law firm Collier Shannon Scott, which wages dumping cases on behalf of U.S. clients. "China overwhelms a market so quickly you don't see it coming."

"Shock and Awe"

Georgetown Steel Co. is a case in point. The Georgetown (S.C.) maker of wire rods used in everything from bridge cables to ball bearings had battled Asian and Mexican imports for years. But last year it shut its 600-worker plant, citing a tenfold leap in Chinese imports, to 252,000 tons, from 2001 to 2003. International Steel Group Inc. (ISG) has since bought the facility after U.S. anti-dumping duties on imports and a rise in global demand helped hike domestic prices. The Gardiner (Mass.) plant of Seaman Paper Co., a maker of crepe and decorative paper, is highly automated. Yet Chinese imports have grabbed a third of the market. It sells 81-foot streamers to big retailers for as little as 9 cents each. That's below Seaman's cost of materials. "We thought we could offset Chinese labor cost by automating, but we just couldn't," says Seaman President George Jones III.

In bedroom furniture, 59 U.S. plants employing 15,500 workers have closed since January, 2001, as Chinese imports have rocketed 221%, to $1.4 billion -- half of the U.S. market. Prices have plunged 30%. Dumping certainly seems to be one factor: At its Galax (Va.) factory, Vaughan-Bassett Furniture Co. displays a Chinese knockoff of one of its dressers that wholesales for $105 -- below the world market cost for the wood. But the main competition comes from Chinese megaplants that sell directly to U.S. retailers and can get a new design into mass production in two months. The new Chinese factories of suppliers such as Lacquer Craft Furniture, Markor, and Shing Mark, some of them Taiwanese-owned, employ thousands and are so big they seem meant to build Boeing 747s, making most U.S. factories look like cottage industries. "The first wave is shock and awe," says John D. Bassett III, CEO of Vaughan-Bassett, whose sales and workforce have shrunk even though it has boosted productivity fivefold at its 600-worker Galax plant since 1995 by investing in computer-controlled wood drying, cutting, and carving gear. "American industry has never encountered [such] competition."

As component industries and design work follow assembly lines to China, key elements of the U.S. industrial base are beginning to erode. American plastic-molding and machine-tool industries have shrunk dramatically in the past five years. Take Incoe Corp. in Troy, Mich., a maker of steel components for plastic-injection machines. "When the economy turned soft, we anticipated the business would come back," says Incoe CFO Robert Hoff. "But it didn't. We saw our customer base either close or migrate to China." The U.S. printed-circuit-board industry has seen sales go from $11 billion to under $5 billion since 2001. In that time, PCB exports from China have more than doubled, to a projected $3.4 billion this year, says market researcher Global Sources Ltd. (GSOL) Most U.S. production of key electronics materials, such as copper-clad laminates, has fled, too. "The whole industry is hollowing out," says Joseph C. Fehsenfeld, CEO of Midwest Printed Circuit Services Inc. in Round Lake Beach, Ill.

The migration of electronics to China began when the Taiwanese shifted plants and suppliers across the Taiwan Strait in the late 1990s. As recently as four years ago, though, the U.S. exported $45 billion in computer hardware. Since the tech crash, that number has slid to $26 billion as the industry headed en masse for China, which is even more competitive than Taiwan. "All electronics hardware manufacturing is going to China," says Michael E. Marks, CEO of Flextronics Corp (FLEX)., a contract manufacturer that employs 41,000 in China. Flextronics and other companies are hiring Chinese engineers to design the products assembled there. "There is a myth that the U.S. would remain the knowledge economy and China the sweatshop," says BCG's Hemerling. "Increasingly, this is no longer the case."

A visit to Flextronics' campus in the Pearl River Delta town of Doumen vividly illustrates Marks's point. The site employs 18,000 workers making cell phones, X-box game consoles, PCs, and other hardware in 13 factories sprawled over 149 acres. The bamboo scaffolding is about to come down on an additional 720,000-square-foot factory nearing completion. Almost every chemical, component, plastic, machine tool, and packing material Flextronics needs is available from thousands of suppliers within a two-hour drive of the site. That alone makes most components 20% cheaper in China than in the U.S., says campus General Manager Tim Dinwiddie. Plus, China will soon eliminate remaining tariffs on imported chips. In the past five years, electronic manufacturing-services companies such as Flextronics have cut their U.S. production from $37 billion to $27 billion while doubling their China output, to $31 billion. That's likely to double again by 2007.

"Gravitational Pull"

China is even making its presence felt in the U.S. market for networking gear, a bastion of American comparative advantage. On Nov. 15, struggling 3Com Corp. (COMS) in Marlborough, Mass., launched a data-communications switching system for corporate networks of 10,000 users or more. It claims twice the performance of Cisco Systems Inc.'s (CSCO) comparable switch. At $163,000, 3Com's list price is 25% less. Its secret? 3Com is settling for lower margins and taking advantage of a 1,200-engineer joint venture with China telecom giant Huawei Technologies Co. This is the first high-end piece of networking gear sold by a U.S. company that is designed and manufactured in China. For the price of one U.S. engineer, the joint venture can throw four engineers into the task of making customized products for a client. Even if 3Com does not succeed, similar tie-ups are expected, which could drive down prices of high-end gear sold in the U.S. Says 3Com President Bruce Claflin: "We want to change the pricing structure of this industry." 3Com hopes this is the start of a whole line of networking gear designed and made in China for the global market. Without referring to China, Cisco CEO John T. Chambers says "we are starting to see a stream of good, very price-competitive competitors, particular from Asia."

The next step for China is critical mass in core industries. Outside Beijing, Semiconductor Manufacturing International Corp. (SMI) has just opened a chip plant fabricating 12-inch silicon wafers that experts say is just two generations behind Intel Corp. (INTC) A foundry that makes chips on a contract basis, this plant won't compete directly with U.S. chipmakers. But with four more 12-inch wafer plants due by 2006 and many more fabs in the pipeline, the U.S. Semiconductor Industry Assn. warns that a "gravitational pull" could suck capital, people, and leading-edge research-and-development and design functions from the U.S.

Digital technologies aren't the only areas where the Chinese have huge ambitions. In the past decade, U.S. petrochemical makers have invested in little new capacity. But at a three-mile-long site in Nanjing, 12,000 workers are erecting a $2.7 billion network of pipes and towers for China's Sinopec (SNP) and Germany's BASF (BF) that by next year will be among the world's biggest, most modern complexes for ethylene, the basic ingredient in plastics. An even bigger complex is going up in Shanghai. "The Chinese understand everything that scale means," says Fluor Corp. (FLR) Group President Robert McNamara, who lives part-time in Shanghai and whose company has design contracts at both complexes. "When they target an industry to dominate, they don't mitigate."

Can China dominate everything? Of course not. America remains the world's biggest manufacturer, producing 75% of what it consumes, though that's down from 90% in the mid-'90s. Industries requiring huge R&D budgets and capital investment, such as aerospace, pharmaceuticals, and cars, still have strong bases in the U.S. "I don't see China becoming a major car exporter in the foreseeable future," says GM China (GM) Chairman Philip F. Murtaugh. "There is no economic rationale." Murtaugh cites high production costs and quality issues at Chinese car plants, as well as just-in-time delivery needs in the West, as impediments.

Burning Rubber

Don't tell that to Miao Wei, president of Dongfeng Motor Corp. On Nov. 7, Dongfeng and Honda Motor Co. (HMC) announced that their joint venture will invest $340 million to boost output of Honda CR-Vs and Civics fivefold, to 120,000, by early 2006. The plant aims to achieve world standards by employing Honda's flexible manufacturing system. "Honda will sell some of the Chinese-built cars in Europe," says Miao. Nissan Motor Co. (NSANY) is also talking about exporting with Dongfeng.

China's carmakers are developing the suppliers that one day could sustain exports. Auto-parts maker Wanxiang Group in Hangzhou started as a tiny township-owned farm-machinery shop in 1969. Now it's a $2.4 billion conglomerate that supplies the Chinese assembly plants of GM, Ford Motor (F), Volkswagen, and others and also exports 30% of its output. In two years, China will drop the rule that its auto plants buy at least 40% of parts locally. Wanxiang is getting ready: It is opening a $42 million plant loaded with U.S. and European testing gear. And since 1995, Wanxiang has bought 10 U.S. auto-parts makers. "Our goal is to acquire technology, management, and most important, to get access to overseas markets," says Chairman Lu Guanqiu.

Some U.S manufacturers hope China will run out of steam. This year, factories in Guangdong and Fujian faced serious labor shortages for the first time. Red-hot demand has meant skyrocketing costs for China's producers, most of which rely on imported goods such as steel, plastics, and components. Energy shortages have forced manufacturers to shut factories several times a week. In almost any industry one can think of, vicious price wars are biting into already razor-sharp margins. "There are so many small companies competing that they crowd out all profit," says Beijing University economist Zhang Weiying. Indeed, given the low emphasis on profits and the unsophisticated accounting of many Chinese companies, often their pricing isn't based on a full understanding of costs. Having gotten as far as they can on cheap production costs, Chinese manufacturers must develop their own technologies and innovative products to move ahead -- areas in which they've made slow progress so far.

The juggernaut will slow, but only slightly. While salaries for top Chinese designers are rising fast, they are still a fifth to a tenth of those in Silicon Valley. If China's wages rise 8% annually for the next five years, says a Boston Consulting Group study, the average factory hand will still earn just $1.30 an hour by then. If China allowed the yuan to appreciate by around 10% in the next year, productivity gains would more than offset the higher costs, figures China expert Nicholas R. Lardy of the Institute for International Economics. "I don't think revaluation will have a significant impact," he says.

And Chinese producers are hardly standing still. In a recent survey of Chinese and U.S. manufacturers by *IndustryWeek* and Cleveland-based Manufacturing Performance Institute, 54% of Chinese companies cited innovation as one of their top objectives, while only 26% of U.S. respondents did. Chinese companies spend more on worker training and enterprise-management software. And 91% of U.S. plants are more than a decade old, vs. 54% in China. Shanghai-based TV maker SVA Group, for example, has opened China's first plant to make flat panels, a venture with Japan's NEC (NIPNY) Corp. That is enabling SVA to secure a U.S. beachhead by selling liquid-crystal display and plasma TV sets through channels such as the online sites of Costco Wholesale (COST) and Target. Starting price: $1,600 -- 30% below similar models by Royal Philips Electronics (PHG) and Panasonic (MC).

More innovation. Better goods. Lower prices. Newer plants. America will surely continue to benefit from China's expansion. But unless it can deal with the industrial challenge, it will suffer a loss of economic power and influence. Can America afford the China price? It's the question U.S. workers, execs, and policymakers urgently need to ask.

By Pete Engardio and Dexter RobertsWith Brian Bremner in Beijing and bureau reports

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ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

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July 27, 2007

The Honorable Andrew C. von Eschenbach, M.D.
Commissioner
Food and Drug Administration
5600 Fisher Lane, Room 1555
Rockville, MD 20857

Dear Dr. von Eschenbach,

Under Rules X and XI of the Rules of the United States House of Representatives, the Committee on Energy and Commerce and the Subcommittee on Oversight and Investigations are investigating questions regarding the ability and the will of the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA) to protect Americans from contaminated and otherwise unsafe items in our food supply. On February 9, 2006, we wrote you regarding the series of related decisions by the Center for Food Safety and Applied Nutrition (CFSAN) to permit the use of carbon monoxide (CO) to alter the color of meat and fish to make those products appear fresh, safe, and wholesome, regardless of their actual condition and well beyond the time when they may be safe to consume.

We remain seriously concerned about the public health risks of this deceptive practice, particularly in light of information regarding imported fish delivered in CO containing packaging that has been rejected as unfit for human consumption. We understand that 20 percent of such fish imports tested have been rejected by the FDA laboratory in San Francisco since the practice was first discovered. If the regulatory authorities at CFSAN were aware of these findings and still determined that meat and fish so deceptively packaged should be considered "Generally Recognized As Safe" (GRAS) then something is seriously and dangerously amiss in the Center.

Even before we became aware of degraded fish imports, we were at a loss to understand how FDA could have disregarded established law by accepting GRAS notifications from companies seeking FDA approval, permitting the use of carbon monoxide to preserve the red color of fresh meat, despite the meat's age or conditions under which it has been held. We find it particularly troubling that FDA made this decision behind closed doors, rather than through the public notice and comment process that should have been employed. We request FDA's

Ex. 10

responses to the following questions to clarify the agency's decision-making process in this matter.

1. Color Additive: Precept Foods, LLC (Precept) submitted a GRAS notification to FDA regarding its use of carbon monoxide in modified atmosphere packaging (MAP) for fresh meat. Precept's GRAS notification (GRN 000143) makes clear that the carbon monoxide in its packaging system functions to make the meat appear to have the red color associated with fresh, wholesome meat indefinitely, as long as the meat remains in the package. Upon receiving Precept's purported GRAS notification, did FDA consider that the carbon monoxide in the Precept MAP system was a color additive and therefore not eligible for GRAS status? If not, why not?

   Please provide all documents, including but not limited to, internal agency and inter-agency communications as well as external communications, relating to the legal determination that carbon monoxide in the Precept MAP system is not a color additive.

2. Safety Considerations: FDA is responsible for determining whether the use of carbon monoxide in fresh meat is safe. It is well recognized that regardless of the age of the meat or whether it has been temperature-abused, carbon monoxide masks the visual signs of microbial spoilage.

   a. Was the safety risk associated with carbon monoxide's ability to mask indicators of microbial spoilage in fresh meat addressed in FDA's review of this use of carbon monoxide? If not, why not?

   b. In particular, did FDA consider the safety implications of consumption by at-risk populations such as the elderly, children, pregnant women, persons taking immunosuppresent drugs, or AIDS patients of apparently fresh looking meat containing high levels of bacteria ($>1x10^7$ colony forming units per gram)?

3. GRAS Standard: FDA's GRAS standard requires that there be consensus among qualified experts that a substance is safe for its intended use. FDA has advised that the "common knowledge" element of the GRAS standard generally requires that such consensus be documented through scientific data and information in the published literature, and that "an ongoing scientific discussion or controversy about safety concerns raised by available data would make it difficult to provide a basis for expert consensus about the safety of a substance for its intended use."

   We are aware of a number of published studies that have raised or acknowledged questions about the safety of carbon monoxide in fresh meat packaging because its coloring effect can mask signs of spoilage, e.g., Sørheim (1997 & 1999), Kropf (1980). Most significantly, the European Commission's Scientific Committee on Food observed that the use of carbon monoxide would be safe only if the temperature during storage and

transport never exceeds 4°C (39°F). Recognizing the realities of temperature abuse and, therefore, the likelihood that carbon monoxide's coloring effect would mask spoilage, the European Parliament banned this use of carbon monoxide in fresh meat.

Most importantly, FDA documents provided to the Committee and interviews by Committee staff of FDA laboratory and other field personnel in San Francisco and New York, clearly show that the agency knew that fish unfit for human consumption was imported in atmospheres containing carbon monoxide. Disregarding the data from its inspections, FDA decreed that fish and, later, meat treated with CO were GRAS. In fact, the agency issued an Import Bulletin on "Tuna Processed with Tasteless Smoke and/or Carbon monoxide" on May 27, 1999, that "responds to numerous complaints that FDA has received on the importation of tuna that has been processed with 'tasteless smoke'(TS) or carbon monoxide." It is our understanding that carbon monoxide is the coloring agent in "tasteless smoke."

Furthermore, FDA e-mails and other documents indicate the agency was well aware of the problem to many species including tuna. In fact, the agency required importers of all fish products that arrived in an atmosphere of carbon monoxide to identify the CO on the labeling and import documents.

a. Given the agency's own experience with contaminated, decomposed imported fish appearing fresh and wholesome because of carbon monoxide coloring, please explain how FDA concluded that this use of carbon monoxide in fresh meat packaging is deemed GRAS.

b. Given the documented controversy and the European ban due to safety concerns, please explain how FDA analyzed this scientific literature under its GRAS standard and concluded that meat and fish treated with CO is "Generally Recognized As Safe."

c. Did FDA consider the need for a food additive petition for the use of carbon monoxide in fresh meat packaging? If not, why not?

Please provide all documents, including internal agency communications and notes that were not provided to the Committee in response to our February 9, 2006 request, addressing whether the data and information in the Precept GRAS notification satisfied FDA's GRAS standard. In particular, please provide all documents relating to the agency's consideration of the European ban, if any.

Please also provide all records relating to the determination that fish processed using "tasteless smoke" or carbon monoxide is GRAS.

4. Consumer Reliance on Meat Color: It is well documented in published scientific and industry literature that consumers rely heavily upon meat color when selecting fresh meat for purchase and consumption. Indeed, the sole purpose for including carbon monoxide in fresh meat MAP is to give the meat the red color consumers prefer.

    a. Did FDA recognize that consumers would presume that the bright red color of carbon monoxide-treated meat was a sign that the meat was fresh and safe to eat?

    b. Did FDA solicit from Precept or obtain from any other source, consumer perception data, to determine whether the unlabeled use of carbon monoxide could induce consumers to purchase and consume meat that is no longer fresh and may not be fit for human consumption? If not, why not?

    c. If FDA believes that color is not an ideal measure of meat freshness and safety, how would the agency advise consumers to select meat packaged in sealed MAP?

    d. Does FDA plan to conduct a consumer education campaign to train consumers away from their traditional reliance on meat color and appearance?

    Please provide all documents relating to FDA's consideration of consumer behavior in meat selection during the course of its review of the GRAS notifications for the use of carbon monoxide in fresh meat packaging. Please also provide all documents, including but not limited to, all internal notes or other memoranda, as well as correspondence with USDA's Food Safety and Inspection Service (FSIS), reflecting FDA's and FSIS's consideration of the ability of carbon monoxide to conceal the true freshness, quality, and safety of meat.

5. Odor as a Spoilage Indicator:

    a. FDA has stated that consumers should use odor rather than color as an indicator of meat freshness and safety. Please explain how FDA addressed the fact that odor cannot be detected when purchased because the meat is sealed in MAP, and that governing law focuses on and prohibits adulteration and deception at the time of purchase.

    a. The National Geographic Survey (NGS), in a seminal work involving 1.2 million subjects, found that chemical exposure, pregnancy, head injury, and colds and flu can cause permanent loss of smell, but overwhelmingly, such loss occurs as we age. As one article by prominent nutritionists noted, after reviewing the NGS findings, "the decline in sensitivity to the odor with age is large enough to render the odor useless as a warning for about half of the elderly population." The scientific literature also documents olfactory dysfunction among cancer patients, particularly among those undergoing chemotherapy or radiation. Did FDA

consider the sizable portion of the population whose sense of smell may be impaired, particularly among those who may also be most vulnerable to food borne illness because of impaired immune systems? If not, why not?

6. Date Labeling:

   a. FDA has stated that "use or freeze by" date labeling will provide information to consumers sufficient to ensure the safe use of carbon monoxide in fresh meat. Please provide all consumer behavior research or other evidence that supports this assertion, whether submitted in GRAS notifications or obtained independently by FDA.

   b. Does FDA impose any prominence requirements to ensure that such "use or freeze by" date labeling is appropriately read and understood by consumers so that the inclusion of carbon monoxide in fresh meat MAP does not render the meat unsafe? If not, why not?

7. Temperature Abuse: Temperature abuse in meat storage and distribution channels, at retail, and in the refrigerators of consumers, has been widely documented—in published scientific literature, in FDA's Food Code, by FSIS, and in media exposés. Such temperature abuse generally causes meat, not treated with carbon monoxide, to turn brown rapidly. This has historically signaled to consumers that the meat may not have been held under appropriate conditions and may not be safe to consume. Fresh meat treated with carbon monoxide, however, will remain bright red regardless of temperature abuse.

   a. To the extent that FDA considered "use or freeze by" date labeling sufficient to ensure the safe use of carbon monoxide in fresh meat, did the agency consider the fact that temperature abuse would render such date labeling meaningless as an assurance of meat freshness and safety?

   b. Was FDA's consideration of the GRAS status of carbon monoxide in fresh meat packaging limited to information about use of carbon monoxide under laboratory conditions of ideal temperature control? If so, please explain why FDA disregarded the known prevalence of temperature abuse.

   c. Did FDA recognize that the fear of economic loss associated with meat "browning" has historically provided a strong incentive to assure adequate temperature control of meat throughout the chain of distribution, storage, and retail sale, and that such incentives would be eliminated by this use of carbon monoxide, which conceals evidence of mishandling?

8. Shelf life: As a condition of the safe use of carbon monoxide in fresh meat packaging, FDA accepted "use or freeze by" date labeling of up to 35 days following the date of packaging for intact muscle cuts and up to 28 days for ground beef. The documents supporting Precept's GRAS notification appear to indicate that these shelf lives were established under laboratory conditions reflecting ideal temperature control. Even Precept, the original proponent of the 35- and 28-day shelf lives, has stated that it would employ "more conservative dates," reflecting a shorter shelf life.

    a. How did FDA determine that the 35- and 28-day labeled shelf lives would be adequate to assure the safety and wholesomeness of carbon monoxide-treated meat under actual conditions of distribution, storage, retail sale, and consumer handling?

    b. Given that the European Commission's Scientific Committee on Food concluded that carbon monoxide-treated meat could have a shelf life of 14 days for beef loin steaks and 11 days for ground beef, how did FDA conclude that carbon monoxide-treated meat with shelf lives up to 35 or 28 days was "Generally Recognized As Safe"?

9. FDA Regulatory Prohibition of Carbon Monoxide in Fresh Meat: FDA's food additive regulation for combustion products gas (21 C.F.R. 173.350) appears to prohibit the use of carbon monoxide on "fresh meat products." In a February 13, 2002 letter to FDA regarding the Pactiv GRAS notification, FSIS apparently endorsed this view "because of concerns that the treatment of meat with combustion product gases may cause the meat to retain its fresh red color longer than meat not so treated, thereby misleading the customer, and increasing the potential for masking spoilage." Carbon monoxide is the only combustion product gas that affects meat color deceptively.

   Please explain whether FDA now disagrees with its own regulation at 21 C.F.R. 173.350 or considers it no longer operative. If so, why has FDA not addressed the matter through notice and comment rulemaking?

10. Labeling: FDA accepted the use of carbon monoxide in the Precept MAP system without requiring carbon monoxide to be labeled, although it is apparently still required for tuna. Under governing law and FDA regulations, policy, and precedent, however, there is no regulatory category into which this use of carbon monoxide could fall that would not require it to be labeled. As noted above, the use of carbon monoxide in fresh meat meets the statutory definition of a color additive, which must be labeled under 21 U.S.C. 343(k) and 21 C.F.R. 101.22(k). Even if FDA considers carbon monoxide in fresh meat to be GRAS (or a food additive), it would appear to be a functional ingredient in the meat that must be declared on the label.

a. Please explain how this use of carbon monoxide differs from FDA's regulatory example of chemical preservatives used "to promote color retention," which must be labeled under 21 U.S.C. 343(k) and 21 C.F.R. 101.22(j).

b. Please explain why the use of carbon monoxide in fresh meat packaging, which makes the meat red indefinitely, regardless of age or temperature abuse, does not need to be disclosed on the label, as would appear to be the case to comply with 21 U.S.C. 343(a) and 321(n).

11. Processing Aids Exempt from Labeling: FDA regulations provide that substances may qualify as "processing aids" and therefore be exempt from ingredient labeling requirements only if, in relevant part, the substances "are added to a food for their technical or functional effect in the processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food" (21 U.S.C. 101.100[a][3][ii][*c*]). In the Precept system, the carbon monoxide remains functional in the retail package to make the meat appear red indefinitely. Did FDA deem the carbon monoxide in the Precept MAP system to be a processing aid? If so, please explain how the carbon monoxide in that system satisfies FDA's regulatory definition of a processing aid.

    Please provide all records, including but not limited to, internal notes, memoranda, and communications with Precept and FSIS, addressing labeling of the carbon monoxide in Precept's MAP system, including whether it met FDA's definition of a processing aid. To the extent not otherwise requested, please provide all records, including but not limited to, internal notes, memoranda, and inter-agency communications relating to all contacts with FSIS personnel regarding GRN 000143.

12. Carbon Monoxide in Tuna: In response to GRAS Notification No. GRN 000015, FDA accepted the use of "tasteless smoke," of which carbon monoxide is a primary component, as a preservative to protect the taste, aroma, and color of fresh tuna prior to freezing. FDA required the presence and purpose of tasteless smoke to be declared on the labels of treated tuna. The use of carbon monoxide/tasteless smoke was addressed in a recent Congressional Research Service (CRS) Report for Congress entitled, "Seafood marketing: Combating Fraud and Deception, April 11, 2007." CRS reports that this use of carbon monoxide or "tasteless smoke" has alarmed consumer advocates, who say it deceives shoppers who depend on color to help them avoid spoiled fish, and more broadly, noted serious concerns about FDA's enforcement of seafood labeling requirements.

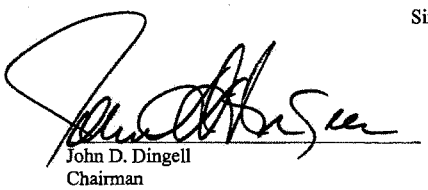
    a. Did FDA consider the labeling requirements for "tasteless smoke" to be a sufficient safeguard to ensure that the use of carbon monoxide/"tasteless smoke" did not deceive consumers into purchasing or consuming tuna that may have become unsafe while remaining fresh-looking?

b. If so, what steps has FDA taken to ensure that treated tuna is consistently and appropriately labeled, whether it is pre-packaged or sold by weight in the retail fish case, so that consumers are not deceived by tuna that may appear fresher or safer than it is?

We remain seriously concerned that FDA's allowance of the use of carbon monoxide to conceal the true freshness and safety of meat and fish has placed the public health at risk. Amid the spate of recent food recalls and food safety incidents, including a number of recalls due to *E. coli* in ground beef, confidence in FDA's ability to assure a safe food supply has been eroding. The unexplained departure from established food safety law and precedent in allowing the use of carbon monoxide in fresh meat, agreed to behind closed doors, does not help inspire confidence in the agency. If FDA still asserts that the use of carbon monoxide to color fresh meat and/or fish does not present a food safety risk, FDA should institute notice and comment rulemaking to permit these uses, as the law requires, and to inspire greater confidence in these suspect determinations.

Thank you for your attention to this public health matter and to our concerns. With regard to questions and related document requests made in this letter, we would appreciate your responses no later than the close of business August 10, 2007. If you have any questions regarding this request, please contact us, or have your staff contact David Nelson or Kevin Bartow of the Committee staff at (202) 226-2424.

Sincerely,



John D. Dingell
Chairman

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Ed Whitfield, Ranking Member
Subcommittee on Oversight and Investigations

cc: The Honorable Michael O. Leavitt, Secretary
U.S. Department of Health and Human Services

Richard A. Raymond, Under Secretary for Food Safety
U.S. Department of Agriculture

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable Bart Stupak
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

SEP 2 8 2007

Dear Mr. Chairman:

Thank you for your letter of August 27, 2007, co-signed by John D. Dingell, Chairman, Committee on Energy and Commerce, concerning decisions made by the Food and Drug Administration (FDA or the Agency), regarding the use of carbon monoxide (CO) in modified atmosphere packaging (MAP) for meat products and "tasteless smoke" (which includes CO) for fish.

To provide some background on this matter, we note that under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic (FD&C) Act (Title 21, *United States Code* [U.S.C.] 321(s) and 348), any substance the intended use of which results or may reasonably be expected to result in its becoming a component of food, or otherwise affecting the characteristics of any food, is a food additive subject to premarket review and approval by FDA, unless the substance falls within one of the exclusions from the definition of "food additive" in section 201(s) or meets the exemption for investigational use in section 409(j) of the FD&C Act. Under section 201(s) of the FD&C Act, substances that are generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use (GRAS), are excluded from the definition of "food additive" and are not subject to the food additive petition process in section 409 of the FD&C Act. The FD&C Act does not provide a process or specific authority for FDA premarket approval of GRAS status.

Under FDA's voluntary GRAS notification program, an interested party may notify the Agency of its conclusion that a substance is GRAS under the intended conditions of use. FDA reviews whether the GRAS notice (GRN) provides a sufficient basis to support the party's GRAS self-determination and then responds to the notifier as to whether the Agency has any questions. Information in the notice corresponding to the substance and conditions of use that are the subject of the GRAS self-determination and FDA's response to the notice are readily available to the public by postings to the Agency's website that are updated regularly (*see http://www.cfsan.fda.gov/~rdb/opa-gras.html*).

Ex. 10a

As you noted in your letter, FDA responded to three GRAS notices for the use of CO in MAP systems for meat products (GRNs 83, 143, and 167) and one notice for the use of tasteless smoke in tuna (GRN 15). In the case of the GRAS notices concerning these uses of CO and tasteless smoke, FDA responded by stating that the Agency does not question the basis for the GRAS determinations. Therefore, the intended use of CO in MAP systems for meat and tasteless smoke for tuna, as described in the notices, would not be a food additive and would not require FDA premarket review and approval.

FDA has set out what constitutes general recognition of safety for GRAS status in Title 21, Code of Federal Regulations (CFR) 170.30. Importantly, the same quality and quantity of scientific data are needed to support a GRAS determination as are needed to support a food additive approval. However, there are additional criteria for the use of a GRAS ingredient. These criteria include a general availability (such as through publication in the scientific literature) of the data and information relied on to establish the safety of the ingredient and consensus among qualified experts about the safety of the ingredient for the intended use. These two facets (i.e., general availability and consensus) are necessary to establish general recognition.

A substance must be shown to be "generally recognized as safe" under the conditions of its intended use. Explicitly, GRAS is not an inherent property of a substance, rather, it is the specific conditions of use for the substance that is GRAS. The person asserting GRAS status, resulting in exclusion from the definition of "food additive" and exemption from the food additive premarket approval process, has the burden of proving that the use of the substance is "generally recognized as safe." To establish such recognition, the proponent must show that there is a consensus of expert opinion regarding the safety of the use of the substance. Unanimity among experts regarding safety of a substance is not required, and mere conflict among experts is not enough to preclude a finding of general recognition.

FDA has entered into a Memorandum of Understanding (MOU) with FSIS that establishes a process to review the joint listing of ingredients used in the production of meat and poultry products. Consistent with the terms of the MOU, FDA consulted with FSIS on the three GRAS notices for use of CO in MAP systems for meat products. The MOU with FSIS dated January 31, 2000, is enclosed at Tab A.

FDA and FSIS routinely consult to address our related, but separate, roles in the regulation of ingredients in meat. FDA has authority under the FD&C Act to determine the safety of ingredients used in food, while FSIS has separate authority for determining whether the intended use of an ingredient in meat is suitable under the Federal Meat Inspection Act (FMIA). Suitability relates to the effectiveness of an ingredient for its intended use and the assurance that the conditions of use will not result in an adulterated product or one that misleads consumers. Under the FMIA, FSIS also has authority regarding the labeling of meat products. FSIS has informed FDA that the use of CO in MAP systems, under the conditions specified in the GRAS notices, complies with the FMIA.

As you are aware, we have pending citizen petitions on this matter, and we continue to receive and review information relevant to the citizen petitions and to GRNs 15, 83, 143, and 167.

We have restated the specific questions posed in your letter below, in bold type, followed by FDA's response. Documents are provided as noted. FDA continues to search for additional responsive documents.

1. **Upon receiving Precept's purported GRAS notification, did FDA consider that the carbon monoxide in the Precept MAP system was a color additive and therefore not eligible for GRAS status? If not, why not?**

   Please provide all documents, including but not limited to, internal agency and inter-agency communications as well as external communications, relating to the legal determination that carbon monoxide in the Precept MAP system is not a color additive.

Response: Color additives require FDA premarket approval. FDA has previously concluded that substances used to fix the natural color of meats are considered to be color fixatives and not color additives. In 1982, a Federal district court agreed with FDA that nitrites fix rather than impart color in bacon and therefore are not color additives in bacon. The mechanism by which CO acts to stabilize the natural red color of myoglobin in muscle (meat) is well-known and described in the scientific literature (for example, "The storage life of beef and pork packaged in an atmosphere with low carbon monoxide and high carbon dioxide;" Meat Science; Sorheim, O., Nissen, H., and Nesbakken, T.; 52(157-164); 1999). FDA concluded that the use of CO, as described in the GRAS notices, (including the notice for the Precept Foods packaging system) is not a color additive because it does not impart color, but rather fixes the natural red color of myoglobin, the color that consumers associate with meat products.

Documents responsive to your request under this question are enclosed at Tab B.

2. a) **Was the safety risk associated with carbon monoxide's ability to mask indicators of microbial spoilage in fresh meat addressed in FDA's review of this use of carbon monoxide? If not, why not?**

   b) **In particular, did FDA consider the safety implications of consumption by at-risk populations such as the elderly, children, pregnant women, person taking immunosuppressant drugs, or AIDS patients of apparently fresh looking meat containing high levels of bacteria (>$1x10^7$ colony forming units per gram)?**

Response: FDA carefully considered the safety of using CO in MAP systems for meat packaging. Our analysis of the notices considered microbiological safety (i.e., level of contamination) and the data submitted assured us that use of CO in MAP systems would not result in an increased risk of foodborne illness to the consumer.

The color of meat is not a reliable indicator of microbiological safety; contamination of meat by pathogenic bacteria is not, in general, something that a consumer could visually detect. Additionally, CO-containing MAP systems (CO is used only up to 0.4 percent) will behave as other MAP systems do, and will not mask other signs of spoilage, such as off-odor, meat that is slimy or tacky to the touch, or packaging that is bulging because of gas formation from spoilage bacteria.

When FDA does a safety analysis of ingredients added to foods, we look at potential effects across the entire population. Our conclusion that the use of CO in MAP systems would not result in increased risk of foodborne illness applies to the general population because we have concluded that CO does not mask signs of spoilage.

We do not understand the source or relevance of your reference to "...meat containing high levels of bacteria ($>1x10^7$ colony forming units per gram)." We would need further explanation in order to understand the significance of this measurement to meat safety.

3. **a) Given the Agency's own experience with contaminated, decomposed imported fish appearing fresh and wholesome because of carbon monoxide coloring, please explain how FDA concluded that this use of carbon monoxide in fresh meat packaging is deemed GRAS.**

   b) Given the documented controversy and the European ban due to safety concerns, please explain how FDA analyzed this scientific literature under its GRAS standard and concluded that meat and fish treated with CO is "Generally Recognized as Safe."

   c) Did FDA consider the need for a food additive petition for the use of carbon monoxide in fresh meat packaging? If not, why not?

   Please provide all documents, including internal agency communications and notes that were not provided to the Committee in response to our February 9, 2006 request, addressing whether the data and other information in the Precept GRAS notification satisfied FDA's GRAS standard. In particular, please provide all documents relating to the agency's consideration of the European ban.

   Please also provide all records relating to the determination that fish processed using "tasteless smoke" or carbon monoxide is GRAS.

Response: First, to clarify what FDA reviewed, we note that FDA did not receive or review a GRN for the use of CO in fish. Regarding the Agency's review of the use of tasteless smoke, FDA reviewed the data presented in GRN 15 and found no reason to disagree with the conclusion that the use of tasteless smoke on raw tuna before it is frozen to preserve its taste, aroma, texture, and color is GRAS. In our response letter, we explained that if someone were to use tasteless smoke (or any other preservative) on partially decomposed fish, the fish would be adulterated. Additionally, the sale of contaminated fish, whether treated with tasteless smoke or not, is illegal because the product is adulterated.

Although you state that "FDA e-mails and other documents indicate the Agency was well aware of the problem to many species including tuna," you identify only FDA's import bulletin on "Tuna Processed with Tasteless Smoke and/or Carbon Monoxide" issued on May 27, 1999. That import bulletin notes that tasteless smoke or CO may be used to preserve the natural red flesh color of tuna during frozen storage. The import bulletin pointed out concerns that tasteless smoke may be abused to enhance color, and that tuna so treated may not be labeled to indicate that fact. Our response letter to GRN 15, issued on March 10, 2000, clearly explains, as noted above, that abuse of tasteless smoke in a way that attempted to conceal signs of decomposition would render the fish adulterated and illegal. The letter went on to point out that abuse of tasteless smoke in a way that enhanced the color of the flesh so that the fish was made to appear of greater value than it was, would render the fish adulterated and illegal. Finally, the letter pointed out that the use of tasteless smoke to preserve the color of tuna upon freezing and thawing must be indicated in labeling in accordance with the FD&C Act. Thus the response letter to GRN 15 addressed the concerns about potential abuse described in the import bulletin. We note that the import bulletin had an expiration date of 90 days after issuance and that it was canceled on June 17, 2003.

FDA and FSIS reviewed the data presented in the notices for the use of CO in MAP systems for fresh meat. FDA found no reason to disagree with the conclusion that the use of CO in MAP systems for fresh meat is GRAS. As noted elsewhere, the uses described in the notices would not result in the masking of signs of spoilage, such as off-odor, meat that is slimy or tacky to the touch, or packaging that is bulging because of gas formation from spoilage bacteria. The agencies concluded that the uses of CO-containing MAP systems do not mask these signs of spoilage.

FDA is aware that the Scientific Committee on Food of the European Union has concluded that there is no health concern associated with the use of CO as a component in MAP systems for fresh meat provided the temperature during storage and transport does not exceed 4° Celsius. FDA agrees with the Scientific Committee on Food that storing products under inappropriate conditions may result in spoilage. However, FDA and FSIS considered this issue and concluded that under the conditions of use described in the GRAS notices, even at abusive temperatures, whether color is maintained or not, off-odors and slime will persist as indicators of spoilage in meat products. Also, we note that the proper storage and transport of foods is a requirement that all food producers must comply with under U.S. law.

As noted earlier, FDA found no reason to question the basis for the notifiers' conclusion that their use of CO-containing MAP packaging described in the notices is GRAS. Further, as noted earlier, GRAS substances are excluded from the definition of a "food additive" in section 201(s) of the FD&C Act and are therefore not subject to the food additive petition process in section 409 of the FD&C Act (21 U.S.C. 348) or to the requirement that a food additive regulation be promulgated prior to marketing of the product. Because FDA had no reason to question the asserted GRAS status of the substances, the Agency had no basis to consider requiring a food additive petition.

FDA is continuing to search for documents responsive to your request under this question.

4. **a) Did FDA recognize that consumers would presume that bright red color of carbon monoxide-treated meat was a sign that the meat was fresh and safe to eat?**

   b) Did FDA solicit from Precept or obtain from any other source, consumer perception data, to determine whether the unlabeled use of carbon monoxide could induce consumers to purchase and consume meat that is no longer fresh and may not be fit for human consumption? If not, why not?

   c) If FDA believes that color is not an ideal measure of meat freshness and safety, how would the agency advise consumers to select meat packaged in sealed MAP?

   d) Does FDA plan to conduct a consumer education campaign to train consumers away from their traditional reliance on meat color and appearance?

   Please provide all documents relating to FDA's consideration of consumer behavior in meat selection during the course of its review of the GRAS notifications for the use of carbon monoxide in fresh meat packaging. Please also provide all documents, including but not limited to, all internal notes or other memoranda, as well as correspondence with USDA's Food Safety and Inspection Service (FSIS), reflecting FDA's and FSIS's consideration of the ability of carbon monoxide to conceal the true freshness, quality, and safety of meat.

Response: As stated in the MOU, under the FMIA and its implementing regulations, FSIS determines the suitability of the use of ingredients in the production of meat products. Suitability relates, among other things, to the effectiveness of an ingredient for its intended use and includes an assessment of whether the conditions of use will result in an adulterated product or one that misleads consumers. FSIS communicated its conclusions that Precept Foods, LLC's MAP system as set out in GRN 000143 was suitable and would not mislead consumers in FSIS' letter to FDA dated June 2, 2004. This letter was previously provided to Chairman Dingell by FDA in its letter of April 7, 2006. We also refer you to FSIS' letters to FDA setting out their conclusions on suitability and potential for consumer deception in their reviews of other MAP systems using CO in GRN 000083 and 000167. These letters were also previously provided in the April 7, 2006, letter. Therefore, we defer to FSIS to address these questions.

FSIS has authority under the FMIA for determining whether the intended use of an ingredient in meat is suitable, and suitability relates, among other things, to an assurance that the conditions of use will not result in a product that misleads consumers. Thus, the issues relevant to these questions are under the purview of FSIS, and we defer to FSIS to address them.

Documents responsive to your request under this question are enclosed at Tab C.

5. **a) Please explain how FDA addressed the fact that odor cannot be detected when purchased because the meat is sealed in MAP, and that governing law focuses on and prohibits adulteration and deception at the time of purchase.**

   b) Did FDA consider the sizable portion of the population whose sense of smell may be impaired, particularly among those who may also be most vulnerable to food borne illness because of impaired immune systems? If not, why not?

Response: As stated above, under the FMIA and its implementing regulations, FSIS determines the suitability of the use of ingredients in the production of meat products. We refer you to FSIS' conclusions from their review of the GRAS notices for MAP systems using CO on fresh meat in their letters to FDA, which were previously produced in our letter of April 7, 2006. Therefore, we defer to FSIS to answer these questions.

6. **a) FDA has stated that "use or freeze by" date labeling will provide information to consumers sufficient to ensure the safe use of carbon monoxide in fresh meat. Please provide all consumer behavior research or other evidence that supports this assertion, whether submitted in GRAS notifications or obtained independently by FDA.**

   b) Does FDA impose any prominence requirements to ensure that such "use or freeze by" date labeling is appropriately read and understood by consumers so that the inclusion of carbon monoxide in fresh meat MAP does not render the most unsafe? If not, why not?

Response: FSIS regulates the labeling of meat under the FMIA, including "use or freeze by" date labeling. Therefore, we defer to FSIS to answer these questions. Also, we refer you to FSIS' conclusions from their review of the GRAS notices for MAP systems with CO for use on fresh meat in their letters to FDA previously produced in our letter of April 7, 2006.

7. **a) To the extent that FDA considered "use or freeze by" date labeling sufficient to ensure the safe use of carbon monoxide in fresh meat, did the agency consider the fact that temperature abuse would render such date labeling meaningless as an assurance of meat freshness and safety?**

   b) Was FDA's consideration of the GRAS status of carbon monoxide in fresh meat packaging limited to information about use of carbon monoxide under laboratory conditions of ideal temperature control? If so, please explain why FDA disregarded the known prevalence of temperature abuse.

   c) Did FDA recognize that the fear of economic loss associated with meat "browning" has historically provided a strong incentive to assure adequate temperature control of meat throughout the chain of distribution, storage, and retail sale, and that such incentives would be eliminated by this use of carbon monoxide, which conceals evidence of mishandling?

Response: FSIS regulates the labeling of meat under the FMIA, including "use or freeze by" date labeling. FSIS' conclusions from their review of the GRAS notices for MAP systems with CO for use on fresh meat were communicated to FDA by letter and were previously produced in our letter of April 7, 2006. We defer to FSIS to answer the question in 7(a).

With regards to the questions in 7(b) and (c) concerning temperature abuse, FDA did not receive any specific data on temperature abuse as part of GRN 143 submitted by Precept on meats that are shipped in MAP systems. We note, moreover, that we have no information that suggests that meats shipped in MAP systems would behave any differently (e.g., the signs of spoilage would remain the same) than meats that are shipped not using a MAP system, even after temperature abuse.

8. **a) How did FDA determine that the 35- and 28-day labeled shelf lives would be adequate to assure the safety and wholesomeness of carbon monoxide-treated meat under actual conditions of distribution, storage, retail sale, and consumer handling?**

   Given that the European Commission's Scientific Committee on Food concluded that carbon monoxide-treated meat could have a shelf life of 14 days for beef loin steaks and 11 days for ground beef, how did FDA conclude that carbon monoxide-treated meat with shelf lives up to 35 or 28 days was "Generally Recognized as Safe?"

Response: FSIS regulates the labeling of meat under the FMIA, including "use or freeze by" date labeling. Therefore, we defer to FSIS to answer these questions.

9. **Please explain whether FDA now disagrees with its own regulation at 21 CFR 173.350 or considers it no longer operative. If so, why has FDA not addressed the matter through notice and comment rulemaking?**

Response: FDA considers 21 CFR 173.350 to be in effect and the Agency would enforce this regulation against a violative product if necessary. However, it is important to note that 21 CFR 173.350 does not apply to CO-containing MAP systems for meat products. These systems are not "combustion gas" and therefore, while it is true that under 21 CFR 173.350 combustion gas is not permitted to be used on meats, this regulation does not apply. Thus, there is no reason to consider amending 21 CFR 173.350.

10. **a) Please explain how this use of carbon monoxide differs from FDA's regulatory example of chemical preservatives used "to promote color retention," which must be labeled under 21 U.S.C. 343 (k) and 21 C.F.R. 101.22 (j).**

    b) Please explain why the use of carbon monoxide in fresh meat packaging, which makes the meat red indefinitely, regardless of age or temperature abuse, does not need to be disclosed on the label, as would appear to be the case to comply with 21 U.S.C. 343 (a) and 321 (n).

Response: As noted previously, FSIS regulates the labeling of meat under the FMIA. FSIS set out its conclusions in letters to FDA previously provided to Chairman Dingell in our letter of April 7, 2006. These questions are under the purview of FSIS, and we defer to FSIS to address them.

11. Did FDA deem the carbon monoxide in the Precept MAP system to be a processing aid? If so, please explain how the carbon monoxide in that system satisfies FDA's regulatory definition of a processing aid.

Please provide all records, including but not limited to, internal notes, memoranda, and communications with Precept and FSIS, addressing labeling of the carbon monoxide in Precept's MAP system, including whether it met FDA's definition of a processing aid. To the extent not otherwise requested, please provide all records, including but not limited to, internal notes, memoranda, and inter-agency communications relating to all contacts with FSIS personnel regarding GRN 000143.

Response: FDA did not consider whether the carbon monoxide in the Precept MAP system was a processing aid because, as noted above, FSIS regulates the labeling of meat under the FMIA. However, FDA did consider labeling of tasteless smoke when it considered the use of this CO-containing product to preserve the color of tuna on freezing. In that case, FDA determined that the tasteless smoke was acting as a preservative, and thus must be declared under 21 CFR 101.22(j).

FDA is continuing to search for documents responsive to your request under this question.

12. a) Did FDA consider the labeling requirements for "tasteless smoke" to be a sufficient safeguard to ensure that the use of carbon monoxide "tasteless smoke" did not deceive consumers into purchasing or consuming tuna that may have become unsafe while remaining fresh-looking?

b) If so, what steps has FDA taken to ensure that treated tuna is consistently and appropriately labeled, whether it is pre-packaged or sold by weight in the retail fish case, so that consumers are not deceived by tuna that may appear fresher or safer than it is?

Response: FDA did not impose the labeling requirements as a "safeguard" for the use of tasteless smoke. Rather, requirements for the labeling of tasteless smoke are a means to communicate material facts. FDA's response on the GRAS status of tasteless smoke was limited to the specific conditions of use asserted by the notifier -- that is, that tasteless smoke is GRAS for use on raw tuna, before it is frozen, to preserve its taste, aroma, texture, and color. FDA considered that this use of tasteless smoke would constitute use as a preservative. Products containing a preservative may not be labeled "fresh" (21 CFR 101.95). This regulation is intended to communicate material facts to help ensure that consumers are not deceived.

FDA evaluated all safety concerns regarding the use of tasteless smoke to preserve raw tuna before it is frozen. Under the conditions of use described in GRN 15, we found no reason to disagree with the notifier's conclusion that this use of tasteless smoke is GRAS. We have no evidence that tasteless smoke represents a public health hazard, or that it promotes economic deception when used responsibly and lawfully. Under the FD&C Act, a company must comply with all labeling requirements or the product is, by definition, misbranded and not legal for sale.

Thank you again for your interest in this matter. We hope this information is helpful. Please do not hesitate to contact us if we can provide assistance in the future.

Sincerely,

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

Enclosures

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

NOV 0 6 2007

Dear Mr. Chairman:

This is in further response to your letter of July 27, 2007, co-signed by Representative Bart Stupak, Chairman, Subcommittee on Oversight and Investigations, concerning decisions made by the Food and Drug Administration (FDA or the Agency), regarding the use of carbon monoxide (CO) in modified atmosphere packaging (MAP) for meat products and "tasteless smoke" (which includes CO) for fish.

We are providing additional documents responsive to request number three of your letter, which is re-stated below. Please be advised that these documents contain trade secret, commercial confidential or other information protected from public disclosure under the Freedom of Information Act (Title 5, United States Code [U.S.C.], section 552), the Trade Secrets Act (Title 18, U.S.C., section 1905) and/or FDA regulations. This information should not be published or otherwise made public. We would be glad to discuss the protected status of any specific information with you or your staff.

3. Please also provide all records relating to the determination that fish processed using "tasteless smoke" or carbon monoxide is GRAS.

Response: Documents responsive to your request are enclosed.

Thank you again for your interest in this matter. A similar response without enclosures is being sent to Chairman Stupak.

Sincerely,

Stephen K. Mason
Acting Assistant Commissioner
for Legislation

Enclosures

Ex. 10b

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

NOV 0 8 2007

Dear Mr. Chairman:

This is in further response to your letter of July 27, 2007, co-signed by Representative Bart Stupak, Chairman, Subcommittee on Oversight and Investigations, concerning decisions made by the Food and Drug Administration (FDA or the Agency), regarding the use of carbon monoxide (CO) in modified atmosphere packaging (MAP) for meat products and "tasteless smoke" (which includes CO) for fish.

We are providing additional documents responsive to your requests which are re-stated below in bold type. Please be advised that these documents contain trade secret, commercial confidential or other information protected from public disclosure under the Freedom of Information Act (Title 5, United States Code [U.S.C.], section 552), the Trade Secrets Act (Title 18, U.S.C., section 1905) and/or FDA regulations. This information should not be published or otherwise made public. We would be glad to discuss the protected status of any specific information with you or your staff.

3. **Please provide all documents, including internal agency communications and notes that were not provided to the Committee in response to our February 9, 2006 request, addressing whether the data and other information in the Precept GRAS notification satisfied FDA's GRAS standard.**

4. **Please also provide all documents, including but not limited to, all internal notes or other memoranda, as well as correspondence with USDA's Food Safety and Inspection Service (FSIS), reflecting FDA's and FSIS's consideration of the ability of carbon monoxide to conceal the true freshness, quality, and safety of meat.**

11. **Please provide all records, including but not limited to, internal notes, memoranda, and communications with Precept and FSIS, addressing labeling of the carbon monoxide in Precept's MAP system, including whether it met FDA's definition of a processing aid. To the extent not otherwise requested, please provide all records, including but not limited to, internal notes, memoranda, and**

EX. 10C

inter-agency communications relating to all contacts with FSIS personnel regarding GRN 000143.

Response: Documents responsive to your requests are enclosed.

Thank you again for your interest in this matter. A similar response without enclosures is being sent to Chairman Stupak.

Sincerely,

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

Enclosures

HENRY A. WAXMAN, CALIFORNIA
EDWARD J. MARKEY, MASSACHUSETTS
RICK BOUCHER, VIRGINIA
EDOLPHUS TOWNS, NEW YORK
FRANK PALLONE, JR., NEW JERSEY
BART GORDON, TENNESSEE
BOBBY L. RUSH, ILLINOIS
ANNA G. ESHOO, CALIFORNIA
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CHARLIE MELANCON, LOUISIANA
JOHN BARROW, GEORGIA
BARON P. HILL, INDIANA

DENNIS B. FITZGIBBONS, CHIEF OF STAFF
GREGG A. ROTHSCHILD, CHIEF COUNSEL

ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOHN D. DINGELL, MICHIGAN
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JOHN SULLIVAN, OKLAHOMA
TIM MURPHY, PENNSYLVANIA
MICHAEL C. BURGESS, TEXAS
MARSHA BLACKBURN, TENNESSEE

September 13, 2007

Mr. José Alvarez
Chairman and CEO
Giant Food, Inc.
8301 Professional Place, Suite 115
Landover, MD 20785

Dear Mr. Alvarez:

Under Rules X and XI of the Rules of the United States House of Representatives, the Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations are investigating the adequacy of the efforts of the Food and Drug Administration (FDA) to protect Americans from unsafe food. We have been informed that Giant Food, Inc. stores (Giant) regularly sell its customers fresh meat that is packaged in an atmosphere containing carbon monoxide, which is designed to alter the color of the meat to make it appear fresh and wholesome indefinitely.

Beyond the consumer deception involved, the Committee has concerns about the public health consequences of this packaging. These concerns are set out in the attached letters to Commissioner von Eschenbach and Secretary Leavitt dated February 9, 2006, and March 30, 2006, respectively.

As a large national grocery store chain that has chosen to sell meat packaged in an atmosphere containing carbon monoxide, we have questions regarding Giant's decision to sell prepackaged fresh meats that have apparently been deceptively colored, and the conditions under which these products are sold. Accordingly, in order to assist the Committee in its investigation of the safety of the Nation's food supply, we request that you provide the Committee with the following information:

1. Temperature Control

We are interested in any special precautions that Giant employs to assure that carbon monoxide treated meats are stored between 34–40°F. This is the temperature range that meatpacking companies used to support the extended "use or freeze by" dates indicated on these

Ex. 11

treated meat packages in their Generally Recognized As Safe (GRAS) petitions to FDA.

a. Has Giant commissioned or performed any in-house studies regarding the temperature of its storage and retail displays that house fresh meat and fish, if applicable, that have been treated with carbon monoxide?

b. Does Giant measure the temperature in its fresh meat display cases? If so, please describe the protocols for measuring the temperature, including where in the display case the temperature is measured, *e.g.*, top, bottom, front, or rear of the case. Please also provide the range of variation in temperature for each measurement period from January 1, 2004, forward for the 10 largest and 10 smallest Giant stores that sell fresh meat (measured by value of meat sales, if available). If Giant does not measure the temperature of its fresh meat display cases, how does Giant ensure that the meat on display is not spoiled?

c. Has Giant received any citations from regulators for inadequate temperature control in meat since January 1, 2004? If so, please provide all documents relating to such citations.

d. Please describe the due diligence that Giant performs on the suppliers of such fresh meat products regarding temperature controls in the processing and transport of these products.

2. Consumer Purchasing Behavior

Please provide all information and all documents Giant has generated or examined relating to the following studies or focus groups regarding:

a. Criteria for consumer selection of fresh meat products;

b. Consumer acceptance of meat whose color is preserved by carbon monoxide;

c. Consumer ability to smell or otherwise detect spoiling meat; and

d. The ability and actual experience of consumers reading "use or freeze by" dates on packages.

3. Labeling/Store Signs

a. If applicable, please provide any special labeling or store signs that Giant employs to inform consumers that the meat has been treated with carbon monoxide, including any labeling or signs advising consumers that the color of treated meat should not be used to judge freshness.

b. Please describe how Giant assures that consumers, particularly those with poor eyesight, can read the "use or freeze by" dates on packages of carbon monoxide treated meat, and provide copies of any special labeling Giant used to assure readability of those dates.

4. Shelf Life

a. Upon receipt by Giant and placement in the retail display case, what is the average shelf life remaining for carbon monoxide treated meat (i.e., how many days before the labeled "use or freeze by" date)?

b. On average, how long is fresh meat that has not been treated with carbon monoxide held in the retail display case?

c. Please describe and provide all documents relating to any protocols Giant employs to ensure that meat that is past its labeled "use of freeze by" date is pulled from the display case and is no longer offered for sale, including steps the company takes to ensure that these protocols are followed. Please provide any disciplinary records regarding store managers that have violated these protocols (names of individuals, but not store locations, may be redacted).

d. What does Giant do with carbon monoxide treated meat that remains unsold past the labeled "use or freeze by" date?

e. How does Giant determine the shelf life of meat not treated with carbon monoxide?

5. Losses Due to Spoilage

a. What is the average loss due to spoilage of (1) ground meat and (2) other cuts that have been prepackaged in an atmosphere containing carbon monoxide?

b. How does this loss compare to meat that is not treated with carbon monoxide?

c. When such losses occur, does Giant absorb the loss or does the meat packer reimburse the stores for spoiled meat?

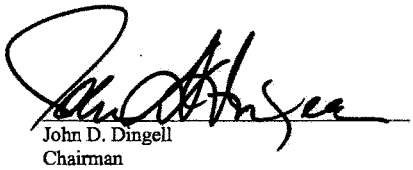
d. Do the same commercial terms apply to carbon monoxide packed meat as meat that has not been so treated?

6. Consumer Complaints

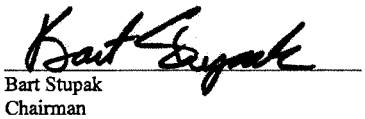
Does Giant have any system in place that is capable of documenting consumer complaints relating to carbon monoxide treated meat? If so, please describe such systems and provide any documents relating to such consumer complaints.

Finally, to the extent not otherwise requested, please provide all records relating to Giant's decision to sell fresh meat products treated with carbon monoxide. Please note that, for the purpose of responding to the above request, the terms "records" and "relating" should be interpreted in accordance with the attachment to this letter. We request you supply all requested information no later than the close of business three weeks from the date of this letter. If this request is interpreted to require production of documents that would constitute an unreasonable burden on the company, it may be modified upon agreement with Committee staff. If you have any questions relating to this request, please contact us, or have your staff contact David Nelson or Kevin Barstow with the Committee on Energy and Commerce staff at (202) 226-2424.

Sincerely,



John D. Dingell
Chairman



Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Ed Whitfield, Ranking Member
Subcommittee on Oversight and Investigations

ATTACHMENT

1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.

2. The terms "relating," or "relate" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.

KING & SPALDING

King & Spalding LLP
1700 Pennsylvania Avenue, N.W.
Washington, DC 20006-4706
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Theodore M. Hester
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Direct Fax: (202) 626-3737
thester@kslaw.com

October 11, 2007

The Honorable John D. Dingell, Chairman
Committee on Energy and Commerce
The Honorable Bart Stupak, Chairman
Subcommittee on Oversight and Investigations
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Dingell and Chairman Stupak:

On behalf of my clients, Giant Food LLC ("Giant") and The Stop & Shop Supermarket Company LLC ("Stop & Shop"), I am writing to advise you that both companies will discontinue the use of low-oxygen, modified atmosphere packaging of meat products later this month. Stop & Shop/Giant will continue to evaluate technology and labeling that maximizes the safety and quality of the package content while making it easier for customers to identify freshness.

Based on conversations I have had with Mr. Nelson on the Committee staff, it is my understanding that this decision by Stop & Shop/Giant addresses the concerns raised by your letter of September 13, 2007, to the CEO of Giant Food, and accordingly, that it will not be necessary for Stop & Shop/Giant to provide the Committee with the information requested by that letter.

Please let me know if you have any questions.

Sincerely,

Theodore M. Hester

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce
The Honorable Ed Whitfield, Ranking Member
Subcommittee on Oversight and Investigations

Ex. 11a

HENRY A. WAXMAN, CALIFORNIA
EDWARD J. MARKEY, MASSACHUSETTS
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Washington, DC 20515–6115

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September 13, 2007

Mr. Robert J. Ulrich
Chairman and CEO
Target Corporation
1000 Nicollet Mall
Minneapolis, MN 55403

Dear Mr. Ulrich:

Under Rules X and XI of the Rules of the United States House of Representatives, the Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations are investigating the adequacy of the efforts of the Food and Drug Administration (FDA) to protect Americans from unsafe food. We have been informed that Target Corporation stores (Target), including SuperTarget stores, regularly sell its customers fresh meat that is packaged in an atmosphere containing carbon monoxide, which is designed to alter the color of the meat to make it appear fresh and wholesome indefinitely.

Beyond the consumer deception involved, the Committee has concerns about the public health consequences of this packaging. These concerns are set out in the attached letters to Commissioner von Eschenbach and Secretary Leavitt dated February 9, 2006, and March 30, 2006, respectively.

As a large national grocery store chain that has chosen to sell meat packaged in an atmosphere containing carbon monoxide, we have questions regarding Target's decision to sell prepackaged fresh meats that have apparently been deceptively colored, and the conditions under which these products are sold. Accordingly, in order to assist the Committee in its investigation of the safety of the Nation's food supply, we request that you provide the Committee with the following information:

1. Temperature Control

We are interested in any special precautions that Target employs to assure that carbon monoxide treated meats are stored between 34–40°F. This is the temperature range that

Ex. 12

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West of Eade lot 6 is a dirt farm road, followed by railroad tracks, Cattlemen Road, another farm field, and the Salinas River. The river is three-fourths to one mile west of the field, at a lower elevation than the field. Approximately one-fourth mile northeast of the field is a reservoir used for pre-planting irrigation and dust control on the farm roads. No composting or waste management operations were observed in the area. Investigators observed a pile of compost stored approximately two and one-half miles north of the subject field, which was gone a few days later.

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Figure 5: Eade Ranch Positive E. coli O157:H7 Sample Locations

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illness in the family. Investigators were unable to determine the nature of the illnesses. NSF did not conduct ATP testing on a daily basis as required by the firm's SOP. No ATP testing was conducted from August 15 – 25, 2006. One ATP test collected from a scale vibrator failed on August 10, 2006, and no retest was documented. While the firm maintained flume water within its specifications for pH, chlorine, and temperature for the entire period of time reviewed, the parameter recorded as turbidity and used to determine the frequency of water changes was actually a measure of water color as determined using a Hach Portable Colorimeter. Mr. Daniels maintained that they had found the measurement of water color to be an acceptable substitute for turbidity but no validation of this method was provided and the firm did not have a turbidity standard for calibration. NSF maintained logs recording the washing of the harvesting totes for the month of August, but NSF was only able to provide logs from August 1 – 14. NSF did not keep a record that documented the washing of harvesting bins.

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Approximately 2,000 head of cattle graze on the Paicines Ranch in the hills and patches of dense vegetation along the San Benito River. Wild pigs and wild pig signs (tracks, fecal material, and rooting), were observed in the cattle grazing areas, in addition to deer, small mammals, and birds. In the hardened dirt of lot 1, no animal tracks were observed by investigators. However, wild pig tracks were observed in and around other lots on the Paicines ranch. Wild pig fecal material and rooting were seen in a field belonging to a different grower, located approximately 1.7 miles south of lot 1. Coyote feces were seen near the lots. Growers from two nearby vineyards reported damage to their vineyards caused by pigs during thinning and harvesting in late summer and fall.

Photo's and figures have been redacted from this report version for users with dial-up internet connections. A version of this report which includes all photos and figures is available at: http://www.dhs.ca.gov/fdb/HTML/Food/EnvInvRpt.htm

Pig Rooting and Tracks, In Field Belonging to Neighboring Grower to Mission Organics

CalFERT investigators collected 351 environmental samples on the Paicines Ranch, including cattle feces, wild pig feces, other animal feces, soil, and water. Of these, 45 samples (13 percent) were positive for *E. coli* O157:H7 and 26 (58 percent) of these 45 matched the outbreak strain as determined by PFGE analysis. PFGE pattern matches were found in cattle feces, wild pig feces, soil, and river water samples.

On the Wickstrom Ranch, no fencing was present around lot 817. Investigators observed that the well used for irrigation of lot 817 had a damaged casing. The Pajaro River flows past the ranch, approximately 150 feet west of the field, in a riverbed that is 15-20 feet lower in elevation than the field. Several cattle were seen grazing on a hill in a fenced pasture about 50 feet from the field. Beyond the Pajaro River, approximately one-third mile from the field, trailer homes with chained dogs and a house with corralled goats were observed. A pile of horse manure/shavings was observed 400 feet north and at a higher elevation than the field. Forty-four environmental and product samples were collected, including water, Moore swabs, soil/sediment, and romaine lettuce from an adjacent field. One (two percent) Moore swab sample from the Pajaro River was positive for *E. coli* O157:H7. However, the PFGE pattern of this sample did not match that of the outbreak strain.

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On the Taix Ranch, no fencing existed around lot 1TA1. The crops grown there were irrigated using well and Blue Valve water. San Juan Canyon Creek runs along the southwest side of Taix Ranch, containing spent NSF processing water and drainage from the nearby hills. The San Benito River flows past the Taix Ranch, approximately one-half mile northeast of lot 1TA1. Steer/bull pens and cows grazing in hills were observed one-half to one mile south of lot 1TA1, on Nyland Ranch. CalFERT investigators collected 133 environmental and product samples in and around the Taix Ranch, including baby greens, cattle and bird feces, soil/sediment, Moore swabs, drag swabs, and water. Of these, four samples (three percent) of soil adjacent to cattle feces at the Nyland Ranch was found positive for *E. coli* O157:H7. However, the PFGE pattern of the isolate did not match the outbreak strain. Investigators sampled the San Justo and San Luis Reservoirs in San Benito County, which feed the Blue Valve water supply system. Samples were negative for *E. coli* O157:H7.

On the Eade Ranch, lot 6C was not fenced. Crops were irrigated with water from a well that was not grouted and lacked good drainage and a concrete slab. The Salinas River flows past Eade Ranch, approximately three-fourths to one mile west of the field, at a lower elevation than lot 6C. To the east of lot 6C, past a neighboring field at a higher elevation, was a 300 – 400 foot wide buffer zone of bare ground, followed by cattle pastureland on the hills. A feed lot was located 1.6 miles south of lot 6C, home to approximately 3,500 head of cattle between June and September. A small herd of goats, a few horses, and some dogs were also observed on the feedlot premises. Pig tracks were observed at the catch pond above the east side of lot 6C and at another pond on the property. Pig scat was collected near the Salinas River and contained partially digested carrots. The farm manager reported problems with feral pigs during October around lot 9, which was planted with carrots. Lot 9 is about 1-1.3 miles north of lot 6C. CalFERT investigators collected 102 environmental and product samples in and around the Eade Ranch, including red leaf product, cattle feces from the feedlot, wild pig feces (collected from the edge of the river), water, and sediment. Of these, nine samples (nine percent) of cattle feces from the feedlot were positive for *E. coli* O157:H7, and one sample (one percent) of water from a cattle water trough was positive for *E. coli* 0157. The PFGE patterns of these samples did not match that of the outbreak strain.

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Exhibit 2	NSF: Organizational Charts; 3/23/06, 3/30/06
Exhibit 3	NSF South: Daily Room Temperature Check records, 8/1/06 - 8/31/06
Exhibit 4	NSF: SOP 106, Raw Material Inspection and Handling, Issued 10/23/06
Exhibit 5	NSF: Conventional Baby Spinach Raw Product Specifications, Issued 10/3/04
Exhibit 6	NSF North: Vacuum Cooling Tube Records, 8/1/06 - 8/31/06
Exhibit 7	NSF South: Pressure Cooling Tube Logs, 8/1/06 - 8/31/06
Exhibit 8	NSF South: Daily Depletion Log, 8/15/2006
Exhibit 9	NSF: Process Flow: Quality Assurance Reference (QAR) 002, Issued 3/30/06
Exhibit 10	NSF: SOP 112, Contaminated Product Procedure, Issued 9/28/06
Exhibit 11	NSF South: Water Systems Diagram
Exhibit 12	NSF South: Site Diagram, Equipment Area Layout
Exhibit 13	NSF: Hazard Analysis, Revised 2/20/06
Exhibit 14	NSF: HACCP Plan, Revised 3/14/06
Exhibit 15	NSF South: Wash Line Monitoring Records, 8/1/06 - 8/31/06
Exhibit 16	NSF South: Foreign Object Investigation Records, 4/29/06 - 9/12/06
Exhibit 17	NSF South: EB–South Master Sanitation Schedule San Juan Bautista, 5/7/06 - 9/10/06
Exhibit 18	NSF South: EB–South Daily Master Sanitation Schedule, 7/30/06 - 9/2/06
Exhibit 19	NSF: SOP 005, ATP Microbiological Testing, Issued 6/21/05
Exhibit 20	NSF South: ATP Testing Results, 7/15/06 - 8/31/06
Exhibit 21	NSF: Tote Washing Logs, 8/1/06 - 8/14/06
Exhibit 22	NSF South: SOP 011, Third Party Microbiological Testing, Issued 5/9/06
Exhibit 23	NSF South: Third Party Microbiological Testing Sample Rotation Schedule; Printed 10/4/06, 10/5/06
Exhibit 24	NSF South: Primus Labs Environmental Sample TPC Analysis Results; 8/7/06, 8/14/06, 8/21/06, 8/28/06, 9/7/06, 9/11/06
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CSPI NEWSROOM

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New CDC Data Show Increases in *E.coli*, *Salmonella* and *Vibrio*

For Immediate Release:
April 12, 2007

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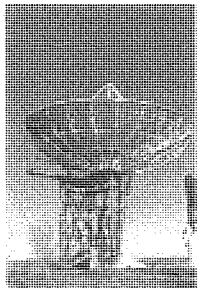

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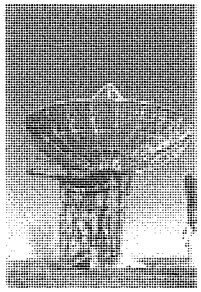

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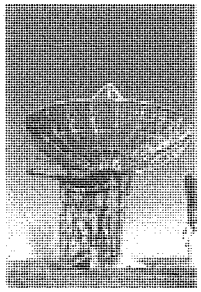

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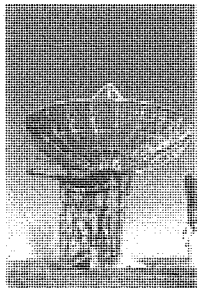

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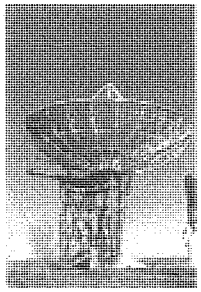

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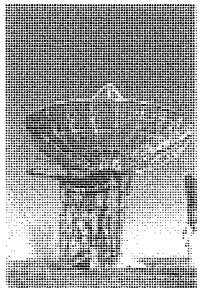

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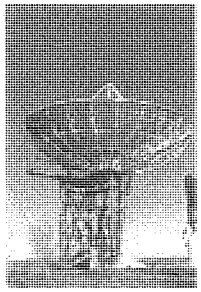

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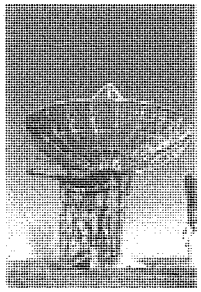

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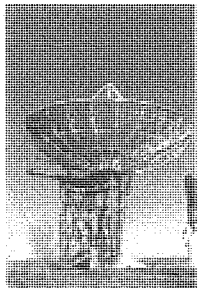

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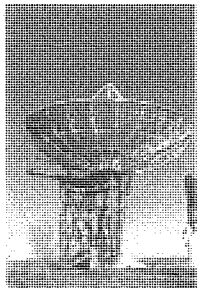

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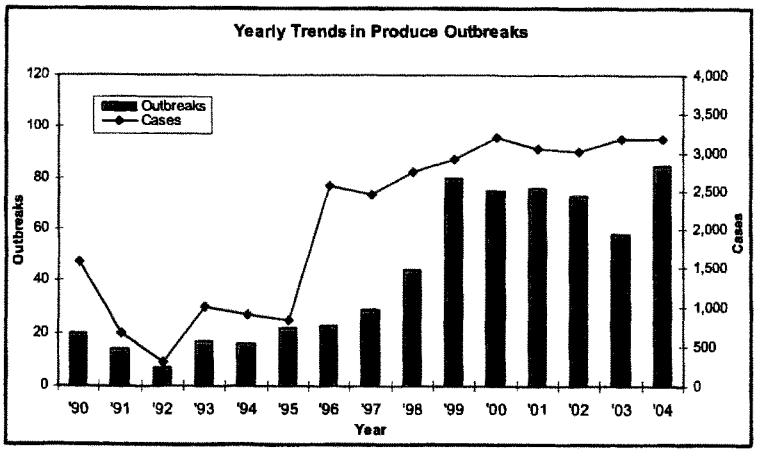
Behind CSPI's Outbreak Data: A look at the Produce Outbreak Numbers

- Outbreaks in produce have doubled between **1998**, which had **44** outbreaks, and **2004**, which had **85** outbreaks. This change may be due to enhanced outbreak surveillance efforts by the CDC starting in 1998.
- Between 1990 and 2004, there have been a total of 639 outbreaks in produce.
- CSPI's Outbreak Alert Database tracks foodborne illness outbreaks by food source using data from CDC and other highly reliable sources. Our database contains 5000 outbreaks with both food and hazard identified spanning 1990 to 2004.
- If you have questions about CSPI's database or about foodborne illness outbreak data, please contact **Farida Bhuiya** at **202-777-8377** or **fbhuiya@cspinet.org.**

All Produce Outbreaks			
Year	Outbreaks	Cases	Cases Per Outbreak
1990	20	1,563	78.2
1991	14	666	47.6
1992	7	293	41.9
1993	17	988	58.1
1994	16	900	56.3
1995	22	830	37.7
1996	23	2,557	111.2
1997	29	2,450	84.5
1998	44	2,749	62.5
1999	80	2,906	36.3
2000	75	3,185	42.5
2001	76	3,045	40.1
2002	73	3,007	41.2
2003	58	3,176	54.8
2004	85	3,181	37.4
Total	639	31496	49.3



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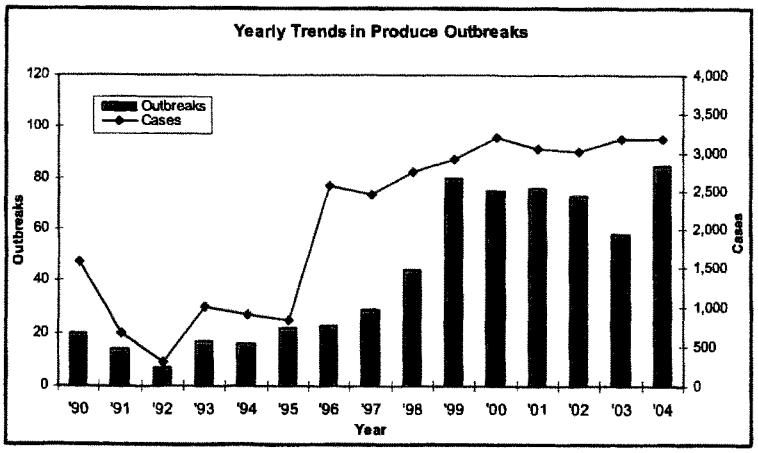

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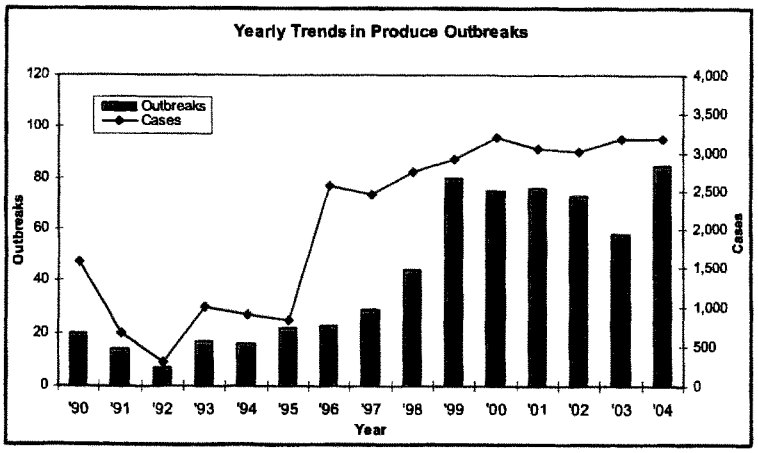

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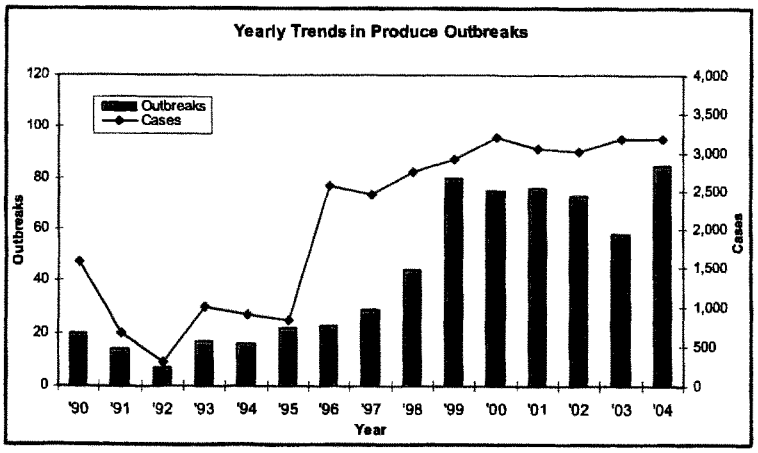

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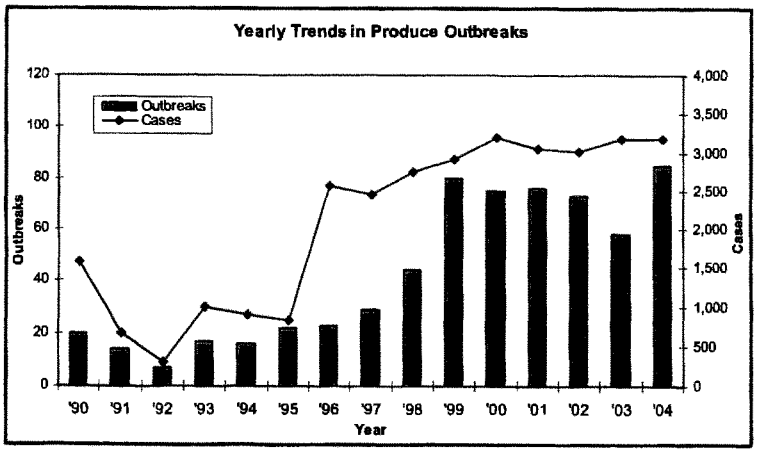

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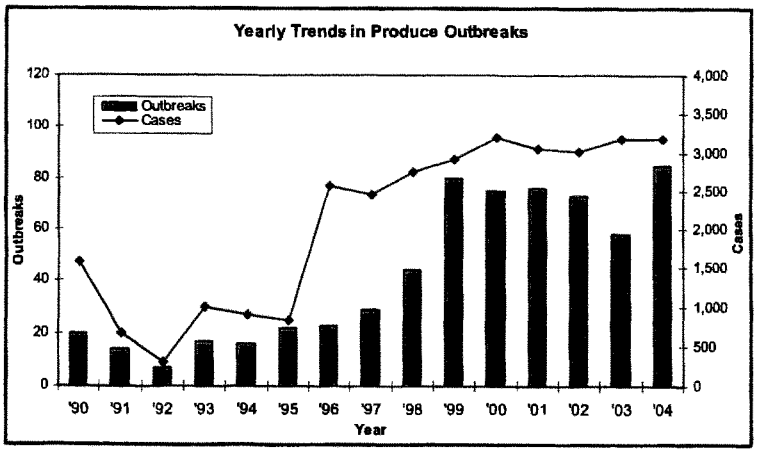

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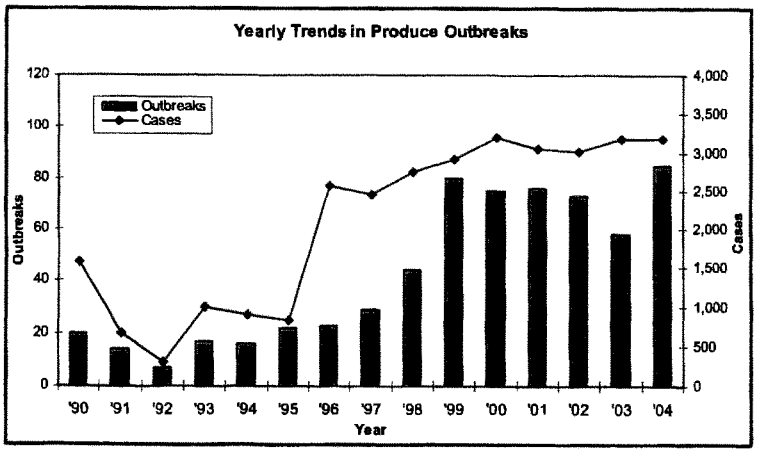

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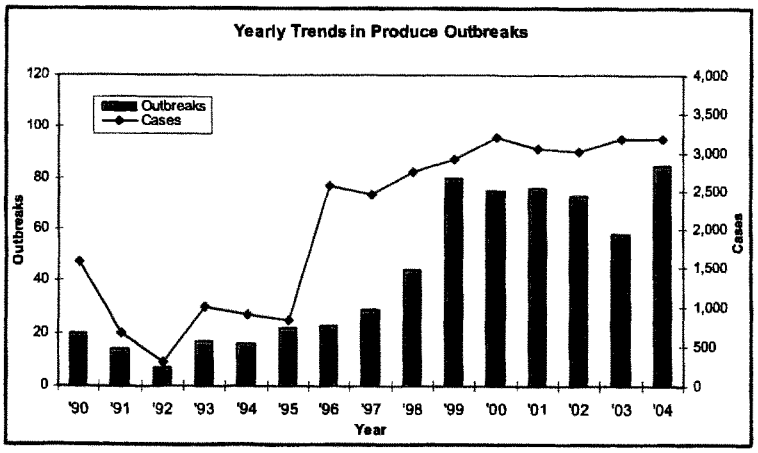

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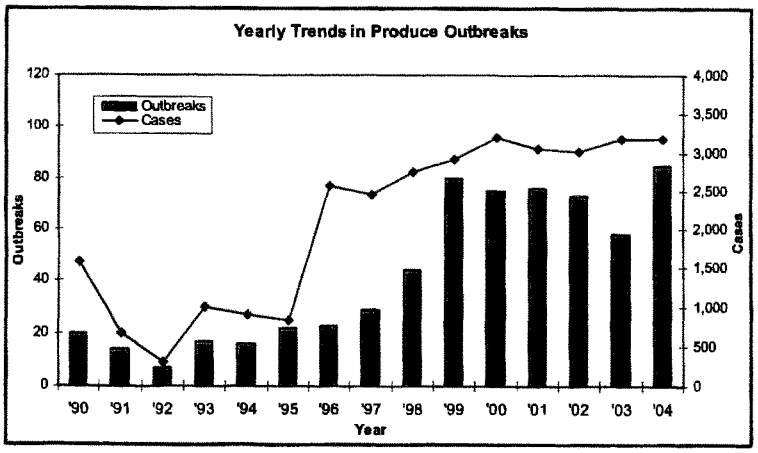

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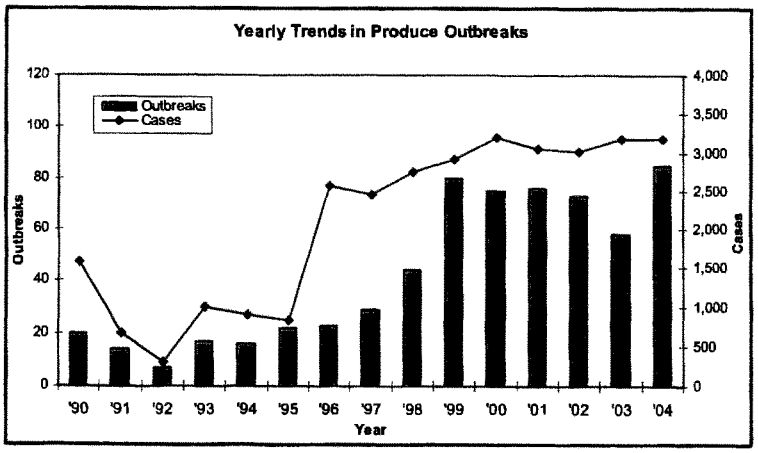

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Tifton, GA Resident Post
P.O. Box 1709
Tifton, GA 31794

MEMORANDUM

Date: 2/13/04

From: Janet B. Gray, CSO
Tifton, GA RP

Subject: Follow-up for Complaint # 22892

To: Blake Bevill, SI
Atlanta, GA DO

On 1/28/04, I was notified by my supervisor, Blake Bevill, to conduct a follow-up investigation for a consumer complaint that was received by the KAN-DO on 1/12/04. The complaint involved an 18 oz. plastic jar of Reduced Fat Crunchy Peter Pan Peanut Butter that had reportedly had a misprint on the nutritional labeling for the correct amount or percentage of carbohydrates. See ATTACHMENT A for a copy of the Consumer Complaint Report. The complainant, Ms. [redacted] noticed on a container of reduced fat peanut butter that she had purchased from Wal-Mart Superstore in located in Jefferson City, MO, the nutritional labeling stated 5 grams of carbohydrates per 2 tablespoons instead of the normal 14 grams of carbohydrates. The manufacturer of the product is ConAgra Foods, Inc., 101 S. Seabrook Dr., P.O. Box 585, Sylvester, GA 31791. The lot code on the product was "S32202311D".

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On 1/30/04, I contacted Ms. [redacted] and ask for details concerning her compliant. Ms. [redacted] said that she is a diabetic, and she has been controlling her diabetes by restricting the amount of carbohydrates in her daily diet. She said that the low-carbohydrate diet was recommended by her dietician and she has been on the regime since November of 2003. She says that she has been able to control her diabetes and since she has been on the diet she has not had to take insulin. She said that she has lost 15 lbs. since November. Ms. [redacted] informed me that since she is on a low-carbohydrate diet, she reads all nutritional labels for everything she eats, so that she will not go over her recommended intake of 195 grams or less of carbohydrates each day. She said that she routinely purchases reduces fat peanut butter, and she is aware of the normal amount of carbohydrates per serving. She said that she had just purchased a new jar of reduced fat crunchy peanut butter and she noticed that the nutritional label stated 5 grams of carbohydrates instead of the usual 14 grams of carbohydrates per 2 tablespoons. She said that she was concerned because there might be other people that are on a low carbohydrate diet for health reasons and she didn't want someone to over-do it thinking that they were getting fewer carbohydrates than they actually were. She said that she called the phone # listed on the jar for comments, and she talked to a man that looked up the lot code # for the peanut butter on a computer, and he said that their computer showed that the nutritional label listed that the product had 15 grams of carbohydrates. Ms. [redacted] told the man that she was looking right at her jar and it said 5 grams. The man said that he would look into it. Ms. [redacted] said that several days later, a woman from Peter Pan left a message on her answering machine, stating that there was a misprint with the labels and it had been taken care of. Ms. [redacted] added that she had recently received some coupons and a letter from the manufacturer stating that the problem with the mislabeling had been corrected and that the label should have read 14 grams not 5 grams.

Ms. [redacted] said that on 1/10/04 while shopping at the same Wal-Mart Superstore, she noticed that the labels on the Peter Pan Reduced Fat Peanut Butter still had 5 grams of carbohydrates instead 14 grams. At this time, she decided to notify FDA. Ms. [redacted] stated that she didn't know if the lot codes were the same. Ms. [redacted] said that she didn't know the specific dates or names of the representatives from Peter Pan that she had talked. Ms. [redacted] said that she went back to the same store again on 1/24/04 and she looked through all of the jars and didn't find any declaring 5 grams. She said that they now said 15 grams and that it appeared that they had gone up a gram. Ms. [redacted] felt that the misbranded amount of carbohydrates could throw off her diet and other people that had to watch their carbohydrate intake. I thanked Ms. [redacted] for her concerns and time, and told her that there would be a follow-up investigation at the manufacturer.

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Ms. [redacted] said that on 1/10/04 while shopping at the same Wal-Mart Superstore, she noticed that the labels on the Peter Pan Reduced Fat Peanut Butter still had 5 grams of carbohydrates instead 14 grams. At this time, she decided to notify FDA. Ms. [redacted] stated that she didn't know if the lot codes were the same. Ms. [redacted] said that she didn't know the specific dates or names of the representatives from Peter Pan that she had talked. Ms. [redacted] said that she went back to the same store again on 1/24/04 and she looked through all of the jars and didn't find any declaring 5 grams. She said that they now said 15 grams and that it appeared that they had gone up a gram. Ms. [redacted] felt that the misbranded amount of carbohydrates could throw off her diet and other people that had to watch their carbohydrate intake. I thanked Ms. [redacted] for her concerns and time, and told her that there would be a follow-up investigation at the manufacturer.

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ATTACHMENT A: Consumer Complaint Injury Report; 3 pages
ATTACHMENT B: Notice of Inspection; 1 page
ATTACHMENT C: Collection Report for Sample # 254933; 3 pages
ATTACHMENT D: Receipt for Samples; 1 page

Janet B. Gray/CSO
Tifton RP

SONIC
America's Drive-In

PRODUCT RECALL NOTICE
READ IMMEDIATELY

Date: February 16, 2007

Memo To: Sonic Partners that sell Peanut Butter Topping from Con Agra Foods

From: Nelson Taylor – Sonic Quality Assurance and Food Safety

Subject: PEANUT BUTTER TOPPING CLASS I RECALL

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Drive-In Address: _____

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America's Drive-In.

PRODUCT RECALL AFFIDAVIT

4 Digit Drive-In Number: _____

Drive-In Address: _____

_____

I _____ (Print Name) do affirm that I have read and understand the attached Product Recall Notice concerning the Peanut Butter Topping, Sonic Item #68585. I have reviewed all peanut butter topping inventory in my drive-in. I am confirming that I DO / DO NOT (Circle One) have peanut butter topping. I am also confirming that I have taken the appropriate action as outlined in the Recall Notice. The above product has been implicated in a CLASS I RECALL. If you DO have the product in question, please note the 14 digit UPC code and quantity below and discard as instructed . The UPC code should be on the can and the case.

Product Code/Pack Date: _____ Quantity: _____

Product Code/Pack Date: _____ Quantity: _____

Product Code/Pack Date: _____ Quantity: _____

Product Code/Pack Date: _____ Quantity: _____

_____
(Print Name and Title)

_____ _____
(Signature) (Date)

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(Signature) (Date)

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TO: Sonic Partners who sell Peanut Butter products from ConAgra Foods

FROM: Christi Woodworth, Director-External Communications

DATE: 16 February 2007

RE: Peanut Butter products recall talking points

Attached to this memo, you will find a Food Safety Alert that Sonic has faxed to all affected drive-ins. Customers and media may have questions for the drive-in about Sonic's reaction to the recall.

Customer Q&A:

Q. I heard about the peanut butter recall on TV. Should I be concerned about my favorite peanut butter topping at Sonic?

→ Although we have not had any incidents related to our peanut butter products, our peanut butter supplier issued a precautionary recall and we have removed impacted peanut butter products from the drive-in.

→ There is no indication at this time that our customers are or were exposed to an unsafe product.

→ We can continue to serve menu items with Reese's Peanut Butter Cups and Butterfingers.

Q. So, when will I be able to order my favorite peanut butter shake or sundae?

→ At this time, we aren't sure when we will receive new peanut butter topping. As soon as we have it, we'll be ready to serve your favorite peanut butter menu items.

Media Protocol – Direct All Media Inquiries to Christi Woodworth, 405.627.1260

	Do	Don't
1	**Do buy time.** **Tell the media it is company policy to refer all media inquires to Sonic's corporate headquarters, and that a company spokesperson will call them back.**	**Don't allow photographers or reporters inside the drive-in.** **You can't tell what the camera lens is seeing.**
2	**Do interview the reporter.** **Ask the reporter the following questions so that you will have information that Sonic's Corporate Communications Department will need in order to assist you:** • **What is your name and the name of the media organization you represent?** • **What is your telephone number?** • **What questions do you have?** • **What is your deadline?**	Don't say "No comment" because this implies guilt. Instead, say, "A company spokesperson will call you back. May I please have your contact information?
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KEYSTONE
Electronics Corp.
Rockaway, New Jersey 07866
PERFECTRON
Model 2000
Serial No. 00-0-0-0-0-0-0-0-0-0
02/22/2007

KRX
Electronic Office
Personal Computer
PC-8201A
02/22/2007

02/22/2007

02/22/2007

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February 16, 2007

To: Carvel Franchisees
From: Gary Bales
President
Re: ConAgra Foods – Peanut Butter Voluntary Class Recall

The Con Agra/Peter Pan Peanut Butter Situation:
ConAgra Foods and the Food & Drug Administration (FDA) are alerting the public that ConAgra's Peter Pan Peanut Butter products may be linked to the food borne illness salmonella. Although the peanut butter products used by Carvel are not produced in the affected Sylvester, GA plant (they are produced in the Humboldt, TN plant), ConAgra Foods is voluntarily recalling all varieties of Peter Pan Peanut Butter. *Extensive product testing has not shown any salmonella*, however ConAgra Foods is taking this precautionary measure because consumer health is their number one priority.

How does this affect Carvel?
Carvel utilizes ConAgra's *Peanut Butter Fudge Topping*, Item #420.

What do I do if I have this Peanut Butter Fudge Topping in my store?
If you currently have this Peanut Butter Fudge Topping in your store, please remove it from your shelves, fill out the attached "Certificate of Destruction" form to send to your distributor to receive credit, and then destroy the product. You will receive credit for the full amount of the purchase price of the Peanut Butter Fudge Topping product that you destroyed.

What about my finished ice cream flavors and products that contain Peanut Butter Fudge Toppings?
If you currently have finished ice cream flavors in your dipping cabinet that contain Peanut Butter Fudge Topping, including the flavors Chocolate Peanut Butter, Peanut Butter Treasure, or Peanut Butter & Jelly (along with any other flavors that you personally created using Peanut Butter Fudge Topping), please immediately remove and destroy them. Also, please discontinue making the Reese's Peanut Butter Sundae Dasher until this issue has been resolved.

Can I produce the flavors and products listed above using a different brand of Peanut Butter Fudge Topping?
There are currently no substitutes in our distribution system for Peanut Butter Fudge Topping, so you will not be able to produce and sell these flavors until further notice.

What about the peanut butter related toppings on my toppings bar?
Other peanut butter related products in our stores – Ground Reese's Peanut Butter Cups (Item #567), Peanut Butter Cups (Item #585), and Reese's Pieces (Item #546) – are not affected by this voluntary recall, and are safe for continued use.

What do I tell my customers if they ask if Carvel has been affected by the Peanut Butter recall?
Carvel's Peanut Butter Fudge Topping is produced by ConAgra Foods, who has issued a voluntary recall for this peanut butter based product. *Please note, however that Carvel's Peanut Butter Fudge Topping was not produced in the same manufacturing plant that experienced the salmonella outbreak*. As a precautionary measure only, ConAgra Foods and Carvel have removed the Peanut Butter Fudge Topping product from our stores until ConAgra Foods and the FDA has deemed it safe.

Ex 15

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Carvel's Peanut Butter Fudge Topping is produced by ConAgra Foods, who has issued a voluntary recall for this peanut butter based product. *Please note, however that Carvel's Peanut Butter Fudge Topping was not produced in the same manufacturing plant that experienced the salmonella outbreak*. As a precautionary measure only, ConAgra Foods and Carvel have removed the Peanut Butter Fudge Topping product from our stores until ConAgra Foods and the FDA has deemed it safe.

Ex 15

February 16, 2007

To: Carvel Franchisees
From: Gary Bales
President
Re: ConAgra Foods – Peanut Butter Voluntary Class Recall

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ConAgra Foods and the Food & Drug Administration (FDA) are alerting the public that ConAgra's Peter Pan Peanut Butter products may be linked to the food borne illness salmonella. Although the peanut butter products used by Carvel are not produced in the affected Sylvester, GA plant (they are produced in the Humboldt, TN plant), ConAgra Foods is voluntarily recalling all varieties of Peter Pan Peanut Butter. *Extensive product testing has not shown any salmonella*, however ConAgra Foods is taking this precautionary measure because consumer health is their number one priority.

How does this affect Carvel?
Carvel utilizes ConAgra's *Peanut Butter Fudge Topping*, Item #420.

What do I do if I have this Peanut Butter Fudge Topping in my store?
If you currently have this Peanut Butter Fudge Topping in your store, please remove it from your shelves, fill out the attached "Certificate of Destruction" form to send to your distributor to receive credit, and then destroy the product. You will receive credit for the full amount of the purchase price of the Peanut Butter Fudge Topping product that you destroyed.

What about my finished ice cream flavors and products that contain Peanut Butter Fudge Toppings?
If you currently have finished ice cream flavors in your dipping cabinet that contain Peanut Butter Fudge Topping, including the flavors Chocolate Peanut Butter, Peanut Butter Treasure, or Peanut Butter & Jelly (along with any other flavors that you personally created using Peanut Butter Fudge Topping), please immediately remove and destroy them. Also, please discontinue making the Reese's Peanut Butter Sundae Dasher until this issue has been resolved.

Can I produce the flavors and products listed above using a different brand of Peanut Butter Fudge Topping?
There are currently no substitutes in our distribution system for Peanut Butter Fudge Topping, so you will not be able to produce and sell these flavors until further notice.

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Other peanut butter related products in our stores – Ground Reese's Peanut Butter Cups (Item #567), Peanut Butter Cups (Item #585), and Reese's Pieces (Item #546) – are not affected by this voluntary recall, and are safe for continued use.

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What do I tell a customer who has additional questions or questions that I cannot answer?
Please direct any additional customer questions to ConAgra Foods at 1-866-344-6970, where food production experts are available to answer their specific questions.

What if I have additional questions regarding this voluntary product recall?
If you have any additional questions, please contact your Franchise Consultant, Director of Purchasing and Distribution Martin Folk (mfolk@focusbrands.com / 404-705-2057), or Director of Quality Assurance Juan Carlos Banderas (jbanderas@focusbrands.com / 770-452-9227).

We will continue to monitor the ConAgra Foods Peanut Butter recall, and will communicate any information as needed to protect the integrity of the Carvel brand. If you have any questions, please don't hesitate to call the franchisee hotline at 1-877-UCARVEL.

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***** Please Post In Stores or Share with Customers As Needed *****

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Until further notice, Carvel has removed our Peanut Butter Fudge Topping and all products made with this ingredient from our stores, including:

1. Chocolate Peanut Butter hand dipped flavor
2. Peanut Butter Treasure hand dipped flavor
3. Peanut Butter & Jelly hand dipped flavor
4. Reese's Peanut Butter Cup Sundae Dasher
5. Any other store-specific hand dipped or soft serve flavor

All other Carvel peanut butter related products are not affected by this voluntary recall, and are safe for continued use, including:

1. Ground Reese's Peanut Butter Cups
2. Reese's Mini-Peanut Butter Cups
3. Reese's Pieces

If you have any additional questions regarding the ConAgra foods voluntary recall, please contact them directly at 866-344-6970 where food production experts are available to answer any questions.

Thanks for your patronage,

Gary A Bales

Gary Bales
President of Carvel

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February 16, 2007

Dear Carvel Franchisees:

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Although the peanut butter products used by Carvel are not produced in the affected Sylvester, GA plant (they are produced in the Humboldt, TN plant), ConAgra Foods is voluntarily recalling all varieties of peanut butter. *Extensive product testing has not shown any salmonella*, however ConAgra Foods is taking this precautionary measure because consumer health is their number one priority.

Until further notice, Carvel has removed our Peanut Butter Fudge Topping and all products made with this ingredient from our stores, including:

1. Chocolate Peanut Butter hand dipped flavor
2. Peanut Butter Treasure hand dipped flavor
3. Peanut Butter & Jelly hand dipped flavor
4. Reese's Peanut Butter Cup Sundae Dasher
5. Any other store-specific hand dipped or soft serve flavor

All other Carvel peanut butter related products are not affected by this voluntary recall, and are safe for continued use, including:

1. Ground Reese's Peanut Butter Cups
2. Reese's Mini-Peanut Butter Cups
3. Reese's Pieces

If you have any additional questions regarding the ConAgra foods voluntary recall, please contact them directly at 866-344-6970 where food production experts are available to answer any questions.

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Firm Mailing Address: 101 S Seabrook Dr/Pob 585, Sylvester, GA 31791 United States

FEI: 1038538 **JD/TA:** 26 **County:** WORTH **Est Size:** 50,000,000 - and over

Phone: (229)776-8811 **District:** ATL-DO **Profiled:** No

Conveyance Type: **% Interstate:** **Inspectional Responsibility:**

Endorsement

Previous inspection of this peanut butter manufacturer was 8/3/2000 and was a follow-up to collect an additional mycotoxin sample from a lot of peanut butter in which SRL reported finding 4 ppb aflatoxin B1 in an initial surveillance sample. Inspection found the lot in question had been shipped and management cited corporate policy in refusing to allow review of production and shipping records.

The current inspection was conducted in response to several complaints including most recently, number 29134, an anonymous complaint alleging poor sanitaton, poor facilities maintenance, and poor quality program management. Specifics in that complaint include an alleged episode of positive findings of Salmonella in peanut butter in October of 2004 that was related to new equipment & that the firm didn't react to, insects in some equipment, water leaking onto product, & inability to track some product.

During this EI, local management acknowledged that an amount of product was placed on a "micro" hold in October of 2004 and was destroyed. Management refused to provide details to include the exact cause of the hold and the type/amount of product involved. Management did report that each day's production is tested for Salmonella and for coliforms, and allowed review of testing results for 2 specific dates in October of 2004 when new votators, or heat exchangers were installed in the peanut butter manufacturing line.

Inspection did not disclose any leaking water lines or overhead condensation, etc. leaking into any exposed product, either on packaging lines or in the raw and roasted peanut handling areas. The latter areas including product elevators and elevator boots, bins some of which are open at the top), aspiration lines, foreign material chutes, (continued in Inspection Summary)

Class: NAI

F/U: Routine

Dist:
O: ATL-File
C: Tifton-RP
C: Complaint Coord/PS
C: CB/FMD-145

Endorsement Location: FACTS

Inspector Name	Date & Time of Signature	Supervisor Name	Date & Time of Signature
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Firm Name & Address: ConAgra Grocery Products , 101 S Seabrook Dr , P.O. Box 585 Sylvester, GA 31791-0585 US

Firm Mailing Address: 101 S Seabrook Dr/Pob 585, Sylvester, GA 31791 United States

FEI: 1038538 **JD/TA:** 26 **County:** WORTH **Est Size:** 50,000,000 - and over

Phone: (229)776-8811 **District:** ATL-DO **Profiled:** No

Conveyance Type: **% Interstate:** **Inspectional Responsibility:**

Endorsement

Previous inspection of this peanut butter manufacturer was 8/3/2000 and was a follow-up to collect an additional mycotoxin sample from a lot of peanut butter in which SRL reported finding 4 ppb aflatoxin B1 in an initial surveillance sample. Inspection found the lot in question had been shipped and management cited corporate policy in refusing to allow review of production and shipping records.

The current inspection was conducted in response to several complaints including most recently, number 29134, an anonymous complaint alleging poor sanitaton, poor facilities maintenance, and poor quality program management. Specifics in that complaint include an alleged episode of positive findings of Salmonella in peanut butter in October of 2004 that was related to new equipment & that the firm didn't react to, insects in some equipment, water leaking onto product, & inability to track some product.

During this EI, local management acknowledged that an amount of product was placed on a "micro" hold in October of 2004 and was destroyed. Management refused to provide details to include the exact cause of the hold and the type/amount of product involved. Management did report that each day's production is tested for Salmonella and for coliforms, and allowed review of testing results for 2 specific dates in October of 2004 when new votators, or heat exchangers were installed in the peanut butter manufacturing line.

Inspection did not disclose any leaking water lines or overhead condensation, etc. leaking into any exposed product, either on packaging lines or in the raw and roasted peanut handling areas. The latter areas including product elevators and elevator boots, bins some of which are open at the top), aspiration lines, foreign material chutes, (continued in Inspection Summary)

Class: NAI

F/U: Routine

Dist:
O: ATL-File
C: Tifton-RP
C: Complaint Coord/PS
C: CB/FMD-145

Endorsement Location: FACTS

Inspector Name	Date & Time of Signature	Supervisor Name	Date & Time of Signature
Jackie M Douglas	03/11/2005 03:31 PM ET	Andrew B Bevill	03/17/2005 03:45 PM ET

Ex 16

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Related Firm FEI: **Name & Address of Related Firm:**

Registration Type

There are no Registration Types

Registration Dates

Establishment Type

M Manufacturer

Industry Code

23 Nuts/Edible Seed

District Use Code:

3 TO BE EDITED

Food and Drug Administration Establishment Inspection Report

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Inspection Basis: Consumer Complaint

Inspected Processes & District Decisions

PAC	Establishment Type	Products/ Process	MQSA	Reschedule Insp Date	Re-Inspection Priority	Inspection Conclusions
03803	Manufacturer	23 C D T				No Action Indicated (NAI

Final Decision?	District Decision Date	District Decision Type	District Decision Made By	Org Name
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Remarks:

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Products Covered

Product Code	Est Type	Description	Additional Product Description
23 C H T 07	Manufacturer	Peanut, Butter; Nonflex Plastic; Packaged Food (Not Commercially Sterile)	
23 C D T 07	Manufacturer	Peanut, Butter; Laminated; Packaged Food (Not Commercially Sterile)	

Assignees Accomplishment Hours

Employee Name	Position Class	Hours Credited To	PAC	Establishment Type	Process	Hours
Douglas, Jackie M	INV	ATL-DO	03803	Manufacturer	23 C D T	15
Douglas, Jackie M	INV	ATL-DO	03803	Manufacturer	23 C H T	15
Douglas, Jackie M	INV	ATL-DO	03R801	Manufacturer	23 C H T	5
					Total Hours:	35

Food and Drug Administration Establishment Inspection Report

FEI: 1038538 **Inspection Start Date:** 02/23/2005 **Inspection End Date:** 02/24/2005

Firm Name & Address: ConAgra Grocery Products , 101 S Seabrook Dr , P.O. Box 585 Sylvester, GA 31791-0585 US

Products Covered

Product Code	Est Type	Description	Additional Product Description
23 C H T 07	Manufacturer	Peanut, Butter; Nonflex Plastic; Packaged Food (Not Commercially Sterile)	
23 C D T 07	Manufacturer	Peanut, Butter; Laminated; Packaged Food (Not Commercially Sterile)	

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Inspection Result

EIR Location **Trips Num**
Hardcopy to ATL-DO/ Turbo EIR

Inspection Summary
(continued from Endorsement)

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Management expressed concern over the complaints and reported that some of the allegations are time-related to a recent employee dismissal, and that recent plant mechanization resulting in a number of employees losing their jobs has resulted in some employee dissent.

No FDA 483 was issued, but several concerns were verbally discussed. Sample 308388 was collected from current production and submitted to SRL for micro analysis per PAC 03803D.

IB Suggested Actions

Action	Remarks

Referrals

Org Name	Mail Code	Remarks

Refusals

Inspection Refusals:

Samples Collected

Sample Number
308388

Recall Numbers

Recall Number

Related Complaints

Consumer Complaint Number
29134

FDA 483 Responses

483 Issued?: **483 Location:**

Response Type	Response Mode	Response Date	Response Summary

Food and Drug Administration Establishment Inspection Report

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Firm Name & Address: ConAgra Grocery Products , 101 S Seabrook Dr , P.O. Box 585 Sylvester, GA 31791-0585 US

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FDA 483 Responses

483 Issued?: **483 Location:**

Response Type	Response Mode	Response Date	Response Summary

United States Food and Drug Administration
Consumer Complaint / Injury Report

This is an accurate reproduction of the original electronic record as of 04/23/2007

COMPLAINT | **# 29134**

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
01/13/2005	ATL-DO	ATL-DO	Letter	Former Company Employee	Harris,Georgette P	Closed

Complainant Identification

Name	Address	
ANONYMOUS	---------- ----------	GA

Phone (W)	Phone (H)	Source POC Name	Source Phone

Complaint/Injury

Complaint Description	Adverse Event Result	Adverse Event Date	Injury / Illness
Complainant, who wishes to remain anonymous, reports issues at firm, to include: poor sanitation practices, poor quality program management and poor facilities maintenance. See attachment for additional details.	None		

Notify DEIO/EMOPS?	Notification Date	Attended Health Professional?	Required Hospitalization?	Emergency Room / Outpatient Visit?	Reported Complaint To?	Need addnl. FDA Contact?
No						

Remarks

Complaint Symptoms

Sympton	System Affected	Onset Time	Duration	Remarks

Health Care Professional

Provider Name	Address	Phone	Occupation

Hospital Informatio

Hospital Name	Address	Phone	Dates of Stay

Emergency Room/Outpatient Visit

Hospital Name	Address	Phone	ER Date

Product and Labeling

Brand Name	Product Name	Product Cod	Product Description	PAC	UPC Code
	various	23CYT07	Peanut, Butter;Not Elsewhere Classified (NEC);Packaged Food (Not Commercially Sterile)		

United States Food and Drug Administration
Consumer Complaint / Injury Report

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Hospital Informatio

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Product and Labeling

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United States Food and Drug Administration
Consumer Complaint / Injury Report

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COMPLAINT | **# 29134**

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
01/13/2005	ATL-DO	ATL-DO	Letter	Former Company Employee	Harris,Georgette P	Closed

Complainant Identification

Name	Address	
ANONYMOUS	---------- ----------	GA

Phone (W)	Phone (H)	Source POC Name	Source Phone

Complaint/Injury

Complaint Description	Adverse Event Result	Adverse Event Date	Injury / Illness
Complainant, who wishes to remain anonymous, reports issues at firm, to include: poor sanitation practices, poor quality program management and poor facilities maintenance. See attachment for additional details.	None		

Notify DEIO/EMOPS?	Notification Date	Attended Health Professional?	Required Hospitalization?	Emergency Room / Outpatient Visit?	Reported Complaint To?	Need addnl. FDA Contact?
No						

Remarks

Complaint Symptoms

Sympton	System Affected	Onset Time	Duration	Remarks

Health Care Professional

Provider Name	Address	Phone	Occupation

Hospital Informatio

Hospital Name	Address	Phone	Dates of Stay

Emergency Room/Outpatient Visit

Hospital Name	Address	Phone	ER Date

Product and Labeling

Brand Name	Product Name	Product Cod	Product Description	PAC	UPC Code
	various	23CYT07	Peanut, Butter;Not Elsewhere Classified (NEC);Packaged Food (Not Commercially Sterile)		

United States Food and Drug Administration
Consumer Complaint / Injury Report

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Remarks

Complaint Symptoms

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Health Care Professional

Provider Name	Address	Phone	Occupation

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				No	

Date Used	Date Discontinued	Amount Remained	Imported Product?	Country of Origin	Label Remarks
			No		

Retail

Problem Ingredient Group

Name	Address

Manufacturer/Distributor

FEI	Name & Address	Home District	Firm Type
1038538	ConAgra Grocery Products 101 S Seabrook Dr P.O. Box 585 Sylvester Georgia United States 31791-0585	ATL-DO	Manufacturer

Initial Evaluation/Initial Disposition

Problem Keyword	Problem Keyword Details

Initial Evaluation	Initial Disposition	Disposition Made By	Disposition Date
FDA Action Indicated	Immediate Follow-Up	Harris,Georgette P	01/13/2005

Initial Disposition Remarks

Referrals

Org Name	HHS Mail Code

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COMPLAINTS FOLLOW - UP

Grouped Follow - Up Operations

Operation Id	Operation Code	Assignment Number	Accomplishing Organization	Performing Organization	Sample Number	PAF	Status	Status Date
2232873	13	604839	ATL-DO	ATL-IB-BB			Completed	03/17/2005
2236760	12	604839	ATL-DO	ATL-IB-BB			Completed	03/11/2005
2291937	31	604839	ATL-DO	ATL-IB-BB	308388		Completed	02/25/2005
2292631	41	604839	SRL	SRL-MBTK	308388-0	MIC	Completed	03/09/2005

Disposition Summary

Is Consumer Responsible?	Responsible FEI	Address	Name	Firm Type
No	1038538	101 S Seabrook Dr P.O. Box 585 Sylvester Georgia United States 31791-0585	ConAgra Grocery Products	Manufacturer

Follow-Up Disposition	Disposition Made By	Disposition Date
Surveillance Information for Next EI	Harris,Georgette P	03/31/2005

Disposition Remarks

Follow-Up Sent To

Organization Name	HHS Mail Code

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Surveillance Information for Next EI	Harris,Georgette P	03/31/2005

Disposition Remarks

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Organization Name	HHS Mail Code

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COMPLAINTS FOLLOW - UP

Grouped Follow - Up Operations

Operation Id	Operation Code	Assignment Number	Accomplishing Organization	Performing Organization	Sample Number	PAF	Status	Status Date
2232873	13	604839	ATL-DO	ATL-IB-BB			Completed	03/17/2005
2236760	12	604839	ATL-DO	ATL-IB-BB			Completed	03/11/2005
2291937	31	604839	ATL-DO	ATL-IB-BB	308388		Completed	02/25/2005
2292631	41	604839	SRL	SRL-MBTK	308388-0	MIC	Completed	03/09/2005

Disposition Summary

Is Consumer Responsible?	Responsible FEI	Address	Name	Firm Type
No	1038538	101 S Seabrook Dr P.O. Box 585 Sylvester Georgia United States 31791-0585	ConAgra Grocery Products	Manufacturer

Follow-Up Disposition	Disposition Made By	Disposition Date
Surveillance Information for Next EI	Harris,Georgette P	03/31/2005

Disposition Remarks

Follow-Up Sent To

Organization Name	HHS Mail Code

Complaint #29134

COMPLAINTS FOLLOW - UP

Grouped Follow - Up Operations

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Follow-Up Disposition	Disposition Made By	Disposition Date
Surveillance Information for Next EI	Harris,Georgette P	03/31/2005

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Establishment Inspection Report	FEI:	**1038538**
ConAgra Grocery Products	EI Start:	02/23/2005
Sylvester, GA 31791-0585	EI End:	02/24/2005

SUMMARY

The current inspection of this large peanut butter manufacturer was conducted under the Domestic Food Safety Program, CP 7303.803, and in response to several complaints (FACTS Numbers 24675, 25509, 27728, 27977, and 28611, received from 4/16/04 to 12/8/04) including most recently, a written complaint (FACTS Number 29134 dated 1/13/05) from an individual requesting anonymity.

The latter complaint included some specific allegations (microbial problems at the firm in October of 2004, insect infestation, etc.) that in summary allege generally poor in-plant sanitation and maintenance and poor quality program management. To preserve the requested anonymity, the copy of the written complaint received by Tifton RP is not attached to this report, but is submitted to the district under separate cover.

The firm continues to function as the only manufacturer of Peter Pan brand of peanut butter, and one of at least two producers of Great Value (a Wal-Mart label) of peanut butter. During this inspection the firm produced Peter Pan Creamy Peanut butter in 18 and 28 oz. plastic jars and in a 6 lb. laminated can. Inspection covered general sanitation and pest control, maintenance of equipment including new equipment installation, complaint handling, and quality control activities including finished product testing and release.

Inspection revealed the following concerns: 2 areas on production lines where filled containers of peanut butter were not completely covered from overhead contamination, an accumulation of spillage and or dust at wall/floor juncture around air handling cabinet in the ingredients room, and a temporary baffle made of cardboard in use on an empty jar line. Insect evidence observed was limited to a single moth flying in the enclosed garage area where bulk trucks of peanuts are pneumatically unloaded. Examination of raw and roasted peanut cleaning, sorting and blanching equipment, including elevator boots and buckets and aspiration collection points and discharges revealed no apparent insect activity. No FDA-483 was issued and the concerns were verbally discussed with management.

During the inspection, covers were placed over the exposed areas on the 2 production lines, and the cardboard baffle was discarded.

Management verbally reported that each day's production is tested in-house for Salmonella and coliforms prior to release of the production for sale. Firm acknowledged that there was some production in October that did not meet product specifications and was put on a Micro hold, and was subsequently destroyed. However, management would not report the exact reason for the hold, nor the amount of product affected.

Ex 17

Establishment Inspection Report	FEI:	**1038538**
ConAgra Grocery Products	EI Start:	02/23/2005
Sylvester, GA 31791-0585	EI End:	02/24/2005

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The firm did provide a review of micro testing results on 2 dates in October that were reported to be 2 dates on which new votators (heat exchangers) were placed on line after having been cleaned and sanitized. Tests on both dates were "negative" for Salmonella and coliforms.

Sample 308388, Peter Pan Peter Butter in 18 oz. jars and packaged on 2/24/05, was collected and submitted to SRL for microbial analysis per PAC 03803D.

ADMINISTRATIVE DATA

Inspected firm:	ConAgra Grocery Products
Location:	101 S Seabrook Dr P.O. Box 585 Sylvester, GA 31791-0585
Phone:	229776-8811
FAX:	
Mailing address:	101 S Seabrook Dr/Pob 585 Sylvester, GA 31791
Dates of inspection:	2/23/2005, 2/24/2005
Days in the facility:	2
Participants:	Jackie M Douglas, Investigator

HISTORY

This firm is part of ConAgra Grocery Products Company, which is a division of ConAgra Foods, Inc. The division office is located in Irvine, CA. ConAgra Foods, Inc. is located in Omaha, NE, and per the Nebraska secretary of State's web posting, is a foreign corporation incorporated in Delaware in 1976, with the registered agent identified as McGrath, North, Mullin, & Kratz, PC, 1601 Dodge Street, Omaha, NE.

The Sylvester, GA firm is reported to be the only facility manufacturing Peter Pan Peanut Butter. The firm also manufactures Great Value Peanut Butter, a brand sold by Wal-Mart and Sam's Wholesale stores. The firm has no FDA regulatory history.

The previous FDA inspection here was 8/4/2000 and was limited to a follow up of 4 ppb aflatoxin B1 found in a surveillance sample of peanut butter. The firm refused to provide review of production and shipping records for the specific lot without a written request. No FDA-483 was issued. Previous

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Sample 308388, Peter Pan Peter Butter in 18 oz. jars and packaged on 2/24/05, was collected and submitted to SRL for microbial analysis per PAC 03803D.

ADMINISTRATIVE DATA

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Phone:	229776-8811
FAX:	
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Dates of inspection:	2/23/2005, 2/24/2005
Days in the facility:	2
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INTERSTATE COMMERCE

The firm routinely ships in interstate commerce via common carrier, and distributes peanut butter from this location to ConAgra's warehouse distribution locations, the nearest of which are located in Atlanta, GA and Jacksonville, FL. The firm ships some product directly to Wal-Mart or Sam's stores.

JURISDICTION

During this inspection the firm manufactured creamy peanut butter and packaged it under the Peter Pan label in 18 and 28 oz. plastic jars, and a 6 lb. composite can. Refer to Exhibits 4 through 6 for labeling of these products. The firm also packages Peter Pan peanut butter in 12, 40, 48, and 56 oz. plastic jars.

Great Value products are packed in 18, 28 and 40 oz. plastic jars only. I did not witness any production of Great Value product, nor any reduced fat peanut butter, or non-standardized peanut butter spreads which the firm also produces.

Management reports the firm uses only domestic peanuts in its production of peanut butter products.

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Great Value products are packed in 18, 28 and 40 oz. plastic jars only. I did not witness any production of Great Value product, nor any reduced fat peanut butter, or non-standardized peanut butter spreads which the firm also produces.

Management reports the firm uses only domestic peanuts in its production of peanut butter products.

RESPONSIBILITY

Upon entering the firm on 2/23/05, I was asked by the receptionist to sign in and to read and sign the attached (see Exhibit 1) Plant Confidentiality Agreement. I advised her I would read it but could not sign it. I read it and asked if I could keep a copy and she agreed.

I asked for the Plant Manager and was directed to Mr. Thomas C. Gentle. Credentials were shown to and the FDA-482, Notice of Inspection (and "Resources for FDA Regulated Businesses" document) issued to Mr. Gentle. Present also at this time were Mr. Michael J. Matis, Quality Assurance Manager, and Mr. Rick A. Young, Maintenance and Sanitation Manager. These 3 individuals accompanied throughout the inspection on 2/23. On 2/24, Messrs. Gentle and Matis accompanied. Mr. Matis and Mr. Gentle accompanied during sample collection on 2/24/05, and the FDA-484, Receipt for Samples, was issued to and signed by Mr. Gentle.

The current Food Security Guidance document was provided to Mr. Gentle, and I inquired as to the firm's registration status under the bio-terrorism rule. Mr. Matis advised the firm was registered and that had been handled by the firm's corporate office.

I explained to Messrs. Gentle, Matis and Young that this was a GMP inspection precipitated by recent complaints and I provided some background information to them. Refer to the heading

FDA contact here was an investigation completed 2/14/04 conducted in follow-up to complaint 22892 regarding inaccurate labeling in reduced fat peanut butter. The firm had corrected the labeling declaration on the product.

INTERSTATE COMMERCE

The firm routinely ships in interstate commerce via common carrier, and distributes peanut butter from this location to ConAgra's warehouse distribution locations, the nearest of which are located in Atlanta, GA and Jacksonville, FL. The firm ships some product directly to Wal-Mart or Sam's stores.

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Complaints/ Product Defects for the content of this discussion and additional information related to the firm's handling of complaints.

Messrs. Gentle and Matis provided information related to complaint handling, history of business, chain of command, and general processing operations. Mr. Matis answered questions related to the firm's quality control operations. Mr. Young answered questions related to equipment operations, maintenance, and sanitation and pest control activities.

On 2/23/05, Mr. Matis cited corporate policy in initially delaying review of written quality procedures related to microbial testing of peanut butter. He said he would have to check with the firm's corporate offices before allowing it. On 2/24, Mr. Matis provided a verbal overview of the firm's microbial testing program and showed to me test summaries on finished product. He reported having obtained permission to do so from the firm's legal counsel, Ms. Sondra Morar, Esq., 1601 Dodge Street, Suite 3700, Omaha, NE 68102. Mr. Matis declined to answer a question as to whether or not aflatoxin test results posted on lot identifications of raw peanut bins were the results from in-house tests or from vendor/USDA supplied certificates.

Mr. Matis reports directly to Mr. Gentle. Mr. Gentle is the most responsible person present here on a day to day basis. Mr. Gentle reports to Mr. Joe McSherry (Omaha NE), Director of Operations for the ConAgra Grocery Products Division. Mr. McSherry, in turn reports to Mr. Greg Smith, Vice President of Operations, and Mr. Smith to Mr. Dean Hollis, President of the Grocery Products Division. Messrs. Hollis and Smith are located at Irvine, CA. (PO Box 57079, Irvine, CA 92619-7078). Mr. Bruce Rhode was identified as president of ConAgra Foods of Omaha, NE.

MANUFACTURING CODES

The code in use is best explained through an example, as follows:

Given the following code of "21115055 00 1037A BEST BY AUG242006", the key is: "2111" is the Sylvester, GA plant identifier; "5" is the year 2005; "055" the Julian date, in this case 2/24/05; "00" is a space filler; 1037 is a variable military time for filling; and "A" is the A line (firm also has B, C, and D lines for consumer products). The "Best By" date is 18 months from the production date. Note that at one time the firm's plant identifier character began with the letter "S". Mr. Matis speculated that this character was misread as a "5" in some of the complaints FDA had received.

Codes are inked on jar lids and on the plastic over wraps of cases. Exhibit 2 shows a case label with the code occupying the 2 lines left of the bar code. Case codes are basically the same, but with the time following the line indicator. Note display units assembled for Wal-Mart stores lack case over wraps. However, individual jars within each flat are coded and the firm records jar codes on shipping documents for each pallet of display units prepared. Mr. Matis showed this to me and explained that in some instances these displays may contain commingled codes.

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