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JOINT HEARING ON IMPORT SAFETY

HEARING

BEFORE THE

SUBCOMMITTEE ON TRADE

OF THE

COMMITTEE ON WAYS AND MEANS
U.S. HOUSE OF REPRESENTATIVES

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JOINT HEARING ON IMPORT SAFETY

THURSDAY, OCTOBER 4, 2007

U.S. House of Representatives,
COMMITTEE ON WAYS AND MEANS,
SUBCOMMITTEE ON TRADE,
Washington, DC.

The Subcommittees met, pursuant to notice, at 10:05 a.m., in Room 2128, Rayburn House Office Building, Hon. John Lewis [Chairman of the Subcommittee on Oversight] and Hon. Sander Levin [Chairman of the Subcommittee on Trade] presiding.

[The advisory announcing the hearing follows:]

ADVISORY

FROM THE COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON OVERSIGHT

FOR IMMEDIATE RELEASE
September 27, 2007
TR–6

CONTACT: (202) 225–6649

Levin and Lewis Announce a Joint Hearing on Import Safety

Ways and Means Trade Subcommittee Chairman Sander M. Levin (D–MI) and Oversight Subcommittee Chairman John Lewis (D–GA) today announced that the Subcommittees will hold a joint hearing on import safety. **The hearing will take place on Thursday, October 4, in the main Committee hearing room, 1100 Longworth House Office Building, beginning at 10:00 a.m.**

In view of the limited time available to hear witnesses, oral testimony at this hearing will be heard from invited witnesses only. However, any individual or organization not scheduled for an oral appearance may submit a written statement for consideration by the Subcommittees or for inclusion in the printed record of the hearing.

FOCUS OF THE HEARING:

This hearing will focus on the mechanisms and legal authorities under current law for ensuring the safety of food and consumer products imported into the United States. The hearing will examine how these mechanisms and authorities are functioning, what problems may exist with respect to each mechanism or authority, and what improvements are needed. The hearing will look into the role of the U.S. Customs and Border Protection (CBP) and CBP's coordination with the Food and Drug Administration (FDA), the Food Safety Inspection Service (FSIS) and the Consumer Product Safety Commission (CPSC) at the ports of entry. In addition, the hearing will address the application of sanitary and phytosanitary measures in the United States and overseas and the consistency of those measures with the World Trade Organization (WTO) rules.

BACKGROUND:

Recent incidents of contaminated food, unsafe toys, and other products have led to an examination of the United States regulatory framework for ensuring that imports meet U.S. public health, product safety, and consumer protection standards. The ability of U.S. Government regulators to identify and take action to prohibit the importation of the unsafe imports is a critical part of the inquiry.

Last year, the United States imported 1.9 trillion of goods. A growing portion of the American food supply is provided through imports. For example, in 2005, more than 84 percent of all fish and seafood was imported. Each day, 25,000 shipments of food are imported.

Similarly, Americans use and depend on imported products for virtually every aspect of daily life, from toys to appliances. In 2006, China was the largest supplier of imported toys, producing 86 percent of toys played with by American children.

The United States has a complex structure at the ports of entry to process imports and monitor compliance with American safety standards. The composition of the President's Interagency Working Group on Import Safety illustrates the multi-

faceted, multi-agency dimension of the system. The Working Group is comprised of members from the following departments, agencies, and Executive Office divisions: Health and Human Services, State, Treasury, Justice, Agriculture, Commerce, Transportation, Homeland Security, Management and Budget, United States Trade Representative, Environmental Protection and the Consumer Product Safety Commission.

The CBP, a component of the Department of Homeland Security, is the primary border agency and the starting point for ensuring the safety of all imports. In the area of food and product safety, CBP must coordinate with a host of agencies, including the Department of Health and Human Services and its Food and Drug Administration, the Department of Agriculture's Food Safety and Inspection Service, and the Consumer Product Safety Commission.

The Trade and Oversight Subcommittees are focused on providing CBP with proper authority and appropriate enforcement tools for ensuring import safety.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Please Note: Any person(s) and/or organization(s) wishing to submit for the hearing record must follow the appropriate link on the hearing page of the Committee website and complete the informational forms. From the Committee homepage, *http://waysandmeans.house.gov*, select "110th Congress" from the menu entitled, "Hearing Archives" (*http://waysandmeans.house.gov/Hearings.asp?congress=18*). Select the hearing for which you would like to submit, and click on the link entitled, "Click here to provide a submission for the record." Once you have followed the online instructions, completing all informational forms and clicking "submit" on the final page, an email will be sent to the address which you supply confirming your interest in providing a submission for the record. You ***MUST REPLY*** to the email and ***ATTACH*** your submission as a Word or WordPerfect document, in compliance with the formatting requirements listed below, by close of business **Thursday, October 18, 2007**. Finally, please note that due to the change in House mail policy, the U.S. Capitol Police will refuse sealed-package deliveries to all House Office Buildings. Those filing written statements who wish to have their statements distributed to the press and interested public at the hearing can follow the same procedure listed above for those who are testifying and making an oral presentation. For questions, or if you encounter technical problems, please call (202) 225–1721.

FORMATTING REQUIREMENTS:

The Committee relies on electronic submissions for printing the official hearing record. As always, submissions will be included in the record according to the discretion of the Committee. The Committee will not alter the content of your submission, but we reserve the right to format it according to our guidelines. Any submission provided to the Committee by a witness, any supplementary materials submitted for the printed record, and any written comments in response to a request for written comments must conform to the guidelines listed below. Any submission or supplementary item not in compliance with these guidelines will not be printed, but will be maintained in the Committee files for review and use by the Committee.

1. All submissions and supplementary materials must be provided in Word or WordPerfect format and MUST NOT exceed a total of 10 pages, including attachments. Witnesses and submitters are advised that the Committee relies on electronic submissions for printing the official hearing record.

2. Copies of whole documents submitted as exhibit material will not be accepted for printing. Instead, exhibit material should be referenced and quoted or paraphrased. All exhibit material not meeting these specifications will be maintained in the Committee files for review and use by the Committee.

3. All submissions must include a list of all clients, persons, and/or organizations on whose behalf the witness appears. A supplemental sheet must accompany each submission listing the name, company, address, telephone and fax numbers of each witness.

Note: All Committee advisories and news releases are available on the World Wide Web at *http://waysandmeans.house.gov*

The Committee seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call 202–225–1721 or 202–226–3411 TTD/TTY in advance of the event (four business days notice is requested). Questions with regard to special accommodation needs in general (including availability of Committee materials in alternative formats) may be directed to the Committee as noted above.

Chairman LEWIS. Good morning.

The hearing is now called to order. Today the Subcommittee on Oversight and Subcommittee on Trade review import safety. This is the first hearing that I have had the pleasure of cochairing with my good friend from Michigan that I've known for many years, Chairman Levin.

It is unfortunate that the first opportunity that we have had to work together is to discuss the really terrible, terrible embarrassment to our country. It seems that practically every week there's another product or food recall announcement. Let me be clear, I believe that some of our agencies have suffered by severe staff cuts and under-funding in recent budget years. I continue to strongly support increasing the funding for food and product safety standards and enforcement.

Many of my colleagues co-signed a letter we sent to a appropriator to increase funding for the Consumer Product Safety Commission. You need to choose the resources, the staff, and the authority to protect all American consumers.

I do not understand why it is so difficult to find a single, clear source that agencies use to share recall information with American consumers. Don't—sat that is, I've sat with myself and I've tried to go through all of the website and all of the links. It is a mess. It is very confusing. I do not understand why a consumer cannot easily go to a single source and learn exactly what toys are safe for their children, what food is safe to eat, what beds are safe to sleep in, and what medicines won't heal them.

Inspecting and stopping harmful products at the border is common sense. It saves us from the headaches of tracking defective products that are already in stores and homes; it is a nightmare. We need to return to being proactive and not reactive.

The creativity and ingenuity of the American people is what made our country a great and powerful force. Our social and economic movements have been a driving force in developing labor, human rights, safety, and quality standards. We have framed a debate, not just here at home, but all over the world. It has not always been easy. It has not always been pretty, and there is always much more to be done, but we have made progress and there is still more progress to be made. America pushed the envelope, pushed the debate, and opened doors.

In the 1970s safety was a priority of the Federal Government. It was understood through the 1980s and much of the 1990s that the American consumer expected nothing less of being the best. At some point, some place, we lost our way. The scrap and test system has got to go. Flawed, defective products should not continue to be a nightmare for American consumers.

In a global world we have the right to know who, what, when, where, why, and how of all these items we use. Talking, working

together, and sharing information is not hard. We can do better, and we must do better. I look forward to the witnesses' testimony, thank each of you for being here this morning.

Now it is my pleasure to recognize the distinguished Chairman of the Subcommittee on Trade——

Chairman LEVIN. Let Ramstad go and then I'll go.

Chairman LEWIS. To recognize my Ranking Member, my good friend Mr. Ramstad from the great state of Minnesota.

Mr. RAMSTAD. Well, I thank both chairmen for yielding time and also for calling this hearing on the safety of our imports. Also want to thank Chairman Levin, Ranking Member Herger, and Chairman Lewis for their work on product safety. Obviously very, very timely and important topic.

The United States consumes almost $2 trillion each year in goods, and of course many sectors of our food market, like fish and seafood, are overwhelmingly comprised of imports. Obviously these imports raise our standards of living as they provide us with fresh fruits and vegetables during the winter months, and try growing fruits and vegetables in Minnesota during February. So, we certainly are well aware of the importance of imports in terms of food. Also, imports provide consumers access to products that simply aren't grown or raised or made domestically. So, imports, obviously, are an important part of our—not only of our trade, but of our quality of life.

Having said that, however, American consumers obviously need to know that the food and products they purchase are safe. That should be axiomatic and certainly I don't think there's any disagreement as to that caveat.

I look forward today, Mr. Chairman, to hearing how our various Federal agencies are working to improve the inspection and safety of our imports, and how private industry can partner with these agencies to better improve these processes. After all, it's the importers as well as the consumers who have the most to lose if these safety issues aren't adequately addressed.

With that, Mr. Chairman, I yield back the balance of my time.

Chairman LEWIS. Thank you very much, Mr. Ramstad. Now I'm pleased to recognize——

Chairman LEVIN. I'd just like to say that I'll speak and then Herger—yeah, go ahead.

Chairman LEWIS. Now I'm pleased to recognize the distinguished Chairman of the Subcommittee on Trade, a gentleman I've known for many years, Mr. Levin from the state of Michigan.

Chairman LEVIN. Well, thank you, thank you. You might say many decades.

Chairman LEWIS. Many decades.

Chairman LEVIN. How pleased we are to be joining your Subcommittee, Mr. Lewis and Mr. Ramstad. I think that the two Subcommittees clearly have an important role to play here. I'll be very brief, Mr. Chairman.

Expanded trade is here to stay. Globalization is here to stay, but there's a critical issue and that is, how much we need to shape the terms of expanded trade, how much we need to act upon it or simply let it happen. Essentially I think what's happened in recent months is an illustration of the need for us to not only welcome ex-

panded trade, but be vigilant about its terms, its content, and its course, to have an active role in shaping its course. There are some who essentially say, "just let it happen," but I think for the consumers of this country—they're saying that we have to do better than that.

We welcome all of you who are here from various agencies. I think everybody here realizes that you come here with some constraints. You're part of an administration, in most cases, but we do hope that you'll be as straightforward as you can be because we need to know where the gaps are and how we fill those gaps, because our constituents expect nothing less.

So, I yield back and the balance of my time, and I guess I yield to Mr. Herger to take as much time as he would like.

Mr. HERGER. Thank you very much, Chairman Levin and Chairman Lewis.

Americans have the right to know that all the products they buy, whether imported toys or U.S.-grown spinach and beef, are safe and healthy. We have seen several recent cases where the products bought by American consumers were not safe. In most cases, our system was able to catch these products before significant harm was done. Unfortunately in some cases the system was not. We need to carefully review the procedures we have in place to ensure the safety and health of American consumers.

I look forward to hearing from the Administration on the steps it takes to ensure the safety of domestic and imported products. I also would like to hear how the Administration is seeking to enhance cooperation, excuse me—cooperation among the many Federal agencies responsible for product safety, especially the role of Customs and Border Protection officers at our ports.

I also want to examine today all aspects of ensuring the safety of the products Americans buy, whether foreign or domestic. As the recent recalls of U.S. agriculture products attest, and just this morning of white chocolate, this is not just an import issue. The Administration is obviously taking this issue seriously with the formation of the President's Interagency Working Group on Import Safety. I'd like to hear from the witnesses about the Working Group's initial report and on what additional recommendations it will be making.

We must also realize that we cannot rely on border inspections alone to ensure the safety of the products we import. It is neither financially nor logistically feasible to inspect every product imported into the country, nor would a hundred percent inspection guarantee safety. Rather, we need to work with producers throughout the supply chain, importers, and foreign governments to ensure that all necessary steps are taken to ensure the products they produce and ship are safe.

I believe we need a risk-based system that is flexible enough to deal with the thousands of different types of products purchased by Americans. The best system for ensuring the safety of seafood is not necessarily the best system for ensuring the safety of furniture. A one-size-fits-all approach will not provide the most effective safety system for the American consumer.

I also want to take this opportunity to point out that our trade agreements do not force the United States to lower its standards.

In fact, our trade agreements allow us to raise the safety standards of our trading partners because the burden is on them to prove that the products exported to the United States meet all safety requirements.

Several pieces of legislation would impose new user fees to pay for increased inspections. Before we impose any new user fees, I'd like to know whether such fees would actually improve safety and whether they would unduly burden trade and increase cost on consumers. Americans rely on imports. Whether it is affordable toys, fresh fruit and vegetables in the winter, or tropical products that do not grow in the United States, we should resist the temptation to use unscientific restrictions simply to limit imports in the name of health and safety.

Shutting off or severely limiting imports is not the answer. We need a risk-based system that pushes out our borders and ensures the safety of products through the entire supply chain, from farm to factory to the final consumer.

I look forward to the testimony. Thank you, Mr. Chairman.

Chairman LEWIS. Thank you very much, Mr. Herger, for your statement. Would any other Member like to make an opening statement?

[No response.]

Now we will hear from our witnesses. I ask that each of you limit your testimony to 5 minutes. Without objection your entire statement will be included to the record. I will have all of the witnesses give their statements, and then the Members will ask questions of the entire panel.

It is now my pleasure and delight to introduce our first witness, Mr. Warren Maruyama, the General Counsel of the Office of the United States Trade Representative. Thank you, sir, for being here.

STATEMENT OF WARREN H. MARUYAMA, GENERAL COUNSEL, OFFICE OF THE U.S. TRADE REPRESENTATIVE

Mr. MARUYAMA. Chairman Lewis, Chairman Levin, and Members of the Committee, it is a privilege to be here today to discuss with you an issue of priority for every American household: ensuring the safety of imported foods and consumer goods.

USTR does not have direct regulatory responsibility, but the safety of the American consumer is paramount for us, just like it is for every other U.S. government agency.

Under WTO rules and our Free Trade Agreements, the United States has a right to determine the appropriate level of health and safety protection for any product that is sold here. All of our FTA's allow the United States, on the basis of a science-based risk assessment, to apply appropriate measures to safeguard life and health, as long as they do not arbitrarily discriminate against imports. From the beginning, the GATT and the WTO have recognized that nothing in trade agreements should prevent parties from adopting legitimate measures to protect human health, animal or plant life or health.

Accordingly, no foreign country can make us accept unsafe products or force us to lower high U.S. safety standards. We set our safety standards; not them. All imported food products, including meat and poultry, seafood, dairy products, beverages, and fruit and

processed fruits and vegetables must meet the same stringent food safety standards that apply to foods produced in the United States.

Of course, we have a right to inspect imported foods at our borders to determine if they are safe. U.S. inspectors review import records, assisted by a computerized statistical sampling system. Products are reviewed based on probable risk and given special scrutiny based on heightened risk, For example, the U.S. Food and Drug Administration recently inspected Chinese seafood imports, determined that certain fish and shellfish were being treated with unapproved antibiotics and food additives, and immediately detained imports of these items into this country until their safety could be assured.

At the same time, there are unprecedented challenges to ensuring that America's food supply continues to be one of the safest in the world and that American consumers continue to have full confidence in the foods they eat, the medicines they take, and the toys their children play with.

First, despite progress in food safety and important advances in pathogen testing technology, recent outbreaks of food-borne illness and the discovery of contaminated food and feed products, involving both imported products from abroad and products grown or manufactured in this country, underscore the vital importance of continuing to improve and adapt our systems, technologies, and strategies.

A second challenge is the unprecedented growth in trade flows. Last year nearly $2 trillion of imported goods entered the United States. Trade flows continue to grow, and many experts believe that trade volumes could triple by 2015. The expansion of trade has brought our consumers the benefits of winter vegetables from Latin America; innovative, life-saving medical discoveries from Europe and Japan; and low-cost shoes, toys, and apparel from Asia, but the increase also means that there are more imported goods crossing our borders. While 20 years ago most food and beverage products were imported from Canada or Western Europe, today we import food products from just about every corner of the world. This means that American consumers have access to an unprecedented array of dietary choices, but with this choice has come new challenges to ensuring appropriate adherence to U.S. safety standards in products shipped from 150-plus countries.

Finally, America is a major exporter of beef, pork and poultry, grains and oilseeds, processed foods, medical devices, cars, and a host of other products that are subject to foreign safety requirements. So, if we were to deviate from science- and risk-based regulation and erect protectionist barriers to trade in the guise of consumer safety, U.S. exports would be vulnerable to mirror restrictions, and some of our trading partners would be only too happy to oblige.

This is a critically important issue for American agriculture. Overall U.S. agricultural exports are up from 50.7 billion in Fiscal Year 2000 to a projected 79 billion in Fiscal Year 2007. The growth in United States agriculture has occurred as a result of both the multilateral 1994 Uruguay round Agreement on Agriculture and our FTA's. Because of NAFTA, Canada and Mexico have emerged as the top two export markets for American agriculture.

Moreover, much of the recent growth in U.S. farm exports is coming from emerging markets, while exports to traditional high-income markets, like the European Union and Japan, have stagnated. As a result, the share of U.S. farm and food exports destined from emerging markets has climbed from 30 percent during the early nineties to 43 percent in 2006. China and Mexico now account for a quarter of U.S. farm imports, nearly triple their share in 1990. Exports to China alone are now nearly equal to exports to Europe. I don't need to explain to the Subcommittee how easy it is for foreign countries to lock out American farm imports through spurious sanitary and phytosanitary measures, just as they have been known to restrict, for example, U.S. manufactured goods through protectionist barriers that are dressed up as legitimate passenger safety or regulatory standards.

At the direction of the President, Health and Human Services Secretary Leavitt is chairing an Interagency Import Safety Working Group that is engaged in a top-to-bottom review of the U.S. import safety system. Secretary Leavitt has made clear that he's prepared to take a fresh look at each and every aspect of our system and that nothing is sacred.

Mr. Chairman, the benefits of international trade are wide-ranging, yet these benefits bring with them new and complex responsibilities for government and the private sector, for U.S. and foreign producers, American growers—okay.

Mr. Chairman, the U.S. food safety system is the import—is one of the safest in the world. We at USTR look forward to working with you to keep it that way. Thank you for inviting me to testify today on these critical issues.

[The prepared statement of Mr. Maruyama follows:]

Prepared Statement of Warren H. Maruyama, General Counsel, Office of the U.S. Trade Representative

Chairman Levin, Chairman Lewis, and Members of the Committee, it is a privilege to be here to today to discuss an issue of priority for every American—ensuring the safety of imported foods and consumer goods.

USTR does not have direct regulatory responsibility, but the safety of the American consumer is paramount for us, just like it is for every other U.S. government agency.

Under the World Trade Organization (WTO) rules and our Free Trade Agreements (FTAs), the United States has a right to determine the appropriate level of health and safety protection for any product that is sold in the United States. All of our FTAs allow the United States, on the basis of a science-based assessment of specific risk, to apply appropriate measures to safeguard life and health, so long as our requirements do not arbitrarily discriminate against imports. From the beginning, the General Agreement on Tariffs and Trade (GATT) and WTO have recognized that nothing in trade agreements should prevent parties from adopting legitimate measures to protect human, animal, or plant life or health.

Accordingly, no foreign country can make us accept unsafe products, or force us to lower high U.S. safety standards. We set our safety standards. All imported food products, including meat and poultry, seafood, dairy products, beverages, and fresh and processed fruits and vegetables must meet the same stringent food safety standards that apply to foods produced in the United States.

And, of course, we have a unilateral right to inspect imported foods at our borders to determine if they are safe. U.S. inspectors review import records, assisted by a computerized statistical sampling system. Products are reviewed based on their probable risk and given special scrutiny based on heightened risk. For example, under the U.S. Food and Drug Administration's (FDA's) recent seafood safety measures, FDA inspected Chinese seafood imports, determined that certain fish and shellfish were being treated with unapproved antibiotics and food additives, and im-

mediately detained imports of these items into the United States until the safety of those products could be assured.

At the same time, there are unprecedented new challenges to ensuring that America's food supply continues to be one of the safest in the world, so that American consumers continue to have full confidence in the foods they eat, the medicines they take, and the toys their children play with.

First, despite progress in the areas of food safety and important advances in pathogen testing technology, recent outbreaks of food-borne illness and the discovery of contaminated food and feed products—involving both imported products from abroad and products grown or manufactured in this country—underscore the vital importance of continuing to improve and adapt our systems, technologies, and strategies to a rapidly changing and growing global economy.

A second challenge is the unprecedented growth in trade flows. Last year, nearly $2 trillion of imported goods entered the United States. Trade flows continue to grow, and many experts believe that volumes could triple by 2015. The expansion of trade has brought our consumers the benefits of fresh winter vegetables from Latin America, innovative life-saving medical discoveries from Europe and Japan, and low-cost shoes, toys, and apparel from Asia, but the increase also means that there are more imported goods entering our borders. And while 20 years ago, most food and beverage products were imported from Canada or Western Europe, today we import food products from just about every corner of the world. This means that American consumers have access to an unprecedented array of dietary choices, but with this choice has come new challenge to ensuring appropriate adherence to U.S. safety standards in products shipped from 150-plus countries from around the globe.

Finally, America is a major exporter—of beef, pork and poultry, grains and oilseeds, processed foods, medical devices, cars, and a host of other products that are subject to foreign safety requirements. So if we were to move away from science and risk-based regulation, and erect protectionist barriers to trade unchecked by WTO and FTA rules in the guise of consumer safety, U.S. exports would be highly vulnerable to mirror restrictions, and some of our trading partners would be only too happy to oblige.

This is a critically important issue for American agriculture. Overall, U.S. agricultural exports are up from $50.7 billion in FY 2000 to a projected $79 billion in FY 2007. The growth in United States agriculture has occurred as a result of both the multilateral 1994 Uruguay Round Agreement on Agriculture, which created new market access opportunities for American farmers and ranchers and our FTAs. In 2006, U.S. agricultural exports to markets covered by FTAs reached $26 billion, about 38 percent of total U.S. agricultural exports, compared to just $255 million, or about one-half of one percent of total U.S. agricultural exports in 1986. Because of NAFTA, Canada and Mexico have emerged as the top two export markets for American agriculture. Moreover, much of the recent growth in U.S. farm exports is coming from emerging markets, while exports to our traditional high-income markets like the European Union and Japan have stagnated. As a result, the share of U.S. farm and food exports destined for emerging markets climbed from 30 percent during the early 1990s to 43 percent in 2006. China and Mexico now account for a quarter of U.S. farm exports, nearly triple their share in 1990. Exports to China alone are now nearly equal to exports to Europe. I don't need to explain to this Subcommittee how easy it is for foreign countries to lock out American farm exports through spurious sanitary and phytosanitary measures, just as they have been known to cynically restrict, for example, U.S. manufactured goods through protectionist barriers that are dressed up as legitimate passenger safety or regulatory standards.

At the direction of the President, Health and Human Services Secretary Leavitt is chairing an inter-agency Import Safety Working Group that is engaged in a top-to-bottom review of the U.S. import safety system for food, drugs, devices, and other consumer products. On September 10, 2007, Secretary Leavitt submitted an interim report to the President. The report urges a fundamental shift in strategic emphasis from traditional border-based inspections and interventions to a comprehensive "life cycle" strategy that focuses on identifying and managing risks through every step of the product life cycle—building safety into products from the very beginning of the supply chain. Such a strategy will require working with foreign producers, U.S. importers, and U.S. retailers to build safety into design, manufacturing, and distribution processes, backed up by government and private sector verifications, certifications, and border inspections. The focus should be on managing risk, using the best of science and technology, and best practices from the private sector, and governments around the world. The Working Group is currently working on a follow-up report that will contain specific recommendations for implementing such an ap-

proach and ensuring that the American public continues to have full confidence that our system is one of the safest in the world.

Conclusion

The benefits of international trade are wide-ranging, yet these benefits bring with them new and complex challenges—for government and the private sector; for U.S. and foreign producers, growers, retailers, importers, and consumers; and ultimately for Congress and the Executive Branch. The American public properly has high expectations for the safety of the food they eat and the products they and their children use. The U.S. food supply is one of the safest in the world due to the cooperation and active participation of all stakeholders—farmers, industry, exporters, importers, and consumers—in protecting the entire U.S. food chain. We at USTR look forward to working with you to keep it that way. Thank you for inviting me to testify today on these critical issues.

Chairman LEWIS. That each member of the panel to try to limit your statement to 5 minutes. Your entire statement will be added to the record. This is a very important issue; we want to get your full statement in if at all possible.

Our next witness is from the United States Customs and Border Protection. I am pleased to welcome the Honorable Daniel Baldwin, the Assistant Commissioner of the Office of International Trade. Welcome.

STATEMENT OF THE HONORABLE DANIEL BALDWIN, ASSISTANT COMMISSIONER, OFFICE OF INTERNATIONAL TRADE, U.S. CUSTOMS AND BORDER PROTECTION, DEPARTMENT OF HOMELAND SECURITY

Mr. BALDWIN. Thank you, Chairman Lewis, Chairman Levin, and Members of the Subcommittee.

I'm pleased to appear before you today to discuss the actions we are taking at Customs and Border Protection to ensure the safety of imported products. My name is Daniel Baldwin. I am the Assistant Commissioner of the Office of International Trade at CBP. My office holds the responsibility of formulating CBP's trade policy, developing programs, and enforcing U.S. import laws.

The recent increase and discoveries of tainted consumer products is an issue that falls within the purview of my office. In response to recent dangers found in some imported apparel, pet food ingredients, toys, seafood, and other products, the President issued an executive order establishing an Interagency Working Group on Import Safety. That working group, chaired by Health and Human Services Secretary Leavitt, is comprised of senior officials from 12 Federal departments and agencies, each with a unique and critical import safety responsibility.

CBP is actively participating in the Working Group and has assigned a senior manager to work full time with the group. She and other CBP staff assisted with the development of the Strategic Framework for Continual Improvement in Import Safety released on September 10th. That strategic framework developed by the working group consists of three organizing principles: prevention, intervention, and response. Within these three principles, the Working Group has targeted six building blocks for further action.

In recent years CBP has worked extensively to coordinate activities and enforcement actions with other government agencies, such as USDA and HHS. As the guardian of our Nation's borders, CBP

has broad authority to interdict imports at the ports of entry. We identify, target, and interdict high-risk shipments using our data along with information from other agencies. It is important to note that long before the recent headlines CBP had been working with agencies such as the Consumer Product Safety Commission on identifying and interdicting products such as flammable children's sleepwear and other products that present a danger to our citizens.

CBP has several tools to interdict potentially unsafe imports. In my testimony today, I'd like to highlight two of these tools that CBP can utilize to interdict unsafe imports: first, CBP qualified personnel, and second, CBP targeting methodology.

As I noted, CBP often coordinates with other agencies to interdict and seize unsafe imports. Action under CBP purview takes place at the frontline. Our diverse workforce on the frontline enables CBP to mount rapid and effective responses by utilizing the specialized expertise of CBP officers, agriculture specialists, import specialists, international trade specialists, and laboratory technicians. Each of these CBP functions can work together to gather intelligence, establish targeting criteria, gather and test samples, and report on results.

The second tool, our targeting efforts. We're able to use various targeting mechanisms to ensure the compliance of products imported into the United States. These mechanisms are specifically designed to incorporate the safety concerns of other agencies in identifying high-risk imports. CBP currently uses the Automated Targeting System, Automated Manifest System, and the Automated Commercial System. CBP uses these three systems to target high-risk cargo, screen inbound merchandise, and process import entries.

There are a couple of key tenets of the Import Safety Working Group that CBP fully supports. First, the Working Group has noted a major challenge related to the need for inter-operability. The International Trade Data System, or ITDS, is a key component to improve safety and to improve systems inter-operability. The recently enacted Security and Accountability For Every, or SAFE, Port Act of 2006 established a requirement of electronic interface for all Federal agencies that monitor or control the movement of imported products in domestic commerce.

The Working Group has taken a strong step toward establishing inter-operable computer systems. On September 10th, the OMB circulated a directive to heads of departments and agencies participating in the Working Group, requiring that each designate a representative to coordinate their agency's involvement in ITDS. We at CBP believe that this will maximize the functionality of ITDS and will re-energize the effort to build inter-operable systems. Requiring additional government agencies to participate in ITDS marks a strong first step in improving safety.

The Working Group has established a sound framework for further exploration of ways to improve safety of our American imports. The Working Group has highlighted the need to shift from reliance on a "snapshot", where unsafe products are simply interdicted at the border, to a cost-effective, prevention-focused "video" model that identifies targets, and those critical points in the import life

cycle where the risk of unsafe products is greatest and verifies the safety of products at those most important phases.

CBP remains committed to partnering with our Federal agencies in order to refine our targeting skills and increase our coordination and collaboration of government personnel, and to ensure the prevention of contaminated and dangerous products from entering the United States.

I thank you for the opportunity to testify, and I'm happy to field any questions.

[The prepared statement of Mr. Baldwin follows:]

Prepared Statement of The Honorable Daniel Baldwin, Assistant Commissioner, Office of International Trade, U.S. Customs and Border Protection, Department of Homeland Security

INTRODUCTION

Mr. Chairman and Members of the Subcommittee, I am pleased to appear before you today to discuss the actions we are taking at Customs and Border Protection (CBP) within the Department of Homeland Security, to ensure the safety of imported products. My name is Dan Baldwin and I am the Assistant Commissioner in the Office of International Trade at U.S. Customs and Border Protection. My office holds the responsibility of formulating CBP's trade policy, developing programs, and enforcing U.S. import laws.

NATIONAL TRADE STRATEGY

As a general rule CBP has not targeted imports based on import safety criteria alone. Pursuant to our twin goals of fostering legitimate trade and travel while securing America's borders, CBP has developed a National Trade Strategy to help our agency successfully fulfill our trade facilitation and trade enforcement mandate. CBP trade enforcement focuses on the collection of import duties and the enforcement of trade laws. Our National Trade Strategy is based upon six Priority Trade Initiatives (PTI). These PTI's are: Antidumping and Countervailing Duty, Intellectual Property Rights, Textiles and Wearing Apparel, Revenue, Agriculture, and Penalties. Under the terms of our trade prioritization strategy we focus CBP resources in our efforts to address areas of key trade importance.

In recent years, CBP has worked extensively to coordinate activities and enforcement actions with USDA and HHS, and in particular the FDA. As the guardian of our Nation's borders, CBP has broad authority to interdict imports at the Port of Entry. We identify, target, and interdict high-risk shipments using our data along with information from other agencies. For instance, we frequently interact with USDA and FDA on questions regarding food enforcement action, as those departments house the subject matter expertise on food and agriculture admissibility standards. CBP enforces safety regulations by relying on the statutory authority of other Federal agencies with the specific mandate of safety issues. It is important to note, also, that long before the recent headlines CBP had been working with agencies such as the Consumer Product Safety Commission (CPSC) on identifying and interdicting products such as flammable children's sleepwear and other products that present a danger to our citizens.

As the value and volume of our imports continue to grow, CBP recognizes the challenges we face in maintaining safe and secure imports. To meet these challenges, President Bush issued Executive Order 13439 on July 18, 2007, establishing an Interagency Working Group on Import Safety (Working Group). The Working Group, chaired by Health and Human Services Secretary Michael O. Leavitt, is comprised of senior officials from 12 Federal departments and agencies, each with unique and critical import safety responsibilities. The review was ordered by the President to ensure that our work with the private sector and foreign counterparts would be comprehensive and effective in promoting the safety of imported products.

CBP is actively participating in the Working Group and has assigned a senior manager to work full time with the group. She and other CBP staff assisted with the development of the "Strategic Framework for Continual Improvement in Import Safety" released by Secretary Leavitt on September 10, 2007.

The Strategic Framework developed by the Working Group is a risk-based approach and consists of three Organizing Principles: 1) Prevention, 2) Intervention, and 3) Response Within these three principles the Working Group has targeted six

Building Blocks for further Administration action. Some of these Building Blocks specifically focus on enhancing current CBP capabilities and programs.

CBP CAPABILITIES

CBP has several tools to interdict potentially unsafe imports. In my testimony today, I would like to highlight two of these tools that CBP can utilize in order to interdict unsafe imports: CBP Personnel and CBP Targeting.

PERSONNEL

CBP maintains a diverse workforce that works to assist, detect and interdict imports that may be harmful to the health of the American public. For instance, CBP Officers and CBP Agriculture Specialists receive specific training on ag/bio-terror incidents. We currently have the ability to deploy more than 18,000 CBP Officers, 2,000 Agricultural Specialists, and 1,000 Import Specialists in response to emerging threats to American consumers. Furthermore, CBP's Laboratory and Scientific Services (LSS) maintains seven separate laboratories around the country, with a 24/7 technical reach back center and employs approximately 220 chemists, biologists, engineers, and forensic scientists.

Our workforce enables CBP to mount rapid and effective responses by utilizing the specialized expertise of CBP Officers, Agriculture Specialists, Import Specialists, International Trade Specialists, and Laboratory Technicians. Within existing authorities, each of these CBP occupations can work together to gather intelligence, establish target criteria, gather and test samples, and analyze and report results.

TARGETING

In addition to our skilled workforce, CBP uses various targeting mechanisms to ensure the compliance of products imported into the U.S. These mechanisms are specifically designed to incorporate the safety concerns of other agencies in identifying high-risk imports.

One of the systems used is CBP's Automated Targeting System (ATS). ATS, which is based on algorithms and rules, is a flexible, constantly evolving system that integrates enforcement and commercial databases. ATS is the system through which we process advance manifest information to detect anomalies and "red flags," and determine which cargo is "high risk" and should be scrutinized at the port of arrival. ATS is essential to CBP's ability to target high-risk cargo entering the United States.

Another system CBP uses is the Automated Manifest System, which provides us with advance cargo information to be used for targeting and screening of all imported merchandise. This advance information allows CBP to identify shipments of interest in advance of arrival. By identifying shipments early, CBP is better able to focus resources on those shipments that may be of concern, prevent their introduction into the commerce and ensure appropriate coordination with other regulatory agencies.

The Automated Commercial System (ACS), CBP's automated system of record for entry processing and cargo clearance, allows us to screen for additional food and agricultural risks. The majority of the targeting criteria present in this system are used to prevent the introduction of contamination, pests, or diseases.

In addition to these CBP automated systems, CBP maintains the National Targeting Center (NTC). The NTC is the facility at which personnel from a number of government agencies are co-located to review advance cargo information on all inbound shipments. At the NTC, CBP personnel are able to quickly coordinate with personnel from other Federal agencies such as the FDA, Food Safety and Inspection Service (FSIS), and Animal Plant Health Inspection Service (APHIS) to target high-risk food shipments.

Furthermore, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (know as the Bioterrorism Act, or BTA) authorized FDA to receive prior information to target shipments of food for humans or animals prior to arrival. The Bioterrorism Act gave CBP the opportunity to assist FDA with the prior notice requirements. CBP worked in concert with FDA to augment an existing automated interface to institute a prior-notice reporting requirement with minimal disruption to the trade. In addition, under the Bioterrorism Act, we worked with FDA to commission over 8,000 CBP officers to take action on behalf of the FDA. This commissioning allows FDA to assert a 24/7 presence to enforce the Act at all ports.

A major challenge we face in our operations is the need for interoperability. Interoperability is the ability of one system to communicate with another. Too often, we build sophisticated data systems without ensuring the systems' ability to interface with one another. We need to finalize implementation of interoperable data systems, already under development, that facilitate the exchange of relevant product information among parties within the global supply chain to ensure import safety.

Government agencies should share the information they collect about activities occurring along the global supply chain to prevent, identify, mitigate, and respond to product safety hazards. Manufacturers test products to ensure that they comply with relevant performance and safety standards; government agencies inspect and test products to ensure that they meet regulatory requirements associated with public health, environmental safety, and consumer protection. Marketplace recalls are conducted to remove faulty or unsafe products from commerce. Information about these activities is often collected and recorded, and should be shared among individual actors in the import life cycle or aggregated and analyzed as a whole.

Information technology has improved the availability and exchange of information on imported products. The import entry process is one area where information technology is being used to improve the exchange of import supply chain information. Throughout most of U.S. history, a revenue-centric import system focused largely on the collection of customs duties on imported goods. In the post-9/11 environment, however, government and industry have recognized the need to expand the focus of the import system to encompass security and safety.

The International Trade Data System (ITDS) is a key component to improve systems interoperability. The recently enacted Security and Accountability for Every (SAFE) Port Act of 2006 established a requirement for an electronic interface among all Federal agencies that monitor or control the movement of imported products in domestic commerce. The ITDS will create a single-window environment in which importers, transportation carriers, and government agencies can exchange information on imported products. When fully implemented, ITDS will facilitate the processing of legitimate import transactions, improve how imported products are identified and classified, strengthen entry screening capabilities, and help to target inspection resources to areas of greatest risk.

CONCLUSION

The Working Group has set out a sound framework for developing specific ways to improve the safety of American imports, and we are assisting the Working Group in developing a follow-on Action Plan. The Working Group has highlighted the need to shift from reliance on "snapshots" wherein unsafe products are simply interdicted at the border, to a cost-effective, prevention-focused "video" model that identifies and targets those critical points in the import life cycle where the risk of unsafe products is greatest and verifies the safety of products at those important phases.

CBP remains committed to partnering with other Federal agencies in order to refine our targeting skills and increase coordination of government personnel and to ensure the prevention of contaminated and dangerous products from entering the U.S.

Chairman LEWIS. Thank you very much.

Our third witness, I'm pleased to welcome William James from the Department of Agriculture, Food Safety and Inspection Service. He is a deputy assistant administrator for the Office of International Affairs.

Welcome, Mr. James.

STATEMENT OF WILLIAM JAMES, D.V.M., M.P.H., DEPUTY ASSISTANT ADMINISTRATOR FOR THE OFFICE OF INTERNATIONAL AFFAIRS, FOOD SAFETY AND INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

Mr. JAMES. Chairman Lewis and Chairman Levin, Members of the Subcommittee, thank you for the opportunity to provide testimony to you on behalf of USDA's Food Safety and Inspection Service.

FSIS is the USDA public health regulatory agency responsible for ensuring that the Nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and properly labeled. I am here today to discuss FSIS procedures for ensuring the safety of the imported food for which we have responsibility. In fiscal year 2006, the imported food FSIS oversees accounted for nearly 4 bil-

lion pounds of meat and poultry from 29 of the 33 eligible countries, and about 6 million pounds of egg products from Canada presented for import re-inspection at U.S. ports and borders.

FSIS employs a comprehensive three-part system for imports. This system consists of establishing the initial equivalence of the meat inspection system of a country wishing to export to the U.S., verifying continuing equivalence of foreign systems through audits, and providing 100 percent re-inspection, 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 sanitary protection, even though the measures employed to achieve this protection may be different from those at home.

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 laws, regulations, and the infrastructure to support an equivalent system. The document review focuses on a country's practices in five risk areas: sanitation, animal disease, slaughter and processing, residues, and enforcement. If the document review is satisfactory, we then move to on-site review, in which an FSIS audit team evaluates all aspects of a country's inspection program including individual establishments and laboratories.

The second part of our system is verifying continuing equivalence through audits. Once a country is determined to have a system equivalent to the U.S., that country is responsible for ensuring that all facilities exporting to the United States employ standards equivalent to those of the U.S. To verify that this is happening, FSIS conducts annual audits of foreign food safety systems through on-site visits by FSIS personnel. Again, these include certified establishments, laboratories, and a review of government controls.

Finally, the last major part of our system is verifying continuing equivalence of foreign systems through re-inspection at the border. Every shipment of meat, poultry, or egg products entering the United States must be presented to an FSIS inspector at a FSIS import establishment. Initial checks include documentation, transportation damage, and proper labeling.

FSIS also performs intensive, random re-inspection on approximately 10 percent of shipments of meat, poultry, and egg products. These re-inspection tests include product examinations, microbiological analysis for pathogens, and/or tests 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 products from the foreign establishment when product fails re-inspection.

In addition to import re-inspection personnel, FSIS currently employs 23 Import Surveillance Liaison Officers who are charged with identifying, tracking, and detaining ineligible, illegal, or smuggled product. These ISLO's work closely with other governmental agencies, including Customs and Border Protection. Access to Customs and Border Protection's Automated Commercial Environment Database has provided FSIS a more targeted approach to identifying

and controlling ineligible entries of amenable product closer to the entry point, rather than after its release into commerce. The Agency and other Federal partners are working to become fully integrated with that system, an effort that will eventually lead to a linkage of all inspection border control data systems among all Federal agencies involved in imports.

Now, in addition to our three-part approach, the Agency is also focused on protecting against accidental or intentional food contamination. Through vulnerability assessments we have been able to seek out ways to strengthen our system, and through comprehensive training, which is shared with our food defense partners, we are better able to prevent and respond to any potential threats to the food supply.

Finally, USDA is working closely with the Interagency Working Group on Import Safety chaired by Health and Human Services Secretary Mike Leavitt. The framework offered by the Working Group in September outlines an approach to food safety and imports based upon the principles of prevention, intervention, and response, supporting USDA's longstanding approach to the issue.

In conclusion, at FSIS we believe that our approach to ensuring the safety of imported meat, poultry, and egg products is the best system in the world. This is due to our three-part, rigorous approach to determining equivalence, the continuous evaluation of that equivalence to ensure that it is maintained, and our vigilant surveillance of food products entering the country.

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.

[The prepared statement of Mr. James follows:]

Prepared Statement of William James, DVM, MPH,
Deputy Assistant Administrator for the Office International Affairs,
Food Safety and Inspection Service, Department of Agriculture

Mr. Chairman and Members of the Subcommittee, I am Dr. William James of the Office of International Affairs at the United States Department of Agriculture's Food Safety and Inspection Service.

The Food and Safety and Inspection Service 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. I am here today to discuss FSIS' procedures for ensuring the safety of the imported food for which we have responsibility. In FY 2006, the imported food FSIS oversees accounts for nearly four billion pounds of meat and poultry from 29 of the 33 eligible countries; and about six million pounds of egg products from Canada presented for import re-inspection at U.S. ports and borders.

FSIS employs a comprehensive three part system for imports. This system consists of:

- Establishing the initial equivalence of the meat 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 sanitary protection, even though the measures employed to achieve this protection may be different from the measures applied here at home.

FSIS has always insisted on the opportunity to assess foreign inspection systems before those nations can export to the United States. This prior review is mandated by Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), which provided that a foreign system be the same as the U.S. system before the foreign product could be admitted. Later, that standard was adjusted to one of equivalency when the United States adopted the *Agreement on the Application of Sanitary and Phytosanitary Measures*, or SPS Agreements, as part of the Final Act of the Uruguay Round of Multilateral Trade Negotiations, signed in 1994.

Any country may apply to be evaluated for equivalence by submitting a request to FSIS. While the importing country maintains the sovereign right to maintain any level of protection that it deems appropriate to diminish food safety hazards within its borders, a country wishing to export to the United States still has the burden of proving that its system is equivalent.

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 laws, regulations, and an infrastructure to support an equivalent system.

The 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 critical points within these risk areas are addressed with respect to those standards, activities, resources, and enforcement mechanisms inherent in the U.S. regulatory system.

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. We are seeking to assure that the country's inspection program is, in fact, what the documentation claims.

The FSIS process for announcing initial equivalence determinations for foreign countries is transparent. When FSIS makes an initial equivalence determination, a proposed rule is published in the Federal Register setting forth the determination and the reasons for the determination. 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.

Verifying Continuing Equivalence through Audits

The second part of our system to ensure the safety of FSIS-regulated imports is to verify continuing equivalence through audits. Once a country is determined to have a system equivalent to the United States, that country is responsible for ensuring that all facilities exporting to the United States employ standards equivalent to those contained in the FMIA and PPIA. 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 a review of government controls. In the fiscal year that has just concluded, FSIS' audit of all countries that are eligible to export and are actively exporting to the United States included 145 establishments, 39 laboratories, and 86 government offices. Final audits are posted on the FSIS Website.

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 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. These initial checks for such matters as documentation, evidence of tampering, transportation damage and proper labeling, are to ensure that the product originated in an approved country and was produced in an eligible establishment. This process is assisted by FSIS' Automated Import Information System (AIIS), a database that schedules re-inspection tasks and stores the results of the re-inspection from each point in the process.

FSIS also performs intensive random re-inspection on approximately 10 percent of 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.

In addition to import re-inspection personnel, FSIS currently employs twenty-three Import Surveillance Liaison Officers (ISLOs) who are charged with identifying, tracking, and detaining ineligible, illegal, or smuggled product. These ISLOs work 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 Customs and Border Protection's Automated Commercial Environment (ACE) database has provided FSIS a more targeted approach to identifying and controlling ineligible entries of amenable product closer to the entry point, rather than after its release into commerce. In FY 2005, prior to the FSIS' use of the ACE system, the amount of ineligible product removed from commerce was just over 36 thousand pounds. In FY 2006, this amount increased to 1.6 million pounds, and so far in FY 2007, over 1.9 million pounds have been identified, destroyed, or redirected to FSIS for re-inspection.

While FSIS currently has limited access to CBP's ACE system, the Agency and other key Federal partners are working to become fully integrated with that system. This effort will eventually lead to a linkage of all inspection and border control data systems among all Federal agencies involved in imports.

In other areas, FSIS has also worked with CBP's National Targeting Center to develop rules for targeting high-risk FSIS-regulated shipments that enter the country. This included a two-month pilot program in 2006 in which 3,229 shipments were screened at two separate ports using the proposed rule sets.

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 seek out ways to strengthen our food import system. Armed with these vulnerability assessments, the Agency conducts workshops to increase awareness of food defense issues among our international trading partners. These have included, in the past, the G–8 countries, Mexico, and the Asian Pacific Economic Council. Through the G–8 Working Group, FSIS is developing a joint exercise to prepare for the possibility of needing to respond to an intentional food contamination incident.

FSIS inspectors engage in comprehensive and ongoing training and education efforts in order to fulfill their role in preventing and responding to any potential threats to the food supply. Coordinated food defense awareness training is conducted in locations nationwide in conjunction with our food defense partners, which are government-wide but specifically 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.

FSIS is participating in a consortium of lab networks developed by DHS. This integrated consortium ensures coordination among Federal and State partners focused on food and agriculture. This consortium 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 to aid them in the development of a Food Defense Plan. Further, while Import Inspectors conduct their regular re-inspection at import facilities, their activities include efforts aimed at protecting consumers from intentional attacks on the food supply, and 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 by increasing and decreasing according to the threat level.

Interagency Working Group on Import Safety

Mr. Chairman and Members of the committee, I have discussed how the imported food products USDA regulates are currently inspected. But USDA is also working closely with the Interagency Working Group on Import Safety established by the President in July.

The President formed this working group which is chaired by Health and Human Services Secretary Mike Leavitt to ensure that we are doing everything we can to promote the safety of imported products. The mission is simple but critical, and that is to conduct an across-the-board review of import safety, including reviewing safety procedures in exporting countries, by U.S. importers, and by Federal, State, and local governments, and to provide recommendations to the President to promote the safety of imported products.

In September, the Working Group issued a strategic framework for ensuring the safety of imported products. This framework outlines a risk-based approach that includes the principles of prevention (prevent harm in the first place); intervention (intervene when risks are identified); and response (respond rapidly after harm has occurred). The framework supports USDA's long-standing approach to evaluating and verifying the ability of foreign food safety systems to ensure the safety of 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 held on October 1 at USDA headquarters here in Washington.

Conclusion

At FSIS, we believe that our approach to ensuring the safety of imported meat, poultry, and egg products is the best system in the world. This is due to our three-part rigorous approach of determining equivalence; the continuous evaluation of that equivalence to ensure that it is maintained; and our vigilant surveillance of food product entering the country.

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.

Chairman LEWIS. Thank you very much, Mr. James.

I am pleased to welcome our next witness, Steven Solomon from the Food and Drug Administration, the Deputy Director of the Office of Regional Operation. Welcome.

STATEMENT OF STEVEN M. SOLOMON, D.V.M., M.P.H., DEPUTY DIRECTOR, OFFICE OF REGIONAL OPERATIONS, OFFICE OF REGULATORY AFFAIRS, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ROCKVILLE, MARYLAND

Mr. SOLOMON. Thank you and good morning, Mr. Chairman and Members of the Committee. I am Dr. Steve Solomon with the Office of Regulatory Affairs of the U.S. Food and Drug Administration. I'm pleased to be here with my colleagues from other Federal agencies which share responsibilities for imported products. Thank you for the opportunity to discuss the important issues related to the safety of imported products.

FDA regulates everything Americans eat, except for meat, poultry, and processed egg products, which are regulated by our partners at the Department of Agriculture. FDA is also responsible for human drugs and biological products, medical devices, radiological products, and animal drugs are safe and effective. I assure you that FDA is committed to ensuring that the Nation's supply of food, drugs, and other FDA-regulated products continue 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 significant challenges. Recent inci-

dents involving unsafe imported products underscore the need to enhance our product safety strategies by targeting out resources to projects having the potential for causing harm public health. We're looking to accomplish this by broadening our knowledge and applying enhanced risk-based criteria to the entire life cycle of imported products.

Recently FDA Commissioner Andrew von Eschenbach has appointed Dr. David Acheson to the new position of Assistant Commissioner for Food Protection to provide leadership with strategic and substantive food safety and food defense matters. Dr. Acheson is coordinating development of a new strategy which will enhance our food safety and food defense systems by addressing the changes in global food distribution and identifying our most critical needs.

FDA's goal is to ensure a comprehensive and robust food safety and food defense program that focuses on a proactive prevention strategy of building safety in from the start; risk-based intervention to ensure that preventive controls are effective; and rapid response when contaminated food or feed is detected or where there is potential for harm to humans or animals. The new food protection strategy, which we expect to announce in the near future, will provide risk-based farm-to-table approach using sound science that integrates food safety and food defense efforts on both imported and domestic products.

You've already heard about the Interagency Working Group on Import Safety. Secretary Leavitt and Commissioner von Eschenbach have traveled extensively throughout the United States during the past few months, visiting ports of entry and reviewing import operations in the field. The insights that they gained on the review helped shape the strategic framework that was released by the Working Group on September 10th.

The report outlined an approach that, like the food protection strategy, is based on the organizing principles of prevention, intervention, and response. The strategic framework recognizes that we must find new ways to protect American consumers and continue to improve the safety of imports. It identifies the need to shift from the current model, that relies on snapshots at the border to interdict unsafe products, to the prevention focused model that identifies and targets those steps on the life cycle of imported products where the risk of unsafe products are greatest. This risk-based, prevention-focused model will verify the safety of products at those important phases of product life cycle and help ensure that safety is built into the products before they reach our borders.

This past Monday the Work Group held a public meeting to receive input from stakeholders and received comment on actions the public and private sector can take to promote the safety of imported products. By mid-November, the Working Group will present an action plan to the President. The plan will reflect the public comment and lay out roadmap with short- and long-term recommendations.

I want to touch quickly on our interactions with U.S. Customs and Border Protections. We collaborate on a continual basis at the Nation's port of entry and FDA's Prior Notice Center, which is colocated with CBP's National Targeting Center.

With respect to well-publicized issues with the safety of imported products from China, FDA is conducting a series of meetings with Chinese officials to negotiate a memorandum of agreement aimed at creating a framework to help assure the safety, quality, and effectiveness of products exported from China to the United States. The frame is also aimed to increase cooperation and sharing between the regulatory bodies of the two nations with the goal of strengthening China's regulatory process. Negotiations are ongoing with a goal of finalizing an agreement by year's end.

Ensuring safety of imported products is a significant task, but I want to assure you that FDA is diligently working to efficiently and effectively use the resources and authorities we've 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 products. I'd be happy to answer any questions.

[The prepared statement of Mr. Solomon follows:]

Prepared Statement of Steven M. Solomon, DVM, MPH, Deputy Director, Office of Regional Operations, Office of Regulatory Affairs, Food and Drug Administration, Department of Health and Human Services, Rockville, Maryland

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT OF

STEVEN M. SOLOMON, D.V.M., M.P.H.

DEPUTY DIRECTOR OF THE OFFICE OF REGIONAL OPERATIONS

OFFICE OF REGULATORY AFFAIRS

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON TRADE

U.S. HOUSE OF REPRESENTATIVES

OCTOBER 4, 2007

For Release Only Upon Delivery

INTRODUCTION

Mr. Chairman and Members of the Committee, I am Steven M. Solomon, D.V.M., M.P.H., Deputy Director of the Office of Regional Operations, which is part of the Office of Regulatory Affairs at the U.S. Food and Drug Administration (FDA or the Agency). Thank you for the opportunity to discuss the important issues relating to the safety of FDA-regulated imported products, including those originating in China.

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, 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 products are subject to examination.

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 violation and the right to provide evidence (such as a laboratory analysis by an independent laboratory) to rebut the appearance or, in some circumstances, to request permission to recondition the product. 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 which 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. FDA's electronic screening system currently reviews 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 secure the border while ensuring the movement of legitimate trade.

FDA has numerous other tools and authorities which enable the Agency to take appropriate action regarding imported products. FDA performs routine surveillance inspections of imported goods to check for compliance with U.S. requirements. Because of the large volume of FDA-regulated foods being exported from a large number of countries, it is not feasible to routinely inspect 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 is the Import Alert, which signals FDA inspectors to pay special attention to a particular product, producer, shipper or importer. Typically, they inform FDA field personnel that FDA has sufficient evidence or other information to initiate refusal of admission into the U.S. without physically examining the product. When an Import Alert is issued and FDA initiates refusal, 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.

Imported Drugs, Biologics, and Medical Devices

The FD&C Act limits the drugs and biologics, as well as certain medical devices, that may be imported into the U.S. Congress enacted these provisions to create a relatively "closed"

distribution system for such products, which helps ensure that the domestic supply is safe and effective.

To comply with the FD&C Act, any entity that intends to import drugs or biologics requiring pre-market approval into the U.S. must ensure, among other things, that the products comply with the FDA approval in all respects. The importer must ensure that each drug or biologic meets all U.S. labeling requirements, and that prescription drugs are not re-imported after export in violation of the Prescription Drug Marketing Act. FDA approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, and container/closure system. Medical devices requiring pre-market approval are subject to similar requirements.

NEW INITIATIVES

Food Safety Strategy

In May of this year, FDA Commissioner Andrew C. von Eschenbach, M.D., created a new position, the Assistant Commissioner for Food Protection, to provide advice and counsel on strategic and substantive food safety and food defense matters. The Commissioner appointed Dr. David Acheson to this position, and Dr. Acheson is working with FDA's product centers and the Office of Regulatory Affairs, which oversees the Agency's field staff, to coordinate FDA's food safety and defense assignments and commitments.

Dr. Acheson is also coordinating the development of a new food safety and defense strategy covering both imported and domestically-produced foods that FDA regulates. The new food 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, 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, 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, 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. Shrimp and catfish products represent two of the ten most consumed seafood products in the U.S.

As the aquaculture industry continues to grow in developing economies, 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 antibiotics and other drugs and chemicals such as malachite green, nitrofurans, fluoroquinolones, and gentian violet can result in the presence of residues 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 residues 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 refuse admission of a shipment, even without physically examining it, unless it is shown to be free of the residues 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 #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 refuse admission of 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.

Drugs

Chemical counterfeiting in many foreign locations are on-going concerns for the U.S. and other nations. Ten years ago, Chinese counterfeit glycerin contaminated with diethylene glycol (DEG) killed nearly 100 children in Haiti. Last year in Panama, Chinese glycerin contaminated with DEG again caused scores of deaths. Recently, toothpaste imported from China to the U.S. was also found to contain DEG.

The recent DEG episode has reinvigorated attention on China's regulation of its finished drug products, active pharmaceutical ingredients (APIs) and excipients. While some Chinese firms are state-of-the-art in technology and manufacturing expertise, many are at the opposite end of the spectrum. Further, in the past four years, the number of FDA-registered drug manufacturers in China has at least doubled. China is in the process of re-writing its existing current Good Manufacturing Practices (cGMPs) for drugs. In the meantime, however, drug manufacturers in China, and some other developing countries, comply with cGMPs inconsistently and to varying

degrees. Provincial authorities who conduct inspections of drug manufacturing sites are not always equipped with the expertise needed for this complex undertaking.

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 (DHHS) 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.

Last May, in conjunction with the 2nd Strategic Economic Dialogue, DHHS initiated discussions regarding the need for legally binding 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 last week when a delegation of senior DHHS 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. I look forward to responding to any questions you may have.

Chairman LEWIS. Thank you, Dr. Solomon.

Our next witness is from the United States Consumer Product Safety Commission. Please welcome Marc Schoem, the Director of Recalls and Compliance. Welcome.

STATEMENT OF MARC J. SCHOEM, DIRECTOR OF RECALLS AND COMPLIANCE, U.S. CONSUMER PRODUCT SAFETY COMMISSION, BETHESDA, MARYLAND

Mr. SCHOEM. Good morning, Mr. Chairman and Members of the Committee. Thank you for the opportunity to testify.

My name is Marc Schoem. I'm the Deputy Director of the Office of Compliance at the U.S. Consumer Product Safety Commission. CPSC is responsible for protecting the public from unreasonable risk of injury and death associated with more than 15,000 different consumer products. It is appropriate that the CPSC testify before this Committee today because increasingly the products under CPSC's jurisdiction are manufactured overseas and imported into the United States.

CPSC's Office of Compliance conducts product recalls and engages in other enforcement activities, and we undertake both routine and targeted surveillance and sampling of imported products at U.S. ports of entry.

We work in close cooperation with Customs and Border Protection. In a memorandum of understanding signed in 1990, the Commission and CBP established a working relationship for the cooperative enforcement of the provisions of our statutes dealing with imported products. This agreement recognizes a number of activities to be taken between the two agencies. This includes product sampling, personnel access, joint inspections, and screening and testing of consumer products. The 1990 M.O.U. is complemented by another one signed in 2002 to establish procedures and guidelines for the exchange of information.

CPSC is also a participating government agency in Customs' Automated Commercial Environment, or ACE. ACE acts as—allows CPSC staff with necessary security clearance to analyze records of incoming consumer products more efficiently and to target shipments before they can be distributed into commerce. CPSC's early experience with using the ACE system is encouraging, and in the case center will provide us with better data about incoming product shipments at an earlier point in the process. This information allows us to more precisely focus our port inspection activities on those products that might provide a safety problem, thus allowing CPSC to be more effective.

One example of the success we have had using ACE and why we are now incorporating ACE into our ongoing surveillance and enforcement activities is a seizure of a large shipment of fireworks earlier this year. We were able to investigate the firm's import history through the ACE system and, working with Customs and Border Protection, we flagged that company's entries nationwide for investigation. We discovered that the company was importing very dangerous and heavily overloaded fireworks disguised as consumer fireworks. Not only were we able to prevent these products from entering commerce, but the company's owner is now facing criminal charges.

Our work with Customs is part of our multi-pronged approach to increase surveillance and enforcement, to meet the challenge of identifying unsafe imported products. In recent years about 2/3 of all U.S. product recalls have involved imported products, and that number appears to be growing. The large majority of these recalled

products came from China. During the last year, working in cooperation with Customs, we have conducted surveillance and sample collections at numerous ports around the country in an effort to identify unsafe products.

CPSC has targeted toys being imported where a foreign manufacturer had been the subject of previous CPSC violation for leaden paint violation. We've also looked at various electrical products and recreational vehicles where we had a concern. Additionally, CPSC is working with Customs' labs at various ports and we're conducting training sessions with Customs personnel so they can assist us in detecting lead in toys. These are just a few of the most recent examples where our joint efforts have and will continue to result in enhanced safety for the American public. We have also been fortunate in that we have hired a number of former Customs agents as CPSC field investigators, and through their past Customs experience and knowledge they have been working closely in their former ports in an effort to strengthen our cooperation and cross-train staff.

We, of course, recognize that the most effective deterrent from having unsafe products brought into the U.S. is at its source, so we are also working closely with our Chinese government counterparts. The work plans we entered into with the Chinese government outlined specific cooperative actions to be taken by them and us to improve the safety of consumer products exported from China to the United States. This is a significant achievement, and the ACE system is an important tool in verifying Chinese compliance with their agreement to weed out toys with lead paint before they are shipped to the United States.

Mr. Chairman and Committee Members, I have been with CPSC for 33 years and, as you can see, consumer product safety is never a completed task but always an ongoing process of research, standards development, enforcement, public education, and international engagement. The Commission is determined to make certain that imported consumer products meet the same high standards that we require of products manufactured in the United States.

Thank you again for the opportunity to testify, and I look forward to answering your questions.

[The prepared statement of Mr. Schoem follows:]

Prepared Statement of Marc J. Schoem, Director of Recalls and Compliance, U.S. Consumer Product Safety Commission, Bethesda, Maryland

Good Morning, Mr. Chairmen and Members of the Committee.

Thank you for the opportunity to testify today on the subject of import safety. My name is Marc Schoem, and I am the Deputy Director of the Office of Compliance and Field Operations at the U.S. Consumer Product Safety Commission (CPSC) which is charged with protecting the public from unreasonable risks of injury and death associated with more than 15,000 types of consumer products. It is appropriate that the CPSC testify before the committee today because increasingly, products under CPSC's jurisdiction are manufactured overseas and imported into the United States.

The CPSC is a small, independent and bipartisan Federal commission. Since its beginnings in 1973, CPSC's work has contributed substantially to the decline in the rates of death and injury related to the use of consumer products. We estimate that injuries and deaths associated with the use of these products under our jurisdiction have declined by almost one-third over this time.

While we are proud of the agency's achievements over the years, there is still much work to be done. In addition to ever more technologically complex products

arriving in the marketplace, and changes in the way that consumers purchase goods and receive information, an unprecedented surge of imports presents the agency with new challenges. Later in my testimony, I will outline the initiatives and methods that the CPSC is using to meet this challenge, but first I would like to discuss CPSC's relationship with Customs and Border Protection (CBP) which I know is of particular interest to this Committee.

At the CPSC we accomplish our mission by executing five Federal statutes, namely the Consumer Product Safety Act, the Federal Hazardous Substances Act, the Flammable Fabrics Act, the Poison Prevention Packaging Act, and the Refrigerator Safety Act.

As noted, I am the Deputy Director of CPSC's Office of Compliance and Field Operations. In addition to conducting product recalls and engaging in other enforcement activities, staff from my office undertake both routine and targeted surveillance and sampling of imported products at U.S. ports of entry, working in close cooperation with CBP which is charged with front line responsibility at the border for enforcing our statutes.

In a Memorandum of Understanding (MOU) signed in 1990, the CPSC and CBP established a working relationship for the cooperative enforcement of the provisions of our statutes dealing with imported products. This agreement identifies a number of activities to be taken between the two agencies including sampling, personnel access, joint inspections, screening and testing of consumer products.

This MOU was complemented by another signed in 2002 to establish procedures and guidelines for the exchange of information, including access by CPSC staff to CBP's current System of Record, ACS. This agreement also provided reimbursement to CBP for its expenses in procuring and maintaining the necessary equipment and developing the appropriate software and programming.

The CPSC is also a participating government agency in CBP's Automated Commercial Environment (ACE). As you know, ACE is the new CBP processing system which is supported by the International Trade Data System (ITDS). ACE allows CPSC staff to analyze records of incoming consumer products more efficiently and to identify potentially non-complying shipments before they can get into the stream of commerce.

CPSC's early experience with using the ACE system is encouraging and indicates that it will provide us with better data at an earlier point in the process so that our port inspection activities can be more precisely targeted and thus more effective.

An example of the successes we expect to have as we incorporate further into the ACE system was a seizure conducted earlier this year of a particularly large shipment of illegal fireworks that were being brought into the country for the Fourth of July holiday. CPSC staff had been able to investigate the firm's import history through the ACE system and, working with CBP, to flag all of that particular company's entries nationwide for investigation.

We discovered that the company was importing very dangerous and heavily overloaded fireworks devices disguised as consumer fireworks. The company's owner is now facing criminal charges. Sometimes government agencies are criticized for not working together. In this instance, CPSC, CBP, and the Bureau of Alcohol, Tobacco, Firearms and Explosives worked together closely to identify and seize dangerous products that had the potential to kill consumers.

Currently, additional CPSC staff are processing through appropriate security clearances to qualify for access to ACE. As their numbers grow and staff gains experience with the system, we expect many more good results like this one.

Enforcement at the port works best when it is simple and straight forward. For example, products that are subject to mandatory standards under the CPSA must be refused admission unless they are accompanied by a certificate of compliance. In this regard, CPSC's authorizing committees are considering changes to our statutes, and I am hopeful that any changes made by Congress recognize the importance of having a certification enforcement system that is simple and straight forward to enforce.

CPSC's cooperative work with CBP is an important part of the increased surveillance and enforcement effort we are conducting as one part of our multi-pronged approach to meet the challenge of assuring the safety of imported products for American consumers. In recent years, about two-thirds of all U.S. product recalls have been of imported products, and that number is growing annually. The large majority of those products are manufactured in China.

Historically, CPSC had not actively engaged in international activities. However, in 2004, recognizing the continuous and significant increase in the number of imported consumer products entering the American marketplace from China, our CPSC Chairman traveled to that country. That was the first step toward a formal relationship between the CPSC and the General Administration of Quality Super-

vision, Inspection and Quarantine (AQSIQ), our counterpart agency in China, and it resulted in the signing of a Memorandum of Understanding (MOU) between our two nations later that year.

In 2005, at the first U.S.-Sino Product Safety Summit, the CPSC signed an Action Plan on Consumer Product Safety with AQSIQ. The Action Plan outlined specific cooperative actions to be taken by CPSC and AQSIQ to improve the safety of consumer products: training; technical assistance; a mechanism to provide for "urgent consultation" when necessary; information exchanges; and the creation of Working Groups to address issues in four priority areas—fireworks, lighters, electrical products and toys.

At the beginning of this year, CPSC staff identified and communicated to our Chinese counterparts specific problems and proposed actions to address these problems with respect to each of the four product categories covered by the Working Groups. In May 2007, I traveled to China with CPSC's Acting Chairman, Nancy Nord, and a delegation of top CPSC officials for in-depth discussions of the issues identified by this process. I was privileged to Chair two of the Working Groups.

This hard work culminated last month at the second U.S.-Sino Product Safety Summit held here in Washington between the CPSC and our Chinese counterpart agency, AQSIQ. At the Summit, the CPSC reached an important agreement with AQSIQ, under which China will immediately implement a plan to eliminate the use of lead paint on Chinese manufactured toys exported to the United States. The Chinese government is working to make sure there is no lead in the paint through stepped up inspections of U.S. destined toys and a registration system for paint suppliers.

China also agreed to broad cooperation with the CPSC in the four major product areas mentioned above. In each of the four work plans, China has agreed to cooperate with the CPSC to ensure that its producers understand and comply with U.S. safety standards for all of their exports to the United States. The work plans provide a roadmap to improve the safety of these products through five main avenues:

First, in cooperation with the CPSC, AQSIQ has agreed to increase its inspections of products destined for the U.S. and to undertake other activities to ensure that exports meet all applicable safety standards.

Second, AQSIQ, again in full cooperation and participation with the CPSC, will expand the knowledge and understanding of U.S. product safety standards among Chinese manufacturers and exporters.

Third, the CPSC and AQSIQ have agreed to various technical personnel exchanges and training activities to ensure full and mutual understanding of our respective laws and systems, including product testing methodologies.

Fourth, the two countries have respectively agreed to establish regular and systematic exchanges of information about emerging product safety issues, including monthly discussions of recall follow-up activities and trends.

Fifth, AQSIQ has agreed to specific steps to assist the CPSC in tracing products with identified safety problems to those Chinese firms involved in their manufacture, distribution and export. This will enable both of our agencies to address safety issues more quickly and effectively as they arise.

This is a significant achievement, and while it is in China's economic interest to enforce U.S. safety standards, CPSC staff will nonetheless be following up to assure that the Chinese government fully implements this commitment.

In this regard, the ACE system will be an important tool in verifying Chinese compliance. ACE access, coupled with data research and analysis support from CBP, has already given us the ability to assess recent industry and Chinese claims that they were making immediate efforts to insure that toys containing lead paint were not being shipped. Previously, CPSC staff had limited ability to track entries from specific foreign manufacturers.

Another prong of CPSC's initiative on import safety is our work with the private sector, both here in the U.S. as well as in China, to educate Chinese manufacturers and exporters not only of the content of U.S. product safety standards, but also the importance of adhering to those standards, including adhering to consensus or what we commonly call "voluntary" standards.

As part of our plan to address this problem, the CPSC has published the *Handbook for Manufacturing Safer Consumer Products* underscoring our message that safety must be designed and built into consumer products in conformance with safety systems planned, established and implemented at the direction of executive management. The Handbook presents a comprehensive systematic approach to manufacturing safe products and has been published in Chinese and distributed throughout China.

The CPSC has also facilitated the translation of the summary provisions of nearly 300 U.S. mandatory and voluntary consumer product safety standards into Chinese

to assist Chinese manufacturers in understanding what U.S. product safety standards require when manufacturing various products.

Additionally, I am one of a number of CPSC staff who have conducted industry-specific safety seminars and retail and vendor training seminars in China. Staff has conducted a number of other safety training activities in China dealing with toy safety, electrical product safety, fireworks safety and a supplier safety seminar for retailers.

Finally, the CPSC is undertaking conversations with specific industry groups to encourage testing and certification programs.

Mr. Chairmen, consumer product safety is never a completed task but always an ongoing process of research, standards development, enforcement, public education and international engagement. In that regard, the CPSC is determined to make certain that imported consumer products meet the same high standards that we require of products manufactured in America and that the products American families bring into their homes and playgrounds are safe and sound.

Thank you again for the opportunity to testify today, and I look forward to answering your questions.

Chairman LEWIS. Thank you very much—each one of you, on behalf of all of the Members—for your testimony.

At this time I will open the panel for question. I ask that each Member follow their 5 minutes rule. If each witness will respond with short and concise answers, all Members should have an opportunity to ask questions.

Let me just start off here, and any of you may want to respond. There are many people, citizens all around our country, who don't have access to nor know how to use the Internet. They've never seen a computer, and so many people tend to rely on what they see on television, hear on the radio, or what they read in the newspaper. But it's very hard and very difficult for many of our citizens, for many consumers, to get the details. What steps do you take that the details of these recalls reach the larger community, reach the larger segment of our society? People who live in all corners, the towns and villages and hamlets of America?

Mr. SCHOEM. At CPSC we have a number of programs that we offer to reach people at the grassroots level. One is our N.S.N., our Neighborhood Safety Network, where we disseminate information to various groups at the state and regional and local level, and we them to then multiply—use the multiplier effect and transfer it down to grassroots level. We also maintain one of the original 800 toll-free numbers in addition to our Internet site for people to access us.

Chairman LEWIS. Thank you.

Mr. SOLOMON. FDA does understand the importance of trying to get outreach and people to have the information. We do put information on the Internet, but we also send out press releases, work with the press to get messages out there. We also have public affairs specialists that work in our district offices that work in the local, that work on the local community level to try and get messages out, particularly for recalls or other actions that are more locally based.

We also translate many of these, for significant actions, into other languages to try make sure we get the message to the right community.

Chairman LEWIS. Thank you. Yes, sir?

Mr. JAMES. At Food Safety and Inspection Service we get the word out to the news media and state and local public health officials to share with the public. We also issue press releases related to recalls and post that information on the FSIS website. We also have a hotline with an 800 number that people can call into, 1–888–MPHOTLINE. It's open from 10:00 to 4:00 each day, and we have on our website an AskKaren.gov question and answer area where questions can be submitted and answered.

Chairman LEWIS. Thank you.

Mr. BALDWIN. I think that CBP will actually rely more on the FSIS, the FDA, the CPSC to actually carry out the message and work with them, with our public affairs office, to get the message out. Of course, most of the contact we'll have will be with the American consumers when they're actually entering the country or leaving the country.

Mr. MARUYAMA. Mr. Chairman, USTR is not involved in direct regulation. On the other hand, in terms of our trade agreements we have a very active press operation and we try and get the word out through media: print, radio, and TV Thank you.

Chairman LEWIS. You know, when you visit a mall or a grocery store, I have never seen anything posted in a shopping mall or the window of a store saying that "this product been recalled, beware." Is anything like that or do you make public service announcement or have notice print in local newspapers and neighborhood papers or in small town papers or community bulletins?

Mr. SCHOEM. When the Consumer Product Safety Commission has a recall, we develop a corrective action plan with the recalling company that includes a number of different notification elements: a joint press release, a recall poster that is posted at the retail store. We work with retailers to try to get ideal placement of those posters. Often times they're at the service counter or in the aisle where the product was sold, but we are working with a number of retailers now on some new, electronic ideas that would be visually displayed where retailers and shoppers would be able to see them a little more clearly.

Depending upon the risk presented by the particular product under recall, it may very well include advertisements in newspapers, and a number of companies have done that. We also require posting of the recall on the company's website and it's also on CPSC's website.

Chairman LEWIS. Well, thank you very much. My time is expired, and maybe you can respond on another Member's time. I turn to the Subcommittee on Oversight Ranking Member, Mr. Ramstad, for a question.

Mr. RAMSTAD. Thank you, Mr. Chairman.

Dr. Solomon, I'd like to ask you a question. I know in July the FDA announced that by the end of this year our country and China would sign a memorandum of understanding on food safety. What aspects of food safety issues will this address, and to what extent would this allow the FDA to certify the effectiveness of the Chinese system?

Mr. SOLOMON. We are in the negotiation of process with them. There's actually two groups within China. One was the Chinese state FDA, which is handles medical products, and the other is the

AQSIQ, which is their General Administration of Quality, Supervision, Inspection and Quarantine. We're looking to get assurance from them about their inspections programs, about their registration programs, and certification programs. The AQSIQ is a body which controls imports and exports leaving China. We want to get confidence in that system, build confidence in it, by working with them, understanding what their registration means, understanding what testing they do, understanding what certification programs would be associated with that, to help assure that the product coming in the United States is safe.

Mr. RAMSTAD. Based on your preliminary discussions and any investigations that are ongoing, are you convinced that the process, the inspection programs, the Chinese inspection programs, will be transparent in this process?

Mr. SOLOMON. That's part—we're in negotiations, and that's part of the process is—we want to make sure that there's the ability to audit and examine exactly what's going on so we develop confidence in such a system.

Mr. RAMSTAD. Are you on schedule to sign the memorandum of understanding on food safety by the end of the year or has that been delayed?

Mr. SOLOMON. We're hoping that it's still on track. We had very fruitful meetings in the past couple weeks, and we're hoping that a delegation will be returning to the United States shortly.

Mr. RAMSTAD. I just think for the safety, and I'm sure you agree, safety and confidence of the American consumers, they certainly deserves nothing less than the certification that the Chinese system is effective, given the imports from China.

I want to ask another question of either Dr. Solomon or Dr. James or for that matter any of the distinguished panelists before us. Have any of your agencies ever had to lower safety standards because of Free Trade Agreements to which the United States is a party? Have you ever been in that situation?

Mr. SOLOMON. FDA is a regulatory public health agency and we've never been in that situation.

Mr. RAMSTAD. Dr. James?

Mr. JAMES. The Food Safety and Inspection Service is also a public health regulatory agency; we have not had to reduce our food safety standards through any Free Trade Agreement. The Free Trade Agreements have always protected our authority to maintain our own high standards.

Mr. RAMSTAD. Any other Members to testify?

Mr. SCHOEM. To my knowledge, CPSC has never reduced any of its standards for a trade issue.

Mr. RAMSTAD. Thank you very much. That confirms what many of us believe and believe to be the case, and I appreciate it—your going on the record, and I yield back the balance of my time.

Chairman LEWIS. Thank you. Now I turn to the Chairman of the Subcommittee on Trade, Mr. Levin, for his questions.

Chairman LEVIN. Thank you very much and, Mr. Ramstad, I'm glad you asked that question, and I think the answer is the correct one. But I must say, if people are watching this, I don't think our constituents have received from you any sense of urgency. I'd like

to say to our distinguished USTR representative just the following if I might, Mr. Maruyama.

On page three you say, "So, if we are to move away from science and risk-based regulation, and erect protectionist barriers to trade unchecked by WTO and FTA rules in the guise of consumer safety, U.S. exports would be highly vulnerable to mirror restrictions, and some of our trading partners would be only too happy to oblige." I think in a sense that's for straw man for this hearing, if I might say so. There's nobody suggesting that we move away from science-based procedures, no one.

In fact, the question among our constituents is this: are science-based procedures being followed? When they see all of these recalls and this bevy of activity in terms of recalls, they wonder, "Where is the science and where is it being applied?" So, let me just ask, as I understand it there was a 2003 memorandum between FDA and CBP You know we use these initials, and maybe we should not. FDA, I guess I should ask Dr. Solomon this, agreed to provide appropriate training for commissioned CBP officers to allow them to conduct FDA examinations and investigations. How many of these 8,000 officers have actually received training? Do you know?

Mr. SOLOMON. All the officers have received a training program from FDA That specific commissioning authority was granted by Congress under the Bioterrorism Act, and the specific provisions of that agreement related to bioterrorism in significant imports that may come in, where we need to have enhanced capacity by using CBP.

Chairman LEVIN. All of them have received their training?

Mr. SOLOMON. My understanding is that they have been trained on understanding how to do FDA examinations and sampling if that capacity was needed.

Chairman LEVIN. I'm not sure what that means. Why don't you submit for the record a complete statement about that?

Mr. SOLOMON. We'd be glad to.

Chairman LEVIN. So, let me ask you, each of you, USTR perhaps isn't involved with this, and I know it may not be possible for you to answer but try: do you and your agencies have enough personnel to carry out adequate functions in terms of safety of products and agricultural goods? Would you tell us today that there is adequate personnel in each of your agencies to do this?

Mr. SOLOMON. I guess I'll start. In the plans I highlighted during my testimony, which is a food protection strategy, and also in the Import Working Group that's being led by the Secretary, there's going to be further discussions about what's needed to implement these activities. So I would suggest that that would be the venue that would be used to be able to talk further about resources.

Chairman LEVIN. What are you advising? I mean, everybody's kind of using the inter-agency function as a rationale for not saying very much as to what will come out. What are you advising the Interagency Committee as to the adequacy of personnel?

Mr. SOLOMON. Our position is personnel is one element of the program, but the other elements of the program include a lot of other activities that need to be used to enhance import safety. This

includes better risk-based targeting products, using the whole life cycle, information technology, the whole gamut of information——

Chairman LEVIN. Personnel assistance——

Mr. SOLOMON. One issue.

Chairman LEVIN. Okay, on that one issue is there adequate personnel today?

Mr. SOLOMON. If we had more personnel, we could do more activities.

Chairman LEVIN. My time's up. Maybe you'd like that you don't have to answer it. Anybody want to in thirty seconds like to say yes or no? Yes.

Mr. BALDWIN. I would like to offer one thought. You had mentioned the Bioterrorism Act and the commissioning of 8,000 officers in support of FDA. I think our records show that as of September 2007 over 9,900 CBP officers have been trained and I think that counts for attrition and new hires since the B.T.A. So, I think we're well on pace in answering your first question.

Second, I think that also points out, though, a critical component that I know is being discussed in the Interagency Work Group, and that is not necessarily focusing so much on plussing up resources, but leveraging existing resources across the Agency. I would offer that there's an important distinction between coordination among agencies and collaboration among agencies, so that the B.T.A. effort, where you actually have CBP officers commissioned to do FDA work, has turned out to be a very positive experience. I'm hoping we can play off of that.

Chairman LEVIN. Okay, my time is up.

Chairman LEWIS. Thank you, Mr. Levin. Now I turn to the Subcommittee on Trade Ranking Member, Mr. Herger, for his question.

Mr. HERGER. Thank you, Mr. Lewis. For Mr. Maruyama and then perhaps Dr. Solomon, a number of bills introduced require or encourage the Administration to establish equivalency agreements with foreign governments before allowing foreign producers to export to the United States. Could you tell me, how necessary is it for the United States to establish equivalency agreements on food safety with our major trading partners? I'm referring to other than our existing agreements on meat, poultry, and eggs.

Mr. MARUYAMA. Well, I think this question is primarily for USDA and FDA, but our Free Trade Agreements allow us to request equivalency from foreign governments. So, far that's been very much of a, I would say, one-way proposition. We used it to get access to a lot of markets in Latin America and other countries where we've gotten FTA's. They've had somewhat greater difficulty establishing equivalency in our markets. We can ask for equivalency. The USDA system for meat, poultry, and eggs is built around equivalency. The FDA has taken a somewhat different approach.

Mr. HERGER. Dr. Solomon?

Mr. SOLOMON. Thank you for the question. As you're probably aware, FSIS regulates around 20 percent of the food supply and FDA has around 80 percent of the food supply. Equivalency is a complex issue when you try and talk about all the different products that FDA regulates. The important question is ensuring the safety coming in. I'm not certain that equivalency is the only way

to get that, because many of our trading partners that are willing to beat FDA standards, that are expected to come in and provide certification to those standards, which may not be—no equivalency for what they're doing domestically in those countries.

Mr. HERGER. Okay, Dr. Solomon, just—H.R. 3610 would restrict imports of food and agricultural products only to those ports that have an FDA lab. Could you tell me, is such a restriction necessary to ensure for safety of the U.S. imports and what would the practical effect be on trade?

Mr. SOLOMON. FDA currently has 13 laboratories. Not all of those laboratories are located at ports of entry. It's not an essential requirement to do a laboratory analysis on every entry. The risk-based criteria that are being talked about by the President's Working Group and the Food Protection Plan involves a number of strategies, and sampling is only one of those aspects of it. In today's era, when we need to collect samples, those samples can be collected from many locations, sent by delivery systems and sent to laboratories, the critical piece of the laboratory piece is having the capacity to run the samples, trying to run the samples using the most rapid techniques and using the right standards and appropriate methodologies.

Mr. HERGER. Dr. James, would you like to comment on this?

Mr. JAMES. FSIS has 140 import houses in proximity to seaports and border crossings on our coasts and on the borders with Mexico and Canada. They represent about 33 major ports of entry through which meat and poultry enter, and we have three laboratories: one in Athens, Georgia; one in St. Louis, Missouri; one in Alameda, California, and our history has demonstrated that this system and arrangement has worked quite well for ensuring the food safety mission that we have.

Mr. HERGER. Thank you. Thank you, Mr. Chairman.

Chairman LEWIS. Thank you very much. I now turn to Mr. Pascrell for his question.

Mr. PASCRELL. Thank you, Mr. Chairman. Mr. Chairman, I ask these questions in honor of Eduardo Arias, the gentleman of Panama who discovered in tube of toothpaste from where he was working that the toothpaste contained diethylene glycol, which is used in antifreeze, and would set off a worldwide review of what is happening. Mr. Chairman, the road to hell is paved with antonyms all over the place.

My first question is with Mr. Solomon. Mr. Solomon, in the last panel today Cal Dooley will testify. He's one of the persons that will be testifying in the next panel. He said the following, and I would like your reaction.

He said, "The FDA resources have not kept pace with the demand posed by rising imports and current food safety challenges. To meet these needs, Congress must provide new funds to dramatically improve FDA's analytical testing capabilities, to increase and better target inspections conducted by FDA, to obtain realtime test results, and to enhance communications during crisis events. With additional resource that are well deployed, FDA should be much better positioned to find any remaining needles before they cross the border and enter into U.S. commerce. Would you give me a brief response to that, please?"

Mr. SOLOMON. Those comments are very much in line with the President's Import Work Group. We need to use the best science, we need to target inspections at the best locations——

Mr. PASCRELL. But what about the part about more resources so you can do your job?

Mr. SOLOMON. That report highlights that among other things. Resources is a critical issue.

Mr. PASCRELL. So, you believe there should be more resources?

Mr. SOLOMON. The—resources is one of the answers——

Mr. PASCRELL. Why haven't there been more resources before this report? We just discovered that FDA doesn't have enough people and enough resources to do its job? Is that what you're telling us?

Mr. SOLOMON. We've, using risk-based approaches to try and target the best products to ensure the safety——

Mr. PASCRELL. Mr. Solomon, let's use an acronym for a second. I asked—the Food Safety Inspector's System, and Import Safety Inspectors are therefore—a 4 billion, there's only—how many inspectors are there to inspect 4 billion pounds of imported meat? How many inspectors?

Mr. SOLOMON. That's for FSIS, not USDA.

Mr. PASCRELL. Mr.—Dr. James.

Mr. JAMES. We have about 77 import inspectors and about 23 import surveillance liaison officers who are responsible for performing this part of our food safety——

Mr. PASCRELL. So, you have 77 inspectors at points of entry throughout the entire country, sir?

Mr. JAMES. Yes, sir.

Mr. PASCRELL. How does this compare with the number 5 or 10 years ago?

Mr. JAMES. It is approximately the same.

Mr. PASCRELL. How much more meat do we import than we did 5 years ago, 10 years ago?

Mr. JAMES. The levels of imported product have remained fairly stable over the last few years.

Mr. PASCRELL. Doctor—the last few years?

Mr. JAMES. Yes, sir. I can't go back 5 years in my head.

Mr. PASCRELL. Mr. Solomon, why is the FDA relying on 8,000 inspectors, officers, to conduct its examinations? Does this mean that the FDA has some staffing shortfalls? Do you think overall you're adequately staffed in all realms to help maximize the safety of the American consumer? Do you believe there are enough inspectors out there to protect the American consumer today?

Mr. SOLOMON. The Administration has asked in Fiscal Year 2008 for additional fundings in the area of 6.5——

Mr. PASCRELL. So, you don't think there are enough inspectors out there to protect the American consumer?

Mr. SOLOMON. Part of those funds would go for more inspectors that we requested, as well as the other, needed improvements in import safety.

Mr. PASCRELL. Mr. Chairman, thank you for holding this Committee today. The American people deserve better than what they've been getting, not only from the President, but from the Congress of the United States. The funding is inadequate, the

number of inspectors is inadequate. This is an absolute disgrace, that we have to rely on people who don't even work for us to bring to our attention what's in our product that's coming into this country. That's unacceptable, and I don't sense urgency here. I don't sense urgency, so we'll have another Work Study Group, I'm sure. I yield back.

Chairman LEWIS. Thank you very much for your questions. Now we recognize the gentleman from New York, Mr. Reynolds, for his question.

Mr. REYNOLDS. I thank the Chairman and I thank also Chairman Levin for holding the hearing, along with our Ranking Members. I've listened very carefully to some of my colleagues today, but I have an interest in bigger picture.

As we refer to the Working Group and as admirable that Secretary Leavitt has tried to convene this, I just look at how much you've handed off to each other, haven't answered the question. I mean, we've got a tremendous opportunity here. We're using two Subcommittees of Ways and Means to convene a hearing that just has five from the government. We have 12 departments, 34 governmental agencies, and 20 Committees within the Congress that have oversight.

While we're addressing that, the stats are so clear, the growth of imports—and we're reading our concerns on whether it be food, or most recently toys and Fisher-Price, headquartered, which is a Mattel company, in my region of the State of New York—it brings us back to looking at how are we going to make, first, the government have this Working Group have a common approach of how we standardize what our expectation and performance will be on imports, before just start throwing cash at fixing the problem in each of the 34 governmental agencies and 12 departments?

Second, the one of the things I've asked the Speaker of the House to look at is, in the spirit of what we've done of her desire among Members of Congress to look at a select Committee in Global Warming—I think with this type of challenge we've had here, I call upon her to convene some way, that we have 20 Committees and Subcommittees of the Congress on a relatively simple page of trying to do our job both in oversight and then trying to make some decisions as to what the investment needs to be for the government to do its job.

We see how the expertise in each of the five of you is, you defer whatever our question is to your particular department and how your agency chooses to address import safety. While the Working Group has been an umbrella to say we're going to advance to tie this down, I think that part of what the Congress needs to do is work at achieving some comprehensive collaboration that works in what our public policy should be in a uniformity of import safety, and also begin to get our own house in order—how we actually have some oversight jurisdiction on it, because it spreads across 20 different Committees of the Congress.

And—one of the things maybe one of you may want to take on is, do you truly expect the Working Group to be the cure-all for advising both the coordination of the Administration on import safety, as well as, how we can do our job both in oversight or looking at some codification of things the Congress may have to do to better

help you do your job, in addition to any consideration of taxpayer money? Anybody want to take that?

[No response.]

Your silence is deafening. Just, as I say, as a Republican I made this very clear, that if you think this is a partisan problem you're out of your mind. I hope you'll go back to your respective agencies and have—just one quarter of you are here on import safety. There's three quarters of the government not here that has oversight of this and responsibilities to do your job. We need both in the wakeup call, I think, of the Congress that we have to have a comprehensive approach. We need to see results of a Working Groups that's providing direction for both the government and what we need from this Congress.

I thank the gentleman.

Chairman LEWIS. Thank you very much. Mr. Becerra of California is now recognized for his question.

Mr. BECERRA. Thank you, Mr. Chairman, and thank you to the witnesses. We appreciate your testimony.

Let me concur with the gentleman from New York and his comments. Obviously, we want to make sure that when we give you a dollar it will be used efficiently, and so perhaps the most important thing is to have this Working Group report back quickly to us and tell us how we can extract as much efficiency out of all of these agencies that are charged with this oversight capacity to provide the safety and well-being of Americans as we continue in this mode of importing and exporting food.

I think it's worth noting that in a 10-year period from 1996 to 2006 we doubled the number of imports of agricultural and seafood products into this country, from some $39 billion to close to $78 billion. Today, 92 percent of all fresh and frozen seafood consumer by Americans in this country is imported. Today, 52 percent of all the grapes that we eat in this country are imported, and it would surprise folks from the State of Washington to know that today 75 percent of all the apple juice we drink here in America comes from a different country.

If that's the case, then we have to make sure that we're getting product that is grown as safely as we would expect to grow it for our own people in this country. So I hope you took some notes as Congressman Reynolds as speaking, because this is not a partisan issue. This is a—clearly an issue that must be addressed "bipartisanly", and so we do need to find out what we can do with all of your agencies and the moneys that you're getting and the people you have in place.

I would urge you to make sure that when you come back to us you've told us what you've done to your budget and to your operating procedures that make it very clear that you don't take this as just another day's work on the job, that you're going to do something differently. Because there is a problem. The President has identified it as a problem, we here in Congress have, I know you have, and so have the American public. So what we need to see is that you all come back with some serious changes to the way you operate.

I do believe you need more resources. Sometimes you're strapped by the economic considerations that the Office of Management and

Budget places on you, but I do believe you have to be serious with this issue and deal with it in a serious way with OMB. So, when OMB says, "You've got to meet a budget," you're letting OMB know if you can, and if you can't you have to be honest with them and say, "With the budget you're telling us we have to live under, we will not be able to provide the American people with the safety you expect."

So, when you come back to us with a number, and we will ask you what your 2008 request is, this "2008 request" is for your budget, and specifically with those issues that deal with inspection and safety, please make sure you can justify what you've requested. Because you've been put on notice here, I think, today, that we will want to know that you're doing things differently.

So I don't really have a question because I think the questions have somewhat been asked. I don't want to put you on the spot to tell me how much more you're going to put down for more resources to do inspections, how many more personnel you're going to hire tomorrow—we'll give you that time. We don't need this to become a witch hunt. We don't need this to become an issue where we try to claim victory for getting some success or point fingers to where it didn't happen, but please get back to us. Show us that you've taken seriously what the American public has told us, and that is that we've got to ensure that what they're going to eat, what our kids are going to play with, will be safe. So I hope that that charge is something that you all will continue to work on as diligently as you can, and we very much thank you for your time here.

Mr. Chairman, with that I will yield back unless anyone else on the panel has any particular questions or comments.

[No response.]

Thank you, Mr. Chairman.

Chairman LEWIS. Thank you very much. The gentleman from Missouri, Mr. Hulshof, is now recognized.

Mr. HULSHOF. Thank you, Mr. Chairman. I know we're in the midst of votes, and so I'll try to yield back some time.

I applaud the passion from the gentleman from New Jersey who spoke earlier. I know the prime focus of this hearing has been centering on—centered on food and product safety because of the very high-profile recalls we've seen of late. For the life of me, Mr. Chairman, I can't understand—and I'm not here to detonate a bomb here among us, but for the life of me I can't understand why a majority of Congress is hell bent on allowing the importation of pharmaceuticals. Dumbing down or allowing the easy importation of drugs that could be counterfeited, I think that should be a red flag for all of us, and yet it seems we are hell bent—"we" collectively, because I don't support it—hell bent on Congress trying to allow the importation of drugs from places across the planet. That's just an editorial comment, sir.

Dr. James, I'm tempted to inquire about the USDA's position about equivalency of inspection systems within interstate commerce, because I know that's been the subject of some interesting discussion of late, but that's not the subject of this hearing. But I do want to inquire—there are annual audits of foreign food safety systems, I think that's in your testimony, correct?

Mr. JAMES. That is correct.

Mr. HULSHOF. So, once a year?

Mr. JAMES. Yes, sir. The regular routine is to go once a year.

Mr. HULSHOF. Then on-site visits—I assume these are announced visits by USDA into another country, to allow you on the premises and then do you correct your battery of tests? Is that a fair assessment?

Mr. JAMES. Yes, sir. That is correct. We arrange to have our people met and conducted on their assessments of plants, laboratories, and government oversight, through audits and visual observations of the systems in place and through checking of records back over a period of time.

Mr. HULSHOF. Is there any concern on USDA's part that some foreign entity, knowing of the impending inspection, suddenly—while they may have been cutting corners for the previous nine months, in the three months coming up to the inspection that suddenly they try to get their act in order? Is there anything that we should be—that you're concerned about that we should be concerned about? Or are annual audits sufficient in USDA's view?

Mr. JAMES. We believe our annual audits are an important part of the entire system, which as I described earlier consists of an initial determination of equivalence, the annual audits, and then the port of entry re-inspections that we perform. Altogether, they get the job done. We believe our auditors are sufficiently trained to review oversight and records to review whether or not what they are seeing while they are on-site is reflective of the history of those plants.

Mr. HULSHOF. We're really running short on time on the floor. Mr. Chairman, I appreciate it. Final quick comment: Mr. Maruyama, thank you for including in your statement how easy it is, and I'm paraphrasing but it's on page four for people to look at, how easy it is for foreign countries to lock out our farm exports through "spurious sanitary and phytosanitary measures, just as they have cynically restricted," again, your terms and I agree with this, by the way, "U.S. manufactured goods through protectionist barriers dressed up as safety and regulatory standards."

Finally, Mr. Baldwin, perhaps you may want to do this in written form, again because our time is short on the floor. "A later witness is concerned about port chopping." That is—I mean, can you give me a 10-second—is that a concern from your point of view?

Mr. BALDWIN. I would say that's always a top concern, particularly on issues like seafood. I know that we were immediately concerned that, because there were restrictions being imposed on one country of origin, that there might be other opportunities for transshipment, either through a foreign port of export or a U.S. port of import.

Mr. HULSHOF. I think what I'd like to do, Mr. Chairman, maybe is follow up with a written inquiry again, because time is drawing short. But I appreciate that short answer, and thank you for the time, Mr. Chairman.

Chairman LEWIS. I thank the gentleman. As you well know, we have a series of votes on the floor and I will suggest, I don't think any of the Members here have any questions at this time, maybe

dismiss. Thank you for your testimony, thank you for taking the time to be here.

We're going to recess the Committee until after the vote. I believe we have about five, 5 minutes vote—six votes. So, it could be a little time, and we ask that the next panel be patient.

[Recess.]

Chairman LEWIS. The hearing will now resume. Let me thank members of this panel for being so patient. Sorry that we had to take so much time to cast a few votes. I really thank you for taking the time to remain.

Now we will here from our second panel witnesses. I ask that each of you limit your testimony to 5 minutes. Without objection, your entire statement will be included in the record. I will have all of the witnesses to give their statements and then the Members will ask questions of the panel.

It is now my pleasure to introduce our first witness, Mark Berman, the Chairman and chief executive officer of Rockland Industries.

I thank you for being here, Mr. Berman.

STATEMENT OF MARK R. BERMAN, CHAIRMAN, ROCKLAND INDUSTRIES, INC., BALTIMORE, MARYLAND

Mr. BERMAN. Thank you. Thank you, Chairman Lewis and Levin and that Member of the Subcommittee for the opportunity to testify about the safety of imported textiles. My name is Mark Berman. I am CEO of Rockland Industries, one of the remaining textile manufacturers in the U.S. I am testifying on behalf of Rockland, but also as a concerned citizen about an under-publicized and unregulated public health risk. That risk comes from the hazardous chemical formaldehyde, found at dangerous levels in textiles imported from China. Formaldehyde can cause cancer, serious respiratory disease and other health problems.

Although you may not recognize Rockland, you have probably come into contact with some of our products. We make the blackout window covering fabrics that are found in almost every hotel and motel room in the U.S. In fact, we export those products to 90 countries.

Because of the time limit, I can only touch on some major points, but there is a more complete discussion in my written submission.

Most textiles are full of chemicals. They give fabrics color, permanent press, fire retardancy and many other features. A textile trade group has identified 146 dangerous chemicals used in textile manufacturing that are subject to regulation someplace in the world. One of the worst is formaldehyde.

Only three years ago, the international cancer research agency found formaldehyde to be a human carcinogen, raising its determination from its previous evaluation is only possible. The EPA and OSHA also recognize it as a carcinogen. Exposure can cause allergy symptoms and repeated exposures can cause asthma. Children are more susceptible than adults. This is the stuff in the FEMA trailers and that has poisoned the pet food.

It is, however, a very useful chemical. Formaldehyde-containing resins impart permanent press, shrinkage control and vibrant col-

ors to apparel fabrics and home use textiles. In the case of coated fabrics like our blackout, formaldehyde produces durability.

The formaldehyde content of textiles is not regulated in the U.S. However, since 1988, OSHA has regulated formaldehyde exposure in the work place, including drapery sewing rooms, hotel rooms, warehouses and retail stores. OSHA requires that products containing 1,000 parts per million or more have a health warning label including the words, potential cancer hazard.

As a result of the OSHA regs, new chemicals were formulated with much lower levels of formaldehyde. The amount of formaldehyde in U.S.-made fabrics fell dramatically. Since 1988, formaldehyde in textiles has been off the radar screen in the U.S. The current generations of buyers who Rockland deals with at the major retail chains are not aware of formaldehyde as an issue. They are interested in price. The old, high-formaldehyde chemical technology still used in China is significantly cheaper than low-level formaldehyde chemicals.

We first became aware of safety problems with Chinese textiles in the international market. Since 2003, we have tested every sample of foreign-made blackout we could obtain. However, it was not in March of this year that we began to see these products in the U.S. market.

Of the 44 different products we had tested at an independent lab, 24 or 55 percent had formaldehyde levels high enough to require the OSHA cancer warning label, with amounts ranging to over 3,000 parts per million. A summary of the test results is in my written testimony.

While most of the samples were made in China, Pakistan, Turkey and Poland also produce dangerous textiles. OSHA work place and EPA environmental regulation of formaldehyde does not protect consumers against exposure from imported fabrics. This problem is one for the Consumer Product Safety Commission under the Federal Hazardous Substances Act.

Currently, the CPSC requires warning labels on household products containing 10,000 parts per million or more of formaldehyde. Textiles do not contain that amount of formaldehyde.

In 1973, the CPSC took the position that formaldehyde in textiles was not covered by the Hazardous Substances Act. However, the 10,000 part per million standard and CPSC position was set before the medical research connecting formaldehyde with cancer, or the growing international consensus among developed nations and, ironically, China, that direct regulation of formaldehyde content in textiles is necessary to protect the health of their citizens.

At least eight foreign countries, including China, have adopted specific limits. They are summarized in my written testimony.

Formaldehyde is undeniably dangerous, yet consumer exposure coming from apparel and home fabrics is unregulated. Limits on the formaldehyde content of textiles are needed. The structure for regulating and enforcement is already in place through the CPSC and the Hazardous Substances Act. Limits could be set through appropriate rulemaking.

Customs could require importers to submit samples for testing at Customs labs before the containers arrived, with the importers required to pay for the tests. Industry self-regulation through vol-

untary standards would not effectively protect the public. I know firsthand the pressures that the big retailers put on their suppliers for ever lower prices. Considering the major cost advantage of using high formaldehyde-level chemicals, I wouldn't want my family's safety to be at the discretion of some unknown supplier being squeezed by a retailer.

Thank you.

[The prepared statement of Mr. Berman follows:]

Prepared Statement of Mark R. Berman, Chairman and Chief Executive Officer, Rockland Industries, Inc., Baltimore, Maryland

Rockland Industries, Inc.

Roc-lon.

Testimony of Mark R. Berman for Rockland Industries, Inc.
before the Subcommittee on Trade and the Subcommittee on Oversight
of the Committee on Ways and Means, U.S. House of Representatives

October 4, 2007

HEALTH RISK AND REGULATION OF IMPORTED TEXTILES
RE-FIGHTING THE "FORMALDEHYDE WARS"

Thank you, Chairman Levin and Chairman Lewis and members of the Subcommittees on Trade and Oversight, for the opportunity to testify before you today on the urgent topic of the safety of imported textiles and textile products. My name is Mark Berman and I am the Chairman and CEO of Rockland Industries. I am testifying today on behalf of Rockland but also as a concerned citizen with knowledge of an under-publicized risk to the health of my family as well as other residents of the United States. That risk comes from the hazardous chemical formaldehyde being found in high levels in textiles imported from China and other countries. Formaldehyde is known to cause cancer, serious respiratory disease and other health problems.

I doubt that any of you have previously heard of Rockland. It is a family owned business that traces it roots back to 1832. It is a U.S. based textile manufacturer that is still conducting manufacturing operations in the U.S. We are headquartered in Baltimore, with factories in Baltimore and South Carolina. We provide approximately 360 jobs, most of which are semi-skilled.

Although you may not be familiar with Rockland, all of you have probably come into contact with some of our products. We manufacture the blackout window covering fabrics that are found in almost every hotel and motel room in the U.S. In fact, we export these products to 90 countries, including China, and have received the President's E and E Star Awards for Exports from the U.S. Department of Commerce.

All the news in recent months about unsafe products being imported into the United States and sold to unsuspecting consumers has missed a whole category of contaminated products and their associated health risks. Many common textile products manufactured in and sourced from Asia contain unsafe levels of formaldehyde. Among the products affected are bed pillows, blankets and draperies. In fact, the formaldehyde levels in some of these products are so high that under OSHA regulations they are required to have a prominent written cancer risk warning label. None of them do.

Rockland manufactures textiles in the United States in two of these product lines. It is the world's leading manufacturer of blackout window covering fabrics. It was also a significant supplier of ticking fabrics to U.S. bed pillow manufacturers. Rockland became aware of U.S. pillow manufacturers importing Chinese tickings about 8 years ago. This business has now gone almost entirely off-shore.

Rockland first started running into Asian-produced blackout fabrics in its foreign markets - from Pakistani producers about 12 years ago and from Chinese mills several years later. The quality of the foreign fabrics was and for the most part remains very poor. However, the price was significantly below the prevailing prices in the U.S. and Rockland's foreign markets, and in some cases below Rockland's cost of production. As a result, in spite of the quality differences, Rockland lost some of its international market share. We had not seen any significant amount of Asian blackout fabrics in the U.S. market until about six months ago.

Formaldehyde is a health danger

Formaldehyde is a colorless gas with a pungent, suffocating odor. It is highly irritating to the eyes and respiratory tract and presents many serious health risks.

Formaldehyde is used in many building materials, including plywood, particleboard and foam insulation and in a wide variety of molded or extruded plastic items, as well as in many household products such as latex paints, wallpaper, fingernail hardener, and nail polish. Formaldehyde is the subject of concern in the trailers provided by FEMA to some Katrina victims. In textiles, formaldehyde is found in permanent press fabrics, carpets, upholstery and, of particular interest to Rockland, coated blackout drapery fabrics. The emissions of formaldehyde from most of these common household products, Rockland's product excepted, can be very high.

Formaldehyde primarily affects the mucous membranes of the upper respiratory airways and eyes. It has been proven to cause nasal and nasopharyngeal cancer. Exposure at the levels that are contained in some of the imported blackout fabrics Rockland has tested, irritates the eyes, nose, and throat, and can cause skin and lung allergies. Formaldehyde can cause an asthma-like allergy. Repeated exposures can cause asthma attacks with shortness of breath, bronchitis, wheezing, cough, and/or chest tightness. Skin contact can produce dermatitis. Human studies suggest that children are more sensitive than adults to formaldehyde toxicity.

The health risks of formaldehyde are significant enough that many scientific organizations and governmental agencies have pronounced on it:

Formaldehyde gas is classified as a substance which may reasonably be anticipated to be a carcinogen, according to the Report on Carcinogens, Eleventh Edition; U.S. Department of Health and Human Services, Public Health Service, National Toxicology Program. (January 31, 2005)

Within the last three years, the International Agency for Research on Cancer (IARC) raised its determination of formaldehyde to be carcinogenic to humans (Group 1) from its previous evaluation as a probable human carcinogen (Group 2(A)) (IARC Monographs, Vol. 88, 2-9 June 2004).

The Occupational Safety and Health Administration (OSHA) of the U.S. Department of Labor has determined formaldehyde to be a potential human carcinogen.

The U.S. Environmental Protection Agency (EPA) has designated formaldehyde as a hazardous air pollutant, water pollutant and waste constituent. EPA regulates formaldehyde under the Clean Air Act; Clean Water Act; Comprehensive Environmental Response, Compensation, and Liability Act (Superfund); Food, Drug, and Cosmetic Act; Resource Conservation and Recovery Act;

Superfund Amendments and Reauthorization Act; and Toxic Substances Control Act. It is classified as a carcinogen in the Environmental Protection Agency's Toxic Release Inventory (TRI).

Federal Regulation of Use and Exposure to Formaldehyde Containing Products in the U.S.

No U.S. law or regulation limits the amount of formaldehyde that may be in a textile or textile product. In the U.S., formaldehyde exposure to workers and consumers is respectively regulated by OSHA and the Consumer Products Safety Commission (CPSC). General environmental exposure is regulated by the EPA and doesn't concern us here.

OSHA regulates exposure in the workplace. With respect to products that ultimately find their way into the home, OSHA's regulations can have only an indirect spill-over effect that may reduce or limit exposure. The CPSC directly regulates the exposure of consumers.

OSHA's regulations work two ways. Formaldehyde is one of only 42 specifically identified toxic and hazardous substances that merits its own standard (29 CFR 1910.1048). First, regulations set specific limits as to how much air-borne formaldehyde gas a person may be exposed to in a work environment. In the case of blackout fabrics, work environments would include sewing rooms, hotel rooms and retail stores.

Second, products containing more than 0.1 percent formaldehyde and "materials capable of releasing formaldehyde into the air, under reasonably forseeable conditions of use, at concentrations reaching or exceeding 0.1ppm" are subject to specific training requirements, the distribution of Material Safety Data Sheets (MSDS) and labeling including the words "Potential Cancer Hazard" as well as informing of the other health risks, and possible medical surveillance of exposed personnel. There are additional requirement for certain workplaces with very high exposure levels, that are not likely in the context of fabrics.

0.1 percent formaldehyde is 1,000 parts per million. As Rockland's tests show, blackout fabrics coming into the U.S. can have many times that amount of formaldehyde. In addition, the concept of "free" formaldehyde, discussed below, shows that the levels of formaldehyde that can be released by these products into the air under normal conditions, can be high.

The Federal Hazardous Substances Act (15 U.S.C. 1261-74)(FHSA) prohibits "(a) The introduction or delivery for introduction into interstate commerce of any misbranded hazardous substance or banned hazardous substance." The CPSC implements and enforces the FHSA (14 CFR 1500).

Under the Act, the CPSC regulates substances that are toxic, irritants or strong sensitizers, if the substances could "cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use."

Specifically, the CPSC has identified formaldehyde as a "strong sensitizer". The regulations require warning labels on household products containing 1% or more of formaldehyde. 1% is 10,000 parts per million, and as such would not cover any imported blackout fabrics that Rockland has so far encountered or any fabric of which Rockland is aware.

However, we believe that the levels of formaldehyde that are in fact found in imported blackout fabrics of 1,000 to almost 3,000 ppm would bring them within the FHSA definitions of

"toxic" and "irritant". In addition, and without getting into the finer points of the regulations and medical literature, we believe the health risks in light of continuing medical research since the regulation was adopted and accepted international norms indicate that the CPSC should revisit the 10,000 ppm threshold as a "strong sensitizer" and reduce it to no more than 1,000 ppm. The high 10,000 ppm requirement provides a "safe harbor" to imported textiles containing dangerously high levels of formaldehyde. The CPSC should also reconsider the position it took in a 1973 letter from the then Chairman of the CPSC to Senator Sam Ervin, to the effect that formaldehyde in textiles was not a strong sensitizer and therefore was not covered by the Federal Hazardous Substances Act. In the intervening 34 years, medical research has show that the CPSC was wrong in downplaying the risks of formaldehyde as a "strong sensitizer."

The FHSA regulations state that "[a] substance is toxic if it is or contains a known or probable human carcinogen". This clearly would apply to the imported blackout fabrics tested by Rockland.

The regulations provide for objective testing to determine if a substance is an "irritant". To date, Rockland has not had any imported blackout fabrics tested under the standard. However, the statutory definition of "irritant" as a non-corrosive substance "which on immediate, prolonged, or repeated contact with normal living tissue will induce a local inflammatory reaction" and the list of medical symptoms previously described as being produced by formaldehyde suggests that imported blackout fabric may well be an "irritant."

The protections of the FHSA are implemented through warning labels required on the products. Failure to provide the mandated warnings to consumers is enforceable by the FTC as "misbranding."

Foreign Regulation of Formaldehyde in Textiles

Many foreign jurisdictions have reached the same conclusions about the health risks of exposure to formaldehyde. At least eight countries limit the amount of formaldehyde that may be contained in textiles. A summary of some of those regulations is attached.

Ironically, China, which is one of the worst offenders recently tightened its internal regulations. Effective January 1, 2005, China adopted GB18401-2003 National General Safety Technical Regulations for Textile Products. Under Chinese law all products sold in China must comply with this national obligatory standard. In addition to establishing the concept of 'basic safety', which requires that products do no harm to human health, the regulations set specific formaldehyde content limits for various types of textiles. To meet the regulations pillow tickings (as a fabric that comes into direct contact with the skin) may contain no more than 75 ppm of formaldehyde and decorative fabrics no more than 300 ppm. These are among the strictest limits adopted anywhere. So far as we can tell this regulation is not being enforced in China. We believe that its purpose is to be used, if necessary, as a non-tariff barrier to entry against textiles being imported into China. Rockland's products meet the Chinese standard.

Further, effective May 1, 2006, the General Administration of Quality Supervision and the Inspection and Quarantine Administration of China implemented a new industry standard, SN/T1649-2005 Safety Inspection Regulations for Imported and Exported. According to this Regulation, all textile products coming into China must be tested against GB18401-2003 and textile products for export are also required to be tested for compliance with the laws and standards of

the importing countries. Rockland is not aware of any active compliance or enforcement of these regulations in China.

Recently blankets in New Zealand and Australia were the subject of safety related recalls. These blankets made by "gluing" short fibers to an underlying textile substrate. The "glue" used was a substance containing high levels of formaldehyde. The cases are instructive because New Zealand and Australia like the U.S. do not set a limit on the formaldehyde content of textile products. Instead, the basis of the recalls was a general concern about the safety of the products.

Blackout Fabrics Containing Dangerous Amounts of Formaldehyde Are Being Imported Into the US

Formaldehyde in textile products has been off the "radar screen" for quite some time in the US. In 1988, when OSHA first adopted standards setting limits to occupational exposure to formaldehyde, it created an enormous stir in the textile finishing industry. You used to go into a textile finishing plant and your eyes would burn. You would smell a distinct fish-like odor, in the air in the plant as well as on the finished fabrics. The same was true in retail fabric stores and certain clothing and drapery departments of department stores and textile sewing workrooms. What you were smelling and what made your eyes sting and your nose burn was formaldehyde gas given off by the fabrics.

However, as a result of the OSHA rule, a great deal of research and product development occurred in a very short time. Manufacturers of textile finishing chemicals developed low and ultra-low versions of their products, albeit at higher costs. Textile finishers were forced to use these products and bear the expense of doing so, in order to come within the permissible exposure limits in their factories.

A beneficial side effect was that the finished textile product contained a fraction of the amount of formaldehyde contained before the new regulations. This meant that downstream workers, in cut and sew operations, retail outlets and hotels, for example, as well as home consumers of textile products, were exposed to very low levels, if any, of formaldehyde.

Formaldehyde in textiles has not been an issue in the US for over 19 years, since the adoption of the OSHA standard. It has been all but forgotten. The generation of merchants that grew up knowing about and concerned with formaldehyde levels in textiles is mostly gone.

Rockland has tested every sample of foreign blackout fabric it could get its hands on. Goods from four countries were tested for many properties. The results are from an independent laboratory using the internationally accepted American Association of Textile Chemists and Colorists test method. The attached table shows the results for "free" formaldehyde content. Free formaldehyde is formaldehyde which can separate from the textile under everyday conditions and thereby constitute a source of exposure. The formaldehyde content of a comparable Rockland product is given for comparison. The competitive products' formaldehyde concentrations ranged from almost four times to over 10 times that of Rockland's product.

Use of Formaldehyde in Fabric Processing Gives Foreign Textile Manufacturers an Unfair Competitive Advantage

Although not a focus of this hearing, use of high formaldehyde textile chemicals affects the competitive conditions of the U.S. textile industry, thereby coming within another part of the jurisdiction of the Subcommittee on Trade. The economics of the use of formaldehyde grow out of its chemical uses. A short, simplified explanation follows:

Formaldehyde is very useful in many manufacturing processes and it is very, very cheap. It has been produced commercially since the early 1900s. It is in the top 25 of the 50 highest volume chemicals made in the US. For example, in 1998 US production was 11.3 billion pounds.

Resins used to treat textiles for permanent press or to form blackout coatings contain formaldehyde. The formaldehyde aids the chemical reaction that allows the long molecular chains of those resins to cross-link. This gives the treatments or coatings their toughness and durability and other characteristics that are the essence of the product.

When you take the formaldehyde out of the resins, you need to engineer more sophisticated chemical means for the molecular chains to cross-link. More sophisticated means more expensive, and in the case of the polymers used in blackout coatings, significantly more expensive. The use of formaldehyde allows the use of less resin or resins with poorer properties or both. And this equates to a significantly lower cost of production.

An educated estimate of the economic advantage of using formaldehyde containing coatings compared to acrylics that produce blackout drapery fabrics that comply with OSHA standards is more than 20%. Depending on the product, that can translate into a minimum cost advantage of $.15 per yard, and can go to several times that number. Add to that the effect of a manipulated exchange rates for the Chinese yuan, and the playing field is far from level. This negatively impacts Rockland's sales of blackout fabrics both domestically and in the international market.

Improvements to the existing mechanisms and authorities

We believe the existing regulatory framework is inadequate to protect Americans from the health risks associated with formaldehyde. In spite of awareness within the regulatory community, the practical ability to enforce is the problem.

OHSA regulation of formaldehyde requires importers of formaldehyde-containing products to provide their customers with the required labeling and MSDSs necessary to determine whether there is a health risk. So far as Rockland is aware, this is not being done.

A number of suggestions were made above with respect to the Hazardous Substances Act. Since formaldehyde is a proven carcinogen, we believe that formaldehyde at the levels in imported blackout fabrics are clearly within the definition of "toxic." However, we have never seen a warning label.

Rockland has worked closely with the U.S. Department of Commerce, Office of Textiles and Apparel (OTEXA) for many years. We kept them informed about our findings with respect to formaldehyde in foreign goods. On April 18, 2006 OTEXA sponsored a meeting on this issue, attended by representatives of U.S. Customs and Border Control, CPSC, OSHA, the Department of Labor, the Department of Commerce, various textile industry groups and Rockland.

At the April 2006 meeting, although sympathetic, OSHA and CPSC, made it clear that they were not in the position to discover violations of their statutes and regulations and take enforcement action in the absence of specific complaints. Thus, under the existing regulatory scheme, individuals or consumer groups or competitors would have to take on the role of watch dog and whistle blower for thousands of imported products. This is unlikely to happen.

At the April 2006 meeting, although sympathetic, Customs and Border Protection made it clear that it does not have the staff, training or budget to police imports for regulatory compliance. Even in the best of circumstances they could see only a small fraction of the goods imported. Acquisitions of samples from closed shipping containers would itself present a potential health hazard to Customs inspectors. Testing is time consuming and expensive and would delay commerce.

Even were OSHA, CPSC and Customs and Border Protection inclined to take on investigative and enforcement duties, the present regulatory scheme is pretty much limited to warning labels. We do not believe this is an adequate protection.

We believe that the time has come for the CPSC to set limits on the formaldehyde content of textiles, whether produced in the U.S. or imported. If the objective is to protect consumers, then this is the direct way to achieve that protection. The structure for regulating and enforcement is already in place in the Hazardous Substances Act. Content limits could be set through appropriate rule-making. The foreign regulations offer a model and starting point for discussion.

We also suggest adopting legislation requiring standard reciprocity. Under such legislation, if a country has a domestic standard, any goods imported into the U.S. must meet the higher of the U.S. standard or the exporter's domestic standard. The blackout fabrics being produced in China and sold in the U.S. do not meet the Chinese safety standard for internal consumption. We believe that if a product produced in China is not safe enough under Chinese law to be sold in China, then it is not safe enough to be sold in the U.S. That said, it is hard to demonize the Chinese for making unsafe textiles when the U.S. has failed to set its own standard and U.S. importers are not carrying out their legal obligations with respect to existing health and safety labeling requirements.

Finally, I do not believe that industry self-regulation would effectively protect the public. I know first hand the pressures that the big retailers put on their suppliers for ever lower prices. Considering the major cost advantage of using high levels of formaldehyde, I wouldn't want my family's safety to be at the discretion of some unknown distributor being squeezed by a retailer. It would be like having a very hungry fox guarding the hen house.

The conditions that led to the development of low formaldehyde resins in the late 1980's as a result of the adoption of the OSHA formaldehyde standard are no longer the case. The growth of imports from countries that have no regulations, do not enforce their own regulations or are taking advantage of the fact that there are no U.S. regulations, have reintroduced the risk that was adequately addressed in the 1980's when domestic production of textiles dominated but which have arisen again as that once vital U.S. industry declined through globalization.

SELECTED INTERNATIONAL REGULATION OF FORMALDEHYDE IN TEXTILES

Country	Regulations / Requirements	Objection Limit / Limit
Germany	Gefahrstoffverordnung (Hazardous Substances Ordinance) Annex III, No. 9, 26.10.1993	Textiles that normally come into contact with the skin and release more than 1500 mg/kg formaldehyde must bear the label "Contains formaldehyde. Washing this garment is recommended prior to first time use in order to avoid irritation of the skin."
France	Official Gazette of the French Republic, Notification 97/0141/F	The regulations apply to products that are intended to come into contact with human skin, including textiles, leather, shoes, etc. Textiles for babies: 20 mg/kg Textiles in direct skin contact: 100 mg/kg Textiles not in direct skin contact: 400 mg/kg
Netherlands	The Dutch (Commodities Act) Regulations on Formaldehyde in Textiles (July 2000)	Textiles in direct skin contact must be labeled 'Wash before first use' if they contain more than 120 mg/kg formaldehyde and the product must not contain more than 120 mg/kg formaldehyde after wash.
Austria	Formaldehydverordnung, BGBL Nr. 194/1990	Textiles that contains 1500 mg/kg or above must be labeled.
Finland	Decree on Maximum Amounts of Formaldehyde in Certain Textiles Products (Decree 210/1988)	Textiles for babies under 2-year-old: 30 mg/kg Textiles in direct skin contact: 100 mg/kg Textiles not in direct skin contact: 300 mg/kg
Norway	Regulations Governing the Use of a Number of Chemicals in Textiles (April 1999)	Textiles for babies under 2-year-old: 30 mg/kg Textiles in direct skin contact: 100 mg/kg Textiles not in direct skin contact: 300 mg/kg
China	Limits of Formaldehyde Content in Textiles GB18401-2001	Textiles for infants and babies: ≤20 mg/kg Textiles in direct skin contact: ≤75 mg/kg Textiles not in direct skin contact: ≤300 mg/kg
Japan	Japanese Law 112	Textiles for Infants: not detectable Textiles in direct skin contact: 75 ppm

From Hong Kong Standards and Testing Centre.

Coated Goods Formaldehyde Test Results

Selected for Rockland goods and goods exceeding OSHA standard requiring warning label

Date of Test Results	Sample Identity	Sample Obtained By Rockland From	Product Distributed in U.S. By	Country of Manufacture	Free Formaldehyde ppm
Multiple	Rockland Budget Blackout Flame Retardant and Non-Flame Retardant	Rockland regular production		USA	290
5/10/2005	1 pass white			Pakistan	1110
5/10/2005	1 pass ecru			Pakistan	1150
2005	3 pass Non-Flame Retardant			Turkey	1280
10/20/2005	3 pass Non-Flame Retardant	TIP Trade Show, Brussels, Belgium, Sep 05		China	1165
11/3/2005	110" 3 pass	Rockland customer		China	1050
11/3/2005	Woven Wood blind w/light filtering coating	Rockland customer		Pakistan	1134
12/1/2005	Brown Suede Sample 1 pass			China	2245
12/1/2005		Rockland customer		Poland	2525
3/9/2006	3 pass blackout fabric	Rockland customer	U.S. competitor	China	1923
3/9/2006	3 pass Non-Flame Retardant	Sarkat Textile Mills		Pakistan	1145
4/4/2006	3 pass blackout Non-Flame Retardant			China	1065
3/28/2007	Burgandy velvet blackout coated ready-made drapery	Major U.S. Retailer #1		China	3085
4/14/2007	Bed Pillow with coated fabring, labeled "hypoallergenic" and "Made in USA"	Major U.S. Retailer #2	Imported by major U.S. textile company	China	2385
4/14/2007	Drapery valance #1	Major U.S. Retailer #3		China	2320
4/14/2007	Drapery valance # 2	Major U.S. Retailer #3		China	1175
4/14/2007	Drapery valance # 3	Major U.S. Retailer #4		China	1440
4/14/2007	Drapery valance # 4	Major U.S. Retailer #4		China	2120
4/14/2007	Drapery Jabot Set	Major U.S. Retailer #4		China	2770
4/14/2007	Drapery valance # 5	Major U.S. Retailer #5		China	2280
4/14/2007	Drapery valance # 6	Major U.S. Retailer #5		China	1940
4/30/2007	Black velour blackout coated ready-made drapery	Major U.S. Retailer #6		China	2190
5/2/2007	Red coated fabric	U.S. ready-made drapery manufacturer/ fabric distributor		China	1610
5/2/2007	Blue coated fabric	U.S. ready-made drapery manufacturer/ fabric distributor		China	1110
5/2/2007	Brown coated fabric	U.S. ready-made drapery manufacturer/ fabric distributor		China	1070
5/2/2007	Gold coated fabric	U.S. ready-made drapery manufacturer/ fabric distributor		China	1610

Formaldehyde is tested according to AATCC Test Method #112, the Sealed Jar test. (1 gram sample over 100 ml of water, 20 hour extraction at 49C/120F.)

"Non-Flame Retardant" indicates product is intended for residential use rather than contract/commercial use.

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Chairman LEWIS. Our next witness is from the Consumers Union. I am pleased to welcome Jean Halloran, the director of food policy initiatives. Thank you for being here.

STATEMENT OF JEAN HALLORAN, DIRECTOR OF FOOD POLICY INITIATIVES, CONSUMERS UNION, YONKERS, NEW YORK

Ms. HALLORAN. Thank you for inviting me and for this opportunity to testify on what has become a serious crisis in import safety.

Almost daily, we are hearing new reports of safety problems with imported food, toys and other products, including pet food from China, seafood from China, and 20 million toys manufactured in China. Just last week, one million cribs made in China were recalled due to design and construction defects that caused babies to strangle.

This raises an obvious question of how did we get into this situation? We see two causes to the problem. One is that two of the most important Federal agencies that the public relies on to ensure that everything in our marketplace is safe, the Food and Drug Administration and the Consumer Product Safety Commission, have not kept up with globalization. In fact, quite the opposite.

Congress has repeatedly cut the budget of the CPSC so that it now has half the employees that it had when it opened its doors in 1973. It only has 15 inspectors to police the millions of toys coming into the country and, according to the New York Times, has exactly one full-time toy tester.

The FDA is equally hamstrung. Today, it inspects less than 1 percent of the food imports entering the country and is present at less than half of the over 300 ports where food can enter. This has led to a phenomenon known as port shopping. If, in fact, you have a product that doesn't make it through an FDA inspector, you can try another port, where perhaps nobody will be watching.

In the absence of adequate FDA and CPSC capacity, Customs and Border Protection becomes the fall-back consumer protection agency at the borders. However, as the previous speakers noted, they have problems coordinating with other agencies and their databases cannot connect with, for example, USDA's database.

Overall, Consumers Union recommends that Congress consider a number of steps to address these problems. It should man date a major increase in the border inspection staffs, which could be paid for through user fees on imports, for CPSC and FDA products. It should require FDA and CPSC to establish federally supervised systems for independent third party certification of imports to certify them to U.S. standards. It should give USDA and FDA explicit authority to recall contaminated food and it should end the USDA policy of secrecy about the identity of retail out lets involved in meat recalls. This is especially a problem and one which could address the fact that many people who don't have computers need to know about recalls.

A rule to do this is currently stuck at OMB as far as I have been informed.

They should strengthen FDA and CPSC overall. If FDA only inspects U.S. facilities once every 10 years, in the United States, then it's difficult to demand more of the Chinese. Especially under WTO rules.

The second major cause of our import problems lies in our trade policy. I also sit on a State Department advisory Committee on trade. For many years, I have seen that our trade policy proceeds with blinders on toward just one goal: That of gaining access for U.S. companies to foreign markets, with little consideration of the impact on the domestic marketplace.

Our trade policy has to take a more holistic approach. One change that would be important would be to pass H.R. 3204, which

would open up the trade Committees, the advisory Committees that advise the U.S. Trade Representative.

Another would be that Congress should examine for its pending trade agreements and delete provisions like Chapter 11.

Other is that the State Department, the USTR and Department of Agriculture should be directed to give attention to counterfeiting problems not just of CDs, but on safety issues like counterfeiting of the Underwriters Laboratory logo.

Congress should also ensure that, where trade negotiators seek harmonization of standards, they always seek to harmonize up and not down. In the case of mad cow disease, we have tried to persuade Japan to harmonize down, rather than the other way around.

Congress should investigate whether WTO rules may hamper the ability of Federal agencies to protect the public and, if so, address the problem. For example, just the kind of risk-based enforcement to FDA did on seafood could be challenged because trade rules prohibit countries from imposing stricter standards on one country than another.

Thank you very much.

[The prepared statement of Ms. Halloran follows:]

Prepared Statement of Jean Halloran, Director of Food Policy Initiatives, Consumers Union, Yonkers, New York

Thank you for the opportunity to testify today on what has become a serious crisis in import safety. My name is Jean Halloran and I am Director of Food Policy Initiatives for Consumers Union, non-profit publisher of *Consumer Reports*.

Almost daily, we are hearing new reports of safety problems with imported food, toys, cribs and other consumer products. In the spring, we discovered that pet food imported from China contained wheat flour that was contaminated with melamine. According to one veterinarian website, thousands of pets may have died as a result.[1] In June, the FDA put five types of farmed-raised fish and seafood from China under a "detain and test" order, due to repeated findings that the fish contained chemicals banned from seafood in the United States.[2]

Over the summer, more than 20 million toys manufactured in China were recalled because of lead paint and other hazards, despite the fact that lead paint was banned on toys in the U.S. thirty years ago.[3] Just last week, one million cribs made in China were recalled due to design and construction defects that could cause babies to strangle. The cribs are believed responsible for the deaths of two infants.[4]

This raises the obvious question, how did we get in this situation? Why do we suddenly seem to be inundated with unsafe and substandard products? Many of the most well publicized examples are coming from China, but they are not the only source. In 2003, 555 people became sick and at least 3 died from hepatitis A in green onions imported from Mexico.[5] There have also been recalls of millions of pieces of children's jewelry made in India that contained large amounts of lead.[6]

We see two causes of the problem. One is that two of the most important Federal agencies that the public relies on to ensure that everything in our marketplace is safe—the Food and Drug Administration and the Consumer Product Safety Commission—have not kept up with the globalization of the marketplace. In fact, while new demands on their expertise have arisen, these agencies have experienced budg-

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[1] Dahlberg, Carrie Peyton, "Vets Survey: Pet Deaths Have Soared" *Sacramento Bee*, April 10, 2007.

[2] FDA News, "FDA Detains Imports of Farm-Raised Chinese Seafood; Products Have Repeatedly Contained Potentially Harmful Residues," June 28, 2007.

[3] Newman, Andrew Adam, "What's a Parent to Do?" *The New York Times*, September 29, 2007, p. C1.

[4] News from CPSC, "About 1 Million Simplicity Cribs Recalled Due To Failures Resulting in Infant Deaths", September 21, 2007.

[5] V Dato et al., *Hepatitis A Outbreak Associated with Green Onions at a Restaurant—Monaca, Pennsylvania*, 2003, 52 MMWR 1155–57 (2003)

[6] News from CPSC, "CPSC Announces Recall of Metal Toy Jewelry Sold in Vending Machines," March 1, 2006.

et cutbacks. In addition, Customs and Border Protection, which also plays an extremely important role, is not being utilized in the best possible way to address threats to consumer safety.

The second problem lies with the direction that Congress and the Executive Branch have given to our trade policy, which has largely ignored the problems of unsafe and hazardous imported products. I would like to discuss both of these problems and how we can remedy them.

First, in recent years, imports have skyrocketed, especially from China. The value of all imports increased by 67 percent between 2000 and 2006.[7] This has proceeded to such an extent that now 80 percent of all toys sold in the United States are imported from China.[8] Likewise, 83 percent of the seafood we eat is imported, 21 percent of that total from China, much of the rest from other developing countries in Asia and Latin America.[9] Of all the food we consume, 13 percent is imported.[10]

While these imports pose new safety challenges to both importers and all regulatory agencies, FDA and CPSC, in particular, have not kept pace with this new challenge. In fact, quite the opposite. Congress has repeatedly cut the budget of the CPSC so that it now has half the number of employees it had when it opened in 1978. It now has 15 inspectors to police the millions of toys and consumer products coming into the country at hundreds of entry points. And, according to the New York Times, it has only one full-time toy tester, named Bob.[11]

The FDA is equally hamstrung. Today, it inspects less than one percent of food imports entering the country. There are over 300 ports (many landlocked) where food can enter.. At the peak of its funding, there were FDA inspectors stationed at only 90 of them, and the number of inspectors has dropped since then.[12] This has led to a phenomenon known as "port shopping." Indeed, if a shipment of seafood is rejected by FDA inspectors at one port because it has begun to decompose, there is nothing at all to prevent the importer from trying another port where FDA simply may not be present.

In the absence of adequate FDA and CPSC capacity, Customs and Border Protection becomes the fallback consumer protection agency at the borders. In fact, when FDA issued its "detain and test" order for Chinese seafood in June, CPB appeared with FDA to discuss how it would be implemented. Until recently, however, little was being done to coordinate these fragmented inspection efforts, or to determine if there could be efficiencies developed through better coordination and communication. The Report to the President of the Interagency Working Group on Import Safety identified "siloed systems" and in particular the inability of CPB and USDA's data bases on imports to connect with each other, as problems that needed to be addressed.[13]

It is essential that we prevent chemical and nuclear threats that might be hidden in shipments coming across our borders. But food can also be a vehicle for doing serious damage to the health of the U.S. population. So far, the health threats we have found in food seem to be the result of neglect, carelessness, or greed. But deliberate contamination could also occur. The CPB, FDA, CPSC, and the U.S. Dept of Agriculture must coordinate better, and get the resources they need to protect the borders.

Overall, Consumers Union recommends that Congress consider three steps to address these problems:

1. Mandate a major increase in the border inspection staffs at both CPSC and FDA. One way to raise the funds to cover this would be through user fees on imports.

2. Require FDA and CPSC to establish federally supervised systems for independent third party certification of imports, and require that those imports be certified to meet U.S. safety standards.

3. Give USDA and FDA explicit authority to recall contaminated food; currently all recalls are voluntary.

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[7] Interagency Working Group on Import Safety, *Protecting American Consumers Every Step of the Way*, September 10, 2007.

[8] Wenske, Paul, "Toy recalls fuel criticism of consumer safety agency," *Kansas City Star*, August 15, 2007.

[9] Food and Water Watch, *Import Alert*, July 2007, available at www.foodandwaterwatch.org.

[10] Bridges, A. "Imported food rarely inspected," *USA Today*, April 16, 2007.

[11] Lipton, Eric, "Safety Agency Faces Scrutiny Amid Changes", *New York Times*, September 2, 2007.

[12] Testimony of Caroline Smith DeWaal, House Energy and Commerce Committee, Subcommittee on Oversight and Investigations, *Import Inspection Failures and What Must Be Done*, July 17, 2007.

[13] Interagency Working Group on Import Safety, *Protecting American Consumers Every Step of the Way*, September 10, 2007.

The second major cause of the import problems we are currently seeing lies with our trade policy. I also sit on the State Department Advisory Committee on International Economic Policy and Trade, and work closely with sister consumer organizations in other countries who belong to Consumers International. For many years, U.S. trade policy, at the direction of Congress and the Executive Branch, has proceeded with blinders on towards just one goal—that of gaining U.S. companies access to markets in other countries—with little consideration to the impact on the domestic economy or marketplace. That approach to trade policy needs to change. Our current trade policy has had profound effects on life in the United States. Our toy manufacturing industry, for example, has disappeared. Congress has begun to think about looking at the impact of trade agreements on labor standards and the environment. We must also, however, look at how trade agreements affect the safety of the products we give to our children, eat for breakfast, feed our dogs and cats, and sleep on. Unless we look more closely at the impact our trade policy has on safety issues, our quality and standard of living will decrease, rather than increase as it can and should do. Our trade policy has to take a more holistic approach.

Consumers Union would like to make several recommendations as a way to begin to improve our trade policy.

1. A simple, yet important change would be to broaden the many advisory committees that provide the marching instructions to the U.S. Trade Representative, to include representatives of consumer, environment, and labor organizations and the general public. Currently those advisory committees include only representatives of the business community. A bill to do this, H.R. 3204 was recently introduced by Representative Chris Van Hollen and was referred to this committee.

2. Congress should examine the four pending trade agreement, past trade agreements, and any new agreements negotiated in the future to determine whether they adequately protect the right of Federal, State and local governments to protect the safety of their citizens. One type of provision that should not be included in such agreements is the "Chapter 11" agreement that is part of NAFTA. This provision allows companies who invest in another country, and whose profits are damaged by a foreign regulatory action, to be compensated for their loss. This probably sounded good in the context of possible nationalization of American investments in telecom infrastructure or oil fields in foreign countries. However, one must always consider how such provisions will work when they are turned around and applied at home. A Canadian company operating funeral parlors in Mississippi sought compensation under NAFTA when new state regulatory actions forced it to end certain anti-competitive and predatory business practices. The case was dismissed, but only because the company had reorganized as a U.S. corporation, and was thus no longer eligible for a claim as a foreign investor.[14] Our negotiators should request from others only those things we would be happy to have others requested from us.

3. Our trade policy and our trade negotiators in the State Dept, USTR, and U.S. Dept of Agriculture, should be directed by Congress to give attention not just to copyright and counterfeiting problems that cut into U.S. company profits, but also to the counterfeiting of safety-related labeling. I have been at many meetings where I have heard how hard the U.S. is working to address exporter's problems with counterfeit CDs in foreign countries. We also think counterfeiting of consumer products is a problem. However I have never heard much talk about working hard to address the problem of counterfeiting of the Underwriters Laboratory logo. This is an extremely serious safety problem, one that can result in serious injury or death to a consumer who buys a defective electrical product. Yet although there are numerous State Dept and USTR initiatives on intellectual property, and enforcement of copyright related to movies and CDs, I am aware of no such efforts on this important safety-related counterfeiting issue.

4. Congress should ensure that where trade negotiators seek harmonization of standards, they seek to harmonize up, and not down. Where our standards are lower than another country's, we should always see how we can improve, not try to force or encourage others to reduce their protection. For example, the U.S. has been involved in a protracted trade dispute with South Korea and Japan about exports of our beef. Japan has stricter standards than we do about testing for mad cow disease—every animal over the age of twenty months is required to be tested at slaughter. We only test about a tenth of a percent of U.S. cattle that die or are slaughtered. One simple solution to our trade problem with Japan would have been to allow U.S. companies who export to Japan to test the cows they slaughter for that market. However, the USDA has actually forbidden one company, Creekstone, from

[14] Public Citizen, *NAFTA's Threat to Sovereignty and Democracy: The Record of NAFTA Chapter 11 Investor-State Cases 1994–2005*, February 2005.

taking that step.[15] Indeed, the government appears to be trying to deepen the divide between us and Japan by opening our border further to Canadian cattle and beef, which have had significantly more cases of mad cow disease than U.S. cattle.[16] To us this seems like the wrong approach to solving trade disputes.

5. Congress should investigate whether WTO rules may hamper the ability of Federal regulatory agencies to protect the public, and if so, address the issue. It is important that all trade agreements, and our trade policy in general, allows for targeted, risk-based enforcement actions against products from particular countries when warranted. WTO trade rules in general provide that one country cannot impose stricter, or differing safety standards on products of other countries than it imposes on its domestic production. In the area of food safety, this may pose a number of dilemmas. As noted previously, our agencies are seriously understaffed. If agencies see a greater incidence of violations in products from a particular area—as they recently did with seafood from China—it is important that they continue to be able to target such problem areas for increased inspection and testing. In addition, many U.S. food regulations are actually in the form of guidance, which is not mandatory, but which is widely followed by U.S. industry nevertheless. It may be necessary for such guidance to become regulation, so that other countries are obligated to conform under WTO rules.

In sum, in recent years, while imports have ballooned, regulatory capacity has shrunk. Our regulatory capacity must be overhauled to meet the import challenge. In addition, our trade policy must be more holistic, and trade agreements must be designed with protection of product safety in mind. Thanks you for considering these issues.

Chairman LEWIS. Thank you very much.

I am pleased to welcome John Connelly, the president of the National Fisheries Institute. Welcome.

STATEMENT OF JOHN CONNELLY, PRESIDENT, NATIONAL FISHERIES INSTITUTE, MCLEAN, VIRGINIA

Mr. CONNELLY. Thank you, Mr. Chairman, Mr. Levin and—excuse me—Chairman Levin, and Mr. Herger.

NFI represents the seafood community in the U.S., from water to table. We have large domestic producers in Alaska, Pacific Northwest and in places like New England. We also represent importers, processors and the shops that sell us seafood at the local restaurant and grocery store.

Fish is a unique product. Just today, there was another major study that was announced encouraging Americans to eat fish, especially young women, to eat fish at least two to three times per week. At a time when half of the people in this room, half of the people on the dais, half the people behind the dais and half the people listening behind me, will die of heart disease, doctors and dietitians are encouraging Americans to eat seafood because of it's positive health benefits, particularly the omega 3s.

Americans have heard that message and we are eating seafood at record levels. But where does our seafood come from?

U.S. seafood—excuse me—U.S. fisheries are very well managed. About four in five are deemed sustainable by the fisheries scientists in the Department of Commerce. But with that sustainability comes a cap on how much fish U.S. fishermen can actually catch. Simply put, demand, because of the health benefits of sea-

[15] Reynolds, George, "Private BSE Testing on Hold Following Appeal," *Food Production Daily–USA*, May 31, 2007.

[16] Consumers Union News Release," Consumers Union Calls on USDA to Continue Ban on Beef from Canada," March 12, 2007, available at www.consumersunion.org.

food, has outstripped supply, because of the U.S. insistence on a sustainable fishery system.

So, now we import about 80 percent of seafood into this country. That is actually a good thing, because it allows families in Michigan or in Georgia or in Minnesota to enjoy the same health benefits as somewhere on the upper east side of New York City.

The vast majority of seafood imports remain safe. There is not a documented case of seafood imports causing a health situation. That said, the seafood import system is not perfect, as evidenced by recent news and press accounts from China.

NFI supports FDA's zero tolerance for the use of unauthorized antibiotics. We also supported FDA's imposition of an import alert on China in June of this year.

While China has not caused an immediate health scare regarding seafood, the import alert was an important shot across the bow of China to make sure they stop any practice that is illegal in the U.S.

NFI supports several concepts to strengthen the food safety system here, to create a targeted, more risk-based approach to imports particularly. First, on the import side, we believe it should be more difficult to become a food importer into the U.S. That's right, we are looking for more regulatory oversight of FDA on our business. FDA should create a certification system for importers that goes beyond the current passive model.

On the export side, NFI believes exporting countries should be required to certify any company exporting food to the U.S. as being in compliance and in good standing with their food safety laws.

As has been mentioned before, NFI strongly supports a significant increase in FDA resources on both the personnel side and in the infrastructure. By doing so, we believe that we can shine a spotlight on those countries or companies that have exhibited a problem, while at the same time rewarding the good companies and countries that do things well.

As an example of how industry and government can work together, in 2005, Vietnam had—the FDA had found out that Vietnam had a number of companies using fluoroquinolone, an unauthorized antibiotic. NFI travelled to Vietnam to encourage both the companies and government to take action. Subsequently, Vietnam banned that product, conducted a significant educational system out in their farm communities. They began 100 percent testing for fluoroquinolones and had swift and sure punishment for anyone misusing that product.

The results have been impressive. In 2006 and 2007, to date, there have been zero shrimp imports from Vietnam with testing positive for antibiotics. There have been zero basa or tra, a kind of Chinese—excuse me—Vietnamese catfish, testing positive for antibiotics. That is a good example of industry and government working together.

We do think there is significant opportunity for the U.S. to take a holistic approach, where FDA can work much more closely with CBP and other government agencies in order to extend the resources that FDA has.

We look for ward to the discussion with the Committee and Congress more broadly in this debate.

[The prepared statement of Mr. Connelly follows:]

Prepared Statement of John Connelly, President, National Fisheries Institute, McLean, Virginia

Good Morning, Chairman Levin, Chairman Lewis and Members of the Subcommittees. I appreciate the opportunity to testify today on the issue of import safety and the work the American seafood industry is doing to ensure that consumers who depend on fish and seafood as part of a healthy diet and lifestyle enjoy the safest products possible. I plan to focus my testimony today on three areas: 1) current food safety practices and regulations designed to protect consumers; 2) specific examples of the seafood community working collaboratively with our trading partners to ensure safe seafood imports; and 3) several key principles and recommendations that Congress should consider when developing a risk-based system for food protection. On this final point, I understand that several legislative and industry plans for food safety have been proposed in recent months; however I feel that our industry principles take a uniquely progressive approach to working with government on these important matters.

For more than 60 years, the National Fisheries Institute (NFI) has been the Nation's leading advocacy organization for the seafood industry. NFI's members provide American families with the variety of sustainable seafood essential to a healthy diet. Our member companies represent every element of the industry—from oyster farmers off Connecticut's shores to fish processors in Minnesota to retail and restaurant chains from Maine to California. From responsible aquaculture, to a marketplace supporting free trade, to ensuring consumers have the facts on the health benefits of fish and shellfish, NFI and its members support and promote sound public policy based on scientific research.

It is imperative to understand the importance of seafood to a healthy diet. As more Americans die from heart and related diseases, the consistent message from public health officials is that we should all be eating more seafood—at least twice per week. Fish is, without question, the protein choice that provides essential omega-3s and other nutrients that doctors and dieticians recommend we take advantage of. Americans have heard that health message and seafood consumption is at record levels.

Domestic fisheries provide excellent products, and NFI is proud to represent the vast majority of the value and volume of domestic producers. Because the U.S. does a very good job managing our Nation's fishery resources, we are limited in our supply. Wild capture fisheries are unlike land based agriculture, where farmers can just plant additional acres of crops. Fishermen are limited in the number of fish they can catch. And we simply cannot produce enough seafood for the demand created for such a healthy product.

Imports are an essential and helpful way to ensure Americans enjoy the benefits of seafood. Approximately 1,000 U.S. firms are in the business of importing fish and shellfish and top imports included shrimp, salmon, tilapia, pollock and tuna. U.S. seafood companies, many of which are small, family-owned enterprises, import fish from more than 130 nations, including Canada, Iceland, Thailand, China, Ecuador, Chile and Mexico.

Consumer confidence is essential to the retailers and restaurants that provide meals to American families. Consumers must have faith that the government and private sector have worked together to ensure the meals they eat are safe. As a result, and because much of our supply is from overseas the seafood community places exceptional emphasis on the safety of the imported seafood supply.

Seafood remains one of the safest foods produced—whether domestic or imported. In fact, there have been no illnesses reported as a result of imported seafood that has been properly handled, stored and prepared. However, as evidenced by recent positive test results for unauthorized antibiotics and substances in a few select seafood imports, it is apparent that our Nation's system is not perfect. There is more that we—the seafood community and government—can and should do to protect consumers.

The cornerstone of a strong food safety program is a strong Food and Drug Administration. NFI has, since the beginning of this Congress, supported enhanced funding for FDA's Center for Food Safety and Applied Nutrition (CFSAN) and development of a risk-based system of food protection. A primary goal for the FDA should be to reduce points at which food safety challenges can occur, at both the exporter and importer level. FDA should develop a preventative approach that prevents problems at their source, rather than at U.S. borders.

Importantly, FDA should seek to work with other agencies, like the Custom and Border Protection, to identify areas of cooperation and coordination, in order to maximize the effectiveness of all Federal Government agencies.

NFI supports a risk-based approach to import inspections. We should "reward the good" and shine a spotlight on those not adhering to our requirements. We should focus the bulk of FDA's resources on imports from foreign companies or countries that do not have a strong record of safe and secure shipments to the U.S. Further, NFI supports the creation of a program to certify private labs that could work under FDA authority where importers of record could pay for expedited inspections. This would help reduce the level of backup at our Nation's ports and also free up FDA's public labs for testing of the riskier shipments.

NFI has a long history of working collaboratively with Federal officials to ensure the wholesomeness of seafood products, including being early supporters and adopters of the Hazard Analysis and Critical Control Point (HACCP) concept. HACCP is the foundation of our comprehensive program for seafood safety and is a cost-effective, prevention-focused "video" model that identifies and targets those critical points in the import life cycle where the risk of unsafe products is greatest and verifies the steps are in place to avoid problems. It is an essential strategy to prevent unsafe products from entering the United States."

Current regulatory requirements have been in place for almost 10 years for controlling the safety of imported seafood products. To summarize, the current regulatory requirements for importers of seafood products are as follows:

Every importer of fish and fishery products is required to have and implement written verification procedures for ensuring that the products that they offer for import into the United States were processed in accordance with the Seafood HACCP and sanitation requirements.

Importers are required to have product specifications that are designed to ensure that the product is not adulterated as defined by the Federal Food, Drug, and Cosmetic Act.

FDA requires seafood importers to take affirmative steps and maintain records to ensure that products being offered for entry are actually produced under controls that meet U.S. Seafood HACCP regulations.

The purpose of the affirmative steps is to assure that overseas processors have and implement HACCP when necessary. Importers have several options suggested by FDA for the affirmative steps:

- Obtain foreign processor HACCP and sanitation monitoring records for each lot.
- Obtain either a continuing or lot-by-lot certificate from the foreign government inspection authority or competent third party certifying that the product was processed in accordance with the HACCP regulations.
- Regularly inspect the supplier's processing facilities to ensure that the product is processed in accordance with the HACCP regulation.
- Maintain a copy of the processor's HACCP plan along with a written guarantee that the product is processed in accordance with the regulations.
- Periodically test the imported seafood products and maintain a written guarantee that product is processed in accordance with the regulation.

Importer affirmative action steps are a cost-effective method for providing the "video" of preventive controls, a key component of the strategic framework for continual improvement in import safety. Requiring importers to be the "eyes" in the field, so to speak, to ensure that the exporting companies understand and follow U.S. regulations, allows FDA to perform "snap shot" risk-based inspections at the ports. This preventative approach identifies and controls problems at the source, rather than at U.S. borders.

As an example of the effectiveness of addressing safety concerns at the source, I would like to highlight how our industry dealt directly with a notable food safety situation in Vietnam. In 2005, the FDA placed two shippers of Vietnamese basa on detention without physical examination status due to residues of fluoroquinolone (FQ) antibiotics found in shipments exported to the U.S. Following the alert, NFI immediately communicated our concern with the U.S. FDA, the Vietnamese government, and most importantly, the Vietnamese exporting companies. We explained the need to: 1) prohibit unauthorized antibiotics for use in fish farming as dictated by market countries; 2) develop an education campaign for farmers and processors about the antibiotics ban; and 3) develop an in-country testing system; and 4) implement swift and sure punishment for violators. NFI met with the FDA to explain our industry-to-industry work and encouraged them to adopt parallel government discussions. NFI also sent a delegation to Vietnam to speak directly to a major aquaculture conference to express the need to adhere to U.S. regulations for commodities exported to this country. In October of 2005, Vietnam announced a ban on use of

antibiotics and began a comprehensive testing program for all seafood exported to the U.S. Results have shown a near complete success in ensuring Vietnamese seafood is not tainted with unauthorized antibiotics.

NFI's work in Vietnam illustrates how industry and FDA can work together to send the message that complying with U.S. regulations for products shipped into this country is imperative if exporters intend to maintain a positive relationship with their American customers.

NFI's specific recommendations for an enhanced food import program include:

- *Require FDA to certify food importers:* FDA should register food importers, after ensuring the company has the training and management expertise to understand and adhere to food safety laws. This proposal would align the U.S. with a Canadian approach to seafood imports.
- *Require foreign countries to certify exporters:* Foreign governments' food safety agencies should certify that food processors intending to export to the U.S. adhere to applicable safety regulations established by the exporter country's competent food safety agency. This program would be similar to the European Union approach to food imports.
- *Strengthen FDA with more resources:* Increase FDA CSFAN funding by at least $200 million, to be used for more personnel and information technology.
- *Develop common standards among countries:* Through *Codex Alimentarius*, (the inter governmental group responsible for establishing food safety and labeling protocols) the U.S. should seek harmonized food safety and labeling laws among food trading partners.
- *Require FDA to certify labs:* FDA should certify labs capable of sampling and testing food in accordance with FDA guidelines and Good Laboratory Practices.
- *Enable third party testing of food imports:* Using FDA-certified labs and operating under an FDA-sampling plan, enables increased testing of imports to be conducted. Importantly, these third party labs are not replacing existing essential government jobs, but adding an additional layer of testing capability for FDA. FDA should use private sector labs to conduct testing, as recommended by a GAO report.
- *Develop rapid test kits:* Seafood companies are examining means to dramatically increase testing of food at its source, either domestically or overseas. FDA should support these efforts.

Alternatively, NFI does not support:

- *Fee for service:* Industry fees for government services are perceived as a conflict of interest. The U.S. cannot "inspect its way" to food safety. Rather, inspections should be targeted at countries or companies that have exhibited problems. Companies that adhere to laws and rules should be rewarded with streamlined importing requirements.
- *Restricting food imports to certain ports:* Ninety percent of seafood shipments enter through 14 ports and only 5 of those ports are associated with an FDA lab designed to test food. Dock workers in nine port cities could no longer be employed to off load seafood in nine cities if this were proposal were enacted.
- *Country of origin labeling for imported seafood. The seafood industry already labels seafood under country of origin requirements for* Customs and Border Protection and the U.S. Department of Agriculture. A third agency labeling requirement (under FDA) will simply confuse the consumer and will do nothing to improve food safety.

None of the current food safety proposals address the notion of "certifying" importers. Because it is unique, this concept deserves special mention. Seafood imports follow the 80:20 rule—80 percent of the seafood imported into the U.S. is imported by about 20 percent of the importers. Therefore about 80 percent of the seafood importers are what we would consider as "infrequent" importers. This is why NFI and its members support the registration and certification of importers. We feel that it is essential that importers recognize, understand, and adhere to the applicable laws and regulations associated with ensuring the safety of seafood products. Importer registration and certification would provide FDA with additional regulatory tools to establish a risk-based import inspection system by enabling the agency perform targeted inspections and surveillance sampling and issue import alerts when warranted. Even with more resources for FDA, a concept which we strongly support, the agency will need additional regulatory tools to prioritize import inspections.

Americans enjoy seafood because it is good for them and they can enjoy a variety of meals, both at home and dining out. Because consumers must trust those that sell them fish, the seafood industry has long been a leader in food safety. We rely on a healthy and secure global supply chain to meet the growing demand for fishery products here at home. As the debate regarding the safety of imports moves for-

ward, NFI looks forward to working with the Committee to address ways Congress can help make the government side of the food safety system as solid.

Chairman LEWIS. Thank you very much, Mr. Connelly for your testimony.

I'm pleased to welcome our next witness, John Williams from the Southern Shrimp Alliance, the executive director. Welcome.

STATEMENT OF JOHN A. WILLIAMS, EXECUTIVE DIRECTOR, SOUTHERN SHRIMP ALLIANCE, TARPON SPRINGS, FLORIDA

Mr. WILLIAMS. Thank you, Chairman Levin, Chairman Lewis, good afternoon. My name is John Williams. I am the executive director of the Southern Shrimp Alliance, and I appreciate the opportunity to testify on the need to significantly improve this country's safety program for imported seafood.

The American public is gravely concerned that the seafood imports they consume may not be safe and our Federal Government is not taking necessary steps to safeguard the health and safety of its people. Consumers have a right to be concerned.

The FDA's imported food safety regime is broken, it is lax, ineffective and dangerous. Weak FDA enforcement coupled with stringent import safety regimes and other major seafood importing markets encourages diversions of unsafe shrimp imports to the United States. As a result, the United States has become a magnet for contaminated shrimp imports.

For example, the E.U. has refused to allow Cambodian seafood exports into the E.U. market because of severe deficiencies in Cambodia's food safety system. At the same time, 99 percent of Cambodia's shrimp exports came to the United States.

Earlier this year, the E.U. banned seafood exports from Pakistan. As exports of seafood to the E.U. dwindled to nothing, Pakistan's exports of shrimp to the United States surged to record highs.

A look at the import seafood safety system used by the E.U., Japan, Canada and the USDA demonstrates the deficiencies of the FDA's model which relies solely on point of entry inspections of only 1 percent of imported seafood products.

The E.U. inspects and certifies exporting countries and individual exporters prior to a product's entry into the E.U. The E.U. inspects 20 percent of all seafood imports at its borders and conducts on-site inspections of foreign facilities.

Japan has a strict risk-based system with a 25 percent inspection rate on shrimp imports and also imposes certification requirements.

Canada imposes a minimum standard inspection rate of 15 percent for all imported seafood products and strict licensing requirements for importers.

For USDA regulated food imports, equivalence is a prerequisite for imports. The USDA conducts foreign on-site inspections and inspects every import at the port of entry. These examples and trade statistics demonstrate a direct cause and effect relationship. Market closures and restrictions on imports by major importing countries directly result in the diversion of contaminated products to the United States. Further, the FDA's import enforcement failures

largely render Customs unable to assist in assuring the safety to seafood imports.

As the U.S. shrimp industry has witnessed firsthand, despite limited resources, Customs aggressively addresses the unlawful activities of U.S. importers. Customs implemented an enhanced continuous bonding requirement to ensure the duties on shrimp imports were collected. Customs uncovered importers schemes to circumvent the antidumping order by transshipping Chinese shrimp through Indonesia and falsely labeling Chinese shrimp as dusted shrimp. Customs can and should play an important role in ensuring the safety of imported food. The implementation of a true equivalence based food safety system like the USDA and the E.U. would require the FDA to certify that an exporting country's food safety laws are at least equivalent to our country's. Customs would be able to evaluate whether a particular product was shipped from an approved exporter located in an approved country. In addition, customs should be given the authority to quarantine imports of high-risk products and products from high-risk countries or high-risk producers. Once quarantined, import shipments that are found to violate U.S. food safety standards should either be destroyed by Customs or, in limited circumstances, redispatched after being marked by Customs with the words, United States refused entry.

Importer interests consistently thwart improvement of U.S. food safety laws by arguing that such improvements would be protectionist and might violate the U.S. international trade obligations. Such assertions are simply incorrect. The FDA's oversight of imported food lags substantially behind that employed in other countries and the USDA. Any improvement in the FDA's regulatory authority would, at most, simply bring the U.S. in line with international best practices.

Moreover, as the FDA has recognized, article 20 of the GATT provides that a nation may adopt or enforce any measure necessary to protect human, animal or plant health. Thus, the improvement of FDA's imported seafood safety program would be consistent with our international trade obligations.

Seafood importers have fought tooth and nail to prevent improvement of the regulation of safety of seafood imports. These importers are more interested in minimizing their cost than in protecting consumers. Voluntary programs undertaken by importers have been ineffective and that is why you have called us here today.

Most like the National Fisheries Institute proposal to mark contaminated products with invisible ink, importers voluntary programs might as well have been written in invisible ink. Multiple reports from a variety of government agencies have repeatedly made clear that the FDA's oversight of seafood imports is woefully inadequate. We urge Congress to take this opportunity to fix this problem and not be distracted by the self-interested empty promises that have been repeatedly made by seafood importers.

In closing, there comes a time when common sense must prevail and Americans' consumer health cannot be negotiated through trade agreements or the bottom line of importers. Thank you.

[The prepared statement of Mr. Williams follows:]

Prepared Statement of John A. Williams, Executive Director, Southern Shrimp Alliance, Tarpon Springs, Florida

Chairmen Levin and Lewis and Members of the Committee on Ways and Means, Trade and Oversight Subcommittees, my name is John Williams and I am the Executive Director of the Southern Shrimp Alliance ("SSA". I appreciate the opportunity to testify on the need to significantly improve this country's safety program for imported seafood.

The SSA, founded in 2002, is a non-profit alliance of the hard-working men and women of the U.S. shrimp industry. We are the national voice for shrimp fishermen and processors in eight states: Alabama, Florida, Georgia, Louisiana, Mississippi, North Carolina, South Carolina, and Texas. In addition to defending and advancing the interests of the domestic industry, the SSA is committed to preserving the safety and integrity of the Nation's shrimp supply.

The American public is gravely concerned that the imported seafood products they consume may not be safe and that the Federal Government is not taking necessary steps to safeguard the health and safety of its people. An examination of the food safety regimes of major food importing countries including the European Union ("EU"), Japan, and Canada make clear that stringent import systems can be effective in protecting food supplies while facilitating trade in safe products.[1] In stark contrast, the U.S. Food and Drug Administration ("FDA") relies solely on point-of-entry inspection of one percent of imported seafood products as the first and last line of defense.[2] As a result of the FDA's lax enforcement, there is a direct cause and effect between market closures or restrictions on imports into other major importing countries and the diversion of contaminated products to the United States.

In short, the imported food safety program administered by the FDA is lax, ineffective and dangerous. Particularly with seafood imports, the FDA has largely abdicated its responsibility to ensure the safety of such imports.

A comparison of the FDA's regulatory oversight over imported seafood with the oversight of imported seafood in the EU, Japan, and Canada and even the U.S. Department of Agriculture's ("USDA") oversight of imported meat, poultry, and egg products makes clear the deficiencies in the FDA's program. Because the FDA inspects only approximately 1 percent of all seafood imports,[3] imports contaminated with harmful drug residues, pesticides, salmonella, and common filth enter the United States virtually undetected. The FDA does not require that seafood be imported from countries that administer food safety laws that are at least equivalent to our own and instead relies heavily on seafood importers to guarantee the safety of the products that they bring into this market.

There is a stark contrast between the FDA's model and the regulatory models employed in the EU, Japan, and Canada: The EU guarantees equivalence by conducting on-site inspections and certifying exporting countries and individual exporters prior to importation of a product. Stringent follow-up inspections are conducted both at the EU's border (currently 20 percent of seafood products are inspected) and regularly at the foreign exporters' facilities.[4] Japan has a strict risk-based system that is reinforced by high inspection rates (currently 25 percent for shrimp imports), as well as certification requirements and significant penalties for noncompliance.[5] Canada imposes a minimum standard inspection rate of 15 percent for all imported seafood products and strict licensing requirements for importers.[6]

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[1] A detailed explanation of the substantial differences between the FDA's regulatory program on seafood imports and the systems employed by other major seafood importing countries and the USDA are provided in the SSA's written submission to the President's Interagency Working Group on Import Safety. The SSA's submission can be obtained from our web-site, www.shrimpalliance.com.

[2] *FDA's Imported Seafood Safety Program Shows Some Progress, But Further Improvements are Needed*, U.S. General Accounting Office, Report to Congressional Requesters, GAO–04–246, p. 3 (2004) ("2004 GAO FDA Report"); *Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation's Food Supply—Part 2*, Hearing before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 110th Cong., p. 2 (July 17, 2007) (Statement of David Nelson, Senior Investigator) ("David Nelson Testimony").

[3] *Id*.

[4] *See EU Import Conditions for Seafood and Other Fishery Products*, Directorate-General of Health and Consumer Protection, European Commission ("EU Import Conditions").

[5] *See Handbook for Agricultural and Fishery Products Import Regulations*, Japan External Trade Organization (Dec. 2005) ("JETRO Handbook for Import of Fishery Products").

[6] *See Guide to Canadian Regulatory Requirements and Examination Procedures for Imported Fish*, Canadian Food Inspection Agency; L. Ababouch, G. Gandini & J. Ryder, *Causes of Detentions and Rejections in International Fish Trade*, Food and Agriculture Organization of the

Continued

For USDA-regulated food imports, equivalence of food safety laws is a prerequisite for import into the United States. The USDA verifies the equivalence of laws through foreign on-site inspections and the USDA inspects every import at the port of entry.[7]

On Monday of this week, the SSA submitted comments and presented testimony at a public hearing before the President's Interagency Working Group on Import Safety ("Interagency Working Group") that were highly critical of the FDA's regulation of seafood imports. I note with particular interest that the opening comments to that public meeting made by the Acting Secretary of Agriculture, Chuck Conner, underscored the immense gulf between the USDA's approach to ensuring the safety of imported food products and that of the FDA's. Secretary Conner noted that the USDA's approach to imported food safety relied on three keystones: prevention, early intervention, and rapid response to problems.[8] He explained that the USDA begins its implementation of these keystone principles "with a thorough analysis of each country's food laws and inspection systems to determine initial equivalents with our own safety procedures."[9] Secretary Conner added that the USDA continues with "on-site audits of each country's food safety system to ensure equivalence is maintained as well."[10] Secretary Conner further observed that a USDA Food Safety and Inspection Service ("FSIS") inspector conducts a port-of-entry investigation on imports of all meat, poultry, and egg products coming into the United States and that "[a]bout 10 percent of our imports of meat, poultry, and egg products as well are subjected to more intense inspection that includes microbiological analysis for pathogens."[11]

In fact, in its own publications, the USDA contrasts the rigors of its imported food safety program with the comparative laxity of the FDA's. In one passage of a recent USDA publication, the agency stresses that the:

FDA relies solely on point-of-entry inspection. FSIS, on the other hand, works collaboratively with the importing establishment's government and uses a three-part process to verify that other countries' regulatory systems for meat, poultry and egg products are equivalent to that of the U.S. and that products entering the U.S. are safe and wholesome.[12]

The September 10, 2007 report issued by the Interagency Working Group further underscored the fundamental disparities of our food safety laws. Specifically, the report noted that:

[I]n 2006, [Customs] intercepted 45 containers with chicken, chicken parts, pork and meat products being smuggled into the U.S. *as frozen seafood*. These meat products were prohibited entry into the U.S. because they were from a country that was not approved by USDA to export them to the U.S.[13]

This example is important for three reasons. First, seafood products routinely enter the United States from countries that the USDA does not permit to export meat, poultry, or egg products because the agency has determined that those countries do not maintain food safety laws equivalent to our own.[14] Second, even where seafood imports enter the United States from countries that do not administer U.S.-equivalent food safety laws, the chances that the FDA will inspect a shipment of imported seafood are so low that importers believe that they can bring in containers filled with meat products, label it as seafood, and enter the product into the United States with no one the wiser. Third, the FDA did not discover that these 45 containers were mislabeled as seafood. The Federal Agency that uncovered an import-

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United Nations, FAO Fisheries Technical Paper 473, pp. 21–22 (2005) ("2005 FAO Fisheries Paper").

In addition, Canada conducts "specialized testing" at a rate of "5 to 15 percent, depending on the product history and nature of the product." 2005 FAO Fisheries Paper at p. 22.

[7] *See Process for Evaluating the Equivalence of Foreign Meat and Poultry Food Regulatory Systems*, Food Safety Inspection Service, United States Department of Agriculture, p. 2 (Oct. 2003) ("USDA Equivalence Guide").

[8] Hearing before the Interagency Working Group on Import Safety (Oct. 1, 2007) (Statement of Chuck Connor, Acting Secretary of Agriculture).

[9] *Id.*

[10] *Id.*

[11] *Id.*

[12] *Importing Meat, Poultry & Egg Products into the United States*, USDA Food Safety and Inspection Service, (Dec. 2003) ("USDA Import Guidelines") (emphasis added).

[13] *Protecting American Consumers Every Step of Way: A strategic framework for continued improvement in import safety*, A Report to the President, Interagency Working Group on Import Safety at p. 9 (Sept. 10, 2007) ("Import Safety Report") (emphasis added).

[14] Large seafood exporting countries to the United States, such as Thailand, Ecuador, and Vietnam, are not certified to export USDA-regulated products. *See Eligible Foreign Establishments*, USDA Food Safety and Inspection Service.

er's blatant attempt to circumvent our food safety laws was U.S. Customs and Border Protection ("Customs").

One consequence of the FDA's failure to implement an equivalence-based safety program for imported seafood is that it makes it extremely difficult for Customs to assist in ensuring the safety of seafood imports. In a system based on verified equivalence, only food imports from approved producers in approved countries can enter the United States. Evaluating whether both the country and producer are accurately disclosed in import entry documentation is exactly the type of activity that Customs officials are trained to undertake.

The U.S. shrimp industry has witnessed firsthand the aggressive nature with which Customs works to address unlawful activities of U.S. importers and the agency does so with extremely limited resources. Three examples of Customs' actions with respect to the antidumping orders on shrimp demonstrate the agency's initiative.

First, after the imposition of the antidumping orders on shrimp, Customs' National Targeting and Analysis Group noted substantial shifts in import patterns that suggested transshipment of shrimp to circumvent high tariffs imposed on shrimp from China and Customs worked quickly to counteract the circumvention. Officials with Immigration and Customs Enforcement in Singapore visited plants in Indonesia identified by the National Targeting and Analysis Group and confirmed that three Indonesian exporters were labeling Chinese shrimp as Indonesian shrimp to circumvent the antidumping orders. Customs found that 54 different importers were responsible for bringing in over $58 million in mislabeled shrimp product to avoid payment of 65 million in antidumping duties.[15] Last Friday, the agency announced that it has already successfully recovered over $2.2 million of the $65 million in antidumping duties owed on these entries.[16]

Second, the domestic industry quickly became aware that many U.S. importers were abusing an ill-conceived exclusion to the antidumping orders granted by the U.S. Department of Commerce ("Commerce"). In the first of many baffling decisions that the agency has taken to weaken the trade relief that the U.S. shrimp industry is entitled to under our trade laws, Commerce carved so-called "dusted" shrimp out of the scope of the orders.[17] Shortly after the exclusion was granted, massive volumes of purportedly "dusted" shrimp from China flooded the U.S. market. The SSA challenged Commerce's decision in Federal court and that appeal is ongoing. At the same time, we approached Customs with evidence that Chinese shrimp entering our market duty-free as "dusted" shrimp was not, in fact, "dusted" shrimp. Customs listened to the domestic industry's concerns, developed an enforcement plan, and then went about stopping importers from abusing the system. Public information indicates that Chinese "dusted" shrimp imports significantly declined once Customs began inspecting these shipments.[18]

Third, after problems collecting duties on previous antidumping orders on food imports, Customs learned from the experience and implemented an enhanced continuous bonding requirement to ensure that the full amount of antidumping duties owed on shrimp imports were collected. After complaints from importers, Customs adjusted the enhanced continuous bond to allow for an individualized review of an importer's condition and the agency ably balanced concerns about preserving the integrity of the antidumping orders with the impact on importers.

The SSA understands that Customs is the primary agency responsible for U.S. border enforcement and that the agency's first priority is to detect and prevent terrorists and terrorist weapons from entering our country. Nevertheless, despite this overwhelming priority and limited resources, Customs officials at the ports, in headquarters, and in specialized field offices have expended significant effort to ensure that the U.S. shrimp industry receives the full benefit of the trade relief it fought hard to achieve. And as importers have developed new schemes to circumvent the

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[15] Declaration of Bruce W. Ingalls, Chief of the Debt Management Branch in the Revenue Division of the Office of Finance, *National Fisheries Institute, Inc. v. United States*, Court No. 05–00683 (Mar. 9, 2006). According to CBP officials, importer members of the National Fisheries Institute were responsible for "approximately 50 percent" of the volume of this transshipped shrimp. *Id.* at p. 4.

[16] "U.S. Customs and Border Protection Collects More Than $2.2 Million in Underpaid Antidumping Duty on Chinese Shrimp" Press Release. U.S. Customs and Border Protection (Sep. 28, 2007).

[17] *See, e.g.*, Certain Frozen and Canned Warmwater Shrimp from India, 70 Fed. Reg. 5147, 5148 (Feb. 1, 2005) (Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order).

[18] *See* Urner Barry's Foreign Trade Data (Seafood Import Data Online) *available at http://ftd.urnerbarry.com/*.

antidumping duties, like transshipping Chinese shrimp through other countries besides Indonesia, we are confident that the agency will listen to our concerns.

For this reason, the SSA believes that Customs can and should play a critical role in ensuring the safety of imported food over which the FDA has jurisdiction. As an initial matter, Customs' import database, the Automated Commercial Environment, maintains real-time data of import shipments, which has been used by the USDA to (1) determine whether shipments arrive from ineligible sources, (2) monitor ports of entry and importers of rejected shipments, and (3) track rejected or suspect shipments from the time of entry until Customs determines whether to detain or redeliver the shipment. The FDA, however, does not use this database in the same manner as the USDA. Moreover, the FDA's lax enforcement efforts have hindered Customs' ability to properly safeguard the Nation from contaminated food imports. For example, in reviewing the FDA's administration of its food safety program, the U.S. Government Accountability Office ("GAO") found that it takes an average of 348 days for the FDA to notify port-of-entry Customs officials of a rejected import shipment.[19]

Further, an equivalence-based food safety program would allow Customs to evaluate whether a particular product was, in fact, shipped from an approved exporter. In addition, Customs should be given the authority to quarantine imports of high-risk products, or products from high-risk countries or high-risk producers. Once quarantined, import shipments that are found to violate U.S. food safety standards should be destroyed by Customs unless the importer can meet the following requirements within 45 days of notification of destruction: (1) if the adulterated shipment is bound for a third country, the third-country food safety agency must first notify the FDA of its acceptance before the rejected shipment is released; and (2) rejected shipments should be conspicuously marked by Customs as "United States Refused Entry."

In any event, the FDA's failure to employ the significant resources of Customs—resources that include an office that deals specifically with agricultural products as one of Customs' priority trade issues—is indicative of the agency's seeming unwillingness to take advantage of available resources that would allow U.S. agencies to focus resources where the risks are greatest. For example, on a weekly basis the EU publishes lists of imported food products that have been found to be violative of EU food safety standards. Japan and Canada go a step further and publish lists of food products refused entry into the country, the reasons for the refusal, and the name of the exporter.[20] These resources help identify where problems may be concentrated. A review of the EU's lists indicates that there have been continued disconcerting findings of banned antibiotics in shrimp and prawn exports from India to the EU. A review of Japan and Canada's refusal lists provides information on the specific exporters of shrimp from Vietnam that have had continued problems with the nitrofurans and chloramphenicol in their shrimp. In addition, both the EU and the USDA publish the results and findings of their on-site verifications of the food safety systems employed in foreign countries.

Taken together, these resources provide a useful warning system for existing food safety problems and an early warning system for food safety problems that are just beginning to appear over the horizon. There is little indication, however, that the FDA pays much attention to any of this material. Seafood exports from Vietnam, for instance, present a significant food safety risk. *With the exception of the United States, every major export market for Vietnamese seafood products has acted to address food safety problems with Vietnamese seafood exports.*

Canada: From 2003 to 2005, Canada imposed a country-wide alert and implemented a 100 percent inspection policy on seafood exports from Vietnam after Vietnamese seafood products repeatedly tested positive for chloramphenicol.[21] In July 2006, the governments of Vietnam and Canada reached a bilateral agreement whereby the government of Vietnam committed to inspecting and certifying that seafood exports to Canada were free of antibiotics.[22] Vietnamese exports not accompanied by a certification are subject to 100 percent testing by Canadian officials;

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[19] 2004 GAO FDA Report at p. 5.

[20] The EU's RASFF system refusals are also available online but do not disclose the name of the exporter responsible for the refused product.

[21] "Removal of the Country Import Alert for Chloramphenicol in Aquacultured Fish Products from Vietnam," Press Release, Canadian Food Inspection Agency (Sept. 30, 2005).

[22] Arrangement Concerning the Inspection and Certification of Aquaculture Fish and Fish Products Exported from Vietnam to Canada for Drug Residues, Canadian Food Inspection Agency and the Vietnamese National Fisheries Quality Assurance and Veterinary Directorate of the Vietnam Ministry of Fisheries (Jul. 17, 2006).

and, to insure compliance, Canadian officials continue to test even some of those exports that are accompanied by certificates.[23]

Japan: Beginning in December 2006, Japan began testing 100 percent of all Vietnamese shrimp exports because of repeated positive tests for chloramphenicol.[24] Vietnam agreed to certify 100 percent of their shrimp exports to Japan.[25] However, even with the certification system established, Japan continued to find banned antibiotics in Vietnamese shrimp imports and has threatened a complete ban of Vietnamese shrimp products unless the problem is resolved.[26]

Russia: Press reports indicate that Russia banned the import of Vietnamese seafood after conducting an on-site inspection in March 2007, citing problems with food safety standards.[27] Russia requires exporters to meet Russian food safety standards and provide quality assurance from the exporting country's government.[28] Russian officials conducted follow-up inspections of twenty seafood processing facilities in July 2007 and mid-September 2007 and, recently, announced that thirteen of these facilities—and only these thirteen—would be approved to export seafood to Russia.[29] These exporters were selected from nearly two hundred companies that applied for inspections from the visiting Russian authorities.[30]

European Union: In 2007, the EU conducted an on-site inspection of Vietnamese seafood processors and the food safety system administered by the Vietnamese government.[31] The findings of the EU officials conducting the inspection help to explain why every major seafood importing market, besides the United States, is taking action to address Vietnamese seafood exports. Specifically, the EU's final report observed:

The ongoing detections of veterinary drug residues in exported consignments tested at EU border inspection posts raise concerns on the effectiveness of residues controls which are weakened by the general availability of drugs without prescription, the limited scope of official testing, the capacity of the laboratory network, and, in some cases, insufficient follow-up.[32]

Thus, the EU's report noted that valid concerns existed regarding the ability of the Vietnamese government and its seafood producers to prevent the export of seafood with harmful contaminants because drugs—including antibiotics—are widely available without the need for a prescription, and the limited scope of the government's ability to test and follow-up on problems.

EU officials also determined that shrimp found to contain antibiotics were not exported to the EU, but neither were the contaminated shrimp destroyed,[33] leaving open the possibility that it was exported to other markets with less stringent enforcement (like the United States). The EU's finding is all the more troubling given the recent comments of Huynh Thi Thanh Giang, the Deputy Director General of An Giang Seafood Import-Export Company, a large Vietnamese exporter of seafood, in the Vietnamese press. Mrs. Giang noted that products rejected from importing countries "cannot be consumed domestically" and that "[t]he only way for enterprises to minimise losses when products are discovered as containing antibiotics, according to Mrs. Giang, is to look for easier-to-please markets."[34] As between Canada, the EU, Japan, and the United States, the "easier-to-please market" is the United States.

Markets in the EU, Japan, Canada, and the United States account for roughly 90 percent of Vietnam's average annual 268 million pounds of shrimp exports. At the same time that every other major market for Vietnamese shrimp has expressed concerns about the safety of the country's seafood products and has taken action to

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[23] *Id.*

[24] "NAFIQAVED declares three reasons for unsafe seafood," Vietnam Economy (Dec. 15, 2006).

[25] *Id.*

[26] "VASEP asks Minister to declare emergency as Japan threatens to halt Vietnamese shrimp exports," Seafood News (July 9, 2007).

[27] "Russia names 11 qualified Vietnamese seafood exporters," Thanhnien News (Aug. 20, 2007).

[28] "Fisheries face tough export rules," Viet Nam News (Jan. 27, 2007) ("Fisheries Face Tough export rules").

[29] "More seafood processors win Russian import license," Vietnam Economy (Sep. 18, 2007).

[30] Fisheries face tough export rules.

[31] *Final Report of a Mission Carried Out to Vietnam from 24 January to 1 February 2007 in order to Evaluate the Control of Residues and Contaminants in Live Animals and Animal Products, Including Controls on Veterinary Medicinal Products*, European Commission, Health & Consumer Protection Directorate—General, Directorate Food and Veterinary Office, DG(SANCO)/2007/7322—MR Final, p. 5 (Feb. 2007).

[32] *Id.* at p. 14.

[33] *Id.* at p. 9.

[34] "Unsafe Seafood Exports: No Solutions?," Vietnam Economy (source: Sài Gòn Tiếp thị) (July 27, 2007).

rectify these problems, the United States, which receives approximately one-third of Vietnam's shrimp exports, has taken no significant action.

In fact, while every other major market has found repeated shipments of Vietnamese shrimp tainted with banned antibiotics, a review of the FDA's import refusals indicates that the agency did not refuse a single shipment of Vietnamese shrimp based on the presence of antibiotics in the past year.[35] At the same time, a comparison of the Vietnamese exporters that have had seafood products refused from the Canadian and Japanese markets with the lists of Vietnamese exporters of seafood to the United States (available through a subscription service) demonstrates that many of these exporters continue to ship to the United States unabated.[36]

At least since 2003, the FDA has had active knowledge of Vietnam's pervasive use of chloramphenicol in aquaculture. At that time the FDA recognized, in a letter sent in response to Citizens Petitions regarding chloramphenicol in crabmeat, that "there is abundant evidence that chloramphenicol is still in widespread use abroad, particularly in Southeast Asia."[37] Specifically, the FDA detailed a meeting it had with its Vietnamese counterparts, where:

[D]uring a March 5, 2003 meeting with Vietnam [and the FDA], *Vietnamese government officials reported that they continue to have problems with chloramphenicol being used in the production of shrimp in their country, and they have acknowledged the use of chloramphenicol in shrimp farming*.[38]

Despite this explicit knowledge and the continued, current findings of antibiotics in Vietnamese shrimp in other markets, the FDA has yet to issue a country-wide import alert on Vietnamese shrimp imports. As a result, Vietnam is now the third largest exporter of shrimp to the United States.[39]

The significant amount of shrimp imports that the U.S. received from Cambodia between 2004 and 2006 provide another example of how the FDA has largely ignored or paid little attention to the food safety concerns voiced by equivalent agencies in other major seafood importing markets. Cambodia cannot export seafood to the EU. In a bid to obtain access to the EU market, Cambodia invited EU authorities to conduct an on-site investigation of seafood processing plants in the country in 2005. The EU officials found that (1) Cambodian regulatory officials did not have the legal authority to perform checks of facilities for food safety compliance; (2) processing facilities with "very poor hygiene situation"; and (3) worse, Cambodia's entire process of certifying the food safety of export shipments was a sham.[40]

Specifically, EU officials reported that Cambodian officials providing certifications as to the safety and fitness of exported seafood "could not have the knowledge of, and could not have the possibility to ascertain and verify the matters they are certifying, which is against the international standards in the field of certification."[41] Based on these findings, the EU continued to prohibit Cambodian seafood exports from entering the EU market.

A review of Cambodia's export statistics between 2002 and 2006 indicates that, at the same time as the EU found that Cambodia's processing plants had very poor hygiene and were accompanied by false certifications to export markets, Cambodia exported over 22 million pounds of shrimp to the world.[42] *Ninety-nine percent* of that shrimp was exported to the United States. U.S. import statistics show that between 2004 and 2006, the United States imported 21.7 million pounds of shrimp from Cambodia.[43] Thus, while the EU refused to accept any seafood products from Cambodia because of the dangers posed by these products to consumers in the EU, substantial quantities freely entered the United States.

Despite the very significant and real risks posed by this country's lax seafood import safety rules, invariably, whenever anyone calls for significant improvement of our laws, certain parties argue that an improvement of U.S. food safety laws would

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[35] *Import Refusal Reports for OASIS By Industry*, U.S. Food and Drug Administration (Jan. 2007—Aug. 2007).

[36] *See* Urner Barry's Foreign Trade Data (Seafood Import Data Online) *available at* http://ftd.urnerbarry.com/.

[37] Letter from the U.S. Food and Drug Administration to Olsson, Frank, and Weeda, P.C., Re: 02P–0321, p. 22 (Jul. 29, 2003) ("FDA Chloramphenicol Decision").

[38] *Id.* at p. 11 (emphasis added).

[39] U.S. Census Bureau, IM–145, U.S. General Imports (July 2007).

[40] *See Final Report of a Mission Carried Out in Cambodia from 19 to 30 September 2005: For the Assessment of the Conditions of Production of Fishery Products Intended to be Exported to the European Union*, European Commission, Health & Consumer Protection Directorate-General, Directorate F—Food and Veterinary Office, DG(SANCO)/7765–2005–MR (Oct. 2005) ("EU Report on Cambodian Fishery Products").

[41] *Id.* at p. 8.

[42] "Cambodian Exports to the United States: January 2002 to July 2007," Dialog TradStat (2007).

[43] *Id.*

be "protectionist" and potentially violative of this country's international trade obligations. Such assertions are simply incorrect. The FDA's regulatory oversight of imported seafood lags substantially behind those employed in other countries (and the oversight of the USDA). Accordingly, any improvement in the FDA's regulatory authority would, at most, simply bring the U.S. in line with international best practices. Moreover, as the FDA has previously recognized,[44] Article XX of the General Agreement on Tariffs and Trade ("GATT") explains that nothing in the GATT prevents a nation from adopting or enforcing any measure "necessary to protect human, animal, or plant life or health. . . ."[45] Accordingly, the improvement of FDA's regulatory program related to the safety of imported seafood would not be inconsistent with our international trade obligations.

The bogus "international obligation" argument offered by importing interests masks the true trade effects of our weak imported seafood safety regulatory regime: the failure to effectively regulate seafood imports creates irresistible incentives for exporters to ship unsafe seafood products to the United States.

As trade statistics demonstrate, the incentives created by the FDA for foreign producers to export unsafe products is not simply a matter of conjecture. *The consequence of stringent import regimes of other major shrimp importing countries coupled with the FDA's lax enforcement of U.S. food safety standards puts U.S. consumers at grave risk, as the United States has become a magnet for unsafe and contaminated shrimp imports. When other major importing markets take action against unsafe seafood products, those products are diverted to the United States.*

There is a direct cause and effect between market closures or restrictions on imports in major importing countries and the diversion of contaminated and likely contaminated products to the United States.

The fact that the United States' failure to implement a strong safety program with regard to imported seafood creates incentives for exporters to ship harmful product to this market is widely recognized. In an op-ed piece published this summer in the New York Times, author Taras Grescoe observed that "if you're a shady seafood dealer trying to unload a container of dodgy shrimp or tilapia, chances are 98 in 100 it will make it into the United States."[46] Indeed, even the organization representing U.S. seafood importing interests, the National Fisheries Institute, has argued that foreign seafood packers will ship to the market of least resistance.[47] In opposing provisions that would allow the FDA to destroy unsafe seafood imports, the National Fisheries Institute argued that any such "provision could cause significant restraint of international trade because suppliers in other countries may elect to avoid the U.S. marketplace rather than face possible destruction of their product."[48] It follows, therefore, that because other major seafood importing markets have the ability to destroy unsafe seafood imports while the National Fisheries Institute has successfully opposed the FDA adopting any such authority, suppliers in other countries elect to ship potentially unsafe product to the U.S. marketplace rather than face possible destruction of their product in other markets. Thus, the most disastrous consequence of the FDA's inability to administer a meaningful seafood import safety program is that the agency's regulatory failure acts as a magnet for attracting unsafe imports to this country.

Examples help to illustrate the trade effects of our weak imported seafood safety regime. In November 2001, a routine on-site inspection of Chinese production facilities by EU officials "revealed serious deficiencies of the Chinese residue control system and problems related to the use of banned substances in the veterinary field."[49] In addition, EU border inspection officials found repeated shipments of Chinese shrimp imports contaminated with chloramphenicol.[50] As a result, the EU banned

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[44] FDA Chloramphenicol Decision at p. 22.

[45] General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A–11, 55 U.N.T.S. 194. User fees for import inspection are also specifically allowed in our WTO commitments. Article VIII of the GATT specifically contemplates and allows for fees to be charged for the "analysis and inspection" of imported goods so long as the fees are "limited in amount to the approximate cost of services rendered and shall not represent an indirect protection to domestic products or a taxation of imports or exports for fiscal purposes."

[46] T. Grescoe, "Catfish With a Side of Scombroid," New York Times (July 15, 2007).

[47] Letter from National Fisheries Institute to the U.S. Food and Drug Administration, FDA Docket No. 2000N–1633 (May 14, 2001), p. 4 (claiming that "U.S. food safety standards are, in many cases, more restrictive than those of other countries.") ("2001 National Fisheries Institute Letter").

[48] *Id.*

[49] "EU Standing Veterinary Committee agrees on suspension of imports of products of animal origin from China," Press Release, European Commission, IP/02/143 (Jan. 28, 2002).

[50] *Id.*

all shrimp, honey, mollusks, rabbit and poultry meat, and pet food imports from China in January 2002.[51] Following a 30-month ban of Chinese shrimp imports, in July 2004, the EU agreed to recertify Chinese shrimp imports only after the Chinese government guaranteed that it would test 100 percent of Chinese shrimp exports bound for the EU, and that it would ship only certified consignments that met the EU's food safety standards.[52]

As a direct result of the EU's 30-month ban, shrimp exports from China were diverted from the EU market and flooded the U.S. market. As Chinese exports of shrimp to the EU fell, shrimp exports to the United States exploded, leading to a 30 percent increase of Chinese shrimp exports to the United States from 2002 to 2003.[53] The influx of Chinese shrimp imports began to abate only when the U.S. domestic shrimp industry filed an antidumping petition to seek relief from these dumped imports.

More recently, in early 2007, the EU completed an on-site review of seafood safety systems in Pakistan that revealed severe deficiencies in the country's food safety oversight and controls.[54] Based on these findings, the EU *decertified all seafood producers* from Pakistan in April 2007. In keeping with these actions, a review of export statistics from Pakistan shows a substantial decline in monthly shrimp exports from Pakistan to the EU, resulting in no reported exports of shrimp to the EU in June 2007.[55]

At the same time, predictably, Pakistan's shrimp exports to the United States skyrocketed in June 2007. The value of shrimp exports to the United States from Pakistan in June 2007 was larger than the monthly value of Pakistani shrimp exports to the United States in any previous month since 2005 and more than twice the monthly average value for Pakistani shrimp exports to the United States.[56] Again, while the EU has refused to accept shrimp products from Pakistan because of the dangers posed by these products to consumers in the EU, significant quantities have begun to enter the United States, apparently unhindered, and will likely continue to be shipped to this country.

We understand that certain parties oppose implementation of an effective and meaningful imported seafood safety program. We realize that importers will fight against any oversight of their activities, as they have for the last decade. Nevertheless, whatever empty promises seafood importing interests make now—similar to promises made years ago—and whatever political pressure they bring to bear to oppose meaningful reform, they cannot change the fact that their rabid pursuit of a greater profit has placed the consumer in unnecessary peril. Changes necessary to ensure the safety of our food supply cannot be derailed by importers' claims that their costs may increase under meaningful regulations. Indeed, in the wake of revelations regarding numerous imported food safety problems, U.S. consumers have made it clear that they are willing to pay a bit more if it means they can be assured of uncontaminated and safe food.[57]

Our government must safeguard the quality and integrity of our Nation's food supply. With imported shrimp, Americans cannot be sure what it is they are eating. Farm-raised in crowded and dirty ponds, with almost no quality control, imported shrimp develop in poor sanitary conditions, in ponds with high feces concentrations, banned antibiotics, and toxic chemicals.[58] As a result, imported shrimp often contain

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[51] *Id.*

[52] "EU eases food imports from China after significant improvements in veterinary standards," Press Release, European Commission, IP/04/943 (July. 16, 2004).

[53] "Chinese Exports to the United States: January 1999 to January 2005," Dialog TradStat (2007).

[54] *See Final Report of a Follow-Up Mission Carried Out in Pakistan from 22 to 26 January 2007: In Order to Evaluate the Control Systems in Place Governing the Production of Fishery Products Intended for Export to the European Union*, European Commission, Health & Consumer Protection Directorate—General, Directorate Food and Veterinary Office, DG(SANCO)/2007–7298—MR Final (Jan. 2007) ("EU Report on Pakistan").

[55] "Pakistani Exports to the United States: July 2006 to July 2007," Dialog TradStat (2007).

[56] *Id.*

[57] "You Are What They Eat," Consumer Reports (July 2007) ("American consumers are willing to pay more for greater safety guarantees. . . .").

[58] *See* "Shrimp's Success Hurts Asian Environment, Group Says," National Geographic News (Dec. 20, 2004) (discussing the Environmental Justice Foundation's "concerns over the levels of antibiotics, disinfectants, fertilizers, pesticides, and other chemicals used by shrimp farmers to maximize profits and combat disease."); *Global and Local: Food Safety Around the World*, Center for Science in the Public Interest, pp. 14–16 (June 2005); "Chicken from China?," Boston.com (May 9, 2007) ("In China, some farmers try to maximize the output from their small plots by flooding produce with unapproved pesticides, pumping livestock with antibiotics banned in the United States, and using human feces as fertilizer to boost soil productivity. But the questionable practices don't end there: *Chicken pens are frequently suspended over ponds where seafood*

harmful antibiotics, pesticides, salmonella, and filth. Consumers rely on the FDA to ensure that the imported seafood products that reach U.S. shores are not so contaminated.[59] Under current circumstances, that reliance is misplaced. Extra profits for the few cannot and must not come at the risk of the safety of the many.

Thank you for allowing me to testify today. I am happy to respond to any questions the Members of the Committee may have.

Chairman LEWIS. Thank you, Mr. Williams, for your testimony.

Our next witness is Chris Knox, the vice president of Vest, Inc. Welcome.

STATEMENT OF CHRIS KNOX, VICE PRESIDENT, VEST, INC., LOS ANGELES, CALIFORNIA

Mr. KNOX. Thank you. Good afternoon. My name is Chris Knox and I am vice president of sales and marketing for Vest Incorporated, a domestic manufacturer of structural steel tubing located in Los Angeles, California.

I am pleased to be here on behalf of our company and the Committee on Pipe and Tube Imports, a non-profit trade association which represents 38 producers nationwide.

This morning, I would like to offer my views about the safety aspect of imports of steel tubing products from China. I provide this information firsthand, as our company and many others in the U.S. industry have confronted this safety problem over the last few months. The examples I will share with you will explain why this issue has a direct impact on the U.S. consumer and why Congress and the appropriate Federal agencies should take corrective actions to ensure that Chinese products entering the U.S. meet our safety standards.

Like most in business, we take great pride in the quality of products we make for our customers. These types of products include rectangular structural tubing products used in the construction of warehouses, mid-rise residential buildings under 10 stories and other public buildings, including schools and healthcare facilities. All these types of structures require a certain high-strength steel to meet requirements for construction. I could allude to the different types of specs and metallurgical qualities that are required. But instead, I will simply state in layman's terms that Vest and other U.S. producers test their products to ensure that the product specifications are met.

There is an international standards group, ASTM, that establishes the bar for this testing. Once the product meets these requirements, it becomes ASTM compliant.

As to structural tubing, the main specification is A–500 grade B, and it requires a minimum strength of 46,000 pounds per square inch. To my knowledge, U.S. producers and foreign producers previously selling in the U.S. market have always met these standards. It is our responsibility.

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is raised, recycling chicken waste as a food source for seafood, according to a leading food safety expert who served as a Federal adviser to the Food and Drug Administration.") (emphasis added).

[59] "Fish Farming: Is it Safe for Humans and the Environment," 17 CQ Researcher 27, p. 630 (July 27, 2007).

However, we have learned by purchasing Chinese tubing from independent steel service centers and having it tested by independent laboratories, that significant quantities, as high as 50 percent from some Chinese producers, have not met the specifications, even though Chinese mills certify that they do.

A number of other U.S. producers located in various geographical locations have performed similar testing with similar results.

It is also important to note that China is our main competitor today. Imports from China of all pipe and tube have continued to soar. In 2006, a total of 2.1 million tons of type and tube entered the U.S., up from a mere 128,000 in 2002. Based on import data available through July, imports will grow to about 2.8 million tons this year.

As to structural tubing, the product where we have observed the most quality problems, China became the number two exporter to the U.S. last year, but was the top foreign supplier in July.

As I stated earlier, it is the normal course of business in our industry to routinely perform a number of tests for strength, durability and weld integrity before shipment to the customer. If for some reason our product fails, it either becomes scrap or is sold as secondary product. With regard to imported materials, this responsibility is also placed on the foreign producer.

It is important to note that the manufacturers must provide detailed mill certifications to our service center customers, who in turn provide them to their building contractor customers to ensure that the engineering requirements are met. To us, it appears that some Chinese producers are simply providing fictitious mill certification.

Something must be done to ensure that these imports are safe. If a weld on a product does not hold, the tube fails and so might a roof section, or might a support section for a pedestrian bridge. I also know that this safety problem has expanded to scaffolding, a product which is also made from the same products we produce.

This imported product has failed tests and has been rejected by some U.S. companies. Unfortunately, there was an accident involving the collapse of a scaffolding in southern California this summer which is currently under investigation.

I would like to refer to the article entitled New Threat From China, Shoddy Steel Imports, which appeared in the September 7th edition of the Kiplinger Newsletter. As noted, the article goes into detail about steel imports from China failing and why fabricators and construction firms are more than a little nervous about the implications of these safety failures, because inferior high-strength steel could cause catastrophic failures of buildings, pipelines and transportation projects.

Unfortunately, these reports continue to grow.

We have raised this issue with Customs and Border Protection was and the Federal Trade Commission. We have provided test results and names of Chinese producers and importers to the agencies to encourage them to intervene, to ensure that the public safety is not compromised. To the Members today, I would encourage you to take a serious look at this issue and take the appropriate action to ensure that the Customs Service can certify that products entering the U.S. are indeed the product they claim to be.

I understand that Customs currently has only a few labs on site at our Nation's top ports. I believe there should be adequate resources directed by the agency to ensure that testing can be done on site and the agency needs to have more staff assigned at the ports to over see these activities.

In addition, legislation is needed to charge those distributing unsafe products throughout our economy to be personally accountable for the public safety.

I do hope that this Committee will be able to address this issue and to direct the appropriate agencies to act quickly. To date, there has been no official warning, advisory or recall of unsafe building materials. Still, none of us ever wants to read about a building collapse because of our failure to act.

Thank you.

[The prepared statement of Mr. Knox follows:]

Prepared Statement of Chris Knox, Vice President, Vest Inc., Los Angeles, California

Written Statement of Chris Knox, Vice President of Sales and Marketing of Vest, Inc.
And the Committee on Pipe and Tube Imports (CPTI)

Before the Subcommittees on Oversight and Trade of the Committee on Ways and Means
U.S. House of Representatives
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Joint Hearing on Import Safety
Thursday, October 4, 2007

Good morning, my name is Chris Knox and I am Vice President of Sales and Marketing for Vest, Inc. a domestic manufacturer of structural and mechanical carbon steel tubing located in Los Angeles, California. It is an honor to appear before this Joint Subcommittee and its members this morning. I am pleased to be here on behalf of our company and also on behalf of the Committee on Pipe and Tube Imports (CPTI) a non-profit trade association which represents 38 producers nationwide on a variety of trade issues impacting the industry and its workers.

This morning I would like to offer my views about the *safety aspect* of imports of steel tubing products from China. I provide this information first hand as our company and many others in the U.S. industry have confronted this problem over the past few months. As a result we have all become very engaged on this issue and have been very active in expressing our concerns to state and local public officials, to Members of Congress and to officials in the U.S. Government. The examples I will share with you will explain why we believe that this issue has a direct impact on the U.S. consumer and why we believe Congress and the appropriate federal agencies should take corrective actions to ensure that Chinese products entering the U.S. meet safety requirements.

Vest, Inc. welcomes competition from other producers in the global marketplace. Like most in this business, we also take great pride in the quality of the products we make for our customers. These types of products include rectangular structural tubing products used in the construction of warehouses, mid-rise residential buildings, under 10 stories and other public

buildings, including schools and health facilities. All of these types of structures require a certain "high - strength" steel to meet requirements for construction. I could allude to the different types of specs and metallurgical qualities that are required, but instead I will simply state in layman's terms that Vest, Inc. and other U.S. producers test their products to ensure that product specifications are met. There is an international standards group, ASTM that establishes the "bar" for this testing and once the product meets these requirements it becomes ASTM compliant. As to structural tubing, the main specification A-500 Grade B requires a minimum strength of 46,000 PSI. To my knowledge U.S. producers and foreign producers previously selling in the U.S. market have always met the standards. It is our responsibilities. However, we have learned by purchasing Chinese tubing from independent steel service centers and having it tested by independent laboratories that *significant* quantities, as high as 50% from some Chinese producers have not met the specification, even though the Chinese mills certified that they met the specification. A number of other U.S. producers located in various geographic locations have had similar testing performed with similar results.

It is also important to note that China is our main competitor today. Imports from China of all pipe and tube have continued to soar. In 2006, a total of 2.1 million tons of pipe and tube from China entered the U.S., up from only 128,000 tons in 2002. Based on import data available through July, 2007 imports will be approximately 2.8 million tons this year. As to structural tubing, the product where the most quality problems have surfaced, China became the Number 2 exporter to the U.S. last year, but was the top foreign supplier in July 2007.

As I stated earlier, it is the normal course of business in our industry to routinely perform a number of tests for strength, hardness, durability and weld intensity, before shipment to the customer. If for some reason our product fails, it either becomes scrap or is sold as secondary product. With regard to imported materials, this responsibility is placed with the foreign producer. It is important to note that manufacturers must provide detailed mill certifications to our service center customers who in turn provide them to their building contractor customers to insure that engineering requirements are met. In fact, it appears to us that some Chinese

producers are providing fictitious mill certificates.

All I do know is that something must be done to ensure that these imports are safe. If a weld on a product does not hold, the tube fails and so might a roof being held up by the product or so might a supporter for a pedestrian bridge. I also know that this safety problem has expanded to scaffolding - a product which is made from products we make. This imported product has failed the tests and has been rejected by U.S. companies. Unfortunately, there was an accident involving the collapse of scaffolding in Southern California this summer which is under investigation. What I am trying to reiterate is that these would not be news stories if the product was made in accordance with the required specifications.

I would like to refer to the article entitled "New Threat from China: Shoddy Steel Imports" which appeared in the September 7, 2007 edition of the Kiplinger Business newsletter. As noted, the article goes into detail about steel imports from China failing and why U.S. manufacturers and construction firms are more than nervous about the implications of these safety failures because inferior high-strength steel could cause catastrophic failures of buildings, pipelines and transportation projects. Unfortunately these reports continue to grow.
In fact, our company and others have raised this issue with the Customs and Border Protection Service and the Federal Trade Commission. Our company and others have provided test results, names of the Chinese producers and importers to the agencies to encourage them to intervene to ensure that the public's safety is not compromised.

To the Members here today, I would simply encourage you and your colleagues to take serious look at this issue and take the appropriate action to ensure that the Customs Service can certify that the imports entering the U.S. are indeed the product they claim to be. I do recognize that the Customs Service is charged with many responsibilities, one of course being the first responder for the nation's homeland security. However, I also believe that it is important that they are the first responder at U.S. ports. I understand that Customs currently has only a few labs on site at the nation's top ports. I believe that there should be adequate resources directed by the

agency to ensure that testing can be done on site and I also believe that the agency needs to have more staff assigned at the ports to oversee these activities. In addition, legislation is needed to hold those distributing unsafe products throughout our economy personally accountable for the public safety.

I do hope that this Committee will be able to address this issue and direct the appropriate agencies to act quickly. We have witnessed the product recalls on toys and tires, we have read about the quarantine of imported seafood and we now are learning more about the safety failures of imported materials used in constructing our nation's bridges, overpasses and buildings - putting the public at even greater risk. To date there has been no official warning, advisory or recall of unsafe building materials. None of us ever want to hear or read about a building collapse.

I thank you for this opportunity to appear before the Subcommittees today and would welcome any questions.

Submitted to the House Committee on Ways and Means
Joint Oversight and Trade Hearing On Import Safety – October 4, 2007

Bio Profile

Chris Knox, Vice President of Vest, Inc.
Los Angeles, California

Chris Knox serves as Vice President of Sales and Marketing for Vest, Inc. of Los Angeles, California. In his role, Mr. Knox oversees all sales and marketing functions for the company in the production of structural and mechanical carbon steel tubing. Vest has been in operation for over two decades and is the successor company to Bernard Epps Co. which was established in the mid- 1950's. Today Vest employs 100 workers at its Los Angeles plant and manufactures a variety of products used in construction applications for warehouses, mid-rise residential and public buildings, including schools and hospitals. These products are also widely used for the construction of pedestrian bridges and open space areas in public arenas. In addition, these products are used for transportation projects, for the automotive after market and for recreational equipment.

Mr. Knox has been with the company for 22 years is an active member of the Committee on Pipe and Tube Imports (CPTI) and a subcommittee chairman for the Steel Tube Institute's Hollow Structural Product Group. He is a native of Los Angeles, California and obtained his B.A. in Economics from UCLA.

10/2007

Chairman LEWIS. Thank you very much, Mr. Knox, for your testimony.

Our next witness is Craig Thorn, a partner at DTB Associates. Welcome, sir.

STATEMENT OF CRAIG THORN, PARTNER, DTP ASSOCIATES, LLP

Mr. THORN. Thank you Mr. Chairman, Members of the Committee. I am here today to talk about U.S. obligations under international agreements regarding the application of food safety standards and other sanitary and phytosanitary measures.

The most important set of rules governing such measures are found in the Agreement on the Application of Sanitary and Phytosanitary Measures also known as the SPS agreement, which was negotiated during the Uruguay round of trade negotiations.

The SPS agreement is a relatively simple collection of rights and obligations. First and most fundamentally, it explicitly recognizes the sovereign right of member countries to impose measures that restrict trade in order to protect health. Each country also has the

right to determine its own level of sanitary or phytosanitary protection, provided that level of protection is appropriate to the risk concerned and to apply that standard to imported products.

In return, member countries agree to base their SPS measures on scientific principles, to ensure that they are nondiscriminatory, and to refrain from imposing measures that are more trade restrictive than necessary to achieve their objective.

The agreement encourages countries to base their SPS measures on international standards where those standards exist. However, members are free to impose measures that result in a higher level of protection than that afforded by the international standard, as long as those measures are based on sound science.

In cases where countries face a risk about which scientific information is insufficient, that country is free under the agreement to adopt a provisional, precautionary measure, based on available information, provided it works to obtain additional information it needs to make a more informed decision within a reasonable period of time.

The SPS agreement has been a useful tool for U.S. exporters of agricultural products. As tariffs and other conventional trade barriers have been reduced or eliminated in recent years, some countries have replaced those barriers with questionable SPS restrictions, often in response to pressure from activists or business interests. The SPS agreement is useful in such cases because it establishes an objective standard of legitimacy for SPS regulations.

U.S. trade officials have been able to use the leverage of the SPS trade rules to challenge illegitimate measures and open markets for U.S. exports.

Some have criticized SPS trade rules, claiming that they force countries to accept unsafe products. I would like to list some of the points these critics have made and respond to them briefly.

First, some critics claim that the SPS agreement limits the ability of U.S. regulators to set domestic safety standards. In fact, the United States is free under the SPS agreement to determine its own level of protection against food safety risks, as long as that level of protection and the measures used to reach it are scientifically defensible. The United States can impose that standard on imported food and agricultural products, provided the same standard is also applied to domestic products.

I have never heard a regulator in the United States or any other country make the claim that these rules adversely affect a country's ability to protect its consumers.

A second claim, that the equivalence obligation under the SPS agreement forces the United States to rely on foreign regulatory systems to ensure the safety of imported food. This claim is also unfounded. Nothing in the SPS agreement requires countries to delegate the job of ensuring food safety to foreign regulators. WTO members are obliged to recognize foreign SPS measures as equivalent only if the exporting country is able to demonstrate to the importing country objectively that the measure meets the standards of the importing country. The importing country is then free to continue monitoring imports and to revoke an equivalency determination if appropriate.

Criticism number three, the United States is vulnerable to challenges under the SPS agreement if it changes its regulations or acts to block unsafe imports. In actual fact, no U.S. SPS measure has ever been challenged under the SPS agreement. Indeed, there have been just six dispute settlement panels under the agreement since it entered into force 12 years ago.

One reason for the infrequency of cases is the degree of latitude the agreement affords to domestic regulators. Countries recognize that challenges are unlikely to be successful—sorry, are likely to be successful only where violations are particularly clear cut. The rulings in the cases that we have seen thus far underscore that fact.

Finally, critics claim that U.S. free trade agreements, bilateral free trade agreements, aggravate the problem by facilitating imports from FTA partners. Now, it is true that certain U.S. FTAs, including the four that are currently awaiting congressional action, include a section on SPS measures. However, those provisions simply affirm the rights and obligations of both parties under the SPS agreement and establish a standing Committee to assist in resolution of SPS-related trade problems. The agreements do not confer additional rights nor impose additional obligations. In other words, the rules of the SPS agreement continue to govern trade between parties to the FTA.

To be clear, I am not arguing that there is no need to examine the U.S. system for ensuring the safety of food imports. However, I believe that the problems and vulnerabilities that have been identified are not the result of constraints imposed by international trade rules. The United States has plenty of latitude under those agreements to ensure the safety of food imports. The only real constraints are the amount of emphasis the FDA and USDA place on the issue and the resources allocated by Congress.

Thank you.

[The prepared statement of Mr. Thorn follows:]

Prepared Statement of Craig Thorn, Partner, DTB Associates LLP

Testimony of Craig Thorn

DTB Associates, LLP

before the

House Ways and Means Committee

Subcommittee on Oversight

Subcommittee on Trade

October 4, 2007

INTERNATIONAL RULES REGARDING THE SAFETY OF IMPORTED FOODS

Mr. Chairman and Members of the Subcommittee:

My name is Craig Thorn. I am a partner in the firm DTB Associates. Our firm represents a number of companies and trade associations in the agriculture sector, but I am here today in a personal capacity to talk about international rules governing the application of food safety standards and other sanitary and phytosanitary (SPS) measures. It is a subject that has been a particular interest of mine throughout my career.

International trade rules have long recognized the right of countries to impose measures to protect consumers, the agricultural economy and the environment from unsafe products, even if such measures act as barriers to trade. The General Agreement on Tariffs and Trade, which entered into effect in 1948 and which still forms the foundation of the international trading system, permits contracting parties to adopt measures "necessary to protect human, animal or plant life or health", provided such measures are not discriminatory and are not disguised trade barriers. During the Uruguay Round of trade negotiations, when countries were working to bring agricultural trade more fully under international disciplines and to eliminate most forms of non-tariff trade barriers, negotiators recognized the need for more detailed rules to govern SPS measures. Therefore, they began a negotiation that resulted in the *Agreement on the Application of Sanitary and Phytosanitary Measures*, or the "SPS Agreement". That Agreement entered into force in 1995, along with the 16 other agreements that are administered by the World Trade Organization.

The SPS Agreement is a relatively simple collection of rights and obligations. First and most fundamentally, it explicitly recognizes the sovereign right of member countries to impose measures that restrict trade in order to protect health. Each country also has the right to determine its own level of sanitary or phytosanitary protection, provided that level of protection is appropriate to the risk concerned, and to apply that standard to imported products. In return, member countries agree to base their SPS measures on scientific principles and a risk assessment, to ensure that they are non-discriminatory, and to refrain from imposing measures that are more trade restrictive than necessary to achieve their objective or are simply disguised trade barriers.

The Agreement encourages countries to base their SPS measures on international standards where such standards exist. All measures that are based on international standards are presumed to be in conformity with the Agreement. However, members are free to impose measures that result in a higher level of protection than that afforded by the international standard as long as those measures conform to the other provisions of the Agreement.

In cases where countries face a risk about which scientific information is insufficient, they are free to adopt a provisional, precautionary measure based on available information, provided they work

to obtain the additional information they need to make a more informed decision within a reasonable period of time.

Several of the bilateral free trade agreements (FTAs) to which the United States is a party contain a section on SPS measures. In most cases, the agreements simply affirm the rights and obligations of both parties under the WTO SPS Agreement and establish standing committees to assist in the resolution of SPS-related trade problems. The agreements do not confer additional rights or impose additional obligations on SPS matters. In other words, the rules governing trade between the parties to the FTA are those found in the WTO SPS Agreement.

The SPS Agreement has been a useful tool for U.S. exporters of agricultural products. As the Uruguay Round negotiators predicted, some countries were that were forced to give up non-tariff barriers under the Uruguay Round *Agreement on Agriculture* have tried to replace them with bogus SPS restrictions. Others have ignored scientific evidence and imposed barriers in response to pressure from activists or politicians. The SPS Agreement is useful in such cases because it establishes an objective standard of legitimacy for food safety and plant and animal health regulations. U.S. trade officials have been able to use the leverage of SPS trade rules to challenge illegitimate measures and open a number of markets to exports of U.S. products.

Most SPS trade problems have been solved through bilateral consultations under the threat of a formal WTO challenge. However, WTO members have taken six disputes all the way to a WTO dispute settlement panel. In each of these cases the complaining party prevailed on at least one important claim. The most recent successful challenge was the case brought by the United States, Canada and Argentina against the EU's pre-marketing approval system for agricultural biotech products. The WTO Panel ruled that the EU had delayed unduly the processing of applications for approval. The four parties to the dispute are currently engaged in consultations on the implementation of the ruling. EU officials, most of whom recognize the importance of the SPS Agreement and are interested in improving the functioning of the EU biotech regulatory system, have been cooperative thus far. U.S. officials are hopeful of using the ruling to restore lost trade opportunities and prevent future problems.

Some have criticized SPS trade rules, claiming that they force countries to accept unsafe products. I would like to list some of the points that these critics have made and respond to them.

Criticism: The SPS Agreement limits the ability of U.S. regulators to set domestic food safety standards.

Response: In fact, the United States is free under the SPS Agreement to determine its own level of protection against food safety risks, as long as that level of protection and the measures used to reach it are scientifically defensible. The United States can impose that standard on imported food and agricultural products, provided the same standard is applied to domestic products and the measures applied to imports are not more trade-restrictive than necessary to achieve the objective . Some regulators in certain countries might view the Agreement as an annoyance, since it may require them to justify their decisions to foreign governments. However, I have never heard a regulator in the United

States or any other country make the claim that the rules adversely affect a country's ability to protect its consumers.

Criticism: The "equivalence" obligation under the SPS Agreement forces the United States to rely on foreign regulatory systems to ensure the safety of imported food.

Response: Nothing in the SPS Agreement requires countries to accept imports of food that do not comply with legitimate domestic food safety standards or to delegate the job of ensuring food safety to foreign regulators. WTO members are obliged to recognize foreign SPS measures as equivalent only if the exporting country is able to demonstrate objectively to the importing country that its measure meets the standards of the importing country. The importing country is free to continue monitoring imports and to revoke an equivalency determination if appropriate.

Criticism: Once the United States begins to accept imports from a country, SPS rules make it difficult to cut off those imports.

Response: Under the SPS Agreement, the importing country has the right to block the importation of any product that does not meet its standards, no matter where that product originates. It makes no difference whether or not the country has previously permitted imports from the same source.

Criticism: The United States is vulnerable to challenges under the SPS Agreement if it changes its regulations or acts to block unsafe imports.

Response: No U.S. SPS measure has ever been subject to challenge under the SPS Agreement. Indeed, there have been just six cases under the Agreement since it entered into force twelve years ago. One reason for the infrequency of cases is the degree of latitude the agreement affords to domestic regulators. Countries recognize that challenges are likely to be successful only when violations are particularly clear-cut. The rulings in the cases taken thus far underscore this fact.

Criticism: The SPS Committees established under U.S. free trade agreements aggravate the problem by facilitating imports from FTA partners.

Response: The purpose of the SPS Committees is to provide a forum for addressing SPS-related trade problems. However, as indicated above, the operative rules are those of the WTO SPS Agreement. The FTAs do not in any way alter U.S. rights or obligations under the WTO Agreement. This means that U.S. regulators retain the right to block unsafe or substandard imports, even if the product comes from an FTA partner.

To be clear, I am not arguing that there is no need to examine the U.S. system for ensuring the safety of imported foods. On the contrary, increases in international trade have placed greater burdens on U.S. regulatory agencies, and it is appropriate both to review current practices and to determine whether or not methods of enforcement, and the resources allocated to enforcement, are adequate.

However, I believe that the problems and vulnerabilities that have been identified are not the result of constraints imposed by trade rules. The United States has plenty of latitude under international agreements to ensure the safety of food imports. The only real constraints are the amount of emphasis that FDA and USDA place on the issue and the resources that Congress allocates to the task.

Thank you, Mr. Chairman.

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Chairman LEWIS. Thank you very much for your testimony.

Our final witness is a good friend, wonderful friend, former colleague of ours, the Honorable Cal Dooley, from the great state of California. He is the president and chief executive officer of the Grocery Manufacturers Association. Welcome, Cal

STATEMENT OF THE HONORABLE CAL DOOLEY, PRESIDENT AND CHIEF EXECUTIVE OFFICER, GROCERY MANUFACTURERS ASSOCIATION AND FORMER REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. DOOLEY. Well, thank you, Mr. Chairman. I am delighted to be joining all of you and I really have the honor of representing over 350 food, beverage and consumer products companies that manufacture tens of thousands of products.

You know, every day, your constituents and our customers throughout the country visit thousands of stores. Every time they go in to one of the grocery stores, they see literally 100,000 different products. The member companies I represent are very pleased and are very proud of the fact that the overwhelming majority of those products are consumed by consumers every day without posing any threat to the safety of their families.

But we would acknowledge that, due to some of the recent events, that there is more that we can do, and, in fact, can institute some new practices, that can further enhance the safety of the products that we are providing to consumers.

That is what led the Grocery Manufacturers Association to issue a "Commitment to Consumers: The Four Pillars of Food Safety". What we have introduced is a proposal to work in partnership with the regulatory community and the Federal Government, to have a public/private partnership where we can enhance the safety of the food products. It is a proposal that is based more on prevention rather than on inspection. We don't believe it is possible to give FDA the resources it would need to elevate the rate of inspection that you could, in fact, markedly improve the safety food. A far better investment is relying on the expertise and the capacity of the private sector to do a better job on the prevention.

The way we do that is, is that we suggest that we should develop a mandatory foreign supplier quality assurance program, that would require any importer of record to have a defined program that would be consistent with the guidance that would be developed by FDA, that would ensure that we would have a record of audits from a supplier of an ingredient or product internationally, that we would maintain the track of that product throughout the supply chain, that we would have testing protocols that would be developed to ensure that that product is, in fact, safe when it comes inside our borders.

We would also have a second pillar that would ensure that we could provide an opportunity for suppliers and manufacturers of products to go an additional step, to share additional information with FDA that could give them greater confidence that the products that they are providing consumers pose less of a risk.

Our whole objective here is that, really, when you look at the incidence of food safety problems in this country it is like finding the needle in the haystack. What our objective is on pillar one is to reduce the number of needles, the number of problems that are in our food supply. The objective in the number two is how do we reduce the size of the haystack so that FDA can be targeting their inspection focus on those products and those practices that could pose the greatest risk.

Our third pillar is really focused on the need for us to invest in developing the capacity in some of the exporting countries so that they can, in fact, have regulations that are more consistent with those in the United States and also have the ability to do a better job enforcing compliance with those standards. This is something that both the private sector and the public sector can commit and can do a better job of.

Our pillar four is one which is shared by all the stakeholders of FDA, whether you are a patient advocacy group, whether you are a consumer interest group, or whether you are a food, a cosmetic manufacturer or pharmaceutical manufacturer. We need to increase the funding for FDA. We are committed in, the Coalition for a Better FDA, to try to double the funding of FDA over the next five years.

You know, Mr. Thorn did an excellent job, I think, touching on the issues related to whether or not we are in any way constrained by enhancing the food safety programs in the United States by our free trade agreements. That is absolutely not the case in any instance. As long as we are applying an equivalent standard to those products that are coming—from outside our borders as well as to domestic products, we face no problems.

I just want to touch on a few concerns that we have with some of the legislative proposals that have been introduced by some of your colleagues in Congress. One is calling for user fees for imported products. I would say that this is a proposal that we have serious objections to. We have objections to it because we have never seen a user fee that could be applied in an equitable manner and that also wouldn't undermine the credibility and the integrity of our inspection program.

We also think it might have some adverse and unintended consequences. Just to give you an example of that, I brought in two different food products. We have this one product, Madras lentils, that is a product of India. I have another product here which is a vegetarian chili, which is manufactured in Napa, California, actually.

This product from India, if it was imported into the United States, would pay one user fee of $50 a line item, under the proposed legislation.

This product that was manufactured in the United States could have included ingredients that might number as high as 20. If 10 of those ingredients were imported from outside the borders of the United States, they would be paying a $50 line item import fee on half the products that are in this. You would actually be creating a perverse incentive for manufacturers to manufacture a product in Mexico, or in Canada, rather than in the United States with an application of a user fee that would have these type of consequences.

So, I would just encourage certainly the Committee on Ways and Means to be diligent when you see a user fee, which might actually be construed as a tax, and should be under your jurisdiction, about how we approach these.

In closing, I would just say that, you know, the member companies I represent are absolutely committed to working in partnership with you, with people at the FDA, to ensure that we can, in

fact, enhance the safety of the products that we are providing to consumers. I thank you for the opportunity to testify.

[The prepared statement of Mr. Dooley follows:]

Prepared Statement of The Honorable Cal Dooley, President and Chief Executive Officer, Grocery Manufacturers Association and former Representative in Congress from the State of California

Written Testimony of the Honorable Cal Dooley
Grocery Manufacturers/Food Products Association
President and Chief Executive Officer

Before the
Subcommittees on Oversight and Trade
Joint Hearing on Import Safety
October 4, 2007

I am Cal Dooley, President and CEO of the Grocery Manufacturers /Food Products Association. I am here today to discuss an issue of paramount importance to our members—ensuring the safety of imported foods.

Food producers have an abiding interest in safe food. Maintaining consumer confidence in our products, our brands, and our companies is the single most important goal of the food, beverage, and consumer packaged goods industry, and product safety is the foundation of consumer trust. My industry devotes enormous resources toward this goal, and effective regulation and oversight by federal regulatory agencies such as the FDA are critical and complementary elements of the fabric of consumer protection.

Last month, GMA/FPA issued "*Commitment to Consumers: The Four Pillars of Imported Food Safety*," a comprehensive proposal designed to protect consumers by strengthening, modernizing, and improving the system governing food imports. Our proposal envisions new mandatory requirements for the food industry to assure the adequacy of foreign supplier food safety programs and new responsibilities for FDA. Other elements include a new program to help identify and prioritize imports of potential concern, new efforts by FDA to help enhance the capacity of foreign governments to

prevent and detect food safety issues, improvements to FDA's scientific capabilities and its use of information technology, and a significant increase in FDA resources.

Underlying this comprehensive set of proposals is a fundamental emphasis on prevention.

Let me put the challenge before us in plain terms. As the volume of imported food steadily increases, the FDA's job at the border can be compared to trying to find a needle in a haystack. We need to approach this task from different angles: (1) by reducing the number of needles to find; and (2) by reducing the size of the haystack in which to find them.

I will take just a few minutes to briefly outline each of the four pillars for you now.

Pillar One: Mandatory Foreign Supplier Quality Assurance Program – Under this pillar, all U.S. importers of record would be obligated to adopt a foreign supplier quality assurance program that assures that all imported ingredients and products meet FDA food safety and quality requirements. As U.S. importers of record, companies, including GMA members, would utilize FDA guidance to adopt food safety programs and practices needed to ensure food safety, such as audits, testing, good manufacturing practices, good agricultural practices, HACCP plans, food defense programs, product management systems, and recall programs. Requiring importers of record to ensure the safety and quality of their supply chain – and giving FDA the authority to review the effectiveness of these programs – would reduce the number of needles in the haystack.

Pillar Two: Voluntary Qualified Importer Food Safety Program – To help prioritize FDA resources and to relieve congestion at ports, we further propose that U.S. importers of record who are able and willing to meet additional standards and conditions than those required under Pillar One could voluntarily participate in a program entitling them to expedited entry at U.S. borders. This is similar to the Safe and Secure Food Importation Program Chairman Dingell has proposed in the Food and Drug Import Safety Act introduced last month and builds upon the C-TPAT program currently in place. In addition to demonstrating the presence of well-designed and implemented food safety systems, importers could demonstrate a secure supply chain and conduct and share additional testing and program data with FDA to be eligible for expedited entry. By permitting expedited entry for imported foods that pose no meaningful risk, Congress can further reduce the size of the haystack needing closer scrutiny by the FDA.

Pillar Three: Build the Capacity of Foreign Governments – FDA would work with foreign governments to improve their capacity to prevent and detect threats to food safety. FDA would work with foreign governments to expand training, accelerate the development of laboratories, ensure the compliance of exports with U.S. regulations, permit appropriate FDA inspections of foreign facilities, and ensure adequate access to data and test results conducted abroad. In addition, FDA would be encouraged to use Codex to harmonize requirements among countries. The food industry has long supported international harmonization through Codex, and we believe that FDA must once again provide international leadership towards the adoption of strong, science-based

international food safety standards. All of these foreign capacity building steps would further reduce the likelihood of contamination and thereby further reduce the number of needles for FDA to find at the border.

Pillar Four: Expand the Capacity of FDA – Expanding FDA resources – including personnel, equipment, laboratory capacity, and scientific expertise – is an essential component of an effective food safety system. FDA resources have not kept pace with the demands posed by rising imports and current food safety challenges. To meet these needs, Congress must provide new funds to dramatically improve FDA's analytical testing capabilities, to increase and better target inspections conducted by FDA, to obtain real-time test results, and to enhance communications during crisis events. With additional resources that are well-deployed, FDA should be much better positioned to find any remaining needles before they cross the border and enter U.S. commerce.

We believe that the adoption of these four pillars of food safety will result in significant improvements in our food safety net. By focusing our efforts on prevention, and by leveraging the expertise and resources of the industry, we believe that our proposal will do far more to ensure the safety and quality of imported food products and ingredients than would the adoption of many of the legislative proposals pending before Congress, including the recently introduced Food and Drug Import Safety Act.

Food companies recognize that the growth of the global marketplace with increasing imports from many countries pose new challenges. We welcome the opportunity to work

with Congress to put in place comprehensive prevention-based measures to ensure the safety of imported foods and food ingredients.

Trade Commitments and Food Safety

I would like to take a moment to address an issue that has been raised recently regarding the impact of U.S. trade commitments on the ability of the U.S. to set and enforce food safety standards. Most immediately, this issue has been raised in the context of the U.S.-Peru Free Trade Agreement (FTA). In large measure, the FTAs entered into by the United States reconfirm each country's commitments under the WTO Sanitary and Phytosanitary Measures Agreement (SPS). As you know, the SPS Agreement does not limit, and in fact explicitly permits, a country's ability to establish measures to protect health and safety, as long as these measures are science-based, non-discriminatory, based on international standards and not merely intended to disrupt trade. And in fact, the SPS Agreement has been successful in creating a framework for food safety regulations.

FTAs do not impose any additional limitations on the U.S.' ability to implement standards and regulations to protect the food supply in our country and no provision of the FTAs limits the ability of the U.S. to set and enforce U.S. food safety standards. In fact, FTAs should be viewed as an important tool to build the capacity of foreign governments, to harmonize food safety standards, and to facilitate cooperation to improve current food safety regimes and ensure safer imports to the United States. In addition, the

trade negotiations themselves provide a great opportunity to address pending SPS issues between countries.

All food products entering the United States are required to meet the same food safety and quality standards as those products produced domestically. FTAs do not weaken U.S. food safety standards, prohibit the U.S. from imposing new science-based standards or prohibit the U.S. from enforcing border inspection measures on imported food products.

Legislative Proposals

Several proposals have been introduced in Congress to address the issue of imported food safety. We have reviewed these proposals, and I would like to take a moment to discuss the concerns that we have with some of these proposals. One of the proposals that seems to have generated great interest is the imposition of user fees on U.S. importers of food and food ingredients, including GMA members. While we would agree that inspecting products at the border is an important element of a comprehensive approach to food safety, we believe that inspections alone will not provide enough improvement to the safety of our food supply. We strongly agree with efforts to find more resources for FDA, which needs to restore its scientific base as well as its capacity to conduct an appropriate level of inspection and examination, and have urged Congress and the Administration to do so for the past several years. However, we strongly oppose the user fee proposals that

have been introduced in the House and Senate. We have five significant concerns with user fees.

We believe that the benefits of a safer food supply accrue to the public generally, much like the benefits of a strong national defense, and believe that the costs of providing FDA with sufficient resources to perform the various responsibilities to protect the public health that have been given to it by the Congress should come through general revenues, not user fees. As you know, a user fee is appropriate when the benefits of the government service flow to an individual (such as postage stamps, recreation fees, or public transportation) or to a particular business (such as harbor maintenance fees, accelerated review of prescription drugs, or bankruptcy filing fees). The benefits of inspection, effective science-based standards, and research and enforcement activities clearly flow to all Americans, not simply to food companies.

Second, the proposed user fees would impose significant financial burdens on U.S. companies, not just on importers. This is especially true for companies with facilities in both the U.S. and Canada, for example, where there is a steady flow of ingredients and finished products, all of which would be subject to import user fees. We are in the process of collecting data to estimate the added costs to U.S. businesses, but we have reason to believe they would be substantial.

Third, the imposition of user fees on imported products and ingredients could have the unintended consequence of encouraging companies to locate production facilities outside

the United States. Let me provide an example of why this is so. Suppose a company makes a product in the United States that consists of 20 ingredients, half of which are imported. Under the user fee proposal, a fee would be imposed on each one of those ten ingredients each time they are imported. If, on the other hand, the production facility was located in Mexico or Canada, for example, the fee would only be imposed once: when the finished product was brought into the United States.

Fourth, we are concerned that a user fee on imports would violate our trade commitments by creating a preference for domestic sources of food products and ingredients, violating our national treatment commitments. Finally, we are also concerned that such a fee could invite other countries to place similar fees on our food exports.

We strongly agree that FDA needs more resources to increase inspectors, improve its scientific capabilities, and meet other critical needs. For the past year, GMA/FPA has worked with the Coalition for a Stronger FDA to substantially increase FDA funding. In our view, FDA does not simply need "more" resources, but needs the "right" resources. In particular, we believe that the agency needs additional resources for both its "science" and its "compliance" activities. The agency cannot operate effectively without both. Our goal is to double FDA's food-related spending over five years.

We have serious concerns with other proposals that have been introduced in Congress, and I would like to highlight some of these today.

We are concerned that proposals to limit imports to certain ports and to require the development and implementation of certain tests could create havoc at the border and create costly and unachievable new burdens on FDA and the food industry. In particular, we are concerned that the proposal to limit food imports to ports of entry located in the same metropolitan area where FDA has a laboratory could unintentionally block food imports to many ports. While there are more than 300 ports of entry, there are only 13 FDA labs. As a result, many ports – including all ports in Texas and Florida – would no longer be able to import food products and ingredients. We believe a better course would be to expand and better target FDA inspectors, as we have proposed in our second "pillar" and Chairman Dingell has proposed in Section 7 of the Food and Drug Import Safety Act, and to expand FDA's capacity to quickly analyze food products and ingredients.

We are also concerned about new labeling requirements being proposed, such as in the Food and Drug Safety Act. These proposals appear to be redundant of current law in many respects, which already requires country of origin labeling for virtually all imported products, including packaged food. Moreover, Congress passed the Country of Origin Labeling Act of 2002 (COOL) to address some of the products that had been exempted from the broader statutory requirements. The recently House-passed Farm Bill includes provisions that will allow COOL to be implemented after several years of delay. We believe that current statutory requirements for country of origin labeling are sufficient and that proposals that would require specific ingredients to be labeled would be very

costly to implement and provide no safety benefit. Further, such steps could spur copy-cat measures in our export markets.

In addition, we are concerned that a requirement that all foreign facilities importing food into the U.S. obtain FDA certification would place enormous new burdens on FDA, would likely violate trade commitments on national treatment, and would invite reciprocal demands by our trading partners. Further, the cost of such a program, requiring FDA to certify products from nearly 150 countries, would be prohibitive, and unlikely to be funded adequately. We believe that there are much more cost effective ways to achieve the goals we all share.

In addition, proposals for mandatory recall authority seem to ignore the fact that the current recall system works well as food companies have powerful incentives to remove adulterated products from commerce as quickly as possible and have worked closely with FDA to implement recalls quickly and effectively.

Conclusion

In conclusion, we share your commitment to improving the safety of imported food. We are also committed to working for increased FDA resources, including resources to increase the ability to detect adulterated food at the border. However, we believe that far more emphasis must be placed on the prevention of threats to food safety throughout the supply chain and look forward to working with you to make a safe and secure supply

chain the responsibility of every importer of record and to expand the capacity of foreign governments to detect and deter threats to public health.

Our "Four Pillars" proposal builds on the long history of public-private responsibilities and cooperation in ensuring food safety, while providing new and innovative approaches to the latest challenges to our nation's food safety net. Its focus on prevention would be complemented by an enhanced ability to quickly detect and address public health threats. Meeting the challenges of the modern supply chain requires additional public resources for FDA and related agencies and demands an integrated approach that leverages the significant investment of the private sector in product safety. We look forward to working with the Committee to fashion a comprehensive solution that will address the new challenges posed by rising food imports and will continually improve the safety of our food products and ingredients.

Chairman LEWIS. Thank you very much for your testimony this morning. I thank each Member for your patience and for being here and being willing to testify.

At this time, I will open the panel for questions. I ask that each Member follow the 5-minute rule. If each witness will respond with short and concise answers, all of the Members should have the opportunity to ask questions.

Ms. Halloran, were you or any other consumer rights advocate organization consulted by the interagency working group on import safety? Did anyone get in touch with you or any other group that you know and ask for your advice or ideas?

Ms. HALLORAN. Very late in the process, they had a meeting with about a half dozen consumer groups. However, I didn't see any evidence of our input in the report that they brought out. We were very disappointed in the report because it was so vague and general and really included no specifics about including either resources or budgets to the agencies that need them, just more about strategies and frame works.

Chairman LEWIS. Would any of you like to respond? If you could recommend a single best action practice that the U.S. Government should take to improve the safety of food and product imports, what would it be? What recommendation would you give?

Ms. HALLORAN. At this point, I think the best measure that they could take without a budgetary impact, I mean, we need to have more inspection, but we also need to have independent third party certification and we need it to be required. That applies to consumer products and food products. It needs to be government supervised and that would allow us to have some method for making sure that products coming into the country do meet our standards and that the standards are being imposed in the country of origin, not just at the border.

Chairman LEWIS. Anyone else care to respond?

Mr. DOOLEY. Yes, I will, Mr. Chairman. I guess people need to step back and just look at who has the greatest vested interest in insuring that their product is not going to pose a safety risk to consumers? I mean, that company that has their brand name on it is absolutely committed because any time there is a recall or a problem that is a result of a food safety—with their product out there, it has significant financial impact.

All of our companies today that are acting responsible are in fact employing third party audits that are ensuring that the suppliers of their ingredients are, in fact, meeting some standards that have been identified as providing that level of safety that is appropriate.

So, that is where we think that FDA should be in a role where they can cooperate with a private sector who is in fact using audits that have some defined standards in order to meet that higher level of certainty that these products won't pose a risk.

Chairman LEWIS. Mr. Berman, in your view, why haven't OSHA and the CPSC been more aggressive in their testing of textile products containing dangerous substances or dangerous material?

Mr. BERMAN. Well, in the instance of OSHA, it is—consumer protection is not within their jurisdiction; they are protecting workers in the work place. They, in recent years, have not had the budget to do proactive inspections within plants. They—the effect that we have had since the OSHA standards have been imposed in the U.S. has been indirect. The fact that the work places had to meet the OSHA standards had a carryover effect and products that

were produced in the U.S. were—had formaldehyde at safe levels for consumers. It is since globalization that we have gone back a step.

The CPSC has the same problem. In each instance, they need a complaint before they are going to take action. There is nobody minding the store.

Chairman LEWIS. Are you suggesting that before they take action, there must be a particular complaint? Must someone wait to be harmed or something serious happen to a person before someone takes some action?

Mr. BERMAN. Well, with respect to the formaldehyde in textiles, there is no U.S. standard right now, so in that case, you are going to have to wait for an actual harm. So, I think really what needs to be done first is that there needs to be some rulemaking and perhaps the CPSC should be empowered to do some investigative work to determine the extent of the problem.

I only spoke about the products that we have actually tested. But I know anecdotally from talking to other people in the textile industry, that apparel is full—that is coming in from China and other Asian countries is full of formaldehyde.

The same blankets that were recalled in Australia and New Zealand are coming into the U.S. Formaldehyde is not the only dangerous substance in products, in textile products coming to the United States.

Friends who are in the stocking industry have tested stockings where they are asked by the retailers, gee, why can't you give us the same vibrant colors that we are getting from India and Pakistan? After they test them, say said, it is because they have formaldehyde binders putting the pigments—holding the pigments on. We are not allowed to use high formaldehyde in the United States.

So, it is a much bigger problem and it is one that I think people are generally unaware of.

Chairman LEWIS. Well, thank you very much. I notice that my time had expired, but I just wanted to suggest that the Associated Press had an article on Sunday that noted the Japanese may have the strictest food standards of anyplace in the world and that the Chinese have approached Japan to help address many of their standard issues.

I would like to enter this article into the record.

[The information follows:]

The Associated Press
Sunday, September 30, 2007

China holds up foreign-linked exporters as role models for food safety

QINGDAO, China: First comes the "wind shower." Wearing overalls and rubber boots, employees at Fusheng Food Co. stand in a narrow room as air jets in the walls blow away any dust on them. They wade through ankle-deep disinfectant and don caps, gloves and surgical masks.

Only then can they enter the chilly, white-tiled room where they pack Alaska salmon for American dinner tables and Russian cod for McDonald's fish sandwiches in Japan. The Japanese-owned company says the fish already has been tested for more than 100 banned chemicals.

"I am very confident in saying our food is excellent and the safest in the world," Zhong Yuhua, the general manager, told reporters who were invited on a government-organized tour of three food exporters in Shandong province, southeast of Beijing.

Fusheng is part of a Chinese food industry elite of export-oriented companies that, often with foreign help, have improved quality to meet import standards in Japan, the United States and elsewhere.

As the government tries to repair the battered "Made in China" brand, it is holding them up as models to reassure foreign consumers and to help improve the rest of the industry.

"Foreign companies have done a good job. They can play a leading role. Other companies can learn their advanced management model to promote quality control," said Huang Kunlun, the executive deputy director of the Agriculture Ministry's product testing center.

The reputation of China's US$31 billion-a-year (€22 billion-a-year) food export industry has taken a beating after incidents over toxic chemicals in Chinese pet food and toothpaste and banned drugs in seafood. Other exporters have been hammered by recalls or warnings about Chinese goods ranging from faulty tires and baby cribs to toys tainted with lead paint.

U.S. authorities restricted imports of Chinese shrimp, eel and three types of fish in July after tests found unapproved drugs in some shipments. Chinese officials criticized the move as excessive. Last month, American officials announced that one Chinese supplier was cleared to resume shipments.

At Fusheng, visitors saw masked and gloved employees cut and pack salmon in a tidy workshop. Public areas were scrubbed clean. In bathrooms, signs over the sink reminded employees to soak their hands in disinfectant after washing.

Conditions in the rest of the industry vary widely, from companies with the newest equipment and rigorous inspection to competitors that are accused of substituting cheaper materials and skimping on hygiene. Chinese authorities argue that product liability cases have involved only a small fraction of China's food processors.

Even before the recent safety cases, regulators were using leading exporters as industry role models, organizing delegations of managers to study their plants.

"A lot of visitors from companies across the country come to see how we ensure food safety," said a spokesman for the Longda Food Group Inc., who would give only his surname, Jiang. "Last year we had 200 groups of visitors."

Longda, which has joint ventures with Japanese partners, says 90 percent of its US$203 million (€143 million) in exports last year

went to Japan. That included vegetable snacks sold by Itochu Corp. and 5,000 tons of Vienna sausages.

Shandong province is the heart of China's food export industry and has close ties with Japan and with South Korea, which lies a short ferry ride away across the Yellow Sea.

Its 2,600 food exporters sell frozen chicken patties, vegetables, fish and dumplings. One-third of their US$3.5 billion (€2.5 billion) in exports in the first five months of this year went to Japan, according to the government. Other markets include the United States and Britain.

People in the industry say Japan's standards are the world's most stringent, forcing Chinese companies to improve if they want to sell into its huge market.

"Japanese standards for imported food products are high, maybe too high," said Fusheng's Zhong, a three-decade veteran of food processing. "There might be political reasons, such as Japan wanting to protect its farmers. But we have no alternative but to meet those standards if we want to get into the market."

Once a state-owned company, Fusheng was bought in 1994 by Japan's Rinken Vitamin Co., which brought in consultants from the U.S. Department of Agriculture and food testing companies to meet Japanese import standards, Zhong said. Last year, the company reported US$63 million (€44 million) in exports to the United States, Japan and Europe.

Today, Zhong said, enforcement measures include docking employees' paychecks by up to 40 percent if inspectors find bones left in fish or other errors.

The third company, Kaijia Food Co., a Chinese-Japanese joint venture, exported US$50 million (€35 million) worth of goods, including Japanese-style pickles to the United States and chicken patties to Britain.

After foreign reports of tainted products, all of Shandong's food plants are being inspected to see that none use chemicals cited by the United States and other countries, according to Jiang Zongliang, deputy director general of the province's export safety bureau.

Some 600 companies in Shandong have been granted "self-testing" status, with their own lab results deemed adequate for export clearance, Jiang said.

But that system is not foolproof, and products cleared by company labs sometimes later fail government tests, he said.

"There is this kind of incident, but not often," he said. "Once this occurs and there are differences between the two labs, we must find out what the problem is and take steps to fix it."

Chairman LEWIS. Now I turn to the Subcommittee on Trade Ranking Member, Mr. Herger, for his questions.

Mr. HERGER. Thank you very much, Mr. Chairman. I have a question I would like to ask of both Mr. Connelly and Mr. Dooley as you represent your organizations.

Mr. Dooley, it is great to see you back. Thank you for the years of representing our common state of California. It is good to see you doing so well in your life after Congress. Thank you for testifying here.

I would like to follow up on some comments that you made in your testimony. Could you describe the process that your member companies use to ensure the safety of the products they produce and import? How can the Federal government incorporate such processes in its development of a strengthened food and safety regime?

Mr. DOOLEY. Just this week, Monday and Tuesday, we held a conference, a global sourcing conference, where we brought in representatives of our companies to talk about some of the best practices that they were employing today, and what we could do to even enhance those best practices. That is what we are suggesting should become mandatory and developed as FDA guidance under our Pillar One.

What we would suggest that would be components of this, and these are still in development, that you would have a requirement that there would have to be a supplier audit that would have to be done on site at the source where you are procuring the ingredients or the products that you would be importing into the United States. That that audit would have to have certain standards that would have to be complied with. We would also have provisions that would ensure that you would be able to maintain the chain of custody for that product when it came into the United States.

We would further suggest that there are going to be the need to develop certain testing protocols for some products. They wouldn't be necessarily uniform for every product you are bringing in. But some testing protocols that would—could be determined, you know, or could mitigate the risk of contamination.

We are also considering further development in terms of would we have the same requirement for the development of HACCP plans that are currently in place for domestic products. So there are a host of issues here that we know—some of which and many of which are being employed today by the companies that are utilizing the best practices. What we are suggesting, we ought to mandate those to apply to all companies, all importers of record, regardless of their size or what products they are engaged in importing.

Mr. HERGER. Thank you. I think that makes a great deal of sense. I think the idea that it is your name on this product, and I think we get the best use of our dollars if we can have those of you who are most affected to a great degree be the ones that are helping to enforce this.

Mr. DOOLEY. Well, we would agree most heartily. We can double the budget of FDA, and it is still going to have limited resources. So, the challenge, I think, you face is, how do we define that role of the private sector and the FDA so that FDA can invest their capacity in a way that is going to make the greatest difference.

We think that there is an appropriate inspection role for FDA there. But this idea of them going into importing countries and certifying their labs, you—when I was on and testified at Energy and

Commerce just last week, Dr. Acheson said there is as many as maybe 400,000 facilities that are producing ingredients and food products in China. Not all these are importing in the United States. But the thought that you would have FDA having the resources to go in to China and certify 100,000 facilities, it is just not feasible in terms of being financially viable. That is where we think the private sector has the better opportunity to do that effectively.

Mr. HERGER. Well, we obviously have to do both, but what is important, I think the point that you are making is that we do what we can do the most effectively from both parts of government and the private sector.

Mr. Connelly, would you like to comment on the same question?

Mr. CONNELLY. Interestingly, our organization came up with an approach very much like Mr. Dooley's independently. Right now there are inspections required of both domestic and imported seafood under what's called HACCP. An importer has a requirement to ensure that his export partner overseas follows a HACCP plan.

We would go one step further, though, in a parallel program to the GMA program and actually require certification of an importer here in the U.S. My 16-year-old son is getting his drivers license and he has done 40 hours of classroom work to do that. He drove me down to Gonzaga this morning, which is always exciting to have a 16-year-old drive you when he has his permit.

But he will actually have more requirements placed on him to get his drivers license than it does to become a food importer. We think we should tighten up that requirement.

Those companies, like our members, that spend time in Latin America, spend time in Asia, ensuring that their partners do the right things, should be rewarded. We think having a list of certified importers is one step toward that. We think it also will help FDA identify those companies that import a lot or import a little and then they can target their resources appropriately.

Mr. HERGER. I thank you have much.

Chairman LEWIS. Now I turn to the Chairman of the Subcommittee on Trade, Mr. Levin, for questions.

Chairman LEVIN. Well, as you know, we have a vote and I'm sorry I had to leave the room for a bit.

I know an issue is the balance between the public and the private sectors. I just want to say—let me just ask you how many of you watched the interagency process up to now are optimistic about the results? Are all of you? Ms. Halloran, you are not?

Ms. HALLORAN. As I mentioned just a moment ago, we are very disappointed.

Chairman LEVIN. All right, I'll read the record.

Anybody else? Yes.

Mr. DOOLEY. Yes, Mr. Chairman, we are optimistic that the interagency working group is going to offer suggestions that are going to provide a road map for us to enhance a level of products that we are importing. There is going to be a lot of work that is going to continue to be done. We are looking at this as—there is not a short-term, quick fix solution out there. This is something that we are going to have to continue to work on over an extended period of time.

Chairman LEVIN. All right. But let me just say my reaction to the first panel was there did not seem a sense of urgency. I know that nothing will be done completely short term. But if the status quo or anything close to it remains and there is another or a rather explosive event—I don't mean militarily—the public will lose still more patience with us. It wouldn't take much more to diminish the impatience of the public.

I think it has been a useful hearing. You haven't had a chance to——

Mr. HULSHOF. I've got a couple of quick questions if I might.

Chairman LEWIS. The gentleman, my friend and colleague from Missouri is recognized, Mr. Hulshof.

Mr. HULSHOF. Thank you, Mr. Chairman. I am beginning to think that there is a conspiracy afoot that just as I begin to get to my questions, that the votes are being called. So, let me be directly to the point.

Ms. Halloran, can you point to any instance where a free trade agreement has required the United States to relax its safety standards? The reason for my question is, the previous panel had representatives from the U.S. Trade Representative, Department of Homeland Security, U.S. Department of Agriculture, the Food and Drug Administration and the U.S. Product Safety Commission and none of those individuals could ever point to an instance where we had—the United States had to relax any part of its inspection regime. Do you differ with their opinions?

Ms. HALLORAN. Our concern is—we do have—that has—that has not happened, but many things have given us concern. One is, for example, a challenge under NAFTA that was brought by a Canadian corporation under Chapter 11.

Mr. HULSHOF. I am familiar with your testimony. So that has been part of the record.

Ms. HALLORAN. Right.

Mr. HULSHOF. Go ahead.

Ms. HALLORAN. But we are more concerned about the—our concern about the equivalence part of the trade rules is that many of the rules in the U.S. are—are guidance, they are voluntary standards. We have companies who voluntarily have good performance so we haven't had a need to regulate and put out rules.

For example, on formaldehyde, we don't have a formaldehyde problem. So we don't have regulations. As a result, we can require equivalence, but that doesn't get us anywhere in terms of the foreign companies. We can't force on them standards that are adhered to by custom and voluntarily here.

Mr. HULSHOF. Right. I appreciate that. I would point for the record, Mr. Chairman, we won the case under which—that is cited by Ms. Halloran that was brought.

You also suggest that we should harmonize up, and you give as an example, rightly so, this protracted dispute that we have had, for instance, with beef to Japan.

I would point out again for the record, Japan's herd is four-and-a-half million animals. We slaughter 36 million animals annually in the United States. Yet there is a 500 percent higher BSE tests in Japan than in the United States. Yet you seem to take the USDA to task for not allowing private companies to do BSE tests.

In fact, how do you square that inconsistency, because you want more rigorous standards and yet the private companies providing BSE tests don't have as rigorous a test as USDA, do they?

Ms. HALLORAN. The U.S. companies supplying the Japanese market wished to use exactly the test that USDA uses when it conducts tests.

Mr. HULSHOF. Okay.

Ms. HALLORAN. USDA refused to license them or to allow them to use it to meet the demand of the Japanese customers.

Mr. HULSHOF. Final question, because again, once again, time is short on the vote, I noted your concern with for instance counterfeiting Underwriter Laboratories labels. Does the consumer union of which you represent here today, have you all expressed a similar concern about the importation of pharmaceuticals or counterfeiting of pharmaceuticals coming into this country?

Ms. HALLORAN. I don't believe we have a position on that.

Mr. HULSHOF. Thank you Mr. Chairman.

Chairman LEWIS. I thank the gentleman.

I would like to take the opportunity just to thank each and every one of you for your participation, for being here and being so patient. The Oversight and Subcommittee on Trades appreciate hearing your views on how we can improve import safety.

Is there any other business to come before the Subcommittees?

There being no further business, this hearing is now adjourned.

Thank you very much.

[Whereupon, at 1:27 p.m., the Subcommittees were adjourned.]

[Submissions for the Record follow:]

Statement of AdvaMed

We thank the Committee for holding this Hearing today on Import Safety. AdvaMed represents over 1,600 of the world's leading medical technology innovators and manufacturers of medical devices, diagnostic products and medical information systems. Our members are devoted to the development of new technologies that allow patients to lead longer, healthier, and more productive lives. Together, our members manufacture nearly 90 percent of the $86 billion in life-enhancing healthcare technology products purchased annually in the United States, and nearly 50 percent of the $220 billion in medical technology products purchased globally. Exports in medical devices and diagnostics totaled $25.5 billion in 2005, and imports were $23.7 billion. The medical technology industry directly employs about 350,000 workers in the U.S.

The medical technology industry is fueled by intensive competition and the innovative energy of small companies—firms that drive very rapid innovation cycles among products, in many cases leading new product iterations every 18 months. Accordingly, our U.S. industry succeeds most in fair, transparent global markets where products can be adopted on their merits, and intellectual property rights are protected. We strongly support the Administration's effort to expand market access for U.S. products abroad through the World Trade Organization (WTO) negotiations and new free trade agreements (FTAs), as well as oversight of market access barriers in countries with which we have strong trade relationships. In addition, we believe U.S. participation in trade agreements is most effective when provisions are enforced.

Import Safety

AdvaMed believes ensuring the safety and effectiveness of medical technology is a shared responsibility between government, industry and users—wherever the product is designed and manufactured. Government establishes and enforces the laws and regulations intended to provide patients with medical technology that is as safe as possible and functions as intended. Manufacturers have the obligation to make products and establish quality management systems that comply with these

laws and regulations. Both parties have an interest in promoting public confidence in the medical technologies used in healthcare delivery.

U.S. Food and Drug Administration (FDA) regulations governing the sale of medical devices in the U.S. are recognized around the world as providing U.S. patients high quality medical devices. Any medical device sold in the U.S.—including all imported medical devices or devices made with components produced overseas—will have undergone a review and approval process by the FDA, including inspections of the manufacturing facilities for higher-risk products. Medical devices also are subject to FDA's post-market surveillance requirements. While AdvaMed members are confident in the safety of their own products, the U.S. Government has much better access to information to assess whether medical devices being imported into the U.S. meet FDA requirements. We welcome measures that will ensure consistency in the requirements applied in practice to domestically-produced and imported medical devices.

We believe that communication between governments, involving industry in the process, is very important. AdvaMed has developed good working relations with key regulatory agencies in many countries. Our approach with both foreign governments and industry is to seek ways to improve information on best practices, communication and appropriate regulatory systems.

Over the years, AdvaMed and its members have conducted—and continue to conduct—seminars and training programs for government officials on best regulatory practices. By improving understanding of international best practices, we believe the safety and effectiveness of medical devices—along with patient access to those technologies—will be enhanced world wide.

Information Sharing

Under U.S. regulations, the medical technology industry is required to provide FDA information to assist in its enforcement of regulatory requirements. Such information includes pre-market evidence, which enables FDA to evaluate the safety and effectiveness of a product before it is sold in the U.S. The industry also provides FDA considerable post-market information, including adverse event reports and notice of significant changes in product design or manufacture, and is subject to ongoing facility inspections.

The U.S. FDA has access to more information on the U.S. medical technology industry than any other regulatory agency in the world has on its industry. Some of this information is business sensitive and confidential. In the right hands, necessary information can help ensure unsafe products do not reach patients and/or that appropriate and timely corrective action may be taken by industry and government.

In the wrong hands, this same information can prevent safe products from improving patients' lives and be used to block market access. Regulators in other countries who either do not understand, or do not want to understand, or react inappropriately to, the meaning of FDA's information can cite it to unfairly deny access for U.S. medical devices. Many other countries use industrial policy to foster exports and discourage imports. We ask that U.S. Government officials recognize these imbalances—regarding the extent of information available, the understanding of regulatory data, and/or the differences in available resources—in FDA compared to the rest of the world when determining information sharing arrangements between governments.

In particular, we make the following recommendations.

- FDA should provide information to foreign governments only to the extent it receives comparable information in return. Since the task of the Interagency Working Group's activities is to determine ways to protect Americans from unsafe imports, U.S. negotiators should focus on defining the information foreign governments are willing to provide the U.S., and respond accordingly.
- FDA should provide foreign authorities safety information only on the specific medical technology products that are actually sold in the other country's market. Information on other products, which might be similar to products sold in another country, could be misunderstood and/or misused—e.g., as an inappropriate excuse to deny access.
- If information on specific products sold in a foreign country is shared with foreign authorities, FDA should ensure that the information is used appropriately for safety reasons, which might require training for foreign regulators and/or conditions for denying access to any future data if conditions are not met.
- If FDA provides foreign authorities information on a situation labeled a "recall" in the U.S., that term should not be used with foreign authorities unless a product is being removed from the U.S. market. No other country uses the term "recall" for the broad range of actions, characterized by FDA as "recalls." While the Global Harmonization Task Force (GHTF) term "field safety corrective ac-

tion" would be most appropriate, an alternative would be for FDA to simply describe the action taken, without labeling the action a "recall."

- FDA inspection reports should not be shared with foreign authorities without obtaining a company's approval. Such reports contain sensitive and confidential information. Many countries' regulatory systems are still evolving, and their inexperience with FDA inspections could cause them to over-react. Even if confidential information is redacted from FDA submissions, a foreign government is likely to require the U.S. firm to provide all information as a condition for sales.

Appropriate Regulatory Systems

The GHTF provides excellent guidance documents, with strong emphasis on quality management systems and international standards, as the basis on which to develop regulations for medical devices. The U.S., Europe, Japan, Canada and Australia are founding members of the GHTF and make use of GHTF guidance documents. Many countries outside of the GHTF membership are developing their own regulatory systems for medical devices and tend to rely inappropriately on regulations for pharmaceuticals and type testing, instead of quality management systems. The result is that some countries' regulations and actions do not reflect best international practices and cannot control safety and effectiveness as well as appropriate medical device regulations based on a quality management systems approach. In addition, some foreign regulations often impose more stringent regulatory procedures on imported products—which can be effectively blocked at the border—than on domestic products.

FDA should press for a quality system approach as the basis for medical device regulation and the elimination of type testing, especially testing that is redundant and unnecessary. Foreign countries' resources could be better used for developing a modern regulatory framework than being expended on outdated, costly and inappropriate procedures. This approach would be consistent with the Interagency Working Group's recommendation to use a "video" instead of a "snapshot" to evaluate imports. Such an approach to assessing and controlling imports, from design to post-market surveillance coupled with a risk management philosophy across the product life cycle, are well-established principles in the medical device sector (FDA quality systems regulation and international medical device quality management systems standard ISO 13485). We support their broader application throughout the supply chain. This approach would also encourage international regulatory harmonization.

We recommend that U.S. and foreign governments, in cooperation with U.S. and foreign industry, launch an initiative to assist other countries interested in improving their regulatory regimes for medical technology. This initiative could focus on greater reliance on the quality management systems approach, international standards and perfecting post-market surveillance systems.

Conclusion

AdvaMed and its members strongly endorse government regulations that promote the safety and effectiveness of medical technology in the U.S. and abroad. It is in the best interest of patients, clinicians, and our industry that only the highest quality of medical technology is allowed to be placed on the market in any country. We have made recommendations which we believe will achieve these objectives without imposing barriers delaying or preventing U.S. medical technology from entering other countries.

Statement of Airport Duty Free Stores

The International Association of Airport Duty Free Stores is pleased to submit these comments for the record of your October 4, 2007 joint Subcommittee hearing on Import Safety.

IAADFS represents operators of airport duty free stores. Our members import a narrow range of products for sale duty-free to travelers exiting the United States. Strict government regulations apply to our operations to ensure that only ticketed passengers traveling to a foreign destination may purchase products in a duty free store. As a further precaution, items purchased in a duty free store cannot be carried out of the store by the traveler, but instead must be delivered directly to the departing aircraft at a point of no return. As such, the products never enter the stream of U.S. commerce.

As the Committee exercises its jurisdiction over the serious issue of import product safety, we encourage you to remain aware of its impact on the import process,

including the very unique environment of airport duty free stores. Legislation should reflect the fact that:

- Products sold in a duty-free store never enter U.S. commerce. The products are imported, held in a highly regulated customs bonded warehouse that is subject to stringent security standards, and sold only to passengers leaving the U.S., as described above.
- The duty-free industry was subject to rigorous security and accounting procedures long before the Nation became concerned about terrorist threats or unsafe products. These procedures were established initially to protect the revenue of the U.S. Treasury, but now serve to assure protection against security or safety concerns, as well. The government recognized the need to facilitate personal purchases by individual travelers crossing international boundaries. Therefore, the law creates the framework for U.S. duty-free stores to sell imported products duty- and tax-free to these individual travelers leaving U.S. soil. However, in return, virtually every aspect of a duty free store's operation—from import to export—is subject to the highest regulatory requirements to make certain these products do not enter U.S. commerce but are sold for export only.
- Products sold in duty fee stores are low-risk products. They tend to be high-end luxury items. The range of food products is very narrow and includes items such as expensive chocolates or gourmet packaged food. The supply chain is also very secure, with CBP regulating and overseeing each movement within the U.S.

With the volume of imports at an all-time high, it does not make sense to devote scarce FDA or other agency resources to this highly regulated niche of low-risk, imported products that never enter the stream of U.S. commerce. We therefore urge the committee to apply any new import safety rules to products "imported for consumption in the U.S."

Similarly, any product safety legislation should also provide a narrow exclusion for products brought back to the U.S. by returning citizens and U.S. residents under the personal use allowances (Chapter 98 of the Harmonized Tariff System). There would be no purpose served by subjecting individual Americans bringing back small personal use quantities, purchased during their travels overseas, to the fees, rules, restrictions and penalties that may apply to commercial importers.

Thank you for the opportunity to submit these comments and please let me know if you require additional information and/or have any questions.

Statement of American Academy of Pediatrics

The American Academy of Pediatrics (AAP), a non-profit professional organization of 60,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults, appreciates this opportunity to submit testimony for the record of this hearing on import safety.

The American Academy of Pediatrics commends the Subcommittees on Trade and Oversight for this effort to pay long-overdue attention to the safety of imported products. The AAP supports initiatives to increase staff and funding for regulatory agencies, give them more tools to police the marketplace, and require manufacturers and sellers of products to pursue safety more zealously.

The safety of imported products has special implications for children's health. In 2006, the United States imported to close $2 trillion worth of goods. A substantial percentage of these imports were food that was consumed by children and their families and products for use by or with children. China is the largest producer of imported children's toys, responsible for manufacturing 86 percent of all toys sold in the United States.

In recent months, public attention has focused on the safety of children's products after a wave of recalls of popular children's toys by the Consumer Product Safety Commission (CPSC). Recalls have been issued for toys that violated standards for lead paint as well as those that posed choking, strangulation, fall, and entrapment hazards. It is vitally important that the U.S. set and enforce strong standards to ensure parents that the products used by and with their children are safe. Manufacturers should be held accountable for ensuring that their product designs are sound and do not present a foreseeable safety hazard. In addition, the government should set strict standards for acceptable lead content in children's products.

Lead is Ubiquitous in Our Environment

Lead is a soft, heavy and malleable metal that occurs naturally in trace amounts throughout the environment. Due to its abundance and easy workability, it has been used for thousands of years in plumbing, production of glass and crystal, and manufacture of ammunition.[1] Its toxicity was recognized by the Romans[2] and documented during the twentieth century, as its increasingly widespread use led to unprecedented levels of occupational and environmental lead poisoning.[3] By 1970, science had demonstrated conclusively that lead could cause both acute poisoning as well as a wide range of long-term human health consequences.[3,4] Since then, hundreds of studies have shown that the body has no use for lead, and that a "normal" blood lead level is zero. Because of its widespread use, lead has been concentrated in the environment where it poses a serious threat to children's health. Furthermore, because it cannot be identified easily, even when present in high amounts in paint, dust, or dirt, children can be exposed in their homes and schools and at play without our knowledge. It is an "invisible" poison.

Low Levels of Lead Can Cause Serious Effects

Damage done by small amounts of lead may be hard to measure and even harder to understand. Most children who accumulate lead in their body do not have any physical symptoms, but low lead levels cause a wide array of negative effects, including cognitive, motor, behavioral, and physical harm.[5]

There is no "safe" level of lead exposure. The developing embryo, fetus, and child grow and change rapidly. If, during this period of change, the fetus or child is exposed to a poison of some kind, development can be impacted negatively. These "critical windows of exposure" are specific periods of development during which the embryo or fetus is undergoing some process (such as the development of arms and legs between days 22 and 36 of pregnancy, when thalidomide damages their development.[6,7]) There are many other examples of this effect, including tobacco smoke and behavioral effects, and alcohol and fetal alcohol syndrome. The critical period associated with harm from lead poisoning is brain and nervous system development, which begins in early pregnancy and continues until at least age 3 years.[8]

The vulnerability of children to lead poisoning during development of their brain and nervous system has been amply demonstrated, and the literature is very consistent. On average, children whose blood lead levels (BLLs) rise from 10 to 20 mcg/dL lose two to three IQ points. More recent studies have shown an even greater impact on IQ of BLLs under 10 mcg/dL. Key studies reported a loss of 4 to 7 IQ points in children whose lead levels rose from 1 mcg/dL to 10 mcg/dL.[9,10] These studies suggest that "low" levels of exposure—meaning BLLs less than 10 mcg/dL—cause proportionately greater harm than higher levels. The effects of lead on health do not stop once the child reaches age 6 years. A recent study found that in a group of 7-year old children exposed to lead before the age of 3 years, IQ was more closely related to blood lead at age 7 years than past blood lead at age 5 or peak blood lead at approximately age 2 years.[11]

Another important lasting effect of lead exposure is on behavior, with higher rates of behavioral problems reported in teens and adults exposed to lead during childhood. Children with elevated lead are more likely to have problems with attention deficit, reading disabilities, and to fail to graduate from high school.[12] Investigators have identified associations between lead exposure and increased aggression, commission of crime and antisocial or delinquent behaviors.[13–16] Studies have suggested that several nations which began reducing lead exposure aggressively in the 1970s experienced corresponding decreases in crime rates two to three decades later.[16] Other effects include abnormal balance, poor eye-hand coordination, longer reaction times, and sleep disturbances.[12,17,18]

The loss of a few IQ points or a small increase in the proportion of children with behavioral problems in the population of U.S. children has marked impacts on educational needs and future potential.[19] Since lead exposure is a population-wide risk, even relatively low levels of exposure can affect large numbers of children. This means that more children need special education, there are fewer gifted children, and over time, the average IQ of the entire population falls.

Lead Poses a Serious Threat Hazard to Children At Every Level of Exposure and Every Stage of Development

Lead is easily absorbed by ingestion or inhalation. The most common route of exposure of children is through ingestion, usually by putting hands and other objects in their mouth. Both hand-to-mouth exploration and playing on floors are typical behaviors for children, especially younger children. Studies using videos to record oral behaviors of young children report hand or object in mouth activities 20 or more

times per hour.[20,21] If the dirt on their hands or the dust on the floor contains lead, every one of those activities delivers a dose of lead.

Another significant difference between children and adults is in the rate of their metabolisms. Children have significantly faster metabolisms, which means that they breathe faster and ingest proportionately more food and water.[22] This difference means that in similar environments, children are exposed to a greater extent to contaminants than adults. Since children absorb 5 to 50 percent of any lead they ingest (compared to adults, who absorb 10–15 percent),[23] they are at high risk of lead poisoning every time they are exposed.

Once lead enters the body it remains there for years. Lead is similar to calcium from the elemental perspective. This means that our bodies "see" lead as calcium, absorb it into blood and then store it in bone. These stores of lead can be released years later, when bone changes occur or demands on calcium stores are made.[24] Another consequence of storing lead in bone is that exposures separated by months or years have an additive effect on the body's burden of lead and can exert effects over decades. Acquisition of lead in the body even in small amounts (i.e., amounts that result in BLLs less than 10 mcg/dL) contribute to this accumulation of lead. This means that commonly encountered blood lead concentrations have lasting negative effects.

Another consequence of this accumulation of lead in bone is the exposure of the fetus to lead by the mothers. Women exposed to lead during childhood may have significant stores of lead in their bones. If they do not consume adequate calcium during pregnancy, their bones release calcium as the fetus grows. As the calcium is released, lead is released as well. This lead can be transferred to the fetus—exposing the fetus' developing brain and nervous system at a critical time. Fetal exposure from this route has been demonstrated to cause measurable decreases in IQ.[25]

Sources of Children's Exposure to Lead

The most common source of lead exposure today is lead paint, found in older housing stock. As paint wears off, it contaminates the dust that clings to surfaces, toys and the fingers of children. Other sources of lead exposure include contaminated soil, traditional or folk medicines, and certain types of dishes. In recent years, however, parents have found a new source of anxiety regarding lead exposure: children's toys and other products, particularly those imported from China.

These concerns are justified. Since July 2006, the CPSC has issued at least 11 recalls affecting more than 6.7 million units of children's toy jewelry due to excessive lead content. Since 1998, CPSC has issued at least 29 recalls involving 157,962,000 pieces of toy jewelry due to high lead levels. Other products recalled during that time due to lead contamination include game pieces, candles, sidewalk chalk, and art kits. Consumers are acutely aware of recent recalls of popular toys found to contain lead paint, including Thomas the Tank Engine, Mattel's Barbie, and Fisher-Price's Dora the Explorer toys. The risk of harm to children from these toys is real: in 2006, a 4-year-old Minnesota boy died after ingesting a small Reebok shoe charm that was later found to be 99.1 percent lead.[26] The charm he ingested dissolved in his stomach, releasing the lead into his bloodstream.

Lead Must Be Removed from Toys and Other Children's Products

The American Academy of Pediatrics has consistently urged the Consumer Product Safety Commission (CPSC), the Environmental Protection Agency (EPA), and other agencies to take aggressive, proactive steps to minimize children's exposure to lead. The addition of lead to jewelry or toys is not in any way central or even necessary to the function or purpose of the product. For example, manufacturers add lead to jewelry to give it more weight or heft, rather than using a more expensive but safer metal. None of these factors represent a compelling rationale for including a poisonous substance in a product specifically designed for use by children.

The range of products covered by a ban on lead content must also be considered carefully. "Children's product" must be defined broadly enough to cover the full range of items capable of causing a serious hazards—not just toys or "toy" jewelry but also durable products such as furniture (cribs, strollers, high chairs, etc.) and products meant for the care of children (bath seats, gates, etc.). One of the first pediatric deaths attributed to lead paint was a child who chewed on the railing of his crib—in 1913.[4]

Finally, legislation should cover products meant or designed for use by or with children at least up through the age of 12. Children are susceptible to neurological damage from lead exposure throughout the development of their brain and nervous system. Their long "shelf life," or the period of time over which they can be exposed to and accumulate lead in their bodies, means that every exposure should be eliminated or minimized to prevent future harms. Finally, toys meant for older children

often find their way into the hands of younger siblings and other small children, posing a hazard to these children outside the object's target audience.

Federal Lead Standards

Federal agencies use a variety of standards for unacceptable lead content. This issue is complicated by the fact that lead uptake varies depending upon the route of exposure (ingestion, inhalation, skin contact, etc.) In considering existing guidelines, it is critical to bear in mind that many were set before research demonstrated the harmful effects of lead at low levels. There is no known safe level of lead exposure; as a result, exposure to lead below these levels should not be considered "safe."

- In 1978, the Consumer Product Safety Commission banned the manufacture of paint containing more than 0.06 percent lead by weight on interior and exterior residential surfaces, toys, and furniture.
- Based on that standard for lead paint, the CPSC's current voluntary standard prohibits toy jewelry to contain more than 0.06 percent lead by weight. The standard further requires manufacturers to test for the "accessibility" of lead, although surface accessibility may be irrelevant if an item is small enough to be ingested.
- The EPA requires water provided by public utilities to contain no more than 15 parts per billion of lead. The 1986 Safe Drinking Water Act Amendments banned the use of lead in public drinking water distribution systems and limited the lead content of brass used for plumbing to 8 percent.
- The EPA set guidelines for lead contamination of dust, limiting levels called "safe" to below 40 mcg/ft^2 for floors.[27] It is important to note that this is not a health-based standard; an estimated 20 percent of children exposed to floor dust lead levels at 40 mcg/ft^2 will have a blood lead level above 10 mcg/dL.[28]
- In response to reports of lead contamination in candies likely to be consumed frequently by small children, the Food and Drug Administration (FDA) set a maximum lead level of 0.1 parts per million (ppm). FDA has set different levels for other products; for example, dairy product solids may contain lead at no more than 0.5 ppm.[29]
- The FDA recommends a limit on children's lead intake in food to no more than 6 mcg/day. It is important to note that this is not a health-based standard; this limit is roughly equivalent to the amount of lead that would be expected to lower IQ by 1 point.
- FDA regulates lead content in cosmetics; for example, the colorant manganese violet may contain lead at no more than 20 ppm.[30]
- Airborne lead is regulated by EPA as a "criteria pollutant" under the Clean Air Act. The National Ambient Air Quality Standard for lead is 1.5 mcg/m^3, maximum arithmetic mean averaged over a calendar quarter.
- Both the National Institute for Occupational Safety and Health and the Occupational Safety and Health Administration set permissible limits for lead exposure in the workplace, but these guidelines are designed for adults and not appropriate for children.

Recommendations

To protect the health of our Nation's children, the CPSC must be given the tools it needs to fulfill its mission. In particular, nonessential uses of lead, especially in products to which children may be exposed, must be prohibited. The American Academy of Pediatrics recommends the following:

- The CPSC should require all products intended for use by or in connection with children to contain no more than trace amounts of lead.
- The Academy recommends defining a "trace" amount of lead as no more than 40 ppm, which is the upper range of lead in uncontaminated soil.[31] This standard would recognize that contamination with minute amounts of lead in the environment may occur but can be minimized through good manufacturing practices.
- "Children's product" should be defined in such a way as to ensure it will cover the wide range of products used by or for children. This standard should cover toys intended for use by or with children under the age of 12 years.
- The limit on lead content must apply to *all* components of the item or jewelry or other small parts that could be swallowed, not just the surface covering.
- Legislation or regulations should limit the overall lead content of an item, rather than only limiting lead content of its components. A single product may contain numerous components that could cumulatively contain a dangerous level of lead.

- The CPSC must be funded adequately. The President requested a budget of $63.2 million for CPSC in Fiscal Year 2008, which would require the agency to cut an additional 19 employees. This budget is insufficient to even allow the agency to continue current programs, much less expand its efforts. At its founding, the CPSC budget was $39 million. If the budget had kept pace with inflation, it would be $138.2 million today, more than double its requested allocation.
- An appropriately qualified CPSC chair must be nominated and approved in a timely fashion. The CPSC has been without a voting quorum of commissioners since January 2007, meaning it cannot take many regulatory, enforcement and other actions. The President's recent nominee to chair the commission withdrew from consideration after a public outcry regarding his qualifications.
- The authority of the agency to issue mandatory recalls and provide full information to consumers must be strengthened.

Conclusion

Our government can and must do more to ensure the safety of imported products, particularly those intended for use by or with children. A strong standard for lead content must also be set, since there is no known "safe" level of lead for children.[32,33] No study has determined a blood lead level that does not impair child cognition. Since any measurable lead level causes lasting harm, prevention of exposure is the only treatment.[34] Lead exposure is an important, unnecessary, and preventable poisoning.

The American Academy of Pediatrics appreciates this opportunity to submit testimony for the record of this hearing on import safety. If the AAP may be of further assistance, please contact our Washington, D.C. office.

References

1. Chemistry: WebElements Periodic Table. http://www.webelements.com/webelements/elements/text/Pb/key.html. Accessed March 31, 2004.

2. Lead Poisoning and Rome. http://itsa.ucsf.edu/~snlrc/encyclopedia_romana/wine/leadpoisoning.html. Accessed March 31.

3. Markowitz G, Rosner D. "Cater to the children": the role of the lead industry in a public health tragedy, 1900–1955. *Am J Public Health.* 2000;90(1):36–46.

4. Warren C. *Brush With Death: A Social History of Lead Poisoning*. Baltimore, MD: Johns Hopkins University Press; 2000.

5. Bellinger D. Lead. *Pediatrics.* 2004;113(4 (Supplement)):1016–1022.

6. Brent R. Environmental causes of human congenital malformations: the pediatrician's role in dealing with these complex clinical problems caused by a multiplicity of environmental and genetic factors. *Pediatrics.* 2004;113(4 (Supplement)):957–968.

7. Sadler TW. *Langman's Medical Embryology.* 6th ed. Baltimore, MD: Williams & Wilkins; 1990.

8. Mendola P, Selevan SG, Gutter S, Rice D. Environmental factors associated with a spectrum of neurodevelopmental deficits. *Ment Retard Dev Disabil Res Rev.* 2002;8(3):188–197.

9. Canfield RL, Henderson CR, Jr., Cory-Slechta DA, Cox C, Jusko TA, Lanphear BP. Intellectual impairment in children with blood lead concentrations below 10 microg per deciliter. *N Engl J Med.* 2003;348(16):1517–1526.

10. Lanphear BP, Hornung R, Khoury J, et al. Low-level environmental lead exposure and children's intellectual function: an international pooled analysis. *Environ Health Perspect.* Jul 2005;113(7):894–899.

11. Chen A, Dietrich KN, Ware JH, Radcliffe J, Rogan WJ. IQ and blood lead from 2 to 7 years of age: are the effects in older children the residual of high blood lead concentrations in 2-year-olds? *Environ Health Perspect.* 2005;113(5):597–601.

12. Centers for Disease Control and Prevention. *Managing Elevated Blood Lead Levels Among Young Children: Recommendations from the Advisory Committee on Childhood Lead Poisoning Prevention. Atlanta, GA: Centers for Disease Control and Prevention.*; 2002.

13. Dietrich KN, Ris MD, Succop PA, Berger OG, Bornschein RL. Early exposure to lead and juvenile delinquency. *Neurotoxicol Teratol.* Nov–Dec 2001;23(6):511–518.

14. Ris MD, Dietrich KN, Succop PA, Berger OG, Bornschein RL. Early exposure to lead and neuropsychological outcome in adolescence. *J Int Neuropsychol Soc.* Feb 2004:261–270.

15. Burns JM, Baghurst PA, Sawyer MG, McMichael AJ, Tong SL. Lifetime low-level exposure to environmental lead and children's emotional and behavioral development at ages 11–13 years. The Port Pirie Cohort Study. *Am J Epidemiol.* Apr 15 1999;149(8):740–749.

16. Nevin R. Understanding international crime trends: the legacy of preschool lead exposure. *Environ Res.* 2007;104(3):315–336.
17. Bhattacharya A, Shukla R, Dietrich KN, Bornschein RL. Effect of early lead exposure on the maturation of children's postural balance: a longitudinal study. *Neurotoxicol Teratol.* 2006;28(3):376–385.
18. Chiodo LM, Covington C, Sokol RJ, et al. Blood lead levels and specific attention effects in young children. *Neurotoxicol Teratol.* Apr 21 2007.
19. Bellinger DC. What is an adverse effect? A possible resolution of clinical and epidemiological perspectives on neurobehavioral toxicity. *Environ Res.* 2004;95(3):394–405.
20. Reed KJ, Jimenez M, Freeman NC, Lioy PJ. Quantification of children's hand and mouthing activities through a videotaping methodology. *J Expo Anal Environ Epidemiol.* 1999;9(5):513–520.
21. Ko S, Schaefer PD, Vicario CM, Binns HJ. Relationships of video assessments of touching and mouthing behaviors during outdoor play in urban residential yards to parental perceptions of child behaviors and blood lead levels. *J Expo Sci Environ Epidemiol.* 2007;17(1):47–57.
22. Plunkett LM TD, Rodricks JV,. Differences between adults and children affecting exposure assessment. In: Guzelian PS HC, Olin SS,, ed. *Similarities and Differences Between Children and Adults: Implications for Risk Assessment.* Washington, DC: ILSI Press; 1992:79–94.
23. United State Environmental Protection Agency. *Review of the National Ambient Air Quality Standards for Lead: Exposure Analysis Methodology and Validation.* Washington, DC: Air Quality Management Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency; 1989.
24. O'Flaherty EJ. A physiologically based kinetic model for lead in children and adults. *Environ Health Perspect.* 1998;106 Suppl 6:1495–1503.
25. Schnaas L, Rothenberg SJ, Flores MF, et al. Reduced intellectual development in children with prenatal lead exposure. *Environ Health Perspect.* 2006;114(5):791–797.
26. Centers for Disease Control and Prevention. Death of a child after ingestion of a metallic charm—Minnesota, 2006. *MMWR.* 2006;55(12):340–341.
27. Federal Register. Part III, Environmental Protection Agency. Lead; Identification of Dangerous Levels of Lead: Final Rule. 2001;66:1206–1240.
28. Lanphear BP, Weitzman M, Winter NL, et al. Lead-contaminated house dust and urban children's blood lead levels. *Am J Public Health.* 1996;86(10):1416–1421.
29. Food and Drug Administration. GRAS affirmation petition GRP 1G0371. http://www.cfsan.fda.gov/~rdb/opa-g037.html.
30. U.S. Food and Drug Administration. 21CFR73.2775. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=73.2775.
31. Friedland A, Johnson A. Lead distribution and fluxes in a high-elevation forest in northern Vermont. *J Environ Qual.* 1985;14:332–336.
32. American Academy of Pediatrics Committee on Environmental Health. Lead exposure in children: prevention, detection, and management. *Pediatrics.* 2005;116(4):1036–1046.
33. Centers for Disease Control and Prevention. *Preventing Lead Poisoning in Young Children.* Atlanta: CDC; 2005.
34. Centers for Disease Control and Prevention. *Preventing Lead Exposure in Young Children: A Housing-Based Approach to Primary Prevention of Lead Poisoning.* Atlanta: CDC; 2004.

Statement of AmeriSci Group, Midlothian, Virginia

Chairmen and Levin and Lewis, and Members of the Subcommittees, I am SiuMing Tomi Hong, Chief Executive Officer of the AmeriSci Group. I appreciate the opportunity to present this statement on the critically important issue of imported food and consumer product safety.

The AmeriSci Group is a U.S. company with over 20 years experience in analytical testing of product, food and environmental safety as well as crisis management. We routinely provide unbiased scientific data to risk managers in both government and industry responsible for making decisions that have a direct and immediate impact on public health and safety, as well as the overall well being of American citizens. Accredited by A2LA, AIHA, NVLAP/NIST, NELAC and several state agencies, we believe we are well positioned to provide an objective evaluation and to propose solutions to the current issues bearing on the safety of imported food and consumer products.

As concerned scientists and citizens of this great Nation, we at AmeriSci recognize that the current import safety climate, highlighted most recently by concern over the safety of products from China, has created an untenable level of uncertainty—uncertainty in the eyes of the consumer, of course, but also in the eyes of manufacturers and importers of food and other consumer goods. We also recognize that, if left unresolved, the current climate could erode the trust of consumers in the safety of all goods, not just those imported from China, as well as in the government's ability to protect its citizens.

Loss of consumer confidence in product safety has the potential to negatively affect domestic consumption and the economic well-being of our Nation, this fact highlights the synergy—or balance—between industry and commerce, science and government in providing a stable commercial environment where consumers have access to goods they can trust. This delicate balance, which has been able to deliver safe goods to American consumers for the greater part of the last century, must be maintained in today's global market place. We must recognize and address the new risks associated with the expansion of supply chains across geographic, cultural and national borders. Solutions for restoring this balance must be the product of good science, effective policymaking and a deep commitment to involve all stakeholders in the solution.

In seeking a workable solution, we generally support the principles and framework outlined in the September 10, 2007 Report to the President of the President's Interagency Working Group on Import Safety, in response to Executive Order 13439. In particular, we applaud the Working Group's foresight in proposing that the solution focus on "risks over the life cycle of" imported goods. Congress also has a significant role to play both by ensuring that these important issues are addressed in a public forum and by passing legislation that corrects gaps in the current law without imposing unnecessary costs and burdens on importers and consumers which could stifle creative private sector initiatives.

In seeking a viable and sustainable solution to the perceived "inbalance" in the present import safety arena, AmeriSci, like the Working Group, believes that the solution will come from establishing processes to assess risks at the source of the problem, not at the end of the supply chain—namely, a preventive approach. We must assess all potential risks at each tier of the supply chain and focus our efforts on first eliminating the most egregious risks. The end goal must be to create the necessary mechanisms that will allow risk assessment and risk management professionals to actively engage with manufacturers and importers in assessing and reducing risks along their supply chains.

At the same time, we believe there are four important areas that have been overlooked and must be addressed as we develop the tools to create such mechanisms:

1. **Lack of Clear Standards.** There is a lack of clarity of standards in regard to health risks and testing methodologies among U.S.-based companies and overseas manufacturing contractors and subcontractors. For example, during his recent visit to Washington, Vice Minister Wei from China's General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ) cited a situation where AQSIQ was measuring lead in the surface paint on toys when, in fact, the U.S. standard calls for measurement of the total lead content in the finished product. This difference or breakdown in technical information sharing continues to create challenges in the import safety process.
2. **Failure to Update and Communicate Standards.** Many current product safety standards were established decades ago, and have not been updated to reflect current risk-based science and manufacturing practices. For those standards that have been updated, the efficiency of government communication of these standards to manufacturers and exporters has been less than stellar, with significant lag times in the conveyance of information through commercial channels and delays in implementation of standards by producers. In addition, as new compounds of toxicological concern are added to the product safety target lists, the relevant information—such as compliance levels, testing methods and so on—has, in some instances, never even been received by the overseas contractors and subcontractors, leaving them to rely on an outdated standard.
3. **Understanding the Causes of Contamination.** It is crucial that we understand the underlying cause for the introduction of harmful substances into consumer products. In our view, there are two principal pathways for product contamination. The vast majority of cases result from poorly defined and poorly communicated safety guidelines. This so-called *passive contaminant introduction*, or PCI, into the supply chain can be addressed through education of all stakeholders, as well as through standards that address the most critical

threats to health and safety, and not just those which rise to the level of widespread media coverage.

The second area of concern is *active contaminant introduction* (ACI). We must recognize that unscrupulous producers or distributors can exist along the supply chain, as demonstrated by the apparent intentional introduction of melamine in the recent incident of pet food contamination. In the highly competitive market of outsourcing, pricing of goods has become the major source of competition. There are those that will use substandard materials or even dispose of hazardous materials in an effort to increase profit margins. This threat must not be ignored. It has happened and it will happen again. Only systematic testing at the source of manufacture as well as at high risk links along the supply chain, will enable us to identify this threat before it enters international channels of trade.

4. **Contaminant Concentration.** Stakeholders must review concentration levels and develop effective compound target lists. For example, the current U.S. standard for Lead in Toys, 600 mg/kg, represents a value that is exceedingly high from a toxicological and environmental standpoint. If, for example, another material such as construction debris were determined to have a similar level of lead, State and Federal hazardous waste disposal guidelines would mandate additional studies, likely resulting in the material being declared "hazardous," and too toxic for disposal in a landfill. In essence, the current regulations tell American consumers that a toy containing lead is too toxic to dispose in a landfill, but it is okay to give that same toy to our children.

Additional concerns come about from the lack of broad-spectrum heavy metals testing in consumer products. Although a significant amount of media attention has driven numerous proposals for updating Lead in Toys standards, far more toxic elements have received little to no attention or review. For example, cadmium—an element having toxicity approximately 5 times that of lead for some endpoints, is occasionally found in colored plastics and rubber materials at levels in excess of 1,000 mg/kg. Consequently, it is necessary to avoid the very myopic focus solely on lead as the only hazard associated with pigments/materials used in consumer products. Legislation may be required to ensure that solutions are in place to correct these deficiencies. Finally, I would like to discuss how so-called "third parties" can contribute to successful resolution of the current situation. While there has been much discussion of applying a private sector 3rd party solution, it is essential that a distinction be made between 3rd Party Testing versus 3rd Party Certification.

A 3rd Party Certifier provides the function of quality systems oversight in the form of accreditation of a business operation, ensuring that the performance is in conformance with an industry-specific and/or international standard (e.g., ISO 17025, ISO 9002).

3rd Party Testing is performed by a 3rd Party Certifier-approved testing facility, capable of generating an industry-recognized testing report of compliance and conformance with manufacturing design specifications and healthy & safety guidelines.

Although hundreds of domestic and foreign 3rd Party Testing facilities are available for the ongoing evaluation and validation of a variety of food and consumer products, there is currently no U.S. agency or universally accepted not-for-profit organization providing 3rd Party Certification services for the toy industry.

AmeriSci already has the framework for a not-for-profit private sector 3rd Party Certifying body in place. We will model the operation of this accrediting body after other successful industry-specific agencies such as the American Industrial Hygiene Association (AIHA) and UL Corp. The added benefit of such an accrediting agency will be the ongoing training and sharing of relevant procedural and compliance standards information. This accrediting body will also provide consulting and training services, which will prove especially helpful for the small and mid-size manufacturers lacking the internal resources to develop their own rigorous quality systems programs.

Through implementation of the improved communication and coordination by our certification program, AmeriSci will be able to coordinate improved import safety efforts through rigorous product testing programs, development of standards & distribution of information mutually agreed upon by CPSC and the product industry, similar to FDA/USDA and EPA/OSHA models.

As an extension of our certification program for consumer products, AmeriSci will facilitate the ongoing development of programs geared toward restoring consumer confidence in the marketplace.

One of the extensions of the AmeriSci program associated with consumer product safety will include the development of a "Consumer Product Safety Data Sheet" (CPSDS). Drawing it's framework from existing CPSC references and EPA's man-

dated Material Safety Data Sheets (MSDS), this labeling program will provide a UPC barcode-specific online database for all consumer products. This CPSDS database will be inclusive of relevant product information and material specifications, health and safety hazards, compliance certifications, recall information, point of origin, etc. By allowing this information to be freely available online, the end user will feel a greater sense of awareness and accessibility to information about the products they purchase. An addition critical benefit of this database is its ability to maintain the confidential identity of sub-manufacturers in the supply chain, allowing for traceability and rapid determination of root causes in the event of product quality failures and recalls. In summary, the benefits from implementation of the AmeriSci certification programs are:

- 3rd Party Accreditation of manufacturers and producers focusing at the production level
- Rapid dissemination of relevant standards and compliance information
- 3rd Party on-site quality assessment, sampling and subsequent testing of products
- Supply chain evaluation and monitoring
- Consumer Product Safety Data Sheet generation, cataloguing and distribution

The AmeriSci Group thanks the Subcommittees for their leadership and commitment in the efforts of restoring consumer confidence and improving imported product safety. You have our commitment to continue to develop pathways and processes for increased consumer confidence in the safety of imported products and goods.

Thank you for your consideration of our views.

Statement of Catfish Farmers of America, Indianola, Mississippi

Chairmen Levin and Lewis and Members of the Committee, thank you for this opportunity to submit testimony to the Ways and Means Subcommittees on Trade and Oversight. As a catfish farmer from Yazoo City, Mississippi and President of the Catfish Farmers of America, I am pleased to be able to provide a unique perspective on the safety of seafood imports from Asia, specifically China and Viet Nam.

Catfish Farmers of America was established in 1968 to represent the U.S. Farm-Raised Catfish industry, which is now the largest aquaculture industry in the Nation. Based in Indianola, Miss., Catfish Farmers of America represents catfish farmers, processors, feed mills, research and other entities involved in the industry. The states of Mississippi, Alabama, Arkansas and Louisiana account for 95 percent of commercial catfish production in the United States. CFA has over 800 members, located in more than 20 states. The U.S. catfish industry is a critical component of the agricultural economy in many states and employs thousands of workers—including family farmers—in a region that lacks employment opportunities. This vertically integrated industry processed well-over 600 million pounds of fish annually prior to the onslaught of Asian imports. With the multiplier effects as provided by nationally respected economists, the total economic value of our industry was close to $3 billion annually.

The domestic farm-raised catfish industry is very transparent. By that I mean U.S. farm-raised catfish which are raised for consumer consumption can be traced throughout the production and marketing chain. The U.S. catfish industry has employed rigorous protocols to assure that any particular lot of catfish can be traced from the consumer's plate all the way back to the production pond of origin and every step along the way. The ponds are highly maintained and monitored with only limited use of approved treatment regimes. The product that we produce is antibiotic-free, safe and healthy.

The American people have grown to trust U.S. Farm-Raised Catfish, and made it a part of their "healthy diet". Catfish is America's sixth most popular seafood and seventy percent of this product is consumed in restaurants. Furthermore, U.S. Catfish is the number one aquaculture, or farmed fish in our country.

In recent years, the U.S. catfish industry has been seriously threatened by imported frozen fish fillets from Asia. This problem began with Vietnamese exporters flooding the market with unfairly priced products falsely labeled as catfish. Our industry was so seriously damaged by these trade practices, that in 2003, the U.S. Department of Commerce and the International Trade Commission issued an anti-dumping order against Vietnam.

However, even with tariffs in place, Vietnam continues to expand its exports to the United States. China has now become a major exporter of catfish. Beginning in 2004, China began to export limited quantities of catfish to the United States, but

in late 2006, Chinese export volume surged dramatically. By the end of 2006 China had sent 14 million pounds of frozen fillets of catfish and catfish-like species to the United States.

Catfish imports have increased by 600 percent over five years and in the last year alone, there has been a 304 percent increase from China. This import surge from China has continued into 2007 and by the end of May this year, importers had brought into the U.S. market over 14.3 million pounds of Chinese catfish and like species, more than the record volume they had imported in all of 2006. By the end of May, Chinese imports had captured 18 percent of the market (up from only 4 percent for the same period in 2006, and only 2 percent for all of 2005).

The Chinese have made inroads by pricing their fish well below the price of U.S. fillets and by employing banned antibiotics to sustain their product artificially. On average, in 2006 Chinese frozen fillets of catfish were brought into the U.S. market at prices that were about 33 percent below the price of domestically produced fillets. In 2007, that differential has increased to over 39 percent. This price differential is the result of not only the very low wage rates in China, but also because the Chinese government has targeted aquaculture as a growth sector. These factors, coupled with currency valuation practices that are beneficial to exporters, along with China's lack of enforcement of health and safety standards, has created an extremely difficult situation for our industry.

As it has been widely reported, the Food and Drug Administration (FDA) currently inspects less than 1 percent of all imports. As the representative for the industry, I respectfully suggest the FDA will *never* be capable of fully assuring the safety of imported catfish. By its own admission, the FDA has repeatedly claimed that no amount of appropriations can ever assure 100 percent inspection of imports. While we commend the FDA for its issuance of the recent import alert on seafood from China, that alert has been examined by other Committees in the U.S. House of Representatives and U.S. Senate and has been found to be inadequate in protecting the consumer. However, many states are eager to take on the responsibility of inspecting imported catfish. CFA believes a pilot program between state regulatory bodies and the FDA allowing for state inspection of catfish would better protect the consumer, while allowing for further examination of best practices at the FDA by the Congress.

We believe that FDA should also work more closely with those agencies that do monitor the ports of entry into this country. FDA's own testimony shows that with over 365 ports of entry, the FDA does not have the resources to be present at every point of entry, but Customs and Boarder Protection (CBP) maintains a presence at those ports. CBP has the resources and the database to help the FDA track shipments and importers. In fact, the USDA works closely with CBP and its import database on meat, poultry and egg shipments entering the United States, while the FDA does not have a similar relationship. Coordination of FDA and CBP will be a better use of FDA's limited resources while improving consumer safety.

As has been said many times over the past few months, "the U.S. cannot inspect its way out" of the food safety situation we are currently facing. As an industry, we could not agree more. Despite the efforts of domestic distributors to work with seafood exporting nations such as Vietnam, these seafood exporting countries continue to use unsafe and often dangerous farming practices when it comes to producing catfish. Repeatedly, traces of antibiotics and carcinogens are found on those shipments of catfish that the FDA is able to detain for inspection. In fact, Japan and the EU continue to raise concerns about the use of banned antibiotics and malachite green in Vietnamese seafood despite the assurances from Vietnam and domestic distributors that such substances are no longer being used in their seafood production. We respectfully ask that Congress look to the import safety regimes of other nations, such as the EU and Japan. In every instance, those regimes demand that imported food meet equivalent safety standards to those required of the domestic industry. Even our own USDA inspection arm, the Food Safety and Inspection Service (FSIS) demands verification that exporting countries' regulatory systems for meat, poultry and egg products are equivalent to that of the U.S. and that products entering the U.S. are safe and wholesome, yet the FDA does not require importing countries of all other food products to meet a U.S. food safety equivalent. We believe the FDA should work with FSIS to replicate their import enforcement regimes at the FDA.

Consumer confidence in imported catfish will also increase with a requirement of traceability. By that I mean tracing the product back to its production pond of origin as we as domestic producers are able to do. This will allow for greater control over the product and elimination of those producers in the import market who are subjecting the American people to unsafe catfish.

Furthermore, the American consumer deserves Country of Origin Labeling in restaurants. As you well know, Federal law requires that seafood sold in grocery stores be labeled by its country of origin, yet there is no corresponding requirement for fish served in restaurants. Applying this law to restaurants will better allow the consumer to make educated choices about the foods they are consuming. It is by no means a cure-all, but a recent poll sanctioned by the Catfish Institute indicated that 96 percent of consumers want to know the origin of the catfish that they consume in restaurants. Other national polls have also made it resoundingly clear that U.S. consumers are demanding the right to make informed decisions that the food they order is safe to eat. We are not saying that fairly traded catfish should not be imported, but that it needs to be raised in a manner which ensures a safe product that is clearly labeled so that the consumer knows what they are purchasing.

Chairmen Levin and Lewis and Members of the Committee, I thank you for this opportunity to submit written testimony to your Subcommittees. In this time of heightened food safety concerns, we ask that importers of catfish play by the same rules that domestic producers must play by in order to protect our industry and the American consumer. This can only be accomplished with the proper support from Congress. I thank you for your leadership on this issue.

Statement of Underwriters Laboratories

Underwriters Laboratories Inc. (UL) is pleased to submit testimony for consideration by the Subcommittees on Oversight and Trade of the full Committee on Ways and Means. This statement on import safety issues addresses the important role government authorities, including U.S. Customs and Border Protection (CBP) and Immigration and Customs Enforcement (ICE), play in identifying dangerous and noncompliant products at U.S. borders, seizing products, and bringing perpetrators to justice. UL has worked closely with CBP and ICE for more than a decade to identify and seize products bearing the UL Mark and also prosecute offenders to the fullest extent of the law; our experiences working to seize and destroy counterfeit products have shaped the recommendations found in this testimony. UL is pleased to see increased attention being given to product safety in the United States, and believes that U.S. government support in this area will help focus attention on identifying root causes of safety hazards recently associated with certain imports, in addition to crafting proper solutions. The remarks below highlight current product safety challenges and their interaction with standards development and certification issues. It is UL's hope that the committee will strongly consider the recommendations of this submission.

I. Underwriters Laboratories in Brief

Underwriters Laboratories (UL) Inc. is an independent, not-for-profit product safety certification organization that has been testing products and writing safety standards for more than a century. It was founded in 1894 with a mission of testing for public safety, as defined by its Articles of Incorporation, and strives to ensure that public health and safety is protected through its standards development activities and product conformity assessment services. UL has developed and maintains more than 1000 product-based Standards for Safety, approximately 80 percent of which have achieved American National Standards (ANS) status.[1] UL is a global company, with more than 25 affiliates worldwide, serving more than 71,000 manufacturers in 104 countries. In 2006, UL evaluated over 19,000 different types of products, ranging from electrical goods to fire protection equipment, to medical devices and lasers. Food products and non-electrical toys are not among the products that UL currently tests and certifies.

The UL Anti-Counterfeiting Program

Recognizing that consumers, retailers, regulators, manufacturers and distributors look to the UL Mark to determine if products comply with relevant safety standards, UL established a team of professionals dedicated to protecting UL's intellectual property. Since 1995, UL's anti-counterfeiting team has worked with law enforcement and educated customs officials globally about how to identify legitimate UL certification Marks, as well as common elements of frequently counterfeited products.

[1] ANS is a designation conferred by the American National Standards Institute (ANSI) upon standards submitted by ANSI-accredited Standards Development Organizations (SDO). The ANS designation is awarded after the opportunity for public review and comment, and a certification by the SDO that due process was followed in the development of the standard.

The cost of product counterfeiting is estimated at $500 billion (USD) annually, or roughly 5 to 7 percent of global trade. Many of the counterfeit products entering the global market can directly and dramatically affect the safety of the people who use them. UL practices a zero-tolerance policy regarding counterfeit UL Marks. UL does not consent to the import, export or manipulation of seized merchandise bearing a counterfeit UL Mark. When products with a counterfeit UL Mark are discovered, they are confiscated and disposed of in compliance with all applicable laws.

I. Product Safety Challenges

A. Adulterating Products After Certification

Recent import product safety incidents (e.g. food and toys) require an examination of the current U.S. infrastructure to ensure import compliance and consumer protection. It is important to note that food and (non-electrical) toys are currently not required by any U.S. government agency to be tested and certified by an independent laboratory in order to be sold in the U.S. marketplace. While voluntary standards for toys have been developed by the toy industry, and are widely used today, the Consumer Product Safety Commission (CPSC) does not require that toys be tested and certified by independent laboratories. Therefore, the establishment of working programs involving third-party certification for toys and other products may be considered as a means to provide additional oversight for products that the U.S. government deems as posing significant risks to consumers.

UL believes independent third-party testing and certification of products is a proven model for mitigating potential hazards associated with manufactured products. The UL certification process is a closed-loop system, providing a "video perspective" of a product from design to distribution, rather than a mere "snap-shot." During the product investigation phase, UL engineers thoroughly test and evaluate the product to the relevant standards that apply to it. If the product complies with the relevant standards, UL will authorize the manufacturer to use the UL Mark. However, UL's engagement with the product does not end there.

UL's rigorous Follow-Up Services (FUS) program is designed to ensure ongoing compliance of products. UL will conduct an Initial Product Inspection (IPI), or first inspection, at the manufacturer's site for new manufacturers, and also for existing manufacturers when they establish product certification in a new area. Manufacturers who utilize the UL Mark also submit to unannounced factory inspections by UL representatives, where product is pulled from the manufacturing line and tested to make sure that production continues to comply with the relevant standards. As part of the inspection, UL representatives will verify that key elements of the certified product have not changed over time, and that critical components of the product are also compliant with the relevant standards.

The FUS program has been an effective tool for UL to identify and address situations where manufacturers have altered their product without notifying UL. In some cases, changes are made that may not affect the overall safety of the product. However, as the certifier, UL retains the right to evaluate product changes and make this determination if the UL Mark is to be used. In other cases, manufacturers have intentionally adulterated products after certification was issued, in order to cut production costs and maximize profits. Whether the adulteration of products is independently orchestrated by manufacturers or carried out to satisfy the demands of importers for cheaper products, the result often has a major impact on the products' compliance to relevant safety standards.

UL's FUS program is one means for identifying non-compliant and potentially dangerous products. In 2006, UL completed approximately 600,000 inspection visits in over 100 countries. UL also has a robust Field Report System, whereby UL representatives investigate any claims of noncompliance made by consumers, manufacturers, regulatory authorities and others. If UL receives notification that a product bearing the UL Mark is noncompliant or was involved with a safety incident, action is taken to identify the root cause of the concern. UL representatives will evaluate the product to determine whether the issue is the result of unintentional or intentional practices at the manufacturer's site, a flaw in the standard(s) applied to the product, misapplication or misuse of the product in the field, or some other cause. Once this evaluation is completed, UL takes steps to rectify the problem, working closely with the stakeholders involved, including the manufacturer, retailer, and regulatory authority. If necessary, UL will issue a public notice, detailing potential hazards associated with the product and any actions that are being taken to deal with them.

UL also has a proactive Market Surveillance program in place, which involves UL representatives visiting various retail outlets throughout the country each year, and searching the Internet, purchasing products bearing UL Marks and testing them to verify compliance with the appropriate requirements. UL's Market Surveillance pro-

gram is an effective tool to ensure that products remain compliant when they actually reach consumers.

In some cases, UL has determined that enhanced programs are necessary to ensure compliance for certain products. In recent years, UL has implemented such programs for products such as decorative lighting strings, and flexible cords. In the case of decorative lighting strings, UL's Follow-Up Services Program over the years noted frequent incidences of noncompliance, often because such products were adulterated after certification to make them more cost effective to produce. One common adulteration is to limit the amount of expensive copper used in the wiring of the products, which causes the wire gauges to be thinner than required in the product standards, in effect posing significant fire hazards. After discovering these noncompliance trends, UL put in place a "two-strikes" policy for these products. If a manufacturer's product is found to be noncompliant two times after UL certification is issued, UL will revoke the right of that manufacturer to use the UL Mark. If UL finds that a manufacturer has willfully counterfeited, UL will withdraw certification immediately and will refuse to do business with that manufacturer ever again. It is perhaps an uncommon industry practice to fire one's customers, but UL's enhanced compliance programs are, in fact, designed to do just that if a manufacturer is not acting in good faith or is generally ineffective in maintaining production of compliant products over time.

B. Unbranded, Counterfeit Products in the U.S. Market

Another product safety challenge, beyond products that are adulterated after they are tested and certified, is the proliferation of unbranded and counterfeit products in the U.S. marketplace. Over the years, UL has witnessed a significant and growing problem of counterfeit goods (electrical products in particular) available for sale in the U.S. marketplace. It is clear that counterfeiters can and will penetrate the market with poor quality, noncompliant and hazardous products that can endanger the lives and properties of U.S. consumers.

A good example is low-cost, high-volume extension cords that can typically be purchased for under a dollar at discount stores across the country. These counterfeit products can cause significant property damage, casualties, even death. These types of counterfeit electrical cords are dangerous because to properly conduct current, an electrical cord requires wire of a certain thickness. Counterfeit extension cords have copper wiring so thin that when electrical current is applied they will eventually overheat, melt and potentially catch fire. It is worth noting that CBP vigilance and awareness has been able to determine and seize counterfeit extension cord wiring product and thousands of similar cords. Fire suppression devices, such as fire sprinklers, bearing counterfeit certification marks can also pose a severe health and safety risk to the consumer because life safety is ultimately undermined. Substandard components and shoddy manufacturing processes add to the counterfeiters' profit margin while putting American consumers at risk.

For over a decade, UL has worked-closely with U.S. Customs and Border Protection (CBP) and Immigration and Customs Enforcement (ICE) to identify and seize products bearing counterfeit UL Marks and also prosecute offenders to the fullest extent of the law. Since 1995, more than 1,500 seizures of counterfeit UL products have been made by CBP, resulting in millions of counterfeit products being blocked from entry into the commercial marketplace (a routine inspection at the San Francisco International Airport by a CBP officer of five suitcases containing "undeclared" goods revealed 1500 counterfeit circuit breakers that posed a serious potential fire hazard). UL also continually conducts training for CBP and ICE at key ports of entry throughout the United States, and works closely with the Royal Canadian Mounted Police (RCMP) in Canada.

While UL's Anti-counterfeiting Program, with support from CBP, ICE, DOJ and other government and law enforcement agencies, has amassed several success stories over the years combating counterfeiting problems, additional resources for such groups is necessary in order to continue this positive track-record. With national security concerns such as terrorism stretching the resources and time of our import safety authorities, it is important for the United States to maintain its commitment to safeguarding the public from counterfeit products. UL strongly recommends strengthening CBP with additional personnel, training dollars, and stricter criminal and civil penalties for counterfeiters, especially those that counterfeit third-party certification marks. In the past, UL has observed a general decrease in the number of dedicated CBP officers at U.S. ports, and would encourage additional staff and resources to be stationed at these ports as a deterrent to counterfeiters.

UL also supports measures that would help CBP keep pace with the sophistication of counterfeiters. This means investing in training to help CBP staff understand changing authentication technologies, and investment in equipment to readily

assess the authenticity of product and certification marks. This will help CBP capture copies and look for successfully duplicated security features. UL has supported increased risk-based modeling in cargo screening for trafficking of counterfeit goods, and UL supports technology-based solutions that make CBP processes more streamlined and effective. It is important to note that technology works to the benefit of counterfeiters as well: this is why the hands-on inspection of cargo as it crosses our borders is still vitally important.

In June 2007 the Coalition Against Counterfeiting and Piracy (CACP) released a multi-faceted set of recommendations to further combat counterfeit goods. The CACP, of which UL is a member, is a broad group established to increase understanding and awareness of counterfeiting and piracy issues by working with the legislative and executive branches to drive greater government-wide efforts. In general, the CACP proposals provide for an improved strategy, new legal tools and more resources at the U.S. Department of Homeland Security and other agencies and Federal entities across the spectrum to better address and respond to counterfeit and pirated goods. Beyond what has been mentioned above, as it relates to CBP and ICE, the CACP proposals call for training and deploying a new cadre of CBP enforcement officials whose primary responsibility is to protect against illegal importation and smuggling of counterfeit and pirate goods. Other recommendations include staffing and office improvements, such as increasing funding for the CBP Fines, Penalties and Forfeitures (FPF) office as well as other needed regulatory and statutory reforms to improve the collection of civil fines imposed on importers of shipments of intercepted counterfeit products. These and other recommendations will contribute to stopping counterfeit goods and to the ultimate goal of increased import product safety. UL urges the legislative adoption of these proposals. UL also supports legislation entitled the "Intellectual Property Rights Enforcement Act" (S. 522/H.R. 3578) introduced by Senator Bayh and Representative Sherman. The legislation increases the coordination among Federal agencies charged with intellectual property rights enforcement, strengthens international enforcement, and calls for the creation of a strategic plan to address intellectual property theft.

C. Products Found to be Non-Compliant with Voluntary Standards

Mandatory product safety standards exist for a variety of industries to protect the public from unsafe imports and non-compliant product that may get shipped to U.S. ports. However, recent events have shown that oftentimes products are not compliant with available U.S. voluntary standards widely used by the industry.

The United States is unique to the world in many ways, including the fact that it relies heavily on the private sector for voluntary standards development, as well as product safety testing and certification services. Under the auspices of the 1996 National Technology Transfer and Advancement Act (NTTAA), U.S. government agencies are encouraged to rely on voluntary consensus standards (VCS) and conformity assessment practices whenever applicable and appropriate. While our government generally has not driven the standards development process, it has been an active participant and partner. Federal, State, and local governments develop and issue procurement specifications and mandatory codes, rules, and regulations. The U.S. system, although decentralized, effectively serves the needs of all stakeholders. It promotes comprehensive expertise by encouraging participation of all public and private technical experts. Openness, balance, consensus, and due process are the fundamental principles of the American National Standards process.

Since the private sector drives standards development in the United States, private bodies maintain ownership of the intellectual property contained in most of the standards used in the U.S. marketplace. While this has created challenges to forming one, central repository for U.S.-based standards, private sector standards developers have strived to make their standards readily available to users in the United States, and abroad. All UL standards are available and easily accessible on our public website. UL recently made all of its published standards available to our customers, free of charge. UL also formalized a memorandum of understanding (MOU) structure in 2006 to provide UL standards, free of charge, to national standards bodies in developing countries, to use in their committees and also reference in their own national regulations.

UL and the U.S. Consumer Product Safety Commission (CPSC) have long been partners in carrying out our common mission to safeguard the public from product safety hazards. With regard to cooperation between the CPSC and the CBP, UL would note the proposal offered by CPSC Acting Chairman Nord entitled the "Product Recall Information and Safety Modernization" (PRISM) proposal, address changes to the Commission's original authorizing act. A specific PRISM proposal would further allow CPSC to block non-complying imports into the United States. Currently, CPSC can only block entry of products when imports do not meet manda-

tory requirements. Under the PRISM proposal, CPSC or CBP could block entry of imports failing to comply with certain voluntary standards (upon which CPSC would formally rely). The provisions, moreover, would require the importer to post a bond sufficient to cover the cost of destroying confiscated shipments of product. UL commends this provision, as it provides added incentives for better supply chain management, and urges strengthening the cooperation between the CPSC and CBP.

III. Conclusion

CBP and ICE officers are an important line of protection in the fight against counterfeit and unsafe products. UL appreciates and applauds the dedication of CBP and ICE to protecting the American public and it is critically important to remain vigilant: while third-party certification works for many industries, and vigorous follow-up is able to catch a significant amount of non-compliant product, it is crucial that port authorities be adequately resourced, staffed and have strong tools to address counterfeit and unsafe products. CBP and ICE must be adequately supported to sustain the fight against not only terrorist activity, but also the more subtle threats of counterfeits that ultimately jeopardize and undermine the American way of life. UL would be pleased to remain a resource to the Committee on Ways and Means on this and other matters of interest.

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