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HEARING TO REVIEW THE TECHNOLOGIES IN THE MEAT INDUSTRY

HEARING

BEFORE THE

COMMITTEE ON AGRICULTURE
HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

FIRST SESSION

OCTOBER 30, 2007

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HEARING TO REVIEW THE TECHNOLOGIES IN THE MEAT INDUSTRY

TUESDAY, OCTOBER 30, 2007

HOUSE OF REPRESENTATIVES,
COMMITTEE ON AGRICULTURE,
Washington, D.C.

The Committee met, pursuant to call, at 1:32 p.m., in Room 1300 of the Longworth House Office Building, Hon. Collin C. Peterson [Chairman of the Committee] presiding.

Members present: Representatives Peterson, Etheridge, Boswell, Baca, Scott, Cuellar, Costa, Boyda, Gillibrand, Kagen, Pomeroy, Barrow, Goodlatte, Lucas, Moran, Rogers, Musgrave, Neugebauer, Walz, Conaway, Schmidt, and Smith.

Staff present: Nathan Fretz, Alejandra Gonzalez-Arias, Chandler Goule, Tyler Jameson, Rob Larew, John Riley, April Slayton, Kristin Sosanie, Patricia Barr, John Goldberg, Alise Kowalski, Kevin Kramp, Pam Miller, Pete Thomson, and Jamie Weyer.

OPENING STATEMENT OF HON. COLLIN C. PETERSON, A REPRESENTATIVE IN CONGRESS FROM MINNESOTA

The CHAIRMAN. We have a vote in about 10 minutes, so I want to get started anyway and then we will probably have to take a short recess. Good afternoon and welcome to today's hearing of the House Agriculture Committee. I want to thank the witnesses for being with us here today. And today's hearing is an opportunity to hear from those who develop, use, and regulate technologies used in the meat industry from slaughter through packaging. I view this hearing today as an informative, educational hearing. This came about because of a presentation that was done for me and my district where I was given an overview of this technology in all different aspects. I learned a lot of things that I did not know. And I felt that it would be useful for the Members to have this overview to get a better understanding of what the issues are and what the different technologies are. So we are actually going to have some packaging here that is going to be passed around for you to take a look at. And I just thought it would be good, given all the focus there is on food safety, for us to have a better understanding. So I have asked the folks that use this, work with it, develop it, to come in and explain to us the pros and cons of the different technologies. And then also hear from the regulators and scientists that have looked at this and approved it and so forth through the rulemaking process. We could end up having more hearings on this where we would at that time bring in the advocacy groups, consumer groups, farm groups, other folks that have different view-

points and axes to grind to come in and give their points of view later on. But what I am interested in today is really educational, informational and I hope everybody can view it that way.

I would say that one of the people that have been involved in this issue, I believe their name is Kalsec®, was invited to come twice by this Committee. They have not seen fit to be here today and I wanted to make it clear that I am disappointed in that because I wanted to have everybody that has been involved in this issue. They are the company that actually petitioned the FDA to change the current system and so it is unfortunate that, for whatever reason, they didn't want to be here.

I also want to welcome today the FSIS Administrator Almanza, who will be testifying. This is his first opportunity to testify at the Agriculture Committee and he will be providing an overview of the agency's activities to improve and encourage industry to implement new technologies that improve food safety.

And I think that our interest in this Committee is that whatever we end up doing in this regard improves food safety, makes food safer for the American people and is based on sound science and developed in public view, so everybody can understand how we get where we are.

[The prepared statement of Mr. Peterson follows:]

PREPARED STATEMENT OF HON. COLLIN C. PETERSON, A REPRESENTATIVE IN CONGRESS FROM MINNESOTA

Good afternoon and welcome to today's hearing of the House Agriculture Committee. Today's hearing is an opportunity for the Committee to hear from those who develop, use and regulate technologies used in the meat industry from slaughter through packaging.

Over the past several decades, technology has improved the quality and safety of meat products available to consumers. We have moved from an inspection system that relied on sight and smell to a system that uses microbiological testing for dangerous pathogens. Technology has increased the shelf life of meat products and reduced costs both for processors and consumers.

I would like to welcome FSIS Administrator Al Almanza who will be testifying today. This is his first opportunity to testify at the Agriculture Committee, and he will be providing an overview of the agency's activities to approve and encourage industry to implement new technologies that improve food safety.

My purpose for holding this hearing is to educate the Committee and the public about the development, use and regulation of new technologies in the meat industry. I appreciate our witnesses for being here today and look forward to their testimony.

The CHAIRMAN. With that, again, I would welcome all the witnesses and I would be glad to recognize my good friend, the Ranking Member from Virginia, Mr. Goodlatte.

OPENING STATEMENT OF HON. BOB GOODLATTE, A REPRESENTATIVE IN CONGRESS FROM VIRGINIA

Mr. GOODLATTE. Well, thank you, Mr. Chairman. I appreciate your holding this informational hearing and I would like to extend my gratitude to those witnesses who have traveled to Washington to appear before the Committee.

Today the Committee will be considering questions related to certain packaging technologies utilized in the meat and poultry industry. Specifically, we will be discussing modified atmosphere packaging using carbon monoxide. Over the last couple of years, several proposals have been introduced as amendments, stand-alone bills or as a part of a larger legislative initiative that would impose re-

strictions on the use of carbon monoxide packaging in meat, poultry and seafood. Other food uses of this technology would be unaffected by these proposals.

While I recognize that there may be some legitimate questions regarding the applicability any new food technology has, I would underscore the fact that the Congress has established procedures wherein experts within the regulatory agencies, operating in many cases with the advice of the scientific community, conduct extensive evaluations of these technologies before rendering a decision on their safety. The Congress of the United States is not a scientific body. We have neither the expertise nor the resources to conduct safety evaluations on food technologies. Having established a transparent, science-based process, it is essential that we allow this process to operate.

I do think it is important that the Members of the Committee be assured that that process is operating and that the people who are working in it are fully aware of what the important issues are that they are addressing and that is why I think it is very important that we hear from these witnesses today.

So Mr. Chairman, I thank you and yield back.

The CHAIRMAN. I thank the gentleman.

I would ask that all other Members submit their statements for the record.

[The prepared statements of Messers. Boswell, Baca, Graves, and Smith follow:]

PREPARED STATEMENT OF HON. LEONARD L. BOSWELL, A REPRESENTATIVE IN CONGRESS FROM IOWA

I would like to thank the Chairman, Mr. Peterson and Ranking Member Goodlatte for holding this important hearing today and would like to give a special thanks to our witnesses for offering their insight into the current technologies in the meat industry. I look forward to hearing your testimony.

As Chairman of the Livestock, Dairy & Poultry Subcommittee oversight of the new technologies in the meat industry is of great interest to me.

The witnesses today will give us an accurate picture of what the industry is doing today and hopefully where we can expect to go in the future.

Today we will hear about high and low oxygen packaging, case ready, and Modified Atmosphere Packaging (MAP), amongst others. I am hopeful this hearing will not solely focus on MAP technologies but all the new technologies that the industry is currently doing and what we can expect to see as we look to the future in meat packing.

I would specifically like to welcome Dr. Joe Sebranek from Iowa State University. As a leader in animal and meat science I look forward to the scientific background he will be able to offer here today.

The United States is in a very unique position; we have the safest, most plentiful, and most affordable food supply in the world. If we wish to continue to pay the lowest percentage of disposable income of developed nations we must continue to strive to find the next new technology, the best innovation.

Once again I would like to thank our witnesses and look forward to their testimony.

PREPARED STATEMENT OF HON. JOE BACA, A REPRESENTATIVE IN CONGRESS FROM CALIFORNIA

Chairman Peterson and Ranking Member Goodlatte:

I am pleased to be here today to discuss technology in the meat and meat packaging industries, and the best possible methods to ensure America's consumers are eating only the safest products available.

I thank the Chairman and Ranking Member for convening this hearing and hope we will be able to gain insight into the different options available for the packaging of fresh meat—and the advantages and disadvantages of each.

I also want to thank each of our witnesses for coming here today and taking time from their busy schedules to help us in Congress better understand this often complex issue.

Everyone in this room is aware of the recent recalls of *E. coli* tainted beef from the Topps Beef Company in New Jersey.

We are here today to explore the proper balance between innovations in food technology and the safety of America's consumers.

We are also here to ensure the economic security of America's cattlemen and the meat packaging and cutting industries.

This is an issue of the utmost importance. We must keep America's beef supply safe.

In recent months, we have had recalls of foreign products ranging from pet food, to toothpaste, to toys. The last thing we need is to become reliant on foreign countries for our meat and beef needs.

Mr. Chairman, all the Members of this Committee know that perhaps the most important part of our job is to keep the American consumer safe.

We must find a way to do this without reducing the quality of our products, and without endangering the livelihood of thousands of Americans who make their living on livestock and meat packaging operations.

I look forward to hearing from all of you today and thank the Chairman and Ranking Member again for their leadership.

Thank you.

PREPARED STATEMENT OF HON. SAM GRAVES, A REPRESENTATIVE IN CONGRESS FROM MISSOURI

Thank you, Chairman Peterson and Ranking Member Goodlatte for holding this hearing.

Oversight of the safety of the American food supply is one of the most important mission's of this Committee, and I think it is a credit to the Chairman and Ranking Member of this Committee that we are holding this hearing today to focus on new technology in the meat industry, and what impact that technology has most importantly on safety, but also on marketability and consumer satisfaction. I look forward to hearing from Administrator Almanza as he testifies before this Committee for the first time, as well as from our distinguished witnesses from the meat industry and academic world.

With regard to this issue, I believe it is paramount that the government evaluates all new technology with safety in mind first, and after ensuring that a fundamental level of safety exists for a technology, then allowing consumers to make the determination regarding which product they want to purchase at the grocery store. Consumers will be happier if they are provided with the most possible options that can be guaranteed as safe.

Thank you again Chairman Peterson and Ranking Member Goodlatte for holding the hearing.

PREPARED STATEMENT OF HON. ADRIAN SMITH, A REPRESENTATIVE IN CONGRESS FROM NEBRASKA

Good afternoon and thank you, Mr. Chairman.

The meat industry is extremely important to Nebraska. Nebraska has 81 animal slaughter facilities (excluding poultry processing), more than any other state, except Texas, California, and Iowa. Nebraska leads the nation in value of meat product shipments, with almost $10.5 billion in receipts. Nebraska's meat packing industry employs over 20,000 people, more than any other state, with an annual payroll of nearly $550 million. Clearly, the meat industry is important to Nebraska's economy.

I am pleased that we are holding this hearing today, and I look forward to hearing the testimony of our knowledgeable witnesses. I hope that what we learn today about the technologies of the meat industry will allow us to aggressively pursue new markets and breakdown barriers to trade, with the assurance that our products are the safest in the world.

I want to thank our witnesses for coming here today to provide testimony for the Committee, and I look forward to hearing from you.

I appreciate the Committee for holding this hearing as an important step to meeting our goals.

Mr. Chairman, I look forward to continuing to work with you, and I thank you for your time.

The CHAIRMAN. We probably have 10 minutes before we have to leave to vote, I thank the gentleman. Now, we have Dr. Minerich.

Dr. MINERICH. Minerich.

The CHAIRMAN. Minerich. Okay, sorry. Vice President of Research and Development at Hormel. I think we have time for your testimony, then we have two votes, we are going to take a break and we will come back and get to the rest of the panel. So, Doctor, welcome to the Committee and are we going to pass around some of that stuff or how are we going to do that?

Dr. MINERICH. Do it during the question and answer period.

The CHAIRMAN. We will do that during question and answer, okay. Go ahead, Doctor.

STATEMENT OF PHILLIP L. MINERICH, PH.D., VICE PRESIDENT, RESEARCH AND DEVELOPMENT, HORMEL FOODS CORPORATION, MEDINA, OH

Dr. MINERICH. Thank you, Mr. Chairman. You should have a package like this in front of you and I will reference certain page numbers if you want some visual aids during my conversation. I am Dr. Phil Minerich, Vice President of Research and Development for Hormel Foods Corporation and I do thank you for this opportunity to talk about this important topic.

I am here today to discuss advances in meat packaging technology, specifically the many benefits of low-oxygen packaging. On page 2, you will see that Hormel Foods is a 116 year old company with a long and proud history of innovations in the food packaging and food safety environment. This stretches back to products such as Spam® and Dinty Moore® that represented packaging breakthroughs in their day and have provided safe, flavorful and nutritious meals for several generations of Americans.

On page 3, you will see one of those innovations that continues today with products such as our Natural Choice®, which uses a new, high-pressure processing technology that literally kills bacteria and allows us to remove chemical preservatives from processed foods. We are the leader in the nation in this technology and have invested a great deal in bringing it to the market.

On page 7, you will see how important packaging technology is to the food industry, delivering food to consumers in a safe and convenient format is fundamental to our business. Oxygen deteriorates food. It causes oils to turn rancid, meat to turn brown, vegetables to discolor and cheese to spoil. And by removing oxygen from food packaging and replacing it with another gas, such as carbon dioxide or nitrogen, food producers can ensure their products remain fresh for consumers longer. This process is common throughout the food industry and has been used for decades. All of the packaging systems you see here use some form of modified atmosphere packaging.

On page 10, I will briefly talk about some specific meat packaging technologies and how they have evolved, significantly evolved, becoming more controlled and thereby safer for the American public. Years ago, the bulk of our meat supply was packaged at the retail level, which created greater opportunity for contami-

nation to be introduced into the system. Today, the bulk of our meat supply is packaged in facilities that are USDA inspected, follow good manufacturing practices and adhere to HAACP guidelines. Once packaged, the product is not touched again until it reaches the consumer's home.

On page 11, you will see meat producers who have enhanced convenience and safety by introducing numerous packaging formats over the years and these are just some of the examples that greet consumers at the retail level. Consumers, who once relied on their neighborhood butcher, have come to rely on these packages backed by strong national brands to deliver consistent quality and safety. Please note, a critical component of this packaging is the sell-by date. In a majority of the packages you see, color is not an accurate indicator of freshness either because the product is vacuum-sealed or because the product itself, whether it be chicken, pork or turkey, does not change color as it ages. In fact, color can be a very poor indicator of freshness.

On page 14, I would like to briefly highlight one packaging system, high-oxygen packaging, which actually accelerates the rancidity of meat while maintaining its red color. And once out of the package, a product that is packaged in high oxygen can actually look cooked even though it is cooked below the recommended temperature for safety.

Page 19, low-oxygen packaging has been reviewed and approved by a long list of safety experts and food scientists that are acclaimed throughout the world. These scientists have endorsed this technology for the same reasons we use it and for the same reasons the consumers have embraced it, it works.

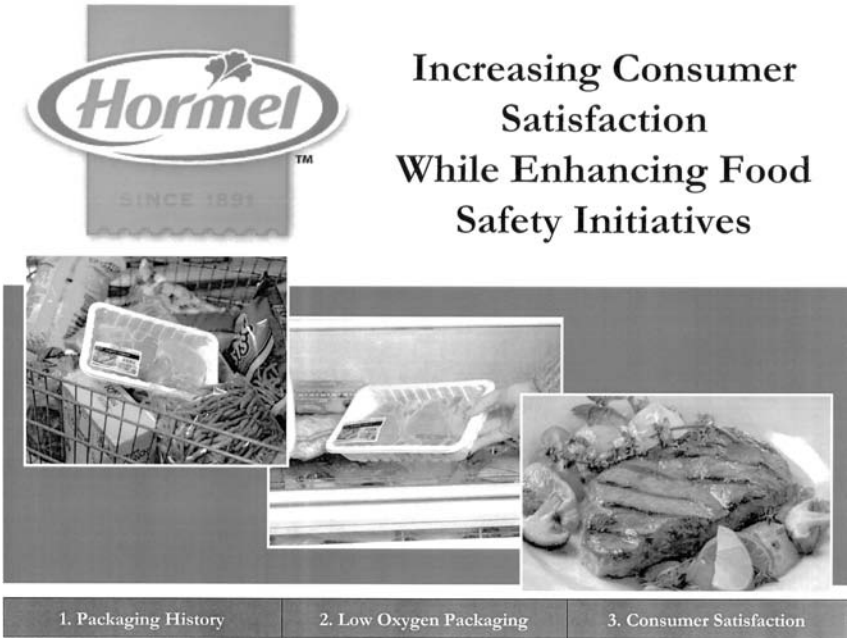
On page 23, you will see that low-oxygen packaging retards spoilage, delivers high-quality product that is consistent, clean and safe. In addition, the packaging eliminates opportunities for cross-contamination. It is tamper evident, it is leak proof and it is packaged and dated under a USDA inspection, which complies with the 9/11 initiatives for food safety and enhanced consumer confidence and consumer safety.

Critics of this technology have focused on the fact that the color of the product remains red whatever the condition of the product. But on page 25, you will see color is not the only or even the best indicator of freshness. Consumers also rely on sell-by dates, not only for meat products but other foods. Also for batteries, medications, film and all types of consumer products.

Let me close on page 28 by stating the product has been in the market 4 years and it has been extremely well-received by retailers and our consumers. In fact, it is one of the highest acceptance rates of any product that we have ever introduced, over 120 million packages, more than 600 million servings. And during this time no documented cases of food-borne illness have been reported. As a matter of fact, our complaint ratio rivals the legendary Maytag repairman. Our consumers love the product because it delivers exceptional flavor and texture in a clean and safe package. Thank you very much.

[The presentation by Dr. Minerich follows:]

PAGE 1


Hormel
SINCE 1891
Increasing Consumer Satisfaction While Enhancing Food Safety Initiatives
1. Packaging History
2. Low Oxygen Packaging
3. Consumer Satisfaction

PAGE 2

Hormel
Innovative & Branded Food Co.
SPAM
Dinty Moore BEEF STEW
HORMEL
SPAM
SPAM Single
Hormel Chili WITH BEANS
Hormel Chili with Beans

PAGE 3

Hormel
High Pressure Pasteurization
NATURAL CHOICE
3
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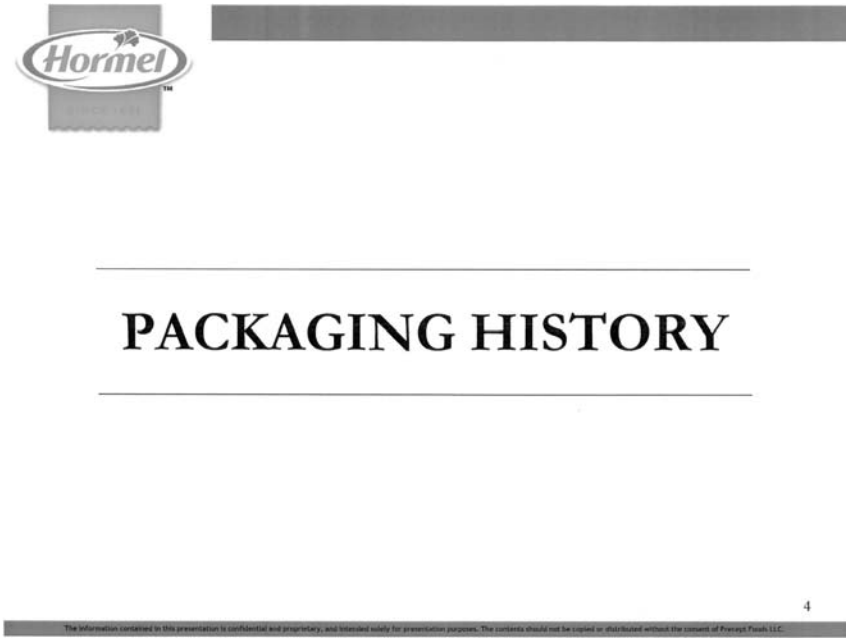
PAGE 4


Hormel
PACKAGING HISTORY
4
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PAGE 5

Enhancing Product Quality

- Controlled Atmosphere Storage (CAS)
  - Introduced in '30s
  - Vacuum packaging for meats in late '50s and early '60s
- Modified Atmosphere Packaging (MAP)
  - Introduced in '70s in Europe and '80s in United States

5

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PAGE 6

Packaging History

- What is MAP?
  - Modified Atmosphere Packaging
  - Normal atmospheric air is modified to protect content of package
- Why MAP?
  - Keep meat fresh
  - Protect meat
  - Prevent cross-contamination (tamper resistant/leak-proof)
  - From the plant to the consumer's kitchen
- What is Case Ready?
  - A means to pre-package meat in a USDA inspected, controlled facility and to provide the retailer/customer with a consistent, convenient and safe product
- Why Case Ready?
  - Efficient production
  - Food safety – HAACP controlled/USDA inspected product
  - Consistency of production
  - Reallocation of retailer labor for service
  - Easy inventory management for retailer, resulting in fewer out of stocks for consumers

6

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PAGE 7

Hormel
Food Has Been Packaged In Modified Atmospheres In United States Since 1980's
Lay's
Classic
Jet-Puffed
KRAUT
SHRIMP
7
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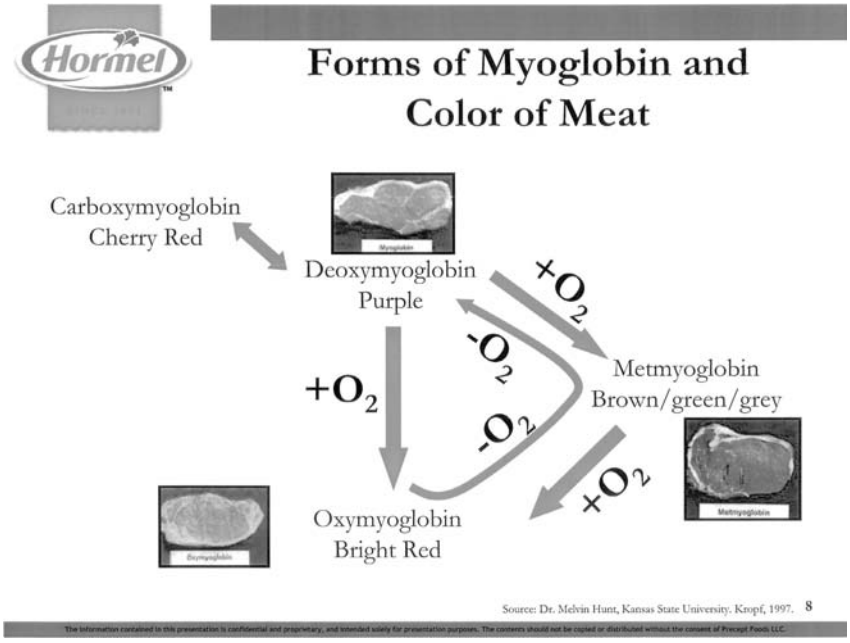
PAGE 8


Hormel
Forms of Myoglobin and Color of Meat
Carboxymyoglobin
Cherry Red
Deoxymyoglobin
Purple
+O2
-O2
-O2
+O2
+O2
Metmyoglobin
Brown/green/grey
Oxymyoglobin
Bright Red
Source: Dr. Melvin Hunt, Kansas State University. Kropf, 1997.
8
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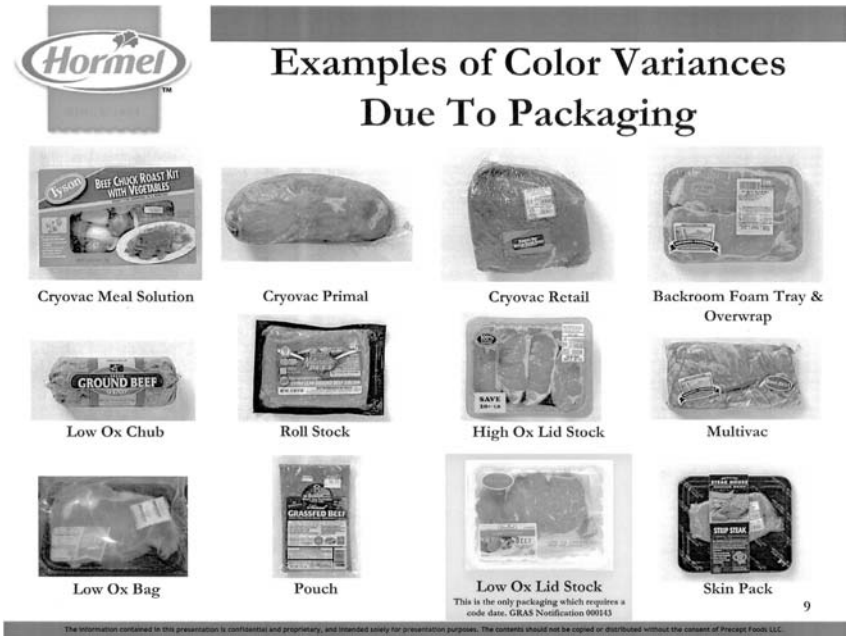
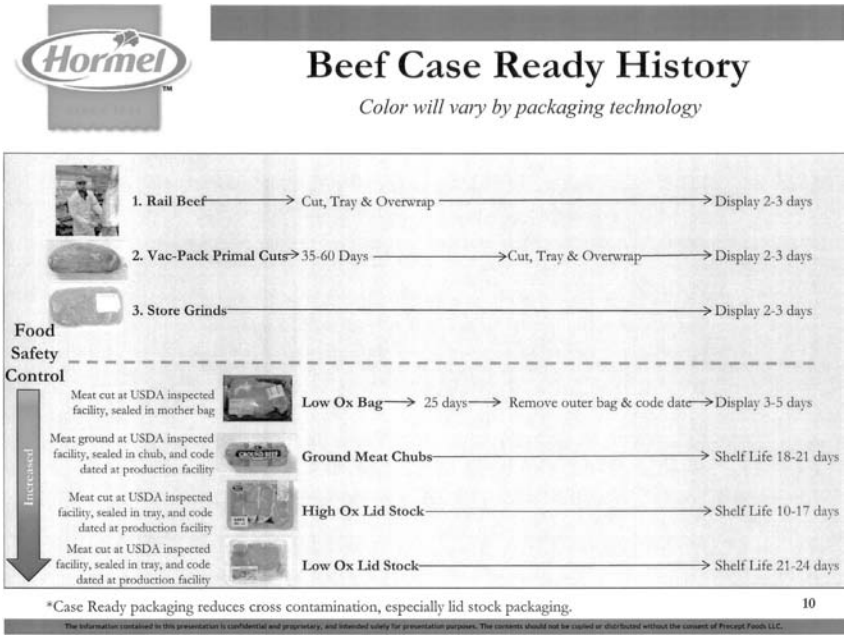
PAGE 9



PAGE 10



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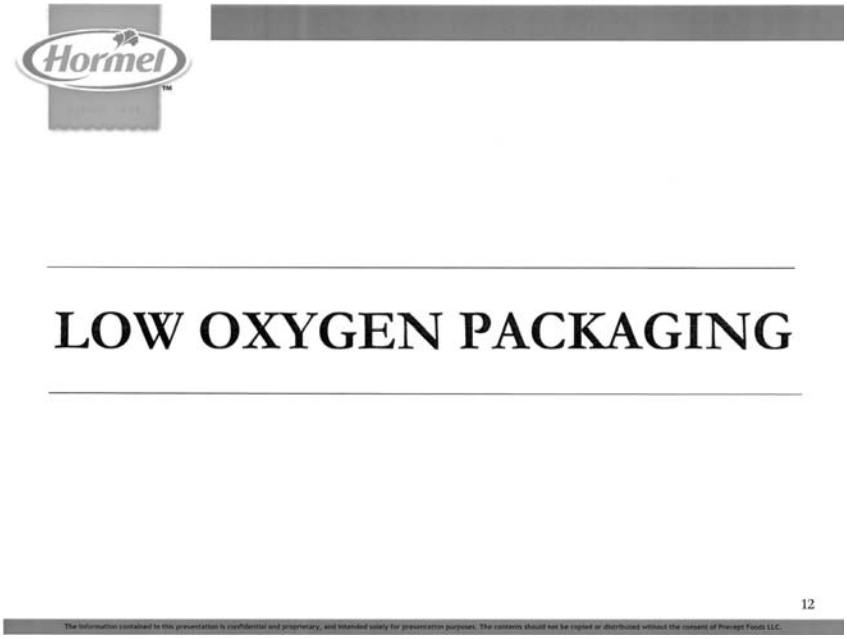
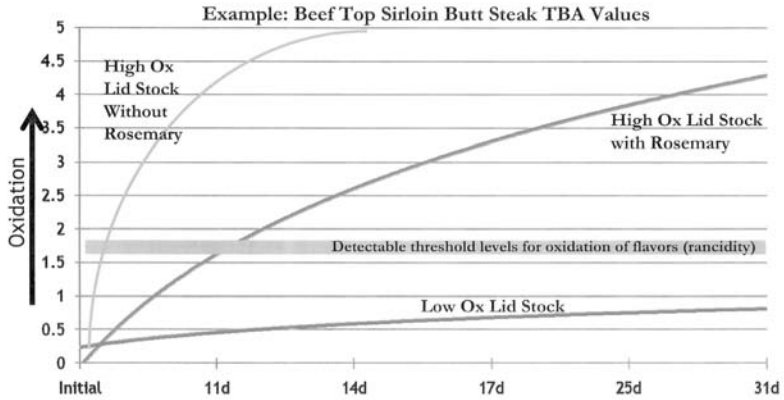
PAGE 12



PAGE 13

High Oxygen Packaged Beef Becomes Oxidized Sooner



*Precpt Foods data. Dr. Daren Cornforth, Utah State University paper supports above data. 13

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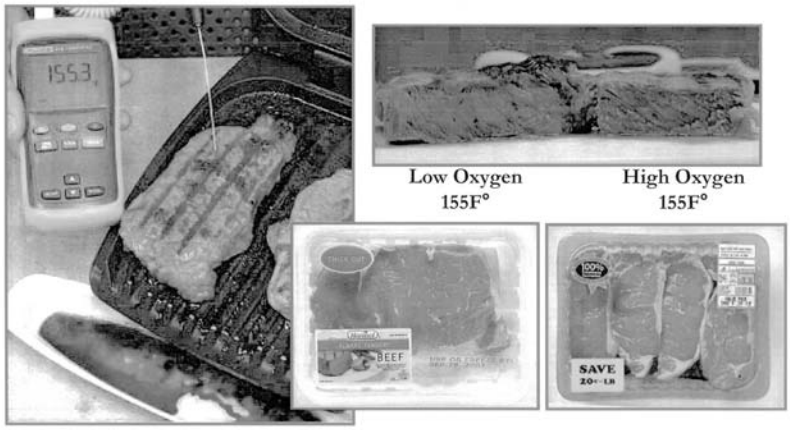
PAGE 14

High Ox Packaging Creates Premature Browning



Dr. Joseph Sebranek, Iowa State University, Dr. Terry Houser, University of Florida. Research demonstrates premature browning effects. 14

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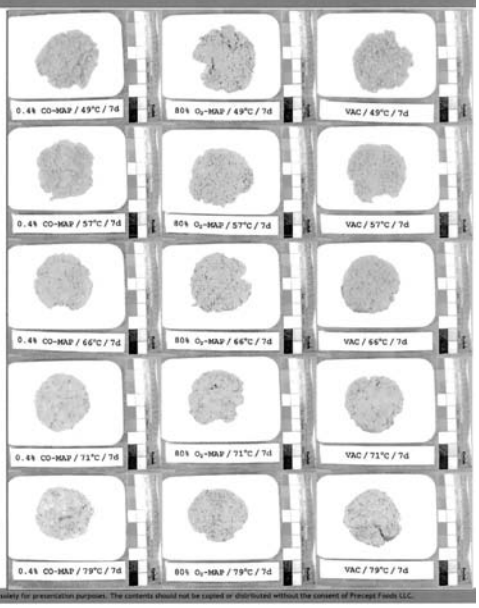
PAGE 15

- Internal color of cooked burger after holding in 80% O2-MAP for 1 week. Note premature browning at internal temps of 49-66 C

(John et al. 2004. J Food Sci 69:C pgs 608-14).
*Study funded by NCBA check-off dollars

Slide provided by Dr. Cornforth, USU



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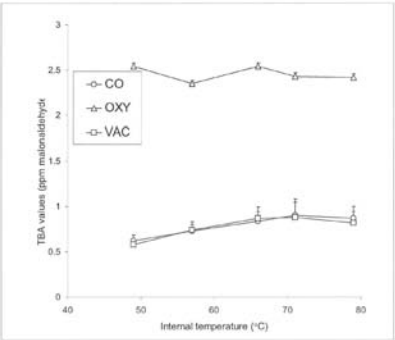
PAGE 16

Cooked Meat Quality

Cooked patties have less oxidation & better flavor (lower TBA values) when raw meat is packaged in 0.4% CO-MAP, versus meat held in 80% O2-MAP

(John et al., 2004. J Food Sci 69:C608-14).



Slide provided by Dr. Cornforth, USU

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PAGE 17

Low Oxygen Packaging Formats

Low Ox Bag Technology
(FDA GRAS Notification 000083)

Low Ox Lid Stock
(FDA GRAS Notification 000143)

*As part of GRAS Notification, product must be date coded at plant.

MORE "GREEN"
More sustainable,
less waste, more
packages per truck

Dr. Mindy Brashears, Texas Tech University. Pathogens decrease in Low Ox packaging

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Tamper-Proof Trays in Accordance with 9-11 Food Safety Initiatives

Packaged under USDA inspection

Print is tamper-proof and printed directly on package

Date is printed in bold, 15 point font on front

Date is also printed on back

Tamper-proof lidded tray reduces cross-contamination

Customer service 800# printed on every package

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Scientists Endorsing the Safety & Quality of Low Oxygen CO MAP Packaging:

- Dr. Alden Booren – Michigan State University
- Dr. Joseph Sebranek – Iowa State University
- Dr. Melvin Hunt – Kansas State University
- Dr. Daren Cornforth – Utah State University
- Dr. Chance Brooks – Texas Tech University
- Dr. Mindy Brashears – Texas Tech University
- Dr. Gary Acuff – Texas A&M University
- Dr. Mike Doyle – Director of the Center for Food Safety at University of Georgia
- Dr. Michael Osterholm – Director of Center for Infectious Disease Research & Policy – University of Minnesota
- Dr. Oddvin Sorheim – Norwegian Food Research Institute*
- Dr. Roger Mandigo – University of Nebraska
- Dr. Susan Brewer – University of Illinois
- Dr. Terry Houser – University of Florida

*CO MAP was used successfully for many years in Norway. It was not "borrowed" in the EU, but for competitive reasons, was not approved when Norway joined the EU.

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CONSUMER SATISFACTION

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Consumers use the following to determine wholesomeness…

1. Sell By Dates
2. Packaging Appearance
3. Smell
4. Color
5. Texture
6. Taste

*Studies conducted by FMI, AMI, and CFA show that consumers rely on sell by dates. 21

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Consumers Want Fresh Meat Packaging That…

- Prevents leaks & mess
- Keeps meat fresh
- Facilitates a good eating experience
- Promotes attractive meat appearance

*Precept Foods Studies. Dr. Daren Cornforth, Utah State University. 22

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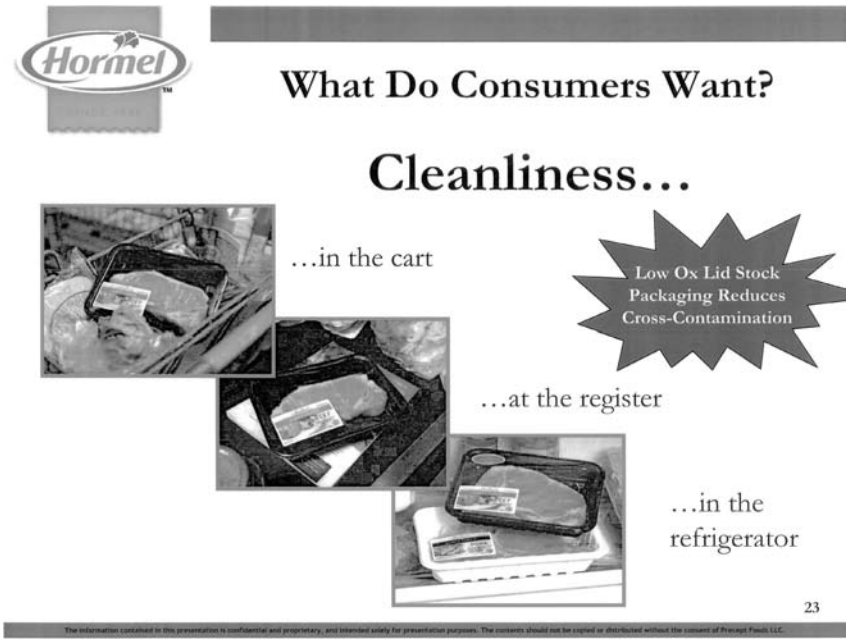

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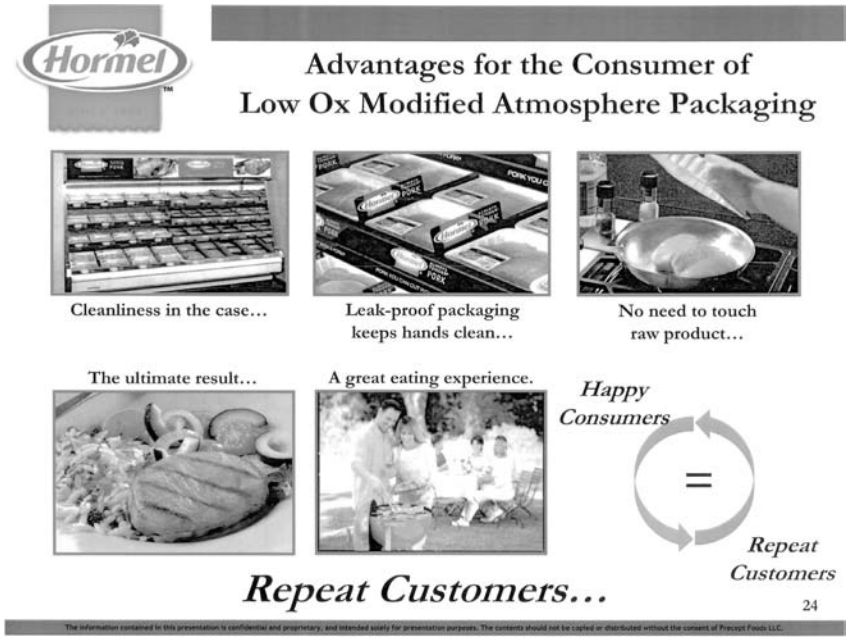

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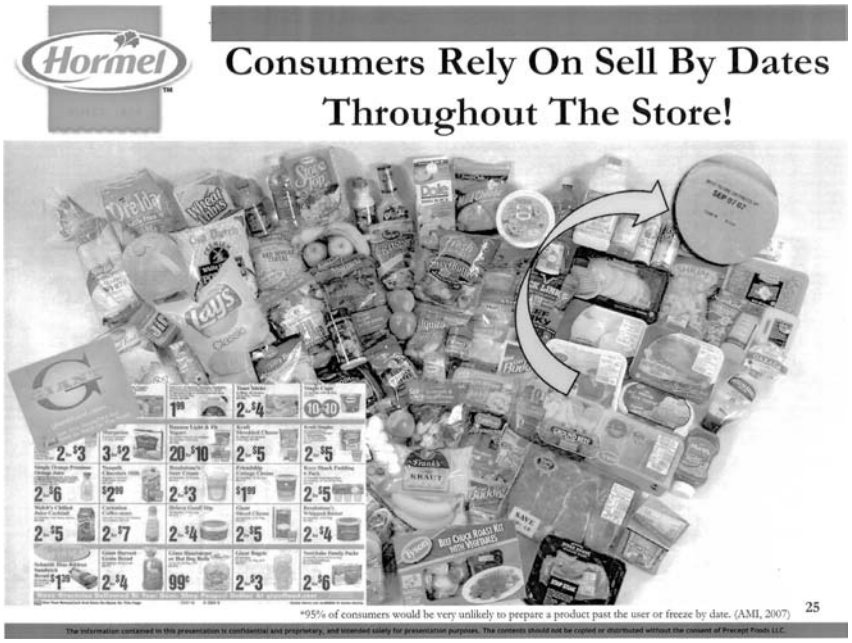

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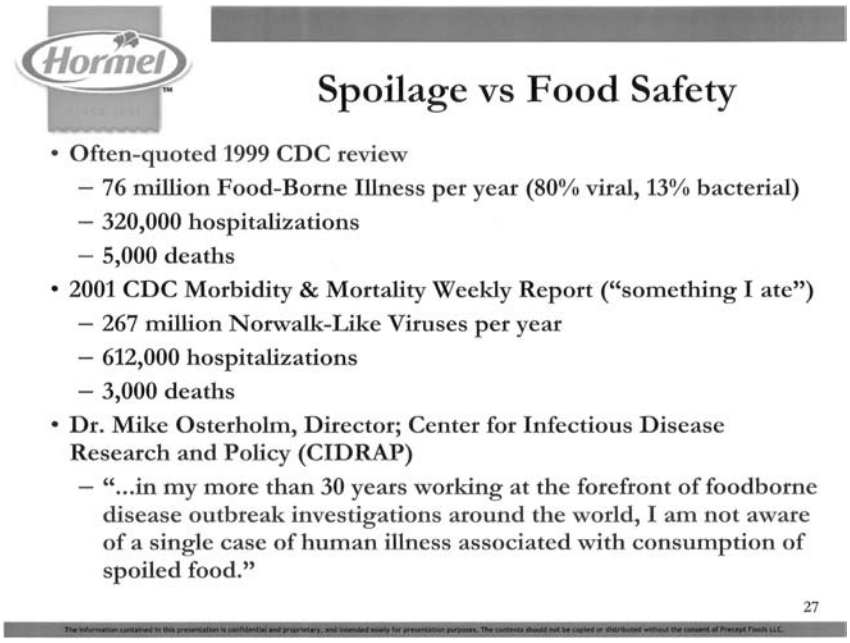

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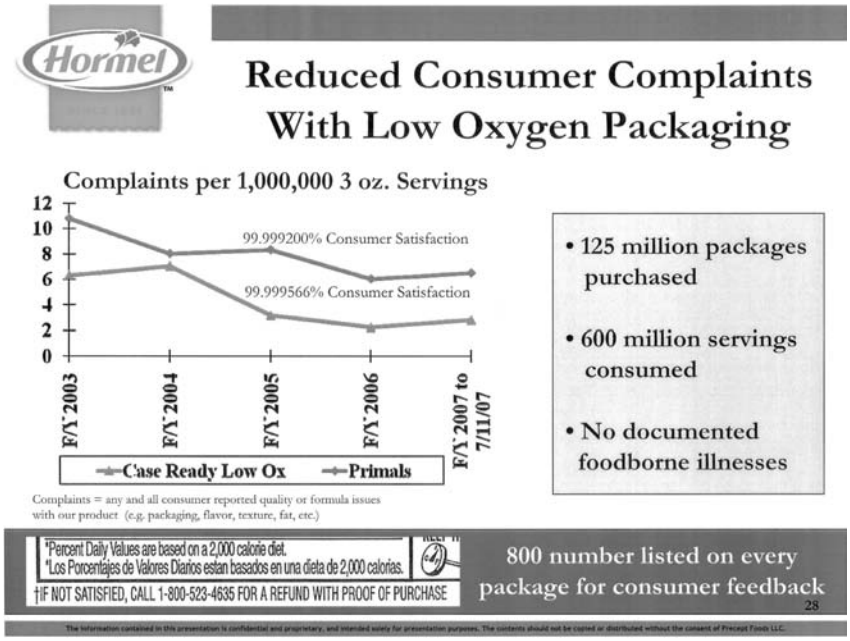

Statements from Scientists Concerning the Safety and Quality of Low Oxygen Modified Atmospheric Packaging with Carbon Monoxide

Dr. Alden Booren, Professor, Michigan State University	May 4, 2006, in a letter to the Honorable Carl Levin, U.S. Senate	"The risk of a significant food safety hazard occurring in meat packaged using this low-oxygen carbon monoxide modified atmosphere packaging (MAP) technology does not change when this technology is compared to conventional retail meat wrap technologies. For this reason I would not hesitate to utilize the technology in the Meat Laboratory Pilot Plant, a facility I help manage at Michigan State University."
Dr. Joseph Sebranek, Iowa State University; Dr. Melvin Hunt, Kansas State University; Dr. Daren Cornforth, Utah State University; and Dr. Susan Brewer, University of Illinois	May, 2006, Perspectives Article in *Food Technology*, a scientific publication of the Institute of Food Technologists	"The claim that CO packaging will result in unsafe products is not scientifically sound." "Because scientific studies have validated the safety of low-CO packaging technology for fresh meat, it seems appropriate to let the marketplace decide the success or failure of the process."
Dr. Melvin Hunt, Professor, Kansas State University	March 14, 2006, Letter to the Editor, submitted to the Kansas City Star	"Over the last few weeks, media have persuaded some consumers that they are being misled because meat that would have otherwise turned brown is still red. Some retailers are now fearful of selling products packaged in this impressive, safe and cutting edge technology. The effort to discredit the science that went into it – and efforts to discredit the federal agency that reviewed it three times – is scientifically inaccurate and unfortunate. A close look at this media scare shows motives that are as transparent as carbon monoxide itself. But carbon monoxide packaging technology has a real benefit to consumers. The only benefits generated by these unfounded safety allegations are to the company that stirred the controversy – and to the media outlets that benefit from the attention grabbing story."

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Statements from Scientists Concerning the Safety and Quality of Low Oxygen Modified Atmospheric Packaging with Carbon Monoxide

Texas Tech University researches, Dr. Chance Brooks and Dr. Mindy Brashears	June 26, 2006, Texas Tech University Press Release	"In a related microbiological study, a research team headed by Dr. Mindy Brashears found that beef inoculated with pathogenic bacteria, *Salmonella and E. coli* o157, and then packaged with carbon monoxide had less pathogenic bacteria after 14 days than similarly inoculated beef wrapped in traditional packaging without carbon monoxide."
EU Scientific Opinion	2001, EU Scientific Committee on Food	"The EU Scientific Committee on Food (SCF) in 2001 determined that the use of CO under intended conditions of use in meat packaging is safe. The committee concluded "there is no health concern associated with the use of 0.3% to 0.5% CO in a gas mixture of carbon dioxide and nitrogen as a modified atmosphere packaging gas for fresh meat provided temperature during the storage and transport does not exceed 4 C."
Dr. Gary Acuff, Professor of Microbiology, Texas A&M University	May 26, 2006, Letter to Editor of Meating place Magazine	"Low-oxygen modified atmosphere packaging is a safe technology that provides significant consumer benefits, not the least is a longer shelf-life than aerobic packaging. Adding very low levels of carbon monoxide to the atmosphere provides an acceptable color that helps meet consumer expectations. The use-by date on every package tells consumers the point at which the product will no longer be acceptable. This is not a misleading technology, however facts seem to be getting lost in the publicity generated by critics."
Dr. Daren Cornforth, Professor Food Science, Utah State University	March 16, 2006, Letter to the Deseret News	"The FDA has looked at, and approved the use of CO in meatpacking on three separate occasions, most recently noting that the use of CO "will not mislead consumers into believing that they are purchasing a product that is fresher or of greater value than it actually is or increase the potential for masking spoilage."
Mike Doyle, Director of the Center for Food Safety at the University of Georgia	July 27, 2006, Interview with Food Production Daily USA	"I don't think that carbon monoxide packaging is a deceptive process at all, certainly not from a safety standpoint. I think that carbon monoxide packaging technology deserves an award, from a scientific perspective this is a profound idea," said Doyle. "If manufactures have a reasonable date on the product and it looks good, smells good and tastes good…well, what's wrong with that?"

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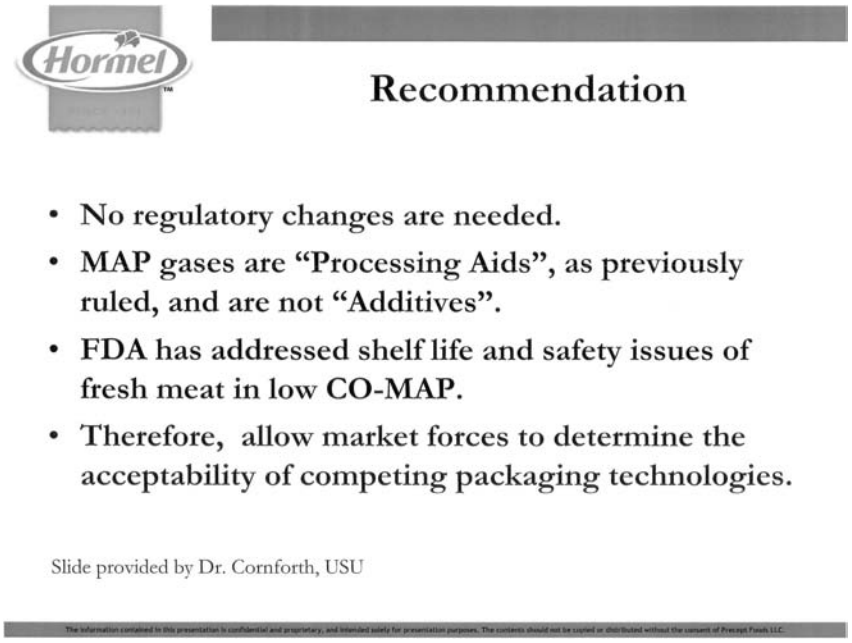


The CHAIRMAN. I thank the gentleman. How much time do we have? Six minutes? I think we are going to have to recess the Committee. We just have two votes. We should be back in 10, 15 minutes, so we appreciate your patience and we will be back shortly.

[Recess]

The CHAIRMAN. The Committee will come back to order. We next have Scott Eilert, the Vice President of Research and Development for Cargill Meat Solutions, Wichita, Kansas. I guess it is Dr. Eilert?

Dr. EILERT. Yes.

The CHAIRMAN. Welcome to the Committee and we would be happy to hear your testimony.

STATEMENT OF SCOTT EILERT, PH.D., VICE PRESIDENT, RESEARCH AND DEVELOPMENT, CARGILL MEAT SOLUTIONS CORPORATION, WICHITA, KS

Dr. EILERT. Okay. Thank you, Chairman Peterson and the Committee. We really appreciate the opportunity to visit with you today about innovations and advancements in food safety and quality. We also want to recognize this Committee for its contribution to ensuring a safe and wholesome food supply to our population. We really see you as effective partners in that goal and we thank you for all of your efforts.

I am going to spend some time today talking to you about an innovation that we think has been pretty important in the last few years in moving to a safer and more wholesome and more fresh food supply, meat supply, and that is the adoption of modified atmosphere packaging.

Through modified atmosphere packaging, we are able to deliver to the consumer a product that has less chances for cross-contamination at retail level and as well as at store level. It also has conveniences and safety assurances, such as a tamper-proof package and a leak-proof package inclusive also of a mandated user freeze-by date.

Now, there have been several Members of Congress over the last couple of years, as was pointed in the introductory comments, that have been very critical of this technology. They believe that we are deceiving consumers with the advancement of this technology. My remarks today are going to hopefully ensure to you that that is not our intent or purpose. Rather, our intent and purpose is to ensure a safe, high-quality, wholesome food supply to our consumers and that is our primary goal.

Let us talk a little bit about how meat arrives at the retail store today. As Dr. Minerich has pointed out, there are a couple of avenues. In conventional systems, the meat may be vacuum packaged and sent to a retail store for processing and packaging at the retail store. In case-ready packaging, we actually cut and package and label that product in a centralized facility under USDA inspection. Now, as we think about the shelf life of those various formats, whether it be conventional packaging or case-ready, in beef, for instance, that goes to a retail store, the beef that goes to a retail store has roughly a shelf life of around 35 days in a vacuum package. The shelf life of case-ready products will vary depending on the technology that is used. In low-oxygen modified atmosphere packaging that we are speaking about today, the shelf life is roughly 35 days. Very similar to the vacuum package of beef that typically went to a retail store. The shelf life of high-oxygen, case-ready packaging, which is a competing technology, it is the technology that we are referencing today, is only about 14 to 15 days. A key point that we want to make to this Committee: With these advancements we are not extending shelf life of fresh meat today, we are protecting it. We are making sure that the shelf life potential of that product can be realized for the consumer and our customers.

Additionally, protecting shelf life and protecting the quality of the product, these are critical precious commodities to us. Also what is a precious commodity is the flavor experience of that product. And as has been discussed previously by Dr. Minerich, oxygen is the enemy of meat flavor. And so we have seen several research studies by universities that have shown that at the end of shelf life in a high-oxygen package, the quality of that product is actually lower than at the end of shelf life in a low-oxygen package, even though the product was in that low-oxygen package for a longer period of time. There is a great maintenance of flavor and natural quality of the meat that comes with these packaging technologies.

As we think about why we then use carbon monoxide, it is key to remember that as we remove oxygen from these packages, meat exists in its natural-colored state, a purplish kind of brown state that is the natural color of meat. As we expose meat to oxygen, it turns bright red. As we expose meat to low levels of carbon monoxide, it turns bright red. So what we are trying to do with these modified atmosphere packaging systems is deliver the product that

works as well for the consumer as possible, that has the freshness and flavor of a low-oxygen package, has the shelf life maintenance of low-oxygen packaging formats and then with small levels of a gas like carbon monoxide, we deliver the color that the consumer prefers.

This campaign of misinformation that has taken place against this technology is not advancing food safety and is not advancing food quality. It is impeding our ability to advance food safety and advance the quality of our products.

We greatly appreciate the time and attention that this Committee is giving to this topic and we want to just further emphasize that this unfortunate campaign of misinformation is not moving the bar or raising the bar on food safety or quality. It is jeopardizing our ability to deliver a high-quality, wholesome product to our consumers.

Thank you very much for your time and I'll entertain questions at the appropriate time.

[The prepared statement of Dr. Eilert follows:]

PREPARED STATEMENT OF SCOTT EILERT, PH.D., VICE PRESIDENT, RESEARCH AND DEVELOPMENT, CARGILL MEAT SOLUTIONS CORPORATION, WICHITA, KS

Thank you Chairman Peterson and Mr. Goodlatte. I appreciate the opportunity to speak before you today on innovations in food safety and quality. The House Agriculture Committee has for many years been deeply committed to the understanding of science and risk in protecting public health. For that we are grateful.

My remarks address one of the most important food safety innovations in the harvest and manufacture of safe and wholesome meat products—the adoption of Modified Atmosphere Packaging (MAP).

Through a MAP system, meat is packaged at processing plant and then delivered to the retail grocery store in a tray covered with a protective film. This helps eliminate the potential for cross contamination that can come from human handling both at the retail store and in the home. The package is both leak-proof and tamper proof, adding additional consumer protections.

Several Members of Congress have recently raised questions with the concern that MAP packaging may allow meat to retain its characteristic red coloration for too long, potentially masking spoilage. I appreciate the opportunity to help ensure that this technology is more fully understood and that that we are deeply committed to consumer protection.

Today beef is typically delivered to a grocery store in one of two ways—as boxed product sealed in a vacuum packaged bag, or as individual packages ready for display in the meat case for consumer purchase. Boxed, vacuum packaged product will be opened at the grocery store and cut into steaks or roasts and then wrapped for retail display. Case ready products come completely packaged and labeled, and will be simply taken from a lined box and placed in the retail display.

Meat products in a vacuum bag have a shelf life of about 35 days. The shelf life of case ready products will vary depending on the use of the packaging technology used.

There are two types of case ready MAP product offerings—those packaged in a high oxygen (high-ox) format and those in a low oxygen (low-ox) format. Both are good formats, but the low-ox format in many respects, has significantly better functionality, especially in the area of ensuring freshness and convenience for the consumer.

Steaks and roasts that are packaged in a low-ox environment have a shelf life roughly equivalent to the 35 days of the vacuum bag. Steaks and roasts in high-ox packaging have a shorter shelf life of only 14 or 15 days. You can observe this shelf life concern not only in meat packaging but also in produce. As a point of reference, note that the spoilage of a head of lettuce accelerates rapidly after the packaging is removed.

It is critical for the Committee to understand that our technology does not in any way extend shelf life—rather it protects the shelf life in a manner the performs equal to the vacuum package, yet in a much more consumer friendly, convenient format.

It is a given that protecting freshness and shelf life is critical. Beyond preserving freshness, low-ox packaging also protects against flavor degradation. High levels of oxygen in a high-ox packaging will deteriorate the flavor of meat. Many university studies have shown that meat in a high ox package can look acceptable, but will have a significantly less acceptable flavor than low oxygen products. Low oxygen packaging helps to maintain the natural flavor of meat.

There are numerous additional benefits of low-ox packaging. It greatly reduces product waste, helping keep costs down because retailers can make larger, more efficient purchasing decisions. It also gives consumers the flexibility to plan ahead for meals, rather than make more trips to the grocer. It ensures the ability of smaller retailers in both rural and very urban areas the opportunity to have a diverse product offering. As further protection against product failure, our packaging is tamperproof, and includes an imprinted use or freeze-by instruction that cannot be removed.

Let me cover just a little bit about the science of our packaging technology.

One of the challenges with low oxygen packaging is that the removal of oxygen has a visual impact on meat coloration. You've probably noticed that when you can see a blood vessel through your arm, it can appear bluish rather than red. This is because the blood is not exposed to oxygen. Once exposed to oxygen, blood becomes red. This principle also applies to MAP packaging. To provide the most consumer protection and to preserve freshness, we flush all the oxygen from the packaging. This process will affect the meat coloration, turning the product somewhat purple. As you might imagine, this doesn't look very appealing to the customer. In contrast, the traditional grocery tray is more exposed to oxygen, and therefore it retains the red color.

To gain the functional and appearance performance for low-ox packaging, we substitute the oxygen with other acceptable and safe gasses. One of these gasses we use involves a trace amount of carbon monoxide. This is fully approved by the FDA, based on volumes of scientific study. As with all MAP products, the packaging gas dissipates immediately once the package is opened.

We want consumers to have all the benefits of MAP. But to do so, the package must be as attractive as competing products in the case. We believe it unfortunate that there has been misinformation about low oxygen MAP. We have seen some retail customers who have found this technology serves them and their customers best, find the need to back away from it because of pressure campaigns led by a competitor offering a different, similarly performing technology. This has led to greater waste, less efficiency, and ultimately higher prices for consumers. We are hopeful that this will abate.

We recently had the opportunity to host investigators from the House Committee on Energy and Commerce at one of our case ready plants. We learned clearly that the most important issue concerning Committee Members was the potential that a consumer may not fully understand that color is not the only indicator of freshness. For this reason, we have decided to add new wording to our labeling. We will now include the statement, "Color is not an indicator of freshness. Please refer to use or freeze by dates." We believe this effectively addresses the concerns of the Committee in protecting public health, while not undermining the adoption of the safety and convenience offered through case ready packaging.

In summary, Cargill is deeply committed to serving the needs of our customers. Case ready packaging meets the needs of today's consumers, and is a very effective way to deliver fresh and wholesome products to the retail store. The low ox technology that we have discussed today is an important evolution in packaging technology. The pressure campaigns against this technology are unfortunate. They are preventing us from using this technology to better ensure a safe and high quality meat supply to the consumer.

Again, we thank this Committee for its commitment and leadership in the area food safety. I would be pleased to answer any questions.

The CHAIRMAN. Thank you, Dr. Eilert and we appreciate your being with us today. Dr. Roop, Senior Vice President of Science and Regulatory Affairs for Tyson Foods in Washington. Welcome to the Committee.

STATEMENT OF RICHARD ROOP, PH.D., SENIOR VICE PRESIDENT, SCIENCE AND REGULATORY AFFAIRS, TYSON FOODS, INC., WASHINGTON, D.C.

Dr. ROOP. Good afternoon, Mr. Chairman, and Members of this Committee. My name is Dr. Rick Roop and I manage food safety, quality assurance and laboratory services for Tyson Foods. And I thank you for inviting me here today to talk about our company's efforts to lower the incidence of *E. coli O157:H7* in beef.

Controlling microbes is one of the many ways we keep our perishable products safe and ensure that they stay safe and fresh until they reach the consumer. FSIS data shows that the incidence rate of *E. coli O157:H7* in ground beef has declined since 2000. For 2007, however, FSIS has indicated that there is a slight increase in the incidence rate and also an increase in beef recalls due to *O157:H7*. It is noteworthy, however, that CDC reports that *O157:H7*-related illnesses in 2007 are at about the same level as they were in 2006. Overall, as the industry continues to find better technologies and product handling procedures, the decline in incidences is expected to continue.

Tyson uses several best practice methods to prevent contamination and preserve beef safety. Among the key practices are hygienic hide and viscera removal, use of steam vacuums on key areas of the carcass, use of organic acid solutions on the surface of carcasses and parts, treating carcasses with a final thermal pasteurization, using antimicrobial carcass washes, quickly chilling all carcasses and parts, managing the cold chain from the start to finish and, finally, using extensive testing to verify that our process controls have worked.

I would like to discuss three key food safety programs developed at Tyson to reduce pathogens in beef. Niche-Buster™ targets micro-organisms that could be harbored in niche environments. For example, seams and cracks of equipment in facilities. The program is employed in every beef slaughter and processing plant Tyson owns. A constant search and destroy effort is undertaken by our plant quality and sanitation experts to eliminate these harborage areas for bacteria. Originally for use in preventing *Listeria* contamination in ready-to-eat plants, Niche-Buster™ has proven to be extremely helpful in preventing *O157:H7* cross-contamination in Tyson beef plants.

The carcass thermal pasteurization technology blasts every beef carcass with sufficient heat to raise the surface temperature above 160 degrees Fahrenheit, which is an immediate kill point for pathogens on the carcass surface. It is a validated critical control point in all of our beef slaughter HACCP plants.

Tyson Total N60™ is a name for a Tyson-developed, extremely comprehensive and sensitive testing system to prevent *O157:H7* from contaminating ground beef. Tyson tests all raw beef components destined for ground beef production. Tyson Total N60™ is among our most powerful food safety tools, as it augments the other anti-microbial programs. It is so powerful that it has been adopted by many other companies across the industry and recognized by the USDA.

Tyson believes that programs such as Tyson Total N60™ that find and remove *O157:H7* containing meat from the ground beef

supply chain, have contributed to the significant decline in incidents in the U.S. over the last several years.

Tyson Foods Safety and Quality Assurance, FSQA, consists of approximately 2,500 professionals. This team works side by side with production to ensure the safety and quality of every product. Our organizational structure is built to enhance independent, non-biased decisions for FSQA managers. All FSQA team members, including myself, report parallel to operating groups. Training is a key success factor for continuous improvement. Tyson Foods' team members are provided ongoing food safety and quality assurance training. For example, in partnership with the University of Arkansas, Tyson Foods funded and helped develop a food safety training and education program available to Tyson team members and others throughout industry, government and the public.

Tyson Foods also partners with Texas A&M University to offer one of the few industry-sponsored training programs approved by the International HACCP Alliance.

In conclusion, we have made tremendous progress in learning how to improve meat safety over the past decade but we understand that we can't rest. The world continues to change, including the microbial world. Tyson, in addition to our colleagues at other food companies, are doing everything we can to produce safe, quality products every day. Thank you for your time and attention.

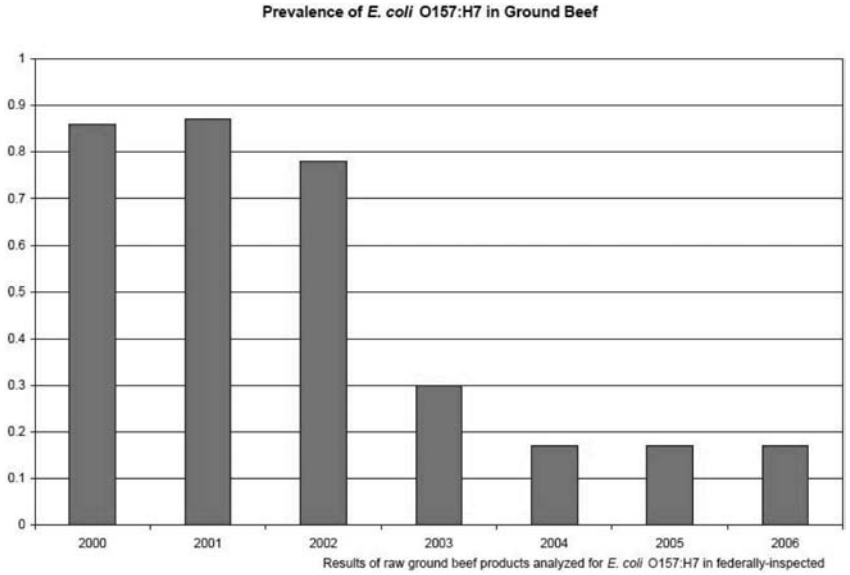
[The prepared statement of Dr. Roop follows:]

PREPARED STATEMENT OF RICHARD ROOP, PH.D., SENIOR VICE PRESIDENT, SCIENCE AND REGULATORY AFFAIRS, TYSON FOODS, INC., WASHINGTON, D.C.

Good afternoon, Mr. Chairman and Members of this Committee. My name is Dr. Rick Roop, and I manage food safety, quality assurance and laboratory services for Tyson Foods. Tyson is the world's largest producer of meat and poultry, as well as the Nation's second largest food company. We are highly committed to food safety innovations, and I thank you for inviting me here today to talk about our company's efforts to lower the incidence of *E. coli O157:H7* in beef.

Preventing Pathogens in Beef

As you can see from the chart below (which was constructed using data from USDA's Food Safety and Inspection Service), the incidence rate of *E. coli O157:H7* in ground beef has declined since 2000. For 2007, FSIS has indicated there is a slight increase in the incidence rate, and also an increase in beef recalls due to *E. coli O157:H7*. It is noteworthy that the Centers for Disease Control and Prevention reports *E. coli* related illnesses in 2007 at the same level as 2006. Overall, as the industry continues to find better technologies and product handling procedures; the decline in incidence is expected to continue.



Tyson operates nearly 100 food processing plants in 22 states and around the world. Our eight beef plants produce ¼ of the beef in the U.S. With such a significant role in the market—not to mention the trust Tyson has earned from consumers and our brand name reputation—Tyson team members utilize state-of-the-art food safety technologies and techniques in our plants. We employ risk assessment, training, testing, special handling, anti-microbial treatments, refrigeration and sanitation to get the job done.

When it comes to beef, we assume that every head of cattle entering our facility is contaminated with pathogens. Our goal is to prevent the potentially contaminated parts of the animal—the exterior of the animal and the interior of its digestive tract—from touching the uncontaminated parts: the meat. And we use many tools and technologies to further prevent contamination and preserve safety.

Tyson Beef Safety Programs

Several state-of-the-art methods to prevent contamination and preserve beef safety are used within Tyson fresh meat facilities. Among the key practices are: hygienic hide and viscera removal; use of steam vacuums on key areas on the carcass; use of organic acid solutions on the surface of carcasses and parts; treating carcasses with a final thermal pasteurization; using antimicrobial carcass washes; quickly chilling all carcasses and parts; managing the cold chain from start to finish and finally, using extensive testing to verify that our process controls work and the products are safe.

Three key food safety programs developed at Tyson to reduce pathogens in beef include the "Niche-Buster™," "Carcass Thermal Pasteurization," and "Tyson Total N60™" programs. These are all examples of effective and proactive food safety enhancements that were direct results of Tyson's commitment to risk-assessment, innovation and continuous improvement.

Niche-Buster™ targets microorganisms that could be harbored in niche environments, e.g. seams and cracks of the equipment or facilities. The program is employed in every Tyson beef slaughter and processing plant. A constant search and destroy effort is undertaken by our plant quality and sanitation experts to eliminate these harborage areas for bacteria. Originally for use in preventing *Listeria* contamination in ready-to-eat plants, Niche-Buster™ has proven to be extremely helpful in preventing *E. coli O157:H7* cross-contamination in Tyson beef plants.

The "Carcass Thermal Pasteurization" technology blasts every beef carcass with sufficient heat to raise the surface temperature above 160F, which is an immediate kill point for pathogens on the carcass surface. It is highly effective against all pathogens, and is a validated Critical Control Point (CCP) in all of our beef slaughter plants' HACCP plans.

"Tyson Total N60™" is a nickname for a Tyson-developed, extremely comprehensive and sensitive testing system to prevent *E. coli O157:H7* from contaminating ground beef. Tyson tests all raw beef components destined for ground beef production. The Tyson Total N60™ program provides a 95 percent or greater assurance of finding and eliminating *E. coli O157:H7* from beef which is used for ground product. Tyson Total N60™ is among our most powerful food safety tools, as it augments the other antimicrobial programs. It is so powerful that it has been adopted across the industry and recognized by the USDA. Tyson believes that programs such as Tyson Total N60™ that find and remove *O157:H7* containing meat from the ground beef supply chain, have contributed significantly to the significant decline in incidence the U.S. over the last several years.

Tyson Foods' dedication to safe, quality food is buttressed by the programs and controls we have to deliver on our promise of providing safe foods. From our laboratories, to our product and process monitoring programs, to our HACCP verification processes, we are focused on "feeding our families, the nation, and the world with trusted food products," a phrase you will find in our company's core values.

Our Food Safety and Quality Assurance Team

Tyson Foods Food Safety and Quality Assurance (FSQA) Team consists of approximately 2,500 professionals. This team works side by side with production to ensure the safety and quality of every product. FSQA Team Members execute and manage all phases of the Company's food safety and quality assurance programs including:

- Food safety and sanitation,
- Policy adherence and regulatory compliance,
- Laboratory services and statistics support,
- Product and process performance,
- Good manufacturing practices, and
- Food safety and quality training.

Our organizational structure is built to enhance independent, nonbiased decisions for FSQA managers. All FSQA team members, including myself, report parallel to Operating groups.

The safety of our products is also closely monitored by a Food Safety Team located at each facility. These multi departmental teams systematically evaluate key aspects of our production processes to prevent potential food safety concerns. The Food Safety Team will then work with their facilities to develop, implement, and monitor controls and procedures to drive continuous improvement.

Training is a key success factor for continuous improvement. Tyson Foods' Team Members are provided on-going food safety and quality assurance training. For example, in partnership with the University of Arkansas, Tyson Foods helped developed the Food Safety Training and Education Initiative.

Tyson Foods also partners with Texas A&M University to offer one of the few industry-sponsored training programs approved by the International HACCP Alliance.

Food Safety Laboratories

The Tyson Food Safety and Laboratory Services Network are recognized throughout the industry as research leaders in serological testing, food chemistry, microbiological testing, food safety research, and environmental water testing. Our accreditations include numerous Federal Government agencies.

- USDA–FSIS Food Chemistry,
- USDA–FSIS Pesticide Analysis,
- USDA/AMS Russian Export/Chemistry and Microbiological Testing,
- National Poultry Improvement Plan (NPIP) for Testing Avian Influenza and Mycoplasma synoviae and Mycoplasma gallisepticum, and
- USDA–APHIS for Salmonella Analysis.

Tyson Food Safety and Laboratory Services Network includes 17 laboratories across the country. This includes a 25,000 square foot, state-of-the-art food testing and research laboratory at Tyson Foods' World Headquarters in Arkansas. This laboratory is dual certified under the International Organization for Standardization (ISO) quality management system standard ISO 9001:2000 and the ISO/IEC 17025 standard for the competence of testing and calibration laboratories. In addition, seven other Tyson Foods regional and corporate laboratories are certified under the same ISO/IEC 17025 standard.

Tyson Foods also has 61 plant-based Quality Assurance laboratories. All tests conducted in these laboratories are thoroughly detailed in the corporate Laboratory

Manual. A 3½ day microbiology and chemistry course is offered regularly for management personnel and laboratory technicians located in our processing and rendering plants. Audits of these laboratories underline Tyson Foods' continuing commitment to quality.

Food Defense

Tyson Foods takes extraordinary measures for protection against deliberate acts of food product sabotage. We require each facility to take appropriate measures to ensure the security and protection of the food products they produce. Specifically, we require all facilities and co-packers to conduct vulnerability assessments. From this assessment, each facility then develops and maintains a facility food defense plan. This plan identifies the measures the facility will employ to avoid risk involving deliberate product tampering. Tyson Foods also requires each facility develop a response strategy in the event a threat to the food products they produce is made or detected.

Internal and External Food Safety Audits and Inspections

Tyson Foods' facilities receive routine internal quality assurance and food safety assessments. These assessments are conducted by quality assurance managers. They focus on:

- Critical food safety elements,
- Sanitation performance,
- Company policy adherence, and
- Regulatory compliance.

Each facility is also audited in accordance with the Tyson Foods Comprehensive Food Safety Audit Program. These internal audits are composed of audit team members that are independent of the facility being audited.

Tyson Foods' facilities also receive periodic third party audits of their food safety systems and good manufacturing practices (GMP's). These reviews, conducted by or on behalf of our customers, are performed by nationally recognized independent auditing firms.

These independent audits serve as additional verification that each facility is producing safe and quality food products. They also verify our compliance with applicable regulations, company policies, and customer specification requirements.

Tyson Foods' commitment to food safety is premised on the basis that food safety is not a point of competition between manufacturers. We openly share food safety research and technologies with our peers and colleagues. With the support of our Laboratory Services Group, Tyson Foods' partners with government, academia, trade associations, and other industry members to sponsor food safety research. We have made substantial contributions to research covering *E. coli O157:H7*, *Salmonella*, Avian Influenza, Bovine Spongiform Encephalopathy (BSE), *Listeria monocytogenes, Campylobacter,* and other public health issues and initiatives aimed at improving food safety.

Conclusion

We have made tremendous progress in learning how to improve meat safety over the past decade. But we understand that we can't rest—the world continues to change, including the microbial world. Tyson, in addition to our colleagues at other food companies, are doing everything we can to produce safe, quality products every day. Thank you for your time and attention.

The CHAIRMAN. Thank you, Dr. Roop, for that testimony. And last on the panel is Dr. Joseph Sebranek, Professor with the Department of Animal Science at Iowa State University in Ames, Iowa. Welcome, Doctor, we are looking forward to your testimony.

STATEMENT OF JOSEPH G. SEBRANEK, PH.D., UNIVERSITY PROFESSOR, DEPARTMENT OF ANIMAL SCIENCE AND DEPARTMENT OF FOOD SCIENCE, IOWA STATE UNIVERSITY, AMES, IA

Dr. SEBRANEK. Thank you, Mr. Chairman, Members of the Committee.

One of my research areas at Iowa State University has been the use of low-oxygen packaging systems including carbon monoxide for

fresh meat packaging. The technology has been criticized as deceptive and hazardous. This is an issue I want to address today because in my opinion, there is no scientific basis for these claims.

When considering fresh meat packaging technology it is important to understand the options that are available for packaging fresh meat and the advantages and disadvantages of each. For example, vacuum packaging, which is one packaging option, is universally practiced for wholesale meat cuts because it results in several-fold longer refrigerated storage life without spoilage. It is important to note that vacuum packaging is effective because it eliminates oxygen. Eliminating oxygen prevents growth of primary spoilage bacteria and prevents oxidative off flavors from developing at the same time. Unfortunately, vacuum packaging is not a suitable option for retail because the color is not attractive to consumers. However, the advantage of eliminating oxygen from contact with fresh meat in terms of vastly improved storage stability is an important point to remember.

The second option for packaging fresh meat is aerobic packaging. This approach uses a permeable film to allow oxygen from the air to contact the product surface. Oxygen is bound by the meat pigment to form the bright, cherry-red color. The color is clearly preferred by consumers but, unfortunately, the shelf life of fresh meat in aerobic packages is relatively short.

The third option for fresh meat packaging is modified atmospheres where air is replaced with a mixture of gases that provides for better control of product properties. One approach to use modified atmosphere packaging is a high-oxygen concentration, as much as 80 percent. This results in a red color with longer color stability but keep in mind that contact with oxygen allows aerobic bacterial growth and development of potentially rancid flavors.

A second approach to modified atmosphere packaging is to use 0.4 of 1 percent carbon monoxide with carbon dioxide and nitrogen. This approach produces attractive red meat color because carbon monoxide binds to the meat pigment in the same way as oxygen, only with a stronger bond and produces a cherry red color that is visually identical to that produced by oxygen. The most immediately obvious advantage to this approach is a stable red color that can last for 28 to 35 days, depending on the cut and refrigerated storage. This has been the basis for much of the criticism of this packaging concept with claims that this is deceptive and hazardous. But science does not support these claims and numerous scientists have expressed concerns over unwarranted criticisms of this technology.

Carbon monoxide is colorless and affects meat color in the same way as oxygen, that is by combining with the meat pigment. The color is derived from the pigment in both cases, not an external coloring agent.

It has been suggested that that color will last too long resulting in a spoiled product that still looks good. However, remember that eliminating oxygen slows spoilage a great deal. Further, spoilage, when it does occur, manifests itself in several other ways, one of which is odor. Perhaps more importantly, very recent research by Dr. Michael Doyle at the University of Georgia has shown that modified atmosphere packaging with carbon monoxide repressed

the growth of pathogenic *E. coli* on ground beef. Dr. Doyle concluded, "refrigerated or mildly temperature-abused modified atmosphere packaging with carbon monoxide for ground beef has better quality and microbial safety characteristics than over-wrapped beef under similar conditions."

Recent studies have also shown that meat cuts in high oxygen atmospheres were also less tender than those packaged without oxygen.

Consequently, the use of carbon monoxide packaging and modified atmospheres for fresh meat offers numerous advantages including improved product appearances, potentially better flavor, greater tenderness and suppression of bacterial growth. The use of carbon monoxide provides all the advantages of a vacuum package for maximizing storage stability with the attractiveness of an aerobic package for retail display. This is neither deceptive nor hazardous.

Seems to me it would have been most appropriate to let the marketplace decide the ultimate success or failure of this technology.

Thank you, Mr. Chairman.

[The prepared statement of Dr. Sebranek follows:]

PREPARED STATEMENT OF JOSEPH G. SEBRANEK, PH.D., UNIVERSITY PROFESSOR, DEPARTMENT OF ANIMAL SCIENCE AND DEPARTMENT OF FOOD SCIENCE, IOWA STATE UNIVERSITY, AMES, IA

Mr. Chairman and Members of the Committee:

Thank you for the opportunity to visit with you today about some of the current issues associated with technologies in the meat industry. My name is Joe Sebranek. I am a University Professor in the Department of Animal Science and the Department of Food Science at Iowa State University where I have been responsible for research and teaching in Meat Science for the past 32 years. I received a joint Ph.D. in Meat and Animal Science from the University of Wisconsin—Madison prior to joining the faculty at Iowa State. I have conducted research and published several peer-reviewed scientific reports on meat packaging technology which I understand to be the focus of this hearing. In particular, I have researched the use of carbon monoxide in fresh meat packaging which has been criticized as a "deceptive and hazardous" technology. This is an issue that I would like to address today because, in my opinion, there is no scientific basis for these claims.

When considering fresh meat packaging technology, it is important to understand the options available for packaging of fresh (refrigerated, unfrozen) meat and advantages and limitations of each. Meat is a highly perishable commodity and packaging plays a very critical role in protecting meat products from contamination and spoilage during distribution to consumers. For example, vacuum packaging of wholesale, primal cuts of meat, which is one packaging option, is universally practiced for wholesale packaging because it results in a several-fold longer refrigerated storage time without spoilage in comparison with products exposed to air. It is important to note that vacuum packaging, which consists of placing meat into a gas-impermeable bag or container and evacuating all of the air before sealing the package, is effective because it eliminates oxygen from contact with the meat. Eliminating oxygen prevents growth of aerobic bacteria which are the primary spoilage bacteria of fresh meat. Eliminating oxygen also prevents development of oxidative rancidity and associated off-flavors at the same time. Unfortunately, vacuum packaging is not a suitable option for retailing fresh meat because in vacuum, meat color reverts to a dark purple-red which is not attractive to consumers. There have been several attempts by the meat industry in the past to offer fresh meat to consumers in vacuum packages but these attempts have been unsuccessful because of the color issue. However, the advantage of eliminating oxygen from contact with fresh meat in terms of greatly improved storage stability is an important point to remember.

The second option for packaging fresh meat is aerobic packaging. This approach uses a permeable, clear film which allows oxygen from the air to permeate the film and contact the product surface. The oxygen is bound by the meat pigment myoglobin and in doing so, forms oxymyoglobin which has a bright, cherry-red color.

This is the color clearly preferred by consumers as documented by many, many studies on meat color. Unfortunately, oxygen contact allows rapidly-growing aerobic spoilage bacteria to proliferate and also initiates chemical oxidation reactions that eventually result in rancid flavors. Consequently, the "keepability" or shelf life of fresh meat in an aerobic package is relatively short, consisting of a few days to a week or two at most, depending on the meat cut and how it has been handled.

The third option for fresh meat packaging that has developed more recently is use of a impermeable film similar to a vacuum package but includes first evacuating the air from the package and replacing the air with a specified mixture of gases that provides for better control of product properties. This is modified atmosphere packaging or MAP. The air in the atmosphere we live in is 75% nitrogen, 21% oxygen, and less than 1% carbon dioxide with minute amounts of a few other gases, thus, changing the gas composition in a package from that of air is considered MAP. For fresh meat, two forms of MAP have been utilized. One approach is to use an oxygen concentration greater than air, as much as 80%, in MAP. This results in red color that may last as long as 10 to 14 days compared to about 5 days in a conventional oxygen-permeable package. Keep in mind that contact with oxygen allows many of the same effects as conventional aerobic packaging; that is, aerobic bacterial growth and development of rancid flavors over time. It has also been observed that high oxygen exposure can result in what is called "premature browning" when the meat is cooked. This means that meat turns brown at cooking temperatures lower than what is typical. Some scientists have expressed concern that consumers may not thoroughly cook products, particularly ground beef, to achieve bacterial safety in this case because the cooked color will look "well-done" when that is really not the case.

This brings us to the use of carbon monoxide in MAP. This is an alternative MAP system that has been approved by the regulatory agencies and has been available for a little more than 4 years. This system uses 0.4% carbon monoxide (CO), 30% carbon dioxide (CO_2) and 69.6% nitrogen (N_2). This approach produces very attractive meat color because CO binds to meat pigment in the same way as oxygen, only with a stronger bond, and produces a cherry red color that is visually identical to that of oxymyoglobin. The most immediately obvious advantage of this approach is a stable red color that can last for 28 to 35 days in refrigerated storage. This has been the basis for much of the criticism of this packaging concept, with claims that this is "deceptive and hazardous". There is simply no scientific basis for these claims. Carbon monoxide is colorless and affects meat color the same way as oxygen, that is, by combining with myoglobin. The color is derived from the meat pigment in both cases, not an external coloring agent.

It has been suggested that the color will last too long, resulting in a spoiled product that still looks good. I would like to point out that spoilage also manifests itself in other ways, the most obvious of which is odor. Thus, there are other very obvious warning signs of spoilage. Further, the MAP with CO packages include "use by" and/or "freeze by" dates to give consumers guidelines on the time by which the product should be used. It is also important to remember that elimination of oxygen prevents aerobic bacterial growth and dramatically slows spoilage compared with aerobic packaging. Perhaps more importantly, very recent research by Dr. Michael Doyle at the University of Georgia has shown that MAP with CO repressed the growth of pathogenic *E. coli O157:H7* on ground beef compared to conventional aerobic packaging, thus there is an impact on this pathogen as well. Dr. Doyle concluded that ". . . refrigerated or mildly temperature-abused MAP–CO ground beef has better quality and microbial safety characteristics than over-wrapped beef stored under similar conditions." Recent studies have also shown that meat cuts in high oxygen atmospheres were less tender than those packaged without oxygen probably due to the activity proteolytic, tenderizing enzymes that are known to be inhibited by oxidative conditions.

A final issue raised by some critics of MAP–CO system is the human exposure to CO, a recognized environmental hazard. However, at 0.4% in a package, it would require over 200 packages to exceed what the Environmental Protection Agency considers a limit for exposure to CO. This issue has been addressed many times and it is widely accepted that CO exposure from meat packaging is negligible.

Consequently, the use of MAP–CO for fresh meat offers numerous significant advantages including improved product appearance, better flavor, greater tenderness, and suppression of bacterial growth. The use of CO provides all the advantages of a vacuum package for storage stability with the attractiveness of an aerobic package for retail display. To quote one of my colleagues in Meat Science, Dr. Daren Cornforth of Utah State University, "What's not to like about that?"

There is one other point to be made. Carbon monoxide packaging can be combined with other antimicrobial treatments to dramatically improve fresh meat shelf life

and safety while retaining attractive color. A good example is irradiation, which when applied to ground beef to reduce or eliminate bacteria, typically results in a color change to a purple-red resembling vacuum packaged meat. However, if ground beef is irradiated in MAP–CO, cherry red color is retained while bacteria are reduced to very low numbers. Commercial ground beef processed with this combination has been advertised with a 38 day refrigerated shelf life which is a dramatic improvement over the typical 5 days. I fully recognize that irradiation is itself a controversial process. However, this provides a good example, in my opinion, of the often-unrecognized potential to combine MAP–CO with other technologies to maximize food quality and safety. Packaging with CO should continue to be available as an option to allow for development of new and innovative combinations of packaging with other new technologies to maximize quality and safety of fresh meat.

Finally, the MAP–CO technology has now been used commercially for almost 5 years and there have been no complaints that I am aware of from consumers about unexpected or unusual spoilage. This technology is establishing a track record that has been free of problems and has not been an issue with consumers. It seems to me that it is most appropriate to let the marketplace decide the ultimate success or failure of this technology.

The CHAIRMAN. Thank you, Dr. Sebranek. We appreciate the testimony. We appreciate all of the members of this panel being with us. Unfortunately, the way these hearings go and these time limits, we don't always get the time we need to figure out what is going on here. Now, Dr. Minerich, you have some packaging here. I had an hour to be showing all of this and ask questions when I had this, which we don't have here today. But have you got somebody with you that can hand these things around and just explain the different packaging and what the issues are with them?

Dr. MINERICH. Yes, I would be happy to do that. Thank you. Just quickly, and as my slide showed, modified atmosphere packaging has been used on a number of different packaging systems throughout the food industry. And I think if you recall, the last time you have walked through the grocery store, you see these packages all the time. Consumers are very, very familiar with modified atmosphere packaging.

As you heard from several of the other guests speaking today, you heard the conversation talking about vacuum-packaged meat. This is a good example of a vacuum-packaged primal. This packaged meat is dated at the production facility with the date it was put in the bag. And that could be 10, 20, 30, up to 60 days old, kept refrigerated and be totally wholesome. And when you open that package and then cut it and package it in the tray in the back room of the store, it would bloom bright red and still have 3 to 5 days of shelf life on the retail shelf. That is what Dr. Eilert mentioned. That is the ideal packaging system and that delivers the longest shelf life in the most wholesome environment.

What low-oxygen packaging does is the same. It removes the oxygen and yet with the 99.6 percent nitrogen or carbon dioxide gas and 0.4 percent carbon monoxide gives you all the benefits of vacuum packaging, as Dr. Sebranek mentioned, but also with the color, the visual color, we are looking for.

When you compare that to the alternate package, high-oxygen, we were in this package back in 1991. And for the reasons you have heard by those people testifying, the experience that the consumers had and the eating quality of that product lead us to help develop alternate packaging technologies.

As you see by all the packages in front of you, all of these technologies are advancements built on the benefits of the previous

packaging system and on some of the challenges and downfalls. You talk about the 9/11 Commission's interest in food safety and protecting package integrity. You look at eliminating cross-contamination issues that happen either in the back room or as consumers are handling the products and I think we can all think back to the times we have handled food products at the checkout counter and some of these juices have slipped over the line, maybe from the person in front of you, maybe as you have lifted this piece of meat up, your lettuce was in contact with that and now you have had a cross-contamination issue at this point.

So that is what these intact packages offer. One other thing that has been mentioned as well is the code dating. In the GRAS approval status for the low-oxygen packaging system, we mandated that code dating be a part of that GRAS standard and it is very prominently displayed and you will see it on the packages going around. And this is nothing new. We talked about all the packages that are code dated including our friends at Tyson with chicken. Code dating in the meat industry is nothing new and consumers wholly understand that they use this chicken by November 3 or they do not buy it. And the store, the retailer, will stop selling it. So code dating is a very important attribute.

Now, as you look at different systems, Hormel has been on the forefront of helping develop many of these packaging systems. And one of the alternatives, low-oxygen systems, is what we call the potato chip bag. We developed this back in the late 90's. And this was the pre-cursor to the low-oxygen, what we call, tray pack bag. And the reason we advanced technology from this to this is because sustainability is an important issue to Hormel Foods. This is what gets displayed to the consumer, it will look just like this package. This gets thrown away. It is film. There is an oxygen-absorbing scavenger in here. And when we ship this in a truck, we can only ship half as much as what we can ship here. So knowing that means twice as many trucks on the road, then here. So when you talk about sustainability, this was a challenge to Hormel Foods on how do we take this technology to the next step. The other thing is this package is not leak-proof, so we did not achieve what the consumer wanted, a leak-proof package. This low-ox packaging system does achieve that. And this really is the epitome of what we are trying to accomplish with these cuts of meat that do rely on visual evidence of quality and intactness of the package and leak-proof and code dating.

The other thing we do to this package, we have our brand name on it, we have the code date prominently displayed, we also have the code date on the back and we have an 800 number displayed, so that we encourage consumer interaction concerning our products to see if there is some part of this packaging attribute that we are missing. And to date, as I stated in my presentation, this was one of the best products we have ever introduced in our 116 year history as far as having consumer compliments and a very, very low consumer complaint ratio.

The CHAIRMAN. This package here, this is high-oxygen?

Dr. MINERICH. Yes, it is.

The CHAIRMAN. Does the oxygen go through this membrane or not?

Dr. MINERICH. No, Mr. Chairman, the oxygen stays. When we talk about modified atmosphere, the air we are breathing is about 80 percent nitrogen and 20 percent oxygen. That package is about 80 percent oxygen and 20 percent carbon dioxide.

The CHAIRMAN. Why doesn't this package have a date on it?

Dr. MINERICH. It probably is on the label. That was probably dated on the front label where the price tag is.

The CHAIRMAN. I don't see it but——

Dr. MINERICH. Okay. Typically, they would label that at retail and that is another one of the challenges. That is why we put mandatory dating as part of our GRAS notice on our packaging system.

The CHAIRMAN. But the difference between this and the low-oxygen is that the meat stays fresher with the low-oxygen.

Dr. MINERICH. The meat in the high-oxygen package that you have will have a shelf life based on color of about 10 to 14 days. Now, when you open that package and you taste it, you cook it, it will have a rancid or an off-flavor to it. It is not a good eating experience. And then also recall, because of that high-oxygen technology, the meat will turn brown at a very low temperature. So when you cook it, if you wanted to have a medium rare or a rare steak, you are going to have a hard time achieving that because the meat will turn brown faster. And one of our concerns from a food safety perspective with ground beef, we are asking our consumers to cook ground beef to a minimum 165 degrees Fahrenheit. If you cook by color like many consumers do, that ground beef will be brown far below that temperature of 160 degrees.

The CHAIRMAN. And how much of the ground beef is packaged like this?

Dr. MINERICH. I don't have that information. I don't know.

The CHAIRMAN. But that was one of the things I didn't understand until I had this presentation, you wouldn't be able to tell if it is still rare.

Dr. MINERICH. Correct.

The CHAIRMAN. It is brown.

Dr. MINERICH. Correct.

The CHAIRMAN. I am not much of a cook but when I cook something I kind of break it open to see if it is cooked or not and with this you sometimes wouldn't be able to tell.

Dr. MINERICH. No. No, sir.

The CHAIRMAN. And why don't people get concerned about that?

Dr. MINERICH. That is a good question. Like I said, we were in that technology in 1991 and it took us a few years to work our way out of it. It was a great advancement in technology but there were better technologies that have come over the years.

The CHAIRMAN. And on the low-oxygen, you actually increased the size of the freeze-by date, didn't you? I mean, it is a pretty good size on the front of the package and the back.

Dr. MINERICH. Yes, we did. We looked at Tyson and some other leaders in the industry that have used a code date, a very prominent code date right on the front. As I said, it is also code dated on the back but that is put on at our manufacturing facility. So that date is fixed and nobody can change that date. When it reaches the end of that date, the retailer disposes of that product.

The CHAIRMAN. All right. I have gone over my time I think. You guys were generous. I have some more questions but I will save those. The gentleman from Oklahoma, Mr. Lucas.

Mr. LUCAS. Thank you, Mr. Chairman. And, gentlemen, let us touch on the issue about consumer awareness, the dating on the packages, and the effect of trying to maintain a wholesome product out there with the consumers.

We saw recently where a company which had a difficulty with health issues, so to speak, and the ground beef industry went away. So the consumers tend to be very punishing in their decisions. If you make a mistake, they tend to respond with great intensity.

Discuss with us a little bit, and I know you all are from the scientific perspective on this, about the issues involved in that concern of consumers being able to make an informed decision by looking at your product. Do you think the way the packaging is done, do you think that the consumers will be able to make the right decisions on these issues? Just anyone on the panel care to touch on that?

Dr. EILERT. Congressman, at Cargill we were very focused and we paid particularly close attention to, in fact, we have been affected by recent recalls. We take this issue very seriously. And we do a risk assessment. As we develop new technologies, we assess the risk to make sure that we are not increasing additional risk. As we think about the fresh meat packaging system we think about any potential risk that may occur. One of the things that we are very comfortable with as we have studied this is that because we are able to control the life of that product, we are able to control the supply chain of that product, in a case-ready packaging format. We think we have greater ability to maintain the safety of that product throughout the chain. And so we do take these issues very seriously and, at the same time, we are very confident that because we are able to control the supply chain and the packaging of the product and minimize the opportunities for cross-contamination, case-ready packaging and modified atmosphere packaging is but another step to help maintain the safety of the product that has been engineered into it at the harvest-level facility.

I hope I have answered your question.

Dr. MINERICH. If I could add to that please?

Mr. LUCAS. Please.

Dr. MINERICH. There have been three independent studies that we are aware of that really support the additional safety of this low-ox and low amount of carbon monoxide packaging compared to the other packaging technologies. Dr. Michael Doyle, who is the Director for the Center of Food Safety at the University of Georgia, independently reports that this packaging technology retards the growth of *E. coli O157:H7* in ground beef, even under temperature-abusive conditions. And he calls MAP-sealed treated meat a revolutionary technology providing greater protection against food-borne pathogens. Dr. Mindy Brashears at Texas Tech also supports that with her work. Excuse me, Mindy. And also an independent study by the European Commission, Scientific Committee on Food, back in 2001 studied this packaging format and concluded that there is no health concern associated with 0.3 to 0.5 carbon monoxide gas

and a carbon dioxide and nitrogen modified atmosphere packaging. They also documented that this packaging system inhibits the growth of pathogens such as *Listeria monocytogenes, Yersinia enterocolitica* and *E. coli O157:H7*. Those are very important food safety studies that help support this type of technology over and above the other packaging options. Which is why you see more than a dozen of the food safety experts around the world endorsing this technology and really have not endorsed the high-oxygen technology. Thank you, Mr. Chairman.

Mr. LUCAS. Anyone else?

Dr. SEBRANEK. Well, I might add that one advantage of the carbon monoxide technology is that it allows incorporation of additional microbial control agents. For example, the elevated carbon dioxide, that is an anti-microbial treatment that can extend shelf life and control pathogens. The inclusion of carbon monoxide allows a higher than usual level of carbon dioxide to improve the stability and shelf life of the product. It, potentially, would also allow incorporation of other technologies. For example, there have been several demonstrations that combining carbon monoxide packaging with irradiation is a highly effective combination because irradiation, even though it is a very controversial process in itself, is completely effective against bacteria. So by using packaging technology for color preservation, irradiation for microbial control, you can vastly improve shelf life, even over those that we have been talking about. So my point is not to promote irradiation but to promote the option of combining this packaging technology with other technologies that might have a particularly good impact.

Mr. LUCAS. Very good point, doctor. Thank you, Mr. Chairman.

The CHAIRMAN. I thank the gentleman. The gentleman from Minnesota, Mr. Walz.

Mr. WALZ. Well, I thank you, Mr. Chairman, and I thank all of our panelists for being here today and listening to your testimony. And I would associate myself with the gentleman from Oklahoma talking about how the market will be very punishing, especially the three sitting here, to your industries if you are not providing food safety. And this issue comes up, I guess I just have a couple of questions because it seems and, in full disclosure here, Dr. Minerich is a constituent of mine and Hormel is located in my district and Cargill is a Minnesota company. With that being the case though, I approach this more as a consumer as I look at this. The issue and as you have discussed on this is not so much a food safety issue but as the way the food looks, the consumers are looking at the sell-by dates and all of that. Who is opposed to the low-oxygen technology? Where is this coming up as an issue if we have the scientists and many of the studies reporting that this is a safe technology, it is not doing anything. We still have the sell-by dates and you have indicated, Dr. Minerich, there have been no cases of foodborne illness through this technology. Then who is talking about this or is this a solution looking for a problem?

Dr. MINERICH. Thank you, Congressman Walz. I am not going to comment on the last question but on the first question, this whole issue arose from a spice manufacturer, who sells spices under control of several patents that help the high-oxygen technology stabilize that color longer. And that competing technology against ours

now is at risk. And that all generated about 2 years ago. We had been in the market 2 years by that time already, so total market time is about 4 years for us. And the interest, it is almost unfortunate that they are alarming consumers with the food safety issue when leading scientists endorse this technology. There are some entities protecting their constituents along that line instead of allowing the marketplace to settle the difference.

Mr. WALZ. This spice manufacturer is the one who did not show up today, is that correct?

Dr. EILERT. That is correct, being invited twice.

Mr. WALZ. What does their product do as a food additive that differs from low-oxygen? Their product keeps the product fresher or just keeps the color?

Dr. MINERICH. It keeps the color.

Mr. WALZ. So there is no difference?

Dr. MINERICH. They use oxygen to stabilize the myoglobin pigment in a high-ox atmosphere but their ingredient helps stabilize that color longer, according to their patents. Whereas, when you go to a low-oxygen format, you don't need that ingredient, so that ingredient is no longer necessary in these products. The color is stabilized by the small amount of carbon monoxide instead. So they are just competing technologies. When you said is this a solution trying to solve a problem that doesn't exist, as I said consumers are investing a lot of money into these meat products.

Mr. WALZ. Would I be naïve to think on this, I guess, from Tyson, Cargill and Hormel's perspective on this, if this different technology, the spice additive or whatever, if it were cheaper and did the same thing, you would probably switch to that, is that correct, if it would save money? I am just checking on this as you go.

Dr. MINERICH. No, we would not do it to save money.

Mr. WALZ. Okay.

Dr. MINERICH. Like I said, we were in this in 1991 and the eating experience was not a happy thing for our consumers.

Mr. WALZ. So you have been through this a long time of seeing what is best for the consumer, what is best for bottom line in terms of sales and what is going to, as you said, keep the food safe and not be an issue.

Dr. MINERICH. Correct. And these food safety attributes that this package offers over high-oxygen provide a much better packaging system for the consumer. And from food safety, from cross-contamination, less hands touching the meat.

Mr. WALZ. This is just in your opinion, this is a better technology.

Dr. MINERICH. Yes, sir.

Mr. WALZ. That is why you are using it.

Dr. EILERT. Congressman, we also—in Cargill, we offer a lot of different packaging solutions to our customers and the choice of which is dependent upon economics, consumer preference, supply chain needs. There are retailers in the United States that effectively can use a shorter shelf life product like these high-oxygen packaging systems can provide. They can manage the supply chain and it is an effective solution for them. There are some retailers without as sophisticated a distribution system that this is not as good of a solution as a shelf life that is more near the natural shelf

life potential of the products. And that is one of the key things that I want to make sure that the Committee understands, is that we are not talking about creating shelf life out of thin air. We are talking about protecting the natural shelf life of this product and using that protection to benefit our customers and the consumers. Will we still sell meat if we have only a high-oxygen format? I suppose we will but it won't be as high a quality as what we can achieve with this advancement and this technology.

Mr. WALZ. Okay. Well, I thank you and I yield back, Mr. Chairman.

The CHAIRMAN. I thank the gentleman. The gentleman from Kansas, could I follow up just for a second?

Mr. MORAN. Certainly, Mr. Chairman.

The CHAIRMAN. This company, do they have a patent on this other process?

Dr. EILERT. Yes, they do.

The CHAIRMAN. Do they then charge people and make money off that patent, I assume?

Dr. EILERT. The specifics, we can't comment to their exact commercialization.

The CHAIRMAN. But there is some kind of charge for that patent.

Dr. EILERT. Certainly, certainly. And the speculation might be that the license might be inherent with the use of the technology.

The CHAIRMAN. Is that the same situation with this low-oxygen? Is there some patent on that?

Dr. EILERT. Currently today there are no patents. There are patents in this area but there are no patents granted on the packaging technologies today.

The CHAIRMAN. So there is a difference there then?

Dr. EILERT. Yes, there is.

The CHAIRMAN. Okay. Thank you. The gentleman from Kansas, Mr. Moran.

Mr. MORAN. Mr. Chairman, thank you very much. The phrase "shelf life" has been used throughout your testimony and my first question is, what is the definition of "shelf life"? Is it agreed upon within the industry? First answer those questions and then I will see, I may have a third.

Dr. EILERT. Congressman, "shelf life" is in essence that period of time in which product is maintained in an acceptable quality level. It is the period of time in which spoilage is not evidenced at a noticeable level. Is there a standard shelf life for every single product on this table and the answer is no.

Mr. MORAN. Would each of the companies represented here today reach a different shelf life?

Dr. EILERT. They could very well. Now, what tends to happen is that with companies like represented here and some of our colleagues in the rest of the industry, there is a certain level. I talk a lot about shelf life potential. And when we take a piece of fresh beef, if we process that in a hygienic fashion and we store and distribute those products and managing the cold chain as best we can, then most of the companies are going to achieve the shelf life potential or very near the shelf life potential of the products. And so it is going to vary somewhat processor to processor. At the end of the day, any company, the ones represented here at the table, as

well as our colleagues in the industry, any company that puts their name, their brand, their inspection legend on those products, is obligated to protect and maintain that any shelf life that they put on those products is going to deliver for the consumers.

Mr. MORAN. Is shelf life related to food safety or related to customer satisfaction?

Dr. EILERT. Shelf life is related to customer satisfaction, it is not related to food safety.

Mr. MORAN. So who makes the determination that after a certain date the product has been on the shelf it is no longer safe for consumption by the consumer?

Dr. EILERT. Those are generally made by the—well, first——

Mr. MORAN. Safe?

Dr. EILERT. Okay. Again, from a safety standpoint, shelf life, we want to draw a distinction between safety and shelf life. When we talk about raw meat products today the primary control of the pathogens that can occur on those products takes place at the harvest facility. Those pathogens, and in the case of beef, let us talk specifically on beef, the *E. coli O157* organism is on the exterior of the animal, as well as in its digestive tract. The meat itself is sterile. It is perfectly safe for consumption. So the job of Tyson, the job of Cargill, the job of Hormel, is first and foremost to prevent the contamination from the outside of the carcass or from the interior of the animal to the meat product. That is the first line of defense that takes place. Now, everything else that takes place beyond the harvest process is making sure that temperatures are maintained, cross-contamination is minimized. And so when we talk about that, the occurrence of the pathogen at the harvest level has very little to do with the ultimate shelf life of the product. I hope I was able to draw that distinction.

Mr. MORAN. But those other factors, temperature, they do have an effect upon not shelf life but upon the safety of the product?

Dr. EILERT. If the pathogen is there, if the pathogen is present and if temperature abuse does occur.

Mr. MORAN. Maybe this is the point you are making with me, the pathogen, if it is going to be there, it is there from the slaughter.

Dr. EILERT. The harvest facility.

Mr. MORAN. Right.

Dr. EILERT. That is correct, Congressman. Yes.

Mr. MORAN. Okay.

Dr. EILERT. And so we have to maintain—I mean, our——

Mr. MORAN. If you do your job in the beginning——

Dr. EILERT. If we do our job in the beginning and then we control the cold chain throughout and that is from harvest, that is from processing, that is from case-ready packaging that is even distribution into the retail store, we will maximize the shelf life of the product and the quality and the eating experience. And additionally, if by some chance that organism was there to occur, we will minimize the potential for growth.

Mr. MORAN. When I read on a package that it says use by or sometimes it says use-by, sometimes it says sell-by, is there a distinction that is made by your company in what that means?

Dr. EILERT. You want to take that?

Dr. MINERICH. No, there is no difference. There is use-by, sell-by, freeze-by, best-by. There are a number of words used to describe an estimated end of shelf life.

Mr. MORAN. And really that is a marketing phrase——

Dr. MINERICH. It is the——

Mr. MORAN.—because it is consumer satisfaction.

Dr. MINERICH. Correct. You know, there have been a number of studies as to what makes the most sense to consumers. Use or freeze-by is the date most often used by manufacturers because that is a date that is very familiar to consumers. But it is placed by the manufacturer, determined by the manufacturer because the quality attributes of these products are measured in different ways. Some could be a color change. Some could be texture. Some could be flavor. Some could be loss of vitamins. Or on medications, a loss of an active bioactive ingredient. So a use or sell-by date really is a manufactured date. We could put 10 days, 20 days, 30 days. But it is up to us, as Dr. Eilert mentioned, to be sure that we deliver to our consumer a product that gives them an enjoyable eating experience, otherwise they won't come back and buy from us. So we are usually very conservative on sell-by dates or use-by dates.

Mr. MORAN. Mr. Chairman, thank you.

The CHAIRMAN. Thank you, gentlemen. The gentleman from Wisconsin, Mr. Kagen. Now, we have our own doctor who I know knows more about this than I do but Dr. Kagen.

Mr. KAGEN. Well, you probably want comparison by how much we eat. I want to thank you, first of all, for your testimony and also for your industry for bringing forward a wide array of food products that have been safe and very nutritious. And I grew up on Hormel and now that I am no longer a practicing physician but a politician, tell you, without chicken, we wouldn't be having very many fundraising events because that is all they seem to serve. But I won't get into the appearance of that meat or the tastiness or its rubber quality.

Dr. Sebranek, you went to one of the finest universities in this land, University of Wisconsin, as did I, and I want to thank you. I assume you don't represent any commercial interest here at Iowa State University and you don't receive any funding from corporations, is that true?

Dr. SEBRANEK. No, my research emphasis, my research supports comes only from the USDA. My packaging work has not been funded by the industry.

Mr. KAGEN. Well, let me address most of my few minutes of questioning towards you because in your written testimony, you indicated that carbon monoxide has some benefits. Has benefits for the appearance, the product, the flavor and the tenderness. I am going to have to take your word for it because I haven't studied it. And you also mentioned that Dr. Doyle from the University of Georgia has studied the potential anti-microbial activity of carbon monoxide. Am I correct that he compared the use of carbon monoxide in the packaging *versus* the aerobic packaging?

Dr. SEBRANEK. Yes, that is correct.

Mr. KAGEN. And he didn't study the anaerobic. Because as you and I know as scientists, if you take the oxygen away, you get much less bacterial growth.

Dr. SEBRANEK. That is correct.

Mr. KAGEN. So he didn't study the anaerobic packaging of the meat, he studied it against aerobic open-air packaging, basically?

Dr. SEBRANEK. Correct. But it is important to keep in mind, the absence of oxygen is the major advantage in all these systems, whatever they are.

Mr. KAGEN. Right. You also indicated, hinted in somewhat strong fashion, that irradiation might actually be better as an anti-microbial protection of meat products than carbon monoxide, is that true?

Dr. SEBRANEK. From the microbial standpoint, that is correct. It can be very, very effective.

Mr. KAGEN. Okay. And the other question I have, with regard to these studies that you mentioned and also your counterparts, were these studies on the ability of carbon monoxide to protect the meat, to prevent it from spoiling, were they done before or after it was put into the field and into practice?

Dr. SEBRANEK. The studies that——

Mr. KAGEN. Yes.

Dr. SEBRANEK.—we talked about?

Mr. KAGEN. The studies themselves, were they performed after it started to be used in the public?

Dr. SEBRANEK. Well, I guess from the standpoint of scientific studies they have accrued in both situations. There were studies prior to the commercial introduction, if I am understanding your question correctly.

Mr. KAGEN. So if I looked at the——

Dr. SEBRANEK. And after as well.

Mr. KAGEN. So if I looked at the date of Dr. Doyle's publication, it would be before the use of carbon monoxide was approved by any government organization?

Dr. SEBRANEK. Yes, right.

Mr. KAGEN. Okay. Very interesting. Now, the other thing I am learning here, because I really don't know all the rules of the USDA, but in the field in which I practiced for 30 years, allergy immunology, we had expiration dates on our allergy vaccines and every prescription drug that is licensed by the FDA has expiration dates that have some scientific merit and some scientific determination. Am I correct if I interpret what all of you have said that freeze or sell-by dates are sort of made up as you go along?

Dr. ROOP. I would like to comment on that.

Mr. KAGEN. Sure.

Dr. ROOP. They are not made up. They are scientifically determined by R&D staffs at our companies.

Mr. KAGEN. Okay.

Dr. ROOP. So it is not a random date.

Mr. KAGEN. So every product that your company makes releases to chain stores has the same date?

Dr. ROOP. No. All like products are evaluated based on how they are packaged and how they are handled through the process and then a sell-by date is determined.

Mr. KAGEN. So you determine the sell date by some objective means?

Dr. ROOP. That is correct.

Mr. KAGEN. Is it the initial bacterial load in the product as it goes out your door or how do you determine that?

Dr. ROOP. It is done by actually taking packaging prior to introduction and putting it in storage and observing the organoleptic properties and measuring the bacterial load as it increases over time.

Mr. KAGEN. So each product that you send out the door isn't studied for its potential degradative rate?

Dr. ROOP. Is or isn't?

Mr. KAGEN. Is not.

Dr. ROOP. All like products that have a sell-by date are.

Mr. KAGEN. Okay. So do you sample each product that comes off the line? Do you take a sample as we do in the dairy industry? We take samples from our milk producers, we take samples into the laboratory and do colony counts and bacterial counts. Do you do that with the meat product as well?

Dr. ROOP. All products are verified on a regular basis, not every product.

Mr. KAGEN. But in the production line, like let us say October 19, we could look at some bacterial data that you have? I see somebody nodding their head in the background. Either they are falling asleep or they are agreeing.

Dr. ROOP. There will be verification checks, yes, sir.

Mr. KAGEN. Okay. All right. Well, I thank you very much for your time and for your attention. I look forward to asking you more questions in written form. I yield back my time.

The CHAIRMAN. I thank the gentleman. The gentleman from Virginia, the Ranking Member, Mr. Goodlatte.

Mr. GOODLATTE. Thank you, Mr. Chairman. Mr. Chairman, the gentleman from Missouri, Mr. Graves, has asked that this statement be made part of the record.

The CHAIRMAN. Well, all Member statements will be made part of the record for today's hearing.

Mr. GOODLATTE. Thank you. Let me just ask all the panelists, there has been some testimony referencing the role of modified atmosphere packaging in reducing the prevalence of pathogens such as *E. coli* and since we are having a subcommittee hearing next week to discuss recent recalls for that pathogen, I wonder if you might take a moment to expand on this particular quality of the technology. Some of those who are advocating certain labeling requirements and so on seem to be suggesting that the technology is primarily used for the appearance of the product. I am hearing you reassure us that it is primarily for the safety of the product. I wonder if you might address that particular concern with regard to *E. coli* or modified atmosphere packaging that utilized to address that?

Dr. MINERICH. Congressman, you are correct on your earlier statement. The primary development goal for this technology was to advance previous technologies in delivering a quality product to our consumer. Some of the follow-up studies that were asked about by a previous Congressman were done following market introduction but I refer back to the study done by the European commission in 2001, which was done prior to the introduction of this low-ox lid stock technology. So there were follow-up studies and what the sci-

entific community tends to do as it is trying to validate technologies is explore all possibilities. You never do explore every possibility but you certainly want to be looking for opportunities that maybe this technology might actually encourage growth of *O157:H7*, which would be negative. We don't want to do that. So we were pleasantly surprised to see in these follow-up studies that actually this packaging environment suppressed the growth of that pathogen. That was an unexpected evaluation of the technology but it was something that we certainly embraced. The packaging technologies were created to extend the shelf life of the product or, as Dr. Eilert says, preserve the shelf life of the product that existed prior to being placed in the tray and give our consumers a good eating experience while maintaining integrity of the package, preventing cross-contamination and putting on the code date and the manufacturing facility.

Mr. GOODLATTE. But are you saying it also appears to have some other benefits?

Dr. MINERICH. Yes, it does.

Mr. GOODLATTE. Is that the answer to my question?

Dr. MINERICH. And that is the data on three separate studies.

Dr. EILERT. Congressman, if I may expand on that?

Mr. GOODLATTE. Sure, please.

Dr. EILERT. One of the comments that you made is the ability of this packaging format, this modified atmosphere packaging format, to prevent the prevalence of a *O157:H7*. Let me go back to the conversations from Dr. Rubin, Tyson, and then some of the earlier points. We are controlling the prevalence of the pathogen at the harvest facility. Now, at the point of packaging and in the supply chain in our packaging, the goal is to minimize the opportunity for growth if that pathogen did occur. Now, when our companies, Cargill and Hormel were a part of the joint venture precept, when we first looked at this technology, the first place we looked, as Dr. Minerich pointed out, was to make sure that the environment that we were putting the meat in was not going to contribute to increased risk. And the studies done in Norway and other studies done in the United States, we were confident that there had been enough scientific evidence that we weren't increasing risk with this format. Now, because of the high levels of CO_2 that Dr. Sebranek talked about that are in this product, high levels of carbon dioxide, not carbon monoxide, we are able and we have proven now under abusive conditions, it will actually inhibit the growth under temperature-abuse conditions. That is not why we did it, it is an added benefit. But let me just assure the Committee that we went into this fully knowing, from the scientific evidence, years of scientific evidence around carbon monoxide, that we were not going to increase risk.

Mr. GOODLATTE. Well, let me follow-up on that. Consumer groups have raised concerns related to the fact that modified atmosphere packaged meat retains it color well beyond its shelf life. Are you working on any new technologies to address that concern?

Dr. MINERICH. Yes, we are always looking to advance technologies. So as we have been made aware how sensitive that issue is to some consumer groups, we continue to look forward to advances in this technology. I don't think you will ever see any of

these three companies stop in our tracks on trying to advance food technology and food packaging technology that advances consumer acceptance and food safety.

Mr. GOODLATTE. Anybody want to add anything to that?

Dr. EILERT. I think I would agree with Dr. Minerich. I mean, this is not the end. This is not the pinnacle of our work. Any good scientist, any good progressive research group within one of these large companies, once the first technology is introduced, then they should start working upon what the replacement or what the advancement of that next technology is. And I think all of the companies represented here, amongst some of our other colleagues, are committed to that whether that pertains to freshness or whether that pertains to safety. And so we are going to continue to advance this area. In the meantime, this technology represents one of those said advancements. And we think it is incredibly unfortunate that we are being inhibited to advance the technology because of a campaign of pressure from a competing technology.

Mr. GOODLATTE. Is there any concern and have you heard from any consumers when the carbon monoxide is not used and you have a problem with a meat turning brown with the consumer not knowing whether or not that has been cooked before they start utilizing it?

Dr. EILERT. We have heard some of those comments and we have been aware of this evidence that meat can prematurely brown in high-oxygen packaging. That worries us. It is not where we want to be. At the same time, however, this has been a packaging format that has worked very well for a number of years for a variety of customers in supply chains. We recognize that that is an opportunity that we want to work on. So we think that as the technology evolved to high-oxygen packaging, that was a good thing. That allowed us to minimize that cross-contamination that we spoke about. That allowed us to maintain the integrity of the supply chain in these products. Did we want to improve? Absolutely. We want to improve for a lot of the reasons that you heard today. And so we recognize that there were limitations to that technology, one of which was the flavor development issue, one of which was this concept of premature browning. We want to move past that. We want the technology to evolve.

Mr. GOODLATTE. And let me just ask you to satisfy all the consumers out there, do each of you feel comfortable serving meat that has been packaged in modified atmosphere packaging using carbon monoxide to your family and your friends?

Dr. EILERT. I have two daughters. One is 12, one is 10. I am thankful to report that they are as carnivorous as the day is long. And I proudly and assuredly serve that product to my children on a regular basis.

Mr. KAGEN. Would the gentleman yield for a moment?

Mr. GOODLATTE. Yes, sir.

Mr. KAGEN. Would either of you object to the presence on a label of one of your products that carbon monoxide is being used?

Dr. EILERT. Yes, we would.

Dr. MINERICH. Yes.

Dr. EILERT. Now, one of the comments that I forgot to mention verbally but it is in my written text, because of the concerns that

have been emphasized, we are willing to add additional language on our labels. And that additional language would read something to the effect of color is not an adequate indicator of freshness, please refer to use or freeze-by dates. We see that, Congressman, as being an instructive statement. If we were to put a statement, such as this product is packaged in carbon monoxide, we see that as a declarative statement. What the consumer doesn't necessarily—the consumer can't use that information. It would be the same as if we declared what the particular plastic resins are in the material. It doesn't provide the consumer with a lot of benefit. However, a statement that says—and we probably should have done this earlier. A statement that says color is not an adequate indicator of freshness, please refer to use or freeze-by dates. We are highly supportive of that and we are willing to implement that as soon as we can work with the USDA upon approval of that statement.

Mr. KAGEN. But if carbon monoxide is a good thing because it decreases the bacterial load in the product, wouldn't you want the consumers to know about the good things you are doing for them?

Dr. MINERICH. Packaging gases have never been labeled—if you were to label the packaging gas on this packaging system, on the cheese or on the sliced meats or on the bag of potato chips, if that is a level playing field we want to be in, we are all for it. If everybody labels their packaging ingredients but, as Dr. Eilert mentioned, we don't know what value that brings. Do you want to know that this is packaged in a high-nitrogen atmosphere? Does that change your purchase decision? Do you want to know that this is a combination of gases to maintain freshness of bagged lettuce? What you really want is a good eating experience. That is what you want. And a use and freeze-by date is an important attribute to that.

Mr. KAGEN. I yield back.

Mr. GOODLATTE. I thank the gentleman for that question. I would say that information that is useful to the consumer is that they know what to do with it is more valuable than information that simply says something that may raise questions that are not answered on that same label.

Dr. EILERT. We agree.

The CHAIRMAN. I thank the gentleman. The gentleman from North Carolina, Mr. Etheridge.

Mr. ETHERIDGE. Thank you, Mr. Chairman. Dr. Minerich, the bulk of your testimony is pretty much directed toward packaged meats as I read it and mainly beef. And my question is, North Carolina is probably number two in pork and we have a lot of poultry. We have very little slaughtering of beef. To your knowledge, is there any operation that uses carbon monoxide or low-oxygen packaging that is utilized in the pork packaging?

Dr. MINERICH. Well, modified atmosphere packaging is used in pork but, to my knowledge, not carbon monoxide.

Dr. EILERT. That would be incorrect, we do. Both Cargill and Hormel, in the joint venture, we produce and package beef and pork in the modified atmospheres containing carbon monoxide.

Mr. ETHERIDGE. Okay, thank you. Let me ask this, direct this question at each of you. Hopefully, we will have time to get an an-

swer. The opponents of the modified atmosphere packaging charges that this practice deceives people in purchasing, what they call, spoiled meats. And assuming, and I know you don't want to assume this, correct, but just let us for a moment assume that to be correct. Seems to me that we would be seeing two results. One, an increase in the number of food poisoning from eating spoiled meats and, consequently, an increase in litigation against your companies and others or the supermarkets for selling it. So, generally, how often has your company been subject to litigation of this type since this technology has been utilized? Have your companies seen an increase in either the packaging processes litigation or can any of you explain to me why a company would engage in a practice if their opponents were correct, that would subject it to greater litigation?

Dr. MINERICH. We have not seen any litigation at all on this packaging technology. As I said, this has been one of the highest consumer acceptances of a product introduction in our company's history. So we have the 800 number boldly posted on there. We also stand alone in the food industry as having a money-back guarantee on this meat product. So we are encouraging consumers not only to call us if there is a problem, but we will give them their money back if there is a problem. And I understand the concern that people are buying spoiled meat. That is not happening. It goes back to the consumer acceptance level. They are not buying spoiled meat. But if they did buy spoiled meat, how did they know it was spoiled? It smelled or it looked funny for some reason or the package was bulging. There was some indicator that that was spoiled. Very similar to how do you know when milk is spoiled? You pour some on your cereal and you take the first bite and it is sour or it gurgles out. It is the same thing with orange juice. We have all consumed product that, I am not going to say has gone past its code date because it may have spoiled before its code date, depending on how it was handled, and still looked good, still looked wholesome. But you knew, through your experience of eating food your entire life, that that was going to give you a poor eating experience. It did not, however, increase your risk of food safety. It spoiled. It did not increase your risk of food safety. And that is a very difficult concept to understand but I will give you some very simple examples that will help you maybe, no pun intended, digest that. Yogurt. This used to be milk. It is curdled. By definition it is spoiled. And, as a matter of fact, you are eating this product because of how many bacteria are in this product. But it spoiled in a way that you enjoy it. You get a good eating experience out of this. You can spoil yogurt and if you leave it in the sun and different bacteria will grow in there, it will spoil and give you a poor eating experience but it will not jeopardize your health. This is not a food safety issue, it is a spoilage issue and that relates back to the shelf life: same thing with dry sausage; same thing with sauerkraut; same thing with cheese. Those are all products that have been selectively changed by the use of bacteria to, in one sense of the term, spoil it in a way that gives you a good eating experience. And the other spoilage organisms that cause the meat to sour or get milky or turn color or form gas, those will give you a poor eating experience. And you will smell it, you will see it, there will be an obvious reason as to why that spoiled and you will dispose of the product. And our

1–800 number and our money-back guarantee on this product line certainly encourages people to communicate with us.

Mr. ETHERIDGE. Thank you.

Dr. EILERT. Congressman, to directly answer your question, we have not entered into any litigation due to complaints from this packaging format. The rate of complaint, we are not going to say that we are perfect every time, sometimes we do not deliver because of one reason or another. The shelf life from these products can be highly variable. And so when our shelf life is not as good as it should be, we receive that feedback and react upon it. And if we don't, we won't be in business.

Dr. ROOP. Well, my answer has to be a little bit different because we are not into this type of packaging to the same degree as my colleagues. However, we do not oppose that type of packaging. I am unaware of any litigation to it. Thank you.

Dr. SEBRANEK. Well, the separation of spoilage and pathogens is a critical one. People have commented that spoiled food has never caused food poisoning because it prohibits consumption. And that is actually, as we teach in some of our elementary courses in meat science, a protective mechanism. So it is very important in this situation to separate spoilage and pathogens.

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

The CHAIRMAN. I thank the gentleman. The gentleman from Nebraska, Mr. Smith.

Mr. SMITH. Thank you, Mr. Chairman, and the panel. This has been quite educational and so I appreciate that. I know that through research and development everyone here on the panel devotes a great deal of effort into answering the concerns of the marketplace. I mean, I hear you saying that the marketplace is what speaks loud and clear and I would assume that a food safety issue will cost you far more than any savings on packaging. So I appreciate that. Are there any numbers that you would point to specifically that would lead us to support that last statement?

Dr. MINERICH. Can you repeat the last statement?

Mr. SMITH. Well, maybe job losses as to loss in consumer confidence after a particular food safety issue was reported or what have you.

Dr. MINERICH. Well, as Dr. Eilert mentioned, we work very hard in the industry to avoid that situation. I am aware that one recent food safety incident has caused the closing of a major food processing company in the East here and that is the type of concern that we have as we bring any product or any technology to market is that our brand, specifically, is not put at risk. So the science that is done before we go to market, the science that continues after we are in the market, continues to be strong to protect our brand and protect the product, protect the consumer.

Mr. SMITH. Okay. Thank you. I yield back.

The CHAIRMAN. I thank the gentleman. The gentleman from Iowa, Chairman of the Livestock Subcommittee, Mr. Boswell.

Mr. BOSWELL. Thank you, Mr. Chairman, and thank all of you for your participation today and I hope America is listening. Just to emphasize some things that some of you have said, I apologize to have you repeat it but I wanted to make it clearer. Dr.

Sebranek, you mentioned that some critics say that MAP is deceptive and hazardous. Again, for the record, in your opinion, are either of these assertions true? Deceptive?

Dr. SEBRANEK. I am sorry, would you repeat the question for me please?

Mr. BOSWELL. You mentioned that critics say that the modification is deceptive and hazardous. In your expert opinion, are either of these assertions true?

Dr. SEBRANEK. I am sorry, I having a little trouble picking up your question. I would like to ask to have it repeated for me. Yes, that is correct. The reason I say that is because the color is identical to what we have with the aerobic packaging and we have had many comments——

Mr. BOSWELL. I think perhaps we are not understanding you but I think what you are saying is, it is not true, it is not hazardous and it is not deceptive.

Dr. SEBRANEK. That is correct. It is not hazardous nor deceptive.

Mr. BOSWELL. All right. I am sorry for—I have a little laryngitis, so I hope you will forgive me for that. Perception is sometimes like fact in some people's mind, but maybe give us a better way or another way that you could elaborate on how using carbon monoxide, which can be deadly to humans, you know—an old airplane I fly, I keep a little monitor in there. I don't want to go to sleep at the switch, so to speak. And so we have that perception as bad, which it is if it is over-abundance, but how can we point out that it is not detrimental in the packaging you use? Because of the minimal amount?

Dr. EILERT. Yes, that is correct. There is an adage, Congressman, that the dose makes the poison. A good portion of these products today contain ingredients that can be lethal if applied at too high of a level. Sodium nitrite, carbon dioxide, a host of others. And so there was a lot of work. I mean, in addition to the basic product safety work, there was also a human exposure element and a toxicology element to our review that we conducted when we presented this technology to FDA. And ourselves and predecessors in the industry showed that the levels of exposure to carbon monoxide in this packaging format are far below those levels that would be even close to being hazardous to humans.

Mr. BOSWELL. I appreciate that. This is not what you expected today to have a question about but where I come from we have a lot of people that do home butchering and home freezing. And so constituents ask me, "We have all these experts, what is the shelf life of frozen meat in the home freezer in a self-defrosting freezer?"

Dr. MINERICH. Well, that depends on the meats species and how it is packaged.

Mr. BOSWELL. Well, let us say beef.

Dr. MINERICH. If beef is packaged well, you are going to talk about a shelf life that is 3 to 6 months for good eating quality. It will be safe for the entire period but what you risk in a freezer is dehydration. So if you have a packaging system that allows for gas transmission, like you bought some meat that was packaged at the local butcher, that has a high gas-transmission rate, you throw that in the freezer.

Mr. BOSWELL. I think this constituent had something that they took to their local locker, had packaged at their request, they brought home to the farm and stuck in the freezer.

Dr. MINERICH. Yes.

Mr. BOSWELL. So for how long is it safe?

Dr. MINERICH. How long is it safe is a different question. If it was contaminated at the local butcher, it is not safe from day one.

Mr. BOSWELL. Okay, I understand that.

Dr. MINERICH. But you are talking about shelf life and eating quality and if you froze it in the white-wrapped butcher paper, it is probably going to have a good eating quality for maybe a month but it will dry out very fast. So I am sorry to say, as a scientific answer, it usually depends.

Mr. BOSWELL. Usually depends. I yield back.

The CHAIRMAN. I think the gentleman was wondering whether the pheasants and goose that he shot this weekend are going to last for——

Mr. BOSWELL. No, I haven't got around to that yet.

The CHAIRMAN. The gentlelady from Kansas, Mrs. Boyda.

Mrs. BOYDA. Thank you so much, Mr. Chairman. I just had some questions, somewhat out of curiosity and learning about this. I certainly appreciate what you are saying about competing technologies and maybe there is some lack of truthfulness that is going on here. But I have a couple of questions. When we are talking about—in the other packaging that you were referring to, does anything else use carbon monoxide in their modified environments?

Dr. MINERICH. Not that I am aware of.

Dr. EILERT. We are aware that carbon monoxide is approved for some produce applications but we are not knowledgeable to know whether or not it is being applied.

Mrs. BOYDA. My question here coming up is more one of curiosity.

Dr. EILERT. Okay.

Mrs. BOYDA. When you are talking about carbon monoxide, that it actually is binding and that what it is doing, is it binding with the hemoglobin in there to keep the bright red color. So, in fact, it is not an inert gas that is just sitting on top of everything, it is actually something that is now part of the product and it is really now part of a preservative.

Dr. EILERT. The carbon monoxide does bind but it is not an irreversible bond. And so as the package is opened, then that carbon monoxide dissipates. Additionally, if there is carbon monoxide that is bound to the myoglobin molecule, during the heating process it also gases off in the heating process. And perhaps Dr. Sebranek could explain that even a little better than I have.

Dr. SEBRANEK. Yes, that is correct. Even though it is a stronger bond than in the case of oxygen, it is lost from the pigment over a period of time or in exposure to heat. So you do get browning of the product during cooking, for example. The preservative, the anti-microbial effect is primarily due to carbon dioxide.

Mrs. BOYDA. Correct.

Dr. SEBRANEK.—in that atmosphere.

Mrs. BOYDA. And I got that one too. Because that is what I was wondering. What happens to the carbon monoxide? If it is driven

off, then we have the same problem of brown is brown and how do you know if it is pink? I cook towards pink and, quite honestly, I like my steak very pink, forget that, I like it red. But it has just got to be, and just logically it has got to be kind of one or the other. The high-oxygen environment has the problem with turning it brown so you can't tell if it is cooked. So either the CO is hanging on and it is staying pink or it is gone and it is going brown. I am just trying to figure out where that is coming in.

Dr. SEBRANEK. Well, you do in some cases get a longer retention of pinkness sometimes in the center of cuts with carbon monoxide to retain pink for a longer period of time during cooking. But that is not necessarily a bad thing——

Mrs. BOYDA. No.

Dr. SEBRANEK.—from the cooking standpoint.

Mrs. BOYDA. What I am curious about is who helps you with your labels? Does USDA have label requirements or is it FDA?

Dr. EILERT. Yes. The Standards of Labeling Division of the USDA.

Mrs. BOYDA. I am just curious again. This is interesting. The competing technology that you had and I don't even know what it is, was it required to be on the label?

Dr. EILERT. Yes, it was. It was an ingredient.

Mrs. BOYDA. You know where I am going with this. I don't understand why the carbon monoxide—it is not like it—the rest of the packaging environments that you are talking about are inert environments meant——

Dr. SEBRANEK. No.

Mrs. BOYDA.—to be pretty much inert.

Dr. EILERT. But they are not inert. Even the oxygen that is in a high-oxygen package is not inert. It has a——

Mrs. BOYDA. Well, obviously, because that is what——

Dr. EILERT. Right.

Mrs. BOYDA. Right.

Dr. EILERT. Right. The carbon dioxide that we have in these packages, as well as in a lot of perishable items, even, for instance, produce, cheese, and a lot of perishable items, non-shelf stable items, will use carbon dioxide. That carbon dioxide reacts with the moisture in the food to form carbonic acid in the food and that has an inhibitory effect against micro-organisms. Now, as the product is consumed, as it is removed from that environment and it is prepared, that dissipates. And so, again, I think as you think about gases, you almost have to think about gases in terms of they are almost like packaging materials and less like ingredients. Because at the end of the day as I consume the meat, as my daughters consume the meat that is in that carbon monoxide packaging, the intake of carbon monoxide is negligible.

Mrs. BOYDA. Yes.

Dr. EILERT. However, if I add——

Mrs. BOYDA. That I don't disagree with you about.

Dr. EILERT. Okay. But if I add an ingredient—if I add what is being referenced as a natural flavoring, which is the competing technology. It is referred to as a natural flavoring but it has a functional effect, it is there in the meat that my family consumes. And so I think, as I look at packaging gases, as we look at packaging

gases, and I believe this is how the Labeling Division has also looked at packaging gases, since they no longer have a lasting effect or a residual content in the product that is consumed, then it is not an ingredient.

Mrs. BOYDA. Then can I cook a steak and keep it red?

Dr. MINERICH. In our package, yes.

Dr. EILERT. Can you cook a steak——

Mrs. BOYDA. Can I grill a steak and keep it red?

Dr. EILERT. As long as you don't cook it to too high.

Mrs. BOYDA. But if I cook my steak to medium rare or to rare——

Dr. EILERT. Right.

Mrs. BOYDA.—then it is going to be red?

Dr. EILERT. Correct.

Dr. MINERICH. In the low-ox packaging system.

Dr. EILERT. Right.

Dr. MINERICH. Yes.

Dr. EILERT. Right.

Dr. MINERICH. But you will have a very difficult time doing that in a high-ox packaging system.

Mrs. BOYDA. Yes.

Dr. MINERICH. Especially at the end of the code date.

Mrs. BOYDA. I appreciate the update. This is a learning experience for me.

Dr. EILERT. We appreciate the questions.

Mrs. BOYDA. I come from a background with the FDA, so the whole thing of binding—it seems to be, even though it must be an incredibly small amount of ingestion, I just don't understand how it is not part of the label. I can understand why you wouldn't want it to be part of a label. I am just kind of wondering how it doesn't seem to be part of a label.

Dr. EILERT. And to me it still comes down to the base fact that——

Mrs. BOYDA. Sure. You are talking about absolutely negligible amounts.

Dr. EILERT. Negligible amounts——

Mrs. BOYDA. Extremely negligible amounts.

Dr. EILERT.—and compositional quantities. So, I mean, the meat that we eat is made up of moisture, fat——

Mrs. BOYDA. Yes.

Dr. EILERT.—protein, minerals, vitamins. We can analyze for those things. Those things are there. We can analyze for the carbon dioxide or the carbon monoxide and we would hardly be able to find them.

Mrs. BOYDA. No, I wouldn't disagree with that.

Dr. EILERT. Okay.

Mrs. BOYDA. All right. Thank you so much.

Dr. EILERT. Thank you.

The CHAIRMAN. I thank the gentlelady and I think in light of this last discussion, it again points out how disappointing it is to me that the other company that is involved in this chose not to be here today. I think this has been a very educational process. I have learned some more today. I think a lot of the Members did and that was the purpose of what I was trying to do here. Had that other

company been here, I think we could have gotten a little bit more understanding of exactly what is going on here but there may be another day for that. We have a vote in 15 minutes. Unless any other Members, Mr. Costa, do you have questions? The gentleman from California.

Mr. COSTA. Sorry, gentlemen. This will only be 5 minutes and relatively tame I hope. I am not sure who is the best to address this question but you might look around since you folks feel comfortable with one another. Is there, in your view, any changes that we ought to be considering as it relates to the law with the FDA, the Food and Drug Administration, on how we deal with food packaging in its entirety in this country? I mean, the whole issue of food safety, of course, is on people's minds these days, not only in terms of issues like *E. coli* and importation of various food products. You were talking earlier about state of the art and always moving science forward, I am trying to remember which gentleman indicated that. What else could we be doing?

Dr. MINERICH. I would encourage innovation. One thing we haven't talked about in the form of packaging is active packaging. I don't see it in here right offhand but many of these types of packages have an oxygen-absorbing scavenger in it and that is an actual element, just like this, that is placed in the package to absorb oxygen. And as you look at these advances in packaging technologies, different films, different papers, different trays, they are all designed to protect the food from the point of manufacture to the consumer. And so anything that can be done to encourage innovation would be appreciated.

Mr. COSTA. So those are other processes that control microbial activity outside of the packaging? What about those?

Dr. MINERICH. As Dr. Eilert mentioned, carbon dioxide has been used now for a number of years because it does react with the moisture in the package, creates carbonic acid, which actually acts to inhibit microbial growth in packaging systems. As Dr. Sebranek mentioned, irradiation is a great combination technology with some other packaging atmospheres that helps, as a synergistic effect, it will help boost the lethality of that system.

Dr. SEBRANEK. I might add that in the research arena, there are people looking at ways of incorporating a variety of anti-microbial protective agents into packaging films. They would interact with the product in such a way to prevent that oxidative change or microbial changes and so forth. That is a very active area of research right now. I think we might see incorporation of various kinds of protective agents into packaging films in the future.

Mr. COSTA. It seems to me that all of you folks, both working on the academic side and the scientific community and those representing various leading companies in this country, have been at the cutting edge. I think all of you probably agree that sound science is the best methodology in terms of the pursuit of health and safety goals. Is that not correct?

Dr. EILERT. Correct.

Dr. MINERICH. Correct.

Mr. COSTA. I want to make note on that point, recently an industry from my district received the Richard L. Knowlton Innovation Award, which I think is sponsored by Hormel and others. Dave

Wood and the Harris Ranch operation won for their innovation and their technology. They always are focusing on, and I have toured their facility a number of times on, Best Sound Science. I want to know, do any of you believe whether or not science indicates that there are any current health risks associated with the various packaging on food safety? I know we talked about the different methodologies that are preferred or used today. Is there any preferred methodology in terms of the science?

Dr. EILERT. I think that it is important to remember and as we have discussed in this forum, as it pertains to fresh red meat or fresh meat and poultry, the primary point of control of the occurrence of pathogen is at the harvest level. As long as packaging systems do not increase the potential for rate of growth or do not increase the overall risk if that pathogen should happen to occur, then I think a lot of these packaging formats can be as safe as each other. The importance of using packaging is to prevent the opportunity for risk like cross-contamination.

Mr. COSTA. But based on risk assessment *versus* risk management, there has been no comparative analysis on the various methodologies that we have discussed here today?

Dr. EILERT. I don't think there has been a comprehensive risk analysis, as well as risk prevention, comparison of each of the technologies.

Mr. COSTA. From nitrogen to carbon monoxide to high——

Dr. EILERT. Well, in that respect, there are gases that—the primary gases we use in food packaging that has an anti-bacterial effect, at the levels that we would normally use, is carbon dioxide. Oxygen has really no inhibitory effect on pathogen growth.

Mr. COSTA. Nitrogen?

Dr. EILERT. Nitrogen does not have an inhibitory effect on pathogen growth. And at the levels that we are using, carbon monoxide——

Mr. COSTA. And irradiation.

Dr. EILERT. Irradiation does, irradiation is a kill step. It is not an inhibitor, it is a kill step.

Mr. COSTA. All right. Thank you, Mr. Chairman, and I thank the members of the panel for your very thoughtful testimony.

The CHAIRMAN. I thank the gentleman and hearing no further questions, we will dismiss this panel. We still have Mr. Almanza, the new Administrator for FSIS with us. So, gentlemen, thank you very much. It has been very informative and we appreciate your being with us here today.

Dr. EILERT. Thank you, Mr. Chairman.

The CHAIRMAN. And Mr. Almanza, we will call you to the witness stand and welcome your testimony and get your take on what all these guys have said here. Mr. Almanza, am I saying that right, Almanza.

Mr. ALMANZA. Yes, sir.

The CHAIRMAN. Welcome to the Committee. I understand this is the first time you have been before the Agriculture Committee. We welcome you here today.

Mr. ALMANZA. Yes, sir.

The CHAIRMAN. You are accompanied by Mr. Phil Derfler, is that correct? Am I saying that right?

Mr. DERFLER. Yes, sir.

The CHAIRMAN. And Dr. Engeljohn?

Dr. ENGELJOHN. Yes, thank you.

The CHAIRMAN. All right. So we are going to have a vote here in a little bit but I think we have enough time to get through your testimony. I have some questions and I don't know what your timing is but we may have to run over and vote and come back, are you okay with that?

Mr. ALMANZA. I am here for as long as you need me.

The CHAIRMAN. Very good. Well, welcome to the Committee and we look forward to your testimony.

STATEMENT OF ALFRED V. ALMANZA, ADMINISTRATOR, FOOD SAFETY AND INSPECTION SERVICE, U.S. DEPARTMENT OF AGRICULTURE, WASHINGTON, D.C.; ACCOMPANIED BY PHILIP S. DERFLER, ASSISTANT ADMINISTRATOR; AND DANIEL L. ENGLEJOHN, PH.D., DEPUTY ASSISTANT ADMINISTRATOR, OFFICE OF POLICY, PROGRAM AND EMPLOYEE DEVELOPMENT, FOOD SAFETY AND INSPECTION SERVICE, U.S. DEPARTMENT OF AGRICULTURE

Mr. ALMANZA. Thank you. Mr. Chairman and Members of the Committee, thank you for inviting me to appear before you today to discuss technologies in the meat industry and the processes that the United States Department of Agriculture and the Food Safety and Inspection Service use to review new technologies to protect public health.

Before I begin, as this is my first time appearing before this Committee, let me take a moment to introduce myself. I am Al Almanza, Administrator of USDA's Food Safety and Inspection Service. I have been with FSIS for almost 30 years and have held numerous positions beginning on the slaughter line in Dalhart in the Texas Panhandle. Prior to becoming Administrator at FSIS, I was the Dallas District Manager. I believe my field experience at the front lines of the agency helps my work a great deal as the Administrator. As the District Manager and now as Administrator, I know that there are things that can be done at the agency that would benefit all, consumer groups, industry and employees. One such thing is encouraging the use of beneficial new technologies in the meat industry.

The development of new technologies is largely initiated by industry itself as it responds to consumer demands. There are two different types of technologies that are subject to review, processing technologies and ingredient technologies. Processing technologies are those technologies developed to aid in the production of meat, poultry and egg products. Examples of processing technologies that have been reviewed include carcass washes, steam vacuum and steam pasteurization. Ingredient technologies are those technologies that involve the addition of an ingredient to a product or the use of packaging to ensure safety, increase shelf life or provide other consumer benefits. Examples of this kind of technology include carbon monoxide packaging and irradiation.

For my oral testimony I will focus on ingredient technologies. A second aspect of new technology involves the use of new food ingredients in meat food products. Prior to the year 2000, the review

process for new ingredients was lengthy and cumbersome. FDA was responsible for the initial safety review. This was then followed by a review by FSIS to determine the acceptability or suitability of the technology. That is to determine whether the ingredients serve the purpose for which it was intended.

In the year 2000, FSIS and FDA entered into a Memorandum of Understanding allowing simultaneous review of new technologies to increase the speed with which useful new food ingredients could be used. FDA determines the safety of the use of a food ingredient and its safe levels of use. At the same time, FSIS evaluates whether the ingredient is effective for its intended use. For example, as a flavoring agent. What this means is that FDA evaluates the available evidence to see if there is a reasonable certainty that no harm will result from the use of the substance. FDA looks at a range of evidence in making this determination, from published studies to data from studies performed by the sponsor to establish the safety of the use of the substance. As for FSIS, we evaluate data on whether the substance will have its claimed effect. In addition, we look to ensure that the substance will not mislead consumers by making it appear fresher or more appealing than it actually is. Because FSIS and FDA perform their functions at the same time, rather than sequentially, a food ingredient spends less time in review than it did before the agencies started working in this way.

One form of technology used by the meat industry that has received a great deal of attention in recent months is carbon monoxide in packaging. Carbon monoxide is used to stabilize the color pigment of meat. When it is red and, therefore, most appealing to consumers, use of carbon monoxide in packaging does not impart a color to the meat, it simply maintains its naturally-occurring color.

In 2002, carbon monoxide, for use as a component of modified atmosphere packaging, was accepted by FDA as being Generally Recognized As Safe or GRAS. Carbon monoxide does not become a part of the product and dissipates as soon as the package is opened. This is unlike other ingredients used to stabilize the red color of meat, such as citric acid, sodium ascorbate and rosemary extract, all of which actually do become a part of the product. However, to be sure consumers are not misled, FSIS has required a use-by, freeze-by date to be included on meat products that use carbon monoxide packaging. This is to ensure that the shelf life of the product ends before spoilage occurs.

As Members of the Committee are no doubt aware, FDA has received a petition asking it to withdraw its decision that carbon monoxide in meat packaging is Generally Recognized As Safe. FSIS will continue to make its labeling decisions and its suitability reviews on the basis of FDA's safety conclusions.

Thank you for the opportunity to testify before you today. I look forward to addressing any questions you may have and I also brought along Dr. Englejohn and Mr. Phil Derfler to assist me with the technical questions. Thank you.

[The prepared statement of Mr. Almanza follows:]

PREPARED STATEMENT OF ALFRED V. ALMANZA, ADMINISTRATOR, FOOD SAFETY AND INSPECTION SERVICE, U.S. DEPARTMENT OF AGRICULTURE, WASHINGTON, D.C.

Mr. Chairman and Members of the Committee, thank you for inviting me to appear before you today to discuss technologies in the meat industry and the processes that the U.S. Department of Agriculture (USDA) and the Food Safety and Inspection System (FSIS) use to review new technologies and to protect public health.

Before I begin, as this is the first time I am appearing before this Committee, let me take a moment to introduce myself. I am Al Almanza, Administrator of USDA's Food Safety and Inspection Service (FSIS). I've been with FSIS for almost 30 years and held numerous positions, beginning on the slaughter line in Dalhart, in the Texas panhandle. Prior to becoming Administrator at FSIS, I was the Dallas District Manager. I believe my field experience at the front lines of the agency helps my work a great deal as Administrator. As a District Manager, and now as Administrator, I know that there are things that can be done at the agency that would benefit all—consumer groups, industry, and employees. One such thing is encouraging the use of beneficial new technologies in the meat industry.

FSIS' New Technology Staff

Application of new technologies may help protect consumers from physical, chemical, or biological hazards; reduce or eliminate such hazards in the product itself; and improve product quality. Conversely, the use of an inappropriate technology could result in a product that could endanger public health.

At FSIS, we recognize the value that new technologies can offer for public health. Many new technologies have resulted in significant improvements in the safety of meat and poultry products. For this reason alone, FSIS would like to see new technological advances continue, provided those advances are deemed safe and appropriate.

Because the development of new technologies often requires large amounts of capital and extensive infrastructure, many establishments—especially small and very small establishments—have difficulty taking advantage of new technologies. This is one of the reasons why FSIS set up a New Technology Staff (NTS). NTS, working with our training, outreach, and education employees, provides assistance and disseminates information on new technologies.

Evaluating New Technologies

The development of new technologies is largely initiated by industry itself, as it responds to consumer demands. There are two different types of technologies that are subject to review: processing technologies and ingredient technologies. Processing technologies are those technologies developed to aid in the production of meat, poultry, and egg products. Examples of processing technologies that have been reviewed include carcass washes, the steam vacuum, and steam pasteurization.

Ingredient technologies are those technologies that involve the addition of an ingredient to a product or the use of packaging to ensure safety, increase shelf life, or provide other consumer benefits. Examples of this kind of technology include carbon monoxide packaging and irradiation.

Processing Technologies

There are four basic questions FSIS asks when evaluating a new processing technology:

- Will this technology affect product safety?
- Will this technology affect inspection program personnel safety?
- Will this technology interfere with inspection?
- Will this technology be consistent with existing regulations?

Establishments planning to use a new technology are responsible for ensuring the continued safety of their workers, their products, and the environment, inside and outside the establishment, as well as responsible for providing the information necessary for FSIS to examine the impact of the new technology on inspection procedures and inspection program personnel safety. We encourage facilities wishing to employ new technologies to notify to FSIS before they implement them. That way, the agency can assess the technology in light of the four questions I listed. The agency convenes an ad hoc group of experts from all relevant parts of the agency to perform this assessment. FSIS attempts to complete its assessment of the technology within 60 days. Once the assessment is complete, the agency lets the company know if it has a concern in any of the four areas. If the agency does, the company has an opportunity to do a study to address that concern.

If the agency finds no basis for objection to the use of the technology, it posts a brief description of the technology on the FSIS website in order to inform all interested parties.

Ingredient Technologies

A second aspect of new technology involves the use of new food ingredients in meat food products. Prior to 2000, the review process for new ingredients was lengthy and cumbersome. FDA was responsible for the initial safety review. This was then followed by a review by FSIS to determine the acceptability or suitability of the technology; that is, to determine whether the ingredient served the purpose for which it was intended. In 2000, FSIS and FDA entered into a Memorandum of Understanding allowing simultaneous review of new technologies to increase the speed with which useful new food ingredients could be used.

FDA now determines the safety of a food ingredient and its safe levels of use, while simultaneously FSIS evaluates whether the ingredient has its intended technical effect. Allowing these evaluations to occur at the same time effectively decreases the time any food ingredient spends in review.

Carbon Monoxide in Meat Packaging

One form of technology used by the meat industry that has received a great deal of attention in recent months is carbon monoxide in packaging. Carbon monoxide is used to stabilize the color pigment of meat, when it is red and, therefore, most appealing to consumers. Use of carbon monoxide in packaging does not impart a color to the meat; it simply maintains its naturally occurring color.

In 2002, carbon monoxide, for use as a component of modified atmosphere packaging, was accepted by FDA as being "Generally Recognized as Safe," or GRAS. Carbon monoxide does not become a part of the product and dissipates as soon as the package is opened. This is unlike other ingredients used to stabilize the red color of meat, such as citric acid, sodium ascorbate, and rosemary extract, all of which actually do become a part of the product. However, to be sure consumers are not misled, FSIS has established a use-by/sell-by date to be included on meat products that use carbon monoxide packaging. This is to ensure that the shelf life of the product ends before spoilage occurs.

As Members of the Committee are no doubt aware, FDA has received a petition asking it to withdraw its decision that carbon monoxide in meat packaging is Generally Recognized as Safe. FSIS will continue to make its labeling decisions and its suitability reviews on the basis of FDA's safety conclusions.

Conclusion

Thank you for the opportunity to testify before you today. I look forward to addressing any questions you might have.

The CHAIRMAN. I thank you very much Administrator and thank you for being patient. I purposely put you after the first panel so we could educate the Committee a little bit about what the issues are. I thought it might help people focus on some of the questions that would be raised, although I think the other panel did a pretty good job. Can you explain, I think you did a little bit, but what the difference between an ingredient, which is regulated by FDA, and a process, which is regulated by you guys, exactly how all that works? I guess that is part of why we are in this situation we are in right now where we have the Energy and Commerce Committee over here doing one thing. So, just explain that process a little bit for me.

Mr. ALMANZA. Well, as I said, we focus on the ingredient technologies or the addition of an ingredient to a product or the use of the packaging to ensure the safety. And the processing technologies are the intervention steps or other processes along the way of the process of producing the meat or poultry product.

The CHAIRMAN. So the carbon monoxide decision was made by you guys but FDA had proclaimed it to be safe, is that correct?

Mr. ALMANZA. Yes, sir. The FDA determines the safety of a food ingredient and its safe level of use and FSIS evaluates the suitability of its use.

The CHAIRMAN. And you both did that on this product back, what, 2002 or 2003 or something like that?

Mr. ALMANZA. 2002.

The CHAIRMAN. Yes. Now, this rosemary stuff that this other company is using that wasn't here today. That has not been approved by you? That is approved by FDA, is that right, or how does that all work?

Mr. ALMANZA. FDA determines the technology or approves the use of it, yes, sir. And then we were the ones that evaluate the suitability of it.

The CHAIRMAN. So you have a role in that as well?

Mr. ALMANZA. Yes, sir.

The CHAIRMAN. And that was approved by FDA and by you?

Mr. ALMANZA. Yes, sir.

The CHAIRMAN. When?

Mr. ALMANZA. We would have to check but we could certainly get back to you.

The CHAIRMAN. So probably some time prior to 2002?

Mr. ALMANZA. It would be speculative on my part but I can certainly get back to you on that, and provide you that information.

The CHAIRMAN. So in this approval process, in this area, it is just you and FDA that have a role, there is nobody else involved in this?

Mr. ALMANZA. Yes, sir. It is just us and the FDA. I think Mr. Derfler had something to add.

Mr. DERFLER. From rosemary extract, if it is Generally Recognized As Safe, it can go on to the market actually without prior approval.

Mr. ALMANZA. It is exempt from the food additive provisions and, therefore, can enter the market. So we are not exactly sure when it went on.

The CHAIRMAN. So why is it exempt?

Mr. ALMANZA. Under the definition of a food additive in the Food, Drug, and Cosmetic Act.

The CHAIRMAN. I don't understand. So certain things are exempt because they have their, what, minimal or something?

Mr. ALMANZA. If there is a general recognition of safety among scientists, it doesn't meet the definition of a food additive and so then there is no pre-market clearance required.

The CHAIRMAN. Required.

Mr. ALMANZA. Yes.

The CHAIRMAN. So they didn't have to get approval to do this?

Mr. ALMANZA. I am not sure of the exact status of rosemary. I just wanted to make that clear to you.

The CHAIRMAN. And explain to me how this works. It turns the meat or keeps the meat pink like carbon monoxide does, is that what it does?

Mr. ALMANZA. Yes, sir.

The CHAIRMAN. So why aren't the consumer groups complaining about this? I mean, if they think the problem is that carbon mon-

oxide keeps meat pink, why aren't they concerned about this other process?

Mr. ALMANZA. I really can't answer that, sir. I don't know why.

The CHAIRMAN. Do any of you know?

Mr. DERFLER. No, sir.

The CHAIRMAN. Well, hopefully we will be able to talk to them at some point. What do you do at FSIS to encourage the industry to adopt new technologies? Do you have any kind of ongoing process where you work with the industry to encourage them to improve their technologies or with research universities?

Mr. ALMANZA. Well, we have a staff that handles all these new technologies that are submitted to the agency and certainly anything that is beneficial to the consumers and is in the best interest of the consumers. We have a lot of requests from the industry to evaluate new technologies.

The CHAIRMAN. But you don't actually go out and find new technologies or have anybody within your agency that is working on this?

Mr. ALMANZA. No, sir.

The CHAIRMAN. You just sit back and wait to look at whatever people bring you?

Mr. ALMANZA. Yes, sir.

The CHAIRMAN. The gentleman from Wisconsin.

Mr. KAGEN. Thank you, Mr. Chairman, and thank you very much, Administrator, for being here today. We had a few moments to chat beforehand and I appreciate how you got into the business of food safety and USDA. I understand your father served at USDA for many years.

Mr. ALMANZA. Yes, sir.

Mr. KAGEN. Well, I congratulate you in following in his footsteps. One of the things that concerns me is the fact that if we are going to have progress in new technologies that is really industry-dependent instead of being generated, perhaps, by your department. Has the FSIS ever been interested in developing new technologies? And I will give you just a couple of examples. Some concerns that everybody in America has today about the safety about imported food, not just from China but from anywhere in the Caribbean or elsewhere. Would your Administration be interested in developing a new technique or technology to assay and test and determine very rapidly and cost effectively if an imported food substance was contaminated with *E. coli* or other pathogens?

Mr. ALMANZA. Well, sir, and that is a very good question because as a regulatory agency, we don't fund research *per se*. I think that those are great ideas but I don't know how we would reach that level to do that.

Mr. KAGEN. Well, let me get to a basic question. Who is inspecting our imported food stuff? I understand that 0.1 percent of imported foods, be it meat or vegetables or fish, is being inspected. Who is doing that?

Mr. ALMANZA. We have import inspectors, yes, sir.

Mr. KAGEN. So that is under your purview?

Mr. ALMANZA. Yes, sir.

Mr. KAGEN. And when they inspect this imported food stuff, what is it that they do? Do they use a magnifying glass? What is the extent of their inspection?

Mr. ALMANZA. Actually, 100 percent is visually inspected, meat and poultry products, before they come into the country or as they are coming into the country. But again, it is only meat, poultry and egg products. And also, we also do a 10 percent more-intense inspection of some of those imported products, such as we make sure that the containers are still intact, we make sure that the product is as it is labeled and things of that nature. So we do some residue——

Mr. KAGEN. So that the containers—

Mr. ALMANZA.—testing.

Mr. KAGEN. Correct. So the can isn't punctured or dented or the cellophane is not perforated.

Mr. ALMANZA. Exactly.

Mr. KAGEN. I understand. Well, are any other countries, other than the United States, using carbon monoxide and if they are, are they putting carbon monoxide on the label? And the reason I get at this question is because if you are visually inspecting imported meat products from any country, other than the United States, if it looks good, it must be good. Is that what they are doing, they are visually inspecting? You wouldn't know if it wasn't on the label if CO or any other stabilizer of the myoglobin or hemoglobin was present.

Mr. DERFLER. Actually, in addition to them doing the visual inspection, we, and other countries that export this to the United States, have to have inspection systems that are equivalent to ours. And so in the course of that, we make sure that their systems do provide the same level of safety protection.

Mr. KAGEN. So part of your inspection process is to trust that a foreign nation is doing their job and living up to our standards or whatever standards are in the trade agreement, is that right?

Mr. ALMANZA. Well, we go over and verify on an annual basis.

Mr. KAGEN. I see. So you actually go to other countries to inspect their food processing facilities?

Mr. ALMANZA. Yes, sir.

Mr. KAGEN. Excellent. Have you ever found any other facilities elsewhere, offshore facilities, that did not meet our standards? No pun intended.

Mr. ALMANZA. We have found countries that were not equivalent.

Mr. KAGEN. What did you do to remediate that situation?

Mr. DERFLER. We de-list the individual. We work with the foreign country to de-list the individual plants and ultimately we may take more action.

Mr. KAGEN. And is that list generally available? I mean, if Hormel or Tyson had any such problem, our national media would be all over it. Do you present that to the public in any form or fashion? Is there any way that my constituents in Wisconsin would understand which companies or which nations had fallen to *arrears* with this regard?

Mr. DERFLER. We list the nations that are equal to in the *Code of Federal Regulations* and we do a rule-making process before we list them.

Mr. KAGEN. Okay, all right. So maybe off camera, maybe you can provide my office with a list of companies or food processors elsewhere offshore that have not met up to our standards so I could at least take a sampling of what the inspection process really is all about. Finally, you are aware of the studies done on irradiated food. Is irradiation a safer technique for eliminating bacterial contamination than use of carbon monoxide?

Mr. ALMANZA. Is it safer? I would say that the product is, for the experience that we have, the product is safe. I really can't comment on it being safer.

Dr. ENGELJOHN. If I could Congressman? We do agree that irradiation is an effective technology. It has been found to be safe. And it is, as was mentioned earlier in the testimony, a kill step in that it does eliminate pathogens as opposed to just prevent them from growing.

Mr. KAGEN. Is it something that you then recommend to industry that they pursue such studies or such use?

Dr. ENGELJOHN. The issue of irradiation, much like what we are discussing with carbon monoxide, also relates to FDA approving the technology, in this case, as a food additive. FSIS, in this particular case for irradiation and its use on meat and poultry products, petitioned our sister agency to allow its specific use on meat and poultry as well because we did find that it would be an effective elimination of pathogens on the products that we regulate.

Mr. KAGEN. What is the current status of that solicitation?

Dr. ENGELJOHN. Irradiation is approved for use on certain meat and poultry products and, much like all food additives, once it is determined to be safe and effective and suitable for its use, we let the marketplace determine whether or not its use is going to be available to consumers.

Mr. KAGEN. And my final question would be, do you have an opinion from your Administration as to whether or not there should be any labeling of meat or other products with regard to the use of carbon monoxide?

Mr. ALMANZA. No, we would certainly evaluate it when we got the request. The other thing I would answer to your earlier question. We have ARS, the Agriculture Research Service, and C-R-E-E-S, that both do research and we let them know of our needs, so that is the research question.

Mr. KAGEN. Very good. Thank you very much for your time. I yield back.

Mr. ALMANZA. Thank you.

The CHAIRMAN. I thank the gentleman—just one moment—we sent you a letter, Administrator, on September 17 regarding a public health alert that you issued on August 30. We are having a hearing next week in Mr. Boswell's Subcommittee. We have not received a response yet. Will we have a response before that hearing?

Mr. ALMANZA. Yes, sir.

The CHAIRMAN. Very good. The gentleman from Virginia, Mr. Goodlatte.

Mr. GOODLATTE. I thank you, Mr. Chairman. Administrator Almanza, welcome. Welcome all of you. I would like to follow up on some of the questions I asked the first panel. Legislation has been introduced that would require a safety notice be included on

meat and poultry labels warning consumers that carbon monoxide was used and that they should not rely on the use-by, freeze-by labels. USDA mandated the use-by, freeze-by label and I wonder if you would support legislation that suggests that this label is insufficient?

Mr. ALMANZA. We would look at the request, as we do with any other request, Congressman.

Mr. GOODLATTE. Do you have any feeling about how the current system is working?

Mr. ALMANZA. We are confident with the system and how it currently functions with FDA and FSIS doing it simultaneously.

Mr. GOODLATTE. And on the previous panel, Dr. Sebranek stated in his testimony that carbon monoxide technology has been used commercially for almost 5 years and there have been no complaints that he was aware of from consumers about unexpected or unusual spoilage. The technology is establishing a track record that has been free of problems and has not been an issue with consumers. Now, that is his statement. In your experience, are you aware of consumer complaints regarding spoilage or do you agree with Dr. Sebranek's finding that there hasn't been an issue over this with consumers?

Mr. ALMANZA. I am not aware of any consumer complaints with carbon monoxide packaging.

Mr. GOODLATTE. I wonder if either of your deputies could indicate whether they are aware of the agency receiving complaints about problems with purchase of meat that appeared to be fresh because of the use of carbon monoxide technology but proved to be spoiled?

Mr. DERFLER. I am not aware of any such complaints.

Mr. GOODLATTE. Very good.

Dr. ENGELJOHN. I am not aware either although we do have a consumer complaint monitoring system by which we do receive consumer complaints and that would be one place where we would go to look to see if there have been any registered there.

Mr. GOODLATTE. But you are not aware of any registered there as of this point?

Dr. ENGELJOHN. I am not.

Mr. GOODLATTE. Okay. Thank you very much, Mr. Chairman.

Mr. BOSWELL [presiding.] Thank you. I just have one question and then I will defer to you, Mr. Walz. Earlier you heard a quote from Dr. Rubin at Iowa State that critics that say MAP is deceptive and hazardous are incorrect. Do you agree with that?

Mr. ALMANZA. I am sorry, I didn't——

Mr. BOSWELL. Critics have said that using modified procedures, MAP, is deceptive and hazardous. And we asked one of our previous witnesses if he thought that was so and he said no. Do you agree?

Mr. ALMANZA. I would say that the FDA determines the safety of that process and all we do is evaluate it for its suitability.

Mr. BOSWELL. Do you think it is deceptive and hazardous, yes or no?

Mr. ALMANZA. No.

Mr. BOSWELL. Thank you. Mr. Walz please.

Mr. WALZ. Thank you, Mr. Chairman, and thanks to our panel. I am sorry I didn't get to get in all of your testimony but I have read it. We are here today because FDA received a petition to withdraw the Generally Recognized As Safe designation, is that correct?

Mr. ALMANZA. That is correct.

Mr. WALZ. All right. As you know of and I guess the FDA might be the best but I will ask the USDA people here, have they ever received a consumer complaint on low-oxygen packaging?

Mr. ALMANZA. Not that I am aware of.

Mr. WALZ. Okay. Is there any scientific data that shows lox-oxygen environment has hurt anyone in this country?

Mr. ALMANZA. No.

Mr. WALZ. Okay. Irradiation, as a way to kill pathogens, will not alleviate the need for packaging to move that from the point of production through the whole food chain, is that correct?

Mr. ALMANZA. Yes.

Mr. WALZ. So the point that had been made by our previous witnesses is, if the point of the production at the initial stage, if it is done correctly under proper conditions of safety, the pathogens will not be there. Meat can spoil and still not have *E. coli*, correct?

Mr. ALMANZA. Correct.

Mr. WALZ. So the issue of this is that we have a procedure that appears by all accounts to move food through the safety system, does not have an adverse affect on consumers and its only, I guess, one take on this is that people say they are being misled because the meat is red longer or something? But we have also heard that the same thing could be said for high-oxygen environments where a person could cook it, it would turn brown, it wouldn't be cooked to 165 degrees, is that correct as you understand it?

Mr. ALMANZA. As I understand it.

Mr. WALZ. So how will USDA respond? You will wait for FDA to make a determination on the Generally Recognized As Safe and then you will proceed accordingly on that?

Mr. ALMANZA. Yes, sir.

Mr. WALZ. Will you have any ability, sir, to go back and say, "Why are we going through all of this when, again, we have had no complaints, no sickness and the only thing we have is a petition from a competing technology? Does that seem like the right way to do business for our consumers and consumer safety is?" I guess, what I am asking is, where are you at in this process?

Mr. ALMANZA. Well, I would say that we would get together with FDA and go through the process of determining the safety of the ingredient and just work through it as we did the first time.

Mr. WALZ. I am trying to figure out as to the jurisdictional part that you have here—we have directors here, Food Safety and Inspection Service and things like that. Do you gentlemen have the ability to weigh in on this, I mean, as independent voices on this?

Mr. DERFLER. We consult with FDA but FDA makes the safety determination.

Mr. WALZ. So they will make the final decision?

Mr. DERFLER. With respect to the safety.

Mr. WALZ. Okay. And as they come down on that, then the procedure would be back through FDA if we believe that is not correct. But USDA is the administering authority, if you would, as opposed

to the authority that is going to authorize what is safe and what is not.

Mr. DERFLER. Yes.

Mr. WALZ. But they do consult with you?

Mr. DERFLER. Yes.

Mr. WALZ. They do let you know. Okay. I have no further questions. I yield back.

Mr. BOSWELL. Well thank you very much. I think that brings us to closure on our questions and Mr. Moran has indicated he has no questions. I want to, on behalf of the Chairman and all of us, on the Committee, thank you very much for your time to come up here and meet with us today and we will come back to you as we have further questions. So we want to extend our appreciation to this panel, the previous panel, and we look forward to continued work with you. Thank you very much. That brings us to closure.

[Whereupon, at 4:10 p.m., the Committee was adjourned.]

[Material submitted for inclusion in the record follows:]

SUBMITTED MATERIAL

American Meat Science Association

1111 North Dunlap Avenue • Savoy, Illinois 61874 • (217) 356-5368 • Fax (217) 398-4119
www.meatscience.org

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Executive Director

September 18, 2007

The Honorable Collin Peterson
Chairman, House Agriculture Committee
2159 Rayburn House Office Building
Washington, DC 20515

The Honorable Bob Goodlatte
Ranking Member, House Agriculture Committee
2240 Rayburn House Office Building
Washington, DC 20515

Congressmen Peterson and Goodlatte,

Recently, a significant amount of misunderstanding has occured about a safe food packaging system called modified atmosphere packaging. This system has been effectively used with wide consumer acceptance for years. Today, it is employed with bag salads, pre-cut vegetables, shredded cheese, potato chips, beverages, seafood and meat products. In essence, the system utilizes a combination of protective gases in the food package to maintain freshness. Different foods benefit from the use of different gas combinations, all with one thing in common: regardless of the technology used, the Food and Drug Administration must review and accept all food packaging systems. When used for meat, USDA Food Safety and Inspection Service must also add its acceptance.

For four years, an innovative packaging system for some meat products has been safely used. The system removes the oxygen that can cause wholesome meat to turn brown and adds several other gases, including carbon monoxide at very low levels of less than one percent. It helps meat stay fresh and appealing longer and has been documented as safe by leading scientists. This packaging system competes with several other packaging technologies, each with its benefits, limitations and costs. Unfortunately, the technology that uses minute levels of CO has been unfairly attacked despite evidence that it is safe and effective.

As an association of meat scientists, we do not globally promote one technology over another. Once accepted by the federal government, that is for the marketplace to decide. However, we do believe that important tools are lost when promising new technologies fall victim to misinformation or misrepresentation. That moves the food production chain backwards and ties hands as our members strive to ensure the safety and quality of the food supply.

Given the current level of misunderstanding surrounding the use of CO in meat packging systems, the American Meat Science Association has commissioned a group of the top scientists in meat color chemistry and safety to develop a white paper addressing the current science on the issue. We expect to release the white paper in late October.

Like any other approved technology, the use of CO in modified atmosphere pakaging applications deserves a chance to succeed or fail on its scientific merits, and not on misinformation.

Sincerely,

Collette Schultz Kaster
President

Thomas H. Powell
Executive Director

Safe Tables Our Priority – S.T.O.P.

Consumer Federation of America

Food & Water Watch

Government Accountability Project

October 22, 2007

The Honorable Collin Peterson, Chairman

House Agriculture Committee

1301 Longworth House Office Building

Washington, DC 20515

Dear Chairman Peterson:

We are writing concerning the October 30, 2007 hearing which the House Committee on Agriculture is holding to discuss new technologies being used by meat and poultry processors. Among the technologies we understand the Committee will evaluate is the use of carbon monoxide in meat and poultry packaging that is used to prolong the shelf-life of such products. We are requesting that you invite participation in your hearing by consumer advocates who are opposed to the use of such technology because of the deceptive impact it can have on consumer purchasing decisions.

All of us who are signatories to this letter are opposed to the use of carbon monoxide in meat and poultry packaging and have communicated our opposition to both the Food and Drug Administration and the Food Safety and Inspection Service at the United States Department of Agriculture for their decisions to permit industry to use this technology. We believe that both agencies based their decisions on faulty information and did not conduct consumer research to determine how this technology would affect consumer purchasing decisions since it is well-documented that consumers rely on appearance to judge freshness. This is particularly critical since all modified atmosphere packaging including those using carbon monoxide create a barrier to using smell to evaluate freshness.

As you know, some major supermarket chains have decided not to sell meat and poultry products treated with carbon monoxide. Among those supermarket chains are Kroger's, Safeway, Stop & Shop, Giant, Publix, and A & P. Furthermore, the largest processor of meat and poultry in the

United States – Tyson Foods – recently announced that it would cease using this technology on its products. All of these companies have decided to listen to consumers who think that the use of this technology is deceptive. In addition, this is a practice that is banned by the European Union.

Consequently, we respectfully request that you include consumer representatives on one of your panels to present an alternative viewpoint on this technology.

Should you have any questions regarding this letter, please feel free to contact Donna Rosenbaum at Safe Tables Our Priority at 1-847-831-3032.

Sincerely,

Safe Tables Our Priority

Consumer Federation of America

Food & Water Watch

Government Accountability Project

food&waterwatch

FACT SHEET

Carbon Monoxide in Packaged Meat

Consumer Deception and Public Health Risk

We urge FDA and USDA to regulate the use of carbon monoxide in fresh meat by applying the same standards and procedures that apply to all coloring substances added to fresh meat and other food products. We support consistent and fair regulatory standards that satisfy the requirements of the Federal Food, Drug, and Cosmetic Act. Failing action by FDA and USDA, Congress should ban the practice.

The facts

Carbon monoxide (CO) colors meat

Carbon monoxide creates a bright red pigment that masks the natural aging and spoilage of meats. Meats treated with CO and remaining in their packages will remain red indefinitely, well beyond the point at which they begin to spoil.

Consumers judge meat by its color

The appearance of meat, and specifically its color, is the primary factor in consumers' decisions to buy the product. The use of carbon monoxide in meat makes it impossible for consumers to know with certainty about the meat's freshness merely by looking at it. Because of the possible presence of carbon monoxide, a bright red color does not necessarily mean that the meat is fresh and safe.

Consumers are kept in the dark

Without labels that would inform consumers that carbon monoxide is present, and a public education campaign to inform consumers about the possible effects of carbon monoxide and that color is no longer a valid indicator of freshness, purchasers of carbon monoxide-treated meats cannot know, merely by looking, that the meat they are buying is fresh or safe.

Consumers can no longer rely on use-by dates

Because carbon monoxide meat does not turn brown, the government has allowed extended use-by dates of 28 days for ground beef, and 35 days for muscle cuts for carbon monoxide-treated meat. However, a recent study suggests that even consumers who follow use-by date labeling could encounter spoiled meat. Testing conducted by Consumer Reports and reported on in the July, 2006 issue indicates that some CO-treated meat available on supermarket shelves could be spoiled by its use- or freeze-by date. Consumer Reports recommends that consumers "check the package and buy meat whose stamped date is a couple of weeks away."

CO use in meat is banned in Europe

The European Union prohibited the use of carbon monoxide in meat after the European Commission's Scientific Committee on Food concluded: "[t]he stable cherry-colour can last beyond the microbial shelf life of the meat and thus mask spoilage."

Several supermarket chains refuse to carry CO treated meat
Kroger, Publix, Stop & Shop, Giant, Safeway, Pathmark, A&P, Wegmans and Whole Foods are among the leading supermarket chains who have said they will not sell CO-treated meat. "Publix does not use carbon monoxide to disguise the color of our meat," company spokeswoman Barbara Reid told the Atlanta Constitution-Journal. "Ethically, we disagree with it." Saying that the use of CO could be viewed as "deceptive," Kroger executive Lynn Marmer told the paper the company does not sell CO-treated meat. "This is food for your family. We want to make sure that everything we offer is something you can trust us with," said Reid of Publix.

Coloring meat is against government regulations
The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) regulations prohibit the introduction of ingredients in fresh meat that "function to conceal damage or inferiority, or to give the appearance the product is better or of greater value." FDA circumvented existing laws and regulations through a fast-track process in allowing CO-treated meat on the market.

CO-meat will add to industry profits at consumer expense
It should be noted that the proponents of this use of carbon monoxide apparently stand to benefit substantially. An industry report estimates that, "U.S. retailers fail to capture at least one billion dollars of revenue annually from fresh beef sales, due to product discoloration." The report suggests that CO meat packaging, " could contribute to longer shelf life for T-bone steaks, sirloin steaks and ground beef patties."

Consumer groups urge a Congressional ban
Six consumer groups have urged the U.S. Congress to ban the use of carbon monoxide in meat saying, "This meat is sitting, unlabeled, on grocery store shelves now and no action by FDA or USDA … seems to be forthcoming, despite the numerous concerns raised" by the consumer groups. They include the Consumer Federation of America, Consumers Union, Food & Water Watch, Government Accountability Project, National Consumers League and Safe Tables Our Priority.

For additional information:
http://www.consumerfed.org/pdfs/CO_Meat_Consumer_Press_Release_9.25.06.pdf
http://www.fda.gov/ohrms/dockets/dockets/05p0459/05p0459.htm
http://www.co-meat.com
http://www.consumerfed.org/pdfs/CO_&_Meat_Press_Release_1.17.06.pdf
www.consumerfed.org/pdfs/CO_Meat_Consumer_Survey_Results_9.25.06.pdf

What YOU CAN DO to end the FDA/USDA's Bad Experiment with CO-meat

Go to:
http://www.democracyinaction.org/dia/organizationsORG/fwwatch/campaign.jsp?campaign_KEY=6113

Or Write to:
Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Refer to: Docket Number 2005p-0459, Citizen Petition Requesting FDA to Enforce Ban on Carbon Monoxide in Case-Ready Fresh Meat Packaging

CASE READY MEAT TREATED WITH CARBON MONOXIDE (CO) WILL REMAIN RED INDEFINITELY, WELL BEYOND THE POINT AT WHICH IT BEGINS TO SPOIL

BEFORE | **AFTER**

Conventional Butcher Overwrap Meat →

CO-treated Case Ready Meat →

The above packages of meat were photographed within 30 minutes of being purchased.

After being left out at room temperature for 24 hours, the conventional package turned brown. The CO-treated meat maintained its red color and fresh appearance. No odor is detectable.

Consumers Have a Right to Know

UNIVERSITY OF MINNESOTA

Twin Cities Campus

Center for Infectious Disease Research and Policy

Mayo Memorial Building
420 Delaware Street S.E.
MMC 263, Room C-315
Minneapolis, MN 55455
Office: 612-626-6770
Fax: 612-626-6783
www.cidrap.umn.edu

September 26, 2007

Phil Minerich, PhD
Vice President, Research and Development
Hormel Foods, LLC
2 Hormel Place
Austin, MN 55912-4935

Dear Phil,

Thank you for your inquiry regarding the risk of spoiled food serving as a source for the transmission of foodborne pathogens.

First, as you know, spoiled food is characterized by changes in food odor, taste and texture in such a way as to make its consumption unacceptable. Individuals with impaired sensory faculties who may have limited taste or smell can still readily detect the significant changes in the texture of spoiled food. The group of bacteria that causes food to spoil create as a byproduct of their growth, chemicals which cause the changes in the food that we detect. These bacteria and their resultant chemicals do not cause disease in humans when such food is consumed in contrast to what we find with foodborne disease pathogens like *Escherichia coli*, Salmonella, Campylobacter. In addition, the growth of spoilage bacteria actually inhibits the growth of foodborne pathogens in food making such spoiled food a lower risk for causing "classic foodborne disease."

Second, in my more than 30 years of working at the forefront of foodborne disease outbreak investigations around the world, I am not aware of a single case of human illness associated with consumption of spoiled food. This includes among the elderly who may have impaired sensory faculties. Also, I was not able to identify any examples of illness associated with spoiled food after inquiring of my colleagues in public health who have extensive experience in foodborne disease outbreak investigations.

In conclusion, while the issue of food spoilage is an important one from the standpoint of food wastage, it does not pose a risk for foodborne disease transmission.

I hope this information is helpful. Please feel free to contact me if I can provide any additional clarification on this point.

Sincerely,

Michael T. Osterholm

Michael T. Osterholm, PhD, MPH
Director, Center for Infectious Disease Research and Policy
Professor, School of Public Health
Adjunct Professor, Medical School

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Inside AMI

Leading Food Safety Expert Dr. Mike Doyle Calls Modified Atmosphere Packaging Technology 'Revolutionary'

Doyle Tells Canadian Meat Council His Research Demonstrates Food Safety Benefits

September 13, 2007

"MAP with CO packaging of fresh beef is a major technological achievement in providing extended shelf life and reduced microbiological hazards to fresh beef," Dr. Michael Doyle, director of the Center for Food Safety at the University of Georgia said today.

Doyle delivered his remarks in a keynote address to the Canadian Meat Council symposium on Advances in Antimicrobial Interventions for Quality Control of Meat and Poultry Products held in Toronto, Canada. The symposium was attended by more than 110 microbiologists, industry, academic and government scientists from across Canada and the U.S. Dr. Doyle's keynote address was entitled "Advances in Antimicrobial Interventions: A Key to Meat Quality and Safety."

During his talk covering a variety of cutting-edge food safety technologies, Doyle described a study that he and his colleague, Dr. Li Ma, conducted at the University of Georgia, which demonstrated that low-oxygen modified atmosphere packaging with minute levels of carbon monoxide in the gas mix in addition to nitrogen and carbon dioxide "retarded the growth of E. coli O157:H7 in ground beef under temperature abusive storage conditions."

He said his study also found that this packaging system extended shelf life based on appearance -- color, odor and texture of ground beef -- even under abusive temperature conditions.

He also mentioned information from the peer-reviewed scientific literature that agrees with the University of Georgia results. He noted 2006 research conducted at Texas Tech University reached similar conclusions.

"MAP CO-treated meat is a revolutionary technology providing greater protection against foodborne pathogens and extended shelf life to fresh beef," Doyle said.

Doyle also described the food safety and quality benefits of case ready packaging generally including its production under controlled processing conditions.

Doyle has served on the National Advisory Committee on Microbiological Criteria for Foods and is considered one of the world's leading experts in food microbiology and food safety. He joins numerous other scientists in supporting the quality and safety benefits of this packaging system.

To read comments from other experts, go to
http://www.meatami.com/Content/PressCenter/factsheets/statementsconcerningthesafetyoflowoxmapwithco.pdf

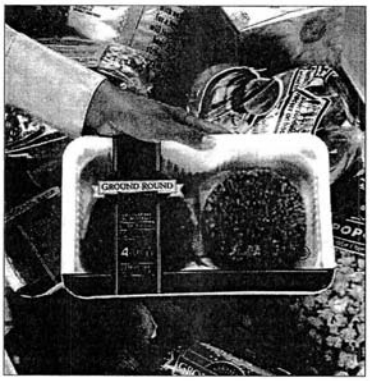
Return to Previous Page

CATEGORY: MEAT

By Randall D. Huffman, Ph.D., and Janet M. Riley

Low-Oxygen Packaging with CO: A Study in Food Politics That Warrants Peer Review

Maintaining meat's color throughout its shelf life has been a perennial challenge for the meat industry. Numerous systems have been tried with varying degrees of success. A low-oxygen packaging system that uses minute amounts of carbon monoxide (CO) either in a master bag around meat packages or in the gas mix in modified atmosphere packages offers new options for retailers—options that have been increasingly embraced over the last few years.



But the maker of a competing technology that uses rosemary extract as part of a high oxygen environment to maintain meat's red color petitioned the U.S. Food and Drug Administration (FDA) in 2005 to disallow the technology. At the same time, the petitioner launched an aggressive media relations campaign disparaging its competitors in the case-ready packaging market. This issue has become a remarkable study in the intersection of science, regulatory oversight and media influence.

An examination of the history of the issue shows that the low-oxygen CO system was developed in response to consumer demand for fresh, appealing and in-stock case-ready products, packaged in convenient ways, with the sensory traits that will ensure repeat purchases. This packaging system has been subjected to careful scrutiny by federal regulatory agencies and leading food scientists and microbiologists and should be permitted the opportunity to succeed or fail in the marketplace based upon its merits.

Emergence of Case-Ready Meat Products

Changing consumer demographics, coupled with new regulatory pressures and food safety concerns in the 1990s, drove processors and retailers to experiment with case-ready meat products. These products are cut into consumer-ready portions at federally inspected facilities, packaged and typically sold under brand names that consumers can seek or reject when making purchasing decisions.

The shift to case-ready made sense. The consumer of the '90s sought convenient cuts that were always available. At the same time, in the face of unparalleled food safety pressures and high profile recalls

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and foodborne illness outbreaks, some retailers preferred to shift processing and handling to a centralized location where products could be cut, processed and packaged in a more controlled environment.

This concept was not new–the poultry industry has sold prepackaged and branded chicken in increasing volumes throughout the 1990s. Chicken maintained essentially the same color throughout its shelf life–a fact that made it ideal for case-ready. By 2002, 83 percent of chicken was sold case-ready, and by 2004, that number had climbed to 95 percent. By contrast, only 23 percent of beef and 66 percent of ground beef products were sold case-ready in 2004.

But the "will" was there. case-ready offered an array of other benefits–like preventing out of stocks. Research showed that case-ready products were out of stock far less often than store wrapped packages because these products facilitated better inventory management.

The presence of myoglobin in red meat, however, made case-ready packaging more technically challenging for beef and pork products. Historically, red meat products were cut or ground in the retail store and packaged on styrofoam trays with oxygen permeable films that allowed the bright red "bloom" that came from exposing these meat cuts to oxygen. Consumers came to associate this cherry red color with freshness. Processors and retailers rued the fact that the very contact with oxygen that gave meat the impression of "freshness" also caused it to degrade quickly due to oxidation. Red quickly turned to brown, meat flavor degraded and the product could not be marketed within a relatively short period of time.

Attempts to use vacuum packaging as a retail display technique to lengthen shelf life presented huge obstacles. Even though the vast majority of wholesale primals of beef and pork has been packaged and distributed in large vacuum bags for decades, without oxygen in the retail display package, meat products appeared in their true state: purple. Consumers expect to see red, and they mistakenly equate a red color with freshness. Although vacuum packaging of retail case-ready may be the most effective and cost efficient method, the package generally does not hold appeal for consumers.

High oxygen modified atmosphere packaging (MAP) offered consumers the color they expected and offered retailers some of the inventory control benefits of case-ready systems. Consumers also could choose the brands they prefer. However, the presence of oxygen in the MAP packaging still delivered a shorter shelf life than retailers would otherwise like due to the degradative effects of high oxygen concentrations in meat products. Antioxidant ingredients, such as rosemary extracts, were added in some cases to extend shelf life of products packaged in high oxygen for a few extra days.

Then, U.S. meat processors took their cue from Norway, where researchers found that by adding minute amounts of carbon monoxide into the gas mix in a low-oxygen modified atmosphere package, they could not only offer the extended shelf life that comes with low-oxygen modified atmosphere packaged meat, but also prevent the oxidative processes that result in off-flavors, off-odors and browning that ordinarily occur. When meat turns brown, flavor also is lost. Thus, by preventing oxidation, meat's fresh flavor is maintained longer–a distinct benefit to the consumer.

Research has shown that this system could offer shelf lives that are similar to vacuum packaged products and higher than those of high oxygen packaged products. Research also shows that if temperature abuse occurs, while the meat would maintain its red color, other obvious signs of spoilage would make it nearly impossible for consumers to eat the product. Chief among these signs: a bulging package, a slimy appearance and an unmistakable odor associated with bacterial growth.

> "By **using** CO in a modified **atmosphere**, the need for **oxygen** to **achieve** a red color is **eliminated.**"

Only later in June 2006 would Texas Tech University researchers report that low-oxygen packaging MAP systems with CO could inhibit the growth of pathogens that were deliberately inoculated for research purposes. The lower the load of pathogens, the less risk there is to the public health if the product is undercooked or mishandled.

How It Works

Red meat contains the pigment myoglobin. In the absence of oxygen, myoglobin is in the "deoxymyoglobin" state (without oxygen) and is naturally "purple." When oxygen is exposed, it becomes oxymyoglobin and develops a red color. Over time, a continual exposure to oxygen diminishes the ability of the meat to maintain the oxymyoglobin and the majority of the meat pigment will convert to metmymyoglobin which has a characteristic brown color.

When meat is exposed to small amounts of carbon monoxide, the carboxymyoglobin pigment is formed. This pigment is more stable than oxymyoglobin, and it has a red appearance that is virtually indistinguishable from oxymyoglobin to the naked eye, as well as to more sensitive spectrophotometric methods. By using CO in a modified atmosphere, the need for oxygen to achieve a red color is eliminated, thus the opportunity to eliminate the detrimental product effects that oxygen imparts to the product. Adding small amounts of CO will not convert brown meat back to red, but it will maintain the red color that is present when the product is packaged in the modified atmosphere.

Regulatory Acceptance

The FDA has jurisdiction over packaging, packaging gases and food additives. Because packaging gases contact food, but do not become part of the food product, with proper and well-documented evidence, these gases can be accepted under FDA's Generally Recognized as Safe (GRAS) provisions. When an entity seeks GRAS status for substances used with meat or poultry

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products, it must notify FDA of the use and file a petition (known as a GRAS Notification) with supporting evidence. GRAS Notifications are public, but do not go through the cumbersome and lengthy public rule-making process. FDA reviews GRAS Notifications and informs the petitioner if it has any questions regarding the submission. FDA often will have questions, which results in further data collection and ex-change of information. Both GRAS substances and food additives must be equally safe, but food additives go through a lengthier review because the basis for the safety determination may not be widely known or accepted in the scientific community.

Because meat products are regulated by USDA, when a regulatory action occurs at FDA that directly affects a meat product–like acceptance of a packaging system that includes minute amounts of carbon monoxide–USDA also reviews the process to determine its suitability for use under meat inspection regulations. It is common for the two agencies to communicate and exchange information throughout the process, which is entirely transparent to the public. This dialogue occurred between USDA and FDA in considering GRAS petitions for low-oxygen MAP packaging systems with CO.

In 2001, Pactiv Corp. submitted the first such GRAS petition for its low-oxygen CO MAP system. Pactiv's system places a package or packages of case-ready meat into an outer barrier bag that contains small amounts of CO in a gas mixture. That outer bag remains intact throughout distribution of the meat. At retail, the packages of case-ready meat are removed from the outer bags (i.e., from the CO) and placed on display for sale to consumers. The FDA accepted this system in 2002.

In 2004, Precept Foods sought GRAS status for a system in which a gas mixture containing CO was included in the headspace of the MAP package. This system was accepted in 2004 and products were offered in numerous markets where they were well received. All products using this technology bore use-by dates to inform the consumer. Subsequently, in 2005 a notification submitted by Tyson Foods to use a system similar to Precept's with a slightly different application of the gas mixture was accepted by FDA.

After its own consideration regarding suitability in meat products and after posing follow-up questions, USDA also accepted the technology in each of the three GRAS submissions. At this point, the evidence was clear that FDA and USDA were confident in the safety and appropriateness of low-oxygen systems using CO. It also became clear to the maker of a competing technology that the meat industry was embracing a system that had the potential to make its product–rosemary extract–obsolete in fresh meat applications.

Take It to the Press

Within a month of FDA's third GRAS letter, Kalsec, Inc., submitted a petition, arguing that the agency erred on the occasions that it accepted the GRAS notifications. Although the petition was submitted to FDA, the message was aimed at the media. With a lead paragraph that read in part, "…FDA was asked today to rescind its illegal acceptance of the use of carbon monoxide in case-ready meats. The use of carbon monoxide deceives consumers and creates an unnecessary risk of food poisoning by enabling meat and ground beef to remain fresh-looking beyond the point at which typical color changes would indicate aging or bacterial spoilage," Kalsec hinted at the war that would be waged on the technology over the next year by a Washington, DC public relations agency.

"The **single** most important **factor** consumers reported using in evaluating the freshness of meat was the **use-by** or sell-by date."

A dedicated website, www.co-meat.com, was unveiled to offer one-stop shopping for journalists. On the home page, Kalsec stated, "The use of carbon monoxide in fresh meat causes a chemical reaction that creates a substance that makes the meat look red and fresh beyond the time it is safe to eat." In its media outreach, the presence of use-by dates was consistently ignored. Also ignored was the fact that when consumers bought chub-packed ground beef–packaging that offered consumers absolutely no visual clues about color–consumers could only rely upon use-by or sell-by dates. And yet there were no patterns of complaints for either chub-packed ground beef or low-oxygen MAP packaging with CO.

Station after station–from national networks on down to small local affiliates–contacted the American Meat Institute (AMI). Claims of deception and food safety risks were advanced in detail, an AMI spokesperson offered a rebuttal sound bite and reporters showed their own examples of meat products that had been left out of refrigeration on counters for extended periods of time. Not surprisingly, the packages bulged. Not surprisingly, the meat was still red.

"What no reporter did on camera was open the package and attempt to maintain a telegenic smile," says AMI Foundation President James H. Hodges. "Had they done so, the odor would have sent a strong and unmistakable message to the consumer that the product was spoiled–a fact that the bulging packages also signaled." But according to Hodges, the issue of meat packaged in this way becoming spoiled has been manufactured to add to the controversy. "Distribution systems today ensure with an extremely high degree of accuracy that meat is maintained at proper temperatures during distribution and in the retail meat case," he said. "Use-by dates on all of these packages provide additional information."

In public communications, Kalsec's agency also argued that the European Union had banned the practice–a fact that was never researched thoroughly and never reported accurately in context. In 2001, the European Scientific Committee on Food found the packaging system to be safe and said "there is no health concern" provided temperature controls are followed. Subsequently, a European political body made the decision not to allow the packaging system. This is the American equiv-

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alent of FDA giving a technology its scientific assessment and approval, while politicians in Congress step in to ban the technology.

In defense of the media, one ambitious reporter, Jim Strickland at WSB-TV in Atlanta, broke out of the mold. He collaborated with Dr. Mike Doyle, director of the Center for Food Safety at the University of Georgia, who inoculated ground beef in low-oxygen MAP packages with CO with doses of the pathogen *E. coli* O157:H7. Traditional, store-wrapped packages also were inoculated. Both were temperature abused. According to the report, which originally aired July 17, 2006, after four days, *E. coli* O157:H7 in the conventional packages grew to an average 54,000 cells per gram. But *E. coli* O157:H7 counts in the MAP packages were at less than 3,000 cells per gram. The data suggested that growth of *E. coli* O157 was deterred in low-oxygen CO packages when compared to the control packages. Though the analysis was small and limited, the results generally agree with the larger study done at Texas Tech just a month earlier–a study that has received very limited press coverage.

Media coverage of the issue was fueled by the engagement of consumer organizations in the controversy. Most notably, the Consumer Federation of America issued comments in support of Kalsec's position, buttressed claims of consumer deception and made aggressive calls for labeling. Some members of Congress also engaged in the issue, with Michigan lawmakers (where Kalsec is based) leading the charge.

The industry responded with statement after statement detailing the safety and benefits of the technology. Industry also argued that mandating labels for this technology when they are not required for any other packaging system or packaging gas is arbitrary. Snack foods, fresh produce, dairy products and a host of other foods all use gases to maintain the qualities that consumers desire.

Third-party experts from across the nation echoed industry messages. "I don't think that carbon monoxide is deceptive at all, certainly not from a safety perspective," Doyle said. "I think that carbon monoxide packaging technology deserves an award. This is a profound idea."

Dr. Melvin Hunt, professor of meat science at Kansas State University, has been equally supportive of the technology–and equally frustrated by the controversy that has swirled around it. "A close look at the media scare shows motives that are as transparent as carbon monoxide itself. But carbon monoxide technology has a real benefit to consumers. The only benefits generated by the unfounded safety allegations are to the company that stirred the controversy–and to the media outlets that benefit from the attention-grabbing story."

Even the well-respected publication of the Institute of Food Technologists, *Food Technology*, printed a back page "perspectives" column, authored by four leading scientists who commented on the science surrounding this controversy. One significant quote from this article was "the claim that CO packaging will result in unsafe products is not scientifically sound."

Consumer Attitudes

Despite sustained media coverage of the issue over the last 12 months, consumer confidence in beef safety has remained both constant and high, according to industry data.

In late September 2006, the Consumer Federation of America released polling data that suggested that consumers did not like the idea of the technology. Experts in the field of polling point out, however, that consumers were only asked about the practice of adding carbon monoxide to meat. They were not told how and why the technology is used, nor were they informed that the technology was accepted by both the FDA and USDA, or that it offered distinct consumer benefits.

One question asked in the poll–but not highlighted in the press release–is that the single most important factor consumers reported using in evaluating the freshness of meat was the use-by or sell-by date, followed by smell, followed by color. According to a subsequent poll of 1,000 consumers conducted in November 2006 by Opinion Dynamics Corp. for AMI, only 9% of consumers were very or somewhat likely to buy a meat product that seemed to be excessively bulging in the retail case. Even more importantly, 95% of consumers were very or somewhat unlikely to prepare a meat product that even though red in color, was beyond its use-by data and had a noticeable odor when opened at home. These findings bolster the claim that low-oxygen MAP packaging systems with CO are not misleading and that the use-by dates on the packages, coupled with other sensory factors, all contribute to the decision making process that consumers engage in when preparing product in the home. When handled and cooked properly in the home, these products are just as safe as other products offered in the marketplace, including the traditional packaging techniques.

The Future

The FDA is currently reviewing the multiple submissions filed by Kalsec and the responses filed by the makers and users of this technology. As it should, FDA is taking time to ensure that its decision is based upon the available scientific information. If the testimonials from university experts in support of the technology are any indication of what FDA scientists will find in the literature, the agency will affirm its decisions and reject Kalsec's petition.

If there is a lesson to be learned by the food safety community from the media coverage and regulatory activity over the past year it is this: Good science must be coupled with good, early and frequent communications to multiple audiences in an effort to ensure that government, Congress, consumers and the media have what they need to make thoughtful decisions in the public's interest. ■

Randall Huffman, Ph.D. *is Vice President of Scientific Affairs for the American Meat Institute Foundation (AMIF). Huffman manages the AMI Foundation's food safety research agenda, assists members in improving food safety and quality and serves as the liaison between AMI and various scientific organizations. Earlier in his career, he was director of technical services at Koch Industries, Inc., in Wichita, KS where he had responsibilities for product development and food safety with the Koch Beef Co., and he served as vice president of technical services at Fairbank Farms in Ashville, N.Y., a case-ready meat processor. Huffman can be reached at rhuffman@meatami.com.*

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AMERICAN MEAT INSTITUTE **FACT SHEET**

Statements from Scientists Concerning the Safety and Quality of Low Oxygen Modified Atmosphere Packaging with Carbon Monoxide

Dr. Alden Booren, Professor, Michigan State University	May 4th, 2006, in a letter to the Honorable Carl Levin, U.S. Senate	"The risk of a significant food safety hazard occurring in meat packaged using this low-oxygen carbon monoxide modified atmosphere packaging (MAP) technology does not change when this technology is compared to conventional retail meat wrap technologies. For this reason I would not hesitate to utilize the technology in the Meat Laboratory Pilot Plant, a facility I help manage at Michigan State University."
Dr. Joseph Sebranek, Iowa State University; Dr. Melvin Hunt, Kansas State University; Dr. Darren Cornforth, Utah State University; and Dr. Susan Brewer, University of Illinois	May, 2006, Perspectives Article in Food Technology, a scientific publication of the Institute of Food Technologists	"The claim that CO packaging will result in unsafe products is not scientifically sound." "Because scientific studies have validated the safety of low-CO packaging technology for fresh meat, it seems appropriate to let the marketplace decide the success or failure of the process."
Dr. Melvin Hunt, Professor, Kansas State University	March 14, 2006, Letter to the Editor, submitted to the Kansas City Star	"Over the last few weeks, media have persuaded some consumers that they are being misled because meat that would have otherwise turned brown is still red. Some retailers are now fearful of selling products packaged in this impressive, safe and cutting edge technology. The effort to discredit the science that went into it – and efforts to discredit the federal agency that reviewed it three times -- is scientifically inaccurate and unfortunate. A close look at this media scare shows motives that are as transparent as carbon monoxide itself. But carbon monoxide packaging technology has a real benefit to consumers. The only benefits generated by these unfounded safety allegations are to the company that stirred the controversy – and to the media outlets that benefit from the attention grabbing story."
Texas Tech University researchers, Dr. Chance Brooks and Dr. Mindy Brashears	June 26, 2006, Texas Tech University Press Release	"In a related microbiological study, a research team headed by Dr. Mindy Brashears found that beef inoculated with pathogenic bacteria, Salmonella and E. coli O157, and then packaged with carbon monoxide had less pathogenic bacteria after 14 days than similarly inoculated beef wrapped in traditional packaging without carbon monoxide."
EU Scientific Opinion	2001, EU Scientific Committee on Food	"The EU Scientific Committee on Food (SCF) in 2001 determined that the use of CO under intended conditions of use in meat packaging is safe. The committee concluded "there is no health concern associated with the use of 0.3% to 0.5% CO in a gas mixture of carbon dioxide and nitrogen as a modified atmosphere packaging gas for fresh meat provided temperature during the storage and transport does not exceed 4 C."

Dr. Gary Acuff, Professor of Microbiology, Texas A&M University	May 26, 2006, Letter to Editor of Meatingplace Magazine	"Low-oxygen modified atmosphere packaging is a safe technology that provides significant consumer benefits, not the least is a longer shelf-life than aerobic packaging. Adding very low levels of carbon monoxide to the atmosphere provides an acceptable color that helps meet consumer expectations. The use-by date on every package tells consumers the point at which the product will no longer be acceptable. This is not a misleading technology; however, facts seem to be getting lost in the publicity generated by critics."
Dr. Darren Cornforth, Professor Food Science, Utah State University	March 16, 2006, Letter to the Deseret News	"The FDA has looked at, and approved the use of CO in meatpacking on three separate occasions, most recently noting that the use of CO "will not mislead consumers into believing that they are purchasing a product that is fresher or of greater value than it actually is or increase the potential for masking spoilage."
Mike Doyle, Director of the Center for Food Safety at the University of Georgia	July 27, 2006, Interview with Food Production Daily USA	"I don't think that carbon monoxide packaging is a deceptive process at all, certainly not from a safety standpoint. I think that carbon monoxide packaging technology deserves an award, from a scientific perspective this is a profound idea," said Doyle. "If manufacturers have a reasonable date on the product and it looks good, smells good and tastes good… well what's wrong with that?"
Dr. Oddvin Sorheim, Norwegian Food Research Institute	September 6, 2006, Letter to Center for Food Safety and Applied Nutrition, FDA	"I started studying CO in 1996, and at that time I must admit that I was skeptical of CO. However, by acquiring knowledge through later research and experience, I am convinced that CO packaging is safe and the best available packaging method for fresh meat…There is now a solid base of scientific literature describing and supporting the use of CO for meat, and I am aware of no meaningful scientific controversy as to the safety of its intended use…My sincere recommendation to the US food control authorities is to maintain the GRAS status for meat packaging."

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Sandusky et al.

(54) METHOD OF EXTENDING COLOR LIFE OF MODIFIED ATMOSPHERE PACKAGED FRESH RED MEAT USING LABIATAE PLANT EXTRACTS

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(21) Appl. No.: **11/281,024**

(22) Filed: **Nov. 17, 2005**

Related U.S. Application Data

(63) Continuation of application No. 10/276,675, filed on Oct. 6, 2003, filed as 371 of international application No. PCT/US01/16244, filed on May 18, 2001.

(60) Provisional application No. 60/205,776, filed on May 19, 2000.

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(52) **U.S. Cl.** **426/129**

(57) **ABSTRACT**

The color life of modified atmosphere packaged fresh red meat is extended by contacting the fresh red meat with an extract of a *Labiatae* herb prior to packaging the meat.

METHOD OF EXTENDING COLOR LIFE OF MODIFIED ATMOSPHERE PACKAGED FRESH RED MEAT USING LABIATAE PLANT EXTRACTS

FIELD OF THE INVENTION

[0001] This invention relates to a method for extending the color life of modified atmosphere packaged fresh red meat, and more particularly, to a method of extending the color life of modified atmosphere packaged fresh red meat using extracts of *Labiatae* plants.

BACKGROUND OF THE INVENTION

[0002] It has been a desire for major meat manufacturers to supply retail outlets from centralized processing facilities. In order to facilitate this desire, modified atmosphere packaged fresh meats have been developed. Modified atmosphere packaging, also known as MAP, of fresh meats involves the use of specific gas mixtures in the headspace of gas impermeable meat containers and enables the control of certain physical properties, such as appearance, of the fresh meats for an extended period of time.

[0003] Color shelf life of red meat is important to consumer acceptance. Consumers judge the freshness of red meat by the presence of bright red oxymyoglobin pigment. Oxymyoglobin in fresh red meat decreases with time during storage as it changes to the stable brown pigment, metmyoglobin. Although oxymyoglobin pigment fades during dark storage, for example in a meat locker, pigment loss is most pronounced in lighted, refrigerated display cases in retail establishments. Although pigment loss is primarily cosmetic in nature, it has serious economic consequences. Consumers in search of the freshest looking cuts avoid purchasing red meat containing even small amounts of brown metmyoglobin. The unsaleable product which results from oxymyoglobin loss in red meats costs the industry an estimated $700 million dollars annually.

[0004] Modified atmosphere packaging can be divided into two categories, high oxygen modified atmosphere packaging having an oxygen content above 40 vol. % and low oxygen modified atmosphere packaging having an oxygen content less than 20 vol. %. In low oxygen modified atmosphere packaging, oxygen is excluded from the package and the headspace atmosphere is usually made up of an inert gas such as nitrogen or a mixture of nitrogen and carbon dioxide. With low oxygen MAP, oxymyoglobin initially present on the surface of the meat is converted to deep purple, unnatural appearing, deoxymyoglobin pigment as the last remnants of oxygen are consumed by metabolic processes occurring in the meat tissue.

[0005] Deoxymyoglobin is a fairly stable pigment under completely anoxic conditions although it can convert to metmyoglobin during storage. When oxygen is re-introduced to the meat containing deoxymyoglobin, the meat re-blooms as deoxymyoglobin is converted back into oxymyoglobin. This phenomena has been used by meat companies with so-called "peel-pack" packaging in which the meat is packaged in a tray covered by two, separate plastic films, an outer oxygen barrier film and an inner oxygen permeable film. The meat is transported and stored under anoxic conditions and, prior to display in the retail meat case, the outer film is removed to allow the meat to re-bloom and re-form the bright red pigment, oxymyoglobin, consumers expect to see. The use of "peel-pack" technology has not been embraced commercially because of the handling necessary to remove the oxygen barrier film from each package and the need to insure adequate bloom time prior to display in the retail case. The meat industry is seeking a packaging technology that can be produced at the manufacturing point, distributed and displayed at retail facilities with a minimum of handling.

[0006] In high oxygen modified atmosphere packaging, high oxygen levels are maintained in the headspace atmosphere from the time of packaging through the time of consumption. Mixtures of oxygen and carbon dioxide are typically used, with a gas mixture of 80% oxygen and 20% carbon dioxide being most typical. The high oxygen helps extend the microbial shelf life of the product by inhibiting the growth of anaerobic microorganisms, many of which are pathogens.

[0007] With both types of MAP, gas mixtures are used with carbon dioxide playing a significant functional role and other gases, particularly nitrogen, functioning as optional inert diluents. Carbon dioxide is present in the gas mixtures because at sufficient levels, it is toxic to certain bacteria and thereby enhances the product's shelf life.

[0008] Modified atmosphere packaging has provided a method of extending the favorable appearance and properties of fresh meat but there still is a need for a method of further extending the packaged appearance of fresh meats.

[0009] W. Manu-Tawiah, L. L. Ammann, J. G. Sebranek and R. A. Molins, 1991. "Extending the Color Stability and Shelf Life of Fresh Meat," Food Technology 45(3), 94-102, teach that mixtures of tetrasodium pyrophosphate, sodium erythrobate and citric acid combined with modified atmosphere storage extended the color life of various meat types and cuts. The headspace atmosphere used in this work was 50% CO_2, 15% O_2 & 35% N_2. Pork chops, beef rib steaks, and ground beef samples were examined. Treatment suspensions were applied by marination of prime cuts and by direct addition to ground beef prior to the final grind. Samples were stored at 2° C. in cardboard boxes for 0, 7, 14, 21, or 28 days prior to opening. After master batch storage, individual trays were stored at 2° C. under fluorescent light for 0, 2, 4, 6, 8, or 10 days. Very little effect was seen on pork. Ground beef showed the most improvement with shelf life being extended by 1-3 days. In contrast, steaks gained one day of shelf life while no improvement was seen for chops. The greatest color differences occurred after 7 days dark storage and 3 days storage in the light. Erythrobate was shown to have significant effects on color in beef and to effect TBAs favorably. Sensory panelists were unable to distinguish between treated and untreated materials at any stage.

[0010] C. Faustman, W. K. M. Chan, M. P. Lynch and S. T. Joo, 1996, "Strategies for Increasing Oxidative Stability of (Fresh) Meat Color." Reciprocal Meat Conference Proceedings, 49, 73-79 teach that adding water soluble antioxidants such as ascorbic acid to meat preserves red meat color. Oxymyoglobin is more stable in meat with higher tocopherol concentrations. This work did not involve MAP technology. The authors also reviewed work showing that modified atmosphere packaging was an effective tool for extending color life. These authors showed that meat stored in MAP which contained sachets of iron (an oxygen scav-

enger) demonstrated significantly greater retail color shelf life than those which were not exposed to oxygen scavengers.

[0011] S. D. Shivas, H. H. Kropf, M. C. Hunt, M. C. Kastner, L. L. A. Kendall and D. A. Dayton, 1984. "Effect of Ascorbic Acid on Display Life of Ground Beef," J. Food Protect. 47, 11-15, 19, disclosed that ascorbic acid levels at 0.05 and 0.1% prolonged display life of 20 and 25% fat grade ground beef, with 25% fat content beef giving higher scores. Beef flavor improved with ascorbic acid treatment while TBA values decreased with ascorbic acid treatment. Display life was extended by 5 days. This work did not involve MAP technology.

[0012] B. E. Greene, I. -M. Hsin and M. W. Zipser 1971, "Retardation of Oxidative Color Changes in Raw Ground Beef." J. Food Sci. 36, 940-942, treated ground beef with ascorbic acid plus either BHA or propyl gallate. Treatment was shown to effectively retard oxidation for up to eight days of refrigerated storage. This work did not involve MAP technology.

[0013] Chin S. Cheng, U.S. Pat. No. 4,683,139, Jul. 28, 1987, teaches a process for preserving color in fresh pork using a phosphate, ascorbic acid or iso-ascorbic acid and a chelator (EDTA, citric or tartaric acid) in combination with modified atmosphere packaging. The treatment extended color shelf life up to 21 days. The atmosphere used in this work ranged from about 2% to about 30% oxygen.

[0014] T. Okayama 1987, "Effect of Modified Gas Atmosphere Packaging After Dip Treatment on Myoglobin and Lipid Oxidation of Beef Steaks." Meat Sci. 19, 179-185 dipped beef steaks in an ethanolic solution of ascorbic acid and tocopherol. The MAP (80% O_2, 20% CO_2) steaks with or without dip treatment maintained acceptable color after 13 days of storage. Dip treatment showed no significant improvement in color. TBA numbers of samples stored in air or under 80% O_2, 20% CO_2 atmosphere were lower for the dip treated samples than for the non-dip treated samples.

[0015] Allen, P., Doherty, A. M., Buckley, D. J., Kerry, J., O'Grady, M. N., Monahan, F. J. 1996, "Effect of oxygen scavengers and vitamin E supplementation on colour stability of MAP beef," 42nd In. Cong. Meat Sci. Technol., 88-89, teaches that supplementation of the diet of steers with 2000 units of vitamin E (tocopherol) per day for forty days prior to slaughter had no effect on color stability of steaks stored with or without iron-containing oxygen scavengers in an atmosphere of 50% carbon dioxide; 50% nitrogen.

[0016] Sante, V., Renerre, M., Lacourt, A., J. Food Qual. 17 177-195, discusses the effect of modified atmosphere packaging on color stability and on microbiology of turkey breast meat. The best color results were obtained using a 100% carbon dioxide atmosphere combined with an oxygen scavenger. This treatment outperformed atmospheres containing high levels of oxygen.

[0017] J. H. Hotchkiss et al, "Advances in and Aspects of Modified Atmosphere Packaging in Fresh Red Meats", Reciprocal Meat Conf. Proc. 42 (1989), pages 31-40, states that although rosemary has been added to MAP poultry to preserve the color thereof, "Fortunately for the poultry people, poultry is not judged for myoglobin, so color is not a serious problem."

[0018] Yukichi Kimura et al, U.S. Pat. No. 4,380,506, Apr. 19, 1983, discloses the addition of extracts of herbs such as sage, rosemary, marjoram, thyme, oregano and basil to food products such as ham, sausage and processed marine and livestock-products for their antioxidant and anti-bacterial properties.

[0019] Uy Nguyen et al, U.S. Pat. No. 5,017,397, May 21, 1991, discloses plant extracts which are obtained by supercritical fluid extraction of ground leaves of the *Labiatae* family and added to food products such as processed meats and fish for their antioxidant properties. They do not discuss red meats.

[0020] Paul H. Todd, Jr., U.S. Pat. Nos. 5,061,403 and 5,209,870, Oct. 29, 1991 and May 11, 1993, both disclose a process for preparing an alkaline solution of *Labiatae* antioxidants and the use of these antioxidants in combination with polyphates in the pumping or brining of meats to inhibit "warmed-over" flavor and prevent off-color development.

[0021] Souzan Saad Latif Abd. El-Allm et al, Culinary herbs inhibit lipid oxidation in raw and cooked minced meat patties during storage", J Sci Food Agric (1999), Vol. 79, pages 277-285, disclose the mixing of spice extracts, such as sage, basil, thyme and ginger, with ground pork pretreated with an aqueous salt solution to prevent lipid oxidation.

[0022] F. Timmermann, "Effectiveness of Natural Antioxidants in Salami-type Sausages", Oils-Fats-Lipids (1975), Vol. 2, pages 351-353, discloses the use of natural antioxidants such as tocopherols or spice extracts in prolonging the shelf life of animal fats and cured raw sausages.

[0023] Although the prior art discussed above shows different methods of reducing oxidation effects in meats, particularly in the presence of oxygen scavengers and in inert atmospheres, this work is directed primarily at cured meats, or fresh red meat packaged under low (<30%) oxygen containing atmospheres. Only one author, Okayama, examined fresh red meat stored under a high oxygen atmosphere and his dip treatment was found to be ineffective in improving color. The prior art does not adequately address the problem of color retention in fresh red meats, and the need for a safe, permissible, and effective method of extending color life of prepackaged red meats remains. There still exists a need for a method of greatly extending the color life of modified atmosphere packaged fresh red meat, including meat that has not been subjected to a chemical processing or pretreatment step, through the use of a natural treating agent. While the prior art used oxygen scavengers such as ascorbates and erythrobates to prolong color shelf life, these are not permissible additives to red meats. The combination of these scavengers with conventional antioxidants, such as the synthetics BHA and BHT, and tocopherol, would be expected to slow down lipid oxidation. However, none of these conventional lipid antioxidants are permissible additives in red meats. Consequently, this invention provides the only presently known legal means of extending the color shelf life of MAP red meats.

SUMMARY OF THE INVENTION

[0024] A method of extending the color life of fresh red meat packaged in an elevated oxygen atmosphere comprising a step of contacting fresh red meat with an extract of a *Labiatae* herb prior to packaging the meat.

[0025] It is a further object of the present invention to provide red meat packaged in an atmosphere of greater than about 40% oxygen and containing an extract of a *Labiatae* herb.

[0026] These and other objects of the present invention are accomplished by contacting fresh red meat with an extract of a *Labiatae* plant prior to subjecting the meat to modified atmosphere packaging.

[0027] In one embodiment of the present invention, the *Labiatae* plant extract is applied to the fresh red meat by spraying.

[0028] In a preferred embodiment of the present invention, the fresh red meat is contacted with a rosemary extract prior to subjecting the meat to modified atmosphere packaging.

DETAILED DESCRIPTION

[0029] For the purposes of this invention, "fresh red meat" is red meat that has not been subjected to a curing process to alter the characteristics of the meat and includes meat from cattle, deer, goats, buffalo, elk and swine.

[0030] *Labiatae* plants contain a number of phenolic compounds that can function as food antioxidants. The compounds have different solubility characteristics depending on their structure and extracts can be prepared which contain predominantly lipophilic or hydrophilic phenolic components. One skilled in the art will be able to effect the proper combination to achieve the greatest possible effect at an acceptable dose. It should be recognized that many of the potentially active constituents are presently unknown. While rosemary is the preferred herb, sage, oregano, thyme and mints also are preferred members of the *Labiatae* genus.

[0031] Extracts can be prepared by using solvents in a manner conventionally used to prepare spice oleoresins extracts and infusions. Solvents can include those approved under 21 CFR part 173, such as water, ethanol, methanol, isopropyl alcohol, ethyl acetate, hexane, acetone, methyl ethyl ketone, methylene chloride, dichloroethane or mixtures thereof, or additionally, fluorohydrocarbons alone or in combination with food grade solvents. They can also be prepared by extraction with supercritical fluids such as supercritical carbon dioxide. Fluids which function as solubilizers or carriers can be added to the ground spice prior to the pressing operation. Suitable extraction methods are disclosed in U.S. Pat. Nos. 4,380,506, 5,017,397, 5,061,403 and 5,209,870, the disclosures of which are hereby incorporated by reference.

[0032] Lipophilic extracts can be prepared by extracting the dehydrated, ground spice in a food grade solvent such as hexane, acetone, or mixtures of hexane and acetone. Ethyl acetate or other food approved, relatively non-polar solvents, or mixtures of these solvents can also be used in this process. Active charcoal can be added to the ground spice prior to extraction or to the miscella after extraction to reduce chlorophyll levels in the resultant extract. After extraction, the solvents are removed by vacuum distillation and reduced to below FDA regulated levels. The resulting extracts are diluted with soybean oil to provide oil-dispersible or lipophilic final products with standardized performance in stabilizing test oils. For rosemary and other Labiatae, these extracts contain the lipid-soluble portion of the spice, and can include carnosic acid and carnosol and other as yet unidentified active components. Optionally, food grade emulsifying agents such as lecithin, hydroxylated lecithin, monoglycerides, diglycerides, polysorbates, diacetyl tartaric acid esters of monoglycerides, and the like, or mixtures thereof can be added as carriers or diluents.

[0033] Hydrophilic extracts can be prepared by a two stage extraction process. The dehydrated, ground spice is first extracted with a mixture of hexane and acetone. The solid residue from the extraction is then re-extracted using a mixture of acetone and water, methanol and water, ethanol and water or isopropyl alcohol and water. The resulting miscella is subjected to vacuum distillation to remove the solvent. It can optionally be purified by partitioning between water and an organic solvent. The final aqueous mixture may be diluted with food grade propylene glycol or glycerin to make a standardized, hydrophilic product. For rosemary, oregano, mint and other spices, these extracts contain hydrophilic components including rosmarinic acid. The use of aqueous alkaline solution are not contemplated for use in the methods and products of this invention.

[0034] Dispersible extracts containing both lipophilic and hydrophilic components can be prepared by extracting the dehydrated, ground spice (optionally containing active charcoal) with a mixture of methanol and water, ethanol and water, isopropyl alcohol and water or acetone and water. After solvent removal, the concentrated extract can be diluted with a vegetable oil or with propylene glycol to provide an oil-dispersible or water-dispersible extract, respectively. Optionally, food grade emulsifying agents such as lecithin, hydroxylated lecithin, monoglycerides, diglycerides, polysorbates, diacetyl tartaric acid esters of monoglycerides, and the like, or mixtures thereof can be added as carriers.

[0035] *Labiatae* herbs of two or more species can be combined and extracted to yield a product that can be used to enhance the color life of red meat stored in high oxygen atmospheres. Alternatively, extracts prepared separately from two or more *Labiatae* herbs can be combined and are a useful part of this invention.

[0036] The extracts used in the present invention can either be in the form of both lipophilic and hydrophilic preparations or mixtures thereof.

[0037] Ground rosemary can be extracted with a number of food grade solvents or mixtures thereof, such as hexane, acetone, methanol, ethanol, ethyl acetate, or with supercritical carbon dioxide. Depending upon the polarity of the solvent or solvent mixture different constituents can be extracted. Non-polar solvents favor the lipophilic components. Polar solvents favor the hydrophilic components. Some solvents extract both components and these can be partitioned in subsequent steps if desired.

[0038] After extraction, the solvents are removed by distillation to residual levels that meet FDA regulations. Active charcoal can be added at several points in the process to remove chlorophyll. The charcoal containing adsorbed chlorophyll is removed by filtration. Some volatile oils can be removed by distillation to control flavor. Vegetable oil can be added to the lipophilic extracts as a standardizing agent. Food grade emulsifiers can be added in place of vegetable oils to make water dispersible forms of the rosemary extract. Polar, hydrophilic food grade materials such as propylene

glycol or glycerine or alcohol can be added to the hydrophilic extracts to standardize the flavor and activity. These extracts are well known in commerce under the common name of oleoresins.

[0039] Oleoresin rosemary containing the more lipophilic phenolic ingredients, such as carnosic acid and carnosol, which are specially prepared to have chlorophyll removed therefrom, can be applied directly by a spraying process onto the surface of the meat. The oleoresin can be diluted with a vegetable oil in order to facilitate the spraying thereof. The effective dosage or coating amount generally ranges from about 1 to 40 grams of oleoresin per 20 pounds of meat but can be varied as the situation dictates. A more preferred dosage amount is from 0.025 to 1 wt. % based on the total weight of the meat.

[0040] The water-dispersible forms of the rosemary extracts are rosemary oleoresins containing food-grade emulsifiers such as polysorbates, mono and diglycerides, lecithin, hydroxylated lecithin, sorbitan esters, tartaric acid esters of mono- and di-glycerides. These preparations are best used by combining them with up to 10 times, or more, of their weight of water, or brine, and applying the resulting suspension in amounts ranging from about 20 to 180 grams per 20 pounds of meat. The dilution rate of the water-dispersible rosemary extract can be adjusted depending on the process.

[0041] The hydrophilic rosemary extracts have been found to be particularly effective in stabilizing the meat color in modified atmosphere packaged red meats. A solution of rosmarinic acid and water or a mixture of water and a food grade alcoholic solvent, such as propylene glycol, has been found to be particularly convenient to apply. In one method of application, a propylene glycol/water solution containing approximately 3.2 weight percent rosmarinic acid is diluted by a factor of ten in water and sprayed onto the meat in an amount of about 10 to 120 grams of diluted solution per 20 pounds of meat prior to packaging.

[0042] It is desirable to have the lipophilic extract present in an amount of 100-5000 ppm, preferably 500-2000 ppm, based upon meat weight. The hydrophilic extract is preferably present in treated red meat in an amount of from 50-5000 ppm, preferably 500-4000 ppm. If carnosic acid is present in the extract, it should be contained in the treated red meat in an amount of from 5-300 ppm, preferably 10-50 ppm and if rosmarinic acid is present in the extract, it should be contained in the treated red meat in an amount of from 5-300 ppm, preferably 20-120 ppm. The range of dosages of the extracts which can be employed is very wide because the extracts themselves can be prepared in ways which provide greatly increased or decreased concentrations of the active components. Much smaller dosages of the highly concentrated extracts can provide functional amounts of the active components in the final meat product. It is noted, however, that using higher doses of extracts which are more dilute in active components often confers the advantage of providing a more uniform and therefore more effective dispersion of the dose in the final meat product. The concentrations and doses can be adjusted on a case by case basis by one skilled in the art to provide the optimum performance.

[0043] The present invention can be practiced by spraying techniques such as the utilization of pneumatic sprayers, electrostatic sprayers and atomizers to incorporate the extract onto the meat. Other techniques such as painting, dipping, marinating, vacuum tumbling injecting, mixing and pumping can also be used to incorporate the extract into the meat. The inventive mixtures can also be combined with and mixed into ground meat during the grinding process or at some point thereafter. The inventive mixtures can be combined with other additives such as polyphosphates, salt, water, flavors, broths, added proteins, sugar, starches and the like which are commonly incorporated into meats. Highly water-dispersible compositions formulated with emulsifying agents are particularly suited for this use.

[0044] It is important to distinguish fresh meats which may contain these ingredients and are covered by the present invention from cured meats, which may contain the same ingredients, but also contain one or more of the following: erythorbates, erythorbic acid, ascorbates, ascorbic acid, nitrites, nitrates or cultures. The present invention is limited to fresh meats, and does not include the stabilization of meat color in cured meats. The pigments in cured meat are chemically different from those in fresh red meat which makes them more stable. The inventive mixtures can be applied to a carrier such as maltodextrin, salt, texturized soy protein and the like. These solid dispersions can in turn be added to the meat by mixing or grinding. Combinations of these application techniques will sometimes be advantageous. It is also within the scope of the present invention to combine the *Labiatae* extracts with other naturally occurring antioxidants to stabilize the color of the modified atmosphere packaged meats. That is, it is contemplated that the *Labiatae* extracts can be combined with at least one of tocopherols, tocotrienols, green tea extracts and citric acid, should these become permissible additives. Additionally, mixtures of the hydrophilic and lipophilic *Labiatae* extracts can be used in the treatment of the meat prior to it being packaged. The specific ratios and dosages of the hydrophilic *Labiatae* extracts to the lipophilic extracts in the mixture can readily be determined by one skilled in the art to provide optimum performance depending on the meat and packaging conditions. It is also within the scope of the present invention to combine the *Labiatae* extracts with flavorings in the form of spice extracts such as black pepper, celery, white pepper, garlic and onion or synthetic flavorings such as reaction flavors and glutamates.

[0045] The advantages of the present invention are illustrated by the following examples. Up to three meat sources were blended to achieve the desired fat contents. Coarse ground, vacuum packaged ground chuck or round containing from 14-19% fat was obtained in 14 pound chubs from a local meat company. Lean meat from whole chuck pectoral muscle (approximately 10% fat) was obtained from the same source. Meat removed from beef trim from the same source contained 45% fat. These meat feedstocks were pre-ground through a 3/16 inch plate to reduce their particle size and aid in subsequent blending. The lean and fat portions were weighed into 12 pound batches in appropriate relative amounts to give the desired fat content and blended for two minutes in a Mainca RM-35 meat mixer/blender. Paddle direction was reversed every 15 seconds during the two minute blending time. Where a color-stabilizing treatment was added, one half of the required amount was added initially and the remainder added after 30 seconds of blending. Dry ice, crushed to a particle size of less than 1.7 mm, was added to maintain the meat temperature between 28 and 32 degrees Fahrenheit during blending. The meat was then

ground through a ⅛ inch plate and separated into one pound samples. The ground meat was packaged into Cryovac BT92 trays using an Ilpra Basic 100 VG single mold modified atmosphere packaging machine using a barrier film. A heat seal temperature of 110° C. and heat seat time of 4 seconds was used. The packages were evacuated using a 700 mm Hg vacuum and back flushed with a +30 mm Hg stream of the appropriate gas mixture.

[0046] Headspace oxygen and carbon dioxide levels were measured with a PBI Dansensor Checkmate 9000 analyzer. C.I.E. 1976 L*a*b* values were obtained using a Minolta CR-300 Chroma meter using the "C" light source and multi measure reading (average of three successive readings). Three readings across the diagonal of the package were taken and averaged. The packaging film was cut away from the tray and flattened against the meat prior to the color measurements and the readings were taken through the film. The CIE Lab color measurement system defines a three dimensional color space in which values L*, a* and b* are plotted at right angles to each other. L* is a measure along an axis representing lightness or darkness. A measure along a red/green axis gives a* and a measure against a yellow/blue axis is represented by b*. CIE Lab is a popular color space for use in measuring reflective and transmissive objects. The a* value is widely used in the meat industry as a measure of redness. The time necessary for a sample to lose one third of its color has been arbitrarily chosen as a point at which to compare various treatments. A loss of more than one third of its color may be acceptable under some commercial conditions.

[0047] For the studies of combined dark and light storage, the meat was stored at a temperature of 32-35 degrees F. in the dark for ten days and then placed in a light box capable of providing uniform light of 200 foot candles (cool white fluorescent lamps) at a temperature of 35-40 deg. F. Under incandescent light, color loss is slower.

EXAMPLES

[0048] The following Examples demonstrate that the combination of high (>40%) oxygen modified atmosphere packaging combined with a rosemary or other *Labiatae* extract will extend color life to a commercially viable length of time. The dosages and relative amounts of hydrophilic and lipophilic constituents can be ascertained by techniques described herein by one skilled in the art. They will vary with the fat content, the freshness of the meat, the type of animal and even the strain, and with the feeding prior to slaughter.

Example 1

[0049] Ground beef containing 85% lean and 15% fat was prepared according to the method described above. The standardized lipophilic rosemary extract was added to the meat at a dose of 0.1% by weight based upon total meat weight and provided about 20 ppm carnosic acid to the final meat product. The standardized hydrophilic extract was added to the meat at a dose of 0.1% by weight based upon total meat weight and provided about 32 ppm rosmarinic acid to the final meat product. The meat was packed in oxygen-impermeable packaging under an atmosphere of 70 vol. % oxygen and 30 vol. % carbon dioxide. The meat was stored in the dark at a temperature of 32 degrees F. for 26 days. Samples were pulled at days 3, 5, 7, 10, 12, 14, 16, 18, 20, 22 and 26. The redness of the meat was measured calorimetrically using a* values. The percent a* retained was plotted vs. time in days. From these curves, the time at which each sample had faded to ⅔ of its original a* value (⅓ a* loss) was determined. A level of ⅔ of the starting color is commercially acceptable and is used as a cutoff point herein. In this test, ground beef containing no additive (control) was compared to ground beef containing a lipophilic rosemary extract and to a sample of ground beef containing a hydrophilic rosemary extract. Table 1 shows the days required for each sample to lose ⅓ of its a* value.

TABLE 1

Additive	Days to ⅔ Original a* Value	Percentage Change
Control	6	—
Lipophilic Rosemary Extract	10	167%
Hydrophilic Rosemary Extract	13	216%

The samples containing lipophilic or hydrophilic extracts show dramatic increases in color stability as measured by retention of a* values.

Example 2

[0050] Ground beef containing 75% lean and 25% fat was prepared according to the method described above. The standardized hydrophilic extract was added to the meat at a dose of 0.1% by weight based upon total meat weight and provided about 32 ppm rosmarinic acid to the final meat product. Samples of the meat were packed in oxygen-impermeable packaging under various mixtures of oxygen and carbon dioxide. The meat was stored under cool white fluorescent lights at 200 foot candles at a temperature of 35-40 degrees F. Samples were pulled at daily intervals for six days and the redness of the meat was measured calorimetrically using a* values. The percent a* retained was plotted vs. time in days. From these curves, the time at which each sample had faded to ⅔ of its original a* value (⅓ a* loss) was determined. In this test, ground beef containing no additive (control) was compared to ground beef containing a hydrophilic rosemary extract. Table 2 shows the days required for each sample to lose ⅓ of its a* value.

TABLE 2

Additive	Days to ⅔ Original a* Value	Percent Change
Control ($80\%\ O_2$; $20\%\ CO_2$)	3	—
Hydrophilic Rosemary Extract ($80\%\ O_2$; $20\%\ CO_2$)	4.5	150%
Control ($70\%\ O_2$; $30\%\ CO_2$)	2.2	—
Hydrophilic Rosemary Extract ($70\%\ O_2$; $30\%\ CO_2$)	4.5	205%
Control ($40\%\ O_2$; $60\%\ CO_2$)	2.4	—
Hydrophilic Rosemary Extract ($40\%\ O_2$; $60\%\ CO_2$)	2.6	108%

The improvement seen is more substantial for higher oxygen atmospheres than for meat packaged in a 40% oxygen, 60%

carbon dioxide atmosphere. Meat loses color much more rapidly under fluorescent lighting than in the dark. The hydrophilic rosemary is effective in preventing light-induced color loss in ground beef.

Example 3

[0051] Ground beef containing 75% lean and 25% fat was prepared according to the method described above. The standardized lipophilic rosemary extract was added to the meat at a dose of 0.1% by weight based upon total meat weight and provided about 10 ppm carnosic acid to the final meat product. Samples of the meat were packed in oxygen-impermeable packaging under various mixtures of oxygen and carbon dioxide. The meat was stored under cool white fluorescent lights at 200 foot candles at a temperature of 35-40 degrees F. Samples were pulled at daily intervals for six days and the redness of the meat was measured calorimetrically using a* values. The percent a* retained was plotted vs. time in days. From these curves, the time at which each sample had faded to ⅔ of its original a* value (⅓ a* loss) was determined. In this test, ground beef containing no additive (control) was compared to ground beef containing a lipophilic rosemary extract. Table 3 shows the days required for each sample to lose ⅓ of its a* value.

TABLE 3

Additive	Days to ⅔ Original a* Value	Percent Change (increase)
Control (80% O_2; 20% CO_2)	3	—
Lipophilic Rosemary Extract (80% O_2; 20% CO_2)	3.3	110%
Control (70% O_2; 30% CO_2)	2.2	—
Lipophilic Rosemary Extract (70% O_2; 30% CO_2)	3.5	159%
Control (40% O_2; 60% CO_2)	2.4	—
Lipophilic Rosemary Extract (40% O_2; 60% CO_2)	2.8	117%

Example 4

[0052] Ground beef containing varying fat to lean ratios were prepared according to the method described above. The standardized hydrophilic rosemary extract added at 0.1% by weight provided 32 ppm rosmarinic acid to the final meat product. The standardized hydrophilic rosemary extract added at 0.4% by weight provided 128 ppm rosmarinic acid to the final meat product. The standardized hydrophilic oregano extract added at 0.2% provided 64 ppm rosmarinic acid to the final meat product. Samples of the meat were packed in oxygen-impermeable packaging under an atmosphere of 70 vol. % oxygen and 30 vol. % carbon dioxide. The meat was stored for 10 days in the dark at 32 degrees F. and then placed under cool white fluorescent lights at 200 foot candles at a temperature of 35-40 degrees F. Samples were pulled after ten day's storage and at daily intervals thereafter for testing. The percent a* retained was plotted vs. time in days. In this test, ground beef containing no additive (control) was compared to ground beef containing hydrophilic rosemary extract. Table 4 shows percent a* values retained at various times.

TABLE 4

Additive	% a* Retained Day 10 (% Increase over control)	% a* retained 10 days dark + 2 days light
Control (75% lean, 25% fat)	42	33
0.1% Hydrophilic rosemary 75% lean, 25% fat	74 (176%)	64 (194%)
0.4% Hydrophilic rosemary 75% lean, 25% fat	79 (188%)	68 (206%)
Control (82% lean, 18% fat)	60	55
0.1% Hydrophilic rosemary 82% lean, 18% fat	87 (145%)	66 (120%)
Control (85% lean, 15% fat)	58	38
0.1% Hydrophilic rosemary 85% lean, 15% fat	71 (122%)	57 (150%)
0.2% Hydrophilic oregano 85% lean, 15% fat	68 (117%)	58 (153%)

Meat producers are looking for acceptable color after 10 days storage in the dark followed by 2 days storage in the light. The border between acceptable and unacceptable color is dependent upon the observer, but is around an a* value of 17. This corresponds in these studies to about ⅓ loss of beginning a* value. Therefore, a retained a* value >67% after 10 days dark storage and 2 days in the light would be deemed of real commercial value. None of the control samples were able to achieve this level of color retention. It should be noted that the meat used in this example was perhaps 4-6 days old when purchased. Better performance is expected if the rosemary extracts are added to fresher meat after only a day or two old.

Example 5

[0053] Ground beef containing varying fat to lean ratios were prepared according to the method described above. The dispersible extract was formulated to contain hydroxylated lecithin and diacetyltartaric acid esters of monoglycerides as emulsifying agents. The dispersible extract added at 0.1% by weight provided about 10 ppm carnosic acid and about 5 ppm rosmarinic acid to the final meat product. The lipophilic rosemary extract added at 0.1% by weight provided about 10 ppm carnosic acid to the final meat product. Samples of the meat were packed in oxygen-impermeable packaging under an atmosphere of 70 vol. % oxygen and 30 vol. % carbon dioxide. The meat was stored for 10 days in the dark at 32 degrees F., and then placed under cool white fluorescent lights at 200 foot candles at a temperature of 35-40 degrees F. Samples were pulled after ten day's storage and at daily intervals thereafter for testing. The percent a* retained was plotted vs. time in days. In this test, ground beef containing no additive (control) was compared to ground beef containing a lipophilic rosemary extract. Table 5 shows percent a* values retained at various times.

TABLE 5

Additive	% a* Retained Day 10 (% Increase over control)	% a* retained 10 days dark + 2 days light
Control (75% lean, 25% fat)	42	33
0.1% Lipophilic rosemary 75% lean, 25% fat	62 (148%)	49 (148%)
0.1% Dispersible rosemary 75% lean, 25% fat	70 (167%)	55 (167%)
Control (85% lean, 15% fat)	58	38
0.1% Lipophilic rosemary 85% lean, 15% fat	64 (110%)	44 (116%)

While the percent a* retained in this Example is less than the desired 67%, the example demonstrates that effectiveness can be improved by formulating the extract into a dispersible form, and that the dosage must be increased as the fat content of the meat decreases.

Example 6

[0054] Ground beef containing 82% lean and 18% fat was prepared according to the method described above. The standardized hydrophilic rosemary extract added at 0.1% by weight provided 32 ppm rosmarinic acid to the final meat product. Samples of the meat were packed in oxygen-impermeable packaging under atmospheres of 80 vol. % oxygen and 20 vol. % carbon dioxide; 70 vol. % oxygen and 30 vol. % carbon dioxide and air (21 vol. % oxygen, 0% carbon dioxide). The meat was stored for 10 days in the dark at 32 degrees F., and then placed under cool white fluorescent lights at 200 foot candles at a temperature of 35-40 degrees F. Samples were pulled after ten day's storage and at daily intervals thereafter for testing. The percent a* retained was plotted vs. time in days. In this test, ground beef containing no additive (control) was compared to ground beef containing a hydrophilic rosemary extract. Table 6 shows percent a* values retained at various times.

TABLE 6

Additive	% a* Retained Day 10 (% Increase over control)	% a* retained 10 days dark + 2 days light
Control AIR	55	29
0.1% Hydrophilic rosemary Air	61 (111%)	28 (97%)
Control (70% O_2; 30% CO_2)	60	55
0.1% Hydrophilic rosemary 70% O_2; 30% CO_2	87 (145%)	66 (120%)
Control (80% O_2; 20% CO_2)	79	49
0.1% Hydrophilic rosemary 80% O_2; 20% CO_2	87 (110%)	64 (131%)

[0055] While both treatments provide acceptable color retention, this example shows that 70% oxygen is sometimes superior to 80%. The optimum oxygen content therefore must be ascertained on a case by case basis. It is noted that none of the packages containing an atmosphere of air had acceptable shelf life, demonstrating the significance of elevated oxygen content.

[0056] The treatment of the red meat according to the present invention prior to the modified atmospheric packaging unexpectedly greatly extends the color life of the red meat. The *Labiatae* extract is preferably added to the meat prior to grinding and is effective under high oxygen conditions. When the red meat is treated with hydrophilic rosemary extract and packaged in a modified atmosphere containing 70 vol. % oxygen and 30 vol. % carbon dioxide, the color life of the red meat has its greatest extension. Additionally, the present invention can be used to extend the color life of whole muscle cuts of meat as well as ground meat under similar processing and packaging conditions as ground meat.

[0057] The lipophilic extracts used in the above examples were standardized to give a dose of 10-20 ppm carnosic acid at a 0.1% dose of extract. The hydrophilic extracts used in the above examples were standardized to give a dose of 32-128 ppm rosmarinic acid at a 0.1-0.4% dose of extract. Dosages of carnosic acid in the finished meat product can vary between 5 and 300 ppm, depending on the storage and lighting conditions, and the desired shelf life. Under most conditions, optimum dosages will be in the range of 10 to 50 ppm. Dosages of rosmarinic acid in the finished meat product can vary between 5 and 300 ppm, depending on the storage and lighting conditions, and the desired shelf life. Under most conditions, optimum dosages will be in the range of 20 to 120 ppm. Combinations of lipophilic and hydrophilic constituents generally will reduce the dosage of the individual constituents or significantly increase color life. Up to about 300 ppm carnosic acid and up to about 300 ppm rosmarinic acid are feasible combinations. The optimum dose will depend upon the condition of the meat, the fat content, the desired MAP oxygen concentration, as well as the amount of other active constituents in the individual extracts. The relative amount of active constituents in the *Labiatae* genus varies from species to species. It can be determined by analytical procedures known to the art, such as high performance liquid chromatography (HPLC). In general, oxygen should be greater than 40% of the headspace, preferably greater than 60% and most preferably in the range of 70% to 80%, with carbon dioxide constituting the balance. A portion of the carbon dioxide can be replaced with an inert gas filler such as nitrogen or argon. Those practicing the art will be able to optimize dosages and mixtures of constituents and gases for specific meat applications. While the specification shows methods of extending the color shelf life by several days, an extension of only one day is commercially advantageous and may be achieved in art by regulating the dose.

[0058] It is to be understood that the invention is not to be limited to the exact details of operation, or to the exact compositions, methods, procedures or embodiments shown and described above, as obvious modifications and equivalents will be apparent to one of ordinary skill in the art, and the invention is only limited by the full scope legally accorded the appended claims.

What is claimed is:

1. A high oxygen modified atmosphere package comprising a fresh red meat product in an atmosphere of greater than abort 40% oxygen and wherein said fresh red meat contains a hydrophilic extract of a *Labiatae* herb, wherein the extract contains rosmarinic acid, is free of some of its volatile oils and has high antioxidant activity and little antimicrobial activity in fresh red meat.

2. The high oxygen modified atmosphere package claim 1 wherein the treated meat contains between about 5 and about 300 ppm rosmarinic acid.

3. A high oxygen modified atmosphere package comprising a fresh red meat product in an atmosphere of greater than about 40% oxygen and wherein said fresh red meat contains a lipophilic extract of a *Labiatae* herb, wherein the extract contains carnosic acid and optionally carnosol, is free of some of its volatile oils and has high antioxidant activity and little antimicrobial activity in fresh red meat.

4. The high oxygen modified atmosphere package of claim 3, wherein the treated meat contains between about 5 and about 300 ppm carnosic acid.

5. A high oxygen modified atmosphere package comprising a fresh red meat product in an atmosphere of greater than about 40% oxygen and wherein said fresh meat contains an extract of a *Labiatae* herb, wherein the extract contains both hydrophilic and lipophilic constituents, selected from the group consisting of carnosic acid and rosmarinic acid is free of some of its volatile oils and has high antioxidant activity and little antimicrobial activity in fresh red meat.

6. The high oxygen modified atmosphere package of claim 5, wherein the treated meat contains between about 5 and 300 ppm carnosic acid and between about 5 and 300 ppm rosmarinic acid.

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STATS Articles

Trevor Butterworth, October 26, 2007

A Scandal Over Meat Safety?

Michigan Democrats raise fears over "revolutionary" meat packaging process that reduces risk of *E. coli*, keeps meat fresh longer. Food safety experts say politicians misleading public on science. Is a massive Washington lobbying effort by rival Michigan-based company behind smear campaign?

On September 13, Michael Doyle, a world-leading expert in food safety addressed the Canadian Meat Council symposium on "Advances in Antimicrobial Interventions for Quality Control." Doyle, who is Regents Professor and Director of the Center for Food Safety at the University of Georgia, discussed a study that he and his colleague Dr. Li Ma had undertaken which showed that a popular wrapping system that vacuumed out air and added a tiny amount of carbon monoxide, nitrogen and carbon dioxide (known as MAP–CO) could not only keep meat fresher for longer than conventionally wrapping, but could significantly retard the growth of the *E. coli O157:H7* bacterium in ground beef when the meat was stored above the recommended temperature.

"MAP–CO-treated meat is a revolutionary technology providing greater protection against foodborne pathogens and extended shelf life to fresh beef," Doyle told the symposium.

And yet, despite *E. coli O157:H7* being one of the leading causes of food-borne illnesses in the United States, with an estimated 73,000 cases of infection and 61 deaths each year, and despite the potential reduction in wastage from meat staying fresher for significantly longer, MAP–CO meat is being pulled from the shelves largely due to a campaign by two Michigan Congressmen and various environmental groups claiming that the public is being deceived.

On June 25th, U.S. Rep John Dingell (D–MI), Chairman of the Committee on Energy and Commerce, Rep Bart Stupak (D–MI), Chairman of the Subcommittee on Oversight and Investigations, sent letters to Safeway Stores, Inc., Tyson Foods, Inc., Pactiv Corporation and Precept Foods LLC (Hormel Foods Corporation/Cargill Incorporated), which, as their press release noted, "questioned the companies' practice of packing fresh meat in carbon monoxide, which artificially colors the product and disguises spoilage."

In less than a month, Safeway dropped MAP–CO packaged meat; and Reps Dingell and Stupak released another statement praising the company's decision:

> *"'Americans place a great deal of trust in the hands of grocers and retailers to sell them safe and healthy products,' said Dingell. 'The practice of exposing meat to carbon monoxide deceives consumers and is a potential health hazard. I commend Safeway for its decision to stop selling these meats and I hope other grocers and meat packers will follow suit.'"*

But according to food safety experts and microbiologists at leading academic food safety programs there is simply no science to support the charges made Reps Dingell and Stupak against MAP–CO. It also turns out that Kalsec, a Michigan company with a rival but less effective method of preserving meat freshness, has spent around $850,000 to lobby Congress on food safety issues, with some of that money going specifically to lobby Reps Dingell and Stupak on MAP–CO.

Is carbon monoxide (CO) a colorant?

In contrast to Rep's Dingell and Stupak description of MAP–CO (the acronym stands for "modified atmosphere packaging with carbon monoxide"), scientists say the process is not an artificial way of coloring meat.

"Meat is muscle tissue," explains Susan Brewer, Professor of Food Science at the University of Illinois, "and in an oxygen-deprived environment—inside an animal—it's purple. For it to be red, it has to be exposed to air, and that's the color consumers identify as fresh."

But here's the problem: exposure to air will turn refrigerated meat brown within a few days, and even though it may be perfectly safe to eat, consumers, typically, see the meat as spoiled. Unfortunately consumers are not ready to buy purple-colored oxygen-free vacuum-packed meat either (which is the way meat is packed for the wholesale industry).

"The red color has been shown many, many times to be critical to consumer selection and purchase at retail. So, for fresh meat in retail, oxygen exposure, either using oxygen permeable films or a high-oxygen package atmosphere has always been necessary," says Joseph Sebranek, University Professor in the department of

Animal Science, Food Science and Human Nutrition at Iowa State University (via e-mail).

Modified atmosphere packaging has been around for years, but the key to implementing in wrapping meat for retail was to find a way of achieving the bright red color that consumers understood as signaling freshness. The solution was to add a miniscule quantity of carbon monoxide (CO) into a package that contains no oxygen. "The monoxide bonds to the exact site as the oxygen molecule," says Brewer, "but the bond is much tighter—it's stuck—and it keeps the meat a bright red color. It's not a colorant per se." The Food and Drug Administration an the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture have permitted MAP–CO packaging of meat since February, 2002.

None of the experts interviewed by STATS saw it as an artificial coloring process. "The color is still derived from the meat pigment, not an external coloring agent, and the color is the same as that from oxygen. Therefore, this is not deceiving consumers," says Sebranek.

"MAP with a small amount of carbon monoxide does not add a new color to meat," says Alden Booren, Professor of Food Science and Nutrition at Michigan State University, (via e-mail). "It reacts with the naturally occurring pigment in meat (myoglobin) to produce a form of the pigment that is more stable and is not readily distinguishable from the normal (oxygenated) form of the pigment. Thus it is not a 'coloring' but rather the natural pigment in a slightly different form."

MAP with CO does not disguise spoilage—it slows it down

Rep's Dingell and Stupak's contention that MAP–CO "disguises spoilage" is also dismissed by food safety experts and scientists. The MAP–CO system eliminates oxygen, and without oxygen the key bacterium that generates spoilage is suppressed. "Pseudomonas, which in not pathogenic, is capable of spoiling fresh beef stored in air at refrigeration temperatures within a few days," says P. Michael Davidson, Professor of Food Microbiology at the University of Tennessee's Institute for Agriculture (via e-mail). "If we package the product with low or no oxygen MAP, this microorganism is incapable of growth."

"One of the benefits of the CO system is elimination of oxygen. That alone provides for a longer product shelf life because both chemical oxidation (and resulting off-flavors) and aerobic spoilage bacteria (the fastest growing group of bacteria on fresh meat) are suppressed," says Sebranek. "What so many players in this game have missed is that CO permits the use of additional antimicrobial treatments that provide for greater control of bacterial growth. For example, it is well-recognized that carbon dioxide will slow the growth of many bacteria. However, more than about 30% or so carbon dioxide in a modified atmosphere package with oxygen will cause meat browning. With carbon monoxide, the amount of carbon dioxide that can be used in the package is much greater because there is no discoloration, thus bacterial control is improved."

The result, as Doyle explains via e-mail, is that "The shelf life of refrigerated (<40 F) MAP–CO ground beef is 2 to 3 weeks compared to about 3 to 5 days for typical over-wrapped ground beef."

But the most recent finding about MAP is that the CO component also represses the growth of harmful bacteria when ground beef is stored above recommended refrigeration temperatures. "After 4 days at 50 F, *E. coli O157* cell numbers in over-wrapped ground beef increase by 100 fold or more compared to MAP–CO product," says Doyle. "Hence, refrigerated or mildly temperature abused MAP–CO ground beef has better quality and microbial safety characteristics than over-wrapped beef stored under similar conditions."

When MAP–CO meat spoils

Much of the controversy over MAP–CO is due to the assumption that the color of meat indicates whether it's safe or not—and that if you make the red color more resilient, you can disguise spoilage and pass old meat onto the consumer. But MAP–CO meat will spoil after 3 weeks, and, as Brewer notes, the key indicator of spoilage is not color but odor. "If the meat was spoiled, you would know it," she says.

"The COMb (the red pigment form of CO compared to that formed in air, Oxymyoglobin = OMb) does NOT mask spoilage," says Melvin Hunt, Professor of Animal Sciences and Industry at Kansas State University's Food Science Institute (via e-mail). "Most of the opponents of the use of CO in MAP do not understand the dynamics of meat color (a delicate balance between being purple-red, bright red, and tan/brown)."

"The use of MAP containing carbon monoxide shifts the consumer's ability to detect spoilage from looking at the meat, and deciding it is unacceptable based on color, to examining the sell-by dates or looking for gas production or a bulged pack-

age," says Davidson. "While it does put more responsibility on the consumer to read the package, using color to determine acceptability is not foolproof either. Just because the meat doesn't look particularly bad is not a sign that it is not spoiled or close to spoilage and the reverse is also true. Actually, most consumers probably use their noses to make a final determination as to whether a product is acceptable to cook and that wont change with MAP."

Davidson notes that MAP puts an onus on processors and retailers to set realistic sell-by dates.

"The bottom line here, says Hunt, is that consumers must do their part and smell the product before cooking and consumption—not a new or alarming fact."

Is a rival industry behind the misinformation campaign?

Professor Booren wrote to Rep Dingell a year ago to explain why describing MAP with CO as a colorant was misleading, and why, after reviewing all the peer-reviewed literature on the technology, he concluded that "the safety of the food supply has not been compromised." None of the scientists interviewed saw any reason for supermarkets to drop MAP–CO meat or for consumers to be alarmed.

"My opinion," says Doyle, "is that MAP–CO treatment of ground beef provides a better quality product for an extended period of time than over-wrapped ground beef. This reduces wastage and gives consumers more flexibility in time to use refrigerated ground beef."

But such expert testimony appears to have had no impact on the political campaign against MAP. "The Safeway story is just the tip of the ice berg," e-mails Hunt. "The good Congressmen from Michigan who seem to be championing the charge against CO are just doing their job for a Michigan company (Kalsec®). Kalsec® was going to loose tons of business if the meat industry lead by Wal-Mart switched from the High-oxygen MAP system to the Carbon monoxide MAP system. So they poisoned the pot with a lot of WRONG science, which isn't very hard to do since CO is not the most user-friendly compound."

Kalsec has also "petitioned the FDA to reconsider the approval of CO packaging and that has been generating numerous media releases that are strongly worded criticisms of the concept," says Sebranek. "Kalsec is a supplier of antioxidants used in high oxygen packaging systems, products that are not needed in the CO package. Their motivation, in my opinion, is economic."

Lobbying reports show that Kalsec paid $840,000 to the Washington, D.C. law firm Covington and Burling to lobby Congress and other Federal agencies on food safety issues, over the past year, as well as making two sub-$10,000 payments to Prism Public Affairs to lobby specific Congressmen, including Reps Dingell and Stupak on MAP–CO issues.

And media coverage of the issue has tended to play up fears about the process. "Unsafe food and related public health consequences makes a much better story than does safe food," says Brewer. Don Berdahl, Kalsec's Vice President was extensively cited in a *Washington Post* story on the controversy, which also featured advocacy groups voicing their concerns about safety. No independent food safety experts were quoted in the story; instead, the *Post* turned to FDA and industry sources.

A similar story by *USA Today* featured Berdahl and Kalsec® prominently, but also failed to quote any independent food safety experts.

The result is a sense of alarm among academics that an enormously useful technology—one that might save an enormous amount of meat from being wasted—could be doomed.

On September 17, the American Meat Science Association wrote to the House Agriculture Committee to warn about the misinformation that has characterized recent discussion of MAP–CO and to announce the commission of a white paper by top scientists in meat color chemistry and safety.

"Like any other approved technology," the letter concludes, "the use of CO in modified atmosphere packaging applications deserves a chance to succeed or fail on its scientific merits, and not on misinformation."

This chart depicts typical shelf life for ground beef using common production practices, packaging techniques and normal temperature controls. Ground beef is being used as an example, but similar conditions would apply to steaks, chops and roasts from other meat types. Shelf life can vary widely for meat products depending upon temperature control, packaging and distribution systems. As a result, the actual age of a "fresh" product can also vary greatly. Shelf life is determined through careful scientific research into products' sensory cues over time (odor, visual appearance of the package, color, taste and texture), and through laboratory analysis under controlled conditions to determine how long a product remains safe, wholesome and enjoyable. This information is used by industry to establish "use-by" dates on the package. Shelf life of meat products today is much longer than in the past thanks to modern technologies, refrigerated distribution and sanitary practices. The following is a brief description of each of the major ground beef categories shown on the chart.

Carcass Trim Ground in Store:

Historically, carcass sides or quarters were shipped directly to retail stores where butchers would make steaks and roasts and use the remaining trimmings to produce ground beef. Ground beef was packaged in a foam tray with over-wrap film – what many people call "plastic wrap." Beef in its natural state is dark bluish-purple. However, oxygen can permeate over wrap film and cause a chemical reaction with the myoglobin in meat, leading to a red color. Ongoing exposure to oxygen causes "oxidation" – the same process that turns a cut apple brown – and causes red meat to become brown and develop "off" flavors. This leads to a short shelf life of about three days. This system is rarely used today in modern meat retailing.

Vacuum Packaged Primal / Trim Ground in Store:

During the past fifty years, with the advent of meat sold in boxes of vacuum packages where oxygen is removed, the industry essentially discontinued shipping carcasses to retail stores. Vacuum, low-oxygen packages stored in optimal refrigeration conditions can have dramatically longer shelf lives of up to 70-80 days, and the typical industry average age of vacuum packaged primals at time of use is about 35 days. A survey in 2006 showed the range to be from 3 days to 83 days. Once the vacuum package is opened and large cuts are sliced into smaller ones, trimmings often remain. These are then ground at the retail store, packaged in a foam tray with an oxygen permeable film and given three days shelf life. At the end of this shelf life, the product may be, on average, a total of 38 days old. For decades, vacuum packaged, refrigerated, fresh product has been sent on trans-oceanic shipments. When the product reaches the foreign destination and enters retail, it is typically more than 45 days old, yet still fresh, wholesome and delicious thanks to the oxygen-free packaging environment.

Bulk Chub / Re-ground in the Store:

The largest volume of ground beef at retail is distributed in coarse or fine ground form and packaged in 10 pound "chubs." Upon arrival at the store, workers open the chub, re-grind and re-package the ground beef in a foam tray with oxygen permeable film. Once re-ground and tray packaged, the ground beef has three additional days shelf life. This system allows a maximum shelf life of about 23 days total including three days in the display case. This method has been the mainstay for retail ground beef for several decades.

Case-Ready Retail Chub:

Case ready packaging formats represent a fast growing trend in retail ground beef distribution. With case-ready, all grinding and packaging occurs at a plant under U.S. Department of Agriculture inspection. Finished, retail product is packaged in clip-sealed chubs that resemble packaging used for cookie dough. In this "case-ready" packaging format, the film is impermeable to oxygen, opaque and printed with consumer information, including a use-by date. The consumer cannot view the product until opened in the home; therefore, color is not a factor in the purchase decision. Ground beef in this format has a shelf life of about 23 days from packaging. This format has been widely used by retailers for over 25 years and in certain retail markets, it represents one of the fastest growing formats for ground beef.

Case-Ready
Modified Atmosphere Packaging / High Oxygen

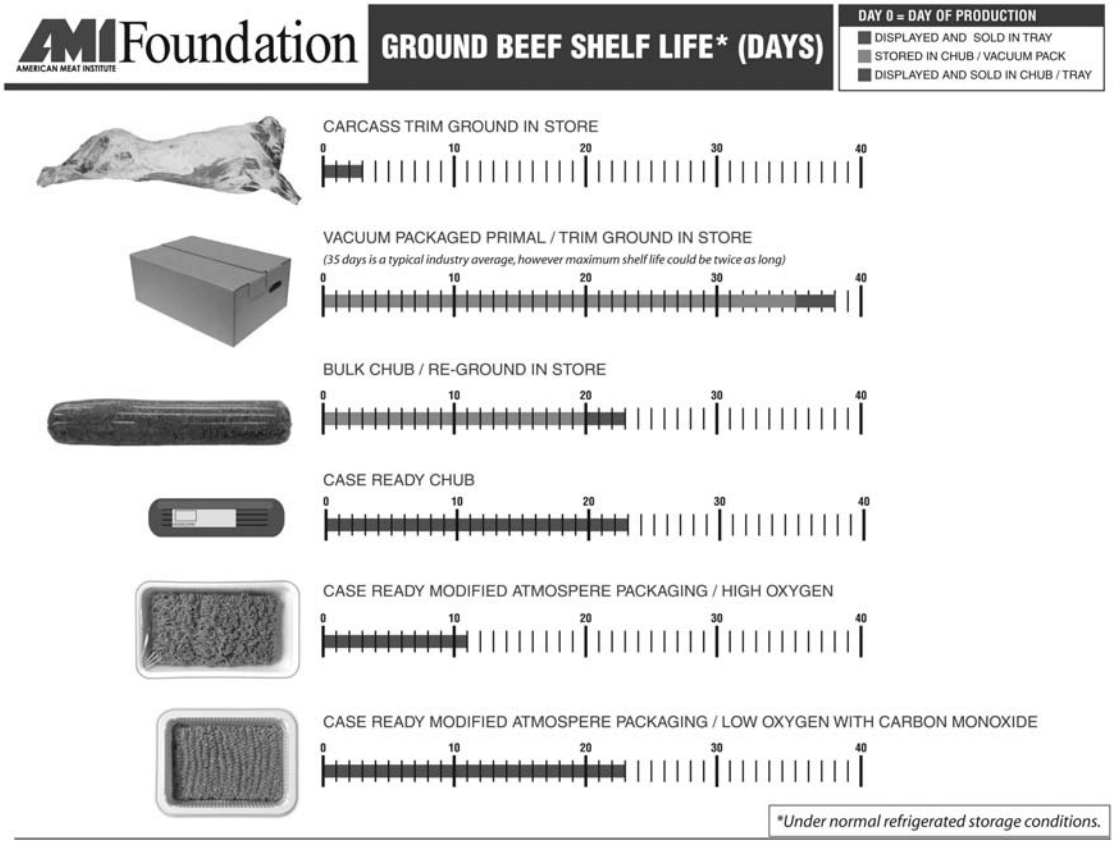
Modified Atmosphere Packaging (MAP) allows for a more attractive presentation to the consumer by allowing a view of the product through a clear film. As with other case-ready formats, the product is ground and processed at the plant under USDA inspection. The package is a rigid gas-impermeable tray with a hermetically sealed lid of clear film. During packaging, the gases normally found in air -- nitrogen, oxygen and carbon dioxide -- are removed and replaced with other gases. One common mixture is 80% oxygen and 20% carbon dioxide. This MAP gas mix results in a bright red color, but due to the negative oxidative effects of oxygen the product only has a shelf life of about 11 days. Frequently, antioxidants, such as chemical extracts of rosemary, must be added to the product to extend shelf life and protect color and flavor against the negative impact of oxygen.

Case-Ready
Modified Atmosphere Packaging / Low Oxygen with Carbon Monoxide

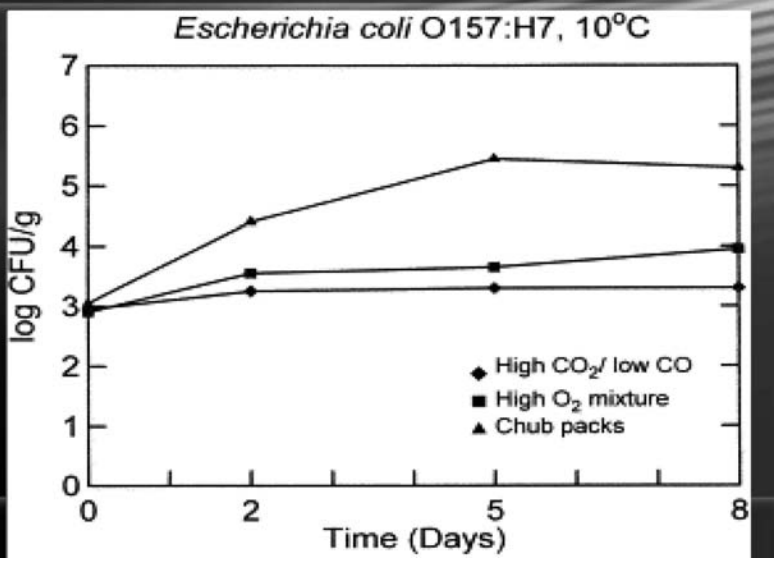
Another MAP case–ready system that has been widely used since 2003 uses a gas mixture containing 70% nitrogen, 29.6% carbon dioxide and 0.4% carbon monoxide. This gas blend differs from the high oxygen blend primarily due to its lack of oxygen. The substitution with minute amounts of carbon monoxide allows the meat to maintain the same natural red color that is present at the time of processing and exposure to oxygen, but without the harmful, oxidative effects that oxygen causes. As a result, the shelf life is equal to other similar low-oxygen formats with about 23 days shelf life from packaging. In this low-oxygen format, antioxidants are unnecessary and only add cost to the system. Bottom line: the consumer buys fresh meat, with an appealing color that has the extended shelf-life normally associated only with vacuum packaged products.

Summary

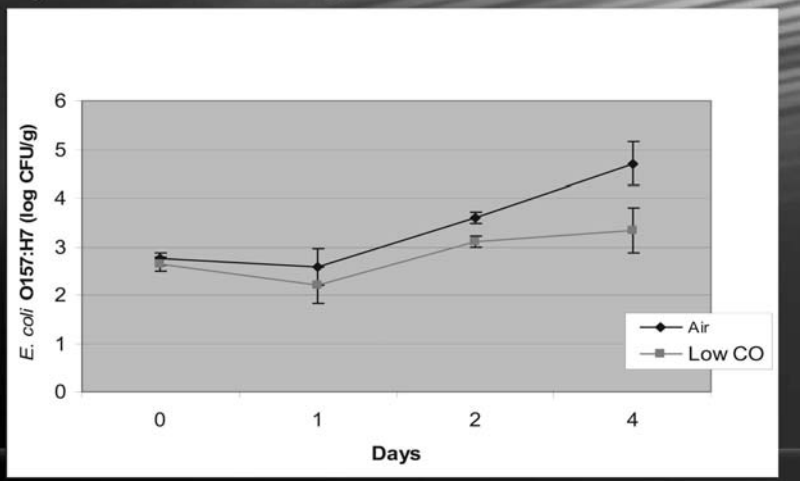
Case-ready processing and packaging of fresh meat provides a multitude of consumer benefits including enhanced quality and safety. The shelf life of low-oxygen packaged products is very similar, and through case-ready packaging, the ability to control the age of meat at the time of processing is greatly improved over traditional methods of retail store cutting. Certain case-ready packaging, such as high oxygen MAP, dramatically reduces potential shelf life of meat and likely will result in increased consumer complaints.


AMI Foundation
AMERICAN MEAT INSTITUTE
GROUND BEEF SHELF LIFE* (DAYS)
DAY 0 = DAY OF PRODUCTION
DISPLAYED AND SOLD IN TRAY
STORED IN CHUB / VACUUM PACK
DISPLAYED AND SOLD IN CHUB / TRAY
CARCASS TRIM GROUND IN STORE
VACUUM PACKAGED PRIMAL / TRIM GROUND IN STORE
(35 days is a typical industry average, however maximum shelf life could be twice as long)
BULK CHUB / RE-GROUND IN STORE
CASE READY CHUB
CASE READY MODIFIED ATMOSPERE PACKAGING / HIGH OXYGEN
CASE READY MODIFIED ATMOSPERE PACKAGING / LOW OXYGEN WITH CARBON MONOXIDE
0
10
20
30
40
*Under normal refrigerated storage conditions.

Growth of E. coli 0157:H7 inoculated in ground beef is inhibited by low CO-MAP (Nissen et al. 2000. Inter. J. Food Microbiol 59:211-20).



Growth of *E. coli* O157:H7 at 10°C in Ground Beef in Overwrap or CO Packages (M. Doyle & Li Ma, Univ Georgia Center for Food Safety).



Conclusions - (Doyle & Ma, Univ of Georgia Center for Food Safety)

- $CO:CO_2:N_2$ gas mixture retarded the growth of *E. coli* O157:H7 in ground beef under temperature abusive storage conditions
- MAP with $CO:CO_2:N_2$ extended the shelf life (based on appearance:color, odor and texture) of ground beef, even under abusive temperature conditions

AMERICAN MEAT INSTITUTE

Carbon Monoxide in Meat Packaging: Myths and Facts

Background: A petition submitted to the Food and Drug Administration (FDA) by Kalsec, Inc., maker of food additives that stabilize color, retard the effects of oxidation, and flavor of meat, makes numerous erroneous allegations about carbon monoxide used in some modified atmosphere packaged (MAP) meat products that are processed and packaged centrally at meat plants. Case-ready MAP packaging using carbon monoxide as one of the protective gases has been permitted for use by the FDA and the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture since February, 2002. In the almost four years leading up to Kalsec's petition submission, the marketplace has increasingly adopted the use of low-oxygen carbon monoxide packaging systems in place of MAP systems using high-oxygen in combination with herbal extracts, such as those supplied by Kalsec. This shift appears to have triggered an aggressive effort to challenge the use of the low-oxygen carbon monoxide MAP systems, and attempt to block their use through erroneous regulatory arguments.

Arguments detailed in the FDA petition include both errors and omissions. This Myths and Facts backgrounder helps detail both the facts and the missing information. When all relevant information is considered, it is clear that FDA acted appropriately when it did not object to the classification of carbon monoxide in meat packaging as "Generally Recognized as Safe."

Myth: Packaging systems that use specific gases are new and untested systems.

Fact: Packaging systems containing a variety of different gases have been used on food products for many years. These packaging systems are referred to as modified atmosphere packaging or MAP, and the range of products packaged in MAP include produce like bagged salads, pre-cut vegetables, and fruits, snack foods such as potato chips and pastries, seafood and a variety of beverage products. These and other products are packaged with food grade gases to maintain an attractive appearance that appeals to consumers. Carbon monoxide systems for meat have been available for approximately four years.

Red meat products are somewhat like sliced apples. Their color can change rapidly – even though the product is still safe and wholesome. In fact, retail stores often discount red meat products that have changed color but are still safe and wholesome – and well within their shelf life. These detrimental effects to foods, including apples and meat, are the result of chemical changes caused by oxygen. But by eliminating the oxygen from the package and adding minute amounts of carbon monoxide along with other protective gases to the headspace of the red meat packages, products like ground beef can maintain their appealing red color throughout their shelf life.

Myth: Carbon monoxide is a color additive requiring FDA to regulate it as such.

Fact: Carbon monoxide is a color stabilizer that maintains the typical red color of fresh meat when the gas mixture is applied to the package. FDA has evaluated the issue of carbon monoxide use in meat products on at least three separate occasions and in each case has necessarily concluded that carbon monoxide is not a color additive.

Myth: FDA erred when it permitted carbon monoxide to be classified as "Generally Recognized as Safe" because FDA determined that nitrite imparts color to meat and therefore is an unapproved color additive. This precedent applies to carbon monoxide.

Fact: FDA does not consider nitrite to "impart color" to meat, as implied by the petition, so the nitrite precedent provides no support for the petitioner's claim that carbon monoxide should be a color additive. In 1979, FDA made a preliminary decision regarding the status of nitrite as a color additive; however, the petition conveniently omits a 1980 FDA determination that reversed the 1979 proposal. In the 1980 determination, FDA said it "agrees that its tentative conclusion was incorrect and now concludes that nitrites do not impart color to bacon…". In other words, FDA returned to its long standing position that substances that maintain color and do not impart color are not color additives. In a follow-up letter dated February 1, 2006, the petitioner continued to focus improperly on the interaction between meat tissue and carbon monoxide, claiming that this interaction could "generate" color, especially when CO is used at high levels. A substance is "color additive" only if it changes color in a noticeable way under its intended conditions of use.

The bottom line: Carbon monoxide as used in the meat industry does not impart color and is not a "color additive"; it is used at low levels that maintain or stabilize the natural red color of oxygenated meat.

Myth: FDA permitted GRAS status for carbon monoxide despite objections by USDA.

Fact: In a letter dated June 2, 2004, USDA's Food Safety and Inspection Service said that in the agency's opinion, modified atmosphere packaging using carbon monoxide (as described in GRAS Notice 143) "for use with case-ready fresh cuts of meat and ground meat will not mislead consumers into believing that they are purchasing a product that is fresher or of greater value than it actually is or increase the potential for masking spoilage."

It is true that FSIS on April 28, 2004 identified questions and concerns in a preliminary response sent to FDA. However, FSIS' June 2, 2004, letter said that those questions and concerns had been resolved based upon additional data and information provided to them. This "back and forth" dialogue between the regulatory agency and the applicant is typical of the review process and speaks to its thorough and robust nature.

Myth: Combustion product gas regulations prohibit carbon monoxide in meat packaging.

Fact: Combustion product gas is made by the controlled combustion in air of butane, propane or natural gas. This mix of gases – which includes carbon monoxide – is not approved for use on fresh meat. However, the purified carbon monoxide gas used in packaging is not covered, much less prohibited, under this rule. The carbon monoxide covered by FDA and FSIS-reviewed GRAS notices is not a product of combustion.

Myth: Carbon monoxide in meat packaging is deceptive to consumers and may mask spoilage.

Fact: All low-oxygen, carbon monoxide packages include a clearly defined use-by date that indicates the date by which product should be consumed. Under the rare circumstance in which a package may be temperature abused and spoilage occurs prematurely before the use-by date, several signs would alert consumers. When spoilage bacteria multiply, packages begin to bulge. When opened, a strong spoilage odor will be readily apparent. Meat also may have a slippery or slimy texture. These are all typical signs of spoilage that consumers should equate with meat that should not be consumed.

The FDA and USDA both reviewed data related to this issue in the GRAS applications. The data submitted show that when products were temperature abused in a sufficient manner to cause spoilage, these products evidenced the tell-tale signs of spoilage: odor, gas formation (bulging package) and slime formation.

Myth: Carbon monoxide in meat packaging extends the normal shelf life of red meat.

Fact: Carbon monoxide does not extend the shelf life of red meat; carbon monoxide simply helps to retain the natural appearance of meat products throughout the established shelf life The most important factor influencing shelf life is bacterial growth and ultimately risk of spoilage. The use of carbon monoxide in MAP meat products has no impact on bacterial growth and therefore cannot extend shelf life. It is important to note that the shelf life of products covered by the FDA and FSIS-reviewed GRAS notices for carbon monoxide are no longer than those used for other low oxygen systems judged to be safe.

Myth: Carbon monoxide in meat packaging increases the risk that consumers will be exposed to *Clostridium botulinum* and other pathogens like *Listeria monocytogenes.*

Fact: *Clostridium botulinum* is a very rare bacteria and has never been associated with the consumption of a fresh, unprocessed meat product regardless of package type. The Centers for Disease Control tracks botulism cases very closely and indicates that approximately 110 cases occur each year. Only one quarter of those cases are linked to food products. Those small number of cases have been associated with home-canned foods – not fresh meat.

If low-oxygen, vacuum packaging (which has been in use for at least 40 years in meat processing) did increase the risk of botulism, one would have expected a steady increase in cases as use of the packaging technology has increased. That is clearly not the case and the misinformation provided in the petition related to this issue calls into question the scientific credibility of the claims made in the petition.

The use of low-oxygen carbon monoxide MAP has no effect on the presence or growth of *Listeria monocytogenes* in fresh meat products. *L. monocytogenes* is pathogen that is considered a risk in ready to eat foods, including sliced lunchmeats and deli salads, and not fresh meat. This pathogen has been the subject of intense scrutiny by both USDA as well as other global regulatory bodies, and several comprehensive risk assessments have been conducted on the risk of *L. monocytogenes* from food. In no case has fresh meat been considered a significant source of foodborne Listeriosis risk. *L. monocytogenes* is easily destroyed by the normal heat associated with cooking. It is unscientific and illogical to suggest that carbon monoxide would change or increase the risk of *Listeria* in fresh meat products, again calling into question the credibility of claims made in the petition.

Myth: Carbon monoxide packaging systems offers no benefit to consumers.

Fact: Carbon monoxide package systems offer significant benefits to consumers. First, these systems are exclusively used in centralized processing facilities under close scrutiny of federal inspectors. Tamper evident packaging is used in MAP meat products, which provides an added layer of benefit to the consumer. Also, because these products maintain their appeal throughout the shelf life, they do not lose their marketability. When products become unmarketable due to purely cosmetic issues during their shelf life, this can add costs to the system, which in turn can raise meat prices.

The fact that each year, consumers spend a fraction of their disposable income on meat – and less than any other nation in the world – can be attributed to efficient, effective systems like carbon monoxide packaging systems.

Myth: Consumers need to be extra vigilant when they handle meat packaged using carbon monoxide systems.

Fact: Consumers need to use the same handling practices for all fresh meat products regardless of their packaging system. These practices are detailed in the federal safe handling label that appears on every package.

Consumers also need to follow the use-by date on packages. Data collected by the Food Marketing Institute show that consumers pay close attention to use-by dates on meat, poultry and dairy products.

Note: Information for this document was taken from the January 23, 2006, submission by Hogan & Hartson to the Food & Drug Administration. This detailed, technical response is available from the Food and Drug Administration Docket Office.

MICHIGAN STATE
UNIVERSITY

May 4, 2006

The Honorable John D. Dingell
U.S. House of Representatives
2328 Rayburn House Office Building
Washington, DC 20515-2215

Dear Representative Dingell:

The purpose of this letter is to comment on issues have been raised regarding the use of low-oxygen carbon monoxide for case-ready fresh meat packaging. Letters by Dingell and others of February 9, 2006 and March 30, 2006 imply that the public health and the safety of the food supply has been compromised by the FDA decision to permit the use of this technology in fresh uncooked meat. I have reviewed the scientific peer-reviewed literature regarding this technology, which was authored by a number of food scientists, including many respected colleagues. Meat that utilizes this technology is at least at the same level of safety as fresh meat that has undergone conventional retail wrap. The safety of the food supply has not been compromised for the following reasons:

1. The growth of microorganisms, including well known pathogens, does not change at storage temperatures recommended for meat when using this technology.
2. Carbon monoxide does not add a new color to meat. It reacts with the naturally occurring pigment in meat (myoglobin) to produce a form of the pigment that is more stable and is not readily distinguishable from the normal (oxygenated) form of the pigment.

I regularly teach Hazard Analysis and Critical Control Point (HACCP) techniques for food processing to both Michigan State University students and Michigan adults in the food industry. A section in these techniques involves assigning risk of a food safety hazard that is likely to occur in a process. **The risk of a significant food safety hazard occurring in meat packaged using this low-oxygen carbon monoxide modified atmosphere packaging (MAP) technology does not change when this technology is compared to conventional retail meat wrap technologies.** For this reason I would not hesitate to utilize the technology in the Meat Laboratory Pilot Plant, a facility I help manage at Michigan State University.

It is critical in the above food safety risk assessment that the raw meat be cooked to a proper endpoint temperature by the consumer. Unfortunately many consumers ignore scientific recommendations and cook to an endpoint judged visually. It is reasonable that consumers who buy with their eyes cook with their eyes. It is also reasonable that undercooking meat before consumption by the consumer because of premature pigment browning will not be an issue when this technology is utilized.

The use of MAP technology, albeit in different forms, occurs in many foods. Often it involves packaging in a centralized location and thus use-by dating is a standard practice in these products. The 2005 Food Marketing Institute consumer trends research study indicates that over 99% of consumers are aware of use-by dates on food products in the grocery store and over 80% of consumers report that they pay attention to them when purchasing uncooked meat and poultry items. It is my opinion, based upon questions I receive from consumers regarding the safety of packaged food, that label dating is observed and used as a tool by the consumer to determine acceptability and safety of many foods.

Thank you for allowing me the opportunity to comment on this issue.

Sincerely,

Alden M. Booren
Professor
Departments of Food Science & Human
Nutrition; Animal Science
3385 Anthony Hall

CC: Michigan Meat Association
G.M. Strasburg, Chair, Department of Food Science and Human Nutrition
K. Plaut, Chair, Department of Animal Science

[PERSPECTIVE]

by Joseph G. Sebranek, Melvin C. Hunt, Daren P. Cornforth, and M. Susan Brewer

Carbon Monoxide Packaging of Fresh Meat

Recent media reports have raised concerns regarding the safety of fresh meat packaged with carbon monoxide. These reports have resulted from persistent efforts by private interests to garner public and legislative support for a ban on CO for fresh-meat packaging.

These efforts have included a petition to the Food and Drug Administration requesting that CO no longer be permitted for meat packaging. The petition does not question the safety of the low (0.4%) levels of CO permitted but instead claims that the practice is deceptive and will result in unsafe products.

CO is useful for fresh-meat packaging because the gas binds with the muscle pigment myoglobin to produce a bright red color. Myoglobin can bind several different substances, including gases, to create a variety of colors. Oxygen in the air, for example, is present in sufficient amount (20%) to produce a bright-red meat color and is often used in meat packaging at elevated levels (80%) to enhance the natural color. When CO binds to myoglobin, it produces a color visually identical to that produced by oxygen but stable longer.

It is widely recognized in the meat industry that consumers select and purchase meat on the basis of color and appearance. Unfortunately, typical oxygen-based fresh-meat color is easily lost during retail display. The longer-lasting color resulting from CO has been the basis for criticism of CO packaging, with claims that consumers might inadvertently consume spoiled or unsafe meat because color might remain unchanged.

While it has been documented that CO-based meat color can remain red even at high levels of bacterial growth, it is highly unlikely that meat which is truly spoiled would be consumed, even if the color was still red, because of the other warning signs such as odors that accompany excessive bacterial growth. FDA has examined this issue thoroughly and requires that meat in low-CO packaging be labeled with a "use or freeze by" date of 28 days after packaging of ground meats and 35 days after packaging of intact steaks or roasts.

One of the criticisms directed at FDA is that CO should have been classified as a color additive and consequently much more rigorously reviewed. However, on at least three occasions, FDA has ruled that CO is a colorless, odorless, "invisible" gas and therefore cannot directly transfer color to meat. Because the FDA definition of a color additive is essentially "a substance that is capable of imparting color," the issue becomes one of interpretation. It seems relevant to consider that the CO reaction with meat is the same as that of oxygen (another "invisible" gas), both of which result in a virtually identical red meat pigment. The oxygen-based meat pigment is unequivocally accepted as a "normal and expected" color for fresh meat. Because there has been no claim that oxygen is a color additive, it seems inconsistent to claim that CO should be a color additive.

The claim that CO packaging will result in unsafe products is not scientifically sound. There is no greater risk of pathogenic bacteria associated with CO packaging than with any other packaging system currently used for fresh meat. In fact, a valid argument can be made that CO packaging creates opportunities to increase safety. It is important to realize that the presence or absence of bacteria of public health significance on meat is independent of meat color.

***The claim that CO packaging will result in unsafe products** is not scientifically sound.*

CO packaging of meat offers opportunities to utilize complementary processing technologies that inhibit or even kill bacteria. The result is a significant improvement in shelf life in terms of both bacteria and color. Some examples include packaging with elevated carbon dioxide concentrations, scrupulous sanitation and antimicrobial treatments during packaging, and post-packaging irradiation. Ground beef with an advertised 38-day shelf life is commercially available because of such combined technologies (see www.cornerstorefoods.com).

Inevitably, introduction of new technology has the potential to alter the marketplace. In this case, CO packaging competes with the high-oxygen packaging methods for fresh meat. The latter improve meat color but typically utilize antioxidants to counter the oxidative effect of the high-oxygen atmosphere. The use of CO packaging has potential to reduce the market for antioxidants and has resulted in an antioxidant supplier's petitioning FDA to rescind approval of CO packaging for fresh meat.

Certainly, it is essential that consumers be informed regarding food safety and be protected from unsafe practices. Consumers should be allowed to make informed decisions in the marketplace. Because scientific studies have validated the safety of low-CO packaging technology for fresh meat, it seems appropriate to let the marketplace decide the success or failure of the process. **FT**

Joseph G. Sebranek *(sebranek@iastate.edu), a Fellow of IFT, is University Professor, Depts. of Animal Science and Food Science & Human Nutrition, Iowa State University, Ames.* ***Melvin C. Hunt*** *(hhunt@ksu.edu) is Professor, Dept. of Animal Sciences & Industry, Kansas State University, Manhattan.* ***Daren P. Cornforth*** *(dcornfo@cc.usu.edu) is Professor, Dept. of Nutrition & Food Sciences, Utah State University, Logan.* ***M. Susan Brewer*** *(msbrewer@uiuc.edu) is Professor, Dept. of Food Science & Human Nutrition, University of Illinois, Urbana. All are Professional Members of IFT.*

November 15, 2007

The Honorable Steve Kagen
U.S. House of Representatives
1232 Longworth House Office Building
Washington, DC 20515

Re: Tyson Foods, Inc.

Dear Congressman Kagen:

I am writing in response to your request for additional information regarding meat packaging technologies relating to the Full Committee on Agriculture- Public Hearing to review the technologies in the meat industry, Tuesday, October 30, 2007.

Attached are documents related to Tyson's GRAS notification (GRN 000167) and pending GRAS submission for (GRN 000188) for the use of carbon monoxide (CO) in fresh meat packages.

The scope of Tyson's GRAS notification (GRN 000167) for the use of carbon monoxide (CO) in fresh meat packages only slightly modified previous GRAS submittals to FDA, namely GRN 000083 submitted by Pactiv Corporation and GRN 000143 submitted by Precept Foods, LLC. These prior submissions informed FDA of the scientific procedures used to show that CO met GRAS standards for use as a component of a modified atmosphere packaging system (MAP) for case-ready fresh beef and pork. GRN 167 simply offered a quantifiable method of calculating the amount of CO that can be added to a package. Rather than duplicate the documentation already submitted to FDA under GRN 83 and GRN 143, Tyson, under the direction of FDA, incorporated the studies submitted in these previous GRAS notices, by reference, into GRN 167.

It may be helpful to note that Tyson's GRN 167 is consistent with the Congressional intent behind the development of food additive regulations and GRAS standards.[1] The Food Additives Amendment of 1958[2] to the Federal Food, Drug, and Cosmetic Act of 1938 established a pre-market approval system for food ingredients for the first time. The Amendment had a two-prong congressional purpose: "(1) to protect the health of consumers . . . .; and (2) to advance food technology by permitting the use of food additives at safe levels."[3] The goal of advancing the benefits of food technology, rather than merely focusing on the potential for harm, was recognized by the Seventh Circuit Court in *Continental Chemiste v. Ruckelshaus*, 461 F.2d 331, 340 (7th Cir. 1972):

> [I]n evaluating the safety of new additives, the agency was to avoid the *per se* approach required by the existing statutory references to poisonous and deleterious substances. The test of safety was intended to take into account the broader concepts of safety under the intended conditions of use; the benefits of the additive were to be evaluated rather than merely its potential for harm.

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[1] The statutory definition of "food additive" only covers, and thus the requirements for food additives only apply to, a substance that "is not generally recognized . . . to be safe under the conditions of its intended use." 21 U.S.C. § 321(s).

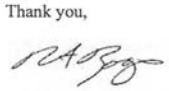
[2] Pub. L. No. 85-929, 72 Stat. 1784 (1958) (codified as amended in scattered sections of 21 U.S.C.). Now, a food additive cannot be used unless and until the FDA deems it safe for the use proposed by the sponsor.

[3] H.R. No. 85-2284, at 1 (1985).

The GRAS exception, as it has evolved over time, is essentially an approval process that seeks to minimize the burden that otherwise would have fallen on both the food industry and the government if the FDA had to evaluate and affirmatively approve all common substances used in food.[4]

Included in the attachment is a copy of Tyson's GRAS notification (GRN 000188). GRN 188 was submitted to FDA on December 22, 2005 and is still awaiting approval. GRN 188 also shares the same application and technical purpose in CO-MAP packaging for "case-ready" red meat products as does GRN 83, GRN 143, and GRN 167. GRN 188, unlike GRN 167, seeks to increase the amount of CO that could safely be used in packaging meat. GRN 143 had previously designated 2.2 mg of CO per pound of meat permissible. Tyson convened an independent, expert panel to conduct a thorough review of acceptable and safe consumable levels of CO. The panel determined that it was safe to increase the amount of CO up to 5.5 mg per pound of meat (or up to 1.2% CO). This increase presented no significant risk of pathogenic growth or spoilage masking to the consumer under conditions of intended use when the product is properly labeled with the "use-or-freeze-by" date. All studies, reports, and scientific data submitted to FDA relating to GRN 167 GRN 188 are enclosed.

Thank you,



Dr. Richard Roop
Sr. V.P. Science & Regulatory Affairs
Tyson Foods, Inc.

Attachments

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[4] See, e.g., H.R. Rep. No. 85-2284, at 40 (statement of A.L. Miller) ("[L]egislation requiring exhaustive laboratory analysis, pretesting and reporting of the old, recognized, safe additives would serve no useful purpose and would be unduly burdensome upon both industry and Government.").

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*PRACTICE WITHIN THE DISTRICT OF COLUMBIA IS LIMITED TO MATTERS AND PROCEEDINGS BEFORE FEDERAL COURTS AND AGENCIES.

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December 22, 2005

BY FEDERAL EXPRESS

Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food And Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Dear Sirs:

On behalf of our client, Tyson Foods, Inc., we are hereby submitting four copies of the enclosed Generally Recognized As Safe (GRAS) Notification for the use of carbon monoxide (CO) in modified atmosphere packaging (MAP) for red meat products. As discussed in this Notice, the application discussed herein is a modification of the application previously reviewed by FDA under GRASN 167. More specifically, Tyson Foods is hereby notifying the agency of its determination that the use of CO in Modified Atmosphere Packaging (MAP) for "case-ready" red meat products where the concentration of CO in the MAP gases does not exceed 5.5 mg per pound of packaged meats is GRAS.

Should you have any questions regarding this notice, please do not hesitate to contact us.

Sincerely,

Mark L. Itzkoff

Mark L. Itzkoff

MLI:jdm
Enclosures

TY-CEC-000001

GRAS Claim for the Use of Carbon Monoxide In Modified Atmosphere Packaging For Red Meat Products

Submitted by Tyson Foods, Inc.

December 22, 2005

GRAS Notification for the Use of
1.0% CO in MAP Packaging
Tyson Food
December 22, 2005

Section I

GRAS Claim

Tyson Foods, Inc. hereby submits this GRAS claim for the use of carbon monoxide (CO) in modified atmosphere packaging (MAP) for red meat products.

A. Name and Address of Notifier:

Tyson Foods, Inc.
2210 Oaklawn Drive
Springdale, Arkansas 72765

B. Common or Usual Name of Substance:

The common or usual name of the substance is carbon monoxide. The Chemical Abstract Services Registration Number (CASRN) for this substance is 630-08-0.

C. Conditions of Use:

In this Notification, CO will be used in Modified Atmosphere Packaging (MAP) for "case-ready" red meat products where the concentration of CO in the MAP gases does not exceed 5.5 mg per pound of packaged meats.[1] This application is the same end use and technical purpose, MAP packaged red meat products, described in GRAS Notices GRASN 167, 83 and 143. This Notice differs only in the consumable amount of CO.

The meat packaged using the MAP described herein will be labeled with a "use-or-freeze-by" date. The package dating is designed to minimize the impact of spoilage organisms, and is the same system used for meats packaged using the MAP system detailed in GRASN 167.

D. Basis for GRAS Determination:

Tyson Food has commissioned a panel of experts (the GRAS Panel) to review the safety of the proposed use of CO. The GRAS panel reviewed publicly available data on the toxicology of carbon monoxide, including the currently effective GRAS Notices (GRASN 43, 83 and 167) and concluded that:

> addition of carbon monoxide at levels intended not to exceed 5.5 mg per pound ... to MAP packaging systems ... is safe for addition to fresh muscle cuts of beef and pork and fresh ground beef. Further, based on

[1] As shown In GRASN 167, 0.4% by weight is equivalent to 2.2 mg/pound of packaged meat. Therefore, 1.0% by weight will be equivalent to 5.5 mg/pound or 12 mg/kg.

current good manufacturing practices, the addition of carbon monoxide to MAP as presented in this notification, presents no significant risk of pathogenic growth or spoilage masking to the consumer when properly labeled with open code or "use or freeze by" dating with expiration dates as specified for the meat types.

The full report of the GRAS Panel is attached in Appendix I.

E. **Data Availability Statement:**

The data and information that are the basis for the Notifier's GRAS is attached in Appendix I.

Respectfully submitted,

Mark L. Itzkoff
Counsel for Tyson Foods, Inc.

Section II

Identity of the Notified Substance

The substance that is the subject of this Notice is Carbon Monoxide (CO), a colorless, odorless gas, with the CASRN 630-08-0. A Material Safety Data Sheet for this material is attached in Appendix II.

The specific CO used in this process will be commercial, "food grade" CO. The purity specifications will be the same as those set forth for CO in GRASN 167, *i.e.*, the minimum purity will be 98 percent carbon monoxide while the other 2 percent will be residual atmospheric gases (nitrogen, oxygen, carbon dioxide, argon, water, hydrogen, methane, etc). Thus, the use of carbon monoxide set forth herein will not result in the introduction into processed red meat of any materials not previously considered under GRASN's 83, 143 and 167.

Section III

INFORMATION ON SELF-LIMITING LEVELS OF USE

As discussed in the GRAS panel report, the function of carbon monoxide in the MAP is to help maintain the appearance of the packaged meat. More specifically, the CO reacts with myoglobin in the muscle, similar to oxygen to form carboxy-myoglobin. The CO-myoglobin complex fixes the red color in the packaged meats that is also imparted by oxymyoglobin. Since the CO must react with myoglobin to produce the desired effect, the effectiveness of additional CO in the MAP is limited by the concentration of myoglobin in the processed meats.

Data in the public literature shows that the use of CO in concentrations between 1.0 and 10% by weight in MAP packaging result in the optimum product appearance.[2] As noted in Table 1, attached, 1.0% by weight in MAP packaging is equivalent to 5.5 mg per pound of meat assuming a standard packaging configuration. In this Notice, we have opted to limit the concentration of CO to the lowest level that will produce the optimum appearance, 5.5 mg per pound of meat.

While this Notice will increase the level of CO in MAP packaging from 2.2 mg/ lb to 5.5 mg/ lb, it should be emphasized that this increase will not affect consumer safety. The GRAS Panel has fully evaluated the safety of the exposure to carbon monoxide and, as noted above, has concluded that such use is safe.

Further, this use will not pose any additional risk from pathogenic growth or spoilage organisms. All meat products packaged will be labeled with a "use-or-freeze-by" date. There is no incentive for meat packagers to add additional CO, since such addition would not extend the period of optimum color. Therefore, there is an economic incentive to limit the quantity of CO used in modified atmosphere.

The increase in CO concentration over GRASN 167 is intended to allow for reduced package size which requires a corresponding reduction in package headspace. Consumers desire this type of package and a .40% CO gas blend will not produce this type of package.

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[2] Clark et. al., *Use of Carbon Monoxide for Extending Shelf-life of Prepackaged Fresh Beef*, 9 J. Inst of Food Science Technology, 114-118 (1976)

Section IV

Basis for Notifier's Claim

The basis for the Notifier's claim is set forth in detail in the attached Expert Panel ("GRAS Panel") Statement, "Determination of the GRAS Status of Carbon Monoxide as a Component of a Modified Atmosphere Packaging System for Use with Fresh Beef and Pork." The Statement and supporting documents are attached in Appendix I.

In brief, the GRAS Panel estimated that the potential exposure to CO from the proposed use in the modified atmosphere packaging will be about 0.14 mg/meal with a "worse case" exposure of 3 mg CO per meal. The Panel compared this exposure to the available literature, including the Environmental Protection Agency's National Ambient Air Quality Standard (NAAQS) for carbon monoxide and concluded that the negligible increased contributions from the intake or inhalation of CO packaging containing MAP gases, the proposed increase in allowable CO concentrations to 5.5 mg per pound of meat or a maximum of 6.6 mg per pound allowing for process variants, from prior approved levels of 2.2 mg per pound poses no health concerns.

As noted in the Expert Panel Statement, the Panel addressed only the potential toxicological affect of CO exposure. The Expert Panel did not address the potential for masking the presence of spoilage organisms on the packaged beef. As discussed above, all products packaged using this system will be labeled with a "use-or-freeze-by" date. The same dating system is used by Tyson in accordance with meat packaged under GRAS No. 167. The only difference between the earlier GRAS Notice and the current Notice is the higher CO concentration.

Under this notification, the quantity of CO present in the food package will be no more than 5.5 mg per pound of meat. In GRN 143, Precept Foods estimated that 30% of the CO present in the MAP package will be absorbed by the meat. Using this same estimate, we calculate that the amount of CO that may be present in package meat from the use of the MAP packaging will not exceed 1.65 milligrams per pound.[3] Published studies indicate that the concentration of CO in the meat is reduced by 85% during cooking.[4] Thus, the final concentration in the cooked meat product should be no more than 0.25 mg/lb.[5]

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[3] (5.5 mg/lb)(0.30) = 1.65 mg/lb.

[4] The studies are discussed in detail in the attached Expert Panel Statement.

[5] (1.65 mg/lb)(0.15) = 0.25 mg/lb

Finally, it is estimated that a typical serving of the package meat consists of an 8.8 ounce portion. Thus, the quantity of CO that may be consumed as a result of this notice will not exceed 0.14 milligrams per meal.[6]

As discussed in the GRAS Panel Statement, the literature shows that the use of 5.5 mg carbon monoxide per lb of meat in the MAP will not result in increased microbial growth. Thus the rate of microbial growth will not exceed the rate in systems where FDA and USDA have already determined that the "use-or-freeze-by" dating system provides proper protection from spoilage organisms. Therefore, the "use-or-freeze-by" dating system currently in place under GRAS No. 167 will also ensure the suitability of meat packaged with the prior CO concentration.

[6] ((8.8 ounces/meal)/(16 ounces/lb.))(0.25 mg/lb) = 0.14 mg/meal

EXPERT PANEL STATEMENT

DETERMINATION OF THE GRAS STATUS OF CARBON MONOXIDE AS A COMPONENT OF A MODIFIED ATMOSPHERE PACKAGING SYSTEM FOR USE WITH FRESH BEEF AND PORK

The undersigned, an independent panel of recognized experts, qualified by scientific training and relevant national and international experience to evaluate the safety of food and food ingredients, was requested by Tyson Foods, Inc. to determine the Generally Recognized As Safe (GRAS) status of carbon monoxide as a component of a modified atmosphere packaging system (MAP) for use with case-ready fresh beef (muscle cuts and ground beef) and fresh pork muscle cuts. Carbon monoxide (CO) will be added at varying concentrations of CO in the MAP gases so as not to exceed 12.0 mg/kg (5.5 mg/lb) in the packaged meats. Three prior GRAS notices to FDA on carbon monoxide as a component of modified atmosphere packaging systems (MAP) for use with case-ready fresh meats were also utilized for this review. The Expert Panel independently evaluated this information and other materials deemed necessary or appropriate. Following independent, critical evaluation, the Expert Panel conferred and unanimously agreed to the decision described herein.

INTRODUCTION

Case-ready packaging systems offer advantages of product quality, presentation and convenience to both retailers and consumers. Significantly, case-ready meat programs allow for less handling of products prior to retail purchase, enhancing not just convenience and efficiency, but product safety and quality as well. In addition, case-ready meat packaging minimizes the amount of effort and involvement expended at retail in the preparation of fresh meat products for display. Not all systems commonly described as "case-ready" employ packaging that is ready for immediate display upon delivery to the retailer. Many of the programs available require some intermediate preparation at the retail level, and thus are not fully case-ready." For instance, primary

packages of meat may be provided to retailers in either a master container or secondary packaging that is flushed with a mixture of gases, including 0_2, C0, $C0_2$ and N_2. Retailers are advised to remove these products from the MAP environment within a fixed or stated distribution shelf life, and then offer products for retail display for a defined period of time. A drawback is that products cannot be open code dated in such systems, as it is not known when in the distribution life the products will be placed in the retail case for display. Thus, the retailer remains responsible for applying the consumer code date on the product.

In the proposed MAP system, fresh meat, either beef or pork, will be placed on a tray within a chamber. Once the desired atmosphere is achieved, a barrier film will be affixed to the tray to ensure that the atmosphere is maintained throughout the product's distribution. The packages will be prepared and labeled with a validated open date code at a central location and will be subject to no further processing or manipulation at retail. Thus, the product will be ready for retail display and delivery to consumers upon packaging, and the product label will not be altered following application of the mark of inspection by the U.S. Department of Agriculture. Food Safety and Inspection Service (FSIS). The open date code or "use or freeze by" dates established for products packed in the MAP system will not exceed 35 days following the date of pack for intact muscle cuts, and 28 days for ground beef. The use of a centralized packing facility for the finished retail package will eliminate all retailer discretion in the process, adding the consumer benefit of an open dating system that is scientifically established, validated and controlled. In addition to minimizing any risk of cross -contamination that can occur in a retail establishment, the use of such a system substantially reduces any risk that the shelf life will be manipulated inappropriately at the retail level.

CO is included in the modified atmosphere to help maintain the characteristic color of fresh meat. Like 0_2, CO has long been known to have a color-stabilizing effect on fresh meat. The desirable red color of fresh beef, in particular, is attributed to oxymyoglobin, which is formed when myoglobin in meat muscle fibers is exposed to oxygen. When CO comes into direct contact with meat, myoglobin is converted to carboxymyoglobin,

resulting in a color that is substantially indistinguishable from that of oxymyoglobin. In the absence of a modified atmosphere, oxymyoglobin is eventually converted to metmyoglobin, which has an unappealing, brown color. This conversion can occur before microbial spoilage renders the product unfit for human consumption. Odor, gas formation and/or slime formation are also indicators of spoilage. Indeed, although the use of CO will stabilize the characteristic color of meat, CO is not intended to affect microbial growth. Microbial shelf life will continue to be determined, as it always has been, on such considerations as anticipated microbial growth, product composition, and distribution conditions, including storage temperatures. Significantly, the proposed system is not intended to extend the shelf life of products in excess of what has been implemented with CO in similar systems.

The proposed use, types of foods and MAP system described herein is the same as described in GRN No. 000167 to Tyson Foods effective September 29, 2005 other than increasing the delivery of carbon monoxide to achieve a meat concentration from 2.2 mg/lb to 5.5 mg/lb of meat. For the current GRAS notification, carbon monoxide is also intended for use as a component of a modified atmosphere packaging (MAP) system for case-ready fresh beef and pork. The carbon monoxide will be used at varying concentrations, depending on the headspace volume and amount of meat in the container to achieve a final meat CO concentration of 5.5 mg/lb or less (6.6 mg/lb maximum with a process tolerance of 20% in the modified environment). As noted in GRN 000167, a 620 cubic centimeter (cc) package containing 1 lb of ground beef would require a 0.89 percent concentration of CO to achieve the required concentration of 2.2 mg/lb CO; a 3000 cc package containing 5 lbs of meat would require 1.19 percent concentration of CO to achieve the required concentration of CO. To achieve 5.5 mg/lb of CO in meat for this notification, comparable CO levels in the MAP would be 2.23% and 2.98% CO for the first and second examples above, respectively. By delivering the CO concentration as a function of headspace volume and contained meat volume, it is possible to better define the meat concentrations of CO than just specifying the CO content of the MAP without consideration of the ratio of meat to headspace volume.

REGULATORY STATUS

There have been three prior GRAS notice submissions to the agency on the use of carbon monoxide in MAP systems that are summarized briefly below. In each case, FDA responded that they had no questions on the proposed use and did not object to the GRAS notice. Further, in each case, USDA has concluded that the use of carbon monoxide as described in these notices in the MAP systems and the notified conditions of use with fresh beef and pork muscle and ground beef were acceptable.

1. GRAS Notice No. GRN 000083: Response dated February 21, 2002 from FDA to a submission from Pactiv Corporation. (Pactiv)

The subject of the notice is carbon monoxide (CO). The notice informs FDA of the view of Pactiv Corporation (Pactiv) that CO is GRAS, through scientific procedures, for use as a component of a gas mixture in a modified atmosphere packaging (MAP) system. The level of CO in this MAP system is 0.4%. The other components of the MAP system are carbon dioxide (30%) and nitrogen (69.6%). The MAP system would be used for packaging fresh cuts of case ready muscle meat and ground case ready meat to maintain wholesomeness, provide flexibility in distribution, and reduce shrinkage of the meat. The case ready meats would be removed from the MAP system prior to retail display. In the ActivTech MAP system, CO is used at a target level of 0.4% in a mixture of N_2 (70%) and CO_2 (30%). The gases are flushed into a "pillow pack" that contains an inner tray upon which the meat is wrapped in a hermetically sealed permeable film. Prior to retail display, the inner tray is removed, exposing the package to normal atmospheric conditions and allowing the CO to escape.

The notice describes the estimated consumption of CO per meal as a consequence of its intended use as a component in a MAP system for storing meat. Assuming that 30% of the CO present in the MAP is absorbed into the meat, and that there is an 85% reduction of CO due to cooking the meat, Pactiv calculates a realistic intake estimate to be 0.084 milligrams (mg) CO per meal. Pactiv also calculates a worst case intake estimate to be 1.88 mg CO per meal, assuming that 100% of the CO present in the MAP is absorbed into the meat and that there is no reduction in CO during cooking. Pactiv cites published

articles to support the assumptions used in the realistic exposure estimate and to support the conclusion that exposure to CO is safe at this level.

Based on the information provided by Pactiv, FDA had no questions at that time regarding Pactiv's conclusion that CO is GRAS under the intended conditions of use. During its evaluation of GRN 000083, OFAS consulted with the Labeling and Consumer Protection Staff of the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture regarding the use of CO in meat products. Based on the information submitted by Pactiv, USDA FSIS has concluded that the MAP system ActiveTech™ 2001) as described in Pactiv's notice, and used under the conditions stated in Pactiv's notice, would be acceptable for packaging red meat cuts and ground meat. In FSIS's view, Pactiv has demonstrated that this MAP system complies with FDA's definition of a processing aid that appears in labeling regulations (21 CFR 101.100(a)(3)). There is no lasting functional effect in the food, and there is an insignificant amount of carbon monoxide present in the finished product under the proposed conditions of use. As such, for similar uses of other MAP gases (e.g., nitrogen), there are no labeling issues in regard to meat cuts and ground meat packaged using this MAP. Additionally, when considering the use of a food ingredient or additive in a meat product, FSIS historically has treated each livestock species separately. However, in this case, the data submitted by Pactiv can be extrapolated to all species of livestock.

2. GRAS Notice No. GRN 000143: Response on July 29, 2004 from FDA to a submission from Precept Foods, LLC (Precept)

The subject of the notice is carbon monoxide (CO). The notice informs FDA of the view of Precept that CO is GRAS, through scientific procedures, for use as a component of a modified atmosphere packaging (MAP) system for case-ready fresh beef and pork. The level of CO in this MAP system is 0.4%. The other components of the MAP system are carbon dioxide (20-100%) and nitrogen (0-80%). Precept states that the CO is included in the modified atmosphere to help maintain the characteristic color of fresh meat. Precept states that the CO is not intended to affect microbial growth and will not extend the shelf life of the product.

Precept estimates that the exposure to CO would be 0.054 mg CO per meal of cooked meat. Precept first assumes a scenario where the meat absorbs 30% of the CO in the package and 100% of the CO present in the meat is absorbed by the consumer. A dietary intake of 0.36 mg of CO per meal would occur when 8.8 ounces (250 g) of meat is consumed. Precept considers that this estimated intake of CO from its use in packaging meat is small compared to the amount that is presently accepted as a safe exposure limit by the Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA). Precept then accounts for the fact that meat packaged with CO will be cooked prior to consumption and assumes an 85% reduction in CO exposure due to cooking of the meat. This 85% reduction decreases the maximum exposure from 0.36 mg to 0.054 mg CO per meal.

Precept makes two additional exposure estimates. First, if 100% of the CO in the package is absorbed, and 100% of the CO is consumed, an 8.8 ounce serving would expose the consumer to 1.2 mg of CO. Second, Precept states that a consumer exposed to 100% of the CO in the package would only be exposed to 2.18 mg CO, which is well below the safety limit set by the EPA and OSHA.

In Precept's packaging system, meat is placed on a tray within a chamber, the chamber is then filled with the desired atmosphere, and finally, a barrier film is affixed to the package. The packages are then labeled with a validated open date code at a central location and will be subject to no further processing or manipulation at retail. The open date code established for products packed in the MAP system will not exceed 35 days following the date of packaging for intact muscle cuts and 28 days for ground beef.

Based on the information provided, FDA had no questions at that time regarding Precept's conclusion that CO is GRAS under the intended conditions of use. During its evaluation of GRN 000143, FDA's Office of Food Additive Safety (OFAS) consulted with the Labeling and Consumer Protection Staff of FSIS regarding the use of CO in meat products. Based on the information submitted by Precept, FSIS concluded that the MAP system as described in Precept's notice, and used under the conditions stated in Precept's notice, would be acceptable for packaging red meat cuts and ground meat.

3. GRAS Notice No. GRN 000167: Response on September 29, 2004 from FDA to a submission from Tyson Foods, Inc. (Tyson)

The subject of the notice is carbon monoxide (CO). The notice informs FDA of the view of Tyson that CO is GRAS, through scientific procedures, for use as a component of a modified atmosphere packaging (MAP) system for case-ready fresh beef and pork. The level of CO in this MAP system is 2.2 milligrams (mg) CO per pound (lb) of meat. The other components of the MAP system are carbon dioxide and nitrogen. This packaging system is used for packaging fresh cuts of muscle meat and ground meat to maintain wholesomeness, provide flexibility in distribution, and reduce shrinkage of the meat.

As compared to Pactiv's and Precept's packaging system, Tyson's packaging system is a reduced head space system, and therefore to achieve the same ratio of CO to meat, they use a higher concentration of CO per unit volume. To achieve this end, Tyson states that they will use the concentration of CO necessary to achieve the same ratio of CO to meat (2.2 mg CO per lb of meat) as is used in the Precept and Pactiv systems. For example, a 620 cubic centimeter (cc) package containing 1 lb of ground beef would require a 0.89 percent concentration of CO to achieve the required concentration of CO; a 3000 cc package containing 5 lbs of meat would require 1.19 percent concentration of CO to achieve the required concentration of CO.

Meat is placed on a tray within a chamber, the chamber is then filled with the desired atmosphere, and finally, a barrier film is affixed to the package. The packages are then labeled with a validated open date code at a central location and will be subject to no further processing or manipulation at retail. The open date code established for products packed in the MAP system will not exceed 35 days following the date of packaging for intact muscle cuts and 28 days for ground beef.

Tyson states that the CO is included in the modified atmosphere to help maintain the characteristic color of fresh meat. Tyson states that the CO is not intended to affect microbial growth and will not extend the shelf life of the product.

Tyson estimates that the exposure to CO would be 0.054 mg CO per meal of cooked meat. Tyson first assumes a scenario where the meat absorbs 30 percent of the CO in the package and 100 percent of the CO present in the meat is absorbed by the consumer. A dietary intake of 0.36 mg of CO per meal would occur when 8.8 ounces (250 grams) of meat is consumed. Tyson considers that this estimated intake of CO from its use in packaging meat is small compared to the amount that is presently accepted as a safe exposure limit by the Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA). Tyson then accounts for the fact that meat packaged with CO will be cooked prior to consumption and assumes an 85 percent reduction in CO exposure due to cooking of the meat. This 85 percent reduction decreases the maximum exposure from 0.36 mg to 0.054 mg CO per meal. If 100 percent of the CO in the package is absorbed, and 100 percent of the CO is consumed, an 8.8 ounce serving would expose the consumer to 1.2 mg of CO.

Based on the information that provided, as well as other information available to FDA, the agency has no questions at this time regarding Tyson's conclusion that CO is GRAS under the intended conditions of use. During its evaluation of GRN 000167, OFAS consulted with the Labeling and Consumer Protection Staff of FSIS regarding the use of CO in meat products. Based on the information submitted by Tyson, FSIS has concluded that the MAP system as described in Tyson's notice, and used under the conditions stated in Tyson's notice, would be acceptable for packaging red meat cuts and ground meat

IDENTITY AND SPECIFICATIONS

The physical properties of carbon monoxide are presented in Table 1 below. The Chemical Abstracts Service (CAS) number for carbon monoxide is 630-08-0.

Table 1. Physical Properties	**Value**
Empirical formula	C=0
Relative molecule mass	28.01
Critical point	-140.2 °C at 34.5 atm (3.5 MPa)
Melting point	-205.1 °C
Boiling point	-191.5 °C
Density, at 0°C, 1 atm	1.250 g/litre

Table 1. Physical Properties	Value
Density, at 25°C, 1 atm	1.145 g/litre
Specific gravity relative to air	0.967
Solubility in water at 0°C, 1 atm	3.54 mL/l00mL
Solubility in water at 25°C, 1 atm	2.14 mL/100mL
Solubility in water at 37CC, 1 atm	1.83 mL/ 100mL

The carbon monoxide will be of a purity suitable for use in contact with food. The specification will require a minimum CO content of 98%. The impurities anticipated to be present in the remaining 2% of the CO gas product consist of components that are found naturally in the atmosphere, such as nitrogen, carbon dioxide, argon, hydrogen, methane and water.

MANUFACTURING PROCESS

Carbon monoxide is typically produced in a steam methane reformer, a single reactor that is used to produce a synthesis gas of hydrogen and carbon oxides. In the reactor, sulfur-free hydrocarbons such as methane and superheated steam are passed over a refractory-supported nickel catalyst (or nickel and lanthanum catalyst) placed in Ni-Cr alloy tubes. When passing the nickel-based catalyst, the feed hydrocarbon/steam mixture converts to hydrogen and carbon oxides. The conversion is used to produce a mixture of hydrogen, carbon dioxide, carbon monoxide, methane and steam. The component gases are separated from each other via such techniques as cryogenic separation.

CONDITIONS OF USE

By this notification, the applicant proposes to increase the CO content in the meat product to 5.5 mg/lb (with a process tolerance of 20% in the modified environment), as compared to the 2.2 mg/lb previously accepted in prior GRAS notices. The proposed MAP system and subsequent distribution to the consumer is the same as described in GRN 000167. CO will be used in a mixture of nitrogen (N_2) (0-80%) and carbon dioxide ($C0_2$) (20%-100%).

In prior notices, no mention was made of the volume of gas-to-beef mass in the MAP systems. A calculation of the volume is presented below for the estimated volume of MAP gas/kg beef added to the packaging.

According to GRN 000143, "if 100% of the CO in the package is absorbed, and 100% of the CO is consumed, an 8.8 ounce serving would expose the consumer to 1.2 mg of CO." Because the notification response does not specify the dimensions of the package or volume of MAP gas used, we will use this information to back-calculate the volume of MAP gas to meat ratio.

Using the standard gas volume as 1 mole = 22.4 liter (l) at STP, and since 1 mole of CO is 28 grams (g), we calculate the density of CO gas as:
(28 g)/(22.4 l) = 1.25 g/l = 1.25 mg/ml

If the package contains 1.2 mg CO per 8.8 ounce serving, then a one kg package will contain:
(1.25 mg/8.8 oz)(16 oz/lb)(2.2 lb/kg) = 5.0 mg/kg.

Further, the volume of CO gas will be:
(5.0 mg/kg)/(1.25 mg/ml) = 4.0 ml CO /kg meat

Since the CO will be only 0.04% of the MAP gas, the total quantity of gas will be:
(4.0 ml)/(0.004) = 1000 ml MAP gas/kg meat or 1 ml MAP gas/g meat.

In the proposed MAP system, fresh meat, either beef or pork muscle meats or ground beef, will be placed on a tray within a chamber. Once the desired atmosphere is achieved that will deliver 5.5 mg/lb, a barrier film will be affixed to the tray to ensure that the atmosphere is maintained throughout the product's distribution. The packages will be prepared and labeled with a validated open date code at a central location and will be case-ready, with no further processing or manipulation at retail. Thus, the product will be ready for retail display and delivery to consumers upon packaging, and the product label will not be altered following application of the mark of inspection by the U.S. Department of Agriculture. Food Safety and Inspection Service (FSIS). The open date code or "use or freeze by" date established for products packed in the proposed MAP

system will not exceed 35 days following the date of pack for intact muscle cuts, and 28 days for ground beef.

Safety Assessment

Regulatory Exposure Standards for Carbon Monoxide

Detailed information establishing the GRAS status of CO intended for use in MAP systems for fresh meat are set forth in GRN 000083, 000143, and 000167 which are incorporated by reference as described herein. Consistent with previous GRAS determinations, an acceptable daily intake (ADI) has not been identified for CO. As described in GRN 000083 and GRN 000143 and summarized below, typical background levels of CO and national air quality standards provide a reference by which the safety of CO in MAP systems may be assessed.

Specifically, as described in GRN 000083 and GRN 000143, typical "background" levels of CO in the atmosphere are <20 mg/m^3 measured as an 8-hour mean. These background levels may result in typical serum CO levels (in the form of carboxyhemoglobin) of approximately 1.2 to 1.5%. Healthy adults are expected to experience no ill health effects at levels of 4 to 5%; compromised or sensitive individuals may experience adverse health effects at levels of 2 to 3%. Background levels may be higher in urban areas or areas with significant traffic congestion. At levels that substantially exceed background, CO is viewed as a significant air pollutant. The health-based national air quality standard for CO, as promulgated by EPA, is 9 ppm (10 mg/m^3), measured as an annual maximum 8-hour average concentration. This level would be expected to result in an exposure of 50 mg CO per 8 hours, based on the amount of air breathed by a typical person (15 m^3 per day or approximately 5 m^3 per 8 hours). The federal safety standard for occupational exposure to CO, as promulgated by OSHA, is 50 ppm (58 mg/m^3), measured as an 8-hour time weighted average and assuming a 5 m^3 per 8 hours breathing rate for workers. This level would be expected to result in an exposure of 290 mg CO per 8 hours, based on the amount of air breathed by a typical worker.

Estimated Carbon Monoxide Intake

The volume of the gas mixture and CO concentration in a package will vary depending upon tray size and product volume. For example, assuming a fresh meat portion of 500 grams and an anticipated meat weight to gas volume ratio of approximately 1.0 as calculated above in conditions of use, the gas volume would be 0.5 liter. As the meat weight to gas ratio is decreased, the CO concentration will increase proportionately to achieve 5.5 mg/lb CO.

Using a concentration of 1.0% CO in this example of a modified atmosphere, CO is estimated to account for approximately 5 ml CO gas per 500 g meat package. The mass of CO per unit volume is 1.25 mg/ml: Therefore, 5 ml of CO gas in the MAP system would be 6 mg CO in contact with 500 g or approximately 12 mg/kg (5.5 mg/lb).

It has been reported (Watts *et al.,* 1978) that 30% of the CO present in a modified atmosphere may be absorbed into packaged meat. Assuming that 30% of the CO is taken up by the meat, the amount of CO absorbed into meat packaged in the proposed MAP system is calculated as follows:

0.3 x (5ml/package) x 1.25 mg/ml / 0.500 kg meat/package = 3.75 mg CO/kg meat.

If it is assumed that the CO content is reduced 85% during cooking (Sørheim *et al.*, 1997) that a person consumes an 8.8 ounce serving portion of meat (250 g = 0.25 kg) at a meal, and that 100% of the ingested CO is absorbed, the estimated intake of CO is calculated as follows:

0.15 x 3.75 mg CO/kg meat x 0.25 kg meat/meal = 0.141 mg CO/meal.

Using "worst case" assumptions, if it is assumed that 100% of CO is taken up by the meat and no reduction occurs during cooking, the maximum theoretical CO content and intake per 8.8 ounce (250 gram) serving portion of the meat is estimated as follows:

12 mg CO/kg meat x 0.25 kg meat/meal = 3 mg CO/meal.

Similarly, if it is conservatively assumed as a worst case scenario that all of the CO in the package was respired by the consumer, it would result in the following exposure:

(5 ml/package) x 1.25 mg/mL = 6 mg CO in package released to air.

As described below, these estimated exposures to CO are negligible as compared to health-based standards for CO intake, are not expected to significantly alter environmental exposure to CO, and therefore present no toxicological concern.

Comparison of Potential Exposure to Regulatory Standards for Carbon Monoxide

The exposure to CO that is estimated to result from the proposed MAP system is a negligible fraction of the exposures considered acceptable under health-based standards for CO. Under realistic conditions of use, inclusion of CO in the planned MAP system is expected to result in an intake of 0.141 mg CO from meat intake. This level of intake corresponds to just 0.28% of the 8 hour exposure expected to result from air in compliance with EPA's health-based National Ambient Air Quality Standard (NAAQS) for CO of 9 ppm (10 mg/m^3) or 50 mg/8 hr period. Even the "worst case" intake exposure of 3 mg that may result from intake of a meal from meat packaged in the MAP system corresponds to only 6% of the likely exposure from air meeting EPA's NAAQS for CO.

In the very worst case that all CO in the package is respired by the consumer, the exposure is similarly negligible as compared to the conservative EPA NAAQS. Assuming a relatively small room of approximately 30 m^3, opening of one bag with 5 ml CO would contribute 0.2 mg/m^3 to the CO concentration in the air, or approximately 2% of the EPA NAAQS of 10 mg/m^3. At this rate, approximately 50 bags would need to be opened in order for the ambient air in the room to approach the EPA standard. This conservative estimate assumes that there is no exchange of air between the room where the package is opened and other rooms or the outdoors.

Similarly, these realistic and "worst case estimates" of intake are nearly a six-fold lesser fraction of the OSHA standard for CO of 58 mg/m^3 that is acceptably safe in the workforce as compared to the EPA NAAQS standard for the public of 10 mg/ m^3.

Accordingly, based on national, health-based standards for CO exposure, it may be persuasively concluded that the use of CO in a MAP system delivering 5.5 mg/lb CO for fresh meats poses no health or safety concern and is not reasonably expected to result in any measurable levels of carboxymyoglobin in the blood of those who consume treated meat or who are nearby when one or more packages of case-ready meat are opened. This conclusion is consistent with the conclusion of Sorheim *et al.* (1997) in the published literature that it is highly improbable that CO exposure from meat packaged in an atmosphere containing up to 0.5% will represent a toxic threat to consumers through the formation of COHb." It is also consistent with GRN 000083, GRN 000143 and GRN 000167 GRAS determinations for CO. Thus, on the basis of the above assessment and the negligible increased contributions from meat intake or inhalation of sealed packaging containing MAP gases, the proposed increase in allowable CO concentrations to 5.5 mg/lb (6.6 mg/lb CO allowing for process variance), from prior approved levels of 2.2 mg/lb, poses no health concerns.

Safety of Proposed MAP System Regarding Food Spoilage and Appearance

The finished MAP system does not pose a safety concern under the intended conditions of use. The finished system will utilize an environment with CO metered at desired concentrations dependent on headspace and meat volume in a mixture of CO_2 and N_2. The CO-containing environment will allow meat to maintain a desirable color, but will neither preclude microbial growth nor affect the characteristic odor or other indicators (e.g., gas or slime formation) of meat spoilage. In other words, the system does not mask spoilage.

In the literature addressing the use of CO in packaging of meat products, it has been observed that objections are sometimes raised because the color stability made possible by CO may exceed the microbiological shelf life. The specific concern that is cited in this regard is that color stability in such circumstances may mask spoilage of the CO-treated meat. Because CO does not inhibit the growth of spoilage microorganisms, it has no effect on characteristic signs of spoilage such as odor, gas formation, and/or slime formation. Indeed, the odor of spoiled meat will be immediately apparent, conveying to

consumers any spoilage that has occurred. The ability of meat packaged in CO to spoil and to emanate off-odors has been reported in the published literature (Sørheim *et al.*, 1999). Low concentrations of 0.4 and 1% CO did not affect microbiological loads of meat when applied in combination with atmospheres containing CO_2.

The effects of CO, O_2 and CO_2 on the microbiological spoilage of MAP packaged meat has been reviewed by Sørheim *et al.*, 2001. In MAP of meat, the effects of low concentrations of CO on microorganisms seem to be of either no or minor importance. Clark *et al.* (1976) found that by adding 0.5 – 10 % CO to N_2 atmospheres, the shelf life based on odor was extended and the growth of psychrotrophic bacteria was reduced at 0.5 and 10°C. In the evaluation of antimicrobiological effects of CO, considerations to other gases in the gas mixtures must be made. In most MAP of meat, bacteriostatic CO_2 at levels of 20–100% are usually present. Low concentrations of 0.4 and 1 % CO did not affect microbiological loads of meat when applied in combination with atmospheres containing CO_2 (Sørheim *et al.*, 1999; Luño *et al.*, 1998). Therefore, in gas mixtures containing high levels of CO_2, the possible antimicrobiological effect of low CO concentrations is likely to be overshadowed by CO_2.

The microbiological benefits of using CO for MAP of meat is two-fold: O_2 can be omitted from the atmosphere, and concentrations of CO_2 can be high, from 60 to near 100%. The absence of O_2 inhibits the growth of aerobic spoilage bacteria. In storage experiments of beef steaks, ground beef and pork chops in a 0.4% CO/ 60% CO_2 / 40% N_2 gas mixture, the shelf life, as evaluated by off-odor, increased with 2 to 7 days compared to storage in a 70% O_2 / 30% CO_2 mixture at 4 and 8°C (Sørheim *et al.*, 1999). The microflora of the meat in the CO gas mixture was dominated by lactic acid bacteria, and this gas mixture reduced the growth of spoilage flora of *Brochothrix thermosphacta* and pseudomonads. Nissen *et al.* (2000) studied the growth of pathogens in ground beef stored in 0.4% CO/ 60% CO_2 / 40% N_2 at 4 and 10°C. The CO mixture reduced the growth of *Yersinia enterocolitica* and *Listeria monocytogenes* compared to a 70% O_2 / 30% CO_2 atmosphere and chub packages. *Escherichia coli* O157:H7 was inhibited at 10°C. However, growth of *Salmonella* spp. was not reduced in meat in the CO mixture at

10°C, which emphasizes the importance of low storage temperatures for inhibiting these pathogenic bacteria.

Exposure of pure bacterial cultures to high CO concentrations of 5–30% in air, inhibited the growth of *E. coli*, *Achromobacter* and *Pseudomonas fluorescens*, but *Pseudomonas aeruginosa* was not affected (Gee and Brown, 1980). In another study, continuous storage of meat in 100 % CO reduced the development of off-odor and bacteria (Tsemakhovich and Shaklai, 2000). Pretreatment of beef steaks with 100 % CO for 30 minutes lowered aerobic plate counts by 1 log after 8 weeks of vacuum storage, compared to no CO pretreatment (Brewer at al., 1994).

These data demonstrate that at low CO concentrations of 0.4-1% in a MAP system with CO_2 and N_2 did not markedly affect microbial growth of spoilage organisms. The presence of CO_2 as an O_2 replacement appears to have a greater overall effect on retardation of spoilage than the CO addition up to 1%.

Other Safety Considerations

As noted in GRN 000143, Precept Foods has also commented on whether the planned system presents any unique or unusual risk of pathogenic growth or other harm to consumers. Significantly, application of a consistent "freeze by" date offers considerable consumer benefit, including enhanced safety, because the product will be subject to less handling than retailer-packed products and an appropriate shelf life will be objectively established and communicated via a validated open date code. Indeed, reliance on a centrally applied open code or "use or freeze by" date offers a far more objective means of assessing product age and quality than highly subjective measures such as color.

With regard to the theoretical risk of pathogenic growth, Precept Foods concluded that a risk of pathogenic growth exists with any packaging system that is subject to temperature abuse or other mishandling, and that the planned system presents no particular vulnerabilities in this regard. Psychrotropic pathogens of theoretical concern for an anaerobically packaged product, such as non-proteolytic *Clostridium botulinum*, are not typically associated with fresh meats, so such organisms are not reasonably expected to

be present in the first place. Moreover, the total time that product will spend in the modified atmosphere, as determined by the anticipated shelf life of 35 days for muscle cuts and 28 days for ground beef, is comparable to time that may be spent in similar anaerobic atmospheres in systems judged to be safe. Such systems include vacuum packaging and the Pactiv master bag system that was asserted to be GRAS in GRN 000083. In the unlikely event that product is mishandled prior to purchase, microbial spoilage can and will occur, and the fact of spoilage will be apparent through off odors or other indicators of spoilage. Thus, in addition to the certainty provided by the open date or "us or freeze by" code, natural spoilage processes provide additional safeguards that will prevent consumption of spoiled meat that may contain food-borne pathogens. The fact that the system will be used to package only raw products that require safe handling instructions and cooking to appropriate temperatures offers an additional assurance of safety.

It is our understanding that the microbiological issues regarding spoilage are of no concern to FDA and USDA, providing the meat products are properly labeled with "use or freeze by" date periods agreeable to these governmental bodies. Consequently, the Expert Panel, in keeping with this understanding, has not pursued the matter of potential for spoilage masking further by requesting additional studies for purposes of safety assessment.

Discussion and Summary

In this GRAS notification, carbon monoxide is intended for use as a component of a modified atmosphere packaging (MAP) system for case-ready fresh beef and pork. The carbon monoxide will be used at a target concentration intended to deliver 5.5 mg/lb CO as a function of headspace and meaty volume (with a process tolerance of 20% in the modified environment). The proposed MAP system and subsequent distribution to the consumer is the same as described in GRN 000143, with CO used in a mixture of nitrogen (N_2) (0-80%) and carbon dioxide ($C0_2$) (20%-100%). Typical concentrations used by meat processors are nitrogen (30-40%) and carbon dioxide (60%-70%).The

presence of 2.2-5.5 mg/lb CO is sufficient to impart the desirable and stable red meat coloration.

The volume of MAP gas to meat volume will be used to determine the concentration of CO. With a ratio of 1 ml MAP gas/g meat, the calculated concentration of CO in the modified atmosphere is 1%. CO is estimated to account for approximately 5 ml CO gas per 500 g meat package at retail. The mass of CO per unit volume is 1.25 mg/ml: Therefore, 5 ml of CO gas in the MAP system would be 6 mg CO in contact with 500 g or approximately 12 mg/kg or 5.5 mg/lb CO.

Using "worst case" assumptions, if it is assumed that 100% of CO is taken up by the meat and no reduction occurs during cooking, the maximum theoretical CO content and intake per 8.8 ounce (250 gram) serving portion of the meat is estimated as 3 mg CO/meal. More realistically, based on literature regarding absorption on CO into meat and loss during cooking, 30% of the CO present in a modified atmosphere is likely to be absorbed into packaged meat and CO content is reduced 85% during cooking, a person consuming an 8.8 ounce serving portion of meat (0.25 kg) at a meal, and that 100% of the ingested CO is absorbed, the estimated intake of CO is approximately 0.14 mg CO/meal.

As noted before, under realistic conditions of use, inclusion of CO in the planned MAP system is expected to result in an intake of 0.14 mg CO from meat intake per serving, an intake corresponding to just 0.28% of the 8 hour exposure expected to result from air in compliance with EPA's health based NAAQS for CO of 9 ppm (10 mg/m^3) or 50 mg/8 hr period. Even the "worst case" intake exposure that may result from ingestion of meat packaged in the MAP system of 3 mg corresponds to only 6% of the likely exposure from air meeting EPA's NAAQS for CO. Similarly, in the worst case estimation of inhalation exposure to CO in a small room from opening a MAP container, the exposure is also negligible when compared to the conservative EPA NAAQS, with worst case exposure to approximately 2% of the EPA NAAQS of 10 mg/ m^3. Thus, even with 1-2 beef or pork meals/day and possible exposure by inhalation of released gas, these CO intakes and exposures are considered unlikely to cause any measurable increase in normal COHb concentration in the blood (typically ~0.5%) above that associated with breakdown of

heme protein or ambient CO levels in the atmosphere or pose any associated health risk to the consumer.

Further, the literature reviewed and studies that have been conducted with MAP containing 0.4-1% CO have demonstrated that addition of a higher level of CO will not result in growth retardation of spoilage microorganisms or mask spoilage of the CO-treated meat as normally indicated by characteristic signs of spoilage such as odor, gas formation, and/or slime formation. It is our understanding that there are no issues regarding spoilage for FDA and USDA, providing the meat products are properly labeled with "use or freeze by" date periods.

CONCLUSION

Based on a critical evaluation of the publicly available data and information summarized above, the Expert Panel members whose signatures appear below, have individually and collectively concluded that addition of carbon monoxide at levels intended to not exceed 5.5 mg/lb (maximum6.6 mg/lb to allow for process variation) to MAP packaging systems meeting the specifications cited above, is safe for addition to fresh muscle cuts of beef and pork and fresh ground beef. Further, based on current good manufacturing practices, the addition of carbon monoxide to MAP as presented in this notification, presents no significant risk of pathogenic growth or spoilage masking to the consumer when properly labeled with open code or "use or freeze by" dating with expiration dates as specified for the meat types.

It is also our opinion that other qualified and competent scientists reviewing the same publicly available toxicological and safety information would reach the same conclusion. Therefore, we have also concluded that carbon monoxide in MAP systems delivering up to 5.5 mg/lb fresh meat, when used as described, are GRAS based on scientific procedures.

James W. Barnett, Jr., Ph.D., DABT — 12/16/05 Date

W. Gary Flamm, Ph.D., FACT, FATS — 12/12/05 Date

Stanley M. Tarka, Jr., Ph.D. — 12/9/05 Date

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Master of Science (Pharmaceutical Chemistry), University of Cincinnati, Cincinnati, Ohio, 1957-1959.

Bachelor of Science (Pharmacy), University of Cincinnati, Cincinnati, Ohio, 1953-1957.

PROFESSIONAL POSITIONS:

Consultant, Flamm Associates, 1988-present.

Director, Office of Toxicological Sciences, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration (US FDA), 1984-1988.

Associate Director for Toxicological Sciences, Bureau of Foods, US FDA, 9/82 - 3/84.

Acting Associate Director for Toxicological Sciences, Bureau of Foods, US FDA, 5/82 - 9/82.

Acting Associate Director for Regulatory Evaluation, Division of Toxicology, Bureau of Foods, US FDA, 10/81 - 5/82.

Deputy Associate Commissioner for Health Affairs, US FDA, 5/81 - 10/81.

Acting Deputy Associate Commission for Health Affairs, US FDA, 7/80 - 7/81.

Associate Director for Regulatory Evaluation, Division of Toxicology, Bureau of Foods, US FDA , 11/78 - 7/80.

Assistant Director for Division of Cancer Cause and Prevention, National Cancer Institute, NCI, 9/74 - 10/77.

Chief, Genetic Toxicology Branch, Bureau of Foods, US FDA, 9/72 - 9/74.

Head, Somatic Cell Genetics Section, National Institute of Environmental Health Sciences, National Institutes of Health, 1/72- 9/72.

Research Chemist, Cell Biology Branch, National Institute of Environmental Health Sciences, National Institute of Health 6/68 - 1/72.

Sr. Research Fellow, Dept. of Zoology, University of Edinburgh, Edinburgh, Scotland, 9/66 - 7/68.

Research Chemist, National Cancer Institute, National Institute of Health, 7/64 - 9/66.

Research Fellow, California Institute of Technology, 6/62 - 7/64.

Predoctoral Fellow, Department of Biochemistry, University of Cincinnati, 9/59 - 6/62.

PROFESSIONAL SOCIETIES AND HONORS:

Fellow, Academy of Toxicological Sciences, 1999 -present

American College of Toxicology (Charter Member) 1977-present
- President, 1984-1985
- Fellow of the American College of Toxicology, since 1986
- Chairman, Program Committee 1983, 1984
- Membership Committee, 1979, 1981
- Program Committee, 1984-1985
- Nominee Committee, 1982-1983
- Council, 1982-1984
- Publications Committee, 1983-1984

Environmental Mutagen Society (EMS) (Charter Member) 1969-present
- Treasurer, 1973-1974
- Council, 1974-1976, 1978-1981

Executive Board, 1975-1976
Chairman, Program Committee, 1974
Chairman, Nomination Committee, 1978-979
Finance Committee, 1979-1980
Long-Range Planning Committee, 1979-1980

Society for Risk Analysis (Charter Member & Co-Founder) 1980-present
Secretary 1992-1997
Council 1988-1990
Program Committee, 1981-1982
President's Advisory Committee, 1981-1982
Membership Committee, 1988-1990

International Society for Regulatory Toxicology and Pharmacology, 1985-present
President, 1990-1992
Vice President, 1988-1990

The Toxicology Forum
Member 1992-present
Program Planning Committee – 1980-1994

Sigma Xi

Member, Federal Executive Institute Alumni Association, 1982

Former Member, American Chemical Society, Genetics Society of America,

Former Biophysical Society, American Pharmaceutical Association, Biochemical Society,

Former American Association for the Advancement of Science, New York Academy of Science, American Forestry Association

George Scott Memorial Award, Toxicology Forum, 1988

U.S. FDA Senior Executive Performance Award for Outstanding Performance during fiscal years 1980, 1982, 1983, 1984

Environmental Mutagen Society's Recognition Award, 1981. "For his accomplishments both in research and the administration of toxicology programs, especially for his untiring efforts to establish genetic toxicology as an essential component of chemical safety evaluation."

U.S. Department of Health, Education and Welfare Superior Service Award, 1977. "For vigorous leadership in reshaping the philosophy and methods for assessing environmental carcinogenic hazard to humans on a national and international scale.

Elected Class Representative to Senior Executive Training Program, 1980

U.S. Public Health Service Predoctoral Fellowships, 1962, 1963, 1964

Sigma Xi - honorary graduate

U.S. Public Health Service Predoctoral Fellowships, 1959, 1960, 1961, 1962

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Otto Mooseburger Award in Pharmacy, 1957

ADDITIONAL TRAINING:

Radiation Biology, University of Sao Paulo, Brazil, 1971

Molecular Biology, University of Edinburgh, Scotland, 1966-1968

Biochemical Genetics, National Institutes of Health, 1965-1966

Molecular Biology, Biophysics, California Institute of Technology, Pasadena, California, 1962-1964

Senior Executive Training Program, Federal Executive Institute, 1980

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Special Foreign Assignment to the University of Edinburgh, Edinburgh, Scotland, 1967-1968

Testimony before US Senate on "Chemicals and the Future of Man," 92nd Congress, Subcommittee on Executive Reorganization and Government Research, Washington, D.C., 1971

Organizer and Chairman "Methods for the Detection of Somatic Mutations in Man," NIEHS/NIH, Research Triangle Park, North Carolina, 1972

Executive Secretary - Subcommittee on Carcinogen Laboratory Standards, DHEW, 1973-1975

Chairman - Subcommittee on Carcinogenicity of NTA, Committee to Coordinate Toxicology and Related Programs, DHEW, Bethesda, Maryland, 1974-1975

Executive Secretary - National Cancer Advisory Board Subcommittee on Environmental Carcinogenesis, Bethesda, Maryland, 1975-1977

Chairman - Working group to develop document on "Approach to Determining the Mutagenic Properties of Chemical Substances," CCTRP, DHEW, 1975-1977

Preparation of testimony and hearing statements before NIH appropriation subcommittees of the Congress on cancer prevention for the National Cancer Institute, 1975, 1976

Preparation of testimony and appearance before U.S. Senate Health Subcommittee on Diethylstilbestrol Hearings, 1975

Member, DHEW Subcommittee on polychlorinated biphenyls, Bethesda, Maryland, 1975
Coordinated and participated in the interdepartmental HEW study on the toxicology and health effects of polybrominated biphenyl, 1975-1977

Chairman, Carcinogenesis Coordinating Committee, National Cancer Institute, Bethesda, Maryland, 1976-1977

Member of the FDA interagency committee to evaluate carcinogenicity of FD&C Red No. 40, Washington, D.C., 1976-1978

Testimony before a U.S. Congress on saccharin, House Health Subcommittee, 1977

Commissioner's Task Force on the 1977 National Academy of Sciences report on the National Center for Toxicologic Research, Rockville, Maryland, 1977-1978

Chairman, Cancer Assessment Committee, FDA/Bureau of Foods, Washington, D.C., 1978-1988

Chairman, Mutagenicity Working Group on Risk Evaluation, U.S. Environmental Protection Agency, 1978-1980

Chairman, Health Effects of Diesel Fuel Emission, U.S. Environmental Protection Agency, 1978

Testimony before U.S. House of Representatives, Committee on Science and Technology on Use of Animals in Medical Research and Testing, 1981

Member of Working Group on methods for the integrated evaluation of risks for progeny associated with prenatal exposure to chemicals - WHO/International Program for Chemical Safety 1981

Working Group on Carcinogen Principles, White House Office of Science Technology Policy, 1982

Testimony before a U.S. House of Representatives, Committee on Science and Technology, hearing on Hazards of Chemicals to Human Reproduction, 1982

Member, Risk Management Working Group, Interagency Risk Management Council, 1984, 1985

Co-chairman, U.S. FDA, Health Hazard Evaluation Board,1982-1988

Chair, Session on Mutagenesis, Annual Meeting of the American College of Toxicology, 1980

Chairman, Food and Risk Assessment, Mechanisms of DNA Damage and Repair: Implications for Carcinogenesis and Risk Assessment, 1985

Chair, Session on DeMinimus Risk, International Society of Regulatory Toxicology and Pharmacology, 1987

Chairman, Approaches to Validation, In Vitro Toxicology, sponsored by the Johns Hopkins Center for Alternatives to Animal Testing, 1986

Chair, Risk Analysis and the Food and Drug Administration, Society for Risk Analysis, Annual Meeting, 1988

Chair, Risk Assessment in the Federal Government: Managing the Process, Toxicology Forum, 1983

Chair, Program Committee, Annual Meeting of the International Society of Regulatory Toxicology and Pharmacology, 1987, 1988, 1989

Chair, Risk Assessment, Toxicology Forum, 1990

Ad Hoc Chair of Expert Panels on Generally Recognized as Safe Substances from

1990-present

FACULTY APPOINTMENTS:

Adjunct Associate Professor, Department of Zoology, University of North Carolina, Chapel Hill, North Carolina, 1968-1972

Visiting Professor of Biochemistry, University of Sao Paulo, Brazil, 1970 and 1971

Adjunct Professor of Genetics, George Washington University, Washington, D.C., 1972-1974

Visiting Professor, European Molecular Biology Organization, University of Zurich, Zurich, Switzerland, 1973

Visiting Professor, University of Conception, Chile, 1979

EDITORIAL AND ADVISORY ACTIVITIES:

Manuscript review for numerous journals, e.g., Biochem. Biophys. Acta, Science, Proc. Natl. Acad. Sci., J. Mol. Biology, J. Biochem, Genetics, Biochemical Journal, Expt. Cell Research, Cancer Research, J. Natl. Cancer Institute, Mutation Research, Radiation Research, Food and Chemical Toxicology, J. Toxicology and Environ, Health, Genetic Toxicology, CRC Reviews in Toxicology

Associate Editor, Journal of Environmental Health and Toxicology, 1974-1978

Section Editor, Journal of Environmental Pathology and Toxicology, 1978-1982

North American Field Editor, Teratogenesis, Carcinogenesis and Mutagenesis, 1994-present

Editorial Board, Genetic Toxicology, 1975-1978

Editorial Board, Food and Chemical Toxicology, 1977-1988

Editorial Board, Biomedical and Environmental Sciences, 1988-present

Sec. Ed., Journal of the American College of Toxicology, 1982-1996

Member of Editorial Board, Journal for Risk Analysis, 1982-1986

Member of Editorial Board, Regulatory Toxicology and Pharmacology, 1986-present

Co-editor, Advances in Modern Toxicology: Mutagenesis, 1976-1978

Co-editor, Carcinogenesis & Mutagenesis, Princeton Scientific Publishers, 1979-1981

Member, Genetics Program Committee, George Washington University, Washington, D.C., 1972-1975

Member, Joint Subcommittee on Mutagenicity, Pharmaceutical Manufacturers Association - Food and Drug Administration, Washington, D.C., 1972-1974

Member, Faculty Group, European Molecular Biology Organization, Geneva, Switzerland, 1973

Member, US/USSR Delegation to Moscow, Environmental Health Agreement, DHEW, 1974

Member, Scientific Advisory Board, National Center for Toxicological Research (NCTR), Jefferson, Arkansas, 1975-1978

Chairman, Subcommittee on Mutagenesis, Science Advisory Board, National Center for Toxicological Research, Jefferson, Arkansas, 1975-1978

Chairman, Subcommittee on Genetic and Environmental Influences on Carcinogenesis (matrix) Sci. Adv. Board, National Center for Toxicological Research, Jefferson, Arkansas, 1975-1978

Member, Toxicology Advisory Committee, Food and Drug Administration, Rockville, Maryland, 1975-1978

Member, National Academy of Sciences, Committee to Develop Principles for Evaluating Chemicals in the Environment, Washington, D.C., 1975

Chairman, Subcommittee on Tissue Culture Resources, Sci. Adv. Board, National Center for Toxicologic Research, Jefferson, Arkansas, 1976-1978

Member, National Academy of Sciences Committee to Revise Publication No. 1138, Toxicologic Evaluation of Household Products, Washington, D.C., 1976-1977

Chairman, Subcommittee on Mutagenesis of NAS committee to revise Publication No.

1138, Washington, D.C., 1976-1977

Member, National Academy of Sciences Visiting Committee to Review the Food and Nutrition Board, Washington, D.C., 1976-1977

Consultant, Organization of American States, Office of Scientific Affairs, Sao Paulo, Brazil, 1971.

Consultant, National Science Foundation, Structure and Function of Human Chromosome, Washington, D.C., 1971.

Advisor, National Science Foundation, Developmental Biology - Cell Biology, Washington, D.C., 1971-1972, 1978.

Consultant, World Health Organization, consultant group on anti-schistosomal agents, Geneva, Switzerland, 1972

Consultant, National Cancer Institute, Carcinogenesis Program, Bethesda, Maryland, 1972-1974

Consultant, Environmental Protection Agency, Washington, D.C., 1972-1973, 1976-1977

Consultant, Bureau of Drugs, Safety Evaluation, Rockville, Maryland, 1972-1974

Consultant, Consumer Product Safety Commission, 1973-1975, 1977

Consultant, National Institute on Drug Abuse, Rockville, Maryland, 1976-1977

Member, Faculty Group - International Course on Methods for the Detection of Environmental Mutagens, Concepcion, Chile, 1979

Chairman of the FDA's Recombinant DNA Coordinating Committee, 1980-1981

Co-Chairman Joint Committee on Agency-Wide Quality Assurance Criteria (FDA), 1980-1981

Chairman, Scientific Advisory Research Associates Program (FDA), 1980-1981

Chairman, International Visiting Scientific Program (FDA), 1980-1981

Chairman, Agency-Wide Research Review and Planning Group (FDA), 1981

Ex-Officio Member National Cancer Advisory Board, 1980-1981

Member, Interagency Regulatory Liaison Group on 1-Mutagenesis; 2-Cancer Risk, 1979-1981

Organizing Committee for First World Congress on Toxicology and Environmental Health, 1983

Organizing Committee for "Symposium on Health Risk Analysis", 1981

Chairman, Toxicology Committee, National Conference for Food Protection, 1985-1986

Member, NAS Committee on Biomedical Models, 1983-1985

INVITED PRESENTATIONS:

"Kinetics of Homogentisate Oxidase", Federation of American Societies of Experimental Biology, Atlantic City, New Jersey, 1961

"Histone Synthesis", invited speaker, First International Conference on Histone Chemistry and Biology, Santa Fe, California, 1963

"Free and Bound Ribosomes", FASEB, Chicago, Illinois, 1963

"Histone Synthesis" Seminar, California Institute of Technology, Pasadena, California, 1963.

"Association and Dissociation of RNP particles" Seminar, University of Cincinnati, Cincinnati, Ohio, 1963.

"Ribosome Synthesis", California Institute of Technology, Pasadena California, 1964.

"Protein and Nucleic Acid Biosynthesis", University of California, Santa Barbara, California, 1964.

Biosynthesis and Assembly of Ribosomes", Dupont Laboratories, Wilmington, Delaware, 1964.

"Isopycnic Density Gradient Centrifugation", University of Pennsylvania, Institute for Cancer Research, Philadelphia, Pennsylvania, 1965.

"Use of fixed-angle rotors" Seminar, Carnegie Institution of Washington, Washington, D.C., 1965.

"Conversion of 23S to 16S RNA", Biophysical Society, Boston, Massachusetts, 1965.

Participant at Gordon Conference on Cell Structure and Function, Meriden, New Hampshire, 1965.

"Turn-Over of Mitochondrial DNA" Seminar, National Cancer Institute, Bethesda, Maryland, 1966.

"Isolation and Fractionation of DNA", invited speaker, Symposium on Subcellular Fractionation, London, England, 1967.

"Isolation and Properties of Satellite DNA", University of Edinburgh, Scotland, 1967.

Properties of Mouse Satellite DNA", University of Glasgow, Glasgow, Scotland, 1967.

"Isolation of Complementary Strands from Mouse Satellite", Oxford University, Oxford, England, 1967.

"Highly Repetitive Sequences of DNA", St. Andrews University, St. Andrews, Scotland, 1968.

"Repetitive Sequences in Rodents", Department of Molecular Biology, University of Edinburgh, Edinburgh, Scotland, 1968.

"Satellite DNA from the Guinea Pig", Newcastle University, Newcastle, England, 1968.

"Isolation, Preparation, and Fractionation of DNA", Imperial Cancer Research Fund, London, England, 1968.

"Properties and Possible Role of Satellite DNAs", Oak Ridge National Laboratory, Oak Ridge, Tennessee, 1968.

"Highly Repetitive DNA", Yale University, New Haven, Connecticut, 1968.

"Structure and Function of Repetitive DNA", invited speaker at Conference on Satellite DNA, American Association for the Advancement of Science, Chicago, Illinois, 1968.

"Properties of Guinea Pig DNA", Symposium on Hybridization of Nucleic Acids, Biochemical Society, Newcastle, England, 1968.

"Complementary Strands of Satellite DNAs", Biophysical Society Meeting, Los Angeles, California, 1969.

Participant at Gordon Conference on Cell Structure and Function, Hanover, New Hampshire, 1969.

"Classes of DNA in Mammals", University of North Carolina, Chapel Hill, North Carolina, 1969.

"Structure and Function of Repetitive DNA", Duke University, Durham, North Carolina, 1969.

"Satellite DNAs in Rodent Species", University of Chicago, Chicago, Illinois, 1969.

"Synthesis of DNA Following Alkylation", Temple University, Philadelphia, Pennsylvania, 1970.

"Repetitive DNA", Case Western Reserve University, Cleveland, Ohio, 1970.

"Repetitive Sequences of Higher Organisms", University of Nebraska, Lincoln, Nebraska, 1970.

"Alkylation of DNA", Biophysical Society Meeting, Baltimore, Maryland, 1970.

"Structure and Function of Mammalian DNA", University of Texas, Austin, Texas, 1971.

"Repair of Human DNA", National Institute for Environmental Health Sciences, 1971.

"Alkylation and Repair of DNA", Oak Ridge National Laboratory, Oak Ridge, Tennessee, 1971.

"Repetitive Sequences of DNA", Brooklyn College, New York, New York, 1971.

"A Gene Mutational Assay in Mouse Cells", North Carolina State University, Raleigh, North Carolina, 1971.

"Lectures on Chemical Mutagenesis", University of Sao Paulo, Sao Paulo, Brazil, 1971.
"Lectures and Demonstrations on Ultracentrifugation", University of Sao Paulo, Sao Paulo, Brazil, 1971.

"Chemical Mutagens in the Biosphere", Environmental Mutagen Society, Washington, D.C., 1971.

"Molecular Mechanisms of Mutagenesis", invited participant in Workshop on Chemical `Mutagens as Environmental Contaminants, sponsored by the Fogarty International Center, Bethesda, Maryland, 1971.

"Lectures on Chemical and Radiation Biology", Winter Biochemistry Course, sponsored by Organization of American States, 1971.

"Structure and Function of Human Chromosomes", National Science Foundation, Boulder, Colorado, 1971.

Chairman of Workshop on "Somatic Cell Mutagenesis", sponsored by National Institute of Environmental Health Sciences, 1972.

"Repetitive DNA, Chromosome Defects and Neoplasia", sponsored by National Science Foundation, Minneapolis, Minnesota, 1972.

"Mutagenesis in Mammalian Cells", Duke University, Durham, North Carolina, 1972.

"Mutagenicity of Hycanthone", University of Sao Paulo, Sao Paulo, Brazil, 1972.

"Gene Mutations at the Thymidine Kinase Locus", John Hopkins University, Baltimore, Maryland, 1972.

"Repetitive Sequences and Neoplasia", University of Minnesota, Minneapolis, Minnesota, 1972.

"Mutagenicity of Chemical Substances", George Washington University, Washington, D.C., 1973.

"Test Systems for Measuring Mutagenicity", Howard University, Washington, D.C., 1973.

"Lectures on Molecular Biology", University of Zurich, Zurich, Switzerland, 1973.

"Mutagenesis and Repair", Swiss Institute for Experimental Cancer Research, Lucerne, Switzerland, 1973.

"Mutagenic Test Systems", Food and Drug Administration, Washington, D.C., 1973.

"Relationship of DNA Repair to Mutagenesis", invited participant to Workshop on Mutagenic Test Methods, sponsored by National Institutes of Health, Research Triangle

Park, North Carolina, 1973.

"A Tier System Approach to Mutagen Testing", invited speaker at International Conference on Chemical Mutagens, Asilomar, California, 1973.

"Lectures on Molecular Genetics", Symposium on Molecular Hybridization, Zurich, Switzerland, 1973.

"A New approach to Mutagen Testing", invited speaker at Symposium on Chemical Mutagenesis, Moscow, USSR, 1974.

"Introduction to Toxicology", Chairman of Symposium on Collaborative Studies in Toxicology, sponsored by Society of Toxicology and the Association of Official Analytical Chemists, Washington, D.C., 1974.

"Relevance of Mutagenicity Tests in Toxicology", Saratoga Conference on Molecular Biology and Pathology, Saratoga Springs, New York, 1974.

"Test Systems for Assessing Mutagenic Potential", invited speaker at Symposium on Collaborative Studies in Toxicology, sponsored by SOT and AOAC, Washington, D.C., 1974.

"Use of Gene Mutational Assays as a Model for Risk Assessment", Symposium on Risk Assessment, sponsored by NIH, Wrightsville Beach, North Carolina, 1974.

"Tier System Approach to Mutagen Testing", National Institute of Health, Research Triangle Park, North Carolina, 1974.

"Carcinogenesis and Mutagenesis", Procter and Gamble Co., Cincinnati, Ohio, 1975.

"The Need to Quantify Risk", National Cancer Advisory Board, Bethesda, Maryland, 1975.

"Mechanisms of Mutagenesis", General Foods Corporation, New York, New York, 1975.

"Problems in Carcinogenesis", Worcester Foundation for Experimental Biology, Worcester, Massachusetts, 1975.

Chairman of Workshop for Developing a Document on "Mutagenic Test Procedures", Ocean City, Maryland, 1975.

"Mutagenesis as a Toxicologic Problem", Chairman of Gordon Conference Session on

Mutagenesis, Meriden, New Hampshire, 1975.

"Open Meeting on Mutagenesis", sponsored by National Institutes of Health, Bethesda, Maryland, 1975.

"Mutagenic Test Systems", Chairman of Session on Short-Term Test, Symposium entitled, "Toxicology and the Food Industry," Aspen, Colorado, 1975.

Session Chairman, Symposium on In Vitro Mutagenicity Tests, Environmental Mutagen Society, Miami, Florida, 1975.

Workshop on "Principals for Evaluating Chemicals in the Environment", sponsored by the National Academy of Sciences, San Antonio, Texas, 1975.

Open Meeting on Mutagenesis, sponsored by DHEW, Bethesda, Maryland, 1976.

"Carcinogenicity Assays, Problems, and Progress", Gordon Conference on Toxicology and Safety Evaluation, Meriden, New Hampshire, 1976.

"Value of Short-Term Tests in Carcinogenesis", Toxicology Forum, Aspen, Colorado, 1976.

"Presumptive Tests", Symposium on Risk Assessment entitled, "Extrapolation II", sponsored by DHEW, Pinehurst, North Carolina, 1976.

"Programs of the National Cancer Institute", invited speaker on cancer, sponsored by the American Association of Science, Boston, Massachusetts, 1976.

"Assessment of Risks from Carcinogenic Hazard", invited speaker to Symposium on Toxicology, sponsored by Synthetic Organic Chemists Manufacturing Association, Atlanta, Georgia, 1976.

Chairman of Session on Short-Term Tests, Symposium on "Status of Predictive Tools in Application to Safety Evaluation", Little Rock, Arkansas, 1976.

"Relevance of Carcinogenicity Testing to Humans", invited speaker at Origins of Human Cancer Cold Spring Harbor Symposium, 1976.

"Human Genetic Disease Versus Mutagenicity Assays", Symposium sponsored by Pharmaceutical Manufacturers Association, Sea Island, Georgia, 1976.

Open Meeting on Mutagenesis, sponsored by DHEW, Bethesda, Maryland, 1976

"Role of the NCI in the National Cancer Program on Environmental Carcinogenesis", invited speaker at Conference on Aquatic Pollutants and Biological Effects with Emphasis on Neoplasia, New York Academy of Sciences, New York, New York, 1976.

"Genetic Disease in Human and Mutagenic Test Systems", Albany Medical School, Albany, New York, 1976.

"Statistical Problems in Carcinogenesis", University of California, Berkeley, California, 1976.

"Carcinogenesis and Animal Bioassay", Grocery Manufacturers of America, Washington, D.C., 1976.

"Problems and Needs in Assessing Carcinogenicity Data", National Clearinghouse for Environmental Carcinogens, 1976.

"Carcinogenesis and Cancer Prevention", University of Eastern Virginia Medical College, Norfolk, Virginia, 1977.

"Overview of Mutagenesis", Food and Drug Administration, Washington, D.C., 1977.

Workshop on Carcinogenicity of Aromatic Amines and Hair Dyes, International Agency for Research in Cancer, Lyon, France, 1977.

"Strengths and Weaknesses of Current Approaches in Carcinogenesis", session Chairman and speaker on "Federal Regulation of Environmental Carcinogens," Center for Continuing Education, Washington, D.C. 1977.

"Program in Carcinogenesis", Cancer Research Safety, NIH, Dulles Airport, Virginia, 1977.

"Predictive Value of Short-Term Tests", invited speaker at Animal Health Institute, Lake Tahoe, Nevada, 1977.

Open Meeting on Mutagenesis, sponsored by DHEW, Bethesda, Maryland, 1977.

"Risk Evaluation", in the Federal Regulation of Environmental Carcinogens, sponsored by Center for Continuing Education, Washington, D.C., 1977.
"Statistical Considerations of the Dominant Lethal and Heritable Translocation Test", The Washington Statistical Society, 1978.

"Testing: Short-Term", 3rd Toxic Substances Control Conference, Government Institutes, Inc., Washington, D.C., 1978.

"The Degree of Concern as Defined by Short-Term Carcinogenicity Assays", Pharmaceutical Manufacturers Association, Point Clear, Alabama, 1978.

"Short-Term Predictive Tests", Pharmaceutical Manufacturers Association, Lincolnshire, Illinois, 1978.

Chairman of Scientific Review Meeting on the U.S. Environmental Protection Agency Diesel Emission Health Effects Research Program, U.S., EPA, Washington, D.C., 1978.

"Strengths and Weaknesses of Tests for Mutagenesis", Banbury Center of the Cold Spring Harbor Laboratory, Cold Spring Harbor, New York, 1978.

"Detecting and Measuring Carcinogens", Seminar on Government Regulation of Cancer Causing Chemicals, National Center for Administrative Justice, Washington, D.C., 1978.

Workshop on "Chemical Scoring Systems", Interagency Testing Committee (TSCA), San Antonio, Texas, 1978.

"Needs for Regulatory Utility of Short-Term Test Data", International Update on Short-Term Tests, The Toxicology Forum, Washington, D.C., 1979.

"Proposed Application of Short-Term Tests", International Update on Short-Term Tests, The Toxicology Forum, Washington, D.C., 1979.

"Current and Proposed Use of Short-Term Tests", Cosmetic, Toiletry and Fragrance Association, Washington, D.C., 1979.

"Application of Mutagenicity Testing on SOM Food Animal Drugs", Subcommittee on Environmental Mutagenesis, DHEW/CCTRP, 1979.

"Application of Mutagenicity Testing in Cyclic Review of Food Additives", Subcommittee on Environmental Mutagenesis, DHEW/CCTRP, 1979.

"Recent Developments on Sorbate/Nitrite", Tripartite (U.S., Canada, U.K.), Annapolis, Maryland, 1979.

"What is Risk?", International Course on the Detection of Environmental Mutagens, Concepcion, Chile, 1979.

"Status of Regulations and Proposed Regulation Covering Environmental Mutagens", International Course on the Detection of Environmental Mutagens, Concepcion, Chile, 1979.

"Food Safety Guidelines", Tripartite (U.S., Canada, U.K.), Ottawa, Canada, 1980.

"History and Progress in Carcinogenesis", Society of Cosmetic Chemists, 1978.

"Introduction and History of Mutagenicity Testing", Annual Meeting of the American College of Toxicology, 1980.

Mutagenicity and Neoplastic Transformation Assays, Course on "Identification and Quantification of Environmental and Occupational Carcinogenic Risks", sponsored by the American College of Toxicology, 1980.

Lectured on Molecular Mechanisms at the American College of Toxicology's course on "Identification of Environmental and Occupational Carcinogenic Risks." "Introduction and History of Environmental Mutagenesis", Second Annual Meeting of the American College of Toxicology.

"Risk-Benefit Considerations in Toxicology", The Toxicology Forum, 1981 Winter Meeting.

"Trends in Biosassay Methodology", 75th Anniversary of the Food and Drug Act, Sponsored by the Animal Health Institute.

"Relationship Between Science & Regulation", Food and Drug Administration Risk Assessment for Carcinogenic Food Ingredients - EPA, 1982.

FDA Experience with Risk Assessment for Carcinogens in Foods, Food and Drug Law Institute, 1982.

Practical Applications of Risk Analysis, The Food, Drug and Law Institute Conference, 1982.

The Future of Carcinogen Testing: Implications for Food Safety, A Symposium on Food Safety Laws: Delaney and Other Dilemmas, sponsored by Boston University, 1982.

Regulatory Use of Genetic Toxicity, Tests, Society of Toxicology - Mid Atlantic Chapter Meeting on Genetic Toxicology/Predictive or Not, 1983.

Aerosol Spray Adhesives, A Workshop on Principles and Applications of Cytogenetic, Sister Chromatid Exchange, Gene Damage to Problems of Human Health, sponsored by the American College of Toxicology, 1982.

Food and Drug Adminstration Viewpoint on Problem Tumor, Toxicology Forum, Winter Meeting, 1983.

Food-Borne Carcinogens, Second International Conference on Safety Evaluations and Regulations of Chemicals, sponsored by Boston University, 1983.

Carcinogenicity of Hair Dyes, Formaldehyde, Nitrates and Berylliu, Symposium on Interpretation of Epidemiological Evidence, sponsored by International Agency for Research on Cancer, 1983.

Use of Acute Toxicity Studies in the Bureau of Foods, Acute Toxicity Workshop, sponsored by the Food and Drug Administration, 1983.

Critical Issues on Science, Technology and Future, The Brookings Institution, 1983.

Challenge to Animal Testing, Chemical Manufacturers Association, 1983.

Regulatory Significance of Workshop Recommendation on Alternatives to Animal Testing, Workshop on Acute Toxicity Testing - Alternative Approaches, sponsored by Johns Hopkins University, 1983.

Role of Mathematical Models in Assessment of Risk and in Attempts to Define Management Strategy, Safety Assessment: The Interface Between Law and Regulation, sponsored by International Life Science Institute, 1983.

Impact of Short-Term Tests on Regulatory Actions, Conference on Cellular Systems for Toxicity Testing, sponsored by New York Academy of Sciences, 1984.

Requirements of Pre-Market Evaluation, Toxicology Forum, April Meeting, 1984.

Use of Short-Term Tests in Risk Assessment, Workshop on RA/RM: Carcinogenesis, sponsored by Society for Risk Analysis, 1986.

A Regulator's Viewpoint, Workshop on Risk Assessment, sponsored by The Procter and Gamble Co., 1986.

Risk Assessment, Sensitivity Analysis, GMA Technical Committee Food Protection Meeting, Grocery Manufacturers of America, 1986.

Update on Current Approaches in Addressing Threshold of Regulations and DeMinimus Risk, Toxicology Forum, Winter Meeting, 1986.

Toxicity Update on BHA/BHT, Toxicology Forum, Aspen Meeting, 1985.

Food Regulatory Issues, Washington Chemical Society, 1984.

Issues in Decision Making, Interdisciplinary Discussion Group in Carcinogenicity Studies, sponsored by ILSI, 1986.

Recent Developments in Risk Assessment, Medical Issues in Toxic Tort Cases: Risk Assessment, Cancer, and Immunological Injuries, sponsored by the American Bar Association, 1987.

Replacement of the LD_{50} Tests at the Food and Drug Administration, Workshop on Alternative Tests, sponsored by Mobil Oil, 1987.

Risk Assessment/Oncology and Regulatory Issues, The American College of Toxicology, Annual Meeting, 1987.

The Need for Situational Analysis and Scientific Judgment in Assessing the Risk from Chemical Carcinogens, New York Academy of Sciences, 1987.

Summary of "Workshop on the Role of Liver Enzyme Induction in Carcinogenesis and Drug Interaction", sponsored by Merk, Sharp and Dohme Laboratories, 1988.

Issues and Directions for the Future, Society for Risk Analysis, Annual Meeting, 1988.

Pros and Cons of Quantitative Risk Analysis, Institute for Food Technology, Basic Symposium, 1988.

Threshold of Regulation for Indirect Food Additives, Workshop on DeMinimus Risk, 1985.

Possible Mechanisms of BHA Carcinogenicity in the Rat, Food Antioxidants: International Perspectives, sponsored by ILSI, 1986.

In Vitro Toxicology, General Principles and Concepts in Toxicology and Toxicologic Pathology, Course sponsored by University of Cincinnati, 1987.

Risk Assessment in Product Regulation, Prevention 85, sponsored by the American College of Preventive Medicine, 1985.

Establishment of Acceptable Limits of Intake, Second National Conference for Food Protection, 1984.

Use of Short-Term Test Data in Cancer Risk Assessment, Society of Toxicology Annual Meeting (Course), 1988.

Critical Assessment of Carcinogen Risk Policy, International Society of Regulatory

Toxicology and Pharmacology, 1988.

The Food and Drug Administration Procedures and Policies to Estimate Risks of Injury to the Male Reproductive System, Sperm Measures and Reproductive Success, sponsored by Georgetown University, 1988.

Risk Assessment of Food and Color Additives, United States-Japan Workshop on Risk Assessment/Risk Management sponsored by The Environmental Protection Agency and Osaka University, 1988.

How Molecular Data is Used in Risk Assessment, Banbury Conference on New Directions in the Quantitative and Qualitative Aspects of Carcinogen Risk Assessment, 1988.

How has the Delaney Clause Impacted on The Food and Drug Administration and Public Health, Food and Drug Law Institute Symposium on The Delaney Clause, 1988.

Presentations at the Toxicology Forum 1989-1994.

American College of Toxicology – Annual Meeting – "Does the Term Carcinogen Send the Wrong Message", Dec. 1998.

PUBLICATIONS:

Shirkey, H.C., Schmidt, G.C., Miller, R.G., and Flamm W.G., "Animal Sera and Specific Enzymes in the Treatment of Poisoning", Journal of Pesticides, 60:711, 1962.

Flamm, W.G., and Crandall, D.I., "Evidence for the Existence of Ferrous Mercaptans in the Active Center of Homogentisate Oxidase", Federation Proc., 21:250, 1962.

Flamm, W.G., and Crandall, D.I., "Purification of Mammalian Homogentisate Oxidase and Evidence for the Existence of Ferrous Mercaptans in the Active Center", J. Biol. Chem., 238:389, 1963.

Flamm, W.G., "Purification of Homogentisate Oxidase and an Investigation of its Properties and Active Center", Dissertation Abstracts, 23:1503, 1962.

Flamm, W.G., Birnstiel, M.L., and Filner, P., "Protein Synthesis in Isolated Nuclei of Exponentially Dividing Cells", Biochem. Biophys. Acta., 76:110, 1963.

Flamm, W.G., and Birnstiel, M.L., "Studies on the Metabolism of Nuclear Basic Proteins in Nucleohistones," In: Bonner, J., and Ts'o, P. (Ed.): The Nucleohistones, San Francisco,

Holden-Day, Inc., 1964, pp. 230-41.

Flamm, W.G., and Birnstiel, M.L., "Nuclear Synthesis of Ribosomes in Cell Cultures", Biochem. Biophys. Acta., 87:101, 1964.

Flamm, W.G., and Birnstiel, M.L., "Inhibition of DNA Replication and its Effect on Histone Synthesis", Experimental Cell Research, 33:616, 1964.

Birnstiel, M.L., Chipchase, M.I.H., Flamm, W.G., "The Chemical Composition and Organization of Nucleolar Proteins", Biochem. Biophys. Acta., 87:111, 1964.

Nicholson, M., and Flamm, W.G., "The Fate of Functional Ribosomes in Tobacco Cell Cultures", Federation Proc., 23:316, 1964.

Birnstiel, M.L., and Flamm, W.G., "On the Intranuclear Site of Histone Synthesis", Science, 145:1435, 1964.

Flamm, W.G., and Nicholson, M., "Synthesis of RNA in Cultured Tobacco cells", Biology, Pasadena, California Institute of Technology, 1964, pp. 136-41.

Nicholson, M., and Flamm, W.G., "Properties and Significance of Free and Bound Ribosomes from Cultured Tobacco Cells", Biochem. Biophys. Acta., 108:266, 1965.

Flamm, W.G., Counts, W.B., and Banerjee, M.R., "Inhibition of RNA Synthesis in Mouse Skin by actinomycin D and 7,12-dimethylbenz(a)anthracene", Nature, 210:541, 1966.

Flamm, W.G., Banerjee, M.R., and Counts, W.B., "Topical Application of Actinomycin D on Mouse Skin: Effect on the Synthesis of RNA and Protein", Cancer Research, 26:1349, 1966.

Counts, W.B., and Flamm, W.G., "An Artifact Associated with the Incorporation of Thymine into DNA Preparations", Biochem. Biophys. Acta., 114:628, 1966.

Flamm, W.G., Counts, W.B., and Bond, E., "Conversion of 23S to 16S RNA: Evidence of Heterogeneity within the 23S Fraction", Abstracts Biophysical Society, 10:7, 1966.

Banerjee, M.R., Flamm, W.G., and Counts, W.B., "Effect of Actinomycin D on RNA and Protein Synthesis in Mouse Skin", Proc. of the Amer. Assn. for Cancer Research, 7:5, 1966.

Bond, E., Flamm, W.G., and Burr, H.E., "Intracellular Location and Metabolism of Satellite DNA in Mouse Liver", American Zoologist, 6:308, 1966.

Flamm, W.G., Bond, E., and Burr, H.E., "Density Gradient Centrifugation of DNA in a Fixed-

Angle Rotor: A Higher Order of Resolution", Biochem. Biophys. Acta., 129:310, 1966.

Flamm, W.G., Bond, E., Burr, H.E., and Bond S., "Satellite DNA Isolated from Mouse Liver: Some Physical and Metabolic Properties", Biochem. Biophys. Acta., 123:652, 1966.

Bond, E., Flamm, W.G., Burr, H.E., and Bond, S., "Mouse Satellite DNA: Further Studies on its Biological and Physical Characteristics and its Intracellular Localization", J. Mol. Biol., 27:289, 1967.

Flamm, W.G., McCallum, M., and Walker, P.M.B., "The Isolation of Complementary Strands from a Mouse DNA Fraction", Proc. Natl. Acad. Sci., 57:1729, 1967.

Flamm, W.G., McCallum, M., and Walker, P.M.B., "Isolation of Complementary Strands from Mouse Satellite DNA", Biochemical J., 104:38-9, 1967.

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CONSULTING GROUP

JAMES W. BARNETT, JR., Ph.D., DABT

SENIOR REGULATORY CONSULTANT

Senior Regulatory Consultant-AAC Consulting Group

KEY RESPONSIBILITIES

- Preparing and submitting food additive notifications to FDA including GRAS determinations and food contact notifications
- Drafting qualified health claim petitions on foods and dietary supplements
- Designing preclinical study packages, placing and managing multiple preclinical studies on drugs for IND submission
- Negotiating with CDER on study plans and designs
- Providing regulatory advice and opinions on FDA compliance for indirect food additives
- Conducting toxicology reviews and safety assessments of dietary supplement products
- Regulatory advice on drug excipient acceptability and use
- Consulting on various regulatory issues regarding FDA, CPSC, EPA and USDA

Group Manager, Burdock Group

KEY RESPONSIBILITIES

- Supervised a professional staff of 4 Ph.D./M.D. staff and the technical support staff of 4 persons.
- Assigned and reviewed the work product of staff prior to submission to clients
- Prepared draft bids on new work.
- Wrote toxicology reviews and GRAS determination documents for multiple food additives.
- Reviewed regulatory compliance on multiple food polymers and additives.
- Prepared environmental impact assessments for drugs subject to FDA approval.
- Worked with clients on food adulteration issues with FDA and USDA and on toxicological assessments of components of drug delivery devices.

Consulting Toxicologist– Tex-Tox

KEY RESPONSIBILITIES

- Provided toxicology consulting services to industrial and legal clients.
- Involved in developing hazard/risk communication documents that are used to maintain workplace safety for industrial clients.
- Risk assessments were conducted for clients to evaluate the potential hazard of industrial site emissions.
- For the legal community, case evaluations were provided by reviewing the medical literature and providing opinions on the likelihood of adverse effects given the exposure situation and

chemicals involved.
- Strategic advice on case management and site sampling were also provided.
- Other services include toxicology study management, regulatory analysis, and writing technical papers for publication.

Senior Scientist – Radian Corporation

KEY RESPONSIBILITIES
- Serve as a project director for multi-media, multi-pathway human health risk assessments for CERCLA/RCRA hazardous waste sites at government and commercial facilities.
- Directed the design, conduct and reporting of the health risk assessments through project teams of statisticians, hydrogeologists, biologists, and other staff.
- Involved as project director for establishing a methodology for deriving acceptable short-term air action levels around Superfund sites for multi-agency government peer review work group.
- Worked on a model to derive appropriate cleanup levels or standards at facilities/hazardous waste sites according to the probable future land use at the various sites.
- Provided toxicology expertise to a variety of projects including air risk assessments, litigation, and toxicity factor evaluations.
- Met with regulatory officials to discuss the parameters for conduct of human health risk assessments.

Manager, Environmental Risk Assessment – Monsanto Company

KEY RESPONSIBILITIES
- In addition to the responsibilities listed for the position of Environmental Toxicology Manager, which are cited below, I was responsible for toxicological and scientific support for mammalian/environmental health risk assessments including risk assessments related to hazardous waste sites, air, and water emissions at Superfund sites.
- Worked closely with operating unit environmental, engineering, regulatory, and health groups throughout the company and provided scientific liaison with outside experts and consulting firms in the environmental/health risk assessment area.
- Provided scientific support to foster government acceptance of risk assessments.

Manager, Product Safety – Monsanto Company

KEY RESPONSIBILITIES
- As Manager, Product Safety in the Chemical Group, I had multiple responsibilities to assure product stewardship and regulatory compliance for two business divisions.
- Advising the business groups and customers on TSCA, RCRA, Clean Air and other laws and regulations for assigned product lines.
- Directed new product development and registration under TSCA.
- Participated in several trade group panels concerned with Section 4 test rules and regulatory matters and served on the divisional business boards to advise on environmental issues.

Environmental Toxicology Manager – Monsanto Company

KEY RESPONSIBILITIES

- Responsible for assessing the potential health risks for process emissions, catastrophic release, waste streams and contaminated sites.
- My scientific expertise in risk assessment practice for the major environmental laws, RCRA, CERCLA, SDWA, TSCA, etc., was applied in regulatory interactions for various activities.
- Provide toxicology and health effects judgments, which were utilized in regulatory negotiations regarding site assessment, remediation and multi-source emission assessments.
- Technical support was integrated into engineering planning for waste minimization or disposal.
- Additional proactive support in the risk assessment area was exercised by identifying critical issues in the government regulatory programs and responding with technical comments or internal strategic direction for enhancing risk assessment procedures.
- These activities have resulted in numerous successful outcomes in regulatory interactions.
- Participant in several industry panels including the CMA Risk Assessment Task Group, AIHA Emergency Response Planning Committee, and in international toxicology working group.
- Other active areas of interest include exposure assessment, sediment quality issues and expert systems for risk assessment.

Senior Product Toxicology Specialist – Monsanto Company

KEY RESPONSIBILITIES

- As a senior toxicologist, in addition to the Monsanto duties below, I was responsible for reviewing the published literature and interacting with industrial hygienists, occupational physicians and appropriate governmental agencies to assure the acceptability of product manufacture and use.
- Preparation and/or review of numerous documents concerning the safety and toxicity of intermediates and products and, in conjunction with the industrial hygienists and occupational physicians, for the establishment of permissible workplace exposure limits.
- I gained experience in utilizing toxicology data in conjunction with human exposure data in order to assess, both qualitatively and quantitatively, the chronic and oncogenic risks associated with the manufacture and/or use of various products.
- My responsibilities also included liaison activities with joint industry panels.
- Served as the technical chairman overseeing an extensive TSCA Section 4 test rule study of environmental fate, aquatic toxicology and human health effects.
- Representative to three other panels, one an international group that conducts joint testing on rubber chemicals. I have had direct participation in the pre-clinical testing and submissions for successful registration with FIFRA, EPA, and OECD PMN authorities. In this capacity, I have interacted with staff at EPA, DOT, NTP and other governmental agencies.

Product Toxicology Specialist – Monsanto Company

KEY RESPONSIBILITIES

- As a toxicology specialist, I was responsible for all facets of toxicology related to the product groups assigned to me as the interface between the business divisions and the technical or regulatory groups.
- It was my responsibility to comprehensively evaluate both existing and potential new products or intermediates to determine whether they would adversely affect human health or the environment. This evaluation includes planning and designing, initiating, monitoring, evaluating, and summarizing a wide variety of toxicology studies.
- Direct responsibility for over 200 studies including acute oral, dermal and inhalation toxicity;

eye and skin irritation; dermal sensitization, aquatic toxicity; subchronic oral, dermal and inhalation toxicity; chronic toxicity/oncogenicity; reproduction/fertility; teratology; in vitro and in vivo mutagencity; metabolism/pharmacokinetic studies and special research designs such as DNA adducts, cell and peroxisome proliferation.

Toxicologist – Gulf South Research Institute

KEY RESPONSIBILITIES

- At Gulf South Research Institute, I was a toxicologist and study director responsible for design, conduct, review, and reporting of studies and findings for research proposals.
- Served as study director on several chronic bioassays to rodents for commercial sponsors.
- Served as study director on two generation rodent reproduction studies and an evaluation of a contraceptive implant in portions of in-life technical examinations, monitored animal health and was responsible for the overall study conduct and performance.
- Evaluated data from these studies in progress and proposed study data modifications to enhance the scientific validity of the results.

Post-Doctoral Fellow – University of California

- As a post-doctoral fellow at the University of California at Irvine, I was involved in research in cell biology using laser microbeams for microsurgery and microinjection of cells with fluorescent-labeled cytoskeletal proteins.

EDUCATION

Ph. D., Environmental Toxicology, University of Texas Medical Branch, 1980
M.S., Biology, West Texas State University, 1976
B.A.& S., Biology, University of Texas, 1972

CERTIFICATION

Diplomate, American Board of Toxicology

PROFESSIONAL AFFILIATIONS

American Board of Toxicology
Society of Toxicology

REGULATORY AND TOXICOLOGY CONSULTING SERVICES

Preclinical Safety Study Design and Conduct for Drug Registration

FDA Regulatory Compliance Assessment

GRAS (Generally Recognized as Safe) Determinations on Food Additives

Indirect Food Contact and Packaging Issues

Food Contact Notifications

Food Safety and Contamination Assessments

Qualified Health Claim Petitions

Scientific Support Documents on Dietary Supplements

Environmental Impact Assessments or Waivers on Drugs

Human Health Risk Assessment

Expert Witness in Toxicology

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Proprietary Technical Reviews and Reports
Author of several hundred reviews on the toxicology of industrial chemicals and food additives provided to multiple clients.

CURRICULUM VITAE

STANLEY M. TARKA, JR.

Home Address: 210 N.Old Stone House Road: (717) 243-9216
Carlisle, Pennsylvania 17015
Email: Tarkagroup@comcast.net

ACADEMIC APPOINTMENTS

1984 to Present: Adjunct Associate Professor of Pharmacology
The Pennsylvania State University
College of Medicine
Hershey, PA

1994 to Present: Adjunct Associate Professor of Nutrition
The Pennsylvania State University
Nutrition Department
University Park, PA

EXECUTIVE PROFILE:

R&D Management/Science and Technology/Scientific and Regulatory Consultation

A proven leadership record with extensive experience in basic and applied research and development with emphasis on the nutrition and safety of food ingredients, processes, and consumer brands. Demonstrated expertise encompasses the fields of R&D, Technical Facilities Design and Renovation, Product Development and Technical Services, Regulatory and Scientific Affairs, and New Business Development including 28 years with a Fortune 500 company and five years of Private Consultation Practice. Proven and demonstrated success and experience in the building and management of customer-focused high performing organizations, technical support to all sectors of the Corporation and in gaining regulatory approval for food ingredients and product labeling and claims. Also, have previously assumed lead role in the interaction with U.S. and international regulatory authorities plus familiarity with FDA, EPA, and CODEX ALIMENTARIUS regulations. Highly skilled in establishing partnerships and alliances in the identification and successful development of new food ingredient and technology initiatives.

BUSINESS EXPERIENCE:

2002-Present: President, The Tarka Group, Inc.

Scientific and Regulatory Consultants
Carlisle, PA

Foods, Food Additives and Dietary Supplements Experience and Practice

Provide Expert scientific and regulatory consultation to the food, nutrition, beverage, chemical and pharmaceutical companies in areas relating to Research and Development of new products, processes and technologies, new product design and execution, technical organization design and effectiveness, confectionery and chocolate processing and technology, ingredient safety assessments, crisis management, critical scientific reviews and pre-market consultation with clients on strategies for ingredient regulatory approval and usage, Expert Testimony, Pre-Market GRAS consultations with FDA's Office of Food Additive Safety and Office of Nutritional Products and Labeling, Selection of Food Safety Experts and formation of Expert Panels for GRAS Assessments, self-GRAS Reviews, Health Claims and Qualified Health Claim Petitions, Structure and Function Claims for conventional foods and dietary supplements, pre-clinical and clinical design and management of Clinical Trials to assess efficacy and safety of compounds including foods and food components in support of GRAS Safety Assessments, GRAS and New Dietary Ingredient Notification preparations and submissions to FDA.

Roster Member of FAO/WHO Joint Expert Committee on Food Additives (JECFA) -4 year appointment (2003-2007). Also, a reviewer of manuscripts for Food and Chemical Toxicology and American Society for Nutritional Sciences (Journal of Nutrition) and European Journal of Nutrition

Prior Professional Positions and Experience

1974 to Jan-2002: Hershey Foods Corporation

1991-2002 **Senior Director Food Science and Technology**

Had responsibility for all basic and applied R&D and support of product development, product improvements, and new ingredients including safety evaluations, new technologies that resulted in product plus attributes, quality improvements, and cost savings. Provided technical support/testing for all incoming ingredients to be used in Manufacturing. Experienced in restructuring and consolidation of technical laboratories and in major facility construction/renovations to accommodate staff. Management responsibility for technical staff of 112 people, including directing all research programs.

Worked closely with Marketing, Manufacturing, Quality & Regulatory Compliance, Sales, Legal, Public Relations, Commodities, Government Relations, Packaging, and Senior Management on special projects.

Externally, represented the Corporation as key technical liaison/representative/ spokesperson in CODEX meetings, trade associations, lead technical partnering alliances, and efforts to survey competitive landscape.

Had responsibility for administration of Centers of Excellence in dairy, chocolate, confectionery fats, and nutmeats, resulting in millions of dollars in product and operational improvements to operating units. Some recent examples of these successes include alternate sources of dairy ingredients, leading the efforts in an external partnership to gain regulatory approval of PGPR (an emulsifier used in chocolate allowing for fat reduction), and development of a line of high oleic acid peanuts whose use in peanut products results in extending the product shelf life from six to 12 months.

Recent product successes included supporting and leading developmental efforts for the launch of Reese's FAST BREAK®, REESESTICKS® with novel antibloom agent, Jolly Rancher Fruit Chews, lollipops and filled licorice, successful toppings and mixes, the integration of Nabisco's technology for Breath Mints and Life Savers gums, the launch of HERSHEY'S Reduced Fat Semi-Sweet Baking Chips (50% fat reduced) with Salatrim, HERSHEY'S HUGS and HUGS with Almonds, HERSHEY'S Cookies 'N Creme, the development of chocolate formulas for use by Hershey International, reduced calorie Chocolate Syrup with acesulfame-K, sucralose & aspartame, a line of reduced calorie and fat chocolate bars called HERSHEY'S Sweet Escapes, aseptic beverages, flavors (including internal development), and use of alternative sources of nutmeats. (Geographic)

1990 to 1991: **Director, Product Development**

One year Cross Functional Training Assignment with responsibilities for all technologists in Dairy Technology, Cereal Chemistry, Pasta, Chocolate and Confectionery, Packaging, and Sensory evaluations in the development of new products. Successful products developed during this time include: KISSES with Almonds, NUTRAGEOUS, Cookies 'N Mint, and lead the team efforts to develop a heat resistant chocolate (DESERT BAR) for Gulf War use within 10 weeks from benchtop to Saudi Arabia.

1983 to 1989: **Director, Food Science and Nutrition**

Had responsibility for all research activities in Analytical Research, Laboratory Services, Microbiology Research, Nutrition Research, Biochemistry Research, Biotechnology, Toxicology, Nutrition Affairs, Ingredients Research, and Process Research.

Also responsible for directing the basic and applied research activities of a staff of 60 scientists and managing their administrative budgets. Served as

the Corporate spokesperson on food safety issues, as well as the internal resource for ensuring compliance with regulatory requirements in the Food Industry. Also, actively involved in research on the pharmacological and toxicological properties of cocoa powder and theobromine in experimental animals and man. Responsibilities also included working closely with other Directors in the areas of Product Development, New Product Planning, and Exploratory Technology to successfully develop scientific information which was used to support new product introductions as well as technology decisions for new manufacturing facilities.

1980 to 1983: **Manager, Life Sciences**

Responsible for all nutritional, toxicological, food safety, and animal research within the Corporation. This involved complete coordination of personnel and research projects in the evaluation of the components of existing and new products for the consumer market. Additionally, as Radiation Safety Officer for the Corporation, had responsibility for purchasing, monitoring, and controlling all radioactive materials within the organization, for the evaluation of potentially hazardous effects, while coordinating and complying with all regulatory agencies.

1977 to 1980: **Group Leader, Nutritional Sciences**

Responsible for all research relating to nutritional and food safety issues of corporate products. This involved monitoring regulatory affairs, as well as the design and implementation of extensive projects to evaluate nutritional quality of current and future products, use of corporate by-products as foodstuffs, effects of processing on nutritive value, and detailed toxicological evaluation of naturally occurring alkaloids in cocoa.

1974 to 1977: **Supervisor, Animal Research**

Responsible for conducting all corporate nutritional and toxicological research. This research involved examining various toxicological, biochemical, and pathological parameters as influenced by nutritional status.

1973 to 1974: **Analytical Biochemist**
Velsicol Chemical Corporation
Chicago, IL

Conducted research on the metabolism of organophosphorus pesticides and herbicides in various crops and animal tissues, and was involved in the metabolic screening of potentially new products.

EDUCATIONAL BACKGROUND

1971 Bachelor of Arts (with honors)
West Virginia University
Major: Zoology
Minor: Chemistry

1973 Master of Science
West Virginia University
Major: Biochemistry
Minor: Nutrition

M.S. Thesis: "The Influence of Taurine and Its Metabolites on Calcium Metabolism"

1980 Doctor of Philosophy
The Pennsylvania State University
Major: Food Science (emphasis Food Toxicology)
Minor: Nutrition

Ph.D. Dissertation: "A Toxicological Evaluation of Foods Containing Methylxanthines with Emphasis on Cocoa"

PROFESSIONAL ASSOCIATIONS / PROFESSIONAL MEMBERSHIP

- American College of Toxicology (ACT)-full member
- American Society for Nutritional Sciences (ASNS)-full member
- American Society for Pharmacology and Experimental Therapeutics (ASPET)-full member
- Institute of Food Technologists-full member
- American Chemical Society-full member
- Society of Toxicology (SOT)-full member

Member - Society of Toxicology Technical Committee 1984-85

- American Association for the Advancement of Science-full member
- Former Representative-Corporate Executive Board; Research & Technology Executive Council
- Former Technical Representative-Grocery Manufacturers Association (GMA)
  - Technical Committee issues - Food Safety, Hypersensitivity, etc.
- International Food Information Council (IFIC)
  Former Board Member representing Hershey Foods
- International Life Sciences Institute-Nutrition Foundation (ILSI-NF)
  - Former Member - Food, Nutrition, and Safety Committee; Oral Health Committee;
  - Proposition 65 Committee; Caffeine Committee
- International Society of Regulatory Toxicology and Pharmacology (ISRTP)-(Reviewer)
- Joint Institute for Food Safety and Applied Nutrition (JIFSAN)

Advisory Group 1999-2001

- University of Pennsylvania School of Dental Medicine, Philadelphia, PA
  Board of Overseers 1991-93
- World Cocoa Foundation; Founding Board Member (2001)
- American Cocoa Research Institute (ACRI), Chairman, Scientific Committee

PATENTS /PUBLICATIONS

Co-inventor on six patents relating to ingredients and processes.
Senior author/co-author on over 40 internationally peer reviewed scientific publications

RESEARCH INTERESTS

Toxicology and pharmacology of the methylxanthines, protein bioavailability in various plants and processed foods, and fetal growth and development as influenced by nutritional status, cariogenic potential of various foods and novel food and flavor components. The establishment of safety and efficacy and application of novel food components in nutraceutical/conventional food preparations is an area in which I am also actively involved.

PATENTS

U.S. Patent No. 4,070,487 (1978). Method of Stimulating Appetite in Ruminants and Ruminant Feed Containing Appetite Stimulant. G.A. Trout, B.L. Zoumas and S.M. Tarka, Jr.

U.S. Patent No. 5,219,573 (1993). L-Sugar Laxatives. S.M. Tarka, Jr., C.A. Shively, J.L. Apgar, and K.L. Koch.

U.S. Patent No. 5,464,649 (1995). Reduced Fat Confectionery Products and Process. J.F. St.John, J.G. Fetterhoff, J.R. Carpenter, B.D. Brown, C.D. Azzara, S.M. Tarka, Jr., C.N. Rank, and G.K. Strohmaier.

U.S. Patent No. 5,709,903 (1998). Reduced Fat Confectionery Products and Process. J.F. St.John, J.G. Fetterhoff, J.R. Carpenter, B.D. Brown, C.D. Azzara, S.M. Tarka, Jr., C.N. Rank, and G.K. Strohmaier.

U.S. Patent No. 5,837,227 (1998). Use of Cocoa Butter or Partially Hydrolyzed Cocoa Butter for the Treatment of Burns and Wounds. B.L. Zoumas, S.M. Tarka, Jr., J.M. McKim, B.J. Simmons, J.G. Marks, Jr., and M. Santanna.

U.S. Patent No. 5,849,729 (1998). Use of Hydrolyzed Cocoa Butter for Percutaneous Absorption. B.L. Zoumas, S.M. Tarka, Jr., J.M. McKim, B.J. Simmons, J.G. Marks, Jr., and M. Santanna.

PUBLICATIONS

Martin, G.G., Sass, N.L., Hill, L., Tarka, S.M. and Truex, C.R., The Synthesis of Taurine from Sulfate. IV. An Alternate Pathway for Taurine Synthesis in the Rat. Proc. Soc. Exptl. Biol. Med. 141(2): 632, 1972.

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Tarka, S.M., Jr., Zoumas, B.L. and Trout, G.A., Examination of the Effect of Cocoa Shells and Theobromine in Lambs. Nutritional Reps. Intl. 18(3): 301-312, 1978.

Tarka, S.M., Jr., Zoumas, B.L. and Gans, J.H., Nutritional Pharmacology and Toxicology of Theobromine: Short-Term Effects of Graded Levels of Theobromine in Laboratory Rodents. Toxicol. Appl. Pharmacol. 49: 127-149, 1979.

Tarka, S.M., Jr., Zoumas, B.L. and Gans, J.H., Effects of Continuous Administration of Dietary Theobromine on Rat Testicular Weight and Morphology. Toxicol. Appl. Pharmacol. 58: 76-82, 1981.

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Miller, G.E., Radulovic, L.L., DeWit, R.H., Brabec, M.J., Tarka, S.M., Jr., Cornish, H.H., Comparative Theobromine Metabolism in Five Mammalian Species, Drug Metabolism and Disposition, 12(2): 154-160, 1984.

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Hurst, W.J., Martin, R.A., Jr., Tarka, S.M., Jr., Analytical Methods for Quantitation of Methylxanthines. Progress in Clinical and Biological Research, Methylxanthine Containing Beverages and Foods, Vol. 158, 1984.

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Shively, C.A., Apgar, J.L., Tarka, S.M., Jr., Postprandial Glucose and Insulin Responses to Various Snacks of Equivalent Carbohydrate Content in Normal Subjects. American Journal of Clinical Nutrition, 43: 355-342, March, 1986.

Brusick, D., Myhr, B., Galloway, S., Rundell, J., Jagannath, D.R., Tarka, S.M., Jr., Genotoxicity of Theobromine in a Series of Short-Term Assays. Mutation Research, 169: 105-114, 1986.

Brusick, D., Myhr, B., Galloway, S., Rundell, J., Jagannath, D.R., Tarka, S.M., Jr., Genotoxicity of Cocoa in a Series of Short-Term Assays. Mutation Research, 169: 115-121, 1986.

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Tarka, S.M., Jr. and Shively, C.A., Methylxanthines. Toxicological Aspects of Food (K. Miller, Ed.), Elsevier Applied Science Publishers, Ltd., London, 1987.

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Hurst, W.J., Martin, R.A., Jr., Tarka, S.M., Jr., Investigations of the Composition of Urinary Calculi by Fourier Transform-Infrared Spectroscopy. Spectroscopy, 4(4): 56-58, 1989.

Hurst, W.J., Martin, R.A., Jr., Tarka, S.M., Jr., Hall, G.D., Authentication of Cocoa in Maya Vessels Using High-Performance Liquid Chromatographic Techniques. Journal of Chromatography, 466: 279-289, 1989.

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Hostetler, K.A., Morrissey, R.B., Apgar, J.L., Shively, C.A., Tarka, S.M., Jr., Three Generation Reproductive Study of Cocoa Powder in Rats. Food and Chemical Toxicology, 28(7): 483-490, 1990.

Hall, G.D., Tarka, S.M., Hurst, W.J., Stuart, D. and Adams, R.E., Cacao Residues in Ancient Maya Vessels from Rio Azul, Guatemala. American Antiquity 55(1): 138-143, 1990.

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Apgar, J.L. and Tarka, S.M., Jr., Chocolate & Cocoa Health and Nutrition, Chapter 10 – Methylxanthines, (I. Knight, Ed.), Blackwell Science, Ltd., Oxford, 1999.

Hurst, W.J., Tarka, S.M., Jr., Dobson G, and Reid, C.J., Determination of Conjugated Linoleic Acid (CLA) Concentrations in Milk Chocolate, J. Agric. Food Chemistry, 49(3): 1264-1265, 2001.

Powis, T.G., Valdez, F., Jr., Hester, T.R., Hurst, W.J., and Tarka, S.M., Jr., Spouted Vessels and Cacao Use Among the Preclassic Maya, Lat. Am. Antiquity, 13(1): 85-106, 2002.

ABSTRACTS

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Martin, W.G., Tarka, S.M. and Robeson, B.L., The Relationship of Taurine to Ion Movement in the Growing Chick and Rat. J. Nutri. 109(6): 26, 1979.

Cornish H., Brabec, M., Tarka, S., Miller, G., Radulovic, L. and DeWit, R. A Comparative Study of the Metabolism of Theobromine in Mammalian Species. The Toxicologist, 1(1): 110, 1981.

Tarka, S.M., Jr., Keeney, P.G. and Borzelleca, J.F., A Comparison of the Effects of Methylxanthine-Containing Foodstuffs on Reproductive Capability in Rats. The Toxicologist, 1(1): 147, 1981.

Tarka, S.M., Jr., Keeney, P.G., and Borzelleca, J.F., The Effect of Pretreatment with Dietary Cocoa on Growth and Reproductive Performance in Young and Adult Rats. Fed. Proc. 40(3): 668, 1981.

Tarka, S.M., Jr., Morrissey, R. B., White, D.M. and Burkholder, B.D., Lack of Effects Due to Subchronic Feeding of Graded Levels of Cocoa Butter to Rats. Fed. Proc. 41(3): 773, 1982.

Tarka, S.M., Jr. and Shively, C.A., Theobromine Metabolism and Pharmacokinetics in Pregnant and Nonpregnant Female Rats. The Toxicologist, 2(1): 79, 1982.

Tarka, S.M., Jr. and Zoumas, B.L., Subchronic and Oral Toxicity Evaluation of Cocoa Powder and Theobromine in Sprague-Dawley Rats. The Toxicologist, 3(1): 4, 1983.

Shively, C.A., White, S.M., Blauch, J.L. and Tarka, S.M., Jr., Evaluation of Theobromine in Dominant Lethal Testing in Rats. The Toxicologist, 3(1): 31, 1983.

Shively, C.A. and Tarka, S.M., Jr., Effects of Dietary Theobromine, Caffeine and Cocoa Powder on Endocrinological and Growth Parameters in the Rat. ASPET, 1983.

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White, D.M., Shively, C.A., and Tarka, Stanley M., Jr., Effects of Dietary Fiber on Theobromine Absorption, Metabolism, and Toxicity in the Rat. The Toxicologist, 5(1): 146, 1985.

INVITED PRESENTATIONS

1983 - First International Conference on Cocoa Powder and Theobromine, Vevey, Switzerland. Co-sponsored by the U.S. Chocolate Manufacturers Associates and the International Office of Cocoa and Chocolate.

1984 - ILSI-NF Fifth International Caffeine Workshop, Cancun, Mexico.

1989 - ILSI-NF Sixth International Caffeine Workshop, Hong Kong.

1990 - Participated on World Health Organization "International Agency for Research - Cancer Working Group - Evaluation of Coffee, Tea, Mate, Caffeine, Theobromine, Theophylline, and Methyl Glyoxal," Lyon, France.

2003- Invited Lecture on "The View from the USA" at a conference on Chocolate, Chocolate Fats and the EU Directive in York, UK at the Central Science Laboratory May 21-22, 2003

AWARDS/RECOGNITION

Personal letter of recognition and appreciation from General Norman Schwarzkopf for development efforts on Desert Bar® and product for troops of Operation Desert Storm.

President's Team Award, Hershey Chocolate North America:

- Development and successful launch of KISSES with Almonds®, 1991
- Development and successful launch of HUGS® and HUGS with Almonds®, 1993
- Development and successful launch of HERSHEY'S Reduced Fat Baking Chips (first commercial product in the market with Salatrim), 1995

Executive Award of Excellence:

- Development and use of high oleic peanuts as an ingredient, Silver Award - Application of Technology, 1997
- Development and commercialization of two new Nuggets products, Silver Award - Communication/BDP Application, 1997
- Regulatory clearance and usage of PGPR in Chocolate, Gold Award – Application of Technology, 1999
- Development of new chocolate formula for International, Gold Award – Application of Technology, 2000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

Mark L. Itzkoff
Olsson, Frank and Weeda, P.C.
Suite 400
1400 Sixteenth Street, N.W.
Washington, D.C. 20036

Re: GRAS Notice No. GRN 000167

Dear Mr. Itzkoff:

The Food and Drug Administration (FDA) has received the notice, dated April 1, 2005, that you submitted on behalf of Tyson Foods, Inc. (Tyson) in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS)). FDA received this notice on April 4, 2005, filed it on April 5, 2005, and designated it as GRN No. 000167.

The subject of the notice is carbon monoxide (CO). The notice informs FDA of the view of Tyson that CO is GRAS, through scientific procedures, for use as a component of a modified atmosphere packaging (MAP) system for case-ready fresh beef and pork. The level of CO in this MAP system is 2.2 milligrams (mg) CO per pound (lb) of meat. The other components of the MAP system are carbon dioxide and nitrogen.

Carbon monoxide was also the subject of GRN 000083 submitted by Pactiv Corporation and GRN 000143 submitted by Precept Foods, LLC. These submissions informed FDA that CO is GRAS, through scientific procedures, for use as a component of a gas mixture in a MAP system. The level of CO in Pactiv's and Precept's MAP system is 0.4 percent; other components of this MAP system are carbon dioxide and nitrogen. This packaging system is used for packaging fresh cuts of muscle meat and ground meat to maintain wholesomeness, provide flexibility in distribution, and reduce shrinkage of the meat.

As compared to Pactiv's and Precept's packaging system, Tyson's packaging system is a reduced head space system, and therefore to achieve the same ratio of CO to meat, they use a higher concentration of CO per unit volume. To achieve this end, Tyson states that they will use the concentration of CO necessary to achieve the same ratio of CO to meat (2.2 mg CO per lb of meat) as is used in the Precept and Pactiv systems. For example, a 620 cubic centimeter (cc) package containing 1 lb of ground beef would require a 0.89 percent concentration of CO to achieve the required concentration of CO; a 3000 cc package containing 5 lbs of meat would require 1.19 percent concentration of CO to achieve the required concentration of CO.

As part of GRN 000167, Tyson incorporates GRN 000083 and GRN 000143 by reference, and states that the detailed information establishing the GRAS status of CO in MAP systems is contained in GRN 000083.

GRN 000167 describes publicly available information pertaining to the identity and characteristic properties of CO. Carbon monoxide (Chemical Abstracts Service Registry Number 630-08-0) is a colorless, odorless, gas. The notice includes a list of properties of CO. Tyson uses the specifications in the previous GRAS notices; CO is a minimum purity of 98 percent and the remaining 2 percent are components found in the atmosphere (nitrogen, oxygen, carbon dioxide, argon, water, hydrogen and/or methane). Tyson considers CO of this purity to be "food grade."

Meat is placed on a tray within a chamber, the chamber is then filled with the desired atmosphere, and finally, a barrier film is affixed to the package. The packages are then labeled with a validated open date code at a central location and will be subject to no further processing or manipulation at retail. The open date code established for products packed in the MAP system will not exceed 35 days following the date of packaging for intact muscle cuts and 28 days for ground beef.

Tyson states that the CO is included in the modified atmosphere to help maintain the characteristic color of fresh meat. Tyson states that the CO is not intended to affect microbial growth and will not extend the shelf life of the product.

Tyson estimates that the exposure to CO would be 0.054 mg CO per meal of cooked meat. Tyson first assumes a scenario where the meat absorbs 30 percent of the CO in the package and 100 percent of the CO present in the meat is absorbed by the consumer. A dietary intake of 0.36 mg of CO per meal would occur when 8.8 ounces (250 grams) of meat is consumed. Tyson considers that this estimated intake of CO from its use in packaging meat is small compared to the amount that is presently accepted as a safe exposure limit by the Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA).[1] Tyson then accounts for the fact that meat packaged with CO will be cooked prior to consumption and assumes an 85 percent reduction in CO exposure due to cooking of the meat. This 85 percent reduction decreases the maximum exposure from 0.36 mg to 0.054 mg CO per meal. If 100 percent of the CO in the package is absorbed, and 100 percent of the CO is consumed, an 8.8 ounce serving would expose the consumer to 1.2 mg of CO.

Based on the information that you provide on behalf of Tyson, as well as other information available to FDA, the agency has no questions at this time regarding Tyson's conclusion that CO is GRAS under the intended conditions of use. The agency has not, however, made its own determination regarding the GRAS status of the subject use of CO. As always, it is the continuing responsibility of Tyson to ensure that food ingredients that the firm markets are safe, and are otherwise in compliance with all applicable legal and regulatory requirements.

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[1]EPA's National Ambient Air Quality Standards is 9 ppm CO in air, resulting in the inhalation of 52 mg CO in 8 hours. The OSHA Permissible Exposure Limit is 50 ppm in air, resulting in the inhalation of 290 mg CO in 8 hours.

During its evaluation of GRN 000167, OFAS consulted with the Labeling and Consumer Protection Staff of FSIS regarding the use of CO in meat products. Based on the information submitted by Tyson, FSIS has concluded that the MAP system as described in Tyson's notice, and used under the conditions stated in Tyson's notice, would be acceptable for packaging red meat cuts and ground meat. If you or Tyson have any additional questions, you should direct your inquiry to Dr. Robert Post, Director, Labeling and Consumer Protection Staff, Office of Policy, Program and Employee Development, Food Safety and Inspection Service, 1400 Independence Ave, S.W., Suite 602, Annex, Washington, DC 20250-3700. The telephone number of his office is (202) 205-0279 and the FAX number is (202)205-3625.

In accordance with proposed 21 CFR 170.36(f), a copy of the text of this letter, as well as a copy of the information in your notice that conforms to the information in proposed 21 CFR 170.36(c)(1), is available for public review and copying on the homepage of the Office of Food Additive Safety (on the Internet at http://www.cfsan.fda.gov/~lrd/foodadd.html).

Sincerely,

Laura Tarantino

Laura Tarantino, Ph.D.
Director
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

cc:
Dr. Robert Post, Director
Labeling and Consumer Protection Staff
Office of Policy, Program, and Employee Development
Food Safety and Inspection Service
1400 Independence Ave, S.W., Suite 602, Annex
Washington, DC 20250-3700

GRAS Claim for the Use of Carbon Monoxide In Modified Atmosphere Packaging For Red Meat Products

Submitted by Tyson's Foods, Inc.

April 1, 2005

Section I

GRAS Claim

Tyson's Foods, Inc. hereby submits this GRAS claim for the use of carbon monoxide (CO) in modified atmosphere packaging (MAP) for red meat products.

A. Name and Address of Notifier:

Tyson's Foods, Inc.
2210 Oaklawn Drive
Springdale, Arkansas 72765

B. Common or Usual Name of Substance:

The common or usual name of the substance is carbon monoxide. The Chemical Abstract Services Registration Number (CASRN) for this substance is 630-08-0.

C. Conditions of Use:

In this Notification, CO will be used in Modified Atmosphere Packaging (MAP) packaging for red meat products where the quantity of CO in the MAP gases does not exceed 2.2 mg per pound of packaged meat. This application is the same end use and technical purpose, MAP packaged red meat products, described in GRAS Notices GRASN 83 and 143. This Notice differs only in the concentration of CO in the MAP gas and the quantity of MAP gas in the packaging. As shown in this application, the permissible quantity of CO per pound of beef proposed herein is the same quantity proposed in GRASN 143. Therefore, this notice does not propose any increase in the dietary exposure to carbon monoxide.

In the previous notices, CO was added to the gas mixture used to package red meat. The CO was added to the MAP gases at a concentration not to exceed 0.4% by volume. While the notices did not include limits on the volume of gas per pound of meat, our calculations show that the limit is based on equal volumes of meat and MAP gas.[1] In this application, the volume of MAP gas will decrease allowing for an increase in the concentration of CO in the gas without any increase in the total quantity of CO in the package. Rather than limit the concentration of CO in the gas, we are proposing that FDA limit the quantity of CO so that the potential exposure does not exceed the exposure that would occur under the two previous Notices, 1.2 mg per 8.8 ounce serving of beef (2.2 mg/lb).[2]

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[1] *See* Table 1 in Appendix I.
[2] *See* Agency Response Letter, GRAS Notice No. GRN 000143 (July 29, 2004), http://www.cfsan.fda.gov/~rdb/opa-g143.html.

D. Basis for GRAS Determination:

FDA has previously reviewed the safety of the use of CO in modified atmosphere packaging in two GRAS Notifications, GRASN 83 and 143. The data submitted to FDA in those Notices is hereby included by reference in this Notice.

The use of CO proposed herein will not result in any increased dietary exposure to CO. The dietary exposure will not increase because the potential concentration of CO in red meat packaged using the method described herein will be less than or equal to the levels that are expected to result from the applications detailed in the previous Notices. Since the product packaged using the modified atmosphere gases detailed in this Notice is the same product currently packaged using the gases detailed in the previous Notices, the exposure to CO from this proposed use is already included in the exposure estimates for the previous Notices, *i.e.*, there will be no increase in CO consumption. Since neither the concentration of CO in the processed food nor new applications for CO will result from the use described herein, there will be no increase in total dietary exposure. Therefore, the data used to support the two effective GRAS Notices also demonstrate the safety of CO in this application.

In addition, since the method of exposure to CO, packaging with CO-containing MAP gases, is the same exposure method reviewed previously, the studies previously cited to demonstrate that the use of CO in application will not "mask" normal spoilage of the processed red meat during storage prior to use by consumers also demonstrate that the Tyson Food's method will not mask normal spoilage.

E. **Data Availability Statement:**

The data and information that are the basis for the Notifier's GRAS determination will be sent to FDA upon request.

Respectfully Submitted,

Mark L. Itzkoff
Counsel for Tyson's Foods, Inc.

Section II

Identity of the Notified Substance

The substance that is the subject of this Notice is Carbon Monoxide (CO), a colorless, odorless gas, with the CASRN 630-08-0. A Material Safety Data Sheet for this material is attached in Appendix II.

The specific CO used in this process will be commercial, "food grade" CO. The purity specifications will be the same as those set forth for CO in GRASN 143, *i.e.*, the minimum purity will be 98 percent carbon monoxide while the other 2 percent will be residual atmospheric gases (nitrogen, oxygen, carbon dioxide, argon, water, hydrogen and/or methane). Thus, the use of carbon monoxide set forth herein will not result in the introduction into processed red meat of any materials not previously considered under GRASN's 83and 143.

Section III

Information on Self-Limiting Levels of Use

FDA has previously reviewed the use of carbon monoxide in modified atmosphere packaging where up to 0.4% of CO would be present in the MAP gas and the gas would be used in a package where the volume of the package was twice the volume of the packaged meat, i.e., the volume of the MAP gas is equal to the volume of the packaged meat.[3] As noted in the Agency Response Letter to GRAS Notice No. GRN 000143, Precept, the Notifier in GRN143 estimated that "if 100 percent of the CO in the package is absorbed, and 100 percent of the CO is consumed, an 8.8 ounce serving would expose the consumer to 1.2 mg of CO." Tyson's Foods is proposing to use CO in other packaging configurations where the concentration of CO in the gas will exceed 04% but the ratio of CO to packaged beef will remain the same as in GRASN 143, 2.2 mg per pound.

For example, in one package configuration one pound of beef (454 g) will be packaged in a container with a volume of 620 ml. Assuming the beef has a density of 1.0 g/ml, 1 lb of beef will occupy 454 ml of volume, leaving 166 ml of "headspace" for the MAP gas.

(620 ml package volume) – (454 ml beef volume) = 166 ml headspace

If the concentration of CO in the gas is 1.0 percent by volume, the volume of CO in the package will be 1.66 ml. The density of CO is 1.25 mg/ml, so 1.66 ml of CO is

(1.66 ml)(1.25 mg/ml) = 2.1 mg.

Thus, the ratio of CO to beef will be 2.1 mg per pound, essentially the same as the ratio in GRASN 143 and is small when compared to the level of CO exposure deemed to be safe by the Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA)[4]

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[3] *See* Table 1.

[4] "EPA's National Ambient Air Quality Standards is 9 ppm CO in air, resulting in the inhalation of 52 mg CO in 8 hours. The OSHA Permissible Exposure Limit is 50 ppm in air, resulting in the inhalation of 290 mg CO in 8 hours." FDA, Agency Response Letter GRAS Notice No. GRN 000143, July 29, 2004 (footnote 1).

In the previous GRASN's, both Precept Foods and Pactiv Corporation estimated that 85% of the CO present in the uncooked red meat would volatilize out of the meat during cooking. Using the same estimate, the quantity of CO present in 8.8 ounces of cooked red meat would be:

$$(1.2 \text{ mg})(0.15) = 0.18 \text{ mg}$$

Section IV

Basis for Notifier's Claim

The proposed use of carbon monoxide raises two safety issues: (1) an assessment of the safety of the consumption of CO from the application; and (2) whether the use of CO will "mask" the effect of spoilage organisms on the processed red meat.

The use of CO in the same food products (red meat) is the subject of GRAS Notification 143. The use of CO in this application for beef products was also the subject of GRASN 83. The information referenced in those Notices is hereby included in this Notice by reference. Further, as discussed in Section III, we have demonstrated that the packaging configurations proposed by Tyson's Foods, Inc will not result in any increase in the dietary consumption of carbon monoxide. Since neither the food products nor the potential concentration of CO in those food products will change, the data cited in support of the previous Notifications also demonstrates the safety of carbon monoxide in these packaging applications.

In terms of possible masking of spoilage organisms, the two previous GRAS notices also addressed this issue and found that the use of CO in modified atmosphere packaging did not mask spoilage organisms. The studies discussed in those notices and included by reference in this notice showed that the effect of the CO on the meat, an improvement in the initial meat color, will dissipate before there is significant growth of the spoilage organisms.

In one study conducted by Excel Corporation and submitted to FDA as part of GRASN 143, 3 MAP systems were studied including two containing carbon monoxide and a "control" system containing carbon dioxide and nitrogen. The samples were stored for 5 days at 35°F followed by storage at 50° F. All samples showed similar rates of microbial growth, odor formation and discoloration. Thus the use of CO did not "mask" possible degradation of the packaged beef.

In a study conducted by Hormel and submitted to the agency in GRASN 143, boneless beef strip steaks and top round steaks were packaged in MAP packages and control conditions and stored to simulate retail sale and home storage. Both the CO and control samples were shown to maintain acceptable taste, odor and bacterial levels after 42 days.

Based on the publicly available information previously cited to FDA, Tyson's Foods, Inc. has determined that carbon monoxide is generally recognized as safe when used modified atmosphere packaging where the quantity of CO in the MAP gases does not exceed 2.2 mg per pound of packaged meat.

TABLE 1

Volume Calculation for GRASN 143 Exposure

According to GRASN 143, "if 100 percent of the CO in the package is absorbed, and 100 percent of the CO is consumed, an 8.8 ounce serving would expose the consumer to 1.2 mg of CO." Since the Agency response does not specify the dimensions of the package, we will use this information to calculate the volume of MAP gas to beef ratio.

Using the standard gas volume as 1 mole = 22.4 liter (l) at STP, and since 1 mole of CO is 28 grams (g), we calculate the density of CO gas as:

(28 g)/(22.4 l) = 1.25 g/l = 1.25 mg/ml

If the package contains 1.2 mg CO per 8.8 ounce serving, then a one kg package will contain:

(1.25 mg/8.8 oz)(16 oz/lb)(2.2 lb/kg) = 5.12 mg/kg.

Further, the volume of CO gas will be:

(5.12 mg/kg)/(1.25 mg/ml) = 4.1 ml/kg beef

Since the CO will be only 0.4% of the MAP gas, the total quantity of gas will be:

(4.1 ml)/(0.004) = 1000 ml.

Thus the ratio of MAP gas to packaged beef in GRASN 143 was:

(1000 ml MAP gas)/(1000 g beef) = 1 ml MAP gas/g beef

And, since the density of beef is approximately 1 g/ml,

1 ml MAP gas/g beef = **1 ml MAP/ml beef.**