READY-TO-EAT OR NOT?: EXAMINING THE IMPACT OF LEAFY GREENS MARKETING AGREEMENTS

HEARING

BEFORE THE

SUBCOMMITTEE ON DOMESTIC POLICY

OF THE

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

JULY 29, 2009

Serial No. 111–126

Printed for the use of the Committee on Oversight and Government Reform

Available via the World Wide Web: http://www.fdsys.gov
http://www.oversight.house.gov

U.S. GOVERNMENT PRINTING OFFICE

64–914 PDF WASHINGTON : 2011

For sale by the Superintendent of Documents, U.S. Government Printing Office
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READY-TO-EAT OR NOT?: EXAMINING THE IMPACT OF LEAFY GREENS MARKETING AGREEMENTS

WEDNESDAY, JULY 29, 2009

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON DOMESTIC POLICY,
COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 2 p.m., in room 2154, Rayburn House Office Building, the Honorable Dennis J. Kucinich (chairman of the subcommittee) presiding.

Present: Representatives Kucinich, Jordan, Cummings, and Watson.

Staff present: Jaron R. Bourke, staff director; Jean Gosa, Clerk; Charisma Williams, Staff Assistant; Leneal Scott, Information Systems Manager, full committee; Adam Hodge, Deputy Press Secretary, full committee; Dan Blankenburg, minority director of outreach and senior advisor; Adam Fromm, minority chief clerk & Member Liaison; Ashley Callen, minority Counsel; and Molly Boyl, minority Professional Staff Member.

Mr. KUCINICH. The committee will come to order. I am Congressman Dennis Kucinich, Chair of the Domestic Policy Subcommittee of Oversight and Government Reform. I am joined today by the ranking member of the subcommittee, Mr. Jordan of Ohio.

Today's hearing will examine the safety of ready to eat produce and the successes and challenges posed by the California Leafy Greens Handler Marketing Agreement. For the sake of this hearing we are going to use the acronym CALGMA. When you hear CALGMA, it stands for California Leafy Greens Handler Marketing Agreement. We are going to also be talking about the proposed nationalization of that agreement.

The hearing will focus on bagged or value-added leafy greens marketed as ready to eat. Consumers are quite familiar with those products. We are going to look at the role of private industry and government in regulating these products and the economic, environmental, and food safety impacts of that regulation.

Without objection, the Chair and the ranking minority member will have 5 minutes to make opening statements, followed by opening statements of other Members not to exceed 3 minutes by any Member who seeks recognition.

Without objection, Members and witnesses have five legislative days to submit a written statement or extraneous materials for the record.

Without objection, the chairman and ranking member will each have 10 minutes for questions in the first round, after which we will proceed under the 5-minute rule.

Pre-cut packaged leafy greens marketed as ready to eat have become increasingly popular, capturing 70 percent of the leafy greens market. Americans appreciate the convenience of this partially processed product and are eating more fresh produce as a result. That is a good and important development that will likely help to improve the health of Americans.

Yet as the popularity of bagged lettuce and spinach has increased, so have rare but serious food-borne illnesses associated with it. Outbreaks of E. coli 0157 and other pathogens have occurred in relation to pre-cut packaged leafy greens at least once a year practically every year since 2003.

Regulation to prevent these outbreaks rest in the hands of the industry. The California Leafy Greens Handler Marketing Agreement, CALGMA, was implemented to stave off regulatory action by the State of California. CALGMA ensures adherence to a specified set of good agricultural practices designed primarily by the Food and Drug Administration to improve the safety of leafy greens.

In spite of its name, CALGMA is having an impact on farmers in all parts of the Nation due to the requirement of compliance with CALGMA imposed by national processing and retailing outlets that buy and market their produce.

The USDA is currently proposing the creation of a national marketing agreement along the lines of CALGMA.

There is much good in the CALGMA initiative. CALGMA embodies private industry's positive efforts to safeguard the American food supply. Handlers responsible for growers' compliance with food safety metrics pay for auditors trained by the USDA and hired by the CALGMA Board to carry out surprise and scheduled inspections of standards adopted voluntarily by signatory farmers.

CALGMA, however, has some blind spots as well. It condones a processing activity favored by the ready to eat processing industry known as coring, coring lettuce in the field. It only suggests minimal guidelines for sanitary treatment of harvest equipment used for coring in spite of recent scientific research identifying the potential for transferring pathogens deep into the cored lettuce where the subsequent washing process would be unable to reach.

CALGMA is silent on the use of certain packaging of ready to eat produce known as modified atmosphere packaging, the bags of ready to eat greens.

CALGMA does not require an enforceable standard of cold chain of distribution. It does not impose tough requirements on packagers and distributors relating to the "best consumed by" date that is stamped on the ready to eat packaging. People have seen those. They don't have any tough requirements on those packagers and distributors who put that stamp on there.

Scientists tell us that if bagged produce labeled as ready to eat is not constantly refrigerated through the distribution chain, it quickly becomes a perfect habitat for bacterial growth. Harmful bacteria such as E. coli 0157 multiply unseen to and undetectable by the eye of the consumer. Legions of pathogens can thereby invade the unsuspecting consumers' intestinal tract, overwhelming

his or her immune system and causing severe and painful complications or, in some cases, death. Everyone who has experienced severe food poisoning knows what is at stake.

While it is largely silent on key questions applying to upstream processing and distribution of ready to eat produce, CALGMA has a lot to say about farming practices and land stewardship. Small and organic farmers in particular have expressed concern about the costs and the scientific justification for some of CALGMA's requirements. Some of CALGMA's metrics seem to be in direct conflict with environmental protection and widely accepted agricultural practices. In some cases, streams have been contaminated, wildlife refuges destroyed, and biodiversity threatened by farmers' efforts to remain in compliance with CALGMA.

Today we hope to address why CALGMA's regulatory framework has focused solely on farming practices to the exclusion of the rest of the supply chain. It seems the farmers have taken the brunt of the burden of minimizing contamination when it may make more scientific sense to focus attention on the processing, packaging, and distribution of ready to eat produce.

Consumers have a right to expect that the food they eat is safe. It is in the public health interest that Americans consume greater amounts of raw vegetables. But whether or not nationalizing CALGMA as the USDA proposed is the best way to achieve those goals is a question of this hearing.

I look forward to hearing from all of our witnesses today on this important issue.

At this time I recognize the honorable Congressman Jordan, the ranking member of the committee, from the State of Ohio.

[The prepared statement of Hon. Dennis J. Kucinich follows:]

ONE HUNDRED ELEVENTH CONGRESS

Congress of the United States

House of Representatives

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Opening Statement
Dennis J. Kucinich
Chairman
Domestic Policy Subcommittee
Oversight and Government Reform Committee

"Ready-to-Eat or Not?: Examining the Impact of Leafy Greens Marketing Agreements"

July 29, 2009

Pre-cut, packaged leafy greens, marketed as "Ready to eat," have become increasingly popular, capturing 70% of the leafy greens market. Americans appreciate the convenience of this partially processed product and are eating more fresh produce as a result. That is a good and important development and will likely help to improve the health of Americans.

Yet as the popularity of bagged lettuce and spinach has increased, so have rare but serious food borne illnesses associated with it. Outbreaks of E. coli 0157 and other pathogens have occurred in relation to pre-cut, packaged leafy greens at least once a year practically every year since 2003.

Regulation to prevent these outbreaks rests in the hands of the industry.

The California Leafy Greens Handler Marketing Agreement (CALGMA) was implemented to stave off regulatory action by the state of California. CALGMA ensures adherence to a specified set of Good Agricultural Practices ("GAPs"), devised primarily by the Food and Drug Administration, to improve the safety of leafy greens. In spite of its name, CALGMA is having an impact on farmers in all parts of the nation, due to the requirement of compliance with CALGMA imposed by national processing and retailing outlets which buy and market their produce. USDA is currently proposing the creation of a national marketing agreement along the lines of CALGMA.

There is much good in the CALGMA initiative. CALGMA embodies private industry's positive efforts to safeguard the American food supply. Handlers, responsible for growers' compliance with food safety metrics, pay for auditors trained by the USDA

and hired by the CALGMA Board, to carry out surprise and scheduled inspections of standards adopted voluntarily by signatory farmers.

CALGMA, however, has some blind spots as well. CALGMA condones a processing activity, favored by the Ready to Eat processing industry, known as "coring" lettuce in the field, and only suggests minimal guidelines for sanitary treatment of harvest equipment used for "coring," in spite of recent scientific research identifying the potential for transferring pathogens deep into the cored lettuce, where the subsequent washing process would be unable to reach.

CALGMA is silent on the use of certain packaging of Ready to Eat produce, known as Modified Atmosphere Packaging – the bags of ready to eat greens. CALGMA does not require an enforceable standard of cold chain of distribution. CALGMA does not impose tough requirements on packagers and distributors relating to the "Best Consumed By Date" stamped on Ready to Eat packaging.

Scientists tell us that if bagged produce labeled as "Ready to Eat" is not constantly refrigerated during the distribution chain, it quickly becomes the perfect habitat for bacterial growth. Harmful bacteria, such as E. Coli 0157, multiply unseen and undetectably to the eyes of the consumer. Legions of pathogens can thereby invade the unsuspecting consumer's intestinal tract, overwhelming her immune system, causing severe and painful complications, even death. Everyone who has every experienced severe food poisoning knows what is at stake.

While it is largely silent on key questions applying to upstream processing and distribution of Ready to Eat produce, CALGMA has a lot to say about farming practices and land stewardship. Small and organic farmers in particular have expressed concern about the costs and scientific justification for some of CALGMA's requirements. Some of CALGMA's metrics are seen to be in direct conflict with environmental protection and widely accepted agricultural practices. In some cases, streams have been contaminated, wildlife refuge destroyed, and biodiversity threatened by farmers' efforts to remain in compliance with CALGMA metrics. Today we hope to address why CALGMA's regulatory framework has focused solely on farming practices, to the exclusion of the rest of the supply chain. It seems the farmers have taken the brunt of the burden of minimizing contamination, when it may make more scientific sense to focus attention on the processing, packaging and distribution of Ready to Eat produce.

Consumers have a right to expect that the food they eat is safe. It is in the public health interest that Americans consume greater amounts of raw vegetables. But whether or not nationalizing CALGMA, as the USDA has proposed, is the best way to achieve those goals is the question this hearing addresses. I look forward to hearing from all of our witnesses today on this important issue.

Mr. JORDAN. Thank you, Chairman. I want to thank you for holding this hearing to examine the impact of the leafy greens marketing agreements.

Most importantly, we need to have a food supply that is safe. Americans should be able to feel confident that the produce they buy at the grocery store or that is served to them at restaurants will not make them sick.

Leafy greens marketing agreements such as CALGMA may be an effective way to ensure safer produce. However, additional guidelines and regulations may be overly burdensome to some farmers, especially small or family owned and run farms. I look forward to hearing from our witnesses about their experiences with the marketing agreements.

The FDA and USDA also play key roles in food safety and agricultural marketing. I am interested to hear how these roles may change if a leafy greens marketing agreement is made national.

Additionally, I hope that our witnesses can discuss the implications of H.R. 2749, the Food Safety Enhancement Act of 2009, which was scheduled to be voted on yesterday and may in fact be voted on later today. I look forward to hearing your thoughts on that legislation as well.

I also look forward to examining the pros and cons of making national the CALGMA agreement.

I thank our witnesses for taking the time to testify here in front of the committee today. With that, I yield back, Mr. Chairman.

Mr. KUCINICH. I thank the gentleman. Does the gentlelady from California have an opening statement?

Ms. WATSON. I do, Mr. Chairman. I want to thank you so much for holding today's hearing to examine the leafy greens market; the role of private industry and Government in regulating these products; and the economic, environmental, and food safety impacts of the California Leafy Greens Handlers Marketing Agreement. The hearing is happening at a very opportune time.

Since 2003, pre-cut bagged lettuce has developed into the second fastest growth industry in U.S. grocery sales. I am from California. We believe in salads, making it critically important that adequate precautions are taken and analyses conducted to ensure that this increasingly popular food is not just nutritious but safe.

We have taken steps, Mr. Chairman, in the State of California to regulate the sale of not only the leafy greens packages but those in the bins as well.

Some 98½ percent of the E. coli outbreaks reported in leafy greens have been associated with bagged and pre-cut greens. The infamous 2006 spinach outbreak resulted in over 200 hospitalizations, nearly $400 million in lost product, and three deaths confirmed by the FDA.

In response to this and other similar instances, industry leaders developed the California Leafy Greens Handlers Marketing Agreement to allow growers to join a voluntary regulatory framework which now encompasses 99 percent of California's leafy greens business and is being considered for official nationalization. I chaired those committee meetings, Mr. Chairman, when I was Chairperson of Health and Human Services.

The CALGMA includes a food safety inspection program conducted by the USDA and the enforcement of metrics or regulations developed by scientists, governmental officials, growers, processors, and businesses to reduce microbial contamination of leafy greens in the field-to-fork supply chain.

While I am pleased that the farming industry has taken the initiative to create this comprehensive framework for food safety, I believe it is important to scrutinize its effectiveness and its impact on the environment. Some have argued that the rules placed on farmers by CALGMA conflict with the movement toward organic and biologically diverse farming methods and could be actually harming the environment. Furthermore, it may prove to be a counterintuitive to create such regulations before there is conclusive scientific knowledge about how E. coli makes its way into the leafy greens supply.

I would like to thank you, Mr. Chairman, for allowing me to make this presentation. I am sorry that I cannot stay. They just called an emergency meeting of the Progressive Caucus to discuss the health care reform bill at 2:30. I just wanted you to know that. But I have staff here and I will be hearing from them as to the witnesses and their testimony. So thank you so much. I yield back.

Mr. KUCINICH. I thank the gentlelady. I am sure she will convey my sentiments in that meeting of the Progressive Caucus. You can let them know that I am given the responsibility of chairing this hearing. Thank you for being here with that opening statement.

If there are no additional opening statements, the subcommittee will now receive testimony from the witnesses before us today. I want to start by introducing our first panel.

Mr. Michael R. Taylor is the Senior Advisor to the Commissioner of Food and Drugs at the Food and Drug Administration. Mr. Taylor, welcome. Mr. Taylor previously served as Deputy Commissioner for Policy and is a member of the National Academy of Science's Committee on Environmental Decision-Making Under Uncertainty. He has held numerous positions in the field of food safety and research, among them Administrator of the Food Safety and Inspection Services at the U.S. Department of Agriculture and Vice President for Public Policy at Monsanto Corp. He was also a practicing attorney in the field at the law firm of King & Spalding.

Ms. Rayne Pegg is the Administrator of the Agriculture Marketing Service, AMS, the marketing and regulatory arm of the U.S. Department of Agriculture. Welcome, Ms. Pegg. Prior to being appointed Administrator at AMS, Ms. Pegg was Deputy Secretary of Legislation and Policy for the California Department of Food and Agriculture. She has also served as director of International Trade and Plant Health for the California Farm Bureau Federation's National Affairs and Research Division and as the director of Governmental Relations to the Agricultural Council of California.

Thank you for appearing before our subcommittee today. It is the policy of the Committee on Oversight and Government Reform to swear in all witnesses before they testify. I would ask that you rise and please raise your right hands.

[Witnesses sworn.]

Mr. KUCINICH. Thank you. Let the record reflect that the witnesses answered in the affirmative.

I ask that each of the witnesses now give a brief summary of their testimony and to keep this summary under 5 minutes in duration. I want you to know that your entire statement and anything else you want to append to it will be included in the hearing record.

Mr. Taylor, you will be our first witness. You may proceed. You have 5 minutes.

STATEMENTS OF MICHAEL R. TAYLOR, SENIOR ADVISOR TO THE COMMISSIONER OF FOOD AND DRUGS, U.S. FOOD AND DRUG ADMINISTRATION; AND RAYNE PEGG, ADMINISTRATOR, AGRICULTURE MARKETING SERVICE, U.S. DEPARTMENT OF AGRICULTURE

STATEMENT OF MICHAEL R. TAYLOR

Mr. TAYLOR. Thank you, Chairman Kucinich and Mr. Jordan. I am Michael Taylor, Senior Advisor to the Commissioner at the Food and Drug Administration which, as you know, is part of the Department of Health and Human Services. I am pleased to be with you today to discuss issues related to the safety of fresh produce.

As you know, FDA is the Federal agency that is responsible for regulating most of the food supply except for meat, poultry, and processed egg products which are overseen by our partners at the U.S. Department of Agriculture. FDA is committed to ensuring that the U.S. food supply continues to be among the safest in the world.

President Obama has made it a personal commitment to improving food safety. On July 7th of this year, the multi-agency Food Safety Working Group that the President established issued its key findings on how to upgrade the food safety system for the 21st century. The working group recommends a new public health-focused approach to food safety based on three core principles: prioritizing prevention, strengthening surveillance and enforcement, and improving response and recovery. FDA has been an integral part of the working group's continuing efforts to establish these principles.

Fresh produce, the topic of today's hearing, presents special safety challenges, as the chairman outlined. The number of illnesses associated with fresh produce is a continuing concern for FDA.

The increased consumption of produce in its fresh or raw form, including ready to eat bagged products, reflects growing consumer interest in healthy eating, as you indicated, which is of course a desirable trend from a public health standpoint. But these new consumption patterns and products challenge our food safety efforts. Fresh produce has the potential to be a source of food-borne illness because it is consumed raw with only minimal processing and generally without interventions that would eliminate any pathogens that may be present.

Because most produce is grown in an outdoor environment, it is susceptible to contamination from pathogens present in the soil, in manure used as fertilizer, from the presence of animals in or near fields or packing areas, or in agricultural water or water used for washing or cooling. Produce may also be vulnerable to contamination due to inadequate worker health and hygiene protections, en-

vironmental conditions, inadequate production safeguards, or inadequate sanitation of equipment and facilities.

Fresh produce is produced on tens of thousands of farms and contamination at any one step in the growing, packing, and processing chain can be amplified throughout the subsequent steps. But we also know that the possibility of harmful contamination can be minimized by understanding these potential entry points for pathogens and by implementing preventative measures wherever possible throughout the system.

Thus, in keeping with the Obama administration's prevention oriented food safety strategy, FDA intends to improve safety of fresh produce by establishing enforceable standards for the implementation of science-based preventative controls throughout the chain of production, processing, and distribution. These regulations will capitalize on what we and the produce industry have learned over the past decade since we published our good agricultural practices guidance in 1998. They will tap the best science to develop appropriate criteria or metrics for ensuring the effectiveness of preventative controls in particular production and processing settings.

In the short term, FDA will issue commodity-specific guidance for industry on the measures that they can implement now to prevent or minimize microbial hazards of fresh produce. FDA will soon publish draft guidance for improving the safety of leafy greens, melons, and tomatoes, three specific commodities that have been associated with food-borne illness outbreaks. The guidance describe preventative controls that industry can implement to reduce the risk of microbial contamination in the growing, harvesting, transporting, and distribution of these commodities.

It is not enough, of course, to issue regulations and guidance. We must also ensure that the preventative measures they call for are widely and effectively implemented. To that end, FDA will work with its Federal and State partners to plan and implement an inspection and enforcement program aimed at ensuring high rates of compliance with the produce safety regulations. FDA recognizes the importance of leveraging the expertise and resources of other Federal, State, and local agencies to be sure that the industry understands the new requirements and to help them achieve greater compliance.

One way we can leverage resources is to work with the Agricultural Marketing Service as they consider and implement marketing agreements and orders. Incorporating FDA standards into voluntary marketing agreements and then conducting audits to ensure compliance by those who subscribe to such agreements thus contributes to the goal we all share, which is widespread compliance with modern preventative control measures. We believe that AMS, by incorporating FDA's produce safety standards in marketing agreements or orders, can help ensure high rates of compliance with FDA's standards.

In addition to highlighting measures that the Executive branch can implement to enhance food safety, the White House Food Safety Working Group also noted the need for Congress to modernize the food safety statutes. Legislative authorities for FDA that would enhance the safety of products include the enhanced ability to require science-based preventative controls, the enhanced ability to

establish and enforce performance standards to measure the implementation of proper food safety procedures, access to basic food safety records, a new inspection mandate, and other tools to foster compliance and other provisions.

The Food Safety Enhancement Act, H.R. 2749, being considered by the House today addresses these needs. The Obama administration strongly supports its passage.

I thank you again for the chance to be here, Mr. Chairman. I look forward to answering your questions.

[The prepared statement of Mr. Taylor follows:]

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TESTIMONY OF

MICHAEL R. TAYLOR, J.D.

SENIOR ADVISOR TO THE COMMISSIONER

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON DOMESTIC POLICY

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

U.S. HOUSE OF REPRESENTATIVES

JULY 29, 2009

FOR RELEASE ONLY UPON DELIVERY

INTRODUCTION

Good afternoon, Chairman Kucinich and Members of the Subcommittee. I am Michael Taylor, Senior Advisor to the Commissioner at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). I am pleased to be with you today to discuss issues related to the safety of fresh produce.

FDA is the federal agency that is responsible for most of the food supply except for meat, poultry, and processed egg products, which are overseen by our partners at the U.S. Department of Agriculture (USDA). FDA is committed to ensuring that the U.S. food supply continues to be among the safest in the world.

Food can become contaminated at many different steps – on the farm, in processing or distribution facilities, during transit, at retail and food service establishments, and in the home. In recent years, we have done a great deal to prevent both intentional and unintentional contamination of food at each of these steps. FDA has worked with other federal, state, local, tribal, and foreign counterpart food safety agencies, as well as with law enforcement and intelligence-gathering agencies, and with industry, consumer groups, and academia to strengthen the nation's food safety and food defense system across the entire distribution chain.

This cooperation has resulted in greater awareness of potential vulnerabilities, the creation of more effective prevention programs, new surveillance systems, and the ability to respond more quickly to outbreaks of foodborne illness. However, changes in consumer dietary patterns, changes in industry practices, changes in the U.S. population, and an increasingly globalized

food supply chain pose challenges that are requiring us to adapt our current food protection strategies.

President Obama has made a personal commitment to improving food safety. On July 7, 2009, the multiagency Food Safety Working Group (Working Group), which he established, issued its key findings on how to upgrade the food safety system for the 21st century. The Working Group recommends a new public-health-focused approach to food safety based on three core principles: prioritizing prevention, strengthening surveillance and enforcement, and improving response and recovery. FDA is playing an integral part in the Working Group's continuing efforts. I will describe below a couple of initiatives specifically related to fresh produce that FDA is taking to implement the Working Group's initial key findings.

In discussing these initiatives, my testimony also will describe some of the challenges we face both in preventing fresh produce from becoming contaminated and in investigating outbreaks associated with fresh produce. I will also discuss some of the specific measures FDA is taking to enhance the safety of fresh produce to prevent future outbreaks and to improve product tracing when an outbreak occurs or there is a product recall. Finally, I will address some of the legislative authorities the Working Group identified as necessary for modernizing the food safety statutes.

CHALLENGES OF FRESH PRODUCE

Fresh produce presents special safety challenges, and the number of illnesses associated with fresh produce is a continuing concern for FDA. Consumption of produce in its fresh (or raw)

form, particularly "ready-to-eat" products such as bagged, prewashed lettuce, has increased substantially during the past decade. These new products and consumption patterns challenge our food safety efforts. Because produce is often consumed raw or with only minimal processing, without intervention that would eliminate pathogens (if they are present) prior to consumption, it has the potential to be a source of foodborne illness.

Most produce is grown in an outdoor environment, and it is susceptible to contamination from pathogens that may be present in the soil, in agricultural water or water used for postharvest practices (e.g., washing or cooling), in manure used as fertilizer, or due to the presence of animals in or near fields or packing areas. Produce also may be vulnerable to contamination due to inadequate worker health and hygiene protections, environmental conditions, inadequate production safeguards, or inadequate sanitation of equipment and facilities. Fresh produce is produced on tens of thousands of farms, and contamination at any one step in the growing, packing, and processing chain can be amplified throughout the subsequent steps.

We also note that traceback investigations for contaminated food are more difficult when they involve fresh produce because the food is perishable and the produce item (along with any packaging or labels) is usually no longer available for examination or testing by the time illnesses are reported. In addition, fresh fruits and vegetables are often sold loose without any packaging that could provide information about their source. Further, practices such as packing or repacking produce from multiple sources add complexity to traceback investigations.

Consequently, addressing the way fresh produce is grown, harvested, and moved from field to fork is crucial to minimizing the risk of microbial contamination. In recent years, FDA has initiated several activities to address safety concerns associated with the production of fresh produce. Some of these activities include: working with industry and others to develop commodity-specific guidance on ways to prevent or minimize potential contamination; working with the states to increase inspections and to develop commodity-specific food safety programs; conducting educational outreach to consumers on safe food handling practices; investigating farms and packing sheds implicated in outbreaks to learn how the produce may have become contaminated; sampling and analyzing both domestic and imported produce for pathogens; developing risk assessment methods and tools to better characterize and understand the effectiveness of controls to reduce hazards in produce; and working with industry and foreign countries to promote the use of good growing, harvesting, packing, transporting, and processing practices.

It also is important to emphasize the critical role of food producers and processors in ensuring the safety of the foods they introduce into commerce. Strong food safety programs begin with the promotion of a strong culture of food safety throughout each farm or firm in the supply chain, including the need for preventive measures and ways to detect and correct problems before they cause harm. Establishing this culture requires a strong sense of corporate responsibility and continuous management oversight.

One of the key messages that FDA has been emphasizing over the last few years is that all food companies, both large and small, must know their suppliers. In today's complex, global market,

this may require close interaction with entities throughout the food supply chain, including growers, manufacturers, distributors, retailers, food service providers, and importers.

From the perspective of both public health and economic interests, preventing foodborne illness from occurring is much more desirable than having to minimize not only the adverse public health impact caused by such outbreaks but also the economic damage by undertaking food recalls, which can often bring production to a halt, disrupt markets, affect consumer confidence, and cause financial loss. It is critical that all segments of the food supply chain, from farm to retailer, take measures to ensure the safety of their ingredients and their finished products.

You asked about the current science on the safety of ready-to-eat bagged leafy greens, especially with regard to the risk of bacterial growth, including *Listeria* and *Escherichia coli* (*E. coli)* O157:H7 pathogens, and about phages. The differences in growth and survival of pathogens on both whole and fresh-cut leafy greens are not sufficiently documented and not fully understood, although some studies have shown the ability of pathogens to survive and grow on fresh-cut products. While comparisons between whole and cut products are scarce in the scientific literature, some studies have demonstrated that pathogens can attach to both cut and intact surfaces of lettuce tissue. Fresh-cut vegetables provide a higher level of moisture, nutrients, and more surface area, which make ready-to-eat/fresh-cut products more susceptible to microbial growth (non-pathogens and pathogens) than the original intact product. Leafy greens that are processed may be exposed to further risk of microbial contamination from workers, surfaces, equipment, water, and aerosols, enabling microorganisms to persist and grow.

Some processes have the potential to reduce microbial risks (e.g., disinfection), control microbial growth (e.g., chilling), and protect the product from further exposure (e.g., packaging). Current technologies or practices do not effectively eliminate all risk incurred during postharvest processing and packaging of fresh and fresh-cut leafy greens, although, some risk reduction is possible. Storage temperature and length of storage time of ready-to-eat leafy greens are of critical importance for the control of bacterial pathogens and ultimately the safety of these products. Growth of *Listeria monocytogenes* (*L. monocytogenes*) at 3-5°C in refrigerated fresh-cut packaged leafy greens has been demonstrated. *E. coli* O157:H7 has also been shown to survive for several days under refrigerated conditions. Viability of viruses is influenced very little or not at all by low temperatures. However studies have shown that naturally occurring viruses were not typically found on fresh vegetables or in the processing environment of these products. Viruses are primarily introduced through human handling processes. Phages infect bacteria and do not pose a public health risk to humans. In fact, certain types of phages are under investigation for biocontrol of pathogens, such as *L. monocytogenes* and *E. coli* O157:H7.

INITIATIVES TO ENHANCE PRODUCE SAFETY

In the short term, FDA's approach is to issue commodity-specific guidance for industry on the measures they can implement to prevent or minimize microbial hazards of fresh produce. To improve compliance with such measures, FDA also plans to work with USDA's Agricultural Marketing Service (AMS) to include these recommended standards in their marketing agreements and orders when appropriate. Our long-term plan is to set enforceable produce safety standards through a regulation. I will discuss these activities in more detail below.

Federal Commodity-Specific Produce Safety Draft Guidances

Soon FDA will be publishing new commodity-specific draft guidances for improving the safety of leafy greens, melons, and tomatoes. The guidances describe preventive controls that industry can implement to reduce the risk of microbial contamination in the growing, harvesting, transporting, and distributing of these commodities. These guidance documents build on FDA's 1998 general guidance on good agricultural practices for fresh produce but go beyond it by tailoring the guidance to these three specific commodities that have been associated with foodborne illness outbreaks and taking into account knowledge gained since 1998.

FDA's guidances recognize and embrace the progress industry has made in establishing quantitative metrics for the control of some of the factors affecting produce safety. FDA is studying the scientific basis for these metrics and will incorporate appropriate metrics in its produce safety regulation.

FDA's commodity-specific draft guidances represent the Agency's current thinking on how to improve the safety of leafy greens, melons, and tomatoes and are a step along the path to enforceable standards and a safer supply of fresh produce. They reflect and promote the best practices for the industry and are an attempt to help both domestic and foreign firms minimize the risk of microbial contamination of their products throughout the entire supply chain.

In addition to the general guidance on good agricultural practices and guidance for safe production of safe sprouts, in recent years, FDA also has published final guidance for industry to minimize microbial food safety hazards for fresh-cut fruits and vegetables (the Fresh-Cut Guide). The Fresh-Cut Guide, which FDA published in 2008, complements FDA's Current Good

Manufacturing Practices for food processing facilities. It is intended to assist firms by providing recommendations specific to fresh-cut processing operations.

In addition, FDA is leading an effort through the Codex Alimentarius Commission, the international food safety standards body, with support of the Food and Agriculture Organization/World Health Organization, to develop commodity-specific annexes to the Codex hygienic code for fresh fruit and vegetable production, starting with an annex for fresh leafy vegetables and herbs. In June 2009, FDA conducted the first Codex international electronic working group with members of the Codex Committee on Food Hygiene (CCFH) to advance the draft Annex for Fresh Leafy Vegetables to the next stage of completion. In November 2009, CCFH will consider how to proceed with the next tier of priority commodities.

Produce Safety Regulation

As I mentioned earlier, preventing harm to consumers is one of the core principles identified by the Working Group, and it is our first priority. Too often in the past, the food safety system has focused on reacting to problems rather than preventing harm in the first place. The Working Group recommends that food regulators shift towards prioritizing prevention and move aggressively to implement sensible measures to prevent problems before they occur.

As the federal regulatory agency responsible for ensuring produce safety, FDA has begun work on a regulation to establish enforceable standards for produce safety under our current authorities. The regulation will be based on the prevention-oriented public health principles embraced by the Working Group. It will capitalize on what we have learned over the past

decade, since we published our "good agricultural practices" guidelines in 1998. The regulation also will utilize the progress industry has made in establishing quantitative metrics for the control of some of the factors affecting produce safety by incorporating appropriate measures of success. These metrics, or measures, will improve our ability to verify that certain measures or practices are being carried out and are effective.

Together with its federal and state partners, FDA will work to plan and implement an inspection and enforcement program to ensure high rates of compliance with the produce safety regulation. If Congress passes food safety legislation that includes explicit authority to require preventive controls, FDA would modify and update this rulemaking in light of the new authority.

The regulation will include the following key elements:

- clear standards for implementation of modern preventive controls by all participants in the fresh produce supply chain, from farm to market. These performance-oriented standards will recognize that operators must tailor their preventive controls to the particular hazards and conditions affecting their operations, but the regulation will ensure they do so in accordance with modern food safety principles;
- product-specific standards and guidance, where appropriate, for high-risk commodities;
- quantitative measures of the effectiveness of control systems, to the extent they are feasible and valid; and
- microbial testing protocols to verify the effectiveness of preventive controls.

FDA will work with the industry to facilitate compliance with the new regulation through the following ways:

- issuance of a science-based "hazards guide" to assist producers and processors in designing their preventive controls;
- provision of other technical assistance and guidance on how to comply with the new rules;
- establishment of reasonable time periods for implementation of the rules, taking into account firm size; and
- cooperation with USDA extension programs and industry-sponsored education efforts to foster understanding and implementation of the requirements.

FDA recognizes that the produce sector consists not only of large national and international operators but also many small producers, including many who market directly to consumers at roadside stands and farmers markets. FDA will carefully consider the public health and economic impacts of applying the requirements of the new rules to very small producers and will consider appropriate adjustments in the regulation.

Enhancing Product Tracing

Another key finding of the Working Group is the need to build a national tracing and response system. A system that permits rapid tracing to the source of the product contamination will protect consumers and also help industry recover faster. Yet, despite the dedicated efforts of food safety officials across the country, our current capacity to trace the sources of produce-related illness suffers from serious limitations.

The ability to trace pathways of any food, including fresh produce, forward and back through every point in the supply chain is crucial for limiting foodborne illness in an outbreak, for preventing future outbreaks, and for reducing the impact on the segments of the industry whose products were not associated with the illnesses. The pathways that fresh produce travels from field to consumer have become increasingly complex, with items sometimes changing hands many times in the supply chain.

FDA has reached out to various organizations, including trade associations and consumer organizations, to gain a better understanding of best industry practices for product tracing. For example, in late 2008 and early 2009, FDA held two public hearings requesting data and other information on industry practices and available technologies relevant to improving our ability to more quickly and accurately track fresh produce through the supply chain, especially during a produce-associated foodborne illness outbreak. Using this information from our stakeholders, FDA will issue draft guidance within the next three months on the steps the food industry can take to establish product tracing systems to improve our national capacity for identifying the origins of foodborne illness.

FDA also has entered into a contract with the Institute for Food Technology to conduct a mock traceback scenario with tomatoes, with the cooperation of representatives of the tomato industry and two technology companies. The pilot is scheduled for completion in September 2009. FDA plans to pursue additional pilots to focus on other commodity-technology combinations in the future.

We have been working extensively with states and the fresh produce industry to encourage incorporation of product tracing procedures and technology. For example, FDA assisted the Florida Tomato Commission and the University of Florida/Institute of Food and Agricultural Sciences in the development of Florida's Tomato Best Practices Manual. This Manual incorporates Good Agricultural Practices, Good Handling Practices, and traceability recommendations for industry. The Manual formed the basis of the State of Florida's tomato safety rule.

Research

Strengthening the research programs that support FDA's program to improve food safety is essential to improving the Agency's effectiveness at protecting public health. Our current research agenda is focused on improving the identification and detection of disease-causing bacteria and contaminants in a variety of foods. Current research topics include questions related to how and where in the food chain microbiological and chemical contamination of foods takes place, biotechnology and allergenicity issues, seafood safety, dietary supplement safety, color additive safety, and consumer studies. The determination of microbiological and chemical risks and their mitigation drives our research program.

FDA and our food safety partners are doing extensive research on the detection, characterization, and behavior of foodborne pathogens, microbial genetics, and molecular virology. For instance, the Centers for Disease Control and Prevention and FDA have developed rapid methods for serotyping *Salmonella* in produce (such as cantaloupes, tomatoes, and peppers). These rapid

methods will aid FDA as we perform analysis of both domestic and imported produce samples. These efforts also are vital for our development of risk assessment models for pathogens and intervention strategies to reduce the public health risk that these pathogens present. More rapid and precise testing methods to identify contaminants are important for minimizing the spread of foodborne disease once it occurs.

Collaborative research efforts further strengthen the scientific basis for our food safety programs. For example, for the past decade, FDA has worked closely with USDA's Agricultural Research Service and Cooperative State Research, Education, and Extension Service to coordinate and mutually support our respective research efforts related to produce safety. In addition, we are working with academia, industry, other federal agencies, and state governments to develop both risk-based microbiological research programs and technology transfer programs to ensure that the latest food technology reaches the appropriate end users along the supply chain.

As part of the Center for Excellence program, FDA maintains four topic-specific centers: the National Center for Natural Products Research at the University of Mississippi; the National Center for Food Safety and Technology at the Illinois Institute of Technology; the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) at the University of Maryland; and the newly established (2008) Western Center for Food Safety (WCFS) at the University of California at Davis, which focuses on the intersection between production agriculture and food safety.

In its first year, the WCFS has focused on conducting produce safety research addressing the science behind Good Agricultural Practices and developing outcome metrics and an updated

literature review related to perchlorate and its impact on food safety. The WCFS quickly responded to our need for work on the validation of processes to destroy *Salmonella* on pistachios and is working with both the pistachio and almond industries to control *Salmonella* on those tree nuts.

Last year, FDA, working with the Interagency Risk Assessment Consortium and with JIFSAN, held a workshop to identify and prioritize research needs for conducting a quantitative risk assessment of foodborne illness caused by *E. coli* O157:H7 from the consumption of leafy green vegetables. That workshop assisted in the development of risk assessment tools to better characterize the hazards in produce. This effort is being enhanced by our contract with Research Triangle Institute for the development of scientific assessments. Other collaborative projects are planned and currently are being executed to interact with other academic institutions to augment our in-house and Center for Excellence research. Such projects are based on current needs and are meant to provide FDA with resources that may not otherwise be directly available to the Agency.

We will continue to work with federal, state, local and international food safety partners and with industry to develop guidance, conduct research, develop educational outreach materials, and initiate other commodity- or region-specific programs to enhance the safety of fresh produce.

Marketing Orders and Agreements

You asked FDA to discuss the Agency's regulation of food safety provisions in agriculture marketing agreements. Although FDA has not had a direct role in creating such agreements, we do work collaboratively with our colleagues at AMS, which is the federal agency responsible for

marketing agreements and orders. When AMS has incorporated food safety standards into its marketing orders, FDA has provided technical assistance to AMS on the appropriate safety practices and would provide such assistance for marketing agreements as well. It is our shared goal that any AMS safety standards would incorporate the applicable FDA regulations or guidance documents. I will defer to my colleague from AMS to describe these programs in more detail.

As FDA moves forward to establish science-based standards to improve the safety of produce, the Agency must have a plan to help ensure high rates of adoption. Given the number of producers, FDA recognizes the importance of leveraging its resources with other federal, state, and local agencies to help achieve greater compliance. In particular, FDA plans to continue to work closely with USDA, which has a great deal of experience in agricultural production and which has a significant workforce, including through its contracts with states. We believe that AMS, by incorporating FDA's produce safety standards in produce-related marketing agreements or orders, can help ensure high rates of compliance with FDA's standards.

LEGISLATIVE INITIATIVES

In addition to highlighting measures that the Executive Branch could implement to enhance food safety, the Working Group also noted the need for Congress to modernize the food safety statutes to provide key tools for FDA, the Food Safety and Inspection Service at USDA, and other components of the federal government to keep food safe. Legislative authorities for FDA that would enhance the safety of produce include:

- enhanced ability to require science-based preventive controls;

- enhanced ability to establish and enforce performance standards to measure the implementation of proper food safety procedures;
- access to basic food safety records at facilities;
- enhanced inspection tools to foster compliance with science-based standards;
- new tools to strengthen standards and oversight for food imports;
- the ability to require the establishment of product tracing systems; and to
- require mandatory recalls.

There are several bills in Congress that incorporate many of the authorities listed above. We look forward to working with Congress on this important legislation to strengthen our food safety system.

CONCLUSION

The safety of fresh produce depends on every participant in the farm-to-table supply chain implementing modern preventive controls to minimize and, where possible, eliminate contamination that can cause illness. We look forward to continuing to work with the produce industry, consumer groups, academia, and our food safety partners at the federal, state, local, tribal, and international levels to help us reduce the incidence of foodborne illness to the lowest level possible. Thank you for the opportunity to discuss FDA's continuing efforts to improve the safety of fresh produce. I would be happy to answer any questions.

Mr. KUCINICH. Thank you very much, Mr. Taylor. Ms. Pegg, you may proceed. Thank you.

STATEMENT OF RAYNE PEGG

Ms. PEGG. Hello, Mr. Chairman and members of the subcommittee. Good afternoon and thank you for the invitation to appear here before you today. I appreciate the opportunity to share with you a brief overview of our activities regarding marketing orders and agreements for fruits and vegetables.

As Mr. Taylor stated, FDA is the Federal agency responsible for food safety of fruits and vegetables. At USDA, the Food Safety and Inspection Service holds similar responsibility for meat, poultry, and egg products.

The mission of AMS is to facilitate the marketing of agricultural products. AMS is not a food safety agency. We are an agency with a long history of working with producers and processors. Our marketing programs involve the inspection of product quality and the verification of production processes.

Under the Agricultural Marketing Agreement Act of 1937, marketing orders and agreements assist farmers and handlers by allowing them to collectively work to solve marketing problems. These programs are industry-initiated and subject to public review.

There is a seven step process in initiating a marketing agreement. The industry petitions the USDA, which recently occurred on the national leafy greens marketing agreement. USDA holds public meetings, which we will be having on the national leafy greens marketing agreement in September and October. We review all comments and either terminate the proceedings or publish a proposed rule.

In the past we have terminated proceedings of a potential marketing agreement or order. USDA publishes a final agreement and appoints a committee. The committee develops best practices. Those best practices are published for public comment and then USDA publishes final metrics or best practices.

Marketing agreements only apply to handlers who voluntarily sign an agreement. Fees are collected from handlers to cover local costs of administering these programs.

The act provides authority to regulate the quality of commodities through Federal agreements. USDA considers harmful pathogens and toxins to be a characteristic of lower quality products. Federal marketing orders and agreements include minimum quality grade requirements which can be identified by the presence of mold, insect infestation, foreign material, or other contaminants.

The marketing order for California prunes has had inspection and fumigation requirements relative to live insect infestations since 1961. Since 1977, California raisins have required the absence of dirt, insects, and mold. Beginning in 2005, pistachio handlers were required to test all nuts destined for human consumption for Aflatoxin, which, if present, would lower the quality and market value of pistachios.

On June 8th, AMS received an industry proposal for a national marketing agreement for lettuce, spinach, and other leafy greens. The purpose of the proposed agreement is to enhance the quality and increase the marketability of fresh leafy greens vegetable prod-

ucts through the application of good agricultural and handling practices. Requirements implemented under the proposed program would be science-based, conform to FDA guidance to minimize food safety risks, and be subject to USDA oversight.

The program would only be binding on signatory handlers. The program would require signatories to verify that any product handled comes from producers or handlers using verified good agricultural and handling practices. The program would authorize unannounced audits and apply to imports. Any product deemed an immediate food safety risk concern by USDA inspection would be reported to FDA.

We are aware that there are concerns from various groups on the proposed marketing agreement. We welcome comments from those and other interested parties and will carefully consider them.

To conclude, Mr. Chairman, I would like to reiterate that the Federal food safety policies for fruits and vegetables fall under the jurisdiction of FDA. However, AMS does have significant experience in the design and delivery of marketing programs, including marketing orders and agreements. The process for potentially establishing a marketing order or agreement is an open and transparent process in which AMS carefully considers all viewpoints.

I am happy to respond to any questions.

[The prepared statement of Ms. Pegg follows:]

Statement
Of
Rayne Pegg, Administrator
Agricultural Marketing Service
U.S. Department of Agriculture

Domestic Policy Subcommittee
Oversight and Government Reform Committee

Wednesday, July 29, 2009
2154 Rayburn HOB
2:00 p.m.

"Ready-to-Eat or Not: Examining the Impact of Leafy Green Marketing Agreements"

Mr. Chairman and Members of the Subcommittee, good afternoon and thank you for the invitation to appear before you today. I appreciate the opportunity to share with you a brief overview of the U.S. Department of Agriculture's (USDA) Agricultural Marketing Service's (AMS) activities with regard to marketing orders and agreements for the fruit and vegetable industries.

First of all, I would like to introduce myself to the Subcommittee. My name is Rayne Pegg and I am the new AMS Administrator. Before coming to USDA, I served as the Deputy Secretary of Legislation and Policy for the California Department of Food and Agriculture. In this role, I advised both the Secretary of the Department and the cabinet of the Governor of California on the Department's legislative and policy issues. I worked with growers and the public to find common ground and reach agreement on controversial issues such as invasive species, organic production, food safety, farmers

markets, government oversight, and trade barriers. Prior to my work for the State of California, I worked for California farmers and farmer cooperatives on various issues.

As you know, the Food and Drug Administration (FDA) is the Federal agency with primary responsibility for the food safety of fruits and vegetables. At the U.S. Department of Agriculture, the Food Safety and Inspection Service holds similar responsibility for meat, poultry, and egg products.

The mission of AMS is to facilitate the strategic marketing of agricultural products in the domestic and international marketplace. AMS is not a food safety agency. The agency, through programs such as marketing orders and agreements, assists handlers and producers in verifying various product quality control efforts.

Marketing Orders and Agreements

Authorized by the Agricultural Marketing Agreement Act of 1937 (the Act), marketing orders and agreements assist farmers and handlers by allowing them to collectively work to solve marketing problems. These programs are initiated by industries that choose to have Federal oversight, through AMS, of certain aspects of their operations. At the request of industry members, AMS reviews a proposal to establish a marketing order or agreement and solicits input, on numerous occasions, from all interested parties in order to reach a decision that addresses the marketing problems identified in the proposal.

Marketing orders and agreements may set minimum quality requirements, standardize packaging, regulate flow of product to market, and implement other regulations including consumer education, research and advertising. Marketing agreements only apply to handlers who voluntarily sign an agreement, while marketing orders set regulations on all handlers in a specified region once the program is approved in a grower referendum. Fees are collected from handlers to cover the local costs of administering these programs. AMS currently administers 32 fruit and vegetable marketing orders, covering 25 specialty crop commodities.

Establishing a Marketing Order or Agreement

After an industry identifies mutual marketing problems and determines that a marketing order or agreement could help the industry solve these problems, a proposal is prepared and submitted, along with a request for a hearing, to AMS. The proposal should indicate the degree of industry support, the problems the program would address, and suggest a possible hearing site and approximate date. A Notice of Public Hearing is then issued, and is published at least 15 days before the hearing. A USDA Administrative Law Judge presides at the public hearing and a verbatim record is compiled of the testimony of opponents, proponents and others, including USDA personnel. Because proponents bear the burden of proof, they must present evidence to support the need for the program, and every provision in the proposal.

Based on hearing evidence, a Recommended Decision is issued by USDA. Persons are

allowed to file exceptions to it for a set time period. For both marketing orders and agreements, the Recommended Decision is followed by a Secretary's Decision. The Secretary's Decision takes into account any comments submitted in response to the Recommended Decision, makes modifications if warranted, and then restates USDA's position on whether or not there is compelling evidence to proceed with implementation of a new program. Accompanying the Secretary's Decision is either a grower referendum order (in the case of marketing orders) or a handler sign-up period (in the case of marketing agreements). An order requires a 2/3 vote, by number or volume, of those voting in the referendum in order to pass and be implemented. The Act does not stipulate a handler sign-up threshold, but USDA has discretion to determine if handler sign-up participation is adequate to implement an agreement. Depending on the outcome of either the referendum or the handler sign-up, a Final Order is issued. The Final Order either implements the new program or terminates the proceeding if participation is not adequate.

Once a marketing order or agreement is established, committees and / or boards of farmers and handlers - appointed by the Secretary of Agriculture - administer the order or agreement. These committees and boards are responsible for the development of production and handling practices (best practices, or metrics) which are submitted to USDA. AMS then publishes the proposed metrics and solicits public comments.

Product Quality Issues under Federal Marketing Orders

Section 608c(6) of the Act provides authority to regulate the quality of various commodities through Federal marketing orders and agreements. AMS considers the absence of harmful pathogens or toxins to be a characteristic of higher quality products. In response to producer requests for support of their product quality control efforts, AMS has incorporated product quality verification requirements into marketing order regulations for a number of years. AMS recognizes the importance of coordinating with FDA as closely as possible because, as stated earlier, FDA is the Federal Government's lead agency with respect to food safety issues. It is also important to reiterate that although certain requirements related to food safety have been incorporated into various marketing agreements and orders, these requirements have been incorporated solely to improve product marketability.

For example, a large majority of the currently active Federal marketing order programs include minimum grade requirements and most U.S. grade standards have criteria that relate to food safety (e.g., lack of mold, insects, foreign material, etc.). The marketing order for California prunes has had inspection and fumigation requirements relative to live insect infestations since 1961. Since 1965, testing for *Aflatoxin* has been required for U.S. grown peanuts originally under a Federal marketing agreement and subsequently through separate legislation administered by AMS. Requirements have been in place since 1977 for California raisins specifying the absence of dirt, insects and mold. Also, beginning in 2005, pistachio handlers were required to test all nuts destined for human consumption for *Aflatoxin*, which, if present, would lower the quality and market value of pistachios. Starting with the 2007-08 almond crop, handlers were required to treat almonds prior to

shipment to reduce the chance of *Salmonella* contamination, which could also lower the quality and value of almonds shipped to market.

In both February 2008 and 2009, the USDA-chartered Fruit and Vegetable Industry Advisory Committee, a group of 25 members of the U.S. produce industry, expressed strong support for making Federal marketing agreements and orders available to industries to facilitate national adoption and compliance with food safety standards, such as Good Agricultural Practices (GAPs), Good Handling Practices (GHPs), and Good Manufacturing Practices (GMPs).

California Leafy Green Marketing Agreement

Following the September 2006 *E. coli* outbreak linked to fresh spinach grown in the Salinas Valley, which lead to a number of deaths and illnesses, the spinach and related leafy green industries collectively worked with the California Department of Food and Agriculture (CDFA) to begin designing a state marketing agreement that would require adherence to GAPs for most signatory companies involved in shipping leafy greens in the state. The California Leafy Green Marketing Agreement (Agreement) became effective in February 2007. Arizona implemented a similar program in October 2007.

The CDFA Agreement is a voluntary program. This program licenses signatory handlers to use a mark to certify the member's use of GAPs on all California grown and handled product. The use of the certification mark would be denied to those firms found in

violation. The Agreement also mandates that handler's source their leafy greens produced in California from growers who comply with a specified set of GAPs. According to CDFA, to date, handlers representing more than 99 percent of the leafy greens produced in California have signed the Agreement. AMS has cooperated with CDFA in the verification aspects of the Agreement, including the design and delivery of training for the California State auditors who monitor compliance.

AMS has also worked with the California and Arizona leafy greens industries, the California tomato industry, and the American mushroom industry to develop a framework for providing audit services. Each industry developed a "best practices" document and requested AMS to develop an audit protocol to monitor compliance with these practices. As a result, AMS is providing auditing services which recognize an operator's adherence to industry-defined best practices and FDA guidance. FDA specialists have interacted with industry as "subject matter experts" in the development of the best practices documents and AMS maintains an active working relationship with these same specialists.

Proposed National Marketing Agreement for Leafy Greens

In response to interests expressed by segments of the leafy green vegetable industries, AMS published in October 2007 an Advanced Notice of Proposed Rulemaking (ANPR) that resulted in the submission and consideration of 3,500 public comments on the need and level of support for a nationwide good agricultural and handling practices program. In short, AMS' analysis indicated public backing for such a measure could be favorable if

certain issues, such as the cost and impact on small entities, the possible impacts on the environment and wildlife habitat, the need for science-based guidelines, and other factors, were addressed in the development and implementation of any Federal regulation.

Subsequent to the analysis of the ANPR, a coalition of U.S. produce industry members began drafting a national marketing agreement proposal that would help minimize the risks of food-borne contamination in leafy green vegetables. On June 8, 2009, AMS received a proposal for a national marketing agreement for lettuce, spinach and other leafy greens. The purpose of the proposed marketing agreement would be to enhance the quality and increase the marketability of fresh leafy green vegetable products through the application of good agricultural and handling practices. Requirements implemented under the program would be science-based, conform to the FDA's guidance to minimize food safety risks, and be subject to USDA inspection audit verification and oversight. As a marketing agreement, the proposed program would only be binding on handlers who voluntarily sign the agreement. The program would require signatories to verify that any product handled comes from producers or other handlers using verified good agricultural and handling practices. The program would authorize unannounced audits and apply to imports, creating the need to audit growing facilities outside of the United States.

The program would license signatory handlers to use a mark to certify the member's compliance with the program. As a result of agreement violation, a signatory would be subject to losing the privilege of the official certification mark, and may be subject to misbranding or trademark violations, thereby possibly losing the ability to sell the

product to a buyer. Any product deemed an immediate food safety concern by USDA inspection would be reported to FDA.

Any requirements under a Federal marketing agreement for leafy greens would reinforce those industries' abilities to meet FDA requirements. AMS could not support any proposed marketing agreement program unless the authorities and regulations under such a program were consistent with FDA guidance and regulations.

The industry proposal initiates a process that involves AMS conducting hearings around the country later this year. The hearings, as well as documents and notices to be published in the Federal Register, will provide ample opportunity for groups and individuals to convey their evidence and views for the record before any such marketing agreement takes effect. If the evidence merits such a program, an extensive outreach effort to make businesses, especially small entities, aware of the marketing agreement and audit requirements would be undertaken.

We are aware that there are concerns from various groups on this proposed marketing agreement and a process is in place to hear all points of view. We want a robust comment period to allow us to make the best possible decision. I would like to again stress that this proposal to establish a marketing agreement is not a USDA proposal, but rather one offered by industry as provided for in the Act.

Conclusion

To conclude, Mr. Chairman, I would like to reiterate that Federal food safety policies for fruits and vegetables fall under the jurisdiction of the FDA. AMS has significant experience in the design and delivery of marketing programs, including marketing orders and agreements. The process for potentially establishing a marketing order or agreement is an open and transparent process in which AMS carefully considers all viewpoints.

I would be pleased to respond to questions.

Mr. KUCINICH. I thank the gentlelady.

We will now proceed with 10 minutes of questions beginning with myself. Then I will turn it over to Mr. Jordan. I would like to start with Mr. Taylor.

Mr. Taylor, ready to eat is a marketing slogan assuring that the salad in the package is safe for consumption without requiring further washing or cutting by the consumer. The California Leafy Greens Handlers Marketing Agreement, CALGMA, is a voluntary industry-sponsored means of ensuring the quality and safety of processed leafy greens, including those to be marketed as ready to eat. It was developed to preempt legislative regulatory action from the California State Assembly.

Has CALGMA made pre-cut salads safer than they were before? If yes, what is the basis for that opinion?

Mr. TAYLOR. Mr. Chairman, the producer practices embodied in that agreement, if implemented, make a contribution to making the food safer. I think we all understand that the safety of the product ultimately depends on what happens not only at that point on the production end but through processing and the way the product is handled throughout.

Mr. KUCINICH. When you say contribution, what do you mean? What is the science behind that?

Mr. TAYLOR. The safety of these products really depends fundamentally on prevention of contamination in the first place. For a raw, fresh product, we don't have processing steps that decisively kill pathogens. So prevention throughout the system is the key to safety. The point is that the on farm practices embodied in the agreement make a contribution.

Mr. KUCINICH. But isn't it true that since CALGMA went into effect there have still been food-borne illnesses traced to the bagged leafy lettuce produce?

Mr. TAYLOR. Absolutely.

Mr. KUCINICH. Do you remember some of them. The 2008 romaine lettuce outbreak, do you remember that?

Mr. TAYLOR. I was not in the Government then but I am aware of these outbreaks.

Mr. KUCINICH. Are you aware of iceberg lettuce outbreak also in that year?

Mr. TAYLOR. Yes, I think.

Mr. KUCINICH. Isn't it true that nearly every case since 1999 of outbreaks of food-borne pathogens that were traced to leafy greens involved pre-cut packaged leafy greens and not whole leafy greens, Mr. Taylor?

Mr. TAYLOR. Improving the safety of these products is a work in progress, Mr. Chairman. Let me just mention another thing——

Mr. KUCINICH. No, wait. You didn't answer my question, though. One of the things about being in front of this committee, it is a lot easier if you answer the question. You didn't answer the question. Please answer the question.

Mr. TAYLOR. If the question is whether the marketing agreement has solved the problem of fresh produce safety, no. The answer is no, of course it hasn't.

Mr. KUCINICH. I asked you a question, though. You didn't answer. I am going to repeat it just to make sure that you heard it.

I asked you, isn't it true that in nearly every case since 1999, outbreaks of food-borne pathogens that were traced to leafy greens involved pre-cut packaged leafy greens and not whole leafy greens? Yes or no.

Mr. TAYLOR. Yes.

Mr. KUCINICH. Thank you. Now, Mr. Taylor, doesn't that suggest that the processing of leafy greens is a significant factor in causing outbreaks of food-borne pathogens?

Mr. TAYLOR. There are features of that process that do create an environment for pathogen growth. You are absolutely right.

Mr. KUCINICH. Is that a yes or a no?

Mr. TAYLOR. Yes.

Mr. KUCINICH. OK. According to the CEO of CALGMA, the FDA reviewed the good agricultural practices and metrics imposed by CALGMA. The USDA insists that its marketing agreement program is consistent with FDA guidelines and regulations.

One thing we have noticed in our review of CALGMA is that a lot of requirements are imposed on farmers while comparatively less burdensome guidance is suggested to the processors who buy the greens from the farmers and turn them into pre-cut packaged salads for marketing to the public. Even when I look at your testimony, you are still pretty heavy on the farmers' side. For instance, CALGMA prohibits farmers from planting within 400 feet of a hedge row on the questionable basis that wildlife poses a significant risk of contamination, but CALGMA allows the processing activity of coring lettuce in the field, an activity that the FDA acknowledges has the potential for contamination, with only minimal guidance for the washing and storing of knives used to core lettuce. It seems to be a double standard, Mr. Taylor.

Is CALGMA's imposition of detailed requirements on farmers but only suggested guidelines on handlers and distributors justified by the science on how to make pre-cut salads safer?

Mr. TAYLOR. The science says we need enforceable preventative measures throughout the system from farm through distribution. That is why the Food and Drug Administration is going to issue regulations that would do exactly that.

Mr. KUCINICH. The science says that but what about CALGMA's requirements on farmers as opposed to guidance on handlers and distributors? What you are saying, then, is there is a gap. Are you saying that?

Mr. TAYLOR. There is a lot of work to do to improve the safety of produce. Absolutely, Mr. Chairman.

Mr. KUCINICH. In fact, doesn't the FDA's 2008 guidance for the industry to minimize microbial food safety hazards for fresh cut foods and vegetables incorporate specific standards for processing, packaging, and transporting leafy greens that CALGMA does not? Isn't that true?

Mr. TAYLOR. Yes.

Mr. KUCINICH. OK, we are making progress.

Ms. Pegg, I can't tell you how many times farmers, especially small farmers, have told me that the USDA represents everybody but the farmers. Let us hope the new administration succeeds in changing that impression.

In the next panel we are going to hear from a farmer who has a lot of criticism for CALGMA. We are going to hear from a survivor of E. coli poisoning related to pre-cut lettuce that she ate in 2008.

As you know, USDA is actively promoting the nationalization of CALGMA. What is the USDA's position on CALGMA's apparent double standard in that it prescribes specific if not always scientifically supportable requirements on farmers while it condones questionable processing protocols that benefit processing companies such as coring lettuce in the field?

Ms. PEGG. We do not have a position on the current national leafy greens marketing proposal. That is before the public. It is at the very beginning of the process. The hearings will begin in September and October.

Mr. KUCINICH. What do you think?

Ms. PEGG. What do I think?

Mr. KUCINICH. What do you think?

Ms. PEGG. I think at the end of the day the program needs to work for small producers. It needs to work for different cultural practices and regional differences. I think at the end of the day that is the only way you are going to have the best national program.

Mr. KUCINICH. At the end of the day do you think the processing companies ought to have protocols that are protective of the consumers?

Ms. PEGG. Processors, yes, should. Everyone has to play a part in food safety in the chain.

Mr. KUCINICH. Including processors? Not just the farmers but processors as well?

Ms. PEGG. Yes, of course.

Mr. KUCINICH. Ms. Pegg, if CALGMA becomes nationalized, there will likely be increased costs on growers, farmers, as they take mitigation measures to be in compliance with the CALGMA requirements. These costs will be both financial as well as environmental. Examples include the costs of turning areas of land that might have been previously wild into empty lots and the associated land erosion, runoff, and stream contamination that follow. With this in mind, do you believe that the USDA should consider environmental impacts when promoting marketing agreements and regulating food production?

Ms. PEGG. Yes. We must consider environmental impacts. We must make sure that it is compliant with State and Federal laws.

I think the other point you bring up is that right now farmers are facing, and I just got an email last night from a farmer I know in California, buyers who are requiring good agricultural practices. So even without the marketing agreement you are seeing buyers demanding good agricultural practices of farmers.

Mr. KUCINICH. Let us talk about a specific issue that would matter to the processors as opposed to the farmers. Isn't it true that the "best consumed by" expiration date that is stamped is now 15 to 17 days after the produce leaves the processing plant while only 7 years ago the "best consumed by" date for fresh cut produce was more like 5 to 10 days?

Ms. PEGG. I actually have no knowledge of the "best consumed by" date. I think that may be an FDA issue.

Mr. KUCINICH. OK, let us go to Mr. Taylor. She deferred to you.

Ms. PEGG. Oh, sorry.

Mr. KUCINICH. Did you get the question?

Mr. TAYLOR. We are partners here, Mr. Chairman.

Mr. KUCINICH. I see that partnership. Now I want to find out how good of a partner you are. Can you answer the question?

Mr. TAYLOR. Those "best consumed by" dates are really a company measure. Those aren't an FDA requirement. They address product quality in principle.

Mr. KUCINICH. OK, they are company measures. But isn't it true that the "best consumed by" date that is stamped right now is about 15 to 17 days after the produce leaves the processing plant? Is that right or not?

Mr. TAYLOR. I don't personally have those facts at my disposal. I don't have any reason to——

Mr. KUCINICH. You need to have them. You are the guy. You got to have them. It is 15 to 17 days after the produce leaves the processing plant. But a few years ago, Mr. Jordan, the "best consumed by" date for fresh produce was more like 5 to 10 days.

I would ask you, Mr. Taylor, to take note of that. Wouldn't it show you that you are closing a window here a little bit on issues of safety? You are opening up the possibilities of contamination, especially if these bagged leafy greens become hothouses of contamination if there is not consistent refrigeration?

Mr. TAYLOR. Again, science-based preventative controls are all about understanding issues just like that. What is the likelihood of growth? What are the conditions that would reduce growth? What is an acceptable holding period for products? So in doing our preventative control regulations, that is the kind of issue that we will need to address.

Mr. KUCINICH. I have one final question and then we are going to go over to my colleague, Mr. Jordan. Ms. Pegg, CALGMA is silent on the selection of "best consumed by" dates. It doesn't require processors to reverse the trend of longer and longer "best consumed by" dates. Isn't that right?

Ms. PEGG. I really don't know. I don't know what the——

Mr. KUCINICH. The correct answer in this case was yes.

Ms. PEGG. Oh, OK.

Mr. KUCINICH. We are going to go to Mr. Jordan.

Mr. JORDAN. Thank you, Mr. Chairman. Let me thank our witnesses again for being here.

Let me just pick up where the chairman was. Mr. Taylor, you said you didn't know the 15 to 17 days now or that it was a few years ago 5 to 10 days. Is it that you personally don't know or is that something that the USDA does not track and does not have any knowledge of?

Mr. TAYLOR. Well, I am with the Food and Drug Administration.

Mr. JORDAN. The FDA, excuse me.

Mr. TAYLOR. I don't personally know. I am confident that our technical experts would have that information. We can certainly share what knowledge we have with you for sure.

Mr. JORDAN. Ms. Pegg, would you say that the chairman's statement was accurate, that what has happened over the last several years is that date has gone from 5 to 10 to 15 to 17?

Ms. PEGG. I remember a lot of discussion about this in 2006 when the outbreak occurred but I don't know what the guidance is or where the trends have gone. I don't have any information on that right now.

Mr. JORDAN. We are going to have votes here in a few minutes. One of the bills we are going to be voting on is Mr. Dingell's legislation, at least it looks like that. Give me your thoughts on that piece of legislation. I know many in the agriculture community are concerned about that.

Ms. Pegg, I think you said in your introduction at least to the chairman that you have a background with the California Farm Bureau. So let us start with you. What are your thoughts on that bill that looks like it is going to be on the floor here in just a few minutes?

Ms. PEGG. We do support the bill. We look at what the working group produces as they review current statutes and regulatory authorities. We are looking at how we can move into the 21st century. I think what many of these measures——

Mr. JORDAN. Let me ask you specifically about some of the concerns we have heard from folks in agriculture.

Ms. PEGG. I got a long email last night.

Mr. JORDAN. In particular, your former employer, the Farm Bureau, do you think they are way off base? Or, recognizing where you worked before, do you think they have some valid concerns?

Ms. PEGG. I think in working with FDA and USDA we have a good partnership where we can both educate one another about what happens in the field and can assist in giving guidance on food safety practices. So I think it is a good partnership. That is why I personally do not necessarily share the concerns of my former employers.

Mr. JORDAN. Mr. Taylor, would you like to comment on that bill?

Mr. TAYLOR. I think the core strength of this bill is that it would have Congress mandate the shift to a prevention strategy and empower FDA to set and enforce standards for preventative controls that will make food safer throughout the system. For produce, it would of course direct FDA to issue regulations to establish enforceable preventative controls. Importantly, it would direct FDA to take into account the diversity of the grower community and to take into account environmental impacts. These are all factors that have to be considered in order to get it right in terms of having an abundant, safe supply of fresh produce, which is an important goal that we all share.

With respect to the concerns of the agricultural community, we have looked at the bill really hard. I think the bill has evolved a lot. It now very much focuses FDA's authorities with respect to on farm activity to those areas such as fresh produce where there is going to be a science-based or risk-based justification for establishing standards. So I think this is a fairly focused bill in terms of its impact on farming.

Mr. JORDAN. Let me ask you a practical question. Think of the family out there who this time of year sets up the sweet corn stand

to make a few extra dollars for their family. Tell me the impact of the legislation on the floor today or of what we are talking about here in this hearing. Tell me how they might be impacted.

Mr. TAYLOR. In developing regulations like this for an industry that has that degree of diversity——

Mr. JORDAN. In my background, I remember dealing with this back at the State House. It was an uproar when there were some changes in the State of Ohio on how we were going to address truck farms or whatever the official title is they are given in the Ohio revised code. We heard from mom and pop produce businesses all over the State.

Mr. TAYLOR. Activities like that, it is very hard to envision how a Federal regulation could establish a meaningful preventative control regime for an operation like that. So again, taking the command of the bill seriously, we would look at where the appropriate exemptions are and how do you put the boundaries around these requirements so that we achieve the food safety objective but also do it in a feasible, realistic way. That is the command we hope we get from Congress. We plan to do that.

Mr. JORDAN. Ms. Pegg.

Ms. PEGG. I think he does bring up a lot. You have to take into consideration what happens at different scales. I think we will be working a lot with FDA on the implementation of it and providing our experience and our guidance there in that area.

Mr. TAYLOR. Absolutely.

Mr. JORDAN. Mr. Chairman, I have no further questions. Thank you.

Mr. KUCINICH. We will go to a second round of questions. This should be a little bit shorter. Then we will go to the next panel.

Mr. Taylor, if you stretch out that "best consumed by" date on ready to eat produce, it is a benefit for the processor. It obviously facilitates long distance transportation. Instead of 5 to 10 days, 15 to 17 days for "best used by." But isn't a shorter "best consumed by" period in the interest of protecting the public's health, Mr. Taylor?

Mr. TAYLOR. The question is what are the holding conditions for that product and what is the nature of the product. I think you have to have a scientific answer to that question. There is no question that if you have pathogen growth potential and you are not using cold chain sorts of safe handling practices then the longer you hold the product, the greater the risk. So I think that we need a science-based answer to what is right there.

Mr. KUCINICH. Let us look at a science-based case. In the case of the 2006 E. coli 0157 outbreak that affected at least 204 people, has the FDA correlated the location and date of the consumption of the tainted spinach and the date of illness with the date of harvesting? Harvested, "best used by," 204 people with E. coli, have you done the correlations?

Mr. TAYLOR. I don't know the answer to that. I started 4 weeks ago. I can find out what investigation was done and we can brief you all and give you an answer later. It is a fair question.

Mr. KUCINICH. OK. Since you don't know the answer and you started 4 weeks ago—it is lovely to have you here—will the FDA submit in writing to this committee for inclusion in the record a

spreadsheet with that information for each of the known victims of E. coli 0157 poisoning? Namely, we want the location and date of consumption of the tainted products, the date of illness, and the original date of processing. Can you do that?

Mr. TAYLOR. We will provide you the information we have.

Mr. KUCINICH. If you could do that, we would really appreciate that. As a matter of fact, while we are at it, could you do that for all produce related outbreaks since 1999? You know which ones they are. We have talked about a few of them.

Just create a spreadsheet. It shouldn't take too long to do since you already have the information. Put it in a usable form for this committee. It can help us in our deliberations about this issue of the transportation time and the "best used by" date, which so many consumers use as guidelines as to whether or not to consume something.

I have one final question for each of the witnesses. Mr. Taylor, given CALGMA's purpose to protect public health by reducing microbial contamination of leafy greens in the "field-to-fork distribution supply chain," wouldn't it be more consistent with the purpose of CALGMA to include science-based restrictions on the packaging, distribution, and marketing practices of ready to eat produce rather than CALGMA's current near silence or lack of specific requirements on those issues?

Mr. TAYLOR. Mr. Chairman, I can't speak to the permissible scope of marketing agreements at USDA. But the answer to whether we need standards at each of those stages along the way that are enforceable and set by the Food and Drug Administration is clearly yes.

Mr. KUCINICH. Science-based?

Mr. TAYLOR. Yes, sir.

Mr. KUCINICH. Ms. Pegg.

Ms. PEGG. Just to differentiate, too, the California Marketing Agreement is based on the California Marketing Act. We are looking at a national program. I think that through this process as well as the public process we can ensure that a final program does include all those components.

Mr. KUCINICH. Before we conclude this, I would like to go back to Mr. Taylor. I want to read you a few opinions about the effect of the packaging used to market ready to eat produce.

"Because of the higher relative humidity of ready to eat packages, the risk of pathogenic growth is higher. Each degree over 40 degrees will increase the rate of pathogenic growth." This is from Larry Beuchat, Ph.D., at the Center for Food Safety of the University of Georgia.

"The problem comes when leafy greens are coming home in ready to eat bags. If they are left anywhere when temperatures are above 50 degrees Fahrenheit, it is widely known they can become breeding grounds for bacteria." That is from Mr. R. Atwill, Ph.D., of the Western Institute for Food Safety and Security.

"It is a perfect environment for all kinds of things to grow." That is from Elisa Odabashian, the West Coast director of Consumer Union, the publisher of Consumer Reports.

Mr. Taylor, isn't true that all confirmed incidents of E. coli 0157 outbreaks since 1999 have been caused by pre-cut packaged greens?

Mr. TAYLOR. As far as I know. I am only qualifying that because I am under oath and just don't want to misstate it.

Mr. KUCINICH. The Chair recognizes Mr. Jordan. Do you want to take 5 minutes?

Mr. JORDAN. Thank you. I will be brief. I just have a quick question on the bill that is going to be on the floor here in a few minutes.

According to what we have looked at in the bill, this gives the FDA pretty broad authority to regulate how crops are raised. In effect—I will be interested, I know we have a farmer on the next panel—dictating how farmers produce their crop. Is that your understanding of how the legislation is going to work?

Mr. TAYLOR. There is no sort of broad authority for FDA to tell farmers how to grow their crops. There is a very specific authority that if we, based on science, can identify a commodity that poses risks that can be addressed through preventative control measures, such as the industry itself is implementing, then we are empowered in that specific case to establish enforceable standards. But it is not a broad preventative control mandate.

Mr. JORDAN. It seems to me, as the chairman has gone to great lengths to point out and I think appropriately so, that the problem doesn't seem to be with the farmer producing the crop. It seems to be elsewhere in the supply chain, elsewhere in the processing or transportation or what have you.

That is my concern. The farmer knows how to produce his crop. Let's not over-regulate and overburden this guy who is producing the food. Let's certainly not go out there and make it difficult for the mom and pop who are setting up the wagon and selling sweet corn to the neighbors and to the neighborhood. But we just know how government works.

Look, we were told last year that we are just going to have one small little bailout. We promise it will just be one little bailout and this thing won't grow. We don't want to get into the private sector. Well, we have seen what has happened in the last year just in the financial industry, let alone the automotive industry. So these always start out with great intentions, but we know the pattern of government and what typically happens. That is my concern. Frankly, it is in a large degree the chairman's concern. Certainly, lots of folks in agriculture, it is their concern because they just know the nature of government.

It is tough enough many times for folks in agriculture to deal with the State Department of Agriculture and other regulatory agencies at the State level, let alone now Big Brother in Washington telling them how to run their farm or how to run their business. That is my big concern.

We will continue to watch this whole process relative to the bill and the issue we are addressing here in the committee.

With that, I would yield back, Mr. Chairman.

Mr. KUCINICH. Thank you, Mr. Jordan. We are going to go to one more round here before we get to the next panel.

Ms. Pegg, here is another example of something farmers have a problem with. CALGMA identifies a number of sources of potential pathogens that must be avoided for certification. These include birds, feral pigs, and other wildlife as well as cattle. To comply, farmers are paying for measures such as the building of large fences to thwart wildlife. But the science is hardly conclusive, Ms. Pegg, that the wildlife was a likely source of contamination in the 2006 spinach contamination. Isn't that so?

Ms. PEGG. Well, in the 2006 outbreak, actually there was, and maybe FDA can speak to this, but there was concern about wildlife in that outbreak that did occur. Wild pigs were the wildlife in question.

Mr. KUCINICH. You are saying there was concern. Is that evidence-based or is it conjectural? What is the basis of that concern? Was it conclusive or was it conjectural? Was it science-based? What was it?

Ms. PEGG. Maybe you can speak to the investigation but if you have been to the Salinas Valley and that region——

Mr. KUCINICH. I have been to Salinas Valley.

Ms. PEGG. OK. In that area there is some known wildlife activity. Now, the California Leafy Greens Handlers Marketing Agreement does look at other potential risks. They also do rank wildlife as high risk or low risk.

Mr. KUCINICH. In order to facilitate this hearing, I would like you to supply to this committee the information about the basis of your statement that wildlife was somehow connected with this. I would like to see some scientific backup of that, OK?

Ms. PEGG. OK, I will get that. It is for the 2006 outbreak?

Mr. KUCINICH. Right, exactly.

Ms. Pegg, a leafy greens field's proximity to cattle is a high risk circumstance for E. coli contamination. Does CALGMA make distinctions between high risk circumstances and low risk circumstances such as the presence of frogs or other wildlife? Does CALGMA prioritize, in other words, high risk circumstances while deprioritizing low risk circumstances?

Ms. PEGG. I believe it does.

Mr. KUCINICH. Isn't it true that all farms have to eliminate riparian areas and hedge rows if they are within a CALGMA specified distance from a crop edge?

Ms. PEGG. I am not positive on the current best practices on that.

Mr. KUCINICH. Ms. Pegg, I want you to look at this slide on the screen. Can staff put the slide up? OK. The aerial photograph above was taken before CALGMA. You can plainly see a strip of green between several fields where trees and hedges are and where birds and wildlife can take shelter. Now look at the aerial photograph below, taken after CALGMA. Here you can plainly see that the strip of trees and hedges has been eliminated. There is no wildlife there.

Isn't it true, Ms. Pegg, that CALGMA would have required the cutting down of those trees?

Ms. PEGG. I don't know if I can speak to that because I don't know if they are CALGMA participants. This has been a huge issue. We have discussed this since 2006, how do you deal with

whether there are there real risks or not. I was talking to California Fish and Game this week about it. It is a big issue.

Mr. KUCINICH. You are the Nation's advocate for farmers. Does it make sense for the USDA to advocate for a processor-based framework that requires all farmers to spend heavily to prevent low-risk events such as contamination by wildlife while the higher risk but rarer circumstance of proximity to cattle and the known risks associated with processing and packaging leafy greens are more significant contributors to the problems CALGMA intends to address?

Ms. PEGG. Any program needs to address the risks and look at high risks versus low risks. I think what we are looking at in terms of any program is all chains in the process and how to reduce the risks.

Mr. KUCINICH. So who should pay for compliance with CALGMA, the farmer or the processing industry? Should the cost be shared?

Ms. PEGG. Under the marketing agreement, I believe they propose a per carton assessment that the handler pays to cover the costs of the marketing agreement.

Mr. KUCINICH. So who currently pays for the measures adopted to comply with CALGMA?

Ms. PEGG. I think for the California Leafy Greens Handlers Marketing Agreement, that is a per carton assessment that pays for it.

Mr. KUCINICH. Farmers.

Ms. PEGG. Their handler signatories. So handlers pay it.

Mr. KUCINICH. Farmers.

OK, I think we have completed questioning of the first panel. We will be in touch with you regarding the followup on questions that we have asked. We appreciate your cooperation with the committee and your presence here today.

Those buzzers that you heard are the reason why I am going to have to recess this meeting until after votes. How many votes do we have? There are three votes so I would like to take a half hour break. Then we are going to come back for the second panel. We will take testimony from those who are here to talk about their experiences.

I want to thank the representatives of the FDA and the USDA for being here. We look forward to working with you on these issues so that we can help consumers across America have more confidence in the safety of our leafy greens packaged foods. Thank you very much.

The committee stands in recess for a half hour. We are going to vote.

[Recess.]

Mr. KUCINICH. Before we begin, I just want to acknowledge the work of our staff on both sides who have helped with this hearing. We appreciate your work. I want to make it known that one of our staffers, Charity Tillemann-Dick, who has done a lot of work on this could not be here today because of an illness. We look forward to her return. But she did a lot of great research and I just want to acknowledge that for the record, actually. Thank you.

We are going to go to our second panel of witnesses. I would like to introduce them. We will start with Ms. Kelly Cobb. Welcome, Ms. Cobb. Kelly Cobb is a survivor of E. coli poisoning and has

come here today to share her story with us. Her husband, Matt Cobb, serves in the U.S. Marines. They are parents of two young children.

Mr. Scott Horsfall is the chief executive officer of the California Leafy Greens Marketing Board. Mr. Horsfall has served as chairman of the U.S. Agricultural Export Development Council, was a member of the Agricultural Trade Advisory Committee for Fruits and Vegetables, and is past chairman of the Produce Marketing Association's International Trade Conference. Welcome, Mr. Horsfall.

Mr. Dale Coke, welcome. Mr. Coke is a farmer and a member of the Community Alliance with Family Farmers. Mr. Coke is also the founder and President of Coke Farm, a produce cooling, storage, and shipping company located in San Juan Bautista, CA that represents local California organic growers in selling throughout the United States and Canada. He is also a partner in Jardines, a diversified organic farming operation growing on approximately 500 acres in Monterrey and San Benito, CA counties. The sixth generation of his family born in California to work in agriculture, he pioneered spring mix lettuce and was instrumental in developing its market.

Ms. Caroline Smith DeWaal, welcome. Ms. DeWaal is the director of Food Science at the Center for Science in the Public Interest where she is a leading consumer analyst on reform of laws and regulations governing food safety. Since 1999 she has maintained and annually published a list of food-borne illness outbreaks organized by food source that now contains over 15 years of outbreak reports. She has presented at numerous conferences. She is a co-author of the book, Is Our Food Safe: A Consumer's Guide to Protecting Your Health and the Environment and has authored numerous papers on food safety.

I want to thank the witnesses for their presence here today. It is the policy of our Committee on Oversight and Government Reform to swear in all witnesses before they testify. I would ask that you rise and raise your right hands.

[Witnesses sworn.]

Mr. KUCINICH. Thank you very much. Let the record reflect that each of the witnesses has answered in the affirmative.

As with panel one, I ask that each witness give an oral summary of his or her testimony. I would like to see you keep that summary a maximum of 5 minutes in duration. Any testimony that you want to add beyond that and your entire statement will be in the record. Anything you want to send to this committee within a few days will be included the record as well. Your complete written statement will be in the record.

Ms. Cobb, welcome. I would like you to be our first witness. Would you please begin?

STATEMENTS OF KELLY COBB, SURVIVOR OF E. COLI POISONING; SCOTT HORSFALL, CHIEF EXECUTIVE OFFICER, CALIFORNIA LEAFY GREENS MARKETING BOARD; DALE COKE, FARMER AND MEMBER, COMMUNITY ALLIANCE WITH FAMILY FARMERS; AND CAROLINE SMITH DEWAAL, DIRECTOR OF FOOD SCIENCE, CENTER FOR SCIENCE IN THE PUBLIC INTEREST

STATEMENT OF KELLY COBB

Ms. COBB. In May 2008, I was busy as a stay at home mom raising my two children, Liberty, who is three, and Matthew, who was one at the time. We were in Washington visiting family from California. We were there without my husband because he was serving as a Marine in Iraq for the second time.

On May 10th, my mom invited me to go to a banquet dinner with her and some of her friends. Little did I know, by accepting her invitation I would be changing my life forever. That night I ate a salad that was contaminated with E. coli. My mom, my children, and her friends who were there with us happened to sit at the same table. I just happened to pick the seat that was contaminated. My children were there with us. My son was on my lap but luckily he didn't eat greens at the time.

On May 15th, I was getting ready for our drive back to California. I went to bed that night with a stomach ache and woke up on May 16th with diarrhea and most painful stomach cramps that occurred every 10 minutes. My stool turned to blood at about 5.

I then proceeded to go to the ER where they just said that I had a bacterial infection. I went home and was unable to hold down water or the medicine that they gave me so I returned to the hospital. Two days later I was told that I had E. coli and that was the cause of the illness, not what they had thought. I was discharged from the hospital only to return a couple of days later because I had developed a condition of HUS.

I was told at that time that my kidneys were only functioning at 50 percent. I was then started on plasmapheresis where they cycled out my blood and put in the new stuff. Over the time that I was in the hospital, I had over 50 blood draws, two ultrasounds, a CAT scan, a colonoscopy, seven IVs, a central line in my neck, four units of whole blood, and 80 units of plasma.

Both my husband and my father were in Iraq at the time. I had to send a Red Cross message to my husband to let him know what was going on. He was unable to come home. I had the kids. I was the only caretaker with him being gone so my mom took over that responsibility and set up child care for them while she was at work. They came to see me at the hospital every day but they did not understand why I wasn't able to go home with them or why they couldn't stay with me. They were so young that they didn't understand what was going on.

There were several times that I didn't think I was going to make it because of how sick I was. I remember on 1 day, I think it was the 28th, I had an allergic reaction to some pain medication that I was given and I got intense chest pain. I remember blacking out and not really knowing what was going on. I honestly thought I was going to die right there on the hospital bed while my husband

and father were in Iraq and the kids were at home. I thought I wouldn't be there with them anymore.

With that, I was unable to really focus on what the nurses were telling me. They gave me another medication to help with the reaction.

From that incident, from the E. coli I no longer eat any produce that I can't see being washed myself. I have gone to restaurants and asked them how they prepare their salads. I clean everything from a bag of lettuce to a watermelon because when you cut through it, it is going to hit your fruit.

The time I have with my family means so much more to me now because I know that at any time it can be taken away from me. I am honestly surprised with how sick I got that I am here today.

If anything, I would want the parties at fault in my particular case to know that they took me away from my kids for 2 weeks. That is time that they will never get back. My son was one. He developed every day that I was gone. He came to the hospital saying new words every day and doing new things.

I can't describe to you the pain that I was in because I don't have a comparison that I could give to you. I would rather break bones than go through that. I would rather have a broken arm right now than go through the pain that I felt from the E. coli. I don't have a comparison to actually give to you on what I felt.

It could be their family. It could just as easily have been one of my kids. Had it been, it would have been devastating to them what I went through.

[The prepared statement of Ms. Cobb follows:]

Ms. Kelly Cobb
Survivor of E. Coli Poisoning

Domestic Policy Subcommittee
Oversight and Government Reform Committee

Wednesday, July 29, 2009
2154 Rayburn HOB
2:00 p.m.

"Ready-to-Eat or Not: Examining the Impact of Leafy Green Marketing Agreements"

In May 2008 I was a busy as a stay at home mom raising 2 children, Liberty 3, and Matthew, 1. We were visiting family in Washington from California. We were there without my husband, Matt, because he was a Marine serving for the second time in Iraq. On May 10th my mom invited me to go to a benefit dinner with her and some friends. Little did I know that by saying yes I would be changing my life forever. That night I eat a salad that was contaminated E. coli, my children, my mom, and her friends eat that same salad off different plates. I just happened to sit down at the "right plate" after what happened to me, I'm just happy that Liberty, or Matthew weren't the one that sat there, the outcome could have been much more devastating.

On May 15th I was getting ready for my drive back to California. I went to bed that night with a stomach ache. I woke up at 0230 on May 16th with diarrhea and the most painful stomach cramps that occurred every ten minutes until my stool turned to blood at 0500. At 0630 I went to the ER at Good Samaritan Hospital, in Puyallup WA. I was sent home later that morning only to return at 1800 because I couldn't hold my medication or water down. I was admitted to Good Samaritan on May 17th because I couldn't keep anything down, I was in a lot of pain and the diarrhea had returned, and stayed there until May 21st. On May 19th I found out that I had E. coli and that was the cause of the diarrhea and pain.

When I was discharged from the hospital I was able to hold down food and water, along with my pain medicine. I woke up May 21st not feeling well and later that evening I started to vomit again; it lasted thru the night and into the morning of May 22nd. I was taken back to Good Samaritan and after a full blood work up I was told that my kidneys were only working at 50% and that they were bringing in a blood and kidney specialist in the morning. I was readmitted to Good Samaritan on May 22nd. On May 23rd the urologist (kidney doctor) told me that I would start plasma exchange, because my kidneys weren't cycling out the toxins and that I had developed Hemolytic-uremic

syndrome (HUS). I then signed all the forms for him to insert a central line into my neck for the treatments. For the next 8 days I underwent 1 full treatment per day. I was discharged on May 30th. Over the two weeks that I spent in the hospital I had over 50 blood draws, two ultrasounds, a CAT scan (This was performed because my body wasn't recovering the way they would have liked to seen), a colonoscopy, seven IVs, a central line in my neck, four units of whole blood, and 80 units of plasma (eight plasma exchanges with ten bags at a time).

I felt so many emotions over the time I was sick. Scared, hurt, angry, upset, depressed. Both my husband and father were in Iraq during that time. I had to send a Red Cross Message to Matt, to let him know what was going on and we had to wait for my dad to call to tell him. I felt horrible for having to tell them what was going on because I didn't want the fact that they were thinking about me to hurt them or one of their men. At times I didn't know if I was going to make it. I didn't know if I would get to see my kids again. Every time they walked out my room, it broke my heart. Liberty would ask me every day if it was time for me to come home and take care of her. There were times that I could hear her and Matthew crying as they walked down the hallway leaving my room. I wondered and worried everyday about who was going to be taking care of them and if I was putting too much on my mom and mother in law. My children are my world and the thought of them not being taken care of crushed me. The thought of not making it through and watching them grow up broke my heart.

My injury affected not only myself but so many people: my two children, my husband, my mother, my in-laws, my father, and my friends. Liberty had only been away from me for two nights before this and that was when I had Matthew. And Matthew, well, he had never been away from me like that. They had to go two weeks without me and even after I got home I still wasn't able to fully take care of them. The week after I got out of the hospital my aunt would come over during the day to care for me and the kids. My husband was in Iraq wondering if I was going to make it or not and who was taking care of his kids, same with my dad. My mom had to wake up at 4 am, an hour to an hour and a half before she normally would to take the kids to either my mother in law or a family friend for the day. Then after work she would pick up the kids and bring them to see me. That was the best part of my day, getting to see my babies. My son did not let me leave his sight for the first six months, not even for a shower. He was so scared that if he could not see me that I was going to leave again. My daughter still talks about bringing me her Daddy Doll while I was sick and she tells people not to be scared of the blood machine because she remembers coming and seeing me while I was getting a unit of whole blood.

My hospital stay was pure hell. I've never had a harder two weeks in my life. The pain that I felt was unbelievable. For the first few days I really wasn't sure what was going on. I remember bits and pieces of talking with the doctors. Every morning at 4 am they would come in to draw my blood and at 7 am my 3 doctors (Physician, kidney, and blood) came to talk with me. Most days were spent by myself, with nurses coming in and out of my room. I remember being so swollen at one point that I couldn't even

bend my fingers. I went from 140lbs to 180lbs. It hurt to get out of bed because I was so swollen; it felt like I was standing on pins. During my plasma exchange I would sleep to help the time go by faster; there was just something about the blood being cycled out of me that was hard for me to handle. I remember the floor I was on, lost four people the first four days I was there. I can remember thinking, "Why did they put me here, everyone around me is dying"? I couldn't shower for eight days because of the central line in my neck; I could only take sponge baths. My hair was so dirty when I left the hospital that I went to a hairdresser to have her wash my hair. When it came time to have my central line out I had to lie on my back for 30 minutes and when the nurse pulled it out it felt like I was giving birth out of my neck.

There were a lot of bad times that stand out in my mind about those two weeks. On May 23rd, when I found out that I was going to have the plasma exchange, that is when I started to think I wasn't going to make it. I remember thinking to myself that I need to talk to my mom to let her know what I wanted if I died. That I would want her to move to CA to help my kids and my husband adjust to me being gone, and so that my babies wouldn't have to go to daycare. There was one day, Wednesday, May 28th, that I was told that it was going to be four more days until I was going to get released and I just broke down. It wasn't fair to my kids that their daddy was in Iraq and that they had to be away from him and now they had to be away from me too. They didn't understand why they couldn't stay with me in the hospital and why I couldn't come home and put them to bed. I cried that whole day. Whenever anyone talked to me I just cried because I couldn't handle it anymore. I was ready to be home with my kids again. I felt like I was missing so much. My son got bigger and both of them started talking more. That same day I honestly didn't think I was going to make it. I remember getting my medicine before my plasma exchange and having such a bad reaction that I had intense chest pain and blacking out. At that point I remember holding my husband's grandmother's hand and thinking that's how I was going to die, in that hospital bed and wasn't able to say goodbye to my husband and kids. Thinking that my kids would grow up without me, with that thought I made myself open my eyes and listen to what the nurses were saying to me.

This whole thing has changed my life. I no longer eat produce that I can't wash myself. When we go out to eat at a restaurant we ask if they make their own salad or if they get it out of a bag. I wash everything from bagged salads to watermelon now. I have to go every six months to get blood draws done. As of right now I haven't been told of any future health problems. I have been told that if I get pregnant that I have to be seen right away and be much more careful about my pregnancy because of the blood issues. I can't even handle watching someone eat a salad. It makes me sick to think about. I get heartburn much easier and more intense than ever before. The time with my family means so much more to me. Thinking that I was going to die showed me that at anytime all of this can be taken away from us.

I want the party at fault to know that they took a stay at home mother away from her children for two weeks. That because of them I went through pain that no person

should ever have to go through. I would rather break bones than have the pain of e. coli again. I would ask them to really think about changing the policies about washing their product. And to think about how they would feel if it was their mother, father, daughter, son, husband or wife that was lying in that same bed as me, with all the tubes and wires that I had. That it could have just of easily been one of my children who ate that salad, that a small child could have been just as sick, if not worse, than me because of a mistake they made. I want them to know that their actions affect a lot more than just their pocket book.

Mr. KUCINICH. Thank you very much for coming here to testify. We are certainly going to be having some questions of you when we go to that phase of this hearing.

At this point, I would like to ask Mr. Horsfall to proceed for 5 minutes. Thank you very much.

Before you proceed, I want to welcome some of our visitors here from China, Macau. Thank you for being here.

Please proceed.

STATEMENT OF SCOTT HORSFALL

Mr. HORSFALL. Thank you. Good afternoon, Chairman Kucinich and Ranking Member Jordan. I am happy to be here. I am always happy to talk about our program.

I will get to my statement but I would express to Ms. Cobb that what she went through does not fall on deaf ears in our industry. Shortly after I started this job, USA Today ran a recap. It was a year after the original outbreak. They presented the stories of the four or five people who had died because they ate spinach. I know, because I work with this industry, that they take that to heart. They are trying to do everything they can do so that there aren't more victims and so that we can reduce that risk as much as possible.

The Leafy Greens Marketing Agreement was established in 2007. It is a mechanism, quite simply, for verifying through mandatory government audits that farmers of leafy greens follow a rigorous set of food safety standards. We are an instrumentality of the State of California and we operate with oversight from the California Department of Food and Agriculture.

Although the leafy greens industry had always prioritized food safety, in the aftermath of that outbreak in 2006, farmers, shippers, and processors recognized that more effort was needed to protect public health. The question was how to do it. A lot of different approaches were looked at, including regulation at both the State and national levels, marketing orders, and a marketing agreement. The decision was ultimately made to go with the tool that was most readily available, which was a marketing agreement.

It is a voluntary organization but it does have the force of government behind it. Our members, when they do join, it is mandatory that they follow the rules of the program. It also has the flexibility to change and amend the program as we get new research.

You have talked about research a lot already this afternoon. We are keenly interested in research that is being done so that we can make the program better. That flexibility is actually one of the key benefits of the LGMA structure.

Our program is focused on preventing the introduction of pathogens into leafy greens fields and farms. We applaud the Obama administration and the President's Food Safety Working Group for their focus on prevention in their approach to improving food safety. On July 7th in their press conference we were happy to hear Vice President Biden and Health and Human Services Secretary Sebelius talk about prevention as job No. 1.

I was asked to talk about where our metrics came from. As the LGMA was being developed, there was a parallel effort to create a set of food safety practices and standards, sometimes referred to

as good agriculture practices or metrics. They were developed by university industry scientists as well as other food safety experts, farmers, and shippers. Those standards were reviewed by FDA, the USDA, and other State and Federal health agencies. They cover the major risk areas that have been identified by FDA and other food safety experts.

Practices include careful attention to site selection for growing fields based on farm history and proximity to animal operations, appropriate standards for irrigation water and other sources of water, prohibition of raw manure and the use of only certified safe fertilizers, and of course good employee hygiene in fields and harvesting.

Our members are subject to mandatory audits by the California Department of Food and Agriculture to ensure that they are in compliance with the program. Those auditors are USDA trained and the process that we use is a USDA certified audit process. Our members face penalties if they are not in compliance up to and including decertification from the program, which can lead to serious and significant repercussions for the company. From July 23, 2007 when we first began our auditing, we have done over 1,000 government audits of our members. Those continue today even as we speak.

We all know that maintaining food safety vigilance is crucial to the future of the produce industry. While there is still very much to do—and we are not done—I believe that the leafy greens industry is doing more to provide a safe, wholesome, and delicious product now than they ever have before.

Thank you very much.

[The prepared statement of Mr. Horsfall follows:]

Statement
Of
E. Scott Horsfall
Chief Executive Officer
California Leafy Green Products Handler Marketing Agreement
Sacramento, California

Domestic Policy Subcommittee
Oversight and Government Reform Committee
Wednesday, July 29, 2009
2:00 p.m.

"Examining the Impact of Leafy Greens Marketing Agreements"

Introduction

Good afternoon Chairman Kucinich, Ranking Member Issa and Members of the Committee. My name is Scott Horsfall and I am Chief Executive Officer of the California Leafy Green Products Handler Marketing Agreement. The Leafy Greens Marketing Agreement – commonly referred to as the LGMA – was established in 2007 as a means of providing handlers and growers of lettuce, spinach and other leafy green products in California a means of verifying, through government audits, that they are following a set of food safety practices designed to improve food safety. We are an instrumentality of the State of California, and operate with oversight from the California Department of Food and Agriculture.

Although the leafy greens industry has always prioritized food safety, in the aftermath of the 2006 outbreak, farmers, shippers and processors recognized that more effort was needed to protect public health. The question was how to do it. Several potential solutions were discussed, including regulatory and legislative options both at the state and federal levels. These discussions were broad and included parties from both inside and outside the industry. As these discussions progressed, it was clear that the leafy greens industry was determined to address the issue in a responsible manner and to do it in a way that would rebuild confidence among consumers, buyers, and regulators.

In the end, the decision was made to create the California Leafy Greens Handler Marketing Agreement (now usually referred to as the LGMA). The marketing agreement gave the farmers, shippers and processors of leafy greens a vehicle to protect public health that could be in place in time for the next year's growing season. This marketing agreement also provided the industry with the flexibility to quickly change and amend

the program based upon sound science and new breakthroughs in food safety research. This flexibility is one of the key benefits of the LGMA structure.

The LGMA is focused on preventing the introduction of pathogens in leafy greens fields and farms. And we applaud the Obama Administration and the President's Food Safety Working Group's focus on prevention in their approach to improving food safety systems in the United States. We were happy to hear Vice President Biden and Health and Human Services Secretary Sibelius describe prevention as job number one at their food safety press conference on July 7th.

So, how does the LGMA protect public health? The LGMA, operating with oversight from the California Department of Food and Agriculture, is a mechanism for verifying through mandatory government inspections that farmers of leafy greens follow LGMA-accepted food safety standards. Farmers, shippers and processors in California have shown their willingness to follow these food safety standards by signing onto the LGMA. Once a company joins the LGMA, it becomes mandatory for that member company to sell and ship product only from farmers who comply with the LGMA-accepted food safety standards.

LGMA food safety audits are conducted by California Department of Food and Agriculture inspectors who received special training and certification from the United States Department of Agriculture. Member companies of the LGMA have agreed to tax themselves to collectively pay for the expense of mandatory government audits.

As I previously stated, the LGMA operates under the authority of the California Department of Food and Agriculture. The LGMA Board of Directors was appointed by the secretary of CDFA. And, all actions of the LGMA and its Board of Directors must be approved by the secretary.

The Food Safety Standards

As the LGMA was being created, there was a parallel effort to develop a set of food safety standards. These standards, sometimes referred to as Good Agricultural Practices or metrics, were developed by university and industry scientists and food safety experts, along with farmers and shippers. The standards were also reviewed by the FDA, USDA and other state and federal government health agencies.

These science-based standards include careful attention to site selection for growing fields based on farm history and proximity to animal operations, appropriate standards for irrigation water and other water sources that can come in contact with crops, prohibition of raw manure with use of only certified safe fertilizers and good employee hygiene in fields and handling. The program is based on GAPs and essentially serves as a standard risk assessment similar to HACCP.

Hazards in the growing and harvest operations have been identified and specific control points have been established. Under the Leafy Greens Marketing Agreement, produce handlers are required to ensure that their product is meeting these standards. They are subject to mandatory audits by the California Department of Food and Agriculture to ensure that they are complying with these standards. It should be noted that not only

are the auditors CDFA employees but they are USDA trained and the process by which they audit is USDA-certified. And, the LGMA handler members face penalties if found not to be in compliance, with the ultimate consequence of decertification if they commit flagrant violations of the program's requirements – and this compliance program is transparent and public.

Documentation is at the heart of all of these efforts. Through mandatory government audits, the LGMA program ensures that all of these standards are being implemented in the field and accurately documented.

The Audit Program

Again, the goal of the LGMA is to protect public health by minimizing potential sources of contamination into the fields and farms through compliance with the LGMA-accepted food safety practices. The mandatory government audits required by the LGMA are designed to determine whether a member company is in compliance and member companies are audited on a regular and random basis at least four times per year. All members are subject to both announced and unannounced audits.

If an LGMA member company is found to be out of compliance with the food safety standards, that company is issued a citation. Each citation is recorded at one of four levels ranging from a Minor Infraction to a Flagrant Violation. The LGMA Compliance Audit Process provides opportunities for member companies to take corrective action on citations that do not pose an immediate threat to food safety and public health. Flagrant violations, which could result in a potentially unsafe product reaching the marketplace, result in decertification from the LGMA program. Decertification from the LGMA has significant sales implications for a company, as the grocery stores and restaurants who buy California leafy greens products support the food safety program by only purchasing these products from the member companies who have passed the mandatory government audits. Further, both Canada and Mexico will only allow imports of California leafy green products from companies who are members of the LGMA in good standing.

From July 23, 2007 when the first LGMA audits began through today, over 1,000 government audits of LGMA members and farmers have taken place. The audit includes five specific areas of inspection with several "checkpoints" that inspectors must review for compliance. There are a total of over 200 checkpoints which government inspectors must verify during an audit.

We have been very pleased with the efforts of the industry to comply with this unique and rigorous program which has become a model program for farmers in other states. But even 1% lack of compliance shows that we must improve, and it is very apparent from what I've seen as the public member of the LGMA board that this industry will continue to work diligently to raise the food safety bar even higher.

Food Safety in the California Leafy Greens Industry

The California Leafy Greens Marketing Agreement is perhaps the most visible part of the industry's commitment to safety, but it is not the whole story. And it's important to recognize the huge strides the industry has taken to improve food safety in the wake of the 2006 tragedy. In 2007, the LGMA commissioned

a survey of its member companies to find out what other steps have been taken to improve food safety systems in order to protect public health.

The survey found that overall spending on food safety practices, already high prior to the outbreak, has tripled since September 2006. Based on the industry survey, LGMA member companies have doubled the number of people employed specifically to work in the area of food safety. Water tests have increased fivefold. And the industry has increased buffer zones due to neighboring operations or animal intrusions which, in some cases, have resulted in the loss of productive acreage.

We have also seen the LGMA become a model for other states and industries. The leafy greens industry in Arizona has already adopted its own marketing agreement based on the California model. The tomato and mushroom industries have established food safety programs using the LGMA model for guidance. And the program has received international recognition as well with the LGMA import requirements by both Canada and Mexico.

There is also an effort underway to create a national marketing agreement that could bring this approach to the leafy greens industry nationwide. Recently, a group of organizations including the Produce Marketing Association, the United Fresh Product Association, the Western Growers Association the Leafy Greens Council and grower groups from Texas, Georgia and California requested that the US Department of Agriculture consider establishing a National Leafy Greens Marketing Agreement. This organization could provide the national industry a mechanism for ensuring, through mandatory government audits, that growers and handlers were implementing food safety practices adopted on a national basis. The program, as currently formulated, would also cover imported leafy greens, providing a new level of verification for products grown outside of the United States.

The proposal currently being discussed would create the mechanism for verifying food safety standards – but the standards themselves would be created by a technical review board made up of representatives from all growing regions.

Conclusion

We all know that maintaining food safety vigilance is crucial to the future of the leafy greens industry. While there is still much work to do, through the creation of the LGMA, we can now say more than ever that the California leafy greens industry is producing a safe, delicious and nutritious product that consumers can buy with confidence.

I thank you for your time and attention and the opportunity to speak about this important program.

Mr. KUCINICH. Thank you very much, Mr. Horsfall. Mr. Coke, you may proceed for 5 minutes. Thank you.

STATEMENT OF DALE COKE

Mr. COKE. Good afternoon, Chairman Kucinich and Ranking Member Jordan. Thank you for inviting me here today.

I have been asked to address the impacts of the California Leafy Greens metrics on farming practices. For growers in California, it is estimated that the economic impacts are on the order of about $18,000 per year on average per farm. That will be higher for larger farms and possibly less for smaller farms.

Growers have to, of course, do testing of water, fertilizer, soil amendments, and anything else that goes onto the crop. They have to document all of this. They have to be aware of animal incursions, pay attention to vegetation, and then also provide some kind of traceability.

Traceability is not such an issue for a grower like ourselves. Organic growers have had to be able to trace a product for years. There have also been prohibitions against manure use for organic production for years. For compost, there is no sewage sludge or other kinds of toxic chemicals used.

But organic growers are facing significant issues with the push by regulators to ban wildlife and non-crop vegetation like wind breaks and habitat, which are things that are supposed to be encouraged by organic laws that pertain to maintaining your certification.

Environmental impacts often vary depending on the inspector and his interpretation of the metrics. There are certain companies that use their own metrics, which are called super-metrics in the industry. Wildlife, non-crop vegetation, and water bodies are normally viewed as food safety risks. A lot of environmentally positive projects have been abandoned by growers who have been threatened with the loss of the ability to sell their crops.

Wind breaks, vegetative filter strips, tail water reuse reservoirs, grass roadways, and vegetative ditches have been removed to comply with the inspectors when they come out to check on the crop. Many fields have deer and pig fencing. Some also have frog and rodent fencing even though those haven't been found to be vectors of pathogens. Some of the fields for leafy greens use poison traps for rodents. Secondary poisoning of raptors and owls can occur with this.

A lot of these practices are more based on the processor's having problems pulling them out of the harvested crop because of the nature of the harvest of the crop than it has to do with being a food safety issue.

Practically, this has been a big step backward from environmental protection. It was just starting to move forward on farms.

There is a lot more money and time that farmers have to spend trying to comply with these metrics and document this. The majority of the food disease-related outbreaks that are associated with leafy greens come from pre-cut processed products. There is some kind of failure during that process to make it ready to eat or to make it clean enough that you don't have the pathogens.

Salad processors tend to point to the fields as being the issue. It is very difficult for farmers to grow sterile crop in a open field. We have always had employee hygiene. We are concerned about our compost and we don't use manure. We test our water and our fertilizer, as many farmers do just to make sure that we are not part of the problem.

Leafy greens farmers are now in the unenviable position of having to pay for and comply with a roster of unproven safety metrics in attempting to grow pathogen-free crops and being held potentially liable for it.

The California Leafy Greens Marketing Agreement has made steps in the right direction, I think, for the processed product that it should be representing. I don't know that marketing agreements are an appropriate way to provide food safety, whether they be State or national. In my mind they are something that focuses on marketing products rather than on the actual conditions of growing products.

This being said, if this were to be moved in that direction and if the focus was just on processed food, you would reduce a lot of impact. There are a lot of farmers that don't grow leafy greens that go into bags. If the focus was just on the processed arena, you could exempt them.

I was there when they started having the meetings to decide about leafy greens in California. They included specific vegetables. I asked why they were just including a few vegetables. There was no answer because they didn't differentiate whether it was a whole head or a bunched product. It was just they are going to include these vegetables.

The only reason I can come up with is that it is something to enhance their competitive edge. It gives them a marketing advantage if you need to adhere to these metrics. You kind of raise the bar and a lot of farmers might not be able to make that.

[The prepared statement of Mr. Coke follows:]

Mr. Dale Coke
Farmer and Member of Community Alliance with Family Farmers

Domestic Policy Subcommittee
Oversight and Government Reform Committee

Wednesday, July 29, 2009
2154 Rayburn House Office Building
2:00 p.m.

"Ready-to-Eat or Not: Examining the Impact of Leafy Green Marketing Agreements"

1.) The impact of ***CALGMA*** metrics on farming practices, including the economic, geographic, environmental and practical effects of ***CALGMA***

a.) Economic impacts for growers are significant. An estimate from leafy green growers in California indicates an average expenditure of $18,000/ year per farm for food safety efforts. Metrics require the expense of regular laboratory testing of irrigation water, soil amendments, fertilizers and sometimes seeds and transplants. Growers must have someone to regularly monitor fields for wildlife and domestic animal incursions and documentation of all their efforts and testing is required. Farms with more acreage generally spend more to comply with the metrics but can see some economies of scale due to larger field sizes and existing staff.. Smaller farms often have smaller field sizes and grow more diverse crop mixes with animals included. These farms don't usually have staff available to help them comply with metrics nor can they afford to hire extra help. They incur higher costs per acre due to their smaller field sizes and greater complexity. The requirement to have traceability of the produce grown also poses significant financial and record keeping challenges for many growers. Organic farmers are in a better position as far as being able to trace their produce since they have been required to do that for years. They are also more familiar with the definitions of compost and how it's tested, and used to restrictions on manure usage. Organic growers are already prohibited from using sewage sludge, spraying toxic chemicals or using radiation as a means to sterilize their harvested crops. However they face difficulties balancing organic requirements to enhance biodiversity with metrics seeking elimination of wildlife and non crop vegetation.

b.) Environmental impacts vary with different field inspector's interpretation of the LGMA metrics or their own metrics, sometimes called "super metrics". Wildlife, non crop vegetation, and water bodies are normally viewed as food safety risks. Many environmentally positive practices that growers have implemented like NRCS Environmental Quality Incentives Program (EQIP) and Resource Conservation District practices have been removed or abandoned by growers threatened with the rejection of their crops. Windbreaks, beneficial habitat, vegetated filter strips, tailwater reuse reservoirs, grassed roadways and vegetated ditches have been removed from fields to comply with food safety inspectors. Many fields for leafy greens now have wildlife fencing, in some cases to exclude deer or pigs, in other cases to attempt to stop frogs and mice from entering the field. Some fields of leafy greens use bait stations around their perimeter to poison rodents that might enter the field. Rodent predators like hawks and owls can be poisoned secondarily by eating the poisoned rodents.

c.) The practical effect has been a big step backwards for environmental protection on many farms and significantly more time and money spent to comply with a variety of unproven metrics that are interpreted in various ways by the field inspectors.

2.) Farmer Liability. The majority of food disease outbreaks related to leafy greens come from pre-cut or processed "ready-to-eat" products. The point of processing food is to make it safe and really ready-to-eat. Logically food disease outbreaks are a failure of processing. Salad processors continue to point to the fields as the problem and want to make farmers liable. How pathogens are vectored or when they develop in these processed salad products is unknown. Nonetheless food safety standards or metrics have been invented and marketed as the answer to the problem of pathogen contamination. Leafy greens farmers are now in the unenviable position of paying for and complying with a roster of unproven food safety metrics in an attempt to try to grow pathogen free crops in farm fields.These crops are grown outside in farm fields, subject to whatever is in the environment, whatever flies over it, drops or blows into it.

3. Food safety risks and ***CALGMA***. It's unclear if the ***CALGMA*** has made pre-cut salads safer. Pre-cut salads have inherently higher food safety risks due to the methods of harvest, processing, packaging and marketing.

Neither ***CALGMA*** nor the proposed National LGMA seems to be a good way to provide food safety. They use Marketing Acts for reasons that were never originally intended. Logically, pre-cut processed salads should be regulated as a processed food. Due to the methods employed growing, harvesting, processing and packaging crops destined for pre-cut salads there may need to be conditions imposed on where and how these crops are grown. Leafy greens or other vegetables grown for harvest as whole heads or to be bunched do not pose the same risks and should not be subject to unnecessary metrics.

In the pursuit of food safety, misdirected action is often worse than no action at all. The Organic Center's June 2007 report "Unfinished Business: Preventing E. coli O157 Outbreaks in Leafy Greens," sets out the evidence showing, even back then, that wildlife was almost certainly not the cause of the outbreak. Instead, dust blowing from a nearby cattle ranch was the likely cause, for reasons set forth in the report. The clearing of riparian areas and removal of vegetation around spinach fields may increase the risk of dust carrying bacteria onto leafy green fields.

One of the most distressing aspects of the California LGMA was its attempt to legitimize "clean fields" metrics for farmers. Not only did these metrics spawn the buyers' more extreme "super metrics," but they also had a spillover effect in other crops, even those not eaten raw, such as potatoes, artichokes, and Brussels sprouts. And the LGMA legitimizes the use of third-party auditors, imposing significant costs on farmers.

There is a common notion in policy circles that consumers are falling ill from eating fresh-cut leafy greens because farmers are not following certain safe practices. The LGMA responded to this by inventing a series of on-farm practices to address potential risks from water, wildlife, and workers. These have simply been amplified by the various private metrics of buyers, the so-called "super metrics."

In reality, we do not know how the produce becomes contaminated by pathogenic bacteria, and so we don't know what the real risks are. The researchers told the industry that it would take years of research to figure it out, but the industry went ahead and invented metrics anyway to demonstrate that they were doing something.

The proof of this is in the continued rejection of loads of leafy greens that test positive for pathogens, even though they are coming from fields following all of the metrics. Though some of these test results are false positives, nevertheless it is undeniable that pathogenic bacteria are still making it on to leafy greens and to the door of the processing plant.

In the wake of the E. coli O157 outbreak in spinach in California in the fall of 2006, wildlife emerged as one of the leading explanations of how the bacteria got into the spinach field. The science supporting the wildlife theory was always shaky, and in fact, much evidence pointed toward other explanations.

Over the last two years, the California Department of Fish and Game has tested 866 animals including 311 deer, 184 feral pigs, 73 birds, 61 rabbits, 58 tule elk, and various other small mammals. The results – only four tested positive (a pig, coyote, and two elk). These findings have led experts to conclude that wildlife was probably not the source of the E. coli O157 in the 2006 outbreak, although some are waiting for more data to reach a final judgment. Notwithstanding, in the last two years farmers killed 33 deer on one farm, have poisoned ponds to kill frogs, ripped out trees and riparian habitats, and spent millions of dollars building chain link and other fences.

Differences between crops for processing and whole head/bunched Growing-

Crops for processed salads are grown in very high densities and fertility for effective machine harvest. Usually grown on wide beds at plant populations of a million or more plants per acre. Crops harvested for whole heads or to be bunched are usually grown at significantly lower densities between 13,000-45,000 plants per acre. High crop densities and fertility create more succulent plants and a moister microclimate on the bed this can create an environment more suitable for plant pathogen development and possibly enable human pathogens to develop. Less dense plantings have more exposure to sun and breezes a more difficult environment for pathogens to colonize.

Harvest-

The day before harvest, litter crews walk the fields of crops for processed salads picking up anything extraneous on the crop beds like trash or sticks because when the machines start harvesting in the night they can't see what they are cutting. Thousand of pounds of leaves are harvested per hour, everything that is on the bed is conveyed into harvest totes, on to the trailer and shipped to the processor where thousand of pounds of cut leaves are washed in a common water bath, dried and packaged into bags or clamshells then into boxes to be stored and shipped. Significant potential exists for spreading any contamination in the common water bath and the packaging provides an excellent incubation environment for pathogens if the cold chain is not maintained all the way to the customer.The volume of leaves processed in these plants precludes any visual inspection of the crop. Even with litter crews inspecting the fields prior to harvest, foreign object contamination of bagged salads remains a significant industry problem.

Crops harvested for whole heads to be bunched are selectively harvested by hand. People trained to harvest decide what is suitable for harvest leaving immature or damaged crops in the field and place the crop into boxes to be loaded on a truck or trailer and shipped to a precooling facility. The heads or bunches are usually precooled, stored and shipped in the box they were harvested into.

If regulations and metrics were focused only on crops grown to be processed for pre-cut salads, then the acreage of leafy greens (and other crops) grown for whole head or bunched harvest were not subject to unproven unnecessary regulations. Significant acreage would be removed from environmentally negative metrics and many smaller growers would avoid the extra expenses and time spent on inspections and documenting their growing practices.

Any regulations decided upon to provide safer salads should recognize these as a ***processed product***. FDA data shows that since a distinction was made between whole leafy greens and fresh-cut leafy greens in late 1999, all confirmed incidents of E. coli O157:H7 outbreaks in these products have been in product shipped in sealed plastic bags. The FDA itself recently was quoted as follows:

"We have a record of fourteen outbreaks from 2002 [to today] linked to fresh-cut leafy greens," says FDA press officer Stephanie Kisnek. "They were all in sealed bags."[1] Elly Hopper, "Of Mice and Men," Terrain, Spring 2009.

The processing industry has resisted this arrangement, since they do not want their processed salads singled out as more dangerous than whole leafy greens.

They also like the arrangement of having all leafy greens grown under similar food safety metrics, allowing them to buy or reject fields depending on market demand. The present requirement for metrics for all forms of leafy greens reduces the competition from the smaller and local growers unable to justify the time and money required to comply with the metrics.

The ***CALGMA*** is dominated by the salad processor industry. It has engaged peripherally with environmental groups giving the appearance of being interested in environmental issues and those of smaller growers but it's only real focus is to help market salads for it's members. This is not a good way to attempt to provide food safety for pre cut salads. Using this model on a Federal level would be unfortunate for consumers and most farmers.

Mr. KUCINICH. I want to thank the gentleman for his testimony. Your entire statement will be included in the record. As someone who has been so involved in the development of this industry, we appreciate your presence here.

The Chair recognizes Ms. Smith DeWaal for 5 minutes. After your testimony, we are going to go to a round of questions of the panel. You may proceed.

STATEMENT OF CAROLINE SMITH DEWAAL

Ms. DEWAAL. Thank you very much, Chairman Kucinich and also Representative Jordan. My name is Caroline Smith DeWaal. I direct the Food Safety Project for the Center for Science in the Public Interest.

CSPI has concerns about the increasing use of marketing orders as a vehicle for regulating safety. Fifteen different agencies administer 30 different laws that regulate food safety in the United States today. Marketing orders really represent a further fractioning of this already widely fractured system.

Food-borne illness outbreaks linked to fresh produce are among the major public health problems when it comes to food safety. Leafy greens and salads are among the top food categories along with beef, poultry, and seafood that cause both outbreaks and illnesses. In addition, the average size of outbreaks linked to produce tends to be larger so they tend to affect more people.

The importance of robust and reliable food safety practices on the farm cannot be understated. Leafy greens, once contaminated, can support, grow, and spread pathogens until they are consumed. Chlorination and other post-harvest controls can help reduce crops' contamination between different lots of salad, for example, but they don't make contaminated product, product that comes in from the farm contaminated, truly safe to eat. In fact, scientists have shown how bacteria can inhabit the washing systems used for bagged lettuce and transfer bacteria from a contaminated lot really onto a full day's production of salads.

While FDA has jurisdiction over on farm food safety, it really has not acted as an effective regulator. They have been using for at least the past 10 to 15 years the concept of guidance, unenforceable guidance, to the industry instead of regulation. But the absence of enforceable rules leaves a significant hole in the fabric of food safety, allowing and even encouraging the industry to weave standards of its own design.

The Agricultural Marketing Service has served as a friendly regulator of choice when food safety problems arise. At AMS, the food industry can draft their own rules, called marketing orders or agreements, to best suit their needs. But AMS is not equipped to monitor the safety of food. The primary focus of AMS is with the promotion of food products.

The mechanisms that it uses are limited in terms of their geographic scope and often they are completely voluntary. These are voluntary systems. Farmers have to agree and the handlers have to agree to comply. They are limited to U.S. companies and sometimes they are limited to companies just in the State of California. This is particularly troubling when you consider that 13 percent of

our diet is from imported produce. So a huge amount of produce is never going to be subject to these marketing orders.

AMS oversees marketing orders for 22 different commodities including things like almonds and shell eggs. These programs can really instill a false sense of security both for the industries involved and for the consumers because they really are quality programs. They are not based on safety. But given the absence of rulemaking at FDA, it is not really surprising that in the aftermath of the 2006 spinach outbreak the leafy greens industry turned to AMS to create these stronger rules.

I just want to note that these standards really do create uncertainty. They give rise to the private standards which are actually the complaint of many of the growers today. The growers today are saying that these standards are too burdensome. But let me be clear: These aren't mandatory standards. They are not FDA standards. They don't apply to imports.

It is critically important that we actually get a system in place that will protect the public. The Food Safety Enhancement Act, which is before the House of Representatives, addresses this issue head on. It requires FDA to consider both food safety and environmental impacts when promulgating regulations for food production. It requires the standards to take into account small scale and diversified farming, wildlife habitat, conservation practices, watershed protection, and organic production methods. This is all in the legislation that is before the House.

This provides an appropriate focus on public safety. It gives the farmers and consumers both an opportunity to weigh in on these standards, which we don't have today with the AMS standards. It would protect the sustainable and organic farming communities that we all value. These are the type of standards that consumers cannot live without.

Thank you.

[The prepared statement of Ms. DeWaal follows:]

CENTER FOR
Science IN THE
Public Interest
The nonprofit publisher of
Nutrition Action Healthletter

Testimony of Caroline Smith DeWaal
Director of Food Safety
Center for Science in the Public Interest
before the
Subcommittee on Domestic Policy of the
House Committee on Oversight and Government Reform

Washington, DC
July 29, 2009

Good morning Mr. Chairman, Ranking Member Jordan and Members of the Subcommittee. My name is Caroline Smith DeWaal, and I am the director of food safety for the Center for Science in the Public Interest (CSPI). CSPI is a nonprofit health advocacy and education organization focused on food safety, nutrition, and alcohol issues. We are supported principally by the 950,000 subscribers to our *Nutrition Action HealthLetter* and by foundation grants. We accept no government or industry funding.

Thank you for asking me here today to discuss the use of food safety marketing orders. CSPI has concerns about the increasing use of marketing orders as a vehicle for regulating safety. First, and foremost, it represents a further fracturing of our already dysfunctional food safety system. Fifteen different agencies administer 30 different laws that regulate food safety in this country.[1]

Food Safety in Leafy Greens

Food-borne illness outbreaks related to fresh produce are a major public health problem. According to CSPI's database of more than 5,000 food-borne illness outbreaks, fruits and vegetables caused 13 percent (768) of outbreaks with an identified food and pathogen and nearly 21 percent (35,060) of the associated illnesses between 1990 and 2006. Norovirus, *Salmonella* and *E. coli* O157:H7 illnesses have been traced to a wide variety of produce, including lettuce, salads, melons, sprouts, tomatoes, and many fruit- and vegetable-containing dishes.[2] Leafy greens and salads are among the top food categories, along with beef, chicken and seafood, that cause food-borne outbreaks and illnesses. In addition, the average size of produce outbreaks is larger than outbreaks from other foods, thus affecting more people.

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[1] The Government Accountability Office (GAO) has designated food safety as a high-risk area. The fragmented nature of federal food oversight is a principle reason for that designation. *See*, GAO, *High Risk Update: Revamping Federal Oversight of Food Safety*, Rep. No. GAO-09-271, Jan. 2009.

[2] Center for Science in the Public Interest, *Outbreak Alert! 2008, (Dec. 2008).* This database of foodborne illness outbreaks is maintained by CSPI. It contains 17 years of data, from 1990–2006. Outbreaks are classified by both food vehicle and disease-causing agent. Food is classified by which agency regulates the product. During the years 1990 – 2006, there were 3,842 foodborne illness outbreaks from FDA-regulated foods (e.g. seafood, produce, eggs, milk); USDA regulated-foods (e.g. beef, poultry, pork) caused 1,567 outbreaks.

A series of produce outbreaks in the fall of 2006 was a wake up call for the public about the critical state of produce safety. Beginning in August, a nationwide outbreak of *E. coli* O157:H7 from bagged ready-to-eat spinach sickened 205 and killed at least three.[3] Then in late September, *Salmonella* found in tomatoes sickened 183 restaurant patrons in 21 states throughout the nation. *E. coli* O157:H7 appeared in produce once more before the year's end when two separate incidents of contaminated shredded iceberg lettuce sickened a total of 152 individuals at chain restaurants Taco Bell and Taco John.

While many produce outbreaks occurred prior to 2006, the spinach outbreak finally sourced the cause all the way to the farm. The Food and Drug Administration (FDA) traced the exact strain of the *E. coli* bacteria to a California spinach farm, finding it in nearby manure piles, in a creek and even in a wild pig.[4] These findings definitively proved that the *E. coli* contamination that sickened so many people started on the farm.

While the produce outbreaks of fall 2006 have triggered a wake-up call for produce safety, large-scale produce outbreaks are not a new phenomenon in this country. Outbreaks from produce, both imported and domestic, have resulted in deaths, illnesses, both mild and severe, and great market disruptions.

Domestic produce is largely unregulated, and FDA has done little more than coax, urge, and warn producers to improve produce safety.

- In February 2004, following 14 outbreaks linked to lettuce and tomatoes, FDA sent a letter to firms that grow, pack, or ship fresh lettuce and/or fresh tomatoes asking them to review their current operations in light of the agency's guidance.[5]

- After seeing 18 outbreaks in 10 years involving *E. coli* O157:H7 in lettuce, FDA sent another letter in November 2005 specifically to California lettuce firms outlining actions the industry should take in order to ensure lettuce safety.[6]

There is also some evidence that understanding of food safety problems on the farm is minimal. A qualitative study examining food safety practices used by Iowa produce growers was conducted by researchers from Iowa State University. Observational and in-depth interview techniques were used to assess current food safety practices at each operation. Researchers found that producers were conscious of product safety, but levels of awareness about risk varied. Areas that needed improvement included improved hand washing facilities and practices;

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[3] FDA News, *FDA Finalizes Report on 2006 Spinach Outbreak*, March 23, 2007, at http://www.fda.gov/bbs/topics/NEWS/2007/NEW01593.html.

[4] Internat'l Society for Infectious Diseases, *E. coli O157, spinach – USA (multistate)(20)*, ProMED-mail, Archive No. 20061027.3067, 27 October: 2006, at http://www.promedmail.org/pls/otn/f?p=2400:1001:::NO::F2400_P1001_BACK_PAGE,F2400_P1001_PUB_MAIL_ID:1000%2C34969.

[5] FDA, *Letter to Firms that Grow, Pack, or Ship Fresh Lettuce and Fresh Tomatoes*, Feb. 5, 2004, at http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/FruitsVegetablesJuices/GuidanceComplianceRegulatoryInformation/ucm118896.htm.

[6] FDA, *Letter to California Firms that Grow, Pack, Process, or Ship Fresh and Fresh-cut Lettuce*, Nov. 4, 2005, at http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/FruitsVegetablesJuices/GuidanceComplianceRegulatoryInformation/ucm118911.htm.

provision of employee training; and the development of cleaning and sanitizing protocols for both products and food contact surfaces.[7]

The importance of robust and reliable food safety practices on the farm cannot be understated. Leafy greens, once contaminated, can support, grow, and spread pathogens until consumed and while chlorination and other post-harvest controls can help reduce cross contamination between lots, they don't make contaminated products truly safe to consume.

For example, a 2008 study examined the extent to which iceberg lettuce could be contaminated with *E. coli* O157:H7 by the field coring devices used during harvest.[8] The study concluded that cells containing *E. coli* on the outer core of lettuce can be transferred to cut tissue during harvest. In addition, processing treatments using water and chlorine reduced but did not eliminate the pathogen. Once the contaminated cells infiltrate the cut tissue, they are protected from contact with chlorine.

On-going studies by the University of Georgia and Michigan State University, among others, are examining the ability of pathogens like *E. coli* to adhere to plant surfaces in the fields and to attach during washing and drying of leafy greens. For example, at the International Association of Food Protection conference this month, presenters showed using Germ Glo how bacteria can inhabit the washing systems used by the bagged lettuce industry today, with sporadic transfer of bacteria from one contaminated lot out to 300 pounds of lettuce.[9]

Notably, although FDA has recently approved irradiation treatments for leafy greens consumers have not indicated a desire for irradiated produce. In fact, the growth of the organic food industry suggests that consumers are seeking less processed varieties of fruits and vegetables.[10] The availability of many safe and wholesome organic fruits and vegetables demonstrates that safety need not be compromised, if robust safety practices are followed from the farm to the fork.

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[7] J Ellis, et al, *Assessing On-farm Food Handling Practices of Iowa-grown Produce and Eggs in Regard to Food Safety*, Food Protection Trends 25(10), 758-61 (2005).

[8] Peter J. Taormina, et al., *Transfer of Escherichia coli O157:H7 to Iceberg Lettuce via Simulated Field Coring*, 72 J. of Food Prot. 465.

[9] Author's notes of presentation on *Research Aimed at Reducing Contamination Levels through Processing* by Elliot Ryser, Mich. State U., Internat'l Assn. for Food Protection Conference, July 15, 2009.

[10] Organic food sales are anticipated to increase an average of 18 percent each year from 2007 to 2010. A Harris Interactive® online survey conducted for Whole Foods Market during August 2008 showed that despite rising food prices, 79 percent of consumers do not want to compromise on food quality and 70 percent continue to buy the same amount of natural and organic foods as always. Primary reasons given for buying organic products by participants in The Hartman Group survey, *Organic2006: Consumer Attitudes & Behavior, Five Years Later & Into the Future*: "To avoid products that rely on pesticides or other chemicals", "To avoid products that rely on antibiotics or growth hormones", "For nutritional needs", "To support the environment", "To avoid genetically modified products", "Health reasons other than allergies", "They taste better", and "To support sustainable agriculture". Last accessed July 22, 2009 at http://www.ota.com/organic/mt/business.html.

Nature Abhors a Vacuum: Industry Use of AMS Marketing Programs for FDA-regulated Commodities

While FDA has jurisdiction over on-farm food safety, it has proven to be an ineffective regulator. The agency has often chosen to issue guidance instead of regulation. Guidance for industry are useful documents, but they do not give the food industries clear direction as to what practices are unacceptable.[11] In addition, standards developed in the form of guidance are unenforceable when it comes to imported produce.

The old adage that nature abhors a vacuum is quite applicable in the business arena as well. With the rise in high-profile outbreaks, retailers are compelled to implement strict standards for produce items to both protect their customers from harm and their companies from liability. The absence of definitive rules leaves a significant hole in the fabric of food safety, allowing—even encouraging—the industry to weave standards of its own design.

One of the reasons for the proliferation of industry-defined food safety standards is that FDA has been hesitant to exercise its authority over on-farm safety. This authority is based in the FDA's authority to ensure food products are not adulterated under section 402 of the Food, Drug, and Cosmetic Act, and in its authority to prevent the spread of communicable diseases delegated to the agency by section 361 of the Public Health Services Act. Citing these authorities, CSPI petitioned FDA to issue safety standards for on-farm food production in 2006 and again in 2008. Those petitions have been met with silence. Meanwhile, the industry has filled the gap through the ad hoc programs applicable to single commodities that are the target of today's hearing.

With the concerns about produce outbreaks growing in recent years—and consumer confidence battered by repeated nationwide food recalls—it is not surprising that growers and handlers of fresh produce have cast around for a safety arbiter who can protect their interests as well as restore public confidence.

Whenever food safety problems emerge in a specific commodity, it is not unusual to see that industry look to the Agricultural Marketing Service at the United States Department of Agriculture (USDA) as a friendly regulator-of-choice. AMS is charged with "facilitat[ating] the competitive and efficient marketing of agricultural products."[12] It does so by overseeing "commodity programs."[13] These programs provide standardization, grading, and market news services for regulated commodities. AMS enforces the Perishable Agricultural Commodities Act and the Federal Seed Act. AMS commodity programs oversee marketing agreements and orders,

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[11] This pattern of issuing guidance at FDA has continued, even after the change in administration. Just this year, for example, the agency has issued guidance rather than rules on peanut production to prevent *Salmonella* in the wake of the largest FDA recall in history.

[12] USDA, *About AMS*, at http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateN&navID=AMSMissionStatement&rightNav1=AMSMissionStatement&topNav=AboutAMS&leftNav=&page=AboutAMSMissionStatement&resultType=&acct=AMSPW.

[13] AMS oversees five commodity programs: cotton, dairy, fruit and vegetable, livestock and seed, poultry and tobacco. USDA, *Commodity Areas*, at http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateA&navID=CommodityAreas&leftNav=CommodityAreas&page=CommodityAreas&acct=AMSPW.

administer research and promotion programs, and purchase commodities for federal food programs.

Notably, AMS is not charged or equipped to monitor the *safety* of food; the primary focus of the AMS mandate is promotion. David Shipman, Acting Administrator of AMS stated this in his testimony before the House Committee on Agriculture in May, saying: "The mission of AMS is to facilitate the strategic marketing of agricultural products in the domestic and international marketplace. AMS is not a food safety agency."[14]

Under the Agricultural Marketing Agreement Act (AMAA), AMS has two regulatory mechanisms that can be used to develop guidelines for the food industry: marketing agreements and marketing orders.[15] Marketing orders are binding on all "handlers" (i.e., "processors, producers, associations of producers, and others engaged in the handling of any agricultural commodity or product thereof")[16] of the regulated commodity in the geographic area covered by the order, while marketing agreements are binding only on those handlers who are voluntary signatories of the agreement. Marketing orders are necessarily limited to U.S. companies and have no effect on imports.

Currently, AMS oversees orders for 22 produce commodities.[17] One of these, the almond industry, offers an example of AMS acting as a food safety regulator. Established in 1950, the Almond Board of California administers Marketing Order 981,[18] to "promote the best quality almonds."[19] The Board describes the marketing order it oversees as having "quasi-governmental status," and says that these orders are "used by many commodity groups as a means of combining their financial resources in pursuit of common interests of the industry."[20] As California's largest tree crop, almonds enjoy a robust market in the U.S. and in the European Union, which accounts for over 50 percent of almond exports. However, the almond industry and its consumers have long-grappled with two major safety concerns: *Salmonella* and aflatoxin.

Since 2001, the almond industry has experienced two significant outbreaks linked to *Salmonella*. While not common in almonds, the outbreaks sufficiently alarmed the industry to lead the Almond Board in 2006 to approve an Action Plan for food safety—the primary tenet of which was the pasteurization of all raw almonds to drastically limit rates of *Salmonella*.

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[14] Statement of David R. Shipman, Acting Administrator, Agricultural Marketing Service, U.S. Department of Agriculture Before the Subcommittee on Horticulture and Organic Agriculture House Committee on Agriculture, May 14, 2009, at http://agriculture.house.gov/testimony/111/h051409/Shipman.pdf.

[15] Agricultural Marketing Agreement Act, 7 U.S.C. § 608b-c (2000).

[16] *Id.*

[17] These are: almonds, apricots, avocados, cherries [sweet and tart], citrus [Florida and Texas], cranberries, dates, grapes, hazelnuts, kiwifruit, nectarines, olives, onions [Idaho-E. Oregon, S. Texas, Vidalia, and Walla Walla], peaches, pears [Oregon-Washington], pistachios, plums/Prunes [California and Washington], potatoes [Idaho-E. Oregon, Washington, Oregon-California, Colorado, and Virginia-North Carolina], raisins, spearmint oil, tomatoes, and walnuts. AMS, *Industry Marketing and Promotion, Marketing Order Commodity Index*, at http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateN&navID=LinktoCurrentFruitandVegetableMarketingOrders&rightNav1=LinktoCurrentFruitandVegetableMarketingOrders&topNav=&leftNav=&page=FVMarketingOrderIndex&resultType=&acct=fvmktord.

[18] Almonds Grown in California Rule, 7 C.F.R. § 981 (2009).

[19] Almond Board of California, *About the Almond Board*, at http://www.almond-board.com/About/content.cfm?ItemNumber=544&snItemNumber=467.

[20] *Id.*

Proposed to AMS as an amendment to Marketing Order 981, the rule was finalized in September of 2007.[21]

The marketing order has also been used to manage other safety concerns. Almonds may also be contaminated with aflatoxins, naturally occurring chemicals produced by certain molds that may be carcinogenic.[22] The European Union has one of the lowest allowable limits for aflatoxins—significantly lower than those allowed under AMS Marketing Order 981.[23] In 2007, after repeatedly rejecting shipments offered for import, the EU concluded that the aflatoxin control system for California almonds was inadequate, and moved to require testing of 100 percent of shipments into the EU. In response, the Almond Board created a voluntary protocol, the Voluntary Alfatoxin Sampling Plan (VASP), to test almonds prior to export. Under that plan, growers could offer 100 percent of their product for sampling prior to shipment; in exchange, the EU agreed to test only 5 percent of imported shipments that have been through VASP.[24]

Another industry overseen by AMS is the shell egg industry.[25] Under current law, that industry is covered by a confusing array of laws, regulations, and voluntary programs administered by three federal agencies:

- USDA's Animal and Plant Health Inspection Service (APHIS) is responsible for preventing the spread of animal disease, and oversees the health of chickens used in egg production;
- FDA is the agency charged with ensuring shell egg safety, just this month announced its rule to minimize *Salmonella enteriditis* (SE) in eggs, nearly two decades after the problem emerged; and [26]
- AMS provides voluntary shell egg grading services and conducts inspection of all shell egg plants four times a year for cleanliness and quality control.

With its current budget and staffing, FDA conducts safety inspections in shell egg facilities approximately once every 10 years. Ironically, while AMS inspects egg plants quarterly, it does not check for SE contamination.

For years, the AMS egg grading program has been the primary arbiter of egg quality in the U.S. The voluntary grading program for shell eggs is paid for by participating producers, and approximately 40 percent of the nation's shell egg producers participate. Participating egg-packing plants are inspected for sanitation and proper washing of eggs, but not to determine

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[21] Almonds Grown in California; Change in Requirements for Interhandler Transfers of Almonds, 72 Fed. Reg. 51990, Sept. 12, 2007.
[22] Almond Board of California, *Fact Sheet, Aflatoxin*, at http://www.almondboard.org/files/aflatoxin%20fact%20sheet%20final.pdf.
[23] 7 C.F.R. § 981.
[24] Almond Board of California, *supra* note 22.
[25] Shell eggs refer to eggs within their shells, which are regulated by the agencies listed here. Egg products (pasteurized liquid or powder eggs) are inspected by USDA's Food Safety and Inspection Service (FSIS) under the Meat and Poultry Act's continuous inspection provision.
[26] Prevention of *Salmonella Enteriditis* in Shell Eggs during Production, Storage, and Transportation, Final Rule, 74 Fed. Reg. 33029, July 9, 2009.

whether the eggs are free of microbial contaminants.

AMS is also responsible for the Shell Egg Surveillance Program. AMS inspectors visit shell egg plants four times a year to ensure that dirty eggs, cracked eggs, and eggs with blood spots are properly disposed of and are not sold to consumers in cartons. However, this program does not include testing eggs for SE and diversion of infected eggs to pasteurization plants.

Notably, these programs may instill a false sense of security for both the industry and consumers. The *quality* AMS inspects for has little relationship to the *safety* consumers deserve. For many years, for example, there were conflicting temperature requirements for the transport of raw shell eggs: AMS mandated 60°F, the temperature at which quality is maintained, while another USDA agency with oversight over pasteurized eggs mandated 45°F, the temperature at which bacterial growth is restricted.

Voluntary Standards Should Not Replace Government Action and Oversight

In 2007, in the aftermath of a devastating *E. coli* O157:H7 outbreak in spinach, California growers formed the California Leafy Greens Products Handler Marketing Agreement, a voluntary, membership-based organization. The group created its own commodity-specific GAP guide (the *Commodity Specific Food Safety Guidelines for the Production and Harvest of Lettuce and Leafy Greens*, hereinafter "CALGMA") to respond to a clear need for greater safety controls on their products. Nearly 120 handlers, representing approximately 99 percent of the volume of California leafy greens, have joined the CALGMA. These companies have voluntarily committed to sell products grown in compliance with the food safety practices accepted by the LGMA board.

While accepted by both the California leafy green industry and the state Department of Agriculture, this voluntary guidance and marketing agreement has not proven effective, as indicated by several recent outbreaks:

- In May 2008, bagged Romaine lettuce sickened 10 people in Washington state with *E. coli* O157:H7. The lettuce was traced to Salinas Valley, California.

- In September 2008, California-produced lettuce was implicated in an *E .coli* outbreak that sickened 40 people in five states. Michigan determined that the lettuce was grown in California and processed in Detroit.

The CALGMA food safety practice standards were developed by university and industry scientists, food safety experts and farmers, shippers and processors, and appear quite robust. They are much stronger than FDA's existing guidelines, and other standards adopted internationally. The FDA—though responsible for the regulation of these products—was noticeably absent from the creation of the guidelines. The government's role in the agreement is secondary: the California Department of Food and Agriculture (CDFA) employs specially certified inspectors to conduct CALGMA audits. These inspectors operate with oversight from CDFA, but are certified and trained by USDA under the auspices of the National Good Agricultural Practice program at AMS.

As a voluntary program, members can simply elect not to participate, and there is no penalty for doing so beyond the removal of a marketing seal on their packaging. While CALGMA has attempted to fill the void left by the lack of government action, such a program is not an appropriate long-term substitute for comprehensive, mandatory regulation to ensure the safety of the food supply.

In 2008, CSPI and the Produce Safety Project, an Initiative of the Pew Charitable Trusts at Georgetown University, undertook an independent analysis of the various guidelines and agreements currently in use for fresh produce, including the CALGMA, FDA's 1998 Produce Guidance, Codex provisions on fresh produce, and several others.[27] The comparison focused on major issue areas deemed by the researchers to be fundamental to food safety on the farm.[28] The comparison also brought into stark relief the differences between and gaps in the various standards.

While the CALGMA performed well in the comparison, indicating that many areas of concern appear to be addressed in the document, this doesn't change the fact that the CALGMA is a voluntary set of opinions and recommendations set forth by the industry for the industry. They do not carry the weight of the U.S. government.

Further, the patchwork nature of these standards create uncertainty for retailers, which can result in the rise in the use of private standards stipulating particular practices or measures for growers. Growers and environmentalists have questioned the use of private standards that require practices recently exposed as causing major disruption of growers and major environmental impacts in California.

The Food Safety Enhancement Act (H.R.2749) currently before the House of Representatives addresses this issue head on, by requiring FDA to consider both food safety and environmental impacts when promulgating rules for food production. H.R. 2749 requires the standards to take account of small-scale and diversified farming, wildlife habitat, conservation practices, water-shed protection and organic production methods. This provides an appropriate focus on public safety, while protecting aspects of sustainable and organic farming that we all value. Further, the very process of rulemaking offers an opportunity for notice and comment among all stakeholders, with the aim of ensuring both the public health and the protection of the environment. Such notice and comment is of course absent from the boardrooms where today's private contracts are drafted.

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[27] FDA, *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*, 1998. Codex Alimentarius Commission, *Code of Hygienic Practice for Fresh Fruits and Vegetables*, 2003. *Food Safety Leadership Council On-Farm Produce Standards*, 2007 (retailer/buyer agreement). GLOBALGAP 2007. CALGMA, *Commodity Specific Food Safety Guidelines for the Production and Harvest of Lettuce and Leafy Greens*, 2007. Florida Tomato Rule, *Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain* (Edition 1.0) and *The Tomato Best Practices Manual*, 2008.

[28] Areas of comparison included agricultural water (microbial standards, sampling, and assessment), growing fields (prior use, flooding), manure (prohibitions on raw manure, composting standards, sampling, storage and treatment), animal control (exclusion of animals, set distance from CAFOs), worker health and hygiene (personal service areas, toilets, destruction of contaminated product), and field sanitation (sanitizing harvesting equipment, disposition of damaged harvest containers). Produce Safety Project, *Comparison of GAPs Governing The Growing and Harvesting of Fresh Produce*, 2009 at http://www.producesafetyproject.org (the Produce Safety Project is an initiative of the Pew Charitable Trusts at Georgetown University.

Over the past year, CSPI has been working closely with the Association of Food and Drug Officials (AFDO), industry representatives, and government regulators to draft food safety standards for the produce industry. These standards address issues relating to the production of all types of produce, including leafy greens, fruits, and other vegetables that are commonly eaten raw. The goal of the project is to produce a comprehensive statement of best practices across the produce industry, developed by all stakeholders—not only industry, but also consumer, academic, and government.

Once complete, it is hoped that the FDA will codify these guidelines into mandatory regulations with the authority and enforcement of the federal government behind them. Unlike the CALGMA, standards enacted by FDA would be adopted through a transparent, public process, including a notice and comment period that would allow environmental impacts to be fully discussed. When codified, the regulations would apply to all members of the industry—not simply those who choose to comply. And importantly, those standards would apply to imported produce as well as domestic, so that consumers could be assured of safe products whether they were produced in California or Mexico.

Marketing Orders Do Not Address Imported Food

Americans eat about 260 pounds of imported foods – approximately 13 percent of their total diet – each year. U.S. imports for 2006 reached a record value of $65.3 billion, roughly $6 billion higher than the year before. Overall, U.S. imports of agricultural and seafood products from all countries have increased by nearly 50 percent over the last decade, with certain countries and commodities are showing exponentially greater increases.

Americans enjoy a variety of fresh fruits and vegetables year-round, and supplying this demand is done by importing produce from around the world. In fact, one-quarter of our fruit, both fresh and frozen, is imported. But lack of adequate import controls has lead to numerous large and occasionally deadly outbreaks linked to imported food. Last summer, an outbreak of *Salmonella Saintpaul* was linked first to tomatoes and then jalapeno peppers from Mexico.[29] In the previous several years, Americans were sickened from green onions[30], cantaloupes[31], and strawberries[32] from Mexico, and raspberries from Guatemala.[33] These outbreaks have caused thousands of illnesses and several deaths, and have had a lasting effect on consumer confidence.

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[29] Over 1,400 people in 43 states were sickened, with 286 hospitalized and two deaths. CDC, *Outbreak of Salmonella Serotype Saintpaul Infections Associated with Multiple Raw Produce Items --- United States, 2008*, MMWR Weekly 57(34);929-934, Aug. 29, 2008, at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5734a1.htm.

[30] In 2003, a major Hepatitis A outbreak linked to raw green onions used in restaurant salsa sickened 555 people in Pennsylvania, killing three of them. Traceback by FDA indicated that green onions supplied to the restaurant were grown in Mexico under conditions where contamination with human waste was likely. Green onions from this area were also linked to outbreaks in Georgia, Tennessee, and North Carolina that occurred earlier that fall.

[31] Three multistate outbreaks of *Salmonella* serotype Poona infections associated with cantaloupe imported from Mexico occurred in the spring of consecutive years during 2000-2002. FDA conducted traceback investigations and determined that the cantaloupes were from farms in Mexico.

[32] In 1997, over 256 cases of Hepatitis A were associated with the consumption of frozen strawberries. The strawberries were harvested in Mexico and processed and frozen in southern California before they were distributed

Unfortunately, the marketing orders and agreements overseen by AMS offer no additional protection to consumers from imported food. Thus, Spanish almonds are sold alongside California almonds in many retail outlets, but only one has been processed to minimize harmful *Salmonella* bacteria. This critical gap in protection is a severe shortcoming of the AMS commodity order.

The most important benefit of a mandatory regulatory program is that it would help assure that all growers and processors – domestic and foreign – implement good agricultural practices. While many of the best growers and processors use HACCP-like systems and adhere to good agricultural practices, compliance is far from universal.

Conclusion

Food-borne illness outbreaks related to fresh produce are a major public health problem. Risk prevention, detection and control measures must be in place at every step of fresh-cut produce production to help ensure food safety risks are minimized. Industry-operated marketing orders are not an effective or appropriate public health response to address the food safety problems cropping up in fruits and vegetables. Ultimately, strong regulatory requirements for fresh-cut produce—promulgated and enforced by the responsible regulatory authority—would provide appropriate protection for the public. Congress should act to curtail the trend toward use of marketing orders by providing FDA with the authority and resources it needs to carry out its food safety responsibilities.

Important new legislation, H.R. 2749, the Food Safety Enhancement Act, includes a provision that clarifies FDA's food safety role on the farm. It will require FDA to establish science and risk-based standards to prevent contamination of farm produce. The bill, by remedying FDA's refusal to act under its existing authority, is the best hope for ending the trend toward private industry-designed standards enforced by regulators of choice. The most important benefit of a mandatory regulatory program is that it would help assure that all growers and processors – domestic and foreign – implement good agricultural practices.

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by USDA to school lunch programs in several states, including Michigan, Wisconsin, Louisiana, Maine and Arizona.

[33] In 1996 and 1997, thousands of people became ill in both the U.S. and Canada from a parasite, *Cyclospora*, on raspberries grown in Guatemala. Illness associated with *Cyclospora* includes watery diarrhea and persistent fatigue, which can persist for a month or longer if untreated. *Cyclospora* is chlorine-resistant and can be transmitted through water or from infected handlers.

Mr. KUCINICH. Thank you very much.

By the way, I just have an update. The bill that was voted on did not receive the required two-thirds so it will end up going back for some work. Some of the concerns that were expressed by Members who voted against it were about the effect of the bill on small farmers and organic farmers. So I think that the Center, which endorsed the bill, needs to take heed of the concerns that are expressed. If we do that, perhaps when the bill comes back out to the floor we can see it pass. Thank you.

Well, that means we will each have 5 minutes for questions. That really does mean that we should move this along.

I just want to thank Ms. Cobb. How are you feeling, by the way?

Ms. COBB. I am fine now.

Mr. KUCINICH. How many years ago was this?

Ms. COBB. It was May 2008.

Mr. KUCINICH. Have you felt any after-effects other than the fact that you are really not keen on eating certain products?

Ms. COBB. Other than at home. No. I am at a higher risk of cardiovascular disease later in life and urinary tract types of issues but as of right now I have had none of that since that same summer.

Mr. KUCINICH. We are glad you are here.

Ms. COBB. Thank you.

Mr. KUCINICH. I think there needs to be a public face of somebody who has dealt with this. You have dealt with it. It takes a lot of courage to come before a congressional committee to relate your experience. We appreciate that you are here.

Ms. COBB. Thank you. I appreciate it.

Mr. KUCINICH. The other thing I want to note is that when Mr. Horsfall began his statement, I was impressed that you said Ms. Cobb's testimony doesn't fall on deaf ears. What I saw was a real, unrehearsed response to hearing what you had to say. I just want you to know that I appreciate that. Sometimes people come in here with a story that can be very difficult and the individuals who may have some responsibility in that area generally seem to be impassive about it. You showed some concern. I think that speaks well.

I would like you to address the concern about some of CALGMA's metrics and the arbitrariness of them. Your auditor must find that the adjacent land to a field of greens be free from compost operations within 400 feet of the crop edge while it only requires that the adjacent land be free from the grazing of domestic animals within 30 feet of the crop edge. What is the justification for allowing domestic animals, the animal waste products of which are a component of compost, to be closer to the crop edge than a compost operation?

Mr. HORSFALL. The LGMA program metrics are based entirely on risk assessments. I think that is in keeping with FDA guidance. The compost operations are considered to be a very high risk situation in terms of pathogens. We also have significant buffer zones if there is a confined animal feeding operation where you have a large number of animals of risk in a field.

Mr. KUCINICH. Remember, you have domestic animals closer to the crop edge than the compost operation.

Mr. HORSFALL. Because the risk assessment tells us that there is a lower risk involved if you have a couple of animals on a farm.

Mr. KUCINICH. But let us look at the 2006 spinach incident. Isn't it true that the field identified as the source of contaminated spinach was less than a couple hundred feet from where domestic animals graze and shade themselves?

Mr. HORSFALL. I don't know that for sure.

Mr. KUCINICH. Well, let us check it out and see. Maybe you could look at that. Maybe you could come to some kind of a conclusion if there is any contradiction there.

Isn't true that CALGMA's auditors would not today find any problem with growing spinach intended for the ready to eat market growing a couple hundred feet from the land where cattle graze, exactly the conditions present in the 2006 spinach incident?

Mr. HORSFALL. It would depend on the number of cattle that were there. I don't have those numbers in front of me. But in that particular case, as I recall, the feces that were found that had the same fingerprint were over a mile away.

Mr. KUCINICH. Should CALGMA be tougher on the processors who make the bagged lettuce than it currently is?

Mr. HORSFALL. I think processors, if I could address that, processors are under the jurisdiction of FDA. They are already inspected.

Mr. KUCINICH. What about CALGMA? We are looking at a possible nationalization of this. Should CALGMA be tougher on these processors? You have heard testimony here. What do you think?

Mr. HORSFALL. I think the processors need to be regulated just as heavily as growers do. That regulation, I believe, is in place through FDA.

Mr. KUCINICH. I appreciate that.

I just want to ask one more question here. Mr. Coke, you are the father of the spring mix. Spring mix helped pre-cut packaged leafy greens become a vegetable consumers like and eat in increasing portions. It has made a significant health contribution. But you are also a critic of the ready to eat leafy greens industry.

In your opinion, is there a way for the American public to get the convenience and health benefits of pre-cut packaged vegetables without the harm to farmers you mentioned in your testimony?

Mr. COKE. Just as a point of clarification, I developed the concept of spring mix but I never put it in bags and it was never ready to eat. It was a field run product. It was washed, cooled, dried, and packed into three pound boxes.

I always had serious reservations about how that product was displayed. I didn't ever want to go into——

Mr. KUCINICH. What would be the long term results, Mr. Coke, in your opinion, on the environment if CALGMA is nationalized in its current form?

Mr. COKE. In its current form, I think it will affect too many growers of lettuce and cabbage and kale and chard, the things that are traditionally harvested as whole heads or bunched items. They don't make a differentiation between them. Those things haven't had any outbreaks associated with them. They often have a kill step associated because people heat them up before they eat them. They steam them or boil them.

Mr. KUCINICH. Thank you.

I have some followup questions to Ms. Smith DeWaal. We are going to put them in writing.

I am going to go now to Mr. Jordan. Thank you.

Mr. JORDAN. Thank you, Mr. Chairman. I will be brief as well since we have a vote pending.

Let me, too, thank Ms. Cobb for being here. How are the little ones doing? Are they doing fine?

Ms. COBB. Oh, yes. Matthew doesn't remember because he was too young. Liberty still remembers and will talk about when I got sick from a salad. She know what it was from. For a while she would tell people not to be afraid of a blood machine because she remembers coming in while I was having a transfusion done. But overall they are doing well.

Mr. JORDAN. Well, let me also thank your family for their service to our country. Thank you all for being with us now. Let me just get a couple basic facts. What is your home State, Ms. Cobb?

Ms. COBB. My home State is Washington.

Mr. JORDAN. Mr. Horsfall, the program is completely voluntary. Is that right? I think this came off your Web site for LGMA. There are 120 handlers for 99 percent of the volume of California leafy greens. They are all voluntary? That was 120 who joined?

Mr. HORSFALL. Yes.

Mr. JORDAN. What is the assessment? How is that determined again?

Mr. HORSFALL. We assess our members based on the volume that they ship. It is a penny and a half per 24-count equivalent box.

Mr. JORDAN. I just want to be clear, are big producers part of it? In other words, are the farmers part of the organization or is it just the folks who take the farm product and then package it?

Mr. HORSFALL. Our members are handlers. They are the people who put products into commerce. The majority of them are growers as well.

Mr. JORDAN. They are both?

Mr. HORSFALL. Yes.

Mr. JORDAN. So some are both. Some actually produce the product and handle it?

Mr. HORSFALL. Absolutely.

Mr. JORDAN. From the field right to their operation or it could be around the same premises?

Mr. HORSFALL. Yes, and they sell to each other as well in the industry quite a bit.

Mr. JORDAN. Since you have come into existence, which was 2006 or 2007—what year was it?

Mr. HORSFALL. It was 2007.

Mr. JORDAN. Have there been any outbreaks of E. coli or any problems?

Mr. HORSFALL. There have been outbreaks that have been reported. I don't believe that the health authorities have conclusively finished their investigations yet to say where the product got contaminated. But there was a small outbreak in Washington State that Ms. Cobb was affected by. Last year there was an outbreak in Michigan.

Mr. JORDAN. So can you definitively say that we have seen an improvement in that there have been less problems since your organization has been formed or is that anyone's guess?

Mr. HORSFALL. The answer is yes, fewer people have gotten sick tied to lettuce and leafy greens in the last 2 years than, say, in the 2 or 3 years before that. But I don't take that as a metric. I think if anybody is getting sick, then we still have to figure out how to make the program better. That is where the research comes in.

Mr. JORDAN. Mr. Coke, you are a farmer and a handler. Are you part of this organization, your farm and your operation?

Mr. COKE. I am not. I have two different entities. One is a sales, shipping, and cooling company. The other is a farming company. The farming company contracts with a handler that is signatory to that. We grow some crops, cilantro, dill, and parsley in this case, for inclusion in the salad that they want to be grown under those metrics. So we do that part. Otherwise we have a diverse crop mix. There are only a few things that would be considered leafy greens.

I have resisted. I think the principle of this agreement is wrong so I didn't want to. It has cost me the ability to sell into Canada because they won't accept product, even though we are organic and we test the soil and water. They won't accept product if you are not signatory to the Leafy Greens Marketing Agreement. I don't know. I would prefer not to go there, to have to. I was hoping that something would become a little more logical and you would focus on the process part.

Mr. JORDAN. This is a country boy from western Ohio who didn't grow up on a farm but we live out in the middle of my wife's family farm. You think about when the product is grown close to a composting site or whatever, but I can remember when they used to spread manure on the field. It seems to me that the problem has to be after the product is taken out of the field. That is just common sense. But maybe I am just a country boy.

Mr. COKE. I think you are right. The product has issues. The slide that you showed about the bagged produce. It is a great concept to give people something that is ready to eat but it is a perfect incubator. How do you keep that? If you can't sterilize it, if you have any little pathogen and you break the cold chain, even the customer just taking it out to their car and then driving home, potentially it is a hazard. It is a difficult issue to get a product to market safely, I think.

Mr. JORDAN. We have to vote. Thank you all for coming. I am sorry we didn't get a chance.

Mr. KUCINICH. I want to thank Mr. Jordan. I want to thank the witnesses for being here.

I am Dennis Kucinich, Chairman of the Domestic Policy Subcommittee. Mr. Jordan is the ranking member. Our hearing today has been Ready-to-Eat or Not?: Examining the Impact of Leafy Greens Marketing Agreements. We have had two panels. The testimony has been very important. We appreciate your participation.

This committee stands adjourned. Thank you.

[Whereupon, at 4:40 p.m., the subcommittee was adjourned.]

[Additional information submitted for the hearing record follows:]

USDA

United States Department of Agriculture

Agricultural Marketing Service

1400 Independence Avenue, SW
Room 3071-S, STOP 0201
Washington, DC 20250-0201

AUG 04 2009

The Honorable Dennis Kucinich
Chairman
Subcommittee on Domestic Policy
Committee on Oversight and Government Reform
U.S. House of Representatives
B-349B Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for the opportunity to testify before the Subcommittee on Domestic Policy on July 29, 2009 on leafy green marketing orders and the safety of "ready to eat" produce. During the hearing, you requested supporting documentation for my statement that feral swine were an area of concern for the 2006 *E. coli* 0157 outbreak in California. Enclosed you will find a study that was published in December 2007 in the Centers for Disease Control and Prevention's *Emerging Infectious Diseases Journal.*

Please contact me should you have any questions or if you require additional information.

Sincerely,

Rayne Pegg
Administrator

Enclosure

Escherichia coli O157:H7 in Feral Swine near Spinach Fields and Cattle, Central California Coast[1]

Michele T. Jay,*† Michael Cooley,‡ Diana Carychao,‡ Gerald W. Wiscomb,§ Richard A. Sweitzer,¶ Leta Crawford-Miksza,* Jeff A. Farrar,# David K. Lau, Janice O'Connell,* Anne Millington,# Roderick V. Asmundson,** Edward R. Atwill,† and Robert E. Mandrell‡**

We investigated involvement of feral swine in contamination of agricultural fields and surface waterways with *Escherichia coli* O157:H7 after a nationwide outbreak traced to bagged spinach from California. Isolates from feral swine, cattle, surface water, sediment, and soil at 1 ranch were matched to the outbreak strain.

Recent experimental and epidemiologic studies suggest that domestic pigs are biologically competent hosts and a potential reservoir of *Escherichia coli* O157:H7 (*1,2*). Cattle are considered the primary reservoir of *E. coli* O157, but fecal shedding by other domestic livestock and wildlife has been described (*3,4*). *E. coli* O157 was isolated from a wild boar in Sweden, but there is limited information on its occurrence in feral swine in the United States (*5*). We report findings from an environmental and laboratory investigation after a nationwide spinach-associated outbreak of *E. coli* O157 in which the outbreak strain was isolated from feral swine and other environmental samples.

The Study

In September 2006, an outbreak of *E. coli* O157 was linked to consumption of fresh, bagged, baby spinach, with 26 states and Canada reporting 205 cases of illness and 3 deaths (*6*). Contaminated product was traced to 1 production date (August 15, 2006) at 1 processing plant and fields located on 4 ranches on the central California coast (*7*). The outbreak strain was isolated initially from cattle feces collected on September 27, 2006, ≈1 mile from an implicated spinach field on a ranch (ranch A) where numerous free-roaming feral swine were observed. We investigated potential involvement of feral swine in *E. coli* O157 contamination of spinach fields and surface waterways.

Feral swine were live-captured in traps or hunted and humanely killed during October–November 2006. Two feral swine corral traps were placed 1.4 km apart, and 1.7 km (trap 1) and 1.2 km (trap 2), respectively, from the implicated spinach field (Figure 1). Photographs from digital infrared remote-sensing cameras (Recon Outdoors, Huntsville, AL, USA) were used in combination with sightings and live-capture to ascertain the minimum number of individual feral swine present on the ranch (*8*). The average population density was calculated on the basis of an estimate of the area sampled by both traps and the estimated mean home range (1.8 km) for feral swine in mainland California by using ArcView version 9.2 (Environmental Systems Research Institute, Redlands, CA, USA) (*8*).

Colonic fecal samples were collected from 40 feral swine (31 live-captured, 9 hunted); buccal swabs, rectal-

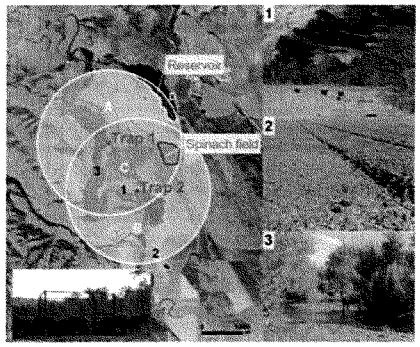

Figure 1. Left: aerial (2 m) photograph of ranch A showing overlapping circular buffer regions around feral swine trap 1 and trap 2 (San Benito Crop Year 2006; Image Trader, Flagstaff, AZ). The radius for the buffer (1.8 km) is the circumference of the mean home range for feral swine in mainland California (*8*). Estimated density = 4.6 swine/km^2 and total area = (A + B + C) – D = 14.8 km^2. Areas A, B, and C, combined with counts of individual feral swine from October through November 2006, were used to calculate the average population density. Bottom left: digital infrared photograph of feral swine at trap 1. Right: potential risk factors for *Escherichia coli* O157:H7 contamination of spinach at ranch A: 1) Feral sow and piglets sharing rangeland with cattle; 2) feral swine feces, tracks, and rooting in a neighboring spinach field; 3) cattle in surface water.

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[1]This work was presented in part as a poster at the 107th General Meeting of the American Society for Microbiology, Toronto, Ontario, Canada, May 24, 2007.

anal swabs, and tonsils were analyzed from a subset of 8 animals (Table 1). Additionally, feces from domestic animals (cattle, dog, goat, horse, sheep) and wildlife (bird, coyote, deer, feral swine), surface water and sediment, soil, and well/irrigation water were analyzed. *E. coli* O157 was cultured by using an extended enrichment–immunomagnetic separation protocol (*9,10*). PCR analysis was used to confirm the presence of *E. coli* O157 and virulence factors (*9,10*). Genotypes of isolates from environmental samples were compared by using 10-loci multilocus variable number tandem repeat analysis (MLVA) and pulsed-field gel electrophoresis (PFGE) after digestion with *Xba*I and *Bln*I by using the PulseNet protocol (*10–13*).

E. coli O157 was cultured from 45 (13.4%) of 335 samples, including cattle and feral swine feces, feral swine colonic feces from necropsy, surface water and sediment, and pasture soil (Table 1). The *eaeA*, *hlyA*, and *stx2* genes were present in all strains, and the *stx1* gene was found in only 1 sample (subtype 5; Table 2, Figure 2). Isolates from 28 environmental samples at ranch A were indistinguishable from the major spinach-related outbreak strain by PFGE (Table 1). In contrast, *E. coli* O157 isolates from 3 other ranches implicated by traceback did not match the outbreak strain. Molecular typing by MLVA provided higher resolution discrimination between environmental strains (Figure 2). Three major MLVA clusters from ranch A and the surrounding watershed were identified. The cluster containing the outbreak strain (subtype E) is shown in Figure 2, and 16 other highly related subtypes were indistinguishable by PFGE (Table 2).

Ranch A is located in the central coast foothills of San Benito County, where the dominant habitat is coastal oak woodland interspersed with dense riparian vegetation near seasonal waterways (Figure 1). Approximately 2,000 range cattle were grazed on the ranch. Spinach and other leafy green vegetables were grown on a leased portion of the property that was separated from cattle pastures by wire mesh fence. Well water was used for irrigation. No evidence of cattle manure–based fertilizer application, runoff from cattle pastures, or flooding from surface waterways (based on topography) onto the implicated spinach field was found during the investigation (*7*).

Feral swine were the most abundant wildlife observed on ranch A, and evidence of intrusion, including tracks, rooting, or feces in crop fields and adjacent vineyards, was documented (Figure 1). Birds, black-tailed deer, cottontail rabbits, coyotes, and ground squirrels also were observed, but the population density of these species appeared lower, and their activity was confined mostly to rangeland areas according to visual observations. Swine visited the traps almost continuously from dusk until dawn with peak activity between 5:00 PM and midnight. An average of 3.6 swine/trap/night were live-captured. The estimated population density was 4.6 swine/km^2 (95% confidence interval [CI] 3.8–5.9), and the actual number of feral swine on ranch A was estimated to be 149 animals (95% CI 124–192) (Figure 1). Feral swine used livestock rangelands and gained access to adjacent crop fields through gaps formed at the base of the fence by erosion and rooting. Cattle and feral swine had access to and congregated at surface waterways on the ranch (Figure 1).

Table 1. *Escherichia coli* O157:H7 isolated from environmental samples collected at ranch A, California, September–November 2006

Sample type	No. tested	No. positive (%)	No. matches*
Cattle feces	77	26 (33.8)	15
Cattle water trough	10	0	NA
Compost (chicken pellets)†	1	0	NA
Feral swine			
Necropsy	40	2 (5)	2
Buccal swab	8	0	NA
Colonic feces	40	2 (5)	2
Rectal-anal swab	8	0	NA
Tonsil	8	0	NA
Feces from ground	47	11 (23.4)	6
Subtotal	87	13 (14.9)	8
Other animal specimens‡	26	0	NA
Surface water§	79	3 (3.8)	2
Soil/sediment	37	3 (8.1)	3
Well/irrigation water¶	18	0	NA
Total	335	45 (13.4)	28

*No. samples indistinguishable from the major spinach-related outbreak strain by pulsed-field gel electrophoresis (*Xba*I-*Bln*I PulseNet profile EXHX01.0124-EXHA26.0015). NA, not applicable.
†Commercial, heat-treated chicken manure.
‡Included feces from coyote (n = 1), deer (n = 4), dog (n = 1), horse (n = 2), sheep/goat (n = 3, composite), waterfowl (n = 2), unknown species (n = 11), and owl (n = 2).
§Surface water (rivers, streams, ponds) was sampled by collection of 100-mL grab samples or placement of a modified Moore swab for 4–5 d.
¶Well water was sampled from 3 wells or sprinkler heads by collection of 100-mL or 1,000-mL grab samples or by concentration of 40,000 mL to 500 mL by using ultrafiltration (*7*).

Table 2. Unique alphanumeric MLVA types of *Escherichia coli* O157:H7 isolated from environmental samples collected at ranch A and an upstream watershed, California, September–November 2006*

Sample type	No. samples	No. isolates	MLVA type
Reference (human stool, bagged spinach)	NA	NA	**E**
Cattle feces	26	34	**A**, **C**, **E**, **F**, I, **J**, L, **M**, P, Q, **R**, **S**, **T**, W, X, Z
Feral swine feces	11	14	**A**, **B**, **C**, **E**, L, O, P, X, 5, 6
Feral swine colonic feces (necropsy)	2	10	**A**, **C**, **D**, **G**, **H**, **K**, L, **U**, V, Y
Sediment (river)	2	8	**A**, **C**, L, **M**, **N**, W, **3**
Soil (cattle pasture)	1	1	**A**
Surface water	3	6	**A**, **C**, L, P, **4**
Surface water Moore swab†	2	3	1, 2

*MLVA, multilocus variable number tandem repeat analysis; NA, not applicable. Samples indistinguishable from the major spinach-related outbreak strain by pulsed-field gel electrophoresis (*Xba*I-*Bln*I PulseNet profile EXHX01.0124-EXHA26.0015) are shown in **boldface**.
†Isolates collected from surface water (river) ≈32 km upstream of ranch A.

Conclusions

We describe the first, to our knowledge, isolation of *E. coli* O157 from feral swine in the United States. The percentage of specimens positive for *E. coli* O157 among feral swine (14.9%) and cattle (33.8%) and the density (4.6 swine/km^2) were high compared with results of previous ecologic studies (Table 1) (*2–5,8,14,15*). Molecular typing of isolates by PFGE and MLVA showed possible dissemination and persistence of the outbreak strain in multiple environmental samples as long as 3 months after the outbreak (Tables 1, 2). MLVA is more reproducible than PFGE and better at discriminating between closely related *E. coli* O157 isolates (*10,12,13*). Recovery of related *E. coli* O157 subtypes by both methods suggested swine-to-swine transmission, interspecies transmission between cattle and swine, or a common source of exposure such as water or soil (Table 2, Figure 2).

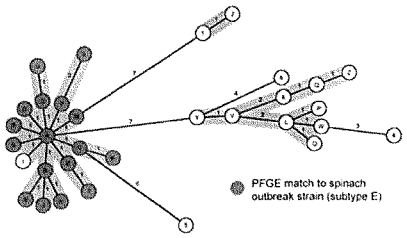

Figure 2. Minimum spanning tree analysis of multilocus variable number tandem repeat analysis (MLVA) data of 76 *Escherichia coli* O157:H7 strains typed from 47 samples compared with the spinach-related outbreak strain (subtype E). A categorical coefficient and the BURST priority rule of the highest number of single-locus changes were used for the clustering (Bionumerics software version 4.601, Applied Maths, Austin, TX, USA). Circles representing unique MLVA types are designated by an alphanumeric value (Table 2). Numbers between circles represent summed tandem-repeat differences between MLVA types (*10*). The shaded areas (red, green, and blue) denote genetically related clusters with MLVA differences <3. Red circles indicate types comprising isolates that were indistinguishable from the spinach-related outbreak strain (subtype E) by pulsed-field gel electrophoresis (PFGE).

Mechanisms of in-field contamination of leafy greens for this and previous outbreaks remain unclear, but hypotheses have emerged. A relatively high density of feral swine near cattle and spinach fields could represent a risk factor for *E. coli* O157 contamination. Wildlife may be sentinels for *E. coli* O157 in the produce production environment, or they may be vectors involved in the contamination of plants directly by fecal deposition or indirectly by fecal contamination of surface waterways or soil. Notably, baby spinach is harvested with a lawn mower–like machine that could pick up fecal deposits in the field and thereby contaminate large volumes of product during processing. Fecal loading of surface waterways by livestock and wildlife with subsequent contamination of wells used for irrigation represents another possible route of transmission to plants in the field. Although *E. coli* O157 was not detected in irrigation water, older agriculture wells at ranch A appeared vulnerable to contamination by surface water (R. Gelting, pers. comm.). Unrecognized environmental and management practices during preharvest and postharvest processing also could have contributed to amplification and dissemination of *E. coli* O157 in raw spinach.

In summary, *E. coli* O157 contamination of spinach and other leafy greens is likely a multifactorial process. Additional research is needed to develop and implement effective risk assessment and management practices. For example, studies are needed to determine colonization potential of and levels of fecal shedding by feral swine, and the importance of interspecies transmission to other vertebrate or invertebrate (e.g., flies) populations near agricultural fields.

Acknowledgments

We thank Richard Gelting, CDC, and the members of the California Food Emergency Response Team, a joint emergency response team of the California Department of Public Health and the US Food and Drug Administration, for their work on the environmental investigation. We also are grateful to the growers, ranchers, and property owners for their cooperation during this study.

Portions of this work were supported by a grant from US Department of Agriculture–Cooperative State Research, Education, and Extension Service Section 32.1 (project no. 2006-01240) and Agricultural Research Service Projects 5325-42000-044 and -45.

Dr Jay is a research scientist at the Food and Drug Laboratory Branch at the California Department of Public Health and an affiliate scientist at the Western Institute of Food Safety and Security, University of California, Davis. Her research interests include the molecular epidemiology of zoonotic pathogens and relationships to vertebrate population dynamics and the environment.

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Address for correspondence: Michele T. Jay, Food and Drug Laboratory Branch, California Department of Public Health, Western Institute for Food Safety and Security, University of California, 1 Shields Ave, Davis, CA 95616, USA; email: michele.jayrussell@cdph.ca.gov

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515–6143

MAJORITY (202) 225-5051
FACSIMILE (202) 225-4784
MINORITY (202) 225-5074

www.oversight.house.gov

August 5, 2009

Mr. Scott Horsfall
Chief Executive Officer
California Leafy Greens Marketing Board
1521 "I" Street
Sacramento, California 95814-2016

Dear Mr. Horsfall:

In your July 29, 2009 testimony to the Domestic Policy Subcommittee, you cited the importance of the scientific justification for CALGMA's metrics. Presumably, both the metrics imposed and the absence of metrics in CALGMA would therefore be based on firm scientific grounds.

Please provide the scientific justification and comment on the adequacy of scientific justification, and any other factors accounting for CALGMA's reliance on generic E. coli water testing, as opposed to testing for pathogenic E. coli. This question is important because, as you know, many strains of E. coli are not harmful to humans and their presence is not a reliable indicator of the presence of harmful strains of the bacteria. Please also provide scientific justification for the use of the 126 MPN standard used by your auditors.

Please also indicate whether or not the results of the audits, including the testing of water, performed in relation to CALGMA are made available to the public, and, if so, in what form. If the results are not made public, please explain your justification for keeping them confidential.

Additionally, please provide scientific justification for:

a. CALGMA's condoning in-field coring of lettuce heads;

b. The exclusion of any CALGMA metric pertaining to "Best Consumed by" dates on packaged leafy greens;

c. The exclusion of any CALGMA metric pertaining to management and recordkeeping practices aimed at ensuring and documenting a continuous cold storage of pre-cut, packaged leafy greens from processing plant to commercial outlet.

The Oversight and Government Reform Committee is the principal oversight committee in the House of Representatives and has broad oversight jurisdiction as set forth in House Rule X. I request that you provide your response as soon as possible, but in no case later than **5:00 p.m. on Wednesday, August 19, 2009**.

If you have any questions regarding this request, please contact Jaron Bourke, Staff Director, at (202) 225-6427.

Sincerely,

Dennis J. Kucinich
Chairman
Domestic Policy Subcommittee

cc: Jim Jordan
Ranking Minority Member

ONE HUNDRED ELEVENTH CONGRESS

Congress of the United States

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Domestic Policy Subcommittee Document Request Instruction Sheet

In responding to the document request from the Domestic Policy Subcommittee, Committee on Oversight and Government Reform, please apply the instructions and definitions set forth below.

Instructions

1. In complying with the request, you should produce all responsive documents in your possession, custody, or control.

2. Documents responsive to the request should not be destroyed, modified, removed, transferred, or otherwise made inaccessible to the Subcommittee.

3. In the event that any entity, organization, or individual denoted in the request has been, or is currently, known by any other name than that herein denoted, the request should be read also to include them under that alternative identification.

4. Each document produced should be produced in a form that renders the document capable of being copied.

5. When you produce documents, you should identify the paragraph or clause in the Subcommittee's request to which the documents respond.

6. Documents produced in response to this request should be produced together with copies of file labels, dividers, or identifying markers with which they were associated when this request was issued. To the extent that documents were not stored with file labels, dividers, or identifying markers, they should be organized into separate folders by subject matter prior to production.

7. Each folder and box should be numbered, and a description of the contents of each folder and box, including the paragraph or clause of the request to which the documents are responsive, should be provided in an accompanying index.

8. It is not a proper basis to refuse to produce a document that any other person or entity also possesses a nonidentical or identical copy of the same document.

9. If any of the requested information is available in machine-readable or electronic form (such as on a computer server, hard drive, CD, DVD, memory stick, or computer backup tape), you should consult with Subcommittee staff to determine the appropriate format in which to produce the information.

10. The Committee accepts electronic documents in lieu of paper productions. Documents produced in electronic format should be organized, identified, and indexed electronically in a manner comparable to the organizational structure called for in (6) and (7) above. Electronic document productions should be prepared according to the following standards:

    (a) The production should consist of single page TIF files accompanied by a Concordance-format load file, an Opticon reference file, and a file defining the fields and character lengths of the load file.

    (b) Document numbers in the load file should match document Bates numbers and TIF file names.

    (c) If the production is completed through a series of multiple partial productions, field names and file order in all load files should match.

11. In the event that a responsive document is withheld on any basis, you should provide the following information concerning the document: (a) the reason the document is not being produced; (b) the type of document; (c) the general subject matter; (d) the date, author, and addressee; and (e) the relationship of the author and addressee to each other.

12. If any document responsive to this request was, but no longer is, in your possession, custody, or control, you should identify the document (stating its date, author, subject and recipients) and explain the circumstances by which the document ceased to be in your possession, custody, or control.

13. If a date or other descriptive detail set forth in this request referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, you should produce all documents which would be responsive as if the date or other descriptive detail were correct.

14. This request is continuing in nature and applies to any newly discovered document. Any document not produced because it has not been located or discovered by the return date should be produced immediately upon location or discovery subsequent thereto.

15. All documents should be bates-stamped sequentially and produced sequentially. In the cover letter, you should include a total page count for the entire production, including both hard copy and electronic documents.

16. For paper productions, four sets of documents should be delivered: two sets to the majority staff and two sets to the minority staff. For electronic productions, one dataset to the majority staff and one dataset to minority staff are sufficient. Productions should be delivered to the majority staff in B-349B Rayburn House Office Building and the minority staff in B-350A Rayburn House Office Building. You should consult with Subcommittee staff regarding the method of delivery prior to sending any materials.

17. Upon completion of the document production, you should submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control which reasonably could contain responsive documents; and (2) all documents located during the search that are responsive have been produced to the Subcommittee or identified in a privilege log provided to the Subcommittee.

Definitions

1. The term "document" means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, working papers, records notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, interoffice and intra-office communications, electronic mail (email), contracts, cables, notations of any type of conversation, telephone calls, meetings or other communications, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto). The term also means any graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, voice mails, microfiche, microfilm, videotape, recordings and motion pictures), electronic and mechanical records or representations of any kind (including, without limitation, tapes, cassettes, disks, computer server files, computer hard drive files, CDs, DVDs, memory sticks, and recordings), and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk, videotape or otherwise. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.

2. The term "documents in your possession, custody, or control" means (a) documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, or representatives acting on your behalf; (b) documents that you have a legal right to obtain, that you have a right to copy, or to which you have access; and (c) documents that you have placed in the temporary possession, custody, or control of any third party.

3. The term "communication" means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether face-to-face, in a meeting, by telephone, mail, telexes, discussions, releases, personal delivery, or otherwise.

4. The terms "and" and "or" shall be construed broadly and either conjunctively or disjunctively to bring within the scope of the request any information which might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neuter genders.

5. The terms "person" or "persons" means natural persons, firms, partnerships, associations, corporations, subsidiaries, divisions, departments, joint ventures,

proprietorships, syndicates, or other legal, business or government entities, and all subsidiaries, affiliates, divisions, departments, branches, and other units thereof.

6. The terms "referring" or "relating," with respect to any given subject, means anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with, or is in any manner whatsoever pertinent to that subject.

August 18, 2009

The Honorable Dennis J. Kucinich, Chairman
Domestic Policy Subcommittee
Committee on Oversight and Government Reform
2157 Rayburn House Office Building
Washington, DC 20515-6143

Dear Chairman Kucinich:

Thank you for your letter of August 5, 2009, requesting more information about the California Leafy Green Products Handler Marketing Agreement (CALGMA) and the food safety requirements its members have agreed to follow. We are happy to provide the information requested.

The specific answers to your question follow, but I would also like to take this opportunity to address some of the questions about the CALGMA that were raised during the July 29th hearing.

CALGMA Metrics and Buffer Zones

During the hearing, it was stated several times that buffer zones between leafy green fields and identified risk areas (such as Confined Animal Feeding Operations) had been stripped of vegetation so that growers would be in compliance with the CALGMA's metrics. In fact, there is nothing in the CALGMA metrics that requires buffer zones to be cleared of vegetation; the metrics specifically encourage growers to consult with local fish and game or other environmental officials to make sure that their food safety practices do not conflict with good environmental or sustainability efforts. We share the concern expressed by some growers and environmental organizations about the unintended consequences of over-aggressive approaches to food safety, and we are seeking acceptance of CALGMA standards by the broader buying community in part to rein in these 'above and beyond' practices.

Leafy Greens Processing

As I stated in my testimony, the creation of the CALGMA allowed the leafy greens industry, working with local and national government, to put in place a set of mandatory standards for food safety practices on the farm – prior to the CALGMA there was no such regulatory program in place. The processing industry is heavily regulated by the US Food and Drug Administration. Therefore, many of the questions raised at the hearing, and in your subsequent letter, are not relevant to the CALGMA's operations.

Now, to your specific questions:

1521 "I" Street
Sacramento, CA 95814
P 916-441-1240
F 916-446-1063
www.caleafygreens.ca.gov

Request: "*Please provide the scientific justification and comment on the adequacy of the scientific justification, and any other factors accounting for CALGMA's reliance on generic E. coli water testing, as opposed to testing for pathogenic E. coli…Please also provide the scientific justification for the use of the 126 MPN standard used by your auditors.*"

Response: The basis for the metrics in the CALGMA best practices is provided in Appendix B (which is available to the public on the CALGMA website[1]). The sections related to the basis for the generic E. coli water testing are provided below.

> *"Metrics for water sources and uses must consider (1) which microorganisms to test for and the test methods, (2) action levels to apply, and (3) appropriate responses. An ideal test method would detect all pathogenic organisms present; however, this is not scientifically or economically feasible for two reasons:*
>
> - *Concentrations of pathogenic microbes can vary widely in fecal matter. Hence, if testing focuses on specific pathogens, the presence of fecal contamination may not be detected even if significant contamination is present (Ashbolt et al. 2001; World Health Organization 2004). While continuous monitoring or daily testing might more reliably detect these microbes, this approach is economically unfeasible.*
>
> - *Existing test methods may not be able to detect the wide variety of pathogenic organisms that might contaminate water (World Health Organization 2004). Even if water is routinely tested for the more common pathogenic organisms, this does not guarantee other pathogens are not present.*
>
> *Given the reasons above, and guidance and/or comments from various regulatory agencies (US EPA 1986; California Department of Health Services (CDHS) and California Department of Food and Agriculture (CDFA) 2006; US FDA 2006), use of an "indicator" microbe was determined to be the most effective and efficient testing approach. Testing for generic E. coli is considered the best available indicator of a fecal contaminated water source.*
>
> *Generic E. coli is generally non-pathogenic; thus, using this as an indicator organism results in action levels that are not necessarily health risk-based. Although increasing levels of generic E. coli in a water source are likely to correlate with increasing health risk, "bright line" levels of generic E. coli above which health risks are unacceptable can not rationally be established. Action levels based on generic E. coli concentrations should not be considered as separating "safe" or "unsafe" levels—they should only be considered as indicators of fecal contamination or increasing bacteriological densities.*
>
> *To set generic E. coli action levels for water used in agricultural applications, it was decided that it would not be possible to use one set of levels for all uses. For instance, water that contacts edible portions of plants should likely have more stringent standards than water that does not contact edible portions of plants. In order to address this issue, use-specific standards were created for three uses determined to be most critical to lettuce and leafy green food safety:*

[1] http://www.caleafygreens.ca.gov/documents/appendix_b_technical_basis.pdf

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- *Pre-harvest foliar applications. Where edible portions of the crop are contacted by water (e.g. overhead sprinkler irrigation, pesticides/fungicide application, etc.).*
- *Pre-harvest non-foliar applications. Where edible portions of the crop are not contacted by water (e.g., furrow or drip irrigation, dust abatement water).*
- *Post-harvest direct contact applications. (e.g. re-hydration, core in field, harvest equipment cleaning, bin cleaning, product cooling, product washing).*

For each use category, a rolling average and single sample maximum metric was set. These metrics were based on water quality standards developed by the U.S. EPA in their risk assessment of E. coli in recreational waters were used to establish action levels (US EPA 1986;2003). U.S. EPA determined that the geometric mean of E. coli in recreational water systems should not exceed 126 MPN E. coli/ 100 mL to protect against unacceptable risk of waterborne diseases. In addition to this geometric mean value, they also determined single sample maximum values for various beach-use types. These single sample maximums are based on certain confidence levels of the geometric mean value of 126 MPN. For a "Designated Beach," U.S. EPA used the 70% confidence level, which is a value of 235 MPN/100 mL. For rarely used beaches, they used the 95% confidence level of 576 MPN/100 mL. These three guidelines were used to establish action levels for pre-harvest water uses. All pre-harvest water uses must meet the geometric mean requirement of 126 MPN/100 mL, but foliar applications must adhere to the lower 235 MPN/100 mL metric while non-foliar applications use the less strict 576 MPN/100 mL standard. The use of these values is bolstered by the adoption of the 126 MPN/100 mL geometric mean and 576 MPN/100 mL values by the state of Arizona as irrigation water quality standards.

For post-harvest direct contact applications, it was determined that stringent requirements should be met due to the potential high-risk for cross-contamination, as well as the lack of additional steps to remove or reduce contamination. Hence, the metric for this standard has been set at <2 MPN/100 mL, which is essentially the limit of detection. Guidelines for continuous monitoring of disinfectant in post-harvest systems are also provided in the CSG2 to facilitate meeting this strict standard."

The use of recreational water quality standards as surrogates for irrigation water quality standards was considered to be health protective compared to using irrigation water quality standards adopted by other government entities (i.e., US EPA, WHO) that are not based on actual quantitative risk assessment data.[2] In addition, most of these governmental irrigation water standards are based on fecal coliform testing (as opposed to generic *E. coli*) which the authors and expert reviewers of the CALGMA metrics thought was a less appropriate indicator organism. The standards are also generally for recycled water, which is not used in the CALGMA.[3]

[2] http://www.who.int/water_sanitation_health/dwq/iwachap2.pdf
[3] http://www.epa.gov/ORD/NRMRL/pubs/625r04108/625r04108chap8.pdf

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Request: *"Please also indicate whether or not the results of the audits, including the testing of water, performed in relation to CALGMA are made available to the public, and, if so, in what form. If results are not made public, please explain your justification for keeping them confidential."*

Response: Results of the audits are periodically compiled and overall compliance results are provided to the public on CALGMA's website. Member handlers that are not in compliance with CALGMA best practices are decertified and posted on the CALGMA website.

The CALGMA is an instrumentality of the State of California, and its actions are under the direct oversight of the California Department of Food and Agriculture. Audits carried out under the CALGMA program are kept confidential, pursuant to Government Code section 6254, subdivision (f), which states (in part) that the following records are exempt from disclosure under the public records act:

> *"(f) Records of complaints to, or investigations conducted by, or records of intelligence information or security procedures of, the office of the Attorney General and the Department of Justice, and any state or local police agency, or any investigatory or security files compiled by any other state or local police agency, or any investigatory or security files compiled by any other state or local agency for correctional, law enforcement, or licensing purposes. However, state and local law enforcement agencies shall disclose the names and addresses of persons involved in, or witnesses other than confidential informants to, the incident, the description of any property involved, the date, time, and location of the incident, all diagrams, statements of the parties involved in the incident, the statements of all witnesses, other than confidential informants, to the victims of an incident, or an authorized representative thereof, an insurance carrier against which a claim has been or might be made, and any person suffering bodily injury or property damage or loss, as the result of the incident caused by arson, burglary, fire, explosion, larceny, robbery, carjacking, vandalism, vehicle theft, or a crime as defined by subdivision (b) of Section 13951, unless the disclosure would endanger the safety of a witness or other person involved in the investigation, or unless disclosure would endanger the successful completion of the investigation or a related investigation. However, nothing in this division shall require the disclosure of that portion of those investigative files that reflects the analysis or conclusions of the investigating officer.*

Request: *"Additionally, please provide the scientific justification for: a) CALGMA's condoning in-field coring of lettuce."*

Response: We are not aware of scientific documentation that indicates in-field coring of lettuce using appropriate disinfection practices (process water, cutting instruments, etc.) is an unacceptable health risk. Thus, the CALGMA best practices focus on providing guidance on appropriate disinfection practices (as determined by the industry authors and expert reviewers) and not on what in-field practices are appropriate. We are also not aware that field coring has been specifically raised as an issue by any regulatory agency's guidelines or recommendations, including the recently released FDA guidelines for leafy green products.

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Request: *"Additionally, please provide the scientific justification for: b) the exclusion of any CALGMA metric pertaining to "Best Consumed by" dates on packaged leafy greens."*

Response: A metric related to the "Best Consumed by" dates on packaged leafy greens was not included in the CALGMA best practices because currently the best practices only apply to the production and harvest of leafy greens. Practices related to processing plants are covered in 21 CFR, require the use of good manufacturing practices (GMPs), and are audited by FDA.

Request: *"Additionally, please provide the scientific justification for: c) the exclusion of any CALGMA metric pertaining to management and recordkeeping practices aimed at ensuring and documenting a continuous cold storage of pre-cut, packaged leafy greens from processing plant to commercial outlet."*

Response: A metric related to recordkeeping of cold-storage conditions for leafy greens from processing to commercial outlet was not included in the CALGMA metrics because the CALGMA only pertains to production and harvest of leafy greens. In addition, the handlers who are members of the CALGMA would have no way to enforce these types of requirements on buyers further up the supply chain.

We appreciate the committee's interest in the actions and accomplishments of the California Leafy Green Products Handler Marketing Agreement.

Sincerely,

E. Scott Horsfall

E. Scott Horsfall
CEO

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COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

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August 5, 2009

Mr. Michael R. Taylor
Senior Adviser to the Commissioner of Food and Drugs
Food and Drug Administration
U.S. Department of Health and Human Services
5600 Fishers Lane, Room 15B-31
Rockville Maryland 20857

Dear Mr. Taylor:

During the July 29, 2009 hearing of the Domestic Policy Subcommittee on "Ready-To-Eat or Not?: Examining the Impact of Leafy Greens Marketing Agreements", I asked you to provide answers and data in writing on a number of topics. This letter reiterates those requests as questions for the record.

1) A spreadsheet with the following information relative to all outbreaks of *E. coli* 0157 traced to pre-cut, packaged produce since 1999: Location and date of illness, date of shipment from the processing plant, date of harvesting, and "Best Consumed by" date printed on packaging.

2) Comment on the decision-making process establishing "Best Consumed by" dates for pre-cut, packaged leafy greens, including who makes the decision, the basis for the decision, and any government oversight of the matter.

3) Provide an update on FDA's compliance with recommendations made in GAO's September 2008 report, "Improvements Needed in FDA Oversight of Fresh Produce," GAO-08-1047.

The Oversight and Government Reform Committee is the principal oversight committee in the House of Representatives and has broad oversight jurisdiction as set forth in House Rule X.

I request that you provide your response as soon as possible, but in no case later than **5:00 p.m. on Wednesday, August 19, 2009**.

If you have any questions regarding this request, please contact Jaron Bourke, Staff Director, at (202) 225-6427.

Sincerely,

Dennis J. Kucinich
Chairman
Domestic Policy Subcommittee

cc: Jim Jordan
Ranking Minority Member

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Instructions

1. In complying with the request, you should produce all responsive documents in your possession, custody, or control.

2. Documents responsive to the request should not be destroyed, modified, removed, transferred, or otherwise made inaccessible to the Subcommittee.

3. In the event that any entity, organization, or individual denoted in the request has been, or is currently, known by any other name than that herein denoted, the request should be read also to include them under that alternative identification.

4. Each document produced should be produced in a form that renders the document capable of being copied.

5. When you produce documents, you should identify the paragraph or clause in the Subcommittee's request to which the documents respond.

6. Documents produced in response to this request should be produced together with copies of file labels, dividers, or identifying markers with which they were associated when this request was issued. To the extent that documents were not stored with file labels, dividers, or identifying markers, they should be organized into separate folders by subject matter prior to production.

7. Each folder and box should be numbered, and a description of the contents of each folder and box, including the paragraph or clause of the request to which the documents are responsive, should be provided in an accompanying index.

8. It is not a proper basis to refuse to produce a document that any other person or entity also possesses a nonidentical or identical copy of the same document.

9. If any of the requested information is available in machine-readable or electronic form (such as on a computer server, hard drive, CD, DVD, memory stick, or computer backup tape), you should consult with Subcommittee staff to determine the appropriate format in which to produce the information.

10. The Committee accepts electronic documents in lieu of paper productions. Documents produced in electronic format should be organized, identified, and indexed electronically in a manner comparable to the organizational structure called for in (6) and (7) above. Electronic document productions should be prepared according to the following standards:

    (a) The production should consist of single page TIF files accompanied by a Concordance-format load file, an Opticon reference file, and a file defining the fields and character lengths of the load file.

    (b) Document numbers in the load file should match document Bates numbers and TIF file names.

    (c) If the production is completed through a series of multiple partial productions, field names and file order in all load files should match.

11. In the event that a responsive document is withheld on any basis, you should provide the following information concerning the document: (a) the reason the document is not being produced; (b) the type of document; (c) the general subject matter; (d) the date, author, and addressee; and (e) the relationship of the author and addressee to each other.

12. If any document responsive to this request was, but no longer is, in your possession, custody, or control, you should identify the document (stating its date, author, subject and recipients) and explain the circumstances by which the document ceased to be in your possession, custody, or control.

13. If a date or other descriptive detail set forth in this request referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, you should produce all documents which would be responsive as if the date or other descriptive detail were correct.

14. This request is continuing in nature and applies to any newly discovered document. Any document not produced because it has not been located or discovered by the return date should be produced immediately upon location or discovery subsequent thereto.

15. All documents should be bates-stamped sequentially and produced sequentially. In the cover letter, you should include a total page count for the entire production, including both hard copy and electronic documents.

16. For paper productions, four sets of documents should be delivered: two sets to the majority staff and two sets to the minority staff. For electronic productions, one dataset to the majority staff and one dataset to minority staff are sufficient. Productions should be delivered to the majority staff in B-349B Rayburn House Office Building and the minority staff in B-350A Rayburn House Office Building. You should consult with Subcommittee staff regarding the method of delivery prior to sending any materials.

17. Upon completion of the document production, you should submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control which reasonably could contain responsive documents; and (2) all documents located during the search that are responsive have been produced to the Subcommittee or identified in a privilege log provided to the Subcommittee.

Definitions

1. The term "document" means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, working papers, records notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, interoffice and intra-office communications, electronic mail (email), contracts, cables, notations of any type of conversation, telephone calls, meetings or other communications, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto). The term also means any graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, voice mails, microfiche, microfilm, videotape, recordings and motion pictures), electronic and mechanical records or representations of any kind (including, without limitation, tapes, cassettes, disks, computer server files, computer hard drive files, CDs, DVDs, memory sticks, and recordings), and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk, videotape or otherwise. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.

2. The term "documents in your possession, custody, or control" means (a) documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, or representatives acting on your behalf; (b) documents that you have a legal right to obtain, that you have a right to copy, or to which you have access; and (c) documents that you have placed in the temporary possession, custody, or control of any third party.

3. The term "communication" means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether face-to-face, in a meeting, by telephone, mail, telexes, discussions, releases, personal delivery, or otherwise.

4. The terms "and" and "or" shall be construed broadly and either conjunctively or disjunctively to bring within the scope of the request any information which might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neuter genders.

5. The terms "person" or "persons" means natural persons, firms, partnerships, associations, corporations, subsidiaries, divisions, departments, joint ventures,

proprietorships, syndicates, or other legal, business or government entities, and all subsidiaries, affiliates, divisions, departments, branches, and other units thereof.

6. The terms "referring" or "relating," with respect to any given subject, means anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with, or is in any manner whatsoever pertinent to that subject.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 19 2009

The Honorable Dennis J. Kucinich
Chairman
Subcommittee on Domestic Policy
Committee on Oversight and Government Reform
House of Representatives
Washington, D.C. 20515-6143

Dear Mr. Chairman:

Thank you for providing an opportunity for the Food and Drug Administration (FDA or the Agency) to testify at the July 29, 2009, hearing, which examined ready-to-eat produce and the impact of Leafy Greens Marketing Agreements. This letter provides responses to the questions for the record provided in your letter of August 5, 2009.

We have restated each question below, in bold type, followed by FDA's response.

1) **A spreadsheet with the following information relative to all outbreaks of *E. coli* O157 traced to pre-cut, packaged produce since 1999: Location and date of illness, date of shipment from the processing plant, date of harvesting, and "Best Consumed By" date printed on the packaging.**

A spreadsheet responsive to this request is enclosed.

2) **Comment on the decision-making process establishing "Best Consumed By" dates for pre-cut, packaged leafy greens, including who makes the decision, the basis for the decision, and any government oversight of the matter.**

FDA has not established requirements for "best consumed by" date labeling for produce or any other foods. Since the shelf life of food products is affected by many factors, such as storage temperatures and handling, a date provided on the label would not necessarily be informative, as it could not account for these factors. Such dates printed on food packages refer to the quality rather than the safety of the product.

Manufacturers mark packages with "Sell by" or "Best if used by" dates to refer to quality aspects, such as freshness. The dates may be established by a firm based on testing the quality of their product over time under simulated "typical" consumer handling conditions. The dates help retailers rotate stock (first-in-first-out) and help consumers choose products

that still have sufficient shelf life remaining between date of purchase and use of the product.

FDA provides advice to consumers on how to purchase, store, and prepare food to minimize food safety concerns. In addition, FDA provides advice to industry throughout the supply chain on handling produce safely, including precut produce. In the "Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables," published by FDA in 2008, FDA recommends that firms consider food safety in establishing "use by" dates for their products. However, for the reasons noted above, FDA does not consider such dates to represent a "safe-to-eat" date.

In 2002, FDA and the United States Department of Agriculture (USDA) asked the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) to provide advice on how "use by" date labels on refrigerated ready-eat-foods should be used to ensure that products are safe to eat when consumed. Published in the Journal of Food Protection in 2005 (Vol. 68, No. 8, pages 1761-1775), NACMCF concluded that safety–based date labeling would not be effective for preventing illness from pathogens such as *Salmonella, Escherichia coli* O157:H7, and viruses that survive but do not grow in foods at refrigeration temperatures. The report concluded that establishing mandatory criteria for the date labeling of refrigerated products may have some food safety benefits with respect to the control of organisms that can grow at refrigeration temperatures, such as *Listeria monocytogenes* (Lm). Establishing requirements for safety-based date labels on consumer packages of leafy greens has not been central to FDA's overall produce safety strategy because, among many other reasons, Lm has not been associated with recent produce-related foodborne illness outbreaks, and bagged leafy greens have not been considered a food that supports the rapid growth of Lm.

3) Provide an update on FDA's compliance with recommendations made in GAO's September 2008 report, "Improvements Needed in FDA Oversight of Fresh Produce," GAO-08-1047.

GAO recommended that FDA take the following actions:

a. develop a plan for identifying research priorities and facilitating research related to fresh produce;

In 2007, FDA enhanced its pre-existing research priority plan, which included produce, to create a strategic research plan specifically for produce, identifying additional research needs so resources could be targeted to address these needs. Some studies that address the identified research needs have already been completed and other research is in progress.

Our current research agenda is focused on improving the identification and detection of disease-causing bacteria and contaminants in a variety of foods. FDA and our food safety partners are doing extensive research on the detection, characterization, and behavior of foodborne pathogens, microbial genetics, and molecular virology. For example, FDA and the Centers for Disease Control and Prevention have developed rapid methods for serotyping *Salmonella* in produce (such as cantaloupes, tomatoes, and peppers). These rapid methods will aid FDA as we perform analysis of both domestic and imported produce samples. These efforts are also vital for

our development of risk assessment models for pathogens and intervention strategies to reduce the public health risk that these pathogens present.

FDA is facilitating and supporting research relevant to the contamination of fresh produce through its Centers of Excellence Program. That program includes collaboration with the National Center for Natural Products Research at the University of Mississippi; the National Center for Food Safety and Technology at the Illinois Institute of Technology; the Joint Institute for Food Safety and Applied Nutrition at the University of Maryland; and the Western Center for Food Safety (WCFS) at the University of California at Davis (established in 2008). In its first year, WCFS, which focuses on the intersection between production agriculture and food safety, has conducted produce safety research to address the science behind Good Agricultural Practices.

FDA also works closely with USDA's Agricultural Research Service and Cooperative State Research, Education, and Extension Service to coordinate and mutually support our respective research efforts related to produce safety.

For extramural research projects, FDA has made it a priority to focus on fresh produce, addressing issues pertaining to transportation and consumer handling of fresh-cut produce in the home.

FDA will continue to make produce safety research a priority and facilitate such research by working with academia, industry, other federal agencies, and state governments.

b. identify approaches for obtaining testing and other information from industry members to inform its research agenda;

FDA has been working with industry associations to identify mechanisms whereby firms collecting data on water testing can share those data with FDA to inform our research agenda. Additionally, FDA plans to participate in a 2009 symposium to promote the exchange of information between FDA and academic and industry scientists on environmental testing during leafy green production. During this meeting, industry will share the trends that it has seen through microbial testing from soil, water, and product testing. FDA will continue to pursue other approaches to working with industry and academia to obtain information valuable to enhancing produce safety. For example, FDA has been working with industry to develop tomato metrics that can assist inspectors and third-party auditors in verifying consistency with voluntary and mandatory tomato safety programs. The draft tomato metrics were pilot-tested in California over the course of several weeks in July. Industry is sharing the results of this pilot with us as results become available.

c. update its good agricultural practices guidance for fresh produce to incorporate new knowledge about safe growing practices;

On July 31, 2009, FDA released draft guidance providing recommendations for three commodity groups (leafy greens, tomatoes, and melons) most often identified in foodborne illness outbreaks associated with fresh produce. These guidances describe preventive controls that industry can

implement to reduce the risk of microbial contamination in the growing, harvesting, transporting, and distributing of these commodities. In addition to providing commodity-specific recommendations, these guidances also provide recommendations based on current thinking (e.g., conducting assessments of the growing area and water systems, worker health and hygiene, and cleaning and sanitation of facilities and equipment) that can be applied broadly to other commodities along the supply chain. In 2008, FDA issued guidance for industry to minimize microbial food safety hazards for fresh-cut fruits and vegetables.

FDA has begun work on a regulation to establish enforceable standards for produce safety. It will capitalize on what we have learned over the past decade since we published our Good Agricultural Practices guidelines in 1998. The regulation also will utilize the progress industry has made in establishing quantitative metrics for the control of some of the factors affecting produce safety by incorporating appropriate measures of success. Comments received on the draft commodity-specific guidances will be considered as we develop the regulation.

d. update its current good manufacturing practice regulations for food to incorporate new knowledge about the food industry and safe manufacturing, processing, and holding practices.

FDA has begun work on revising Current Good Manufacturing Practices and anticipates issuing a proposed rule during fiscal year 2010.

e. seek authority from Congress to make explicit FDA's authority to adopt preventive controls for high-risk foods, and

f. seek authority from Congress to provide FDA enhanced access to firm records during food-related emergencies.

President Obama has made a personal commitment to improving food safety. He established a multi-agency Food Safety Working Group (Working Group) and asked it to make recommendations on updating our food safety laws, fostering coordination throughout government, strengthening surveillance, and enhancing enforcement. On July 7, 2009, the Working Group issued its key findings on how to upgrade the food safety system for the 21st century. The Working Group's findings recognized the need to modernize the food safety statutes. Some of the necessary legislative authorities it highlighted relate to preventive controls and access to food safety records. The Administration agrees that these are essential authorities and has pledged to work with Congress on such legislation. The Administration recently issued a Statement of Administration Policy on H.R. 2749, the "Food Safety Enhancement Act of 2009," which the House of Representatives recently passed. H.R. 2749 includes requirements for preventive controls and provides FDA with access to records during routine inspections, among other provisions.

g. provide specific information to the Congress and the public on the strategies and resources for implementing the *Food Protection Plan* to foster transparency and accountability.

FDA has provided information on implementation of the Food Protection Plan, which was released in November 2007 under the previous Administration, to Congress and the public. For example, FDA posted on its Web site six-month and one-year progress reports on the implementation. The one-year update is available at *http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/FoodProtectionPlan2007/ucm131730.htm.*

In the current Administration, as noted earlier, the President established a multi-agency Food Safety Working Group to make recommendations to improve the food safety system. The Working Group, chaired by the Secretaries of the Department of Health and Human Services and the Department of Agriculture, has recommended a new, public, health-focused approach to food safety based on three core principles: (1) prioritizing prevention; (2) strengthening surveillance and enforcement; and (3) improving response and recovery. To gather input from all corners of the country, the Working Group held a public Listening Day on May 13, 2009, with extensive participation by states and localities, the food industry, consumer advocates, and other experts. To encourage transparency, the Working Group established a public Web site (*www.foodsafetyworkinggroup.org*), which offers the opportunity to submit comments and which provides information on the Working Group's findings and activities. FDA remains committed to transparency and accountability in carrying out its food safety responsibilities.

Thank you again for the opportunity to appear before the Subcommittee. If you have further questions or concerns, please let us know.

Sincerely,

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

Enclosure

cc: The Honorable Jim Jordan
Ranking Member
Subcommittee on Domestic Policy
Committee on Oversight and Government Reform

Outbreaks/Illnesses Associated With Fresh-cut produce,* 1996-2008

Year	Vehicle	Agent	Cases	Deaths	Source	Location of illness	Dates of illnesss	Harvest Date*	Ship date from processing plant*	"Best consumed by" date*
1999	romaine lettuce	*E. Coli* O157:H7	41		CA	PA	2/26/99 - 2/28/99			
2002	romaine lettuce	*E. Coli* O157:H7	29		CA	WA	7/12/02 - 7/19/02			10 days from date of production
2002	iceberg lettuce	*E. Coli* O157:H7	24		CA	IL, SD, MN, WI	11/24/02 - 12/11/02			
2003	precut lettuce	*E. Coli* O157:H7	27		CA	CA	9/30/03 - 10/4/03			10/13/2003
2003	precut spinach	*E. Coli* O157:H7	16	2	CA	CA	10/9/03 - 10/17/03		9/25/03 - 10/3/03	
2004	lettuce	*E. Coli* O157:H7	6		CA	NJ	11/6/04 - 11/14/09			
2005	pre-packaged salad	*E. Coli* O157:H7	32		CA	MN , OR , WI	9/16/05 - 9/30/05	9/4/05 - 9/7/05	9/7/05 - 9/8/05	9/23/2005
2006	lettuce	*E. Coli* O157:H7	81		CA	IA, MN, WI	11/24/06 - 11/25/06 or 11/28/06 - 12/10/06			
2006	spinach	*E. Coli* O157:H7	204	3	CA	AZ, CA, CO, CT, ID, IL, IN, KY, MD, ME, MI, MN, NE, NM, NV, NY, OH, OR, PA, TN, UT, VA, WA, WI, WV, WY	8/19/06 - 9/5/06	8/14/2006	8/15/06 - 8/16/06	8/30/2006
2006	lettuce	*E. Coli O157:H7*	71		CA	NJ, NY, PA, DE, SC, Ontario	11/20/06 - 12/08/06			
2008	romaine lettuce	*E. Coli* O157:H7	9		CA	WA	5/14/08 - 5/26/08			
2008	organic spinach	*E. Coli* O157:H7	13		WA	WA, OR, CA	8/15/08 - 9/2/08			
2008	shredded lettuce	*E. Coli* O157:H7	38		inconclusive	MI, IL	9/6/08 - 9/18/08			
2008	romaine lettuce	*E. Coli O157:H7*	7		CA	CA, IL, SD, NJ, OH	10/12/08- 11/09/08		9/15/08 - 10/15/08	

* FDA does not track these data. In a few cases, the information was readily available and is, therefore, included.