



**Statement
Before the Subcommittee on Oversight and
Investigations
Committee on Energy and Commerce
United States House of Representatives**

**Recent Food Safety Activities at
the Food and Drug Administration**

Statement of

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INTRODUCTION

Good morning, Chairman Stupak and Members of the Subcommittee. I am Dr. David Acheson, Assistant Commissioner for Food Protection at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). FDA appreciates the opportunity to discuss our new Food Protection Plan (or the Plan) and the Import Safety Action Plan, which were released last week. You also asked that we address the use of carbon monoxide in modified atmosphere packaging for meat and fish.

In May 2007, Secretary of Health and Human Services Michael O. Leavitt and Commissioner of Food and Drugs Andrew C. von Eschenbach, M.D., charged FDA with developing a comprehensive and integrated FDA Food Protection Plan to keep the nation's food supply safe from both unintentional and deliberate contamination. Driven by science and modern information technology, the Plan aims to identify potential hazards and counteract them before they can do harm. I would now like to share some of the highlights of this plan.

FOOD PROTECTION PLAN

The Plan builds in safety measures that focus on risks across a product's life cycle, from the time a food is produced to the time it is distributed and consumed. FDA's integrated approach within the Food Protection Plan encompasses three core elements: prevention, intervention, and response.

The *prevention* element means promoting increased corporate responsibility, identifying risks and building in mitigation steps so that food problems do not occur in the first place. The *intervention* element focuses on risk-based inspections, sampling, and surveillance at all points in the food supply chain. The *response* element bolsters FDA's emergency response efforts by allowing for increased speed and efficiency and improved communication.

While American consumers enjoy one of the safest food supplies in the world, growing challenges require a new approach to food protection at FDA – an increased emphasis on prevention. Recent outbreaks linked to fresh produce, peanut butter, and pet foods show how FDA responds quickly to contain food safety problems. While this level of response needs to be maintained and even enhanced, there is also a need to focus more on building safety into products right from the start to meet the challenges of today. FDA will work with the private sector to build on the actions of the food industry to ensure product safety. Building safety into products is described in one word: prevention.

Prevention

Prevention is the first essential step for an effective, proactive food safety and defense plan. FDA's plan implements three key prevention steps: (1) promote increased corporate responsibility to prevent foodborne illnesses; (2) identify food vulnerabilities and assess risk; and (3) expand the understanding and use of effective mitigation strategies. The prevention steps are risk-based and will be implemented as appropriate to particular segments of the industry, taking into account that some foods are inherently safer than others.

First, to promote increased corporate responsibility, FDA must strategically place greater emphasis on preventive measures for food safety and food defense. These measures will promote improved food protection capabilities throughout the food supply chain. This will require close interaction with growers, manufacturers, distributors, retailers and food service providers, and importers. FDA will continue to work with industry and state and local governments to further develop the tools and science needed to identify vulnerabilities and determine the most effective approaches. With regard to imports, FDA will also work with foreign governments, which have a greater ability to oversee manufacturers within their borders to ensure compliance with U.S. safety standards

FDA is requesting new authorities to accomplish this first goal. For example, the Food Protection Plan outlines new authorities to require entities in the food supply chain to implement measures *solely* intended to protect against the intentional adulteration of food by terrorists or criminals at points of high vulnerability. FDA is also seeking explicit authority to issue regulations requiring that high-risk foods be prepared, packed, and held under a system of preventive food safety controls for high-risk foods – those that have been associated with repeated instances of serious health problems or death to humans or animals from unintentional contamination.

Second, to identify food vulnerabilities and assess risk, FDA will work with the food industry, consumer groups, and Federal, state, local, and international partners to generate the additional data needed to strengthen our understanding of food safety and food defense risks and vulnerabilities. A comprehensive, risk-based approach allows

FDA to maximize the effectiveness of its available resources by focusing on food products that have the potential to pose the greatest risk to human and animal health. By analyzing data collected throughout the food product life cycle, we are better able to detect risks posed by food products. We are also better able to recognize key junctures where timely intervention can reduce or avoid those risks. Working with HHS's Centers for Disease Control and Prevention (CDC), FDA will also build the capacity to attribute pathogens to specific foods and identify where in the production life cycle the foods became contaminated. When established and emerging risks are identified, assessed, and ranked, we are able to more effectively allocate our available resources to manage these risks.

Third, in order to expand the understanding and use of effective mitigation strategies, FDA will initiate risk-driven research about the sources, spread, and prevention of contamination. We will also develop new mitigation tools and implement appropriate risk management strategies. Building on risk assessments, FDA will initiate basic research to enhance our understanding of sources of contamination, modes of spreading, and how best to prevent contamination. This information will inform FDA's efforts to promote increased corporate responsibility to implement effective preventive steps. Focusing on higher risk foods, FDA will conduct research and leverage relationships with outside organizations. FDA will also research, evaluate, and develop new methods to detect contaminants in foods, and seek to facilitate new technologies that enhance food safety.

Intervention

Because no plan will prevent 100 percent of food contamination, FDA is also focused on having targeted, risk-based interventions to provide further protection. These interventions must ensure that the preventive measures called for are implemented correctly. The Plan includes ways to focus on inspections and sampling based on risk, enhance risk-based surveillance and improve the detection of food system signals that indicate contamination.

However, the universe of domestic and foreign food establishments subject to FDA inspection is immense and continues to increase. Therefore, legislation to authorize FDA to accredit or recognize and use highly qualified independent third parties to evaluate compliance with FDA requirements would allow FDA to allocate resources more effectively. This would be another effective way to further assess the growing universe of food establishments. Use of accredited third parties would be voluntary and might offer more in-depth review and possibly faster review times and expedited entry for imported goods manufactured in facilities inspected by accredited third parties. FDA would not be bound by these third-party inspections in determining compliance with FDA requirements. However, use of accredited third parties may be taken into consideration by FDA when setting inspection and surveillance priorities.

In order to enhance the Agency's risk-based surveillance, FDA plans to focus on improving our ability to target imported foods for inspection based on risk through the use of advanced screening technology at the border and enhanced information sharing

agreements with key foreign countries.

Also, as part of the FY 2008 budget, the Administration proposed a new user fee requiring manufacturers and laboratories to pay the full costs of reinspections and associated follow-up work when FDA reinspects facilities due to failure to meet current Good Manufacturing Practices (cGMPs) or other FDA requirements. Where FDA identifies violations during an inspection or issues a warning letter, FDA conducts follow-up inspections to verify a firm's corrective action. The proposed fee ensures that facilities not complying with health and safety standards bear the cost of reinspection.

Further, FDA should have the option of moving the inspection of high-risk products of concern "upstream" by entering into agreements with the exporting country's regulatory authority for that entity (or an FDA-recognized third party inspector) to certify each shipment or class of shipments for compliance with FDA's standards *prior* to shipment. FDA would apply this requirement to imported products that have been shown to pose a threat to public health for U.S. consumers. While FDA would retain the authority to verify the safety of imported products, this approach shares the burden of ensuring the safety of food products with the exporting country. For such a system to be effective, FDA will have to establish an in-depth collaboration with the relevant foreign government authority to ensure that the standards, processes, and criteria by which the foreign authority or third party is certifying products are consistent with FDA's. The Agency will also have to take several steps to ensure a secure system that prevents counterfeiting of the certificates and takes into

consideration transshipment of products as a way to avoid certification. FDA would use non-discriminatory, scientific, and risk-based criteria to determine the focus of this proposed authority.

As noted earlier, improving the detection of food system “signals” that indicate contamination is an important component of enhancing our intervention capabilities. FDA can better detect and more quickly identify risk “signals” in the food supply chain by deploying new rapid screening tools and methods to identify pathogens and other contaminants and by enhancing its ability to “map” or trace adverse events back to their causes by improving its Adverse Event and Consumer Complaint Reporting System. This additional information will serve as a supplemental warning indicator for trending emerging food protection problems.

The recent pet food recalls showed us that we must continue to focus our efforts on animal food and feed, as well as human food. For example, to provide the information necessary to allow for early detection of, and intervention with, contaminated pet food, FDA will work with the veterinary community, veterinary hospitals, and other private U.S. sources to develop an early warning surveillance and notification system to alert veterinarians and others about problems with the pet food supply.

Response

During the past year, FDA responded to food safety problems with contaminated spinach, lettuce, vegetable proteins, and peanut butter, among other foods. While

FDA's response to these outbreaks was swift and effective, there is always a need to respond faster and communicate more effectively with consumers and other partners.

To improve our immediate response, FDA will work with stakeholders to develop an action plan for implementing more effective trace-back process improvements and technologies to more rapidly and precisely track the origin and destination of contaminated foods, feed, and ingredients. We will also increase collaboration with foreign, Federal, state, and local FDA partners to identify a contamination source, remove contaminated products, and implement corrective actions.

Another key component of improving FDA's response is additional authority for emergency responses. FDA is requesting authority for mandatory recall authority and enhanced access to food records during emergencies. FDA is seeking mandatory recall authority to be used only when the current process of voluntary recalls fails to promptly remove foods that present a threat of serious harm to humans or animals. Although FDA has the authority to seize adulterated or misbranded food, this is not the most efficient option when contaminated product has already been distributed to hundreds or thousands of locations. And while FDA has been able to accomplish most recalls through voluntary actions by product manufacturers or distributors, there have been rare instances in which a firm was unwilling to conduct a recall. In such situations, FDA needs the ability to require a firm to conduct a recall to ensure the prompt and complete removal from distribution channels of food that presents a threat of serious harm to humans or animals. This authority would be limited to foods that the

Secretary has reason to believe are adulterated and present a threat of serious adverse health consequences or death. It would be imposed only if a firm refuses or unduly delays conducting a voluntary recall. An order to recall food could only be issued by the HHS Secretary, Deputy Secretary, or Commissioner of Food and Drugs, and would be accompanied by appropriate due process rights.

FDA is seeking authority that would give the Agency more complete and streamlined access to records necessary to identify the source or cause of foodborne illness and take needed action during food related emergencies. Improved access to information concerning the safety and security of food, including records related to an article of food or related articles of food that may present a threat, will enhance FDA's ability to identify problems, respond quickly and appropriately, and protect public health. The requirement would not impose any new recordkeeping burdens and would maintain the current statutory exclusions for the records of farms and restaurants.

Currently, access to records under section 414 of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act) is limited to instances where, for an article of food, FDA has a reasonable belief that the food is adulterated and presents a threat of serious adverse health consequences or death. FDA proposes to expand access to records of *related* articles of food, such as food produced on the same manufacturing line. FDA also proposes, in food-related emergencies, to remove the adulteration requirement to allow its inspectors access to records in emergency situations where FDA has a reasonable belief that an article of food presents a threat of serious adverse health consequences or death.

IMPORT SAFETY ACTION PLAN

The President has engaged directly in the effort to make sure we are doing everything we can to protect Americans from unsafe imports. On July 18, he issued an Executive Order creating a Cabinet-level Working Group on Import Safety to promote the safety of imported products. The working group, which includes representatives from twelve Federal departments and agencies, including FDA, the Department of Agriculture (USDA), and the Department of Commerce, reviewed the procedures, regulations, and practices for ensuring that imported food, drugs, and other consumer products are safe.

On November 6, Secretary Leavitt presented the Import Safety Action Plan to the President. This Action Plan presents broad recommendations and specific short- and long-term action steps, categorized under the organizing principles of prevention, intervention, and response. Each action item is based on the building blocks identified in the Strategic Framework, released in September 2007. That report concluded that the United States must transition from an outdated “snapshot” approach to import safety, in which decisions are made at the border, to a cost-effective, prevention-focused model that identifies and targets critical points in the import life cycle where the risk of the product is greatest, and then verifies the safety of products at those important phases.

This Action Plan follows the organizing principles identified in the Strategic Framework – prevention, intervention, and response. I would like to point out a few key recommendations that affect FDA. Consistent with the Food Protection Plan, the Action Plan recommends that

the Agency have explicit authority to issue regulations requiring preventive food safety controls for high-risk foods and authority to require entities in the food supply chain to implement measures solely intended to protect against the intentional adulteration of food.

The Action Plan recommends that FDA examine food-safety control systems of other countries to determine whether improvements can be made to the operation of FDA's food regulatory program to provide the Agency with comprehensive knowledge of food safety systems of other countries. FDA could identify elements or components of those systems that are recognized as food safety system "best practices" and utilize them to strengthen and enhance FDA's prevention, intervention, and response activities.

Another recommendation is that FDA develops a voluntary certification program based on risk for foreign producers of certain products who export to the U.S. Such requirements would apply to designated high-risk products imported from countries with which FDA has an agreement to establish a certification program that provides levels of safety that are consistent with FDA standards. In order to implement this, FDA would need legislative authority to accredit independent third parties to verify compliance with FDA requirements. The Action Plan also recommends that FDA have the authority to issue a mandatory recall of food products when voluntary recalls are not effective.

GRAS STATUS OF CARBON MONOXIDE AND TASTELESS SMOKE

Under sections 201(s) and 409 of the FD&C Act, any substance, the intended use of which results or may reasonably be expected to result in its becoming a component of food, or otherwise affecting the characteristics of any food, is a food additive subject to premarket review and approval by FDA, unless the substance falls within one of the exclusions from the definition of “food additive” in section 201(s) or meets the exemption for investigational use in section 409(j) of the Act.

Under section 201(s) of the FD&C Act, a substance that is generally recognized among qualified experts as having been adequately shown to be safe under the conditions of its intended use (generally recognized as safe, or GRAS), is excluded from the definition of “food additive” and is not subject to the food additive petition process in section 409. The Act does not provide a process or specific authority for FDA premarket approval of GRAS status, and an interested person need not consult with, or even inform, FDA before or after making its own determination that a substance is GRAS under the intended conditions of use.

FDA has set out the standards for what constitutes general recognition of safety for GRAS status in Title 21, *Code of Federal Regulations*, section 170.30. The same quality and quantity of scientific data that are needed to support a food additive approval are needed to support a GRAS determination; however, there are additional criteria for the use of a GRAS ingredient. These criteria include a general availability of the data and information relied on

to establish the safety of the ingredient, such as publication of scientific literature, and consensus among qualified experts about the safety of the ingredient for the intended use.

A substance must be shown to be “generally recognized as safe” under the conditions of its intended use. Explicitly, GRAS is not an inherent property of a substance, rather, it relates to the specific conditions of use for the substance. The person asserting GRAS status has the burden of proving that the use of the substance is “generally recognized as safe.” To establish such recognition, the proponent must show that there is a consensus of expert opinion regarding the safety of the specified use of the substance. Unanimity among experts regarding safety of a substance is not required, and mere conflict among experts is not enough to preclude a finding of general recognition.

Under FDA’s voluntary GRAS notification program, an interested party may notify the Agency of its conclusion that a substance is GRAS under the intended conditions of use. FDA reviews the GRAS notice (GRN) to determine whether it provides a sufficient basis to support the party’s GRAS self-determination and then responds to the notifier as to whether the Agency has any questions. Information in the notice corresponding to the substance and its conditions of use specified in the GRAS self-determination and FDA’s response to the notice are readily available to the public by postings to the Agency’s website (<http://www.cfsan.fda.gov/~rdb/opa-gras.html>).

During the period of 2000 through 2005, FDA responded to three GRAS notices for the use of carbon monoxide (CO) in modified atmosphere packaging (MAP) systems for meat products

(GRNs 83, 143, and 167) and one notice for the use of “tasteless smoke,” (smoke filtered to remove the taste components), in tuna (GRN 15). FDA responded by stating that the Agency does not question the basis for the GRAS determinations.

FDA routinely consults with USDA’s Food Safety and Inspection Service (FSIS) to address our related, but separate, roles in the regulation of ingredients in meat. Consistent with the process established in a Memorandum of Understanding for the review of ingredients used in the production of meat and poultry products, FDA consulted with FSIS on the three GRAS notices for use of CO in MAP systems for meat products. While FDA has authority under the FD&C Act to determine the safety of ingredients used in food, FSIS has separate authority for determining whether the intended use of an ingredient in meat is suitable under the Federal Meat Inspection Act (FMIA). FSIS also has responsibility for the labeling of meat products. FSIS has informed FDA that the use of CO in MAP systems, under the conditions specified in the GRAS notices, complies with the FMIA.

GRAS Notice for Tasteless Smoke

In a revised notice to FDA dated March 11, 1999, Hawaii International, Inc. submitted information that it had determined, based on scientific procedures, that the intended use of tasteless smoke to protect the taste, aroma, and color of seafood at levels sufficient to accomplish this purpose is GRAS (GRN 15). The Agency limited its evaluation of Hawaii International’s notice to tuna.

In our March 10, 2000, response stating that the Agency has “no questions” regarding the GRAS status of tasteless smoke, FDA clearly stated that Hawaii International, or any other party who markets tuna that has been preserved with tasteless smoke, is responsible for ensuring that such tuna is neither misbranded under sections 403(a), 403(i)(2) or 403(k) of the FD&C Act, nor adulterated under sections 402(b)(3) or 402(b)(4).

FDA stated that Hawaii International’s use of tasteless smoke constitutes use as a preservative, therefore, the ingredient statement on labels of tuna treated with the substance must, among other things, declare that the tuna is treated with tasteless smoke, and that it is used as a preservative. In addition, the treated tuna may not be represented as “smoked,” nor identified as “fresh.”

FDA’s response letter further stated that if the application of tasteless smoke causes the color of tuna flesh to be enhanced, potentially causing consumers to be misled about the true nature or value of the tuna, the product may be adulterated.

FDA is aware of the concerns that the use of tasteless smoke or CO, one of its components, on tuna may prevent detection of potentially dangerous histamine formation in tuna. FDA considered these concerns in responding to the GRAS notice and concluded that they were not scientifically sound. Tasteless smoke and CO are effective in preventing the color change that routinely accompanies the freezing and thawing of tuna; however, color change is not a reliable means of screening out decomposed from non-decomposed fish, or of screening out histamine-containing from non-histamine-containing fish. Color change routinely occurs as a

result of the freezing and thawing process, unassociated with the kinds of abuse conditions that produce either histamine or decomposition.

The most effective means of detecting decomposed fish is by odor. This is a highly effective tool for eliminating fish that are unfit for food because of decomposition. This is the method used by FDA examiners and regulatory examiners around the world. However, it has only limited utility in screening fish, such as tuna, for histamine content. The type of abuse conditions that lead to fish decomposition (e.g., being held at low temperature for extended periods of time) often do not lead to histamine formation in fish, which is associated with high temperature abuse. There is no scientific evidence that tasteless smoke or CO affects either the formation of histamine or the ability to detect histamine formation through sensory analysis.

Given the lack of a reliable relationship between odors of decomposition and levels of histamine, it is understandable that consumers on occasion eat fish that tastes fresh, but still become ill from high levels of histamine. This has been a recognized public health problem for many years. FDA has invested considerable research time and dollars to provide the seafood industry with the best possible guidance on how to prevent the hazard. The seafood industry is required to address these public health issues by instituting Hazard Analysis Critical Control Point (HACCP) principles that help prevent abuse conditions that can lead to histamine formation.

Illnesses can occur as a result of lapses in the implementation of these mandatory controls. FDA takes these lapses seriously and uses its regulatory authorities to address them. Testing of imported tuna, which is highly targeted to suspect lots, reveals elevated histamine levels in both untreated products and products treated with tasteless smoke and CO. Nonetheless, if processors are using tasteless smoke or CO treatment to make decomposed fish look better, they are in violation of the adulteration provisions of the FD&C Act. Enhancing the appearance of decomposed fish, however, does not inhibit FDA from uncovering such adulteration by sensory (odor) examination of lots at the border.

GRAS Notice for Carbon Monoxide

In a notice to FDA (GRN 83) dated August 29, 2001, Pactiv Corporation stated its determination, through scientific procedures, that CO is GRAS for use as a component of a gas mixture in a MAP system. The level of CO in Pactiv's MAP system is 0.4 percent. The other components of the MAP system are carbon dioxide (30 percent) and nitrogen (69.6 percent). The MAP system is used for packaging fresh cuts of case-ready muscle meat and ground case-ready meat to maintain wholesomeness, provide flexibility in distribution, and reduce shrinkage.

In its response dated February 21, 2002, FDA stated that based on the information provided by Pactiv, as well as other available information, the Agency had no questions regarding Pactiv's conclusion that CO is GRAS under the intended conditions of use.

FDA responded to two other GRAS notices for the use of CO in MAP systems for meat, stating that it had no questions regarding the sponsors' GRAS determinations. These notifications, which incorporated the information in the Pactiv notification by reference, were from Precept Foods, LLC (FDA response of July 29, 2004) and Tyson Foods, Inc. (FDA response of September 29, 2005). In its review of each of these GRAS notices, the Agency carefully considered the information provided by the notifier, as well as all other available relevant information in reaching the decision not to challenge the notifiers' determinations that their uses were GRAS.

We are aware that concerns have been raised about the possible misuse of CO in seafood and about the use of CO-containing MAP systems for meat. Agency regulations provide for a mechanism whereby parties seeking reconsideration of FDA decisions can make available to FDA data and information in support of their request. Indeed, FDA has received citizen petitions which challenge FDA's acceptance of the GRAS status of CO-containing MAP systems and of tasteless smoke. We continue to receive information relevant to the citizen petitions and to GRNs 15, 83, 143, and 167, and are currently reviewing that information.

CONCLUSION

Ensuring that FDA-regulated products are safe and secure is a vital part of FDA's mission – to protect and promote public health. Changes in consumer preferences, industry practices, and the rising volume of imports have posed challenges that required us to adapt our current food protection strategies. The Food Protection Plan provides an updated approach to ensure

that the U.S. food supply remains one of the safest in the world. The Plan will help prevent harm before it can occur, will provide enhanced intervention measures, and improve our ability to respond to food safety threats.

FDA remains committed to working closely with all of its partners to implement the Plan's measures to protect the nation's food supply. We look forward to working with the Members of this Committee and the entire Congress to obtain passage of the requested legislative authorities identified in the Food Protection Plan and the Import Safety Action Plan. Thank you for the opportunity to discuss FDA's activities to enhance food safety. I would be happy to answer any questions.