Testimony
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Developing a Comprehensive Response to Food Safety

Statement of

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Chairman Kennedy and Members of the Committee, I am pleased to be with you today to discuss the Action Plan for Import Safety. The Plan, which I delivered to the President on November 6th, puts us on the verge of a major transformation in the way we view imported consumer products and assure their safety. At the request of the President, I chaired the interagency working group on import safety which included representatives from twelve Departments and Agencies. The Plan was developed following a careful examination of import product safety issues, and it contains 14 broad recommendations and 50 short and long term action steps that will enhance the safety of imports entering the United States for the 21st Century. Today I want to cover some of the key elements of the Action Plan and explain our strategy for implementing them.

First, it is important to mention why this effort is so important and the challenges involved. Today, Americans import approximately 2 trillion dollars worth of goods from over 800,000 importers through 300 ports of entry. The growth in the volume of imports over the last two decades has been nothing less than astounding and it shows no signs of slowing. The expansion of imports is driven by growth of trade in a global economy. There are many benefits to consumers. A wide variety of fresh fruits and vegetables, seafood, and a range of ethnic and other foods from foreign countries are available year round in our grocery stores in a way that our parents could not have imagined. International trade provides Americans access to innovative products and productivity enhancing technologies from other countries which add to our quality of life.

Imported products are generally safe in the U.S. and Americans enjoy one of the safest food supplies in the world. Yet, we are all aware of recent incidents with unsafe toys and tainted pet foods from China. In addition, there have been concerns about the safety of imported drugs. These incidents of unsafe imports raise legitimate concerns. However, we should not conclude that imports are unsafe or that all products from China or other countries are to be avoided. Instead, these incidents point to the need to revamp the way we deal with import product safety. To put it another way, imports are safe today but, due to the high volume of trade, we need to transform the import system and change the way we verify product safety to meet the challenges of a global economy.

This problem is not unique to the United States. I have raised these issues with the ministers of health from eight of our closest trade partners, and they all have the same concerns. The growth of the global economy has created new challenges for ensuring the safety of imported products. Some of these challenges are: the large and growing volume of imported products; the large number of ports of entry and the need to process imported products quickly at the ports; the increased volume of imports from less developed countries; the complexity and variety of products which carry increased risk; and, the need for stronger safety and quality standards around the world. Further, as global trade has grown, so has the value of trade and the opportunity for unscrupulous businesses to short circuit safety standards or engage in the sale of counterfeit products. Our 20th century approach to ensuring import safety of attempting to screen products at the border is a "snapshot" approach that will not work for the 21st century. The Federal government cannot, and should not, attempt to physically inspect every product entering the U.S. This is like trying to find the needle in the haystack. The Action Plan we are discussing today addresses this challenge.

Now, let me turn to our Strategic Framework for enhancing import safety and some key elements of the Action Plan. The organizing principles fall into three major areas: prevention, intervention, and response, and we have a number of recommendations and specific short and long term action steps in each of these areas.

Our overall goals are to:

- Promote a common vision of import safety with our trading partners and foster a culture of collaboration;
- Focus on risks over the product life cycle rather than a snapshot at the border
- Increase accountability, enforcement and deterrence;
- Build interoperable data systems and encourage data sharing; and
- Promote technological innovation and develop new tools to enhance import safety.

The Action Plan covers all imported consumer goods that could pose a potential safety threat to U.S. consumers-- from toys and tires to drugs, medical devices, dietary supplements, cosmetics, and all foods for both humans and animals. The general thrust of the plan is to broaden our focus from examining products as they enter the U.S. to monitoring imported products throughout their life cycle from production to consumption, paying particular attention to the critical points of risk along the way where safety can be compromised and safety standards are most needed.

Some of the highlights of the Action Plan are:

- **Creating new and strengthening existing standards**. We will work with international standard-setting organizations and foreign government regulators around the world to develop international standards that reflect the same level of protection maintained for consumer products in the U.S.
- **Verifying compliance with safety standards** We are proposing a voluntary certification program whereby products could be certified as meeting U.S. safety standards. This may involve verification - for example, testing or inspection by third parties or by domestic or foreign regulatory bodies. In addition, if HHS is provided the necessary authority, importers of certain high risk products could be required to certify that those products meet certain standards before they are exported to the U.S.
- **Encouraging Good Importer Practices**. Import guidance documents will be developed to encourage the adoption of best practices to improve import safety.
- **Enhancing enforcement**. While voluntary product recalls are usually adequate to protect consumers, we are recommending authority for mandatory recall for the FDA in certain instances.
- **Expediting consumer notification of product recalls.** Track and trace technologies will enable officials to pinpoint where the problem occurred and intervene quickly. In addition, other technologies such as integrated circuit cards, also known as Smart Cards, may allow retailers to notify consumers of potential safety problems.

- **Exchanging import data**. U.S. Customs and Border Protection, the FDA, USDA and other agencies will increase coordination with real-time sharing of product safety information to better inform decisions about clearing or rejecting import shipments. In addition, we are exploring ways to expand the sharing of key data with foreign governments, consistent with applicable law, and gaining more access to data existing in the private sector as well.

The twelve Departments and Agencies involved in the generation of the Action Plan each have a role in the implementation of its recommendations. We also anticipate involvement of private sector stakeholders - retailers and manufacturers, importers, consumer groups, and others. Many of the Action steps can be accomplished by administrative changes, but some will require changes in the law and we are looking forward to working with Congress to accomplish these.

FDA FOOD PROTECTION PLAN

Earlier this year, I directed the FDA Commissioner to develop and submit to me a comprehensive plan for protecting the Nation's food supply. This plan, the FDA Food Protection Plan, was released at the same time that I submitted the Action Plan for Import Safety to the President. It utilizes the same framework as the Action Plan: Prevention, Intervention, and Response, and its action steps are consistent with and complementary to the recommendations of the Action Plan. One distinction is that the Food Protection Plan applies to domestic food producers as well as all imported foods regulated by the FDA. I would now like to provide an overview of the Food Protection Plan.

Prevention

Prevention is the first essential step for an effective, proactive food safety and defense plan. There are 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.

First, to promote increased corporate responsibility, we 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, we will work with foreign governments, which have a greater ability to oversee manufacturers within their borders to ensure compliance with U.S. safety standards.

New authorities will be needed 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 intentional contamination of food by terrorists or criminals at points of high vulnerability. We have also proposed authority to issue regulations in certain circumstances requiring that high-risk foods be prepared, packed, and held under a system of preventive food safety controls.

Second, to identify food vulnerabilities and assess risk, we 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 will 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 the 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, we will initiate additional 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, we 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, we need to increase research and leverage relationships with outside organizations in order to 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, targeted, risk-based interventions are needed to provide further protection. The Food Protection 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 is needed to authorize FDA to accredit or recognize and use highly qualified, independent third parties to evaluate compliance with FDA requirements, thereby allowing the Agency's resources to be more effectively allocated. 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 could be taken into consideration when setting inspection and surveillance priorities.

To enhance the Agency's risk-based surveillance, we plan 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 Practice (cGMP) 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, we recommend 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, we 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. We 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 our ability to "map" or trace adverse events back to their causes by improving the 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 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 sources to develop an early warning surveillance and notification system to alert veterinarians and others about problems with the pet food supply.

Response

To improve our immediate response, we 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 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. The Food Protection Plan recommends requesting mandatory recall authority and enhanced access to food records during emergencies. This recall authority would be used only when the current voluntary recall process 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 the 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 may be 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 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.

We are also seeking authority that would give the FDA 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.

As we continue to move forward with the Food Protection Plan, we will work with other Federal agencies, state, local, and foreign governments as well as industry to develop the food science and tools necessary to better understand the current risks of the food supply, develop new detection technologies, and improved response systems to rapidly react to food safety threats.

U.S - CHINA CHALLENGES

Now I want to turn to the issue of imported products from China. As I have mentioned, although there have been some recent problems with Chinese imports, we must not conclude that all products made in China are dangerous. However, as noted below, we are currently taking a number of steps to improve the flow of information on the risks of imports from China and efforts will be made to increase the safety of Chinese imports through certification of quality controls in goods produced in China for export.

Let me provide some context for the discussion. China has a complex product safety regulatory system that consists of the Ministry of Agriculture which monitors food production and regulates farm inputs; the General Administration of Quality Supervision, Inspection and Quarantine [AQSIQ] which monitors processing and trade, the Certification and Accreditation Administration, which regulates the production certification, and the State Food and Drug Administration [SFDA] which coordinates food and drug policies and investigates safety mishaps. The Chinese system is challenged by rapid growth and decentralization of power which has resulted in overlapping authorities in some areas and gaps in regulatory control.

I have met with Chinese officials on several occasions to discuss import regulatory issues and we are in the process of finalizing negotiations on two binding Agreements that we expect to sign soon. One will cover the safety of food and feed, and the second will cover the safety of drugs and medical devices. These agreements outline the processes

and points of contact for both countries to follow when the importing country rejects a shipment.

We expect that the provisions of the Action Plan will be instrumental to improving the safety and bolstering consumer confidence in Chinese imports

CONCLUSION

Implementing the Import Action Plan and the Food Protection Plan will require resources, including reallocation of existing resources, as well as trade-offs, to fund these priorities. We plan to coordinate with Federal departments and agencies to carefully plan the implementation and submit funding needs through the normal budget process in February 2008 and in subsequent years. To the extent that additional statutory authority is needed to implement the Import Action Plan, we look forward to working with this Committee on import product safety legislation.

U.S. imports are large and growing rapidly. American consumers like the variety and abundance of consumer goods and the competitive prices that result from global trade. The American people, however, have reasonable expectations that the products they buy for their families will be safe. We can and must do more to honor that trust.
The Action Plan will lead to both short and long term improvements in the way we view and regulate imported consumer products and implementing these recommendations will enable us to meet the additional safety challenges of imports in the 21st century. We appreciate the support of this Committee and Congress as move forward with our recommendations.

Thank you for the opportunity to discuss this important topic. I will be pleased to respond to your questions.