



STATEMENT OF
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BEFORE THE
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SUBCOMMITTEE ON HEALTH
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INTRODUCTION

Good morning, Chairman Pallone and Members of the Subcommittee. I am Dr. Randall Lutter, Deputy Commissioner for Policy at the U.S. Food and Drug Administration (FDA or the Agency) in the Department of Health and Human Services (HHS). I am accompanied today by my colleagues from FDA, Dr. David Acheson, Assistant Commissioner for Food Protection, and Dr. Steven Solomon, Deputy Director of the Office of Regional Operations in FDA's Office of Regulatory Affairs. Thank you for the opportunity to discuss the important issues relating to the safety of imported FDA-regulated products and to discuss H.R. 3610, the "Food and Drug Import Safety Act of 2007," introduced by Chairman Dingell.

FDA is the Federal agency that regulates everything we eat except for meat, poultry, and processed egg products, which are regulated by our partners at the U.S. Department of Agriculture (USDA). FDA's responsibility extends to live food animals and animal feed. FDA also is responsible for ensuring that human drugs, human biological products, medical devices, and radiological products as well as animal drugs are safe and effective and that cosmetics are safe.

I assure you that FDA is committed to ensuring that America's supply of the food, drugs and other products we regulate continues to be among the safest in the world. In recent years, the Agency has done a great deal to detect unintentional and deliberate contamination in imported products. However, we face significant challenges. The recent incidents involving unsafe

imported products underscore the need to renew our focus on multidisciplinary and integrated product safety strategies.

One of the significant challenges we face is the rapid increase in the volume of imported products. Each year, approximately \$2 trillion worth of imported products enter the U.S. Experts project that import volume will triple by 2015. The volume of FDA-regulated imports has doubled in the last five years, and 60 percent of these imported shipments are food or food-related. Currently, there are over nine million entries of imported food and food-related products annually and most are large volume commercial shipments. It is estimated that approximately 15 percent of the U.S. food supply is imported, but for some products such as fresh fruits, imports account for 50 to 60 percent of the supply.

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. HHS Secretary Michael O. Leavitt chairs the Working Group. I will discuss the Working Group's activities and recent report below.

REGULATION OF IMPORTED FDA-REGULATED PRODUCTS

FDA's primary authority over imported food, cosmetics, drugs, biological products, and medical devices, derives from section 801 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Imported radiation emitting products are regulated under section 534 of the

FD&C Act. These authorities provide a broad statutory framework to ensure that the products are safe. Imported products are subject to examination. FDA can refuse admission into the U.S. if they appear, based on examination or other information, to be adulterated, misbranded, or otherwise violative.

Imported Food

As you know, in 2002, Congress gave FDA significant new authorities to enhance protection of the food supply in the Public Health Security and Bioterrorism Preparedness and Response Act (Bioterrorism Act). I wish to thank the Members of this Subcommittee and the full Committee for your leadership in enacting this landmark legislation.

One of the major provisions of the Bioterrorism Act that enhances our ability to protect American consumers from contaminated imported food is the requirement to submit to FDA prior notice of food, including animal feed, that is imported or offered for import into the U.S. This advance information enables FDA, working closely with Customs and Border Protection (CBP), to more effectively target imported food that may pose a significant risk so it can be inspected before it moves into the U.S. FDA is currently reviewing approximately 33,400 prior notice submissions per business day.

The prior notice requirement not only allows the electronic system to review and screen the shipments for potential serious threats to health (intentional or otherwise) before food arrives in the U.S., but it also allows FDA staff to review prior notices of those products flagged by the system as presenting the most significant risk and determine whether the shipment should

be held for further investigation. If the result of our prior notice review suggests the food presents a significant threat, we will not release the food into commerce until we have information indicating it does not pose such a threat.

FDA worked closely with CBP in developing the targeting system. In particular, FDA worked with analysts at CBP's National Targeting Center to utilize their Automated Targeting System as an additional tool to enhance the Agency's ability to focus attention on those imported foods that may pose a serious threat to public health.

Another significant provision of the Bioterrorism Act gave FDA the authority to commission other Federal officers and employees to conduct examinations and investigations. Pursuant to this authority, FDA and CBP signed a Memorandum of Understanding in December 2003 to commission CBP officers to conduct examinations on FDA's behalf at ports where FDA may not currently have staff or to augment FDA staff in the enforcement of FDA's prior notice requirements. This collaboration significantly strengthens our ability to secure the border while ensuring the movement of legitimate trade. In accordance with the commissioning authority, FDA has commissioned over 9,900 CBP officers.

To manage the ever-increasing volume of imported food shipments, FDA utilizes risk-management strategies in the review of foods that are being imported or offered for import into the U.S.. In addition to the screening and targeting based on the prior notice submissions, we use information submitted through CBP's electronic systems for import entries, along with other information, to determine if the shipment meets identified criteria for

physical examination or sampling and analysis or warrants other review by FDA personnel. FDA is working to enhance its targeting ability by utilizing data from a much wider range of sources to better inform our entry decisions and by improving our information technology (IT) systems to use this information more efficiently and effectively.

FDA also performs routine surveillance inspections of imported foods to check for compliance with U.S. requirements. If, based on a physical examination or other information, FDA determines that a food shipment is or appears to be violative, the Agency has the authority to refuse its admission into U.S. commerce. It is important to note that while FDA is not able to physically inspect a large percentage of food entries, we electronically screen all import entries through the Operational and Administrative System for Import Support (OASIS). OASIS is an automated system for processing FDA-regulated products offered for import and helping FDA make admissibility determinations. It includes criteria designed to identify those products posing the greatest safety risk.

FDA has additional tools and authorities which enable the Agency to take appropriate action regarding imported products. For instance, FDA can issue import alerts, which signal FDA inspectors to pay special attention to a particular product, producer, shipper or importer. Recently, for example, the Agency established import alerts for certain products from China, including all vegetable proteins and certain types of aquacultured fish. Based on the information in these import alerts, FDA field staff may initiate refusal of admission into the U.S. without physically examining the product. If FDA initiates refusal, the importer has an

opportunity to demonstrate that the products in question are free of the relevant contaminants or otherwise not violative.

FDA also performs laboratory analysis on a sampling of products offered for import into the U.S. and performs periodic filer evaluations to ensure that the import data being provided to FDA is accurate. In addition, certain violations relating to imported food may lead to civil or criminal charges.

Imported Drugs, Biologics, and Certain Devices

The FD&C Act strictly limits the drugs and biologics, as well as certain devices, that may be imported into the U.S.. Congress enacted these provisions to create a relatively “closed” distribution system for such products, which helps ensure that the domestic supply is safe and effective.

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

NEW INITIATIVES

Food Protection Strategy

The FDA Commissioner, Dr. Andrew von Eschenbach, recently appointed Dr. David Acheson to the newly created position of Assistant Commissioner for Food Protection, to provide advice and counsel on strategic and substantive food safety and food defense matters at FDA. He is developing a new strategy to enhance FDA's food safety and food defense systems that will address changes in the global food safety and food defense system, identify our most critical needs, and serve as a framework to help us address the challenges we face. The goal is to ensure a comprehensive and robust food safety and food defense program that is tailored to meet the risks posed by the types of foods FDA regulates and that focuses on prevention, risk-based interventions to ensure preventive controls are effective, and rapid responses when contaminated food or feed is detected, or when there is harm to humans or animals. The strategy will provide a risk-based farm-to-table approach that coordinates food safety and food defense efforts and focuses on prevention, intervention, and response.

Interagency Working Group on Import Safety

As noted earlier, the President has established an Interagency Working Group on Import Safety. The working group, which includes representatives from twelve Federal departments and agencies, including FDA, USDA, and the Department of Commerce, is reviewing the procedures, regulations, and practices for ensuring that imported food, drugs, and other consumer products are safe. Secretary of Health and Human Services Michael O. Leavitt chairs this working group, and FDA plays a key role in the group's activities.

Secretary Leavitt and Commissioner von Eschenbach have traveled extensively throughout the U.S. to examine our nation's import process. On stops in nearly two dozen cities over the last two months, Secretary Leavitt and Commissioner von Eschenbach visited ports and post offices; railroads and airports; supermarkets and retail stores; seafood warehouses and meat processing facilities. They examined the inspection process of fruits and vegetables, meat, fish, toys, and medicines. Along the way, they were accompanied by the USDA Secretary, the Department of Homeland Security Secretary, and the Environmental Protection Agency Administrator. From border towns like Nogales, Arizona, the gateway for nearly 70 percent of imported fruits and vegetables during the winter months to O'Hare International Airport in Chicago where inspectors handle 100,000 pieces of mail every single day, they have seen first hand the sheer vastness of our import system.

The insights that they gained during their review of field operations helped shape the strategic framework that was released by the Working Group on September 10th. That report, "Protecting American Consumers Every Step of the Way: A Strategic Framework for Continual Improvement in Import Safety," outlines an approach that, like the Food Protection Strategy, is based on the organizing principles of prevention (prevent harm in the first place), intervention (intervene when risks are identified), and response (respond rapidly after harm has occurred).

The Strategic Framework recognizes that we must find new ways to protect American consumers and continually improve the safety of imports. It identifies the need to shift from the current model that relies on "snapshots" at the border to interdict unsafe products to a

cost-effective, prevention-focused “video” model that identifies and targets those steps in the import life cycle where the risks of unsafe products are greatest and verifies the safety of products at those important phases. Such a risk-based, prevention-focused model will help ensure that safety is built into products before they reach our borders.

Supporting the Working Group model are six building blocks: 1) advance a common vision, 2) increase accountability and enforcement, 3) focus on risks over the life cycle of an imported product, 4) build interoperable systems, 5) foster a culture of collaboration, and 6) promote technological innovation and new science.

The Working Group has an aggressive schedule for public comment and follow-up. On October 1, the Working Group will conduct a public meeting to identify actions the public and private sectors can take to promote the safety of imported products. By mid-November, the Working Group will present an Action Plan to the President. The plan will reflect the public comments and recommend specific actions that the Federal government and stakeholders can take to enhance import safety at all levels. The Action Plan will be based on the Strategic Framework and will lay out a road map with short- and long-term recommendations.

Although the Action Plan will bring forth more detailed actions, Federal agencies have already begun to implement high-priority Working Group recommendations. The interoperability of import data systems is the fourth of the six building blocks and is an essential component of import safety. By November 12, Federal agencies (including FDA)

that rely on IT systems in their review of imported cargo must develop implementation plans to achieve interoperability with the International Trade Data System managed by CBP. This action is consistent with the Security and Accountability for Every (SAFE) Port Act of 2006. This action will ensure a single-window system for reporting on imports electronically.

H.R. 3610, “THE FOOD AND DRUG IMPORT SAFETY ACT OF 2007”

The bill introduced by Chairman Dingell on September 20 contains a variety of provisions that relate to the safety of imported food and drugs in addition to other matters. The Administration has not yet taken a position on this legislation; however, we would be pleased to provide technical assistance to Committee and Subcommittee staff. We share Chairman Dingell’s interest in enhancing the safety of imported products and look forward to continuing to work with him and his staff and others on the Committee and Subcommittee. We also look forward to working with you on the Action Plan discussed above.

CONCLUSION

Ensuring the safety of imported products is a significant task, but I want to assure you that FDA is diligently working to efficiently and effectively use the resources and authorities we have been provided by Congress to help protect American consumers. Thank you for the opportunity to discuss FDA’s activities to enhance the safety of imported products. I would be happy to answer any questions.