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FOOD SAFETY

Federal Efforts to Ensure Imported Food Safety Are Inconsistent and Unreliable

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Madam Chairman and Members of the Permanent Subcommittee:

Thank you for the opportunity to discuss our work on federal efforts to ensure the safety of imported foods. As the American public consumes more and more foods from other countries, the challenge of ensuring the safety of these foods is growing. Recent outbreaks of foodborne illnesses demonstrate that imported foods have introduced new risks or have increased the incidence of illnesses. As imports increase, it is imperative that federal agencies have the most effective systems in place, and make the best use of their limited resources, to ensure that imported foods are safe to eat. The primary responsibility for ensuring the safety of imported foods is split between two federal agencies: the Department of Health and Human Services' Food and Drug Administration (FDA) and the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS). FSIS and FDA work closely with the U.S. Customs Service (Customs) in the Department of the Treasury and the Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services in carrying out their responsibilities.

Today, I will discuss findings from our recent report in which we pointed out how limitations in FDA's authority and approach for regulating imported foods adversely affect its ability to ensure food safety, how FDA's and FSIS' procedures for selecting shipments to review result in the ineffective targeting of inspection resources, and how weaknesses in FDA's and Customs' controls allow unscrupulous importers to market unsafe products.[1]

In summary, we found the following:

- The Food and Drug Administration lacks the legal authority to require that countries exporting foods to the United States have food safety systems equivalent to ours—an authority that the Food Safety and Inspection Service has and uses to share the burden of ensuring safe foods with the exporting countries. Without such authority, the Food and Drug Administration must rely primarily on its port-of-entry inspections, which covered less than 2 percent of shipments in 1997, to detect and bar unsafe foods. Such an approach has been widely discredited as an effective protective measure.
- Both the Food and Drug Administration and the Food Safety and Inspection Service could make better use of their inspection resources by

[1]Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable (GAO/RCED-98-103, Apr. 30, 1998).

using available health risk information to target shipments for inspection that pose the highest food safety risk. Additionally, the Food and Drug Administration could further improve the use of resources by clarifying its communications to inspectors about which shipments to select and by taking enforcement action when importers are found to inaccurately describe the contents of shipments. With such improvements, the Food and Drug Administration could better ensure that it is using its scarce resources to identify the foods posing greater risks.

- The Food and Drug Administration's procedures for ensuring that unsafe imported foods do not reach U.S. consumers are vulnerable to abuse by unscrupulous importers. Under current procedures, the Food and Drug Administration generally allows importers to retain control over shipments until the agency grants their release. If importers move shipments into domestic commerce without a Food and Drug Administration release—that is, before the Food and Drug Administration inspects them or when a Food and Drug Administration laboratory test reveals the products do not meet U.S. standards—the Food and Drug Administration has no effective means of compelling importers to return the shipments for inspection, destruction, or reexport. In addition, when the Food and Drug Administration requires an importer to provide evidence that a suspect shipment is safe, the agency allows the importer to select the laboratory that picks the samples to be tested and that conducts the tests. Finally, the Food and Drug Administration's and Customs' principal deterrent for ensuring that importers comply with U.S. requirements—the collection of damages from violators—is uneven and uncertain.

Background

Foodborne illnesses in the United States are widespread and costly. While the magnitude of the problem is uncertain, we reported in May 1996 that studies have estimated up to 81 million cases of foodborne illnesses and as many as 9,100 deaths occur each year.[2] Recent estimates suggest that the number of illnesses may be even higher. While there is a wide range of estimates, according to the U.S. Department of Agriculture, the cost of these illnesses and deaths, measured in medical treatment and productivity losses, have been estimated to range from $7 billion to $37 billion a year.

A significant amount of the food we consume is imported, and the percentage is growing. For example, between 1980 and 1995, the imported share of all fresh fruit consumed by the American public rose from about

[2]Food Safety: Information on Foodborne Illnesses (GAO/RCED-96-96, May 8, 1996).

24 percent to about 33 percent, and the imported share of seafood rose from about 45 percent to about 55 percent. FDA estimates that the volume of imported fruits and vegetables will grow by 33 percent between now and 2002. The sheer volume of these imports, along with the difficulty in ensuring that they are safe, adds to the risk of foodborne illnesses and makes it essential that steps to ensure their safety are effective.

Some of these imported foods pose especially significant risks of foodborne illness. They can introduce pathogens previously uncommon in the United States, such as new strains of Salmonella and the Cyclospora parasite. In 1996 and 1997, outbreaks of foodborne illness linked with the Cyclospora parasite in raspberries from Guatemala affected nearly 2,500 people in the United States and Canada, causing prolonged gastrointestinal distress and other painful symptoms. In addition, imported foods may contain pathogens, such as hepatitis A, that cannot be easily detected by examination or even laboratory analysis.

FSIS has jurisdiction over meat, poultry, and some egg products, while FDA regulates all other foods. FSIS and FDA work closely with Customs and CDC. Customs refers imported foods to FSIS or FDA for their review before releasing the shipment into U.S. commerce. CDC monitors the incidence of foodborne illness, works with state and local health departments to investigate outbreaks of illness, and collaborates with FSIS, FDA, and others to conduct research on foodborne diseases.

As we have reported numerous times, the U.S. food safety system is characterized by a fragmented organizational structure with numerous agencies implementing a hodgepodge of inconsistent regulations and laws. This lack of a uniform, risk-based approach has adversely affected our nation's ability to protect itself from a host of domestic food safety problems. That same fragmented structure and inconsistent regulatory approach is being used to ensure the safety of imported foods as well.

Lack of Equivalency Authority Diminishes FDA's Ability to Protect U.S. Consumers

To ensure the safety of meat and poultry imports, FSIS has a statutory mandate to require that each country wishing to export meat and poultry products to the United States demonstrate that it has an equivalent food safety system. As of January 1998, FSIS had certified the eligibility of 37 countries for exporting meat and poultry to the United States. FSIS has used equivalency authority to shift most of the responsibility for food safety to the exporting country, which performs the primary inspection of products before they reach the United States. This approach allows FSIS to

leverage its resources by focusing its reviews on verifying the efficacy of exporting countries' systems rather than by relying primarily on ineffective, resource-intensive port inspections to ensure the safety of imported foods.

In contrast, FDA, although it is expected to ensure that imported fruits and vegetables and other foods meet U.S. standards, does not have a similar equivalency authority and therefore cannot require that countries exporting food products to the United States have safety systems in place that are equivalent to ours.[3] As a result, FDA must rely primarily on selecting and testing import samples at ports of entry to ensure that foods are safe. Such an approach has been widely discredited by the United Nations Food and Agriculture Organization, an FDA Advisory Committee, and our own analyses as ineffective because individual product samples tested at the ports of entry may not represent the health risks of all shipments from that exporter. To exacerbate matters, FDA has been unable to keep pace with increasing imports, and its inspection coverage has fallen from an estimated 8 percent of import shipments in fiscal year 1992 to an estimated 1.7 percent in fiscal year 1997.

Given the ineffectiveness of port-of-entry inspections, FDA cannot realistically ensure that unsafe foods are kept out of U.S. commerce. Even if FDA could inspect more shipments at ports of entry than it currently does, such an approach would still provide little assurance that imported foods are picked, processed, and packed under sanitary conditions because inspectors have no assurance that the exporting country has an effective food safety system. An equivalency requirement would allow FDA to share the burden of ensuring safety with the exporting country and allow it to make better use of limited resources. FDA agrees it needs such authority but believes the authority should be discretionary, so that equivalency could be applied when FDA believes it is most appropriate, thus limiting disruptions in trade. In our April 1998 report we recommended that equivalency should be mandatory for all imported foods, but the requirement could be phased in, so that it would not disrupt trade. Such mandatory authority would (1) impel FDA to take a proactive approach to preventing food safety problems, instead of requiring equivalency in countries after problems become apparent and (2) enable FDA to leverage its staff resources by sharing responsibility for food safety with exporting countries.

[3]In 1997, an administration initiative on food safety proposed equivalency authority for FDA.

Agencies Could More Effectively Target Resources to Inspect Unsafe Foods

FSIS and FDA use computer systems to review information on each import shipment and to help identify the import shipments requiring inspector action. However, neither agency's system takes maximum advantage of available data to target those imported foods posing the greater health risks. Each agency has opportunities to use its resources more effectively.

FSIS relies primarily on the violation history of previous shipments from the exporting firm to target entries for inspections or laboratory tests, but the violation history may not always indicate the shipments more likely to pose health threats. For example, many violations, such as incorrect shipping labels, may not directly affect consumer safety. In 1996, about 86 percent of FSIS' refused shipments, excluding those refused entry for transportation damage, were not directly related to health risks such as excessive residues, microbiological contamination, unsound condition, or defects caused by disease. Nevertheless, these violations triggered a series of inspections on subsequent shipments of the same product from the same exporting firm until at least 10 consecutive shipments were found to be in compliance. When limited resources are targeted in this fashion, fewer resources are available for products posing greater health risks.

FSIS could further improve its automated screening system if it developed information on patterns of violations, which would allow it to determine whether Salmonella contamination, for example, was a recurrent problem in a particular country or an exported product and increase its inspection frequencies for such shipments. FSIS possesses raw data on those problems but has not designed its computer system to use these data to identify patterns of violations, such as firms or countries with repeated problems, that are directly related to food safety. According to FSIS, the agency will consider modifying its automated screening system to identify patterns on violations when it redesigns the system this year.

FDA's system for selecting imports for examination relies heavily on inspectors' judgment. To help its inspectors make informed judgments, FDA provides a number of tools, such as annual work plans, compliance programs, and databases containing historical or other pertinent information to inspectors. However, these tools are often confusing, inconsistent, or not readily available to FDA inspectors and hence provide guidance of little practical value.

Specifically, FDA's annual work plans set the number of activities, such as the number of inspections and tests each FDA district is to conduct for the 10 specific food programs that cover imports. Each day, the inspectors

attempt to select shipments on the basis of the work plan's targets. According to FDA, its compliance programs, not the work plans, contain specific guidance on inspection requirements. However, we found that FDA inspectors rely on the numerical inspection targets set forth in the annual work plan for guidance. These targets are sometimes inconsistent with the direction given in the compliance programs. Such inconsistency in guidance for inspectors serves only to distract and confuse them as they attempt to carry out their duties on a daily basis.

Moreover, FDA's computer system for screening imported food shipments is not programmed to help inspectors effectively use laboratory test results, violation histories, and other information on shipments to identify those shipments posing the greatest food safety risks. With respect to laboratory tests, FDA has not integrated its laboratory database with its automated import screening system; thus, inspectors do not have the results of prior laboratory tests available when making decisions on which imported products to inspect.

Furthermore, FDA inspectors do not have ready access to some useful data on previous violations by foreign plants in the automated import screening system when making their decisions on which products to inspect. For example, FDA has databases with information on prior violations by foreign plants or countries and information on registrations of foreign firms producing certain canned foods, but the automated import screening system cannot review the databases, and the process for having the inspectors do so can be cumbersome and time-consuming. To obtain these data, inspectors must close their automated import screening system and open the other databases. We observed this process and found that it took 3 to 10 minutes each time the inspector wanted to switch from one database to another. Given that inspectors may have to process as many as 200 shipments per day, not all inspectors bother changing databases to look for this information.

Instead, inspectors told us, they often rely on their memory of the information in the database or notes. Because inspectors have these difficulties in obtaining needed data on health-related risks and are under time pressure, they decide which samples to select on the basis of incomplete information. As a result, inspectors may rely on individual biases. For example, one inspector told us he believed one country did not have sanitary facilities and therefore assumed that all food products imported from that country were contaminated with filth. This inspector routinely selected samples of food from that country for filth tests,

although the laboratory staff told us that such tests were lower priority than tests for microbiological contamination and therefore were frequently not conducted. As a result, the resources used to select these samples were not effectively used. According to FDA officials, the agency received funds to enhance the screening system in fiscal year 1998 and will begin integrating the databases (the Laboratory Management System, the Import Alert Retrieval System, and the Low-Acid Canned Food database) with the automated import screening system this year.

Finally, the information identifying the contents of imported food shipments is, in most cases, entered directly into an automated import processing system by importers, some of whom have an incentive to misrepresent their goods in the interest of avoiding inspectors' scrutiny. Importers who have demonstrated competency with the electronic system, known as paperless filers, are allowed to enter shipping information into the system without providing actual shipping documents to FDA. To ensure accuracy, FDA retrospectively verifies a sample of the importer-provided information and, according to its guidelines, may withdraw paperless filing privileges from filers with error rates of 10 percent or higher. However, FDA records show that no corrective actions to withdraw paperless filing privileges have been taken for even the most error-prone paperless filers. According to a January 1998 FDA survey, over 300 paperless filers, nearly 15 percent of those audited, had error rates of 10 percent or greater, but paperless privileges were not withdrawn from any of these filers. As a result, importers aware of FDA's inaction could evade FDA's inspections by incorrectly describing the contents of a shipment. Such intentional circumvention was demonstrated in 1993, when an importer was found guilty on 138 counts, mostly related to misrepresenting the source of seafood in an attempt to avoid FDA's automatic detention.

Weaknesses in Import Controls Allow the Entry of Unsafe Products

In addition to the problems associated with FDA's system for selecting food shipments for inspection, several weaknesses in its controls over imported products enable some importers or their representatives to sell unsafe foods in the United States. Because of these weaknesses, some importers are able to (1) falsify laboratory test results on suspect foods to obtain FDA's approval to release them into commerce, (2) sell potentially unsafe imported foods before FDA can inspect them, and (3) sell imported foods even when FDA has found a violation and prohibited entry. In addition to the absence of controls, violations are seldom punished effectively. In this environment, FDA has little assurance that contaminated products are kept off U.S. grocery shelves.

With respect to falsifying laboratory test results, FDA's system for automatically detaining suspicious products pending testing to confirm their safety may be easily subverted, because FDA does not maintain control over the testing process—importers are allowed to choose the laboratory that selects and tests the samples. In fiscal year 1997, FDA detained nearly 8,000 import shipments automatically because it had identified violations in previous shipments of related products. Most of these shipments, according to FDA, were released after importers presented their private laboratory test results showing that the shipments met U.S. standards. However, Customs and FDA officials are concerned over the reliability of private laboratories chosen by importers and hence the reliability of their test results. According to Customs inspectors, some importers, to ensure their products appear to meet U.S. requirements, share shipments that have already been tested and proven to be in compliance—a practice referred to as "banking." FDA says it lacks the explicit authority to place restrictions on which laboratories importers can use to test products. Thus, FDA cannot control the selection of the samples tested nor insist on objective testing.

FDA does not maintain control over products before releasing them into U.S. commerce, enabling importers to sell products before inspection or even after FDA has found a violation. Importers of FDA-regulated foods generally retain possession of import shipments until FDA releases them and must make the shipments available for FDA's inspection if requested. At the ports we visited, imported shipments under FDA's jurisdiction often entered U.S. commerce before being delivered to FDA for inspection or were not properly disposed of when refused entry. In Operation Bad Apple, which took place in San Francisco in 1997, Customs officials identified 23 weaknesses in controls over FDA-regulated foods. Importers' practices to circumvent FDA's controls included (1) ignoring FDA's requests that shipments in violation be redelivered to Customs for disposition and (2) substituting cargo so that FDA inspectors would not see contaminated foods. In this investigation, Customs found that about 40 percent of the imported foods determined to violate U.S. standards were never redelivered to Customs for destruction or export, as required, and presumably entered domestic commerce. Moreover, when shipments were redelivered to Customs for destruction or export, Customs officials said other products had been substituted in about 50 percent of the shipments before redelivery. The results of this investigation are consistent with the findings in our 1992 report on pesticides,[4] which found that 60 percent of

[4]Pesticides: Adulterated Imported Foods Are Reaching U.S. Grocery Shelves (GAO/RCED-92-205, Sept. 24, 1992).

the perishable foods and 38 percent of the nonperishable foods that FDA found to be adulterated with illegal pesticides were released into U.S. markets, or not returned to Customs for destruction or reexport as required. Customs and FDA officials recognize that this problem is occurring at other ports.

In addition, there are few consequences for importers found to violate safety standards. Lacking the authority to fine importers who distribute adulterated food shipments or who fail to retain shipments for inspection, FDA relies on a bond agreement between Customs and the importer for most shipments as a way to achieve compliance. The bond amount is based on the importer's declared value of the imported shipment, and damages (i.e., penalties) may be assessed against violators at up to 3 times the value of the bond. But such penalties are ineffective because Customs often does not collect full damages from importers that fail to comply with FDA's requirements. For example, in fiscal year 1997, Customs in Miami assessed and collected damages for about only 25 percent of the identified cases involving the improper distribution of food products. Customs and FDA attributed the low figure to (1) laxity in communicating information about refused shipments between the agencies, (2) unclear guidance for Customs officials' handling of the shipments, (3) a malfunction in the Customs computer system for storing case files, and (4) a halt in collections pending the resolution of a court case involving the collection of damages. Even when the damages were assessed, Customs only collected about 2 percent of the original assessment. In one case, Customs collected damages of $100 from one importer for not returning a shipment with a declared value of $100,000. According to Customs officials, any reduction in damages must be in accordance with Customs guidelines, and both Customs and FDA must agree to reduce the damages.

In conclusion, Madam Chairman, we believe that it is vitally important that the nation's efforts to ensure the safety of imported foods be improved. As the portion of the U.S. food supply from imported sources continues to grow, it is clear that the safety of the U.S. food supply cannot be ensured unless food imports are safe. However, our system for keeping unsafe imported foods from entering the food supply has a number of weaknesses. These weaknesses can and should be addressed. We have made a number of recommendations to this end in our recent report, and we hope to develop additional recommendations as part of our ongoing work for you.

That concludes our prepared statement. We would be happy to respond to any questions you or members of the subcommittee may have.

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