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FOOD SAFETY

Weak and Inconsistently Applied Controls Allow Unsafe Imported Food to Enter U.S. Commerce

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GAO/T-RCED-98-271

Madam Chairman and Members of the Subcommittee:

We are pleased to be here today to testify on federal agencies' efforts to prevent unsafe imported foods from entering the U.S. market. With the number of imported food shipments increasing—more than doubling over the past 6 years—ensuring the safety of these imported foods becomes more challenging. As we reported to you in May,[1] we found weaknesses in federal agencies' controls over shipments of imported foods that allow unsafe foods to enter domestic commerce. The agencies responsible for monitoring imported food shipments are the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS), which is responsible for meat, poultry, and some egg products; the Food and Drug Administration (FDA), which is responsible for all other food products; and the U.S. Customs Service (Customs), which refers imported food to FSIS and FDA for their review before releasing the shipment into U.S. commerce.

When a shipment arrives at a port of entry, Customs notifies FSIS or FDA, which determine whether the shipment should be held for inspection or be allowed to enter the U.S. market. FDA-regulated shipments are held by importers at their own warehouses. All FSIS-regulated shipments are held at an FSIS-approved import inspection station. While specific procedures vary by port, if a shipment is refused entry because it does not meet U.S. standards for food safety, FSIS or FDA, in conjunction with Customs, require that the importer properly dispose of the shipment by reexporting or destroying it. Customs is then responsible for ensuring the destruction or reexport of the refused shipment. Customs may penalize importers for (1) not presenting a shipment for inspection when ordered to do so by FDA or FSIS, (2) not redelivering an FDA- or FSIS-refused shipment to Customs for proper disposal in a timely fashion, or (3) not delivering it at all.[2]

In response to our earlier work, you asked us to obtain additional information on the extent to which federal controls ensure that food importers present shipments for inspection when required and that shipments refused entry are destroyed or reexported. You also asked us to identify ways to strengthen these controls. To assess the extent and effectiveness of federal controls over imported foods, we reviewed FDA and FSIS import activities and files on selected imported shipments at

[1]Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable (GAO/RCED-98-103, Apr. 30, 1998) and Food Safety: Federal Efforts to Ensure Imported Food Safety Are Inconsistent and Unreliable (GAO/T-RCED-98-191, May 14, 1998).

[2]In this testimony, the term penalty refers to Customs' actions to collect "liquidated damages" under a bond posted by an importer to ensure it properly presents shipments for inspection or disposes of shipments that have been refused entry.

various ports to determine the ultimate disposition of the shipments.[3] At each FDA port reviewed, we examined the records of FDA import shipments chosen randomly from a list of refused entries and selected entries that were not made available for FDA inspection during the 6-month period from September 1997 through February 1998. At each FSIS port reviewed, we examined selected records on refused entries in calendar year 1997. In addition, we interviewed Customs, FDA, and/or FSIS officials at various ports. We also spoke with representatives of customs brokers and importer associations to discuss opportunities to strengthen controls. In order to ensure the accuracy of the information in this testimony, we met with officials of FDA, FSIS, and Customs, who generally agreed with the facts presented. We performed our work in accordance with generally accepted government auditing standards from May to September 1998.

In summary, FDA's current controls provide little assurance that shipments targeted for inspection are actually inspected or that shipments found to violate U.S. safety standards are destroyed or reexported. Because importers, rather than FDA, retain custody over shipments throughout the import process, some importers have been able to provide substitutes for products targeted for inspection or products that have been refused entry and must be reexported or destroyed, according to Customs and FDA officials. Moreover, Customs and FDA do not effectively coordinate their efforts to ensure that importers are notified that their refused shipments must be reexported or destroyed. Finally, Customs' penalties for violating inspection and disposal requirements may provide little incentive for compliance because they are too low in comparison with the value of the imported products or they are not imposed at all. As a result of these weaknesses, shipments that failed to meet U.S. safety standards were distributed in domestic commerce. Because FSIS requires unique identification marks on, and maintains custody of, each shipment of imported foods under its jurisdiction, we did not find similar weaknesses in FSIS' controls over the shipments we reviewed, although we did identify some coordination problems between FSIS and Customs.

Federal controls would be strengthened by consistently implementing current procedures and by adopting new procedures. Customs and FDA officials and representatives of importer and broker associations identified a number of ways to improve agencies' controls over incoming shipments, strengthen interagency coordination, and provide stronger deterrents

[3]We reviewed the records of selected FDA shipments at Los Angeles and San Francisco, California; Seattle and Blaine, Washington; Laredo and Pharr, Texas; Miami, Florida; and New York, New York. We reviewed the records of selected FSIS shipments at Los Angeles and San Francisco, California; Seattle, Washington; Houston, Texas; Miami, Florida; and Newark, New Jersey.

against repeat violators. Each of these approaches has advantages and disadvantages that should be considered before making any changes.

Background

FDA and FSIS must approve the release of the products they regulate before importers can distribute them in the domestic market. These agencies inspect products to ensure that they comply with U.S. food safety requirements. FDA electronically screened all 2.7 million entries of imported foods under its jurisdiction in fiscal year 1997 and physically inspected about 1.7 percent, or 46,000, of them. FSIS visually inspected all 118,000 entries of imported meat and poultry under its jurisdiction in calendar year 1997 and conducted physical examinations on about 20 percent of them.

Importers must post bonds with Customs to allow them to move the shipment from the port. The bond amount is intended to cover any duties, taxes, and penalties. Importers generally obtain continuous bonds that provide coverage for multiple shipments over a specified time period. The amount of a continuous bond is based primarily on a percentage of duties paid in the previous year. Importers can also purchase bonds for single shipments (single-entry bonds) in an amount 3 times the declared value of the shipment.[4] Once Customs reviews entry documents and verifies the bond, it conditionally releases the shipment to the importer.

After the conditional release, FSIS and FDA exercise different controls over the shipment, according to their statutory and regulatory authorities. FSIS generally requires the importers of the products it regulates to deliver them to approved import inspection facilities for storage until the products are released or refused entry. If FSIS refuses entry, it notifies the importer, who must arrange for reexport, destruction, or conversion to animal food within 45 days. The shipment is not released from FSIS' custody until the importer presents documents to FSIS showing that arrangements have been made.

In contrast, under the Federal Food, Drug, and Cosmetics Act, as amended (FFDCA), importers are allowed to retain custody of food imports subject to FDA regulation in their own warehouses throughout the entire import process, from pick-up at the port of entry to release, destruction, or reexport. FDA releases most shipments without inspection. If FDA decides to examine a shipment, it asks the importer to make the shipment available for inspection at a place of the importer's choosing. If FDA refuses

[4]The declared valued is based on the cost of the goods to the importer.

to allow the shipment to enter the United States as a result of this inspection, it notifies Customs and the importer and gives the importer 90 days to reexport or destroy the refused shipment. FDA's decision to refuse entry may occur immediately after inspection or may occur several days or weeks after a sample is collected, when laboratory results become available.

If a shipment is not presented for inspection as requested by FDA or FSIS or is refused entry by FDA or FSIS, Customs is to notify the importer through a redelivery notice to (1) make the shipment available for FDA or FSIS inspection or (2) redeliver the refused shipment for Customs' supervised reexport or destruction. Customs can penalize an importer that fails to (1) make a shipment available for inspection, (2) destroy or reexport a refused shipment within the time frame set out in the Customs redelivery notice, or (3) dispose of the shipment under Customs' supervision. Customs initially assesses penalties at the maximum amount allowed—3 times the value of the shipment declared on the Customs entry form, up to the amount of available bond coverage. According to Customs' guidelines, Customs must follow FDA's penalty recommendation when an importer fails to redeliver a refused shipment for export or destruction. Customs may reduce the penalty when the shipment is returned (1) late but disposed of under Customs' supervision or (2) on time but not disposed of under Customs' supervision. According to Customs officials, they cannot impose penalties if Customs does not issue a redelivery notice to the importer within 120 days of the FDA refusal date.

Importers Can Circumvent FDA and Customs Inspection and Disposal Requirements

Weak and inconsistently applied controls have allowed some FDA-regulated imported foods that violate U.S. food safety requirements to enter domestic commerce. This occurs when either (1) importers circumvent required inspections or fail to properly dispose of shipments refused entry or (2) federal agencies do not work together to ensure that these shipments are disposed of properly. Although importers are subject to penalties for circumventing inspection and disposal orders, we found such penalties may not effectively deter violations because the penalties are too low and at times are not imposed at all and therefore fail to serve as a deterrent.

Importers' Custody Over Products Allows Unsafe Products to Enter Domestic Commerce

Unscrupulous importers bypass FDA inspections of imported food shipments or circumvent requirements for reexporting or destroying food shipments that were refused entry, according to Customs and FDA officials at the ports we visited. This occurs, in large part, because, under FFDCA, importers are allowed to maintain custody of their shipments throughout the import process. Additionally, (1) FDA does not require shipments to have unique identifying marks that would aid in ensuring that other products are not substituted for those targeted for inspection or disposal and (2) importers, under FFDCA, are allowed a long period of time to redeliver refused shipments to Customs for disposal, which facilitates substitution by unscrupulous importers.

Recognizing this problem, Customs has conducted and is still conducting operations at a number of ports to detect importers that attempt to circumvent inspection and disposal requirements. For example, in a San Francisco operation that started in October 1996 and was known as "Shark Fin," Customs and FDA found that importers had diverted trucks en route to inspection stations so that suspect products could be substituted with acceptable products. According to Customs investigators, the operation revealed that six importers were sharing the same acceptable product when they had to present a shipment for inspection—a practice known as "banking." In a follow-up operation in San Francisco, known as "Operation Bad Apple" and started in July 1997, Customs and FDA found a number of substitution and other problems, such as invoices that falsely identified the product. Customs' concerns were further validated when this second operation found that 40 of the 131 importers investigated had import shipments with discrepancies, such as product substitution and false product identification. According to a Customs official, 10 of the importers were previously identified as suspicious, while the other 30 importers had been considered reliable until the investigation.

Identifying the substitution of products prior to inspection is difficult and labor-intensive, according to FDA and Customs port officials. Because FDA-regulated imports do not have unique identification marks that associate a shipment with the import entry documents filed with Customs, extra efforts are required to identify substitution, such as marking or documenting the products at the port before they are released to the importer, then checking the products when they are presented for inspection. FDA and Customs officials believed that placing additional staff at the ports for such efforts, as in the San Francisco operations, could not be sustained as a normal practice, given the resources required and other priorities.

Substitution problems have also occurred after inspections, when importers are ordered to redeliver refused shipments to the port for destruction or reexport. Three of the eight ports we reviewed routinely examined FDA-regulated shipments delivered for reexport or destruction to detect substitution, according to Customs and FDA officials. At two of these ports—New York and Blaine—Customs found that substitution had occurred on outbound shipments. For example, in New York, Customs instituted a procedure in 1997 to physically examine selected food shipments that were refused entry and were scheduled for reexport. Officials began this procedure after periodic examinations found that some importers had substituted garbage for the refused shipments that were being reexported. For the 9-month period of October 1, 1997, through June 30, 1998, Customs found discrepancies in 31 of the 105 FDA-refused shipments it examined. Nine of the discrepancies were for product substitution and 22 were for shortages—only part or none of the refused shipment was in the redelivered containers. For example, in one instance, the importer presented hoisin sauce for reexport that had a later production date than the date of the entry into the United States on the original refused shipment. Customs officials believed that the importer distributed the original refused shipment into domestic commerce and substituted the hoisin sauce to avoid detection and penalty.

At the other five ports, Customs does not systematically examine the shipments delivered for disposal to detect substitution or only examines them for destruction. For example, at Laredo, Customs officials said they only review the documents provided by the importer and do not examine the shipment to verify that the products being reexported or destroyed are the same products that were refused entry. At Miami, Seattle, and Los Angeles, Customs or FDA officials may examine some products presented for destruction, but, as at the Laredo port, only review the documents provided by the importer to verify the export of refused shipments. At San Francisco, a Customs official told us that he reviews the paperwork on the refused shipment and the paperwork on the shipment presented for destruction or reexport. None of the five ports routinely physically examined the export shipments to ensure they contained the products that were refused entry and listed on the export documents. Customs officials told us they do not have enough time for inspectors to verify each shipment presented for destruction or reexport, given the number of refused shipments and other priorities.

A number of factors contribute to FDA's and Customs' problems in ensuring that targeted shipments are actually inspected and that refused

entries are properly disposed of. First, under FFDCA, importers are allowed to maintain custody of their shipments throughout the import process, thus providing importers with the opportunity to circumvent controls.

Second, imported food shipments under FDA's jurisdiction are not required to contain unique identification marks. As a result, it is difficult to verify whether the FDA-regulated shipments presented for inspection were the actual shipments being imported or whether refused shipments were destroyed or reexported. Furthermore, when FDA determines that a shipment is unsafe, FDA does not mark the shipment to show it was refused entry. In contrast, FSIS requires that imported food shipments under its jurisdiction contain unique identifying marks and are retained under its custody until disposal, and when it refuses entry, it stamps each carton "U.S. Refused Entry." Without such markings, Customs and FDA have less assurance that an importer will not substitute products either before inspection or, in the case of refusal, before redelivery for export or destruction. Furthermore, there is no assurance that an importer will not reimport a refused shipment at a later date.

Third, under FFDCA, importers of FDA-regulated products are given 90 days to redeliver refused shipments for proper disposal, which is twice the amount of time that FSIS regulations give importers of FSIS-refused shipments. According to Customs and FDA officials, allowing an importer up to 90 days to dispose of refused products while retaining custody of the shipment provides more time for the importer to arrange for substitution. That is, unscrupulous importers will distribute into domestic commerce shipments refused entry and substitute for reexport a shipment that arrives at a later date.

Customs and FDA Often Do Not Coordinate Efforts to Prevent Unacceptable Products From Entering the U.S. Market

At five of the eight ports we examined, Customs and FDA do not effectively coordinate their efforts to ensure that importers are ordered to redeliver refused shipments for disposal. At two of these ports—Los Angeles and New York—Customs was unaware of FDA's refusal notices for 61 to 68 percent of the shipments we reviewed. At the other three—Laredo, Pharr, and Seattle—the lack of coordination appears to be less problematic. Nonetheless, as a result of these coordination problems at the five ports, Customs had not issued notices of redelivery to the importers. In contrast, at Miami, San Francisco, and Blaine, Customs and FDA officials coordinate their efforts to issue refusal notices and redelivery notices through joint agency teams or regular reconciliation of records.

(See app. I for information we collected on each port's FDA-refused shipments.)

Refused shipments that are not properly disposed of are likely to have entered domestic commerce. For example, according to a New York Customs official, over three-quarters of the cases we reviewed in which Customs did not have an FDA refusal notice—48 out of 63—were presumably released into commerce because Customs did not issue a notice to the importer to redeliver the shipment. In Los Angeles, we found that Customs had not issued a redelivery notice and had no records of disposal for 21 out of 54 shipments we reviewed.[5] Some of these refused shipments that may have been released into commerce posed serious health risks: 11 of the 48 New York cases and 8 of the 21 Los Angeles cases were refused by FDA because they contained salmonella, a bacteria that can cause serious illness.

It is unclear why Customs was not aware of all the imported food shipments refused entry by FDA. While FDA officials told us they either mailed or hand-delivered notices of refusal to Customs, Customs officials said they did not receive them. Nonetheless, Customs should have been aware of a coordination problem because importers sometimes returned shipments for disposal after receiving a refusal notice from FDA but without having received a Customs redelivery notice. For example, at New York, we found indications that importers returned shipments for destruction or reexport in 15 of the 63 cases in which Customs did not issue a redelivery notice.

At Miami, San Francisco, and Blaine, Customs and FDA officials work together to ensure that required redelivery notices are issued on FDA-refused entries. In Miami, a joint Customs-FDA team sends out a single notice to the importer stating that the shipment has been refused entry and that the importer must return it for proper disposal within 90 days. In San Francisco and Blaine, the agencies reconcile their refusal and redelivery notice records each week. As a result of their efforts, we found that Customs was aware of FDA's refusal notices at these three ports in about 95 percent of the cases we reviewed.

Although we found that Customs was frequently not aware of FSIS-refused shipments, we did not find comparable problems of imported food

[5]When we brought this problem to Customs' attention at Los Angeles and New York and asked what action could be taken on these cases, the officials said they would not issue redelivery notices for any of the shipments with refusals older than 120 days because Customs cannot impose liquidated damage penalties for violations after that time.

products being distributed domestically after they had been refused entry. According to FSIS officials, when FSIS rejects a shipment, it only notifies the importer of the refusal. The importer, in turn, must notify Customs of the refusal and obtain Customs' authorization to destroy or export the shipment, but this information often does not reach Customs' files. In Seattle, for example, of the 15 FSIS cases we reviewed, Customs could not locate files for 7 cases, and only 3 of the remaining 8 case files at Customs contained records of FSIS refusals or Customs notices of redelivery. Despite this apparent lack of coordination, we found records at the FSIS import inspection facility that indicated the refused shipments were disposed of properly. We believe that FSIS' controls over import shipments—requiring unique markings on each carton, retaining custody of shipments until they are approved for release or properly disposed of, and stamping "U.S. Refused Entry" on rejected shipments—reduced opportunities to bypass import controls.

Current Penalties Are Not Effective Deterrents

Customs' penalties for failure to redeliver refused shipments do not effectively deter violations because they are either too low compared with the value of the product or not imposed at all, according to Customs and FDA officials at the ports we reviewed.[6] According to these officials, importers often view these penalties as part of the cost of doing business. Some officials believe importers consider the amount of the penalty from one violation will be covered by the gains made from other shipments that manage to enter commerce.

Although violations for failure to redeliver shipments for which Customs issued a redelivery notice are initially assessed at 3 times the declared value of the shipment, an importer could still profit from the sale of a refused shipment even after buying the product and paying a full penalty for failure to redeliver. For example, we found that the wholesale market price for a 10-pound carton of Guatemalan snow peas ranged from $13 to $15, while the declared value of a 10-pound carton in one refused shipment was $0.75 per carton and the assessed penalty was $2.25 per carton. Thus, in this case, the wholesale value was four to five times the maximum penalty.

[6]Even though these deterrents may not be effective, FDA and Customs have other general authority to prevent the entry into the country or distribution into commerce of adulterated products. This authority includes the seizure of products, prohibitions on distribution, and other actions. See, for example, 21 U.S.C. sections 332, 333, and 334; and 19 U.S.C. section 1595a(b). However, according to FDA and Customs officials, these actions are only taken in egregious cases.

In some cases, Customs did not impose the maximum allowable penalty—3 times the shipment's declared value—because the penalty exceeded the value of the bond that the importer had posted.[7] At least 16 of the 162 penalty cases identified by Customs in Miami and 7 of the 50 cases we reviewed in New York had lower penalties imposed because of insufficient bond coverage. In Miami, for example, the importer of a shipment of swordfish that was refused entry for excessive levels of mercury but not redelivered as required could have been assessed a penalty in excess of $110,000, but the importer was actually assessed a penalty of only $50,000—the value of the bond. Customs and FDA officials said the bond amount may not cover the maximum penalty because most importers obtain continuous bonds, whose value is set as a percentage of duties paid in the prior year and is not tied to the declared value of the entries in the current year. According to Customs officials in Miami and New York, if the importer has a history of violations, Customs may require the importer to post single-entry bonds for additional entries.

At three ports—Los Angeles, San Francisco, and Seattle—Customs did not assess as severe a penalty as agency guidelines suggested because officials at these ports were unable to identify repeat offenders and penalize them accordingly. For example, port officials in Seattle said the computer system that records violation information is difficult to access for identifying repeat offenders, given other priorities. Prior to April 1998, Customs officials for the Laredo and Pharr ports said they could not identify repeat offenders for the same reasons. However, New York, Miami, and Blaine maintained their own records on violations and repeat offenders and usually followed Customs guidelines when assessing penalties on repeat offenders in the cases we reviewed.

Finally, Customs officials said they cannot impose penalties in many cases we reviewed because the agency did not issue a redelivery notice to the importer within 120 days of the FDA refusal date. For example, in Los Angeles, we found that 11 cases had refusal notices over 120 days but did not have redelivery notices. Although some importers reexport or destroy their shipments after receiving only the FDA refusal notice, importers that do not redeliver the refused product will not incur a penalty. From their experience, Customs officials believe that in such cases importers distribute the product.

[7]The maximum penalty that can be imposed is either three times a shipment's declared value or the value of the importer's posted bond, whichever is the lowest amount.

Opportunities Are Available to Improve Controls Over Imported Foods

Customs and FDA officials and importer association representatives suggested ways to strengthen controls over imported foods as they move through Customs' and FDA's import procedures. Some of the more promising suggestions are discussed below. Each of these suggested approaches has advantages and disadvantages, costs, or limitations that would have to be considered before any changes are made.

FDA Could Request Customs to Maintain Control of Certain Shipments Until They Are Released

For certain importers that FDA believes are more likely than others to violate import controls because they have a history of violations,[8] Customs and FDA could work together to ensure that substitution does not occur before either inspection or disposal. For example, FDA could target importers, and Customs could order that these importers' shipments be delivered by bonded truckers to an independent, Customs-approved, bonded warehouse pending inspection. Although FDA can request Customs to require importers to present shipments for inspection at a bonded warehouse, it does not routinely use this authority and make such requests. In Los Angeles, for example, FDA officials said they have had Customs make an importer present a shipment to a bonded warehouse only once in the past 2 years. Given their concerns about importers circumventing federal controls over imported foods, Customs and FDA officials at San Francisco and Miami are considering implementing variations on this option. For example, in Miami, Customs and FDA officials are developing a program to require importers of FDA-refused shipments to deliver them into the custody of a centralized examination station, a type of bonded warehouse, for disposal, rather than allowing the importer to retain custody.

This approach has the advantage of preventing the targeted importers from bypassing inspection controls and of ensuring the proper disposal of the targeted importers' shipments that were refused entry. Furthermore, this approach would serve as a deterrent to importers likely to violate requirements because they would have to pay the additional costs associated with unloading a shipment and storing it at a bonded warehouse.[9] Moreover, this approach would not require any change in Customs' authority. Customs currently uses bonded warehouses for its own inspections and could, at FDA's request, require targeted importers to use bonded warehouses.

[8]FDA is developing through its automated import screening system the capability to identify importers that have a history of food safety-related violations.

[9]Estimates for unloading a 40-foot container range from $350 to $1,000, and storage costs range from $75 to $700 per week, depending on the location.

This approach also has several limitations. First, it does not cover all importers. While ideally it would be preferable to monitor all importers, it may not be practicable because the costs to law-abiding importers would also increase. Second, even if Customs and FDA focused only on problem importers, the agencies would need to develop a coordinated system to identify them. Similarly, this approach would depend on effective coordination after such identification—FDA would need to request Customs to maintain control of a shipment, and Customs would have to act accordingly. As we have noted, effective coordination between FDA and Customs does not always occur.

Targeted Shipments Could Be Marked in Order to Trace Them Throughout the Import Process

Customs and FDA could take steps to better ensure that importers with a history of violations are not substituting products before inspection and are not returning the actual refused cargo for destruction or reexport by adopting variations on controls used by FSIS for meat and poultry imports. To help prevent substitution before inspection, FDA could require the shipments of importers or products with a history of violations to have unique identification marks on each product container and on entry documents filed with Customs. To help ensure that shipments refused entry are destroyed or reexported, FDA could stamp "refused entry" on each carton/container in shipments that it finds do not meet U.S. food safety requirements.[10]

Requiring certain targeted shipments to have unique identification marks would have the advantage of enabling FDA inspectors to better verify that the products presented for inspection were the same products identified on Customs entry documents and help Customs inspectors verify that shipments refused entry were disposed of properly. Similarly, stamping refused entries would increase the likelihood that they were actually destroyed or reexported and reduce the likelihood that reexported products would reenter the country at a later time.

However, these procedures might be difficult to implement. Requiring unique identification marks on imports (1) would require FDA to develop and implement a marking and labeling system for the wide variety of imported food products from many different countries that it regulates and (2) might negatively affect trade. Furthermore, a requirement to stamp refused entries would be labor-intensive for FDA because FDA, unlike FSIS,

[10]FDA does not have explicit statutory authority to require unique identification marks on each product container or on entry documents filed with Customs nor to stamp "refused entry" on each carton/container. We are unaware of any FDA formal determinations that it would have implicit authority for these actions under its statutory authorities.

does not always have custody of the shipments at the time of refusal and would have to travel to the storage location to stamp the cartons.

Customs and FDA Could Work Together to Ensure That Importers Are Issued Redelivery Notices

Customs and FDA could develop a method of ensuring that importers whose shipments are refused entry into the United States are issued notices to redeliver their cargo. Two approaches were suggested to us. First, Customs could retrieve information from its own database on FDA's refusals. Customs records all import shipments in its Automated Commercial System (ACS), and FDA communicates its refusal notice to the importer through ACS. Currently, however, Customs' system is not programmed to identify FDA refusals.

Second, in lieu of the first approach, or until this approach is implemented, Customs and FDA could work out a manual system, such as reconciling FDA refusal and Customs redelivery notices.

Either of these approaches has the obvious advantage of ensuring that Customs is promptly aware of all FDA refusals so that it can issue redelivery notices. The database approach, however, would require some reprogramming of ACS to enable Customs to access FDA's refusals as well as training of Customs officials to ensure that they know how to use the software. The second approach would also address the coordination problem but would require more staff time.

The Congress Could Reduce the 90-Day Period Importers of FDA-Regulated Foods Are Allowed for Redelivery

The Congress could reduce the time allowed for redelivery of FDA-regulated shipments to require importers to dispose of refused shipments more quickly and more in line with the other agencies. By statute, importers of FDA-regulated foods are allowed 90 days to redeliver products after being issued the notice of refusal, in contrast to importers of FSIS-regulated foods, which are allowed a 45-day redelivery period. FDA officials at two ports said the longer time period is intended to give importers enough time to arrange export shipping of refused shipments. In New York, however, Customs officials said some importers use the longer time period to obtain products to substitute for the refused shipments.

The advantage of this approach would be to reduce the opportunity for importers to distribute the products into domestic commerce or to prepare substitute products for disposal. However, importers would have less time to consolidate refused entries with other exports, which may increase

their shipping costs. Reducing the redelivery period would also require changes in FDA's statutory authority.

Penalties Could Be Strengthened to Serve as a More Effective Deterrent for Repeat Violators

Under Customs' current practices, penalties can be lower than the wholesale market value of a shipment and therefore not effectively prevent refused imported foods from entering domestic commerce. To create a more effective deterrent, Customs could take one or more of the following suggested actions.

First, Customs could increase the continuous bond requirement for importers with a history of violations so that the bond would cover potentially higher penalties. Rather than base the calculation for continuous bonds primarily on duties paid in the previous year, Customs could adjust the formula to include the history of violations and damages assessed during the earlier period. Second, Customs could require importers with a history of violations to post separate, single-entry bonds for each import shipment. The single-entry bond amount is 3 times the declared value of the shipment. Finally, Customs could impose higher penalties on repeat violators, as allowed by its own guidelines, by providing the means for Customs staff to identify importers with a history of violations. Currently, Customs cannot always identify repeat offenders.

These approaches have the advantage of creating a more significant monetary disincentive to importers considering circumventing federal controls. The first two approaches would impose higher costs on repeat violators because they involve added expenses in increasing the level of a continuous bond or purchasing individual bonds for each shipment. The final approach would enable Customs to follow its own guidelines when assessing penalties on repeat violators.

The first two approaches, however, would require additional work by Customs staff at each port to review and set bond requirements. The last approach would require Customs to correct deficiencies in its penalty database to allow Customs staff to identify repeat violators.

This concludes my prepared testimony. I would be happy to respond to any questions that you and Members of the Subcommittee may have.

GAO's Analysis of Food Shipments Entering the United States From September 1997 Through February 1998 That Were Refused Entry by the Food and Drug Administration

Port of entry	Total entries refused[a]	Refused entries GAO reviewed	Refused entries for which Customs had no information and did not issue a redelivery notice		
			Total entries	Entries redelivered	Entries not redelivered
Blaine, WA	40	25	1	1	0
Laredo, TX	147	50	2	0	2
Los Angeles, CA	315	88	54	33	21
Miami, FL	228	91	2	1	1
New York, NY	326	93	63	15	48
Pharr, TX	100	36	5	5	0
San Francisco, CA	205	71	6	0	6
Seattle, WA	64	33	6	3	3
Total	**1,425**	**487**	**139**	**58**	**81**

[a]Customs refers to an entire shipment as an "entry," while FDA breaks down the contents of a shipment into "entry lines." As used in this table, "entries" refers to FDA's entry lines.

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