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Press Office
Food and Drug Administration
U.S. Department of Health and Human Services

STATEMENT
May 11, 1998

Print Media: 301-827-6242
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STATEMENT FROM DR. MICHAEL FRIEDMAN, LEAD DEPUTY COMMISSIONER OF THE FDA, ON GAO FOOD SAFETY REPORT

The General Accounting Office's study is a wake up call to Congress to pass legislation to help ensure the safety of imported foods. While FDA believes that imported foods are generally safe, recent outbreaks of food-borne illnesses demonstrate that imported foods can introduce new risks and the increased consumption of imported foods heightens those risks. The President has called for increased resources, better coordination, more scientific research and greater authority for the FDA.

GAO recommends legislation that gives FDA new authority that requires food-exporting countries to have in place essentially the same food safety system as the United States. The Department of Agriculture already has such legal authority over imported meats and poultry. In October 1997, President Clinton proposed legislation to give FDA similar authority and the Administration has expressed its support for the "Safety of Imported Food Act" currently languishing in Congress.

While most of GAO's recommendations mirror solutions FDA already is implementing, the Agency disagrees with GAO's criticism that the agency fails to use its resources appropriately. The agency has faced a steadily rising workload with the number of food imports more than doubling in the last five years, and FDA has warned that it was in danger of being overwhelmed by the volume of products reaching U.S. ports. The Agency is using its available resources and continues to recommend that additional resources are needed to ensure that the food Americans set on their table - both domestic and imported - is safe, wholesome and nutritious.

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FDA Backgrounder on GAO Food Safety Report

The food supply in the United States is among the safest in the world. In recent years, however, there have been a number of serious outbreaks of food-borne illnesses, some of which have been associated with imported foods. Last year, President Clinton launched two separate food safety initiatives designed to lower the risk of food-borne disease from both domestic and imported foods. In his budget submission to Congress for FY 99, the President asked for an additional $100 million for the national food safety program, including $25 million for to enable FDA to expand its international food inspections.

Now, the General Accounting Office has released its evaluation of the safety of imported foods. In its report, "Food Safety: Federal Efforts to Ensure Safety of Imported Foods Are Inconsistent and Unreliable," GAO concludes that some of FDA's import control activities are inadequate. The agency

agrees that more needs to be done to safeguard the quality of imported foods and already has undertaken many of the steps outlined in the GAO report. To make adequate progress, however, FDA will require additional legal authority and resources. The GAO itself has recommended legislation to give FDA additional authority.

The major concerns raised by GAO, and FDA's responses, include:

- Equivalency Authority. GAO proposes that FDA be given authority to require that food-exporting countries have in place a food safety system that is essentially equivalent to the United States' system. GAO notes that the Department of Agriculture's Food Safety and Inspection Service (FSIS) already has that authority and blocks the importation of meat and poultry from any country whose food safety system does not measure up to the U.S. standard. Under current law, FDA cannot prevent food from being shipped to this country. The agency must attempt to identify all unsafe food at the port of entry, an extremely difficult task given the enormous volume of imports. Thus, FDA and the Administration agree with GAO that it is imperative that Congress enact legislation giving FDA authority to require that, as a condition to exporting to the United States, foreign governments adopt adequate measures in their own countries to ensure that food exported to the U.S. is safe.

- Civil Money Penalties. When food importers or brokers bring in shipments, they are required to post a $1,250 bond. If the brokers do not hold the product on the docks while FDA conducts its tests, they may forfeit their bonds. GAO observed that many brokers and importers distribute their products even when ordered to wait and simply include the bond as the cost of doing business. Once the product enters U.S. distribution, U.S. Customs Service has a difficult time getting it back. There are cases where contaminated foods have been distributed. FDA lacks the legal authority to then penalize brokers who violate the law. GAO recommends -- and FDA agrees -- that it should have legal authority to seek sufficiently large civil money penalties (fines) to make it too costly for brokers to flout U.S. law. Legislation will be required to give FDA this authority.

- Private Laboratories. FDA automatically detains imported foods that, on the basis of prior violations, have a high probability of being contaminated. Importers have the option of hiring private laboratories to test their products and certify that they meet U.S. standards. If the lab report clears the product, it may enter distribution. FDA, however, does not control the choice of samples or laboratories, raising questions about the validity of these reports. FDA lacks the authority to restrict brokers to certain laboratories, but the agency is issuing a new guidance to the district offices, emphasizing that results must come from reliable labs and, in some cases, the results should be verified.

- OASIS Computer Update. Last year, in an effort to increase efficiency, OASIS, the Operational and Administrative System for Import Support, became fully operational in every U.S. port of entry where FDA-regulated products come into the country. This computerized system electronically links all FDA inspection offices with the brokers who import foreign products. Based on the information supplied by the broker, OASIS can give automated and immediate clearance for the imports or trigger an inspection by a FDA official. GAO noted that the current computer system requires inspectors to switch between OASIS and other related data bases, such as the FDA Import Alert Retrieval System and the low acid canned food database. Because it takes time to shift from one program to another, the efficiency of the inspector is lessened. FDA has recognized the problem and is already moving to link OASIS to all of the other relevant databases.

- Error Rates. FDA agrees with GAO that action should be taken against importers who continue to

submit erroneous entry data to FDA. Most of the errors result from the complexity and the recent introduction of the OASIS system. FDA is auditing error-prone brokers and has begun implementing both electronic and paper copies of their import documents until they learn to use the electronic system correctly.

- Work Plans. FDA agrees with GAO that the work plans developed each year for the inspectors in regional offices do not always reflect how they actually spend their time, but as with any annual plan, the workplan sets targets and anticipates that unforseen activities or emergencies will supersede planned/routine tasks. Typically, about 80 percent of the tasks on the annual work plan are completed. FDA disagrees, however, with GAO's conclusion that the work plans have failed. Inspectors do not complete all the items on their annual list because they get reassigned as new problems and emergencies arise. It does not mean they are not working 100 percent of the time. FDA is re-evaluating how it constructs the annual work plans.

Overall, there is much in the GAO report with which FDA agrees. The agency shares GAO's concerns about the magnitude of the task it faces in regulating the rapidly rising volume of imported foods. FDA agrees with GAO that it needs additional legislative authority to safeguard the nation's food supply. The American public deserves and expects nothing less.

FDA HOME PAGE

May 11, 1998

PRESS BRIEFING BY MIKE MCCURRY

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release May 11, 1998

PRESS BRIEFING BY
MIKE MCCURRY

The Briefing Room

1:30 P.M. EDT

MR. MCCURRY: Good Monday to you. Let me ask you a question. Have you seen the GAO report on the safety of food items that are imported to the United States? Have you all seen that -- new GAO report that calls on Congress to give the Food and Drug Administration the authority to ensure that food eligible for import to the United States is produced under food safety systems that will provide the same level of protection as the safety systems in the United States. A good study confirming the wisdom of the administration's Safety and Imported Food Act, which is the subject of a letter that the President is drafting for the Speaker and the Majority Leader of the Senate, available to you in a short time, reaffirming that this GAO study is further evidence that we need to take the steps that the President has recommended to protect the food items that are being imported in the United States.

Q That would be by legislation?

MR. MCCURRY: By legislation. That legislation has been introduced -- the President called for it in October of 1997, and we are calling on Congress today to act in light of the GAO report today issued.

Q That the same laws would apply?

MR. MCCURRY: There's a variety of standards that would apply. So, essentially, you would bring into the protected framework that exists for meat and poultry other food items that are imported as well.

Q Who ordered the GAO report?

MR. MCCURRY: That's a good question. Someone in Congress, obviously. And having called that to your attention and having made sure that we get that letter out when it's available, we will move to other subjects.

Q What's the status of the Middle East?

MR. MCCURRY: The Middle East is still, unfortunately, characterized by divisions that exist between the parties.

Q And what are you going to do about it?

MR. MCCURRY: We are doing what the President just indicated a short time ago that he would do. He would see if there was a meeting of the Secretary of State and the Prime Minister of Israel, we might build on some of the exchanges that have occurred in recent days and see if we can't, on the basis of the ideas the United States has put forward, bridge some differences and move on to the accelerated permanent status talks.

Q Well, at this point then are you still hopeful that a summit can take place?

MR. MCCURRY: I don't know that we really know what to expect at this point other than meetings which will try to lead to that outcome. It's desperately important in the view of the President to continue to work to see if we can't bring these parties together so that they can both resolve the issues that are currently pending between them and move on to the even more difficult, more serious substantive divisions that they will have to address if they are to resolve their final status issues.

Q Has she changed some of the ideas? Does she have new ideas to put down in front of the Prime Minister?

MR. MCCURRY: She is proceeding on the basis of the ideas that we have presented. The Prime Minister asked Ambassador Ross if there weren't some clarifications that could be examined. Ambassador Ross reported that to the President today, and based on some of the discussions they had here today, the Secretary will meet further with the Prime Minister later this week presumably. He should be here by mid-week.

Q Mike, when you talked about bringing the parties together, it would seem it's the United States and the PLO on one side and Israel on the other. Would you characterize the current state of affairs as an estrangement between the U.S. government and the government of Israel?

MR. MCCURRY: No, I would -- first of all, I would not accept the premise that we are on one side of the table or the other. We are there at the table with the parties, helping them bridge the differences that exist between them. And then we have been in a position to put forward ideas that have now elicited responses from the parties. And I think our role and our effort in this process is the same as it has been since Madrid. We are anxious to promote the kind of dialogue that the parties have used themselves to reach historic peace agreements and to see if we can't deepen and nurture that peace. And we do so as a long, steadfast ally of Israel and conscious of Israel's security needs, and very respectful of our close ally in the Middle East.

Q&A for GAO Report on Imported Foods
May 11, 1998

Q: What are the GAO's major findings regarding imported foods?

A: The GAO affirmed the Clinton Administration's conclusions that greater attention should be paid to the safety of imported foods. In particular, the report states that "[i]n order to strengthen FDA's ability to ensure the safety of imported foods, GAO recommends that the Congress require food eligible for import to the United States, not just meat and poultry, be produced under equivalent food safety systems." The Administration submitted legislation to Congress earlier this year which addresses this concern. The major conclusion that FDA needs additional authority is fully consistent with the Administration's position about how to strengthen protection against unsafe foods imported into the United States.

Q: The report also notes that some importers illegally distribute imported foods into U.S. commerce and that FDA does not have adequate deterrent power to prevent those imports. Does the Administration agree with GAO's recommendation that Congress give FDA civil money penalty authority for these violations?

A: Yes, FDA agrees with the recommendation that civil monetary penalties would be an effective tool.

Q: What does the Administration's legislation do?

A: This legislation ensures that FDA will refuse imports of any food regulated by the FDA, including fruits and vegetables, from any country or facility that does not meet U.S. food safety requirements or otherwise achieve the level of protection required. The legislation also permits FDA to consider refusal of inspection as a factor in halting imports from a facility or country. In essence, it would do exactly what the GAO says is necessary to ensure the safety of imported food.

Q: Is Congress moving to enact the legislation that the Administration has submitted to give FDA greater authority over food imports?

A: No hearings have been scheduled, and this issue does not appear to be on the Congressional agenda for this year. The President today called on Congress to take action on this legislation.

Background Questions and Answers:

Q: Why did your Administration propose new legislation?

A: There have been dramatic changes in the produce department of the grocery store. Thirty years ago, most produce sections only had around a dozen items year round, increasing to as many as 50 in the summer. Today, the chances are that there are 400 or more items in the produce section and they are there all year round. Last year, 38 percent of the fruit and 12 percent of the vegetables Americans ate were imported.

We have changed as well. Americans are eating more fresh fruits and vegetables than ever before, and our nation's health experts tell us we will live longer, better quality lives as a result. Our environment is also changing. We are finding "new" exotic bugs such as cyclospora and *E. coli O157:H7* on our food that once were not there.

We must ensure that these changes do not increase the risk to American consumers of foodborne illnesses. Although raw produce -- including that imported from foreign countries -- is now safe, experts have suggested ways to make further improvements, and my actions accord with their recommendations.

Q: Are you saying that imported produce is unsafe?

A: There is no data indicating that imported fruits and vegetables are more unsafe than domestic products. But some recent outbreaks of foodborne illness have been traced back to imports, and it is important to ensure that foreign fruits and vegetables meet U.S. food safety requirements or otherwise achieve the level of protection required. The steps we are taking today are adding additional layers of protection. We are making sure that there are no gaps in our food safety system -- that high safety standards apply to imported as well as domestic food, and to fruits and vegetables as well as to meat, poultry, and seafood.

Q: What steps is the Administration taking to improve food safety?

A: Last year we launched a new Presidential food safety initiative, and added more than $40 million to the FY '98 budget. With that money we started putting in place new science-based preventive systems to improve the safety of seafood, meat and poultry and began work on a new early warning system to help detect and respond to outbreaks of foodborne illness. This year, our budget seeks an even more substantial increase in resources, $101 million, to improve food safety. The resources will go to a variety of initiatives, including: giving FDA authority to prevent the import of produce from countries without safety precautions equivalent to our own; hiring FDA inspectors to improve the safety of our nation's fruits and vegetables, both domestic and imported; developing new ways for federal inspectors to detect food-borne illnesses in meat and poultry and determine the source of contamination; improving educational outreach on proper food handling; and further expanding our early warning system and strengthening state surveillance activities for foodborne illnesses.

May 11, 1998

Report Calls for Banning Food From Some Nations

By TIM WEINER

WASHINGTON -- Federal investigators are calling on the United States to stop importing food from nations that do not meet U.S. health and safety standards, saying the Clinton administration and Congress have failed to create a system to prevent food-borne diseases in imports that may sicken and kill people.

The fact that booming global imports have overwhelmed federal efforts to protect the public from food-borne disease is recognized, say investigators from the General Accounting Office. So is the fact that the present system of stopping tainted food at the nation's borders is outdated and ineffective, a new report by the GAO said.

And scientists are seeing outbreaks caused by little-known pathogens, like a parasite called cyclospora, which sickened about 2,500 Americans who ate imported Guatemalan raspberries in the last two years.

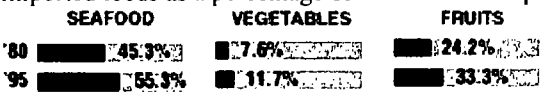
One solution is to demand that foreign nations create food-safety systems that meet U.S. standards, said the GAO, the investigatory arm of Congress. But federal officials have not made this demand, fearing that it would disrupt trade.

Federal scientists recognize that "free trade may present problems that are associated with food poisoning," according to Dr. Marguerite Neill, a member of a federal food-safety advisory board. But what U.S. officials see as a safety issue, foreign nations see as a free-trade issue. And free trade, with the billions of dollars of commerce it brings to exporting and importing nations, may have the power to trump food safety when it comes to laws and regulations, some federal scientists said.

OVERVIEW

More Food, and Some Food Poisons

Imported foods as a percentage of all U.S. consumption.



Selected outbreaks of illness linked to imported food.

YEAR	REPORTED CASES	SOURCE OF TOXIN	FOOD	ORIGIN
'89	**99**	Staphylococcus	*Canned mushrooms*	*China*
'89	**25,000**	Salmonella	*Cantaloupes*	*Mexico*
'90	**1,400**	E. coli	*Raw scallops*	*South America*
'91	**12**	Cholera	*Crab meat*	*Ecuador*
'91	**400**	Salmonella	*Cantaloupes*	*Mexico*
'92	**74**	Histamines	*Fresh tuna*	*Ecuador*
'94	**27**	Salmonella	*Kosher snacks*	*Israel*
'95	**242**	Salmonella	*Alfalfa sprouts*	*Netherlands*
'96	**1,465**	Cyclospora	*Raspberries*	*Guatemala*
'97	**1,012**	Cyclospora	*Raspberries*	*Guatemala*

Source: Centers for Disease Control and Prevention
Credit: The New York Times

Most of the food imported to the United States is wholesome. Consumers, knowing that fresh produce is good for their health, can now buy reasonably priced fruits and vegetables imported from around the world, regardless of the season, and without ill effect.

In 1993, the Food and Drug Administration, citing "enormous inefficiencies in the current food-protection system" and the problems posed by ever-increasing food imports, asked the Clinton administration for the power to bar fruits, vegetables, grains, fish and other food from countries with inferior food-safety systems.

The Department of Agriculture has that power over imported meat and poultry. The power is called equivalency -- requiring a country that exports food to the United States to have a food-safety system equal to the U.S. system. Last year,

the Clinton administration, in the heat of the battle to win "fast-track" free-trade authority, proposed giving the FDA the power to demand equivalency.

But nothing has happened on that front, either by executive order or by legislation.

The GAO, in its new report on the flawed federal food-safety system, to be published this week, recommended that "Congress require all foods eligible for import to the United States, not just meat and poultry, to be produced under equivalent food safety systems."

But senior federal food-safety officials disagreed with that recommendation, arguing that "such mandatory authority would disrupt trade if implemented at one time," the report said. FDA officials now believe that the authority should be discretionary, not mandatory, the report said.

The Centers for Disease Control and Prevention have confirmed thousands of cases of people sickened by pathogens in fruits and vegetables imported from abroad in recent years. These diseases may be caused by polluted water used to irrigate fields, poor sanitary practices at warehouses, or lack of regulation by ineffective governments.

Some food growers say that the risks from imports are insignificant, and that the CDC has exaggerated them.

But roughly 99 percent of food-borne diseases are never traced to their source, the CDC said, so the actual number of illnesses or deaths attributable to imported food-borne disease is unknown. The number is probably far greater than, for example, the number of Americans injured or killed by terrorism abroad.

Overall, the CDC said, domestic and imported food-borne disease kills thousands of Americans and sickens millions, perhaps tens of millions, every year.

The FDA's inspectors test an ever-dwindling fraction of the 30 billion tons of food now imported into the United States. The responsibilities of individual inspectors have increased, but their resources have dwindled.

The FDA inspects less than 2 percent of all foreign food shipments, down from 8 percent in 1992. In 1997, it carried out only half the inspections it had planned to conduct. The system of inspecting foods where they enter the United States is an anachronism, an FDA advisory panel reported seven years ago.

In any case, the inspections cannot detect some food-borne pathogens introduced abroad by unhealthy links in the chain of imported food. And unscrupulous importers can easily circumvent the inspection system, according to the report by the accounting office.

Sen. Susan Collins, R-Maine, requested the report and will hold the first of four Senate hearings on the food-safety system this week. She called the report "a

serious indictment that raises very alarming concerns."

Sen. Collins said that Americans ate more than $33 billion of imported foods in 1996, an increase of almost 50 percent over 1990 imports. While food imports were booming, she said, FDA inspections of those foods were declining, a situation she called "an invitation to trouble." The nation now spends $1 billion trying to protect the safety of the food supply, but may not be spending the money wisely, she said.

"Congress can strengthen the law and it should," Sen. Collins said. "I'm not certain yet what direction we're going, but we need more inspectors, and we need a better system too, a system that will allow consumers to be confident in the safety of the food they eat."

Other Places of Interest on The Web

- General Accounting Office, recent reports on food and agriculture.
- Food and Drug Administration
- U.S. Department of Agriculture
- Centers for Disease Control and Prevention

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May 11, 1998

GAO: Imported Foods May Not Be Safe

A.P. INDEXES: TOP STORIES | NEWS | SPORTS | BUSINESS | TECHNOLOGY | ENTERTAINMENT

Filed at 12:34 p.m. EDT

By The Associated Press

WASHINGTON (AP) -- More than one-third of all fresh fruit and 12 percent of vegetables consumed in America now come from overseas. But a study released today by Congress' investigative agency said the federal government is unable to ensure that imported foods are safe.

The findings by the General Accounting Office could boost President Clinton's efforts to strengthen the Food and Drug Administration's authority to require that other countries adopt safe practices for fruit, vegetables, fish and processed foods.

If Congress passed pending legislation giving FDA that authority -- which the Agriculture Department already has for imported meat and poultry -- it would ``provide greater assurance that the imported foods it is responsible for are safe,'' the report said.

The study did not conclude that imported foods are more dangerous than those produced domestically, but imports grew more than 50 percent since 1990 to reach some $33 billion in 1996.

There have been some high-profile incidents of illness from imported foods, including Guatemalan raspberries, Mexican cantaloupes and alfalfa sprouts from the Netherlands.

Sen. Susan Collins, R-Maine, who requested the GAO report as chairwoman of the Senate Permanent Subcommittee on Investigations, said today the findings are ``a serious indictment'' of FDA inspection systems and promised four in-depth hearings this year to examine the problem.

``We have an obligation to look at the system and fix it,'' she told reporters.

As for increasing FDA's authority to check practices in foreign countries, Collins said, ``I think we should consider it."

FDA spokeswoman Lorrie McHugh said the agency has ``long recognized" it needs greater resources with the sharp increase in imports and ``hopes that this report is a catalyst for congressional action."

The study found that the FDA's reliance on port-of-entry inspections meant that only 46,395, or 1.7 percent, of more than 2.7 million imported food shipments in 1997 were actually checked by an inspector. Of those, only 16,000 underwent a laboratory analysis for disease-causing organisms or other problems.

The Agriculture Department, on the other hand, visually checked every shipment and did inspections on about 20 percent of 118,000 meat and poultry imports. In addition, USDA officials visited 30 countries and checked 336 foreign plants to ensure their safety practices were equal to those in this country.

In a written response to the audit, FDA Associate Commissioner Diane Thompson said the agency is seeking congressional approval for authority to check foreign practices. But to prevent disruptions in foreign trade, Thompson said they should not be a requirement for all imported foods.

``Such a requirement could have the undesirable effect of forcing FDA to bar entry to imports from most of the world" until each countries' practices were certified, she wrote.

The FDA also has proposed safety rules regarding seafood and juice processing that would apply to imports. The agency is pushing voluntary agriculture practices for both foreign and domestic fruit and vegetable growers and processors.

The GAO report found other gaps in the imported food safety system, including:

--USDA's food inspection service focuses too much on violations such as missing shipping labels that ``bear little relationship to food safety" and should instead use health data to zero in on foods likely to pose the greatest hazards.

--Importers, not the FDA, choose which laboratories do sampling when a shipment is held up over food safety questions. In addition, importers often retain control of shipments even if the FDA decides to inspect them and, in some cases, goes ahead and markets them anyway.

--The FDA was able to conduct only about half its planned inspections and about 65 percent of its planned laboratory analyses on imported foods in 1996 and 1997. The agency said these plans are only projections and that inspectors often are called upon to do emergency work that leaves routine tasks undone.

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Comments:

COMMENTS OF THE FOOD AND DRUG ADMINISTRATION ON THE GENERAL ACCOUNTING OFFICE DRAFT REPORT ENTITLED, FOOD SAFETY: Federal Efforts to Ensure Safety of Imported Foods Are Inconsistent And Unreliable GAO/RCED-98-103

Thank you for the opportunity to review the subject draft report. In general, we agree with the report, as the report raises a number of issues that need to be addressed, both by the Food and Drug Administration (FDA or Agency) and by the Congress. It is our hope that the report will provide an added impetus for resolving the issues it identifies. We strongly disagree, however, with the "Results in Brief" characterization of FDA's Workplan.

Specifically, the draft report has misinterpreted the purpose and function of FDA's Workplan. The Workplan is developed annually by Center Directors, the Office of Regional Operations, and the Office of financial Management. The plan reflects the allocation of field resources-based on a given year's established priorities. This tool is a guide for management in utilizing the field resources consistent with the established annual priorities. The Workplan is an implementing instrument for FDA's Program Management System (PMS) which incorporates all the Agency's activities into discrete, mutually exclusive programs, establishes their respective priorities, assigns the numbers of operations (e.g., wharf examinations, sample collections, and analyses) to be done, and allocates resources accordingly. The Workplan does not attempt to plan every operation that is performed by the field, nor does it provide guidance to enable inspectors to make decisions about which entries to examine or the admissibility of entries.

The Compliance Programs, rather than the Workplan, provide guidance to inspectors making decisions about which entries to examine, whether an entry should be sampled and analyzed, and other relevant factors for determining an entry's compliance status. The Compliance Programs are the building blocks for the Workplan. Resources are distributed to the Compliance Programs through the Workplan, with higher-risk food programs given more resources. The risk factors have been incorporated into Operational and Administrative System for Import Support (OASIS), which automatically makes the initial decisions regarding entry admissibility. When there is a question as to which of two or more entries of equal priority to examine, inspectors refer to other guidance documents such as appropriate Compliance Programs, Import Alerts, the frequency at which a product has been examined, the country of origin, any available information about to the product, the importer, the shipper or the country of origin, and other relevant information.

The draft report characterizes the numbers of planned activities reflected in the Workplan as unrealistic, and links this alleged weakness with the difficulty inspectors have in deciding what to inspect and test. While FDA agrees that the planned number of operations most often is not achieved because inspectors may not be available to do routine import work if emergencies arise, the apparent discrepancy between planned and actual operations is not linked with individual decisions by inspectors at the import entry level. The Workplan is only a projection. The overall priorities established by the Workplan, however, remain the same for routine work, and inspectors are expected to make their decisions based on those priorities.

Moreover, there are a number of activities, such as recall and investigations of consumer complaints, for which time is allocated outside of the Workplan. In other words, the hours in these activities are considered separately from those contemplated in the Workplan. While FDA believes that the best approach is to plan for full utilization of its workforce, such planning, of course, includes consideration of the resources that might need to be directed to emergencies and consumer complaints. Emergencies are dealt with immediately, regardless of where or when they occur. Decisions are made after the fact about which category or Compliance Program will be tapped for the resources that were utilized.

AREAS OF AGREEMENT

NEED FOR STATUTORY AUTHORITY

We agree that FDA needs additional authority for controlling the safety of imported foods. Legislation has been introduced in both the House of Representatives and the Senate to expand FDA authority to ensure the safety of imported food. The legislation applies to food safety systems of control. Before an action can be taken against an imported food product, the Secretary must determine that the product does not meet the U.S. food safety requirements or otherwise achieve the level of protection required. The legislation permits the Secretary to consider a refusal to allow necessary inspection, testing, or other relevant factors in determining whether imported food products meet U.S. food safety requirements or otherwise achieve the level of protection required. GAO's support of this legislation is welcomed.

UPDATES TO THE OPERATIONAL AND ADMINISTRATIVE SYSTEM FOR IMPORT SUPPORT (OASIS)

FDA currently is updating OASIS to incorporate automatic review of the Import Alert and Low Acid Canned Food (LACF) databases. The Agency also is incorporating access to the Laboratory Management System database into OASIS. Both will be completed by the end of FY1998. We agree with the General Accounting Office (GAO) that these enhancements will make the system more user friendly and reduce the amount of inspector time required to determine which entries to examine and/or sample.

THIRD PARTY SAMPLING

In general, we agree with GAO that FDA needs to exercise control over the practice of permitting importers of articles subject to Detention Without Physical Examination (DWPE), which are identified on the Import Alert List, to select a laboratory to analyze their products and to certify such products do not violate the Federal Food, Drug, and Cosmetic Act (FFDCA or the Act.) To that end, FDA is issuing new instructions to the Districts regarding the use of independent laboratories. While it has been FDA's policy to accept only analyses done by well-qualified laboratories, and even then to verify the results, this policy is stated more explicitly in the new guidance. Nevertheless, the report should make it clear that FDA does not have explicit authority

to require importers to use certain laboratories, nor to provide a list of accredited laboratories to importers who may inquire. We do provide, however, the laboratory performance guidance used by the Agency upon request. This guidance should help importers select laboratories based on the qualifications of the analysts and how well the laboratories are equipped to do the particular analyses.

TAKE CORRECTIVE ACTION WHEN FILERS HAVE UNACCEPTABLY HIGH ERROR RATES

FDA is in agreement with GAO that corrective action should be taken against filers (importers and brokers) who continue to submit erroneous entry data to FDA. Since implementation of the automated electronic entry processing system, FDA has been working with the filers to help them learn the system in order to submit correct data consistently. We believe this has been an appropriate approach in light of the recent implementation and complexity of the system. To reduce filer problems in determining the correct product code to use for an entry, filers have been furnished a copy of FDA software that enables them to determine the correct product codes. As GAO is aware, FDA conducted two surveys in 1997 to determine how well filers were complying with the new electronic filing requirements. The surveys showed that the error rates were still unacceptably high overall, with some filers consistently exceeding the acceptable error rate of 10%. Consequently, on March 6, 1998 the Director of the Office of Regional Operations directed all District Directors to work with FDA's Division of Import Operations to identify filers who fail to meet the requirements and to determine what action should be taken by the Agency to improve compliance. Such action could include removing the error-prone filers from the paperless entry system by requiring that they submit both paper documentation and electronic data until they demonstrate their ability to meet the requirements for electronic filing. This dual filing approach should provide a strong incentive for improvement, because submitting paper documentation delays entries by several days.

GAO RECOMMENDATION TO CONGRESS

To strengthen FDA's ability to ensure the safety of imported foods, we recommend that the Congress require all food eligible for import to the United States, not just meat and poultry, be produced under equivalent food safety systems.

FDA COMMENT

FDA has the authority, based on the implementing legislation for the World Trade Organization's Agreement on the Application of Sanitary/Phytosanitary Measures, to enter into equivalency agreements with other countries. We do not require such agreements, however, before trade can occur. The wording in the recommendation as written seems to require a finding of equivalence as a precondition of entry. If this is GAO's intent, we do not concur. Such a requirement could have the undesirable effect of forcing FDA to bar entry to imports from most of the world until such time as the Agency could make a determination of equivalency, a process which must be

done on a country-by-country basis, and potentially, a product-by product basis. In contrast, the Administration's proposed import legislation introduced in both House of Congress (S1707/HR3052) would give FDA the authority to deny entry to a food product that has been prepared, packed, or held under conditions, or subject to systems or measures that do not meet U.S. food safety requirements or otherwise achieve the U.S. level of protection. The legislation would not require that FDA have evaluated such systems, conditions, or measures and made an equivalency determination as a condition precedent to entry of imports.

GAO RECOMMENDATION

To provide more accurate and accessible information to FDA and thus minimize inconsistencies in inspectors' subjective decisions, we recommend that the Secretary of Health and Human Services direct the Commissioner, FDA, to

> make annual Workplans more realistic by setting aside time for unplanned activities, such as investigating emergencies and consumer complaints.

FDA COMMENT

We do not concur. For the reasons stated above, FDA continues to believe that the current Workplan approach most clearly reflects priorities while permitting flexibility to handle emergencies as they arise.

GAO RECOMMENDATION

> Modify the Operational and Administrative System for Import Support system so that (1) it automatically reviews the Import Alert and low acid canned food databases and recommends appropriate actions to inspectors and (2) inspectors can consider previous laboratory test results, which are stored in the Laboratory Management System database, in choosing shipments for inspections and tests.

FDA COMMENT

We concur. The automatic review of the Import Alert data already is in place, and the automatic review of the low acid canned food database is under development. FDA also is developing the necessary software to provide inspectors with the capability to review previous laboratory test results through OASIS. Both of these enhancements to the system will be completed and operational by the end of FY1998.

GAO RECOMMENDATION

> Ensure that district offices are taking appropriate corrective action, when warranted, against importers that repeatedly enter incorrect shipping information into [the] Operational and Administrative System for Import Support.

FDA COMMENT

We concur. As stated above, FDA District Directors were reminded recently of the Agency's policy that non-compliant filers should be identified and appropriate corrective action taken, including removal of filers from paperless filing status. We also continue to believe that it is incumbent on the Agency to work with the filers through education and training, which is a form of corrective action, to improve compliance.

3:09 AM (ET) 5/11

GAO: Imported Foods May Not Be Safe

WASHINGTON (AP) -- More than one-third of all fresh fruit and 12 percent of vegetables consumed in America now come from overseas. But a study released today by Congress' investigative agency said the federal government is unable to ensure that imported foods are safe.

The findings by the General Accounting Office could boost President Clinton's efforts to strengthen the Food and Drug Administration's authority to require that other countries adopt safe practices for fruit, vegetables, fish and processed foods.

If Congress passed pending legislation giving FDA that authority -- which the Agriculture Department already has for imported meat and poultry -- it would "provide greater assurance that the imported foods it is responsible for are safe," the report said.

The study did not conclude that imported foods are more dangerous than those produced domestically, but imports grew more than 50 percent since 1990 to reach some $33 billion in 1996.

There have been some high-profile incidents of illness from imported foods, including Guatemalan raspberries, Mexican cantaloupes and alfalfa sprouts from the Netherlands.

"An increase of this magnitude demands more certainty that our food supply is safe," said Sen. Susan Collins, R-Maine, who requested the GAO report as chairwoman of the Senate Permanent Subcommittee on Investigations.

The study found that the FDA's reliance on port-of-entry inspections meant that only 46,395, or 1.7 percent, of more than 2.7 million imported food shipments in 1997 were actually checked by an inspector. Of those, only 16,000 underwent a laboratory analysis for disease-causing organisms or other problems.

The Agriculture Department, on the other hand, visually checked every shipment and did inspections on about 20 percent of 118,000 meat and poultry imports. In addition, USDA officials visited 30 countries and checked 336 foreign plants to ensure their safety practices were equal to those in this country.

In a written response to the audit, FDA Associate Commissioner Diane Thompson said the agency is seeking congressional approval for authority to check foreign practices. But to prevent disruptions in foreign trade, Thompson said they should not be a requirement for all imported foods.

"Such a requirement could have the undesirable effect of forcing FDA to bar entry to imports from most of the world" until each countries' practices were certified, she wrote.

The FDA also has proposed safety rules regarding seafood and juice processing that would apply to imports. The agency is pushing voluntary agriculture practices for both foreign and domestic fruit and vegetable growers and processors.

The GAO report found other gaps in the imported food safety system, including:

--USDA's food inspection service focuses too much on violations such as missing shipping labels that "bear little relationship to food safety" and should instead use health data to zero in on foods likely to pose the greatest hazards.

--Importers, not the FDA, choose which laboratories do sampling when a shipment is held up over food safety questions. In addition, importers often retain control of shipments even if the FDA decides to inspect them and, in some cases, goes ahead and markets them anyway.

--The FDA was able to conduct only about half its planned inspections and about 65 percent of its planned laboratory analyses on imported foods in 1996 and 1997. The agency said these plans are only projections and that inspectors often are called upon to do emergency work that leaves routine tasks undone.

TECHNICAL COMMENTS

1. Page 3, first partial paragraph, lines 4-5: Change to read, "The increased consumption of imported foods in the United States may increase the risk of illness." This is conjecture. FDA has no concrete evidence that imported foods are more or less safe than domestically produced foods. Recently, FDA's concerns have increased, however, based on the limited knowledge available about growing/processing conditions in some foreign countries.

2. Page 3, first partial paragraph, line 5: Change to read, "...or FDA for their review before releasing..." When FDA releases a product, it does not "approve" it.

3. Page 3, last paragraph, first line: Change to read, "Federal agencies cannot ensure that all entries of the increasing amount of imported..."

4. Page 3, last paragraph, line 5: Change to read, "...by allowing imports of meat only from..."

5. Page 3, last paragraph, line 8: Change to read, "...takes on the burden of ensuring the safety of all other imported foods as they arrive..."

6. Page 3, last partial sentence: This is incorrect. It ignores the memoranda of understanding and mutual recognition agreements that FDA has with many foreign governments, which are designed to provide enhanced consumer protection. While these agreements do not extend to all countries or products, their existence should be mentioned at this point in the report, as should the new HACCP regulations that require both domestic producers and seafood importers to take responsibility for the safety of their products.

7. Page 4, second line: Change to read, "...produced under adequately controlled conditions and..."

8. Page 4, first full paragraph, lines 8-12: First, the statement that the workplan doesn't set priorities is incorrect. The overall workplan is based on general priorities set by the Agency as reflected in Compliance Programs, and on the resources available to the Agency to carry out all its inspection, sampling, analyses, and investigative responsibilities. The Agency's priorities are risk-based, with the higher-risk products (such as LACF) given higher priority than low-risk products. The resources are assigned to implementing Compliance Programs on a priority basis, with the higher-priority programs being assigned greater proportionate shares of FDA's limited resources than lower-priority programs.

   Second, in a limited sense, it is true that emergencies and consumer complaints may prevent completion of the Workplan, although there is a separate, additional set-aside for recalls and other specified activities. In a broader context, however, the situations we would define as emergencies are those that fall under FDA's jurisdiction, and are of a

high-priority nature in that human health is at risk if the situation is not remedied promptly. Merely mislabeling a product, for example, would not create an emergency situation unless the mislabeling could lead to injury to human health.

9. Page 4, second paragraph, lines 12-13: The statement that, "FDA does not make health risk data readily available to guide inspectors selections." is incorrect. The Agency's automated import entry review system is based to a great extent on health risk criteria, which are encoded into OASIS. OASIS also contains admissibility information, such as products that are to be DWPE because of prior problems, special compliance programs that require some FDA action, the rate at which a product is to be sampled prior to release, and other information relevant to admissibility. OASIS is designed to determine whether a product may proceed into commerce without examination and to give guidance to inspectors for entry decisions that must be made by inspectors because the issues are not so clear-cut as to be amenable to computer-assisted selection.

FDA has determined that many food products do not pose a health risk and can be admitted into commerce without being subject to examination. At the other end of the spectrum, FDA places firms on DWPE based on as few as one previous violation that involved a potential health risk (i.e., microbial pathogen, pesticide residue, toxic metal, etc.). Inspectors are expected to make decisions affecting product admissibility for the remaining imports, about which there may or may not be any compliance history data that could enlighten the decision. The process does make "heath risk" information readily available to the inspectors for the majority of entries. If more information is needed, the inspectors refer to Import Alerts, compliance programs, LACF registrations, and other relevant databases. Finally, the inspectors are expected to contact the Center For Food Safety and Applied Nutrition staff or the Division of Import Operations and Policy staff if they have questions about the admissibility of a particular entry. As noted in the General Comments above, databases that are not currently directly accessible through OASIS are being integrated into the system to make it more convenient for inspectors to reference them.

10. Page 4, second paragraph, lines 13-15: Change to read, "... FDA, FSIS, and USCS rely on importers descriptions of shipment contents..."

11. Page 4, last paragraph: The report consistently misstates which agency has the responsibility for allowing importers to retain possession of products pending FDA examination, which agency is responsible for setting the amounts of bonds, and which agency determines the amount to be forfeited or penalties to be assessed for failing to redeliver products to Customs when a released product is found to be violative. Change the paragraph to read as follows, and make appropriate corrections throughout the report.

> "FDA 's procedures for ensuring that unsafe imported foods do not reach U.S. consumers are vulnerable to abuse by unscrupulous importers. For example, FDA

detains shipments without sampling or analysis when the exporting firm has a history of violations. The FFDCA provides for the offering of testimony by the owner or consignee once a sample has been delivered to FDA. Although not explicitly stated in the Act, the understood purpose of the testimony is to show why FDA should not find the food shipment subject to refusal of admission. The sampling and examination of a food shipment by the importer is a necessary extension of the right to introduce testimony, which in this case is the analytical results. Importers select the laboratories to perform sampling and analysis that they submit to FDA as proof of compliance. FDA does not have the explicit authority to recommend, certify or otherwise direct an importer to a particular laboratory. FDA is not bound, however, to accept the results from the private laboratories. Private laboratories submitting data in support of an entry must demonstrate to FDA's satisfaction that they have the necessary equipment and expertise to perform the analysis.

After execution of a bond with the U. S. Customs Service, importers retain control of the goods while FDA decides whether to inspect the shipment or while tests are being conducted on it. In some cases, when FDA takes and analyses samples of a shipment, the importers send the food to market before FDA has made a determination about its admissibility, usually because the food is a perishable commodity. When this occurs, and the food product is not in compliance with U.S. food safety requirements, the U.S. Customs Service may assess liquidated damages against the bond. In other cases, when FDA finds contamination..."

It also should be noted that FDA no longer uses the term "automatic detention." As a statutory matter, the U.S. Customs Service has the authority over whether importers must retain control of their goods while FDA determines admissibility. The U.S. Customs Service also sets the amount of any bond and decides whether liquidated damages are assessed for failure to retain control of the imported product, as well as any penalties. Section 801 (b) of the Federal Food, Drug, and Cosmetic Act states that, "Pending decision as to the admission of an article being imported or offered for import, the Secretary of the Treasury may authorize delivery of such article to the owner or consignee upon the execution by him of a good and sufficient bond..."

12. Page 5, last paragraph, last sentence on page --should read, "Such an approach, when used as the sole means of assessing the safety of foods, has been widely discredited..."

13. Page 6, last paragraph, second sentence: Delete "are supposed to guide inspectors' judgement." The Workplan provides general numerical goals and resources to be expended. With the exception of seafood, it is not designed to tell the inspectors which specific products to inspect and/or sample. Such decisions are made by inspectors using the relevant Compliance Programs for guidance, not the Workplan.

14. Page 7, first partial paragraph, lines 4-11: These statements are incorrect. FDA verifies the accuracy of each filer's electronically submitted data until the filer is submitting reliable data routinely. During this initial phase of a filer submitting entry data electronically, the filer is required to submit paper copies of entry documentation as well as the electronic submission. When FDA is confident that the filer is capable of submitting accurate data electronically, the filer is allowed to discontinue submitting paper documentation. Also, during the initial phase, FDA works with filers to help them develop the capability of filing correctly. In addition, FDA regularly follows up by conducting supplemental training for specific filers whose data does not meet FDA's requirements for accuracy, and working with the management of filer firms to correct problems with entry data. This approach often is taken when the districts believe the filers' data errors are not deliberate.

To determine whether filers were deliberately recording the wrong product codes to circumvent FDA coverage, FDA reviewed 100% of imported canned mushrooms and water chestnuts for a three-month period between January 6 and April 4, 1997. Canned mushrooms from China currently are on the DWPE list, which could tempt importers to miscode them as water chestnuts to avoid the DWPE. A total of 1081 entries of canned mushrooms and canned water chestnuts were reviewed. Although there were a few coding errors, there was no pattern to suggest deliberate miscoding. There were no instances of miscoding Chinese mushrooms, nor were there any repeat miscodings by the same importer/broker, indicating that the few miscodings that occurred were not deliberate. When the miscodings were brought to the attention of the filer, they were corrected.

FDA has, in the past, brought criminal charges against firms and individuals who engaged in practices such as submitting erroneous data (i.e., Sigma case), and will do so in the future, if necessary. Where there is no suspicion of deliberate fraud, FDA's Filer Evaluation Procedure states that the corrective action to be taken is to remove the filer who continues to have error rates greater than 10% from the "paperless" entry system. The filer then would be required to submit both paper documentation and electronic entry data until he/she demonstrates an ability to submit accurate data consistently. On March 6, 1998 the Director, Office of Regional Operations, instructed all District Directors to review their import operations to determine which filers exhibit unacceptable error rates, promptly remove such filers from the "paperless" status, or provide additional training and assistance where appropriate.

15. Page 7, last paragraph, line 6: The statement that, "...the agency does not have guidelines to control the selections of samples tested..." is incorrect. Private laboratories are expected to conduct sampling in accordance with FDA written sampling guidance found in the Compliance Programs and Laboratory Procedures Manual (LPM).

It should be noted that the agency does not have the legislative authority to certify private laboratories. The LPM, Chapter 21, provides guidance on the review of analytical data

generated by private laboratories. The guidance is provided to assure the scientific credibility, accuracy, validity and reliability of analytical data submitted by private laboratories. Private laboratory analytical packages are reviewed by FDA for each sample tested by private testing laboratories to assure validity of the tests performed.

16. Page 8, top partial paragraph, full sentence: Change to read, "...importers have been known to substitute shipments that have...." Importers usually do not share shipments or samples between importers but substitute one of their own shipments/samples for another of their own shipments/samples. Also a sentence should be added to state that when FDA finds such activity, the Agency takes regulatory action and, if appropriate, pursues criminal charges.

17. Page 8, first full paragraph, lines 2-3: Change to read, "...until their release into U.S. domestic markets, the U.S. Customs usually allows importers to..." The report also should note that FDA often deals with perishable products such as fresh produce and seafood that deteriorate rapidly. Such products warrant consideration of how best to balance FDA's need for inspectional oversight against the possibility of loss of the shipment because of spoilage.

18. Page 15, last paragraph: This paragraph should state clearly whether the "staff years " and import numbers represent all FDA regulated products or only foods.

19. Page 16, first line: Change to read, "...safety of about 2.7 million food import shipments." It is confusing to include the total number of FDA-regulated import shipments per year when the report is about food imports only.

20. Page 16, first full paragraph, second-to-last sentence: The sentence as written is confusing. Please clarify.

21. Page 18, first bullet, line 3: Change to read, "...and testing activities for 10 food programs, such as...." There are only 10 Compliance Programs dealing with imported food.

22. Page 18, second bullet, lines 4-5: Change to read, "...shipments until the importer provides a showing that the product is not violative." Importers can supply evidence other than a private laboratory result to remove the appearance of a violation, although in the vast majority of cases this is done through private laboratory reports.

23. Page 18, Footnote 5, line 1: Change to read, "...mushrooms, and tuna fish which have a pH value greater that 4.6, water activity values of greater than 0.85 are thermally processed and are stored and distributed non-refrigerated."

24. Page 19, first paragraph, sentence 2: Change to read, "Foreign processors must register with FDA and submit descriptions of their canning processes. These processes must be found acceptable by the Agency before FDA will permit entry of these products."

25. Page 19, second paragraph, last sentence: Change to read, "Shipments, such as some seafood, are less frequently...because they may pose...." Low acid canned foods are never automatically released—there is 100% review of all entries because of the potential risks to consumers.

26. Page 20, second paragraph, line 11: Change to read, "Importers may recondition the shipment if FDA concurs, or they must destroy or re-export the shipment to any country of their choosing." Importers do not need FDA concurrence to destroy or re-export a shipment.

27. Page 21, first full paragraph, 3rd sentence: The sentence should state the total number of FSIS-regulated entries per year. As written, it allows for misleading comparisons between FSIS's and FDA's workloads.

28. Page 21, second full paragraph: Add a sentence stating, "FDA lacks authority to require that shipments be held in a specific warehouse."

29. Page 24, paragraph 2, sentence 2: Change to read, "...by importers, agencies' practices, and USCS's procedures for (1) controlling...." USCS, not FDA, is responsible controlling imports before FDA release, ensuring that refused entries are properly disposed of, and levying penalties.

30. Page 27, second paragraph, sentence 5: Delete. The statement is not true. FDA does not have extra territorial inspectional authority.

31. Page 28, last paragraph, first sentence: Change to read, "...seeking new FDA discretionary authority to require...."

32. Page 29, top partial paragraph: The legislation also has been introduced in the Senate.

33. Page 33, second paragraph: The report does not mention imported seafood HACCP regulations, voluntary equivalence agreements, or MOU's as additional mechanisms that FDA uses to assure the safety of imported products. These should be included. They each contribute significantly to FDA's ability to regulate the safety of imported food.

34. Page 35, second paragraph: Again the workplan, in general, is not designed to identify priorities. The priorities are listed in the import Compliance Programs, with additional guidance from the Centers. Delete "workplans that do not set clear priorities for inspectors in making selection decisions."

35. Page 37, 1st paragraph: The inspectors do not "use the workplan to guide their decisions." The workplan is used to provide general numerical guidance, not to make decisions about which products will be inspected/sampled. Delete "FDA inspectors attempt to use these numbers to guide their decisions on which products to inspect and test."

36. Pages 40-42: The report acknowledges that some improvements already are underway. The draft fails to recognize in a balanced fashion, however, that much relevant health risk information already has been considered in developing the Workplans, e.g., Compliance Programs, the screening criteria and rates used in OASIS, and the Import Alert and Bulletin system. Furthermore, inspectors currently have access to risk information and databases to inform their decisions, although not necessarily in a user friendly format. We agree that making the relevant information more accessible would be beneficial, and are taking steps to do so through enhancements to the OASIS.

37. Page 41, top partial paragraph, last three sentences: The inspectors are trained, knowledgeable professionals who can be relied upon to know what entries to select for sampling. It would be highly unusual and disturbing if FDA inspectors could not remember the many, if not most, of the factors that apply to selecting entries for examination and sample collection. Just as professionals in other fields know their professions, so do FDA inspectors. We suggest that the paragraph be modified to reflect the demonstrated competence of FDA inspectors and that their selecting samples on the basis of their memory of the field is not inappropriate.

38. Page 42, last paragraph, first sentence: - Delete, "...no corrective actions have been taken...." Meetings with filer firms, additional training courses, and letters to firm management are among the corrective actions taken. In addition, FDA has conducted criminal investigations when fraudulent behavior by filers is suspected.

39. Page 46, first paragraph, sentence 3: While this sentence may be true, a more careful observation would note that FDA does not blindly accept the work of private laboratories submitted to demonstrate compliance of a product offered for import. FDA reviews the laboratory worksheets, the qualifications of the analysts, and whether the particular laboratory is equipped to do the required work accurately and with the degree of specificity required. FDA also audits the samples and, when necessary, visits the laboratories. The Agency's LPM, Chapter 21, provides guidance for use when an FDA District office determines that a private laboratory does not produce consistently valid data. The specific analyses submitted in support of a product are not accepted by the Agency for the release of products tested. The Agency will accept only results from private laboratories that demonstrate acceptable performance.

40. Page 47, last paragraph, sentence 2: Change to read, "... importers have the right under 801(a) of the Act to introduce testimony concerning the compliance of products they are

importing. Frequently, this takes the form of private laboratory analysis that shows a food free of the contaminant for which it was detained without physical examination. FDA evaluates the submitted analytical results to determine if they are sufficient to remove the appearance of the violation, and if so, may release the product."

41. Page 48, top partial paragraph, lines 2-3: As we have stated before, FDA does not "generally recognize the results from any private, independent laboratory ...." In fact, the Agency has written criteria, published in the LPM, which outline the Agency's position on acceptance of private laboratory results.

42. Page 50, first full paragraph, line 8: The 90 days referenced have nothing to do with reconditioning. The draft apparently is confusing detention with refusal and what is done under each circumstance. We will be pleased to clarify this point further with the evaluators.

43. Page 50, first full paragraph, item(2): Delete FDA. The agency does not control bond actions on importers.

44. Page 52, first paragraph, line 4: Delete "(of an FDA-selected laboratory tested)." FDA does not select private laboratories for any producers of FDA-regulated products, either foreign or domestic.