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# PESTICIDES

# Status of FDA's Efforts to Improve Import Monitoring and Enforcement

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Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss the status of the Food and Drug Administration's (FDA) efforts to improve its pesticide monitoring program. As you know, consumers rely on FDA to test imported and domestic crops to ensure that they are free of prohibited pesticides. My testimony is based on two reports that GAO prepared for this Subcommittee concerning two key components of this program.

The first report, issued in December 1991[1] discussed FDA's progress in automating its monitoring of imports through a system--known as the Import Support and Information System, or ISIS. We've updated our information on FDA's progress for this testimony. The development and implementation of ISIS is crucial to efficient operations of FDA's pesticide monitoring program because it replaces cumbersome manual processes and it enhances the ability of FDA inspectors to detect and prevent entry of violative products into the United States. The second report, issued in September 1992[2], discussed FDA's progress in preventing imported foods adulterated with illegal pesticide residues from reaching U.S. grocery shelves. An important component of an effective pesticide monitoring program is FDA's ability to prevent these adulterated foods from reaching U.S. markets.

In summary, while we are encouraged that FDA has taken some actions in response to our recommendations to improve the pesticide monitoring program, we believe that more needs to be done to address the unanswered recommendations.

In December 1991, we reported that FDA had repeatedly revised its milestone estimates for ISIS implementation, and we recommended that FDA establish detailed plans and milestones for implementing major components of the ISIS system. Today, we can tell you that unfortunately FDA has once again failed to meet some major system development and implementation milestones, and it does not know when the system will be completed.

In September 1992, we reported that in four FDA districts about a third of the imported foods in which FDA detected prohibited pesticides were not returned by importers to Customs for supervised destruction or export. To deter these illegal distributions, we suggested that the Congress give FDA authority to impose civil administrative penalties, and to order certain repeat offenders to pay for storage of sampled shipments until results are

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[1]Pesticide Monitoring: FDA's Automated Import Information System Is Incomplete (GAO/RCED-92-42, December 31, 1991).

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

received. Congress is considering giving FDA civil administrative penalty authority. FDA has not agreed with nor endorsed either of our suggestions. We also made two recommendations that FDA (1) not release certain related imported food shipments until the sampled shipment is determined to be free of prohibited pesticides, and (2) delegate to its district offices greater responsibility to initiate an automatic detention status--a status that requires importers to prove that subsequent shipments are free of prohibited pesticides. FDA is in the process of adopting the first recommendation, but did not agree to the second.

Mr. Chairman we continue to believe that FDA needs to take further actions to improve the pesticide monitoring program. In implementing ISIS, FDA needs to establish realistic plans and timely milestones for completing the system. In dealing with importers who illegally distribute adulterated foods, FDA needs to support a strategy to deter such violations. In addition, to make more effective use of its limited testing resources, FDA needs to reexamine its policy of requiring headquarters review of automatic detention decisions.

Before I discuss in detail FDA's progress in developing ISIS, and in stopping adulterated imported food shipments from reaching U.S. grocery shelves, let me provide some background information on the operation of the pesticide monitoring program.

BACKGROUND

The Environmental Protection Agency (EPA) sets the amounts of pesticide residues that are permitted on food products to ensure that consumers are not at an unreasonable risk from the effects of pesticides. FDA monitors the acceptability of crops entering the United States to assure that they do not exceed the EPA established pesticide residue tolerances. FDA samples about 1 percent of imported food products for illegal pesticide residues. Increasing consumption of imported produce has heightened concern over the adequacy of FDA's program for monitoring pesticides in imported foods.

In 1988, the Congress enacted the Pesticide Monitoring Improvements Act (PMIA), requiring FDA to develop automated information systems for collecting, summarizing, and evaluating its pesticide-monitoring data. FDA is developing ISIS to increase the efficiency and effectiveness of the agency's program for monitoring imported products, including food. The improvements resulting from ISIS are expected to enhance the agency's ability to detect and prevent entry of violative products, reduce the amount of staff time spent on routine processes, produce more consistent sampling

decisions through uniform application of monitoring criteria, and deter "port shopping".[3]

FDA has designed ISIS as a modular system that allows different parts of the system to be added in stages onto the "baseline", or "core" system. The baseline system is intended to increase the efficiency of FDA's import operations by automating many routine manual functions such as the preparation of notices informing Customs, importers, and brokers of FDA actions. In addition, the baseline ISIS is intended to increase the quantity and quality of information used by FDA personnel, permit national sharing of this information, and produce various summary reports, among other functions.

FDA intends to add several other features, or "completion modules", to the baseline system. The most significant of these modules are the electronic interface between ISIS and the U.S. Custom Service's Automated Commercial System (ACS) and automated screening and profiling modules.[4] These modules will improve the overall efficiency and effectiveness of ISIS by supplying comprehensive import information, reducing paperwork, and providing additional decision-making support to FDA field personnel, according to FDA.

Another important part of FDA's pesticide monitoring program is adequate deterrents against improper distributions. If FDA finds pesticide adulteration in a test sample, importers are expected to return the shipment from which the sample was taken to Customs, where the shipment will be either destroyed or exported under Customs supervision. To ensure that importers carry out their responsibilities, Customs requires the posting of a bond based on the import value of the goods. If an importer fails to return the adulterated food, Customs may claim damages for the importer's failure to honor the agreement.

When an FDA district office detects pesticide-adulterated food, in most cases it notifies FDA headquarters. Headquarters reviews the case and decides if all future shipments of the same food from the same grower should be put on a status called automatic detention. Under automatic detention, the importer must obtain an independent laboratory analysis for all subsequent shipments showing that the food is free of prohibited pesticides before the shipment can be admitted into the country.

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[3]The process whereby importers search for the U.S. port of entry that will provide them with the best opportunity for receiving FDA approval to release their products into commerce.

[4]ACS is a system used by Customs to electronically collect required import information from brokers upon product entry into the United States.

With this perspective, let me now turn to the issues discussed in our two prior reports.

ISIS DEVELOPMENT DELAYS CONTINUE

Mr. Chairman, since we issued our report in December 1991 on the status of ISIS, delays in its development and implementation have continued. At the time of our report, FDA had expected to have the core or baseline ISIS fully operational nationwide by June 1992. However, at this time, the baseline system is not operational in any FDA region. Currently, FDA expects to implement the baseline ISIS in its Seattle District Office in September 1993. Upon successful implementation in Seattle, FDA plans to expand ISIS to its San Francisco and then Los Angeles District Offices. By December 1994, FDA intends to have ISIS operational in its entire Pacific Region. FDA has informed us that these time frames are tight and represent optimistic estimates.

Beyond the Pacific Region, FDA has no specific plans or projections for implementing the baseline ISIS nationally or in any other region. FDA said that implementation in other regions depends on the outcome of the Pacific Region implementation. Although FDA said it is taking a cautious, step-by-step approach in implementing the baseline ISIS, we believe that the agency's failure to develop a specific, comprehensive plan for implementing ISIS nationwide increases the risk of problems and delays in the system's national implementation.

In addition to the delays that have occurred with the baseline system, FDA has substantially revised its plans for developing and implementing ISIS automated screening and profiling modules that will provide FDA field personnel with additional data and guidance to improve their ability to identify violative products. In December 1991, we reported that FDA planned to begin development of these modules in 1992 and planned to implement them in 1993. In our report, we noted that FDA had not established any detailed plans specifying the steps required for developing and implementing these modules. We recommended that FDA develop these plans in order to ensure their timely and successful integration into ISIS.

Unfortunately, FDA has not yet developed such plans and has not made any progress in developing these modules. FDA currently has no specific plans to develop and implement the automated screening and profiling modules. Agency officials said that they will not begin working on these modules until the baseline system is fully implemented. In our 1991 report, we concluded that although the baseline ISIS will improve FDA's import program, this improvement will be limited until FDA adds its planned completion modules to the baseline system.

## PROGRESS MADE IN IMPLEMENTING THE ISIS-ACS INTERFACE

Despite significant setbacks in implementing the baseline system and developing the automated screening and profiling modules, FDA has made significant progress in developing the ISIS-ACS electronic interface with Customs. In April 1993, FDA and Customs completed a pilot test of the interface in FDA's Seattle District Office. According to FDA and Customs officials, the pilot was very successful. The officials indicated that the interface improved efficiency, reduced paperwork handling by the two agencies, and speeded the flow of imported products through the Seattle port. A major accomplishment of the pilot was enhanced efficiency in the processing and release of import entries. For example, about 65% of the entries that were processed through the interface were released by FDA within 15 minutes of their data transmission. Both agencies also received generally positive assessments of the interface from brokers who participated in the pilot.

Although FDA originally intended to implement the baseline ISIS without the ISIS-ACS interface, the agency has since given higher priority to implementing the interface as a result of pilot testing of the baseline ISIS. These tests revealed that ISIS would need to interface with ACS in order to reduce the enormous data entry burden that would be imposed on ISIS users without the interface. As a result, FDA no longer considers the Customs' interface to be a separate module that will be added to the baseline system at a later date. Instead, FDA now considers the interface to be an integral component of the baseline ISIS.

## ADULTERATED IMPORTED FOODS

Our September 1992 report addressed another very important piece that is needed for an effective pesticide monitoring program. Mr. Chairman, all of the potential operational improvements brought on by ISIS are meaningless if importers disregard FDA instructions to destroy or export adulterated foods and sell it to the public anyway. Yet, this is exactly what some importers are doing.

### Deterrents Against Improper Distributions Are Not Effective

While most importers comply with FDA's instructions and properly return adulterated shipments to Customs where they are destroyed or exported, a few repeatedly fail to do so. Some importers choose to pay the relatively low damages assessed by Customs rather than destroying or exporting the food. In GAO's sample of 989 pesticide-adulterated shipments, over 64 percent of the 336 shipments that were illegally distributed came from 10 importers.

Although FDA could criminally prosecute such offenders, these cases have low priority for Department of Justice prosecution. In

addition, Customs damages are based on bond amounts that are set for purposes other than enforcement of pesticide regulations. Our report suggested that the Congress could provide a more effective means of stopping the distribution of pesticide-adulterated food if it gave FDA authority to penalize importers in amounts sufficient to deter such distributions, to remove an importer's economic incentive for distributing adulterated foods, and to be commensurate with the potential danger posed to public health.

FDA did not specifically comment on the need to penalize importers in amounts sufficient to deter distributing adulterated food or to remove an importer's economic incentive for such distributions. On the other hand, the agency told us that it has concerns with assessing penalties commensurate with the potential danger posed to public health. It said that the rate of violative products offered for entry into the United States is very small, and the levels of violative pesticides are also very low. It also said that in most cases, determining a level of actual or potential risk to the public health as a basis for calculating penalties would be scientifically questionable. FDA further said that determining this level of risk would be extremely costly and time-consuming for little or no advantage to the public health, as the health risk is almost uniformly very small.

Mr. Chairman, the problem with importers disregarding FDA instructions to destroy or export adulterated foods is a serious and long-term problem that undermines FDA's pesticide monitoring program. Some pesticides have been shown in EPA testing to cause serious health problems including cancer and birth defects. While EPA sets the amounts of residues that are permitted on crops to assure that consumers are not at an unreasonable risk from these pesticides, FDA's job is to enforce these standards. We continue to believe that it is important that when FDA's testing finds illegal pesticide residues on imported foods that FDA have sufficient deterrents to prevent these foods from reaching U.S. markets. Deterrents are important to stop the relatively few importers who are responsible for the majority of these violations. In addition, illegal distributions of adulterated foods are a long-term problem in this program as evidenced by the fact that our September 1992 report was our third on this subject[5].

Our suggestion for civil administrative penalties is based on eliminating an importer's economic incentive to sell adulterated foods and pay a minimal fine rather than destroying or exporting those foods. For that reason, the appropriate baseline penalty is the removal of this economic incentive. We continue to believe,

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[5]The two prior reports were: Better Regulation of Pesticide Exports and Pesticide Residues in Imported Food Is Essential (CED-79-43, June 22, 1979) and Pesticides: Better Sampling and Enforcement Needed on Imported Food (GAO-RCED-86-219, Sept. 26, 1986).

however, that additional considerations are appropriate to serve as deterrents for repeat offenses and for judging the seriousness of the pesticide contamination in relation to endangering the public health. While we would not envision FDA determining health risks for individual crop or pesticide-specific offenses, we believe that the gravity of the risk to the public from illegal pesticide residues is an important element in determining appropriate penalties. As you know, the Congress is considering giving FDA civil administrative authority.

Our report also discussed an additional means of controlling improper distributions, by taking physical possession of the food shipments, until they have been tested, from the relatively few importers who repeatedly disregard FDA's requirements and distribute pesticide-adulterated foods. We noted that USDA, which controls the distribution of imported meat, stores each sampled meat shipment at a repeat offender's expense until test results are known. We suggested that FDA could use Customs' public bonded warehouses, requiring importers to pay storage costs, for this purpose. FDA said that it plans on studying this proposal.

FDA COULD DETECT MORE VIOLATIONS WITH THE SAME RESOURCES

Our report additionally stated that FDA could make two improvements in its monitoring program to detect more adulterated shipments with the existing level of resources:

(1) The first improvement was that when sampling a food shipment, FDA could prevent companion shipments--that is, shipments of the same crop from the same grower arriving at about the same time--from reaching consumers until FDA determines whether the sampled shipment is adulterated. We pointed out that if the sampled shipment is found to be adulterated, these companion shipments may also be similarly adulterated, but FDA has no way of recovering them. FDA agreed with this recommendation and is currently preparing procedural guidance to implement it.

(2) The second improvement was that FDA could grant its district offices more authority to impose automatic detention status on foods from a grower who has previously violated pesticide restrictions when doing so is within the districts' technical capability. Under automatic detention status, the importer must prove that subsequent shipments are free of prohibited pesticide residues before they are admitted into the United States. Currently, district offices must await headquarters' approval to impose this status. Meanwhile, FDA procedures require them to continue sampling all of the shipments from that source, tying up resources that could be used for sampling other imported food.

FDA did not concur with our second recommendation. It said that it would not be appropriate to grant districts this authority because the technical capabilities of the district offices vary.

It believes that headquarters' review provides consistency across the Nation from both analytical and policy perspectives. We continue to believe that FDA could use its resources more effectively if it allowed its district offices greater discretion in placing growers and their imported foods on automatic detention status. One way to improve uneven district office capabilities would be to transfer existing headquarters resources to those districts lacking technical capability. Another would be to increase training for district office personnel. Giving districts greater authority to initiate automatic detention would result in an earlier transfer of testing responsibility to the importers. This in turn would reduce FDA's work load by decreasing the number of companion shipments FDA's districts are now testing while awaiting approval of automatic detention from headquarters. These resources could be used to broaden the sampling of other food shipments, providing greater assurance that adulterated food is kept out of the United States.

CONCLUSIONS

We are encouraged that FDA has recognized the need to strengthen certain aspects of its pesticide monitoring program and has taken partial actions on the recommendations cited in our two reports. We continue to believe, however, that all of our recommendations are valid and that FDA needs to reconsider its responses to the unanswered recommendations.

Mr. Chairman, despite the past delays and difficulties encountered by FDA and Customs in arriving at an interface agreement, the Seattle pilot has offered a demonstration that FDA and Customs can work cooperatively and successfully together in sharing information. Officials at both agencies told us that importers who have experienced the benefits of the pilot interface in FDA's Seattle district gave high praise to automated processing of import entries because automation reduced their paperwork requirements and speeded the flow of their imported food shipments through ports of entry into the United States. Whether these same benefits will extend to other FDA districts and whether FDA can expand the benefits of automated processing through ISIS depends on what happens next. Unfortunately, there exists a great deal of uncertainty because FDA has not completely followed our recommendation to develop detailed implementation plans and milestones for completing the ISIS system. We continue to believe that in order to reduce the risk of future problems and delays, FDA needs to develop detailed and comprehensive plans specifying the steps required for nationwide implementation of the baseline ISIS, the electronic interface with Customs, and the automated screening and profiling modules.

To deter importers from distributing adulterated foods, FDA needs to support a position on how best to remove an importer's economic incentives for making these distributions. We continue to

believe that FDA needs authority to impose civil administrative penalties on importers who illegally distribute adulterated food shipments. We also continue to believe that FDA could use its resources more effectively if it allowed its district offices--when the district offices have the technical capability--greater discretion in placing growers and their imported foods on automatic detention status.

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Mr. Chairman, this concludes our testimony. We would be happy to answer any questions.

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