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Report to the Chairman, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

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PESTICIDE MONITORING

FDA's Automated Import Information System Is Incomplete

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GAO

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Resources, Community, and
Economic Development Division

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The Honorable John D. Dingell
Chairman, Subcommittee on
Oversight and Investigations
Committee on Energy and Commerce
House of Representatives

Dear Mr. Chairman:

Imports of fruits and vegetables into the United States have increased substantially over the past decade. In 1988, we reported that the import share of the U.S. market for major fresh and frozen fruits had risen from 26 percent in 1980 to about 33 percent in 1986, while the import share for major fresh vegetables had risen from about 5 percent to about 7 percent. The increasing consumption of imported produce has heightened concern over the adequacy of the Food and Drug Administration's (FDA) program for monitoring pesticides in imported food.

Under the Federal Food, Drug, and Cosmetic Act (FFDCA), FDA is responsible for ensuring that imported foods do not contain unsafe levels of pesticide residues. In order to carry out this statutory responsibility, FDA reviews imported food products entering the United States and may inspect, sample, or detain products that are suspected of containing illegal pesticide residues. In an effort to respond to public concerns over the safety of imported food, FDA has initiated over the last 5 years several reforms in its program for monitoring pesticides in imported food. Included among these reforms is FDA's development of the Import Support and Information System (ISIS) to automate nearly all of its import-monitoring operations, including pesticide residue monitoring. You requested that we examine the status of FDA's efforts to implement ISIS.

Results in Brief

FDA has designed ISIS as a modular system consisting of various functional components that will be added incrementally onto a central, or "core," system. The core system will provide the basic data processing and data management capabilities of ISIS. Future components, or "completion modules," will build upon and enhance these capabilities.

FDA's development of ISIS has taken far longer than agency officials previously estimated. Delays have occurred because FDA encountered unexpected technical difficulties and procurement problems. These delays, coupled with unrealistic projections, resulted in FDA's failure to meet

system development and implementation milestones within the time frames provided to the Congress. FDA believes that these problems have been resolved and that it can successfully implement the core ISIS by June 1992.

Although the core ISIS will improve FDA's import-monitoring program, some principal system objectives, such as improved targeting of violative imports, will not be achieved until the planned implementation of additional components is complete. One vital component will be the interface with the U.S. Customs Service's automated information system. This interface will electronically link the two agencies' computer systems so that Customs will be able to send additional information to FDA on a greater number of products while eliminating much of the current paperwork. FDA's development of this interface has been delayed because of disagreements with Customs concerning its design. FDA has recently placed greater emphasis on establishing the interface, but the agency has not yet prepared detailed plans for developing and implementing it nationwide.

Other key components include screening and profiling modules that will provide FDA field personnel with additional data and guidance to improve their ability to identify violative products. Although FDA plans to add these components, it has not yet prepared detailed plans for developing and integrating them in the core ISIS.

Background

FDA samples about 1 percent of imported food products for illegal pesticide residues. Given this limited sampling, it is important that FDA's samples cover a wide variety of commodity/country combinations, particularly such combinations as have been found to violate U.S. pesticide standards in the past. In an earlier report, we concluded that FDA was not using its limited monitoring resources in the most effective way possible.[1] We recommended that the agency produce a comprehensive summary of its import- monitoring results in order to determine, on the basis of factors such as import volume, number of samples taken, and number of violations found, where coverage is most needed.

In 1988, the Congress enacted the Pesticide Monitoring Improvements Act (PMIA), requiring FDA to develop automated information systems for

[1]Pesticides: Better Sampling and Enforcement Needed on Imported Food (GAO/RCED-86-219, Sept. 26, 1986).

collecting, summarizing, and evaluating its pesticide-monitoring data.[2] In particular, the act required that FDA annually summarize the volume of each type of imported food product by country of origin and district of entry. In testimony concerning this legislation, we stated that the improved collection and analysis of monitoring information required by the act would allow FDA to better focus its limited monitoring resources on pesticide health risks.[3]

FDA's current monitoring of imported products depends primarily on manual processes that the agency recognizes as cumbersome and inefficient. Also, the agency operates at least six different computer systems for import monitoring that are not integrated with each other, resulting in data gaps, duplicate data entry, and an inability to share information nationally on a timely basis. In addition, these systems serve only as management tools for overall work planning and evaluation and do not provide support to field personnel for conducting daily monitoring operations, such as reviewing entry documents for imported products. As a result, it is difficult for FDA staff, particularly in busy ports, to review each entry in accordance with FDA guidelines and to decide on the appropriate regulatory action—sampling, field examination, detention, or release of an import entry.

To obtain the information needed to perform import reviews, FDA staff must refer to bulky reference documents or request the information from FDA headquarters by telephone. Often, FDA staff rely on memory and experience in making monitoring decisions because agency documents do not provide enough detailed guidance or are too difficult to review. Even before PMIA was enacted, FDA acknowledged these program deficiencies and began developing ISIS to correct them. Although ISIS was not developed specifically to fulfill the provisions of PMIA, FDA believes that the system will help the agency satisfy the act's requirements.

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

[2]PMIA included two other provisions requiring FDA to (1) establish cooperative agreements with foreign countries to obtain foreign pesticide usage information and (2) develop a research plan for the development and validation of improved pesticide analytical methods.

[3]H.R. 3504: Pesticide Monitoring Improvements Act (GAO/T-RCED-88-12, Dec. 14, 1987).

amount of staff time spent on routine processes, produce more consistent sampling decisions through uniform application of monitoring criteria, and deter "port shopping."[4]

FDA has designed ISIS as a modular system that allows different parts of the system to be added in stages onto the "core," or central, system. The core system is intended to increase the efficiency of FDA's import operations by automating many routine manual functions, such as the assignment of work to FDA personnel and the preparation of notices informing Customs, importers, and brokers of FDA actions. In addition, the core is intended to increase the quantity and quality of import information used by FDA personnel, permit national sharing of this information, track the status of individual entries, provide on-line access to import data bases, and produce various summary reports. FDA believes that access to national import information will enhance the ability of FDA districts to detect port shopping.

FDA intends to add several other features, or "completion modules," to the core system. The most significant of these modules are the planned electronic interface between ISIS and the U.S. Customs Service's Automated Commercial System (ACS) and automated screening and profiling modules.[5] 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.

Delays in Developing ISIS

ISIS' development has taken significantly longer than FDA officials originally estimated. Since the beginning of ISIS' development over 4 years ago, FDA has repeatedly revised its milestone estimates and has failed to meet major milestones within the time frames that agency officials provided to the Congress. For instance, FDA first informed the Congress in May 1987 that ISIS would be pilot-tested in November 1987 and fully implemented in September 1989. Then, in December 1987, FDA told the Congress that ISIS pilot tests would begin in June 1988 and full system implementation would occur in September 1990. In fact, the ISIS pilot test did not begin until December 1990, and national implementation of the core system is not planned until June 1992.

[4]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.

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

FDA officials with whom we spoke claim that these earlier milestone dates were unrealistic. They attributed such overly optimistic projections to the inability of agency officials, in the early stages of ISIS' development, to recognize the complexities of developing such a large system. For instance, according to the Director of the Office of Regulatory Resource Management, FDA had expected to take 6 to 9 months to define the basic ISIS design requirements, but the process actually took about 18 months to complete. The delays in formulating the system's basic design, in turn, delayed FDA's hiring of an ISIS software development contractor. As a result, FDA was unable to begin detailed technical design and development of ISIS until about a year and a half after the ISIS development process had begun.

After a contractor was hired in October 1988 to develop ISIS software and technical specifications, ISIS development delays continued because designing the software was more difficult and took significantly longer than FDA had expected. By 1989, FDA was still unable to project realistic milestones for the development of ISIS. For example, in April 1989, FDA informed the Congress that it expected to complete ISIS pilot tests by the end of 1989, a projection that turned out to be inaccurate by over 1 year.

FDA also experienced difficulties in procuring hardware for ISIS. In 1987, FDA attempted to purchase hardware to be used with ISIS, even though ISIS design requirements and software had not yet been developed. This procurement was cancelled when a 1987 GAO report found that FDA had circumvented federal procurement regulations and Department of Health and Human Services (HHS) procurement guidelines.[6] In addition, we reported in 1988 that FDA had not adhered to all required federal and HHS guidelines in developing ISIS.[7] In particular, we found that FDA's ISIS design requirements specified a particular make and model of hardware and software rather than specifying requirements in functional terms, as required by HHS guidelines. FDA officials told us that, as a result of these investigations, HHS would not approve the procurement request for ISIS hardware until FDA had fulfilled the required system development procedures.

[6]ADP Procurements: Food and Drug Administration Circumvented Procurement Regulations (GAO/IMTEC-87-48, Sept. 11, 1987).

[7]ADP Systems: FDA Can Reduce Development Risks for Its Import Information System (GAO/IMTEC-88-42, Sept. 30, 1988).

FDA officials believe that FDA's efforts to respond to these procurement and development concerns may have significantly delayed the purchase of ISIS equipment and the implementation of the core system. Nevertheless, the officials told us that the additional development steps required to satisfy concerns raised by us had a positive effect on ISIS' development because they led FDA to reexamine and revise its system requirements. For example, further review of system requirements revealed that ISIS would require larger computers than those FDA had initially intended to purchase for the system.

With resolution of the major procurement and system development issues, FDA officials told us that they were on track for successfully implementing the core ISIS. The agency conducted a pilot test of the ISIS core in two FDA districts from December 1990 through February 1991. FDA officials considered the pilot to be a generally successful demonstration of the core system's potential for improving FDA's import operations. As of August 1991, FDA had completed its evaluation of the core pilot results and was making necessary system modifications (e.g., software corrections) and procuring hardware, software, and other equipment to prepare for system implementation. FDA officials predict that the software and hardware that will support ISIS, as well as other FDA systems, will be installed in all six FDA regions by March 1992. FDA plans to begin ISIS core operations nationwide in June 1992.

Core ISIS Benefits Are Limited

Despite the operational improvements that FDA expects will follow from implementation of the core system, FDA acknowledges that ISIS will not fully achieve its intended objectives until other functions or modules are added. In particular, the core ISIS will collect only a limited quantity of import data and will require a substantial amount of manual data entry. In addition, the core system will not assist FDA personnel in deciding which shipments should be sampled, detained, or released. FDA believes that implementation of the ISIS-ACS electronic interface and the automated screening and profiling functions will eliminate these deficiencies and allow ISIS to achieve the levels of efficiency and effectiveness originally envisioned for the system.

An Interface With Customs' ACS Is Planned

One major limitation of the core ISIS is that it will not provide an interface with Customs' ACS, which would allow Customs to electronically transmit FDA import data directly into ISIS. As a result, FDA will continue to collect paperwork from Customs to obtain the data required for FDA

monitoring, and FDA field personnel will have to enter these data manually into the core ISIS.

The core system will not contain information on the total volume of each FDA-regulated product imported from various nations. To limit the amount of data entry required of FDA personnel, the ISIS core will collect information only on import shipments that FDA samples, examines, or automatically detains, which together represent less than 10 percent of the total import entries regulated by FDA. Therefore, the ISIS core will provide FDA with only a limited data base for reviewing and evaluating its import-monitoring operations.

In addition to the data base limitations, the data entry requirements of the ISIS core will prevent the system from attaining the expected efficiency gains. According to FDA headquarters officials, the ISIS core pilot test demonstrated that, without an ACS interface, the data entry requirements of ISIS would be too burdensome on FDA personnel, even after limiting data entry solely to products that FDA samples, examines, or detains. Also, without an interface for electronically exchanging information between Customs and FDA, the core system will not allow FDA (or Customs, importers, and brokers) to reduce the amount of paperwork used in import operations.

FDA officials said that once ISIS has been linked electronically with Customs' ACS, it will provide FDA with up-to-date information on the volume of imported products coming from various nations and will allow ISIS to collect import data on most shipments of FDA-regulated products. With this comprehensive import information transmitted to ISIS through the interface, FDA will be better able to evaluate its import program activities and focus its efforts on relatively risky products.

FDA and Customs officials believe that the interface will also improve FDA's program efficiency by substantially reducing the amount of time needed for FDA personnel to enter data manually into the ISIS core. They agree that huge efficiencies will be gained by allowing Customs to electronically transmit information on FDA-regulated products to ISIS. These electronic transactions will replace, to a large extent, the exchange of paperwork between the two agencies and with brokers. The interface will also permit FDA to inform Customs and brokers electronically of regulatory actions and decisions.

While FDA and Customs had agreed since 1984 that automated system integration was in their mutual interests, the two agencies were unable,

during 7 years of periodic discussions, to reconcile their respective system and program needs. The two agencies disagreed on, among other things, the quantity of data to be collected, the system to be used for classifying data, and the amount of screening to be performed by each agency.

After FDA and Customs had attempted unsuccessfully for several years to reach a consensus on the interface, the Office of Management and Budget (OMB) became involved in the interface discussions to help facilitate an agreement between the agencies. In August 1991, FDA and Customs signed a memorandum of understanding that may ultimately lead to the establishment of an interface between ISIS and ACS.

After the ISIS core pilot test was completed in February 1991, FDA accelerated its plans for implementing the interface. FDA expects to pilot-test this interface with Customs in one FDA district by March 1992. Although FDA is currently placing greater emphasis on developing the interface and has recently completed an interface conceptual design document, it has not yet prepared detailed plans specifying milestones and tasks required for developing and implementing the interface nationally. To establish the interface, FDA must complete several development phases, including development of interface software and more detailed specification of the functional and technical requirements for the interface. In addition, FDA must continue to work with Customs to reach agreement on the interface specifications, develop an interface test plan, and prepare an installation plan.

Advanced Screening and Profiling Modules Are Planned

Another significant limitation of the core system is that it will not contain a screening function to assist FDA personnel in deciding whether to sample, examine, automatically detain, or release a shipment. Screening will help FDA field personnel to classify each import entry in terms of FDA's regulatory interests and to determine appropriate action on the basis of FDA guidance, past monitoring results, import alerts,[8] and other criteria. For example, the screening module could, through such key import data elements as product name or country of origin, identify a product for automatic detention or mandatory sampling in accordance with agency criteria. Without the screening module, FDA personnel using the core ISIS will still have to rely on cumbersome manual reviews and on

[8]Import alerts provide information to FDA district offices about problem products such as those recommended for automatic detention.

their own memory and judgment when determining initial actions for import entries.

A related feature planned for ISIS but also not included in the core system is a profiling module. The profiling module will provide ISIS users with current and historical information on an import entry, such as past sampling results, to help users identify the likelihood of violations. FDA officials said that the profiling function is vital to screening because it will significantly improve FDA's ability to target violative products.

Both FDA and Customs officials emphasized the importance of the screening module for improving the effectiveness of FDA's import program through enhanced targeting of violative shipments. According to FDA district officials who helped to design ISIS, the ultimate objective and justification of the system is to improve FDA's ability to identify and detain violative products. They believe that the screening and profiling modules, together, will allow ISIS to achieve this objective.

In addition, FDA district officials and Customs officials said that after the ISIS-ACS interface is established, an advanced screening capability will be needed to review the greatly increased volume of import information transmitted to ISIS. The district officials said that without an automated screening capability to substantially reduce the amount of information requiring human review, FDA field personnel using ISIS may be overwhelmed by the flow of information. Therefore, the gains in efficiency and effectiveness that are expected to occur when the interface is established may be limited without an advanced screening function to help ISIS users review import data.

Although FDA recognizes that the screening and profiling modules are vital for achieving the full benefits of ISIS, FDA has not yet established any detailed plans specifying the steps required for developing and implementing these modules. As with the interface, FDA needs to establish conceptual design requirements, develop detailed functional and technical specifications, and prepare both test and implementation plans for these completion modules. FDA plans to begin developing these modules in the second half of calendar year 1992 and plans to implement them by mid-1993. But because development of the profiling module will be complex, FDA officials are uncertain how fully it can be developed by this target date.

Conclusions

FDA has repeatedly experienced difficulties and delays in developing ISIS and has failed to meet system commitments made to the Congress. But FDA officials said that they have resolved the ISIS development problems and are preparing to implement the core system by June 1992. Also, FDA has placed increased emphasis on developing the ISIS-ACS interface and is attempting to accelerate its implementation. Still, FDA has not yet developed detailed plans specifying milestones and tasks required for establishing the interface nationwide. Additionally, FDA has not yet prepared any detailed plans for developing and implementing the screening and profiling modules.

We believe that the ISIS core system will improve FDA's import program by creating the agency's first nationally integrated and standardized automated information system for import monitoring. But these improvements will be limited until FDA adds its planned completion modules to the core. These completion modules are intended to automate data entry, supply comprehensive import information, and provide automated support for making monitoring decisions. The addition of these modules, along with others planned by FDA, will, we believe, allow FDA to derive the full benefits from ISIS. Therefore, FDA must ensure that development and implementation of these modules are not delayed.

Although FDA is making progress toward these goals, the agency needs to take additional steps to ensure the timely and successful integration of these completion modules. Because delays occurred during the development of the core system, we are concerned that further delays may hinder development and implementation of these completion modules.

Recommendations

We recommend that the Secretary of Health and Human Services ensure that FDA

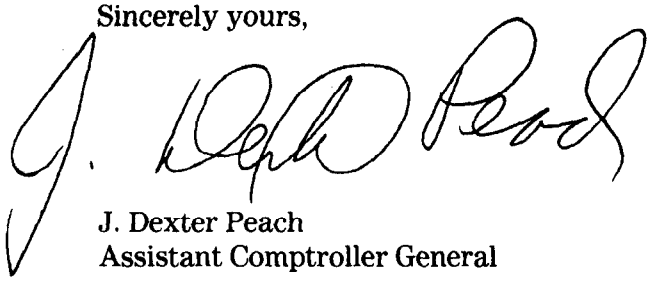
- develops, in coordination with the U.S. Customs Service, detailed plans and milestones for implementing an electronic interface between ISIS and ACS nationwide;
- develops detailed plans and milestones for implementing the ISIS screening and profiling modules; and
- informs the Congress of its established target dates for implementing the interface and the screening and profiling modules and periodically updates the Congress on its progress, including any deviations from these dates.

To determine the progress made by FDA in developing ISIS and to obtain information on the various functions and objectives of the system, we examined agency system development and planning documents and interviewed FDA headquarters and district officials involved in the design, development, and implementation of ISIS. To obtain additional information concerning the ISIS-ACS electronic interface, we met with Customs officials who were responsible for developing the interface with FDA and with OMB officials who were involved in the interface discussions between FDA and Customs.

We discussed the material contained in this report with FDA officials, who generally agreed with our presentation of the facts and did not object to our recommendations. In response to these officials' observation that the development of detailed plans for the interface depends on coordination with Customs, we modified our recommendation to refer specifically to coordination with Customs. Furthermore, in response to their concern that the report would give a negative impression of the agency's ISIS efforts, we added language to better emphasize FDA's recent progress. However, as agreed with your office, we did not obtain written agency comments on a draft of this report. We performed our work from March 1991 to October 1991, in accordance with generally accepted government auditing standards.

Unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of this letter. At that time, we will send copies to the Secretary of HHS and to the Commissioner of FDA. We will make copies available to others upon request. This report was prepared under the direction of Richard L. Hembra, Director, Environmental Protection Issues, who can be reached at (202) 275-6111. Other major contributors to this report are listed in appendix I.

Sincerely yours,



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