United States General Accounting Office

GAO

Testimony

Before the Subcommittee on Human Resources and Intergovernmental Relations, Committee on Government Operations, House of Representatives

For Release on Delivery
Expected at
9:45 a.m. EDT
Wednesday
September 28, 1994

FOOD SAFETY

Fundamental Changes Needed to Improve Monitoring of Unsafe Chemicals in Food

John W. Harman, Director
Food and Agriculture Issues,
Resources, Community, and
Economic Development Division

Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to participate in this hearing on the need to improve the effectiveness of the federal food safety system. In previous reports and testimonies, we have stated that fundamental changes are needed to this system to better protect the nation's food supply from microbiological hazards.[1] Today, we will discuss the federal government's system for ensuring that the food supply does not contain unsafe chemical residues and environmental contaminants. Our testimony is based on two reports requested by this Subcommittee, which are being released today--one analyzes the U.S. Department of Agriculture's National Residue Program (NRP) for monitoring chemical residues in meat and poultry, and the second examines the overall federal structure and systems for controlling chemicals in all foods.[2]

In summary, our recent work demonstrates that there are improvements needed in the approach used to monitor chemicals in the food supply. Specifically we found the following:

-- The NRP has weaknesses in testing and sampling, as well as in the support it receives from regulatory agencies. These weaknesses could be overcome if certain processes were strengthened. However, any improvements made would not address the basic problem with the program: reliance on detecting residues at the end of the production process to ensure safety rather than on preventing these problems from developing.

-- We have identified five basic weaknesses in the structure and systems for monitoring chemicals in food. First, fragmentation of responsibility among multiple agencies results in inefficiencies and gaps in federal monitoring activities. Second, chemicals posing similar risks may be regulated differently under different laws. Third, federal

---

[1]Food Safety: A Unified, Risk-Based Food Safety System Needed (GAO/T-RCED-94-223, May 25, 1994); Food Safety: Risk-Based Inspections and Microbial Monitoring Needed for Meat and Poultry (GAO/RCED-94-110, May 19, 1994); Food Safety: Risk-Based Inspections and Microbial Monitoring Needed for Meat and Poultry (GAO/T-RCED-94-189, Apr. 19, 1994); Food Safety: A Unified, Risk-Based System Needed to Enhance Food Safety (GAO/T-RCED-94-71, Nov. 4, 1993); Food Safety and Quality: Uniform, Risk-Based Inspection System Needed to Ensure Safe Food Supply (GAO/RCED-92-152, June 26, 1992).

[2]Food Safety: USDA's Role Under the National Residue Program Should Be Reevaluated (GAO/RCED-94-158, Sept. 26, 1994) and Food Safety: Changes Needed to Minimize Unsafe Chemical Residues in Food (GAO/RCED-94-192, Sept. 26, 1994).

agencies rely on programs to detect unsafe chemicals in food rather than preventing these problems from developing. Fourth, agencies lack strong enforcement authorities to adequately deter or penalize violators. Fifth, similar problems exist for imported foods, over which the United States has even less control.

Before we discuss the results of our work in more detail, some brief background information may be useful.

BACKGROUND

Potentially unsafe chemicals can enter the food supply from chemicals used during food production as well as from the environment. Before they can be used legally in the United States, pesticides, animal drugs and chemical additives must be approved by the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA), respectively. If these chemicals leave residues, the cognizant agency is responsible for establishing a tolerance level--the amount of residues that can legally remain in or on raw and processed foods.[3] Environmental contaminants, unlike chemical residues, are not intentionally used in food production but enter the food supply through their occurrence in the environment naturally or through air, water, and soil pollution.

Although chemical hazards are generally ranked as less important than microbiological hazards as a public health issue, the long-term and chronic effects of these hazards are an important public health concern. The U.S. Department of Agriculture (USDA) monitors chemical residues and environmental contaminants in meat, poultry, and some egg products, and FDA monitors them in all other food products.

USDA's Food Safety and Inspection Service (FSIS) uses the NRP to detect, measure, and reduce potentially harmful chemicals in meat and poultry products. Under the program, FSIS samples and analyzes domestic and imported meat and poultry for unsafe chemicals at the slaughterhouse. FSIS refers violations it identifies to EPA, FDA, and/or the states, as appropriate for follow-up and regulatory action.

PROBLEMS WITH THE NATIONAL RESIDUE PROGRAM

The NRP has basic flaws in the choice of chemicals tested and the methodology used to select samples for testing. In addition, the program suffers from limited support from EPA and FDA to identify potentially hazardous chemicals and to prosecute

---

[3]Some chemicals may have a tolerance level of zero, and therefore no residues of the chemicals are allowed in food, while others may not require a tolerance.

violations.

NRP's Test Results Are Not as Useful as They Should Be

The NRP's test results are not as useful as they should be in determining whether the meat and poultry supply does or does not contain potentially unsafe chemicals for the following reasons:

-- FSIS cannot ensure that compounds presenting the greatest risk have been identified and are being tested for under the program. This occurs because (1) FSIS has ranked (prioritized) only about one-third of the 367 compounds it has identified as being of potential concern for meat and poultry and (2) test methods have not been developed for all compounds. Furthermore, only 24 of the 56 compounds tested in 1992 were high priority. Although FSIS plans to devote more resources to ranking additional compounds and developing more test methods, these tasks will take many years to complete.

-- Flaws in the NRP's sampling methodology may bias the program's testing results. For example, we found that FSIS does not (1) consistently follow random sampling procedures, (2) adjust its sampling of some species to compensate for climatic/geographic and seasonal changes in slaughter rates and animal drug use, and (3) consistently sample different animal species and chemical compounds.

-- Because the NRP's testing focuses on domestic compounds of concern, it is of limited value in determining whether imported meat and poultry contains animal drugs or pesticides not approved or banned for use in the United States. The potential for hazardous residues in imported products is a concern for two reasons: (1) Certain exporting countries have reported finding high incidents of heavy metal residues in excess of their own domestic standards, and (2) some countries may use animal drugs or pesticides not approved or banned in the United States. However, FSIS does not adjust its testing of imports to reflect these concerns.

Other Agencies Provide Limited Support to the Program

EPA and FDA cannot always provide the support the NRP needs to be effective, as the following examples show:

-- EPA and FDA may not be able to provide FSIS with the most current information on chemical risks and tolerances. EPA is in the process of reregistering pesticide products but may not complete this task until 2006, and FDA has not reevaluated all animal drugs approved in the past because of resource constraints.

-- Because of limited resources, FDA investigated only about 20 percent of the 21,439 residue violations referred to it by FSIS from 1989 through 1992. Of those violations investigated, only about 9 percent resulted in regulatory action against violators, mostly in the form of warning letters that carry no penalty. Only one prosecution resulted from these investigations.

FUNDAMENTAL CHANGES NEEDED IN THE FEDERAL FOOD SAFETY SYSTEM

The problems that we identified in the NRP are not unique. They exemplify problems GAO and others have been describing for the past two decades for many federal programs that monitor chemicals in domestic and imported foods. For example, FDA faces many of the same problems when monitoring pesticides in fruits and vegetables or environmental contaminants in fish products. While the federal agencies have taken steps to address criticisms, we believe they cannot, by themselves, overcome five systemic and structural weaknesses that are responsible for the continuation of these problems. Because some of these weaknesses are the result of legislation and the design of the federal food safety system, successful corrective actions will depend on congressional initiatives.

Fragmentation of Responsibility Impedes the Identification of Chemical Risks

Under the current federal food safety system, responsibilities are fragmented across many agencies. As a result, the system is characterized by inefficiencies and gaps in monitoring. Nowhere is this more apparent than in agencies' efforts to assess chemical risks. To control unsafe chemicals effectively, agencies need a large amount of human exposure and residue data to first assess the risks posed by a chemical. However, because responsibility for collecting these data is split among FDA, EPA, and USDA, there is often little agreement on the data that should be collected, the methods for analyzing these data, and, ultimately, the results of the data analyzed. Consequently, the agencies may not reach the same conclusions on the level of risk posed by a particular chemical and the level of needed regulation.

Problems in the Legal and Regulatory Structure Compromise Efforts to Reduce Risk

Even if agencies had reliable information to better control chemical risks, differences in the basic laws and regulations that govern chemicals in food do not support the agencies' efforts. For example, we found that federal food safety laws (1) have resulted in different standards for chemicals posing similar risks, (2) do not generally require the agencies to regularly reevaluate chemicals approved in the past against current scientific standards, and (3) do not specifically address the critical risk

posed by environmental contaminants in food. In addition, as a result of federal regulation and policy that allow the use of unapproved pesticides and animal drugs to address emergency situations, the use of unapproved chemicals has become a routine practice.

Increased Focus on Prevention Is a Better Approach

The basic federal approach to ensuring food safety--end-product testing--is not only resource-intensive but ultimately ineffective in preventing contamination from occurring. This approach requires an everincreasing amount of resources, both to keep pace with the commodity/chemical combinations of concern and to develop all the multiresidue tests needed to detect these residues. The problems in the NRP demonstrate the shortcomings of relying on end-product testing. Newer approaches to ensure food safety--such as the Hazard Analysis and Critical Control Point (HACCP) approach--recognize these difficulties and seek to build safeguards into food production. The HACCP approach generally integrates chemical prevention, detection, and control functions at critical points throughout the production process. Under this approach, end-product testing becomes a secondary rather than the primary method of ensuring that unsafe levels of chemical residues and environmental contaminants do not remain in food products. While the benefits of HACCP-based systems have been recognized for over 20 years, the federal government has made little progress in implementing such systems.

Limited Enforcement Authority Cannot Effectively Deter or Penalize Violators

Federal enforcement efforts do not provide the backup that is necessary to ensure compliance with federal food safety standards when violations occur. FDA, the primary enforcing agency for food violations, does not always act on violations referred by other agencies, as demonstrated by the problems we found in the NRP, because of a lack of resources and other competing priorities. Moreover, FDA has inadequate enforcement authorities and cannot effectively prevent the distribution of violative products to consumers or prevent future violations from occurring. This happens because FDA lacks the authority to detain violative products and to assess civil penalties. When FDA finds a potentially violative product, it must obtain a court order to seize the products. However, while FDA is obtaining the court order, potentially unsafe food may be shipped and sold to consumers. Similarly, FDA must rely on the Justice Department to pursue criminal action against violators because FDA does not have the authority to assess civil penalties. However, the number of cases pursued under criminal law is minuscule because this is a resource- and time-intensive activity. For example, of the over 21,000 drug residue violations reported to FDA, between 1989 and 1992, only 15 resulted in criminal action.

Similar Problems Exist With Imported Products

Finally, the problems we have identified in the domestic food safety system are also relevant for imported foods because federal agencies have even less control over the production of imported foods. U.S. agencies have no jurisdiction over food producers in exporting countries and therefore rely on the adequacy of exporting countries' food safety systems and/or U.S. inspecting and testing of imported products at the port of entry to ensure the safety of imported foods. However, not only are food safety systems in some exporting countries inadequate but also weaknesses in the U.S. system result in gaps in monitoring imported food for several reasons.

First, FDA's inspection resources cannot keep pace with the growing volume of imported food. Second, some imported products may not be tested for compounds that are used in exporting countries but are not approved for use in the United States because the agencies may have incomplete data on these chemicals, and/or because some of the testing focuses only on domestic compounds of concern. Third, as a result of weaknesses in its regulatory authorities, FDA, in some instances, has been unable to prevent the distribution of contaminated imported products to U.S. consumers. Although FDA has the authority to detain contaminated imports, it does not have the authority it needs to control and prevent the distribution of unsafe imports. For example, while meat and poultry can only be imported from countries that have food safety systems that have been reviewed and certified by USDA as being equivalent to the U.S. system, FDA must rely on voluntary agreements with foreign countries to ensure that imported products comply with U.S. standards. Similarly, as with domestic foods, FDA lacks civil penalty authority and must rely on another agency, in this case the Customs Service, to provide an economic deterrent to violators. However, because of poor coordination between the agencies, these damages are often not assessed.

- - - - -

In summary, Mr. Chairman, as we have continually reported over the past 20 years, the federal system designed to ensure that food is free from unsafe levels of chemicals needs significant improvement. We believe a restructuring of the federal monitoring system for chemical residues and environmental contaminants in food is needed. Our most recent reports suggest that the Congress should take the following steps:

-- Enact a uniform set of food safety laws that include consistent standards for chemical residues and contaminants in food and provide federal agencies with the authorities needed to effectively carry out their oversight responsibilities.

-- Revise the nature of the federal government's role for ensuring food safety by moving it away from end-product testing to preventing contamination from occurring. End-product testing would take a secondary role to monitor the effectiveness of the prevention system.

-- Consider the feasibility of requiring that all food eligible for import to the United States--not just meat and poultry--be produced under equivalent food safety systems.

Mr. Chairman, this completes our prepared statement. We would be happy to respond to any questions.

(150637)

Ordering Information

The first copy of each GAO report and testimony is free. Additional copies are $2 each. Orders should be sent to the following address, accompanied by a check or money order made out to the Superintendent of Documents, when necessary. Orders for 100 or more copies to be mailed to a single address are discounted 25 percent.

Orders by mail:

U.S. General Accounting Office
P.O. Box 6015
Gaithersburg, MD 20884-6015

or visit:

Room 1100
700 4th St. NW (corner of 4th and G Sts. NW)
U.S. General Accounting Office
Washington, DC

Orders may also be placed by calling (202) 512-6000 or by using fax number (301) 258-4066.

Each day, GAO issues a list of newly available reports and testimony. To receive facsimile copies of the daily list or any list from the past 30 days, please call (301) 258-4097 using a touchtone phone. A recorded menu will provide information on how to obtain these lists.

United States
General Accounting Office
Washington, D.C. 20548-0001

Bulk Mail
Postage & Fees Paid
GAO
Permit No. G100

Official Business
Penalty for Private Use $300

Address Correction Requested