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FOOD SAFETY

A Unified, Risk-Based Food Safety System Needed

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GAO/T-RCED-94-223

Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss the need to reinvent the federal food safety system. In previous reports and testimonies, we have stated that fundamental changes are needed to this system, including moving to a uniform, scientific, risk-based system. As you requested, we will also discuss our views on where food safety responsibilities should reside in the federal government.

In summary, the current food safety system hampers and impedes efforts to address public health concerns associated with existing and newly identified food safety risks. The system was not developed under any rational plan but evolved over many years to address specific health threats from particular food products and has been slow to respond to changing health risks. Efforts to address food safety concerns continue to be hampered by inconsistent and inflexible oversight and enforcement authorities, inefficient resource use, and ineffective coordination. In previous reports and testimonies, we concluded that the most effective way for the federal government to resolve long-standing problems, deal with emerging food safety issues, and ensure a safe food supply is to create a single food safety agency responsible for administering a uniform set of laws.[1]

While we believe that an independent federal food safety agency, operating much like the Environmental Protection Agency (EPA), is the preferred approach, we recognize that there are problems associated with setting up a new government agency and, therefore, consolidating food safety activities under an existing department is a more likely scenario. While the question of an independent single agency versus an existing department is a matter of judgment upon which opinions can differ, consolidating such activities under the U.S. Department of Agriculture (USDA) or the Department of Health and Human Service's (HHS) Food and Drug Administration (FDA) has its own set of problems.

In November 1993, we testified before your Subcommittee that food safety inspections should not be consolidated under USDA because of a real or perceived conflict of interests with its role of promoting agriculture.[2] Moving responsibility for all food safety to agriculture would likely compound this problem. However, while FDA has a clear public health mission and thus is free of institutional conflicts, we believe that before food safety

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[1]Our testimony is based on over 60 reports and studies issued over the last 25 years by GAO, agency Inspectors General, and others. (See app. I for a listing of GAO and other reports).

[2]Food Safety: A Unified, Risk-Based System Needed to Enhance Food Safety, (GAO/T-RCED-94-71, Nov. 4, 1993).

activities could be consolidated under FDA, other actions would need to take place, including providing FDA adequate resources and authorities to perform its responsibilities. Regardless of where such an agency is housed, the current food safety legislation needs to be revised to make it uniform, consistent, and risk-based.

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

BACKGROUND

The current federal food safety system consists of as many as 35 different laws administered by 12 agencies. Two agencies account for most federal food safety spending: FDA is responsible for the safety of most foods and the Food Safety Inspection Service (FSIS), under USDA, is responsible for the safety of meat and poultry products.

Despite $1 billion spent annually on the current food safety system, food safety remains a concern. Because many cases of foodborne illness go undiagnosed, the actual number of incidents is probably much higher than the conservative estimate of 6.5 million annually and, according to the Centers for Disease Control, may reach 80 million or more. While it is not possible to put a dollar figure on the pain and suffering caused by foodborne illness, efforts have been made to quantify the economic costs. For example, FDA and FSIS have estimated that the medical costs and lost productivity from foodborne illness total $17 billion to $23 billion per year.

CURRENT FEDERAL INSPECTION PROGRAM HAS SIGNIFICANT LIMITATIONS

During the past 20 years, other organizations--most recently, the Vice President's National Performance Review Team--have issued reports detailing problems with the federal food safety system and made numerous recommendations for change. While many of these recommendations have been acted on, improvement efforts have fallen short largely because the agencies continue to operate under different regulatory approaches contained in their basic laws. Consequently, it is unlikely that basic, long-term improvements in food safety will occur unless fundamental legislative and structural changes are made to the entire food safety system.

The federal regulatory system did not develop under any rational plan. As the understanding of foodborne hazards grew, food safety concerns changed. Addressing one new worry after another, legislators amended old laws and enacted new ones. Programs emerged piecemeal, typically in response to particular health threats or economic crises. The laws not only assigned specific food commodities to particular agencies but also provided the agencies with different authorities and responsibilities,

reflecting significantly different regulatory approaches. As a result, inflexible and inconsistent oversight and enforcement authorities, inefficient resource use, and ineffective coordination efforts, have hampered and continue to impede efforts to address public health concerns associated with existing and newly identified food safety risks. The following examples represent some of the problems we have found.

-- Firms that process food products that pose similar health risks to the public are inspected at widely different frequencies, depending on which agency--and thus which regulatory approach--governs them. Although there is virtually no difference in the potential health risk, meat and poultry plants regulated by FSIS are inspected at least daily, while firms that process rabbit, venison, and quail, for example, which are under FDA's jurisdiction, were inspected at an average rate of about once every 3 to 5 years in 1992.

-- Responsibilities for oversight of chemical residues in foods are fragmented among EPA, FDA, and USDA. As a result, chemicals posing similar risks may be treated differently by the agencies because they operate under different laws and regulations.

-- Enforcement authorities granted to the agencies also differ. USDA agencies have the authority to (1) require food processors to register so that they can be inspected, (2) presume that food firms are involved in interstate commerce and are thus subject to regulation, (3) prohibit the use of processing equipment that may potentially contaminate food products, and (4) temporarily detain any suspect foods. Conversely, FDA, without such authority, is often hindered in its ability to oversee food processors.

-- Federal agencies are not using their inspection resources efficiently. Because the frequency of inspection is based on the agencies' regulatory approach, some foods and establishments may be receiving too much attention while others may not be receiving enough. What constitutes an appropriate level of inspection has been a long-standing issue in connection with FSIS' daily inspection requirement for meat and poultry processing plants when compared with FDA's inspection interval of once every several years. Furthermore, food establishments are sometimes inspected by more than one federal agency because they participate in programs or process foods that are under the jurisdiction of different agencies.

-- Agency coordination agreements aimed at overcoming the fragmented federal food safety system by avoiding duplication and/or gaps in coverage are ineffective.

Unsanitary and other unsafe conditions have persisted in food processing plants because notifications required by the coordination agreements do not always take place or the problems referred to the responsible agency are not always promptly investigated. While the agencies have agreed to update the agreements, history has shown that as time passes the agreements become outdated and ineffective.

CONSOLIDATION OF FOOD SAFETY AGENCIES IS A LONG-STANDING ISSUE

Consolidating food safety activities is not a new concept. Such a concept was debated in 1972 in connection with a proposed bill to transfer FDA's responsibilities, including its food safety activities, to a new independent agency, called the Consumer Safety Agency. This new agency was to be responsible for, among other things, ensuring the safety of the nation's food supply, although meat and poultry inspection was to remain in USDA.

Our position today is similar to the one we voiced in 1972, when we testified that whether an independent single agency was preferable to a component of an existing department was a matter of judgment upon which opinions can differ.[3] While today we believe a single independent food safety agency is the preferred approach, we recognize the difficulties in establishing a new government agency. Regardless of where a single agency is housed, what is most important as we reasoned in 1972, were certain principles, including: a clear commitment by the federal government to consumer protection, adequate resources devoted to that purpose, and competent and aggressive administration of the laws by the responsible agency. Although these principles can be influenced by organizational placement, commitment to them probably depends more on public and political concern for the importance of the mission.

We also still believe, as we testified in 1972, that it is important for the food safety mission to be housed in an agency that is not charged with responsibilities that might conflict, or appear to conflict, with its willingness to aggressively administer its public health protection responsibilities. Although the Secretary of Agriculture had established a separate agency dedicated to meat and poultry inspection and related consumer protection functions, the agency still remained in a department having a principal mission of promoting and serving the agriculture industry. We suggested then that such activities be given to a new independent agency or an existing agency not in USDA in order to consolidate similar functions, allow flexibility in the use of

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[3]Hearings on the Consumer Safety Act of 1972 before the Subcommittee on Executive Reorganization and Government Research, Senate Committee on Government Operations, (1972).

resources, and eliminate overlapping activities. Establishing a new independent agency because of conflicting interests is not unprecedented. In 1974, the Congress established the Nuclear Regulatory Commission, an independent agency, thus eliminating the Department of Energy's dual responsibility for promoting and regulating nuclear power.

Even though the meat and poultry inspection responsibilities were transferred to the current Food Safety and Inspection Service in 1981, they remained, as they do today, in USDA, which has the dual responsibility of promoting agriculture and protecting the consumer. While there are a number of proposals to reorganize USDA to separate its food safety and agriculture promotion responsibilities, they would still be housed under a department with conflicting roles. Conflicting interests or interference by the USDA Secretary's office have been cited by some groups and individuals, including two former FSIS Administrators and a former USDA Assistant Secretary, as one of the reason's why we need an independent food safety agency. Such conflicts and interferences tend to reduce public confidence in the federal government's ability to ensure the safety of the nation's food supply. Consolidating all food safety responsibilities in USDA would only compound this problem since the agency is involved in various ways in promoting or supporting production of most food products.

FDA'S FOOD SAFETY PROGRAM HAS SERIOUS WEAKNESSES

While FDA has a clear public health mission and thus does not have the potential institutional conflict-of-interest problem of USDA, FDA has a different set of problems that would need to be addressed if federal food safety activities were consolidated under its jurisdiction. FDA itself has recognized the limitations of its food safety programs. In a March 12, 1993, memorandum to the Secretary of HHS, the FDA Commissioner outlined the major problems with the federal food safety system and what needed to be done to strengthen the system, including the need to provide FDA adequate resources and enforcement authorities to perform its responsibilities. The Commissioner's analysis is consistent with some of the problems we have reported in the past, including limited resources to carry out its mission and a lack of some necessary authorities. According to senior FDA officials these problems plague the agency today.

FDA Has Limited Resources

The level of effort to protect the food supply has simply not kept pace with the increasing size and complexity of the food industry and food imports. In September 1989 and again in July 1993, we reported that FDA's resources have not kept pace with its

responsibilities.[4] Since 1980, FDA's legislatively imposed responsibilities have greatly increased while at the same time it has had to deal with public health crises, such as the AIDS epidemic and product-tampering incidents which have placed added demands on its resources. In spite of these increased demands, FDA's staffing levels declined during the 1980s from a high of 7,816 staff years in 1980 to a low of 6,855 staff years in 1987 but have increased to 8,900 staff years in 1993. However, while FDA has received additional resources, the vast majority of the increases were devoted to FDA's nonfood activities, such as approval and oversight of drugs and medical devices. (See app. II for details on FDA's resources, inspections, samples, and enforcement actions.)

Although FDA has devoted some additional resources over the past few years to food activities, such as the resources needed to inspect all seafood plants and develop a plan for ensuring the safety of seafood products, resource constraints continue to affect its ability to oversee the food industry. FDA officials said that limited resources, public health emergencies, and other high-priority tasks, such as inspections of blood banks, preclude it from inspecting as many domestic food establishments as it would like. For example, according to the Commissioner's letter to the Secretary of HHS, FDA's resources have dropped to a level where the agency can only inspect food processing facilities on average about once every 8 years.

Former FDA officials and representatives of industry, consumer groups, and academia have also maintained that a large disparity exists between FDA's responsibilities and resources. For example, the number of new food products introduced annually to the retail grocery market has more than quadrupled--from just over 2,000 in 1980 to over 12,000 in 1992--and the number and variety of new food products will continue to increase as industry expands its technological capacity.

FDA Needs Additional Enforcement Authorities

Limitations in existing FDA authority to monitor food firms and take enforcement actions may affect the agency's ability to ensure food safety. In addition to the previously discussed authorities granted USDA but not FDA, FDA lacks the authority to access manufacturers' production and distribution records and impose civil penalties for violations. The need for additional authorities was recommended in the May 1991 Final Report of the Advisory Committee on the Food and Drug Administration (frequently

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[4]FDA Resources: Comprehensive Assessment of Staffing, Facilities, and Equipment Needed, (GAO/HRD-89-142, Sept. 15, 1989) and Food Safety and Quality: Innovative Strategies May Be Needed to Regulate New Food Technologies, (GAO/RCED-93-142, July 26, 1993).

called the Edwards Committee in recognition of the Committee Chairman, Charles C. Edwards, M.D.).

In our 1993 report on new food technologies, we said that the lack of authority to access food plants records may affect FDA's plans to adopt an inspection approach based on the hazard analysis and critical control point (HACCP) concept. Under HACCP, each plant identifies and establishes a system to monitor, by physical observation or chemical analysis, the critical control points in its process to ensure that they are effective. Plant personnel document the results of their monitoring efforts and when a control point is found to be ineffective the line is immediately stopped and corrective actions implemented. However, without access to plant production and HACCP records, FDA would be unable to verify plant compliance with HACCP requirements.

Furthermore, FDA does not have the authority to review plant shipping documents, which limits its ability to track and remove food products found to be adulterated from the market place.

In September 1992 and June 1993, we reported on FDA's need for civil penalty authority to deter importers from abusing food safety regulations.[5] While most importers comply with FDA's instructions and properly destroy or export adulterated shipments, a few repeatedly fail to do so. Rather than destroy or export adulterated food products, some importers choose to distribute them into the U.S. market and pay the relatively low damage assessments. In our September 1992 report, we stated that in the four FDA districts we reviewed, importers did not destroy or export, as required, about one-third of the imported foods in which FDA detected prohibited pesticides. Furthermore, 10 importers were responsible for illegally distributing 64 percent of the 336 adulterated shipments.

Although FDA could criminally prosecute such offenders, these cases have low priority for Department of Justice prosecution. In addition, punitive damages are based on bond amounts that are set for purposes other than enforcement of FDA regulations. As a result, in September 1992 and again in June 1993, we suggested that the Congress give FDA the authority to levy civil administrative penalties to eliminate an importer's economic incentive to sell adulterated foods rather than destroy or export those foods. Similar recommendations have been made by the FDA Commissioner, the Edwards Committee, and others. Although legislation has been introduced to address these issues, it has not been enacted.

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[5]Pesticides: Adulterated Imported Foods Are Reaching U.S. Grocery Shelves, (GAO/RCED-92-205, Sept. 24, 1992) and Pesticides: Status of FDA's Efforts to Improve Monitoring and Enforcement, (GAO/T-RCED-93-55, June 16, 1993).

CONCLUSIONS

The current food safety system's inflexible and inconsistent oversight and enforcement authorities, inefficient resource use, and ineffective coordination efforts, hampers and impedes efforts to address public health concerns associated with existing and newly identified food safety risks. The nature of the threat to public health from food products has changed over time, but the food safety system has not adjusted accordingly. The adoption of a risk-based approach to inspections could lead to safer products and reduced costs as scarce resources are redirected from low-risk operations to high-risk areas that require greater coverage.

Past efforts to correct deficiencies of the federal food safety inspection system have fallen short because the responsible agencies have continued to operate under different food safety statutes. To obtain a uniform, risk-based inspection system, basic changes need to be made to the current regulatory system. In our view, creating a single food safety agency is the most effective way for the federal government to resolve long-standing problems, deal with emerging food safety issues, and ensure the safety of our country's food supply.

Given the problems associated with establishing a new agency, consolidating food safety responsibilities under an existing department is a more likely scenario, although such an option has its own set of problems. USDA has conflicting interests that undermine public confidence in the federal government's ability to ensure a safe food supply, and FDA's food safety program has serious weaknesses that need to be addressed before giving it additional responsibilities.

Regardless of where a single food safety agency is located, there needs to be a clear commitment by the federal government to public health protection, adequate resources devoted to that purpose, and competent and aggressive administration of uniform food safety laws.

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

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Food Safety: Inspection of Domestic and Imported Meat Should Be Risk-Based (GAO/T-RCED-93-10, Feb. 18, 1993).

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FDA'S RESOURCES AND ACTIVITIES

The Food and Drug Administration (FDA) is not only responsible for regulating foods it is also responsible for cosmetics, human drugs, biologics, medical devices, radiological health, and animal drugs and feeds. For the most part, FDA is organized into centers, such as the Center for Food Safety and Applied Nutrition, that are generally associated with its responsibilities. Table 2.1 provides resource, inspection, sample, and enforcement action information on FDA's foods responsibilities.

Table 2.1: FDA staffing levels, inspections, microbiological samples analyzed, and enforcement actions.

Fiscal Year	Total FDA Staff Years	Foods Staff Years (a)	Foods Inspec-tions (b)	Foods Sample (c)	Foods Enforce-ments (d)
1993	8,900	2,695	13,961	8,161	1,010
1992	8,792	2,793	14,655	8,778	1,036
1991	8,267	2,637	17,151	7,939	761
1990	7,629	2,475	14,309	7,593	836
1989	7,228	2,377	15,331	7,059	679
1988	7,103				646
1987	6,855				1,444
1986	6,904				2,219
1985	7,094				1,176
1984	7,172				906
1983	7,219				515
1982	7,085				
1981	7,467				
1980	7,816				

Notes:

[a]Food staff years comprise the staff years devoted to foods by the Center for Food Safety and Applied Nutrition and the field staff of the Office of Regulatory Affairs.

[b]Food inspections comprises both FDA staff inspections and contracted inspections of domestic food plants.

[c]Food samples comprises microbiological samples of domestic and imported foods.

[d]Enforcements are seizures, recalls, warning letters, injunctions and prosecutions.

Source: GAO presentation of FDA data.

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