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Report to the Chairman, Human Resources and Intergovernmental Relations Subcommittee, Committee on Government Operations, House of Representatives

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FOOD SAFETY

USDA's Role Under the National Residue Program Should Be Reevaluated

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GAO

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Resources, Community, and
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The Honorable Edolphus Towns
Chairman, Human Resources and Intergovernmental
Relations Subcommittee
Committee on Government Operations
House of Representatives

Dear Mr. Chairman:

In response to your request, this report examines the effectiveness of the U.S. Department of Agriculture's National Residue Program. This program is intended to ensure that the nation's meat and poultry supply is free of potentially harmful chemical residues.

This report makes recommendations for improving the program to the Secretary of Agriculture and presents an alternative approach for the Congress to consider to increase the program's effectiveness in detecting and controlling potentially harmful residues.

As arranged with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 7 days after the date of this letter. At that time, we will send copies to the appropriate congressional committees, departmental secretaries, agency heads, and other interested parties. Copies will also be made available on request.

This work was performed under the direction of John W. Harman, Director of Food and Agriculture Issues, who can be reached at (202) 512-5138 if you or your staff have any questions. Other major contributors to this report are listed in appendix V.

Sincerely yours,

Keith O. Fultz
Assistant Comptroller General

Executive Summary

Purpose

Meat and poultry can contain residues of drugs and pesticides used in agricultural production, as well as industrial chemicals that find their way into the food chain through environmental pollution. To ensure that hazardous levels of these compounds do not contaminate meat and poultry, the Food Safety and Inspection Service (FSIS) within the Department of Agriculture (USDA) administers the National Residue Program.

At the request of the Chairman, Human Resources and Intergovernmental Relations Subcommittee, House Committee on Government Operations, GAO examined whether (1) FSIS' National Residue Program can assure the public that the nation's meat and poultry supply is free of potentially hazardous chemical residues and (2) assistance from the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) within the Department of Health and Human Services (HHS) is adequate to support the National Residue Program's needs. As agreed with the Chairman's office, GAO also examined the value of a different regulatory approach—one that requires industry to have residue prevention, detection, and control programs that are monitored by the federal government.

Background

FSIS, which is responsible for ensuring that both domestic and imported meat and poultry products are safe and free of potentially harmful chemical residues, conducts thousands of residue tests to ensure that U.S. standards are met. The National Residue Program is designed to identify and select chemical compounds that could present health-based concerns to consumers of meat and poultry, sample and test meat and poultry for residues of these compounds, and take enforcement action against those who market products that contain potentially hazardous levels of these compounds. To operate the program, FSIS relies on assistance from other agencies, primarily EPA, which sets residue limits and provides other information for pesticides approved for domestic use, and FDA, which does the same for approved animal drugs. FSIS, in turn, collects samples of meat and poultry from slaughter plants and at ports of entry throughout the United States and analyzes them against established residue limits. Violations are referred to FDA for investigation and enforcement action at the farm/producer level.

Results in Brief

Testing conducted under the National Residue Program each year is not comprehensive, and the methodology used to select samples is flawed.

Also, FSIS does not adjust its testing of imported meat and poultry to encompass known problems with heavy metal residues or animal drug and pesticide compounds not allowed in the United States but used by exporting nations. Thus, FSIS does not know the extent to which potentially harmful residues may or may not exist in the meat and poultry supply.

In addition, because thousands of agricultural chemicals are used worldwide and new compounds are introduced annually, FSIS may not always have complete information on chemical residues or the potential hazard such residues may present to consumers. For example, there are gaps in knowledge about the health and environmental effects of some compounds previously approved for use under less stringent scientific standards. Also, although FDA is principally responsible for investigating and taking enforcement action on the residue violations referred by FSIS, resource constraints and legislative restrictions limit FDA's ability to do so.

While steps can be taken to strengthen the National Residue Program, recent industry initiatives suggest that a risk-based approach to residue prevention, detection, and control that is an integral part of the production process may better ensure the safety of meat and poultry than the current approach that relies on testing end products. FSIS recognizes the value of this approach and has begun to design systems incorporating it. However, FSIS' resources might be more effectively used if, subject to FSIS' assistance and oversight, industry were responsible for establishing and operating quality assurance systems for preventing, detecting, and controlling residues. FSIS could selectively monitor the effectiveness of industry programs and assist industry by developing information on compounds in use and test methods.

Principal Findings

NRP Is Not Comprehensive and Is Flawed

To obtain reliable results from the National Residue Program, FSIS must ensure that compounds presenting the greatest potential concern are identified, ranked in terms of potential threat, and tested on a priority basis. However, about two-thirds of the 367 compounds already identified as being of potential concern have not been ranked because insufficient resources have been dedicated to the task. USDA now states that the list of compounds needs to be updated and that FSIS plans to devote more

resources to the ranking task. However, it will still take many years to rank the remaining compounds. Furthermore, only 24 of the 56 compounds tested in 1992 were high priority. Also, while certain exporting countries periodically report to FSIS that they have found high numbers of heavy metal residue violations in their testing, no U.S. regulatory limits have been established for heavy metal residues in meat and poultry, and FSIS does not routinely test either imported or domestic products for these residues. In addition, FSIS limits its residue testing of imported meat and poultry to the same animal drug and pesticide compounds it tests for domestically—even though exporting nations may use compounds not approved or banned for use in the United States.

To provide credible results, FSIS must test product samples that are selected randomly using commonly accepted statistical techniques. However, FSIS does not consistently follow random sampling procedures. FSIS also does not adjust its sampling of some species to compensate for climatic/geographic and seasonal changes in slaughter rates and animal drug use. Other inconsistencies in FSIS' sampling of different animal species and chemical compounds potentially skew test results. Consequently, the National Residue Program's test results are not necessarily representative of the true situation with residues.

Limitations Exist in the Support Provided by Other Agencies

EPA and FDA are not able to provide all the information and assistance FSIS needs for the National Residue Program. For example, questions have been raised about the health and environmental effects of many of the pesticides previously approved by EPA, as well as about the regulatory limits set for their residues in foods—including meat and poultry. Although EPA is reevaluating these pesticide products on the basis of current scientific standards, EPA estimates that it will take until 2006 to finish the reregistration process. Also, because of limited resources, FDA investigated only about 20 percent of the 21,439 violations reported to it by FSIS from 1989 through 1992. Only one prosecution resulted from these investigations.

An Alternative Regulatory Approach Might Prove More Effective

Rather than rely on the present federal system of testing end products, some sectors of the meat and poultry industry have integrated residue prevention, detection, and control programs as a quality control function at critical points throughout their production processes. These process-oriented, risk-based systems are designed to guard against potentially hazardous residues in products from the farm through the

slaughterhouse. FSIS recognizes the value of this approach and now intends to incorporate it into the federal meat and poultry inspection program. However, it is currently uncertain whether FSIS would retain the responsibility for day-to-day residue detection. Alternatively, FSIS could delegate this responsibility to industry and adopt an oversight role, much as FDA has done in regulating canning operations for low-acid foods. Although FDA conducts limited testing and reviews program records, the canning industry is responsible for day-to-day testing and for otherwise ensuring that the canning methods used prevent contamination from the bacterium that causes botulism.

Recommendations

While improvements to the National Residue Program could incrementally increase its effectiveness, GAO believes that fundamental changes to the basic regulatory approach now used are needed. GAO believes that a risk-based approach, established by industry with FSIS' assistance and oversight, and operated by industry with FSIS' monitoring, would be a more effective alternative. However, such a fundamental change requires congressional approval before it can be implemented. To strengthen the existing program in the interim, GAO makes recommendations to the Secretary of Agriculture in the areas of compound selection, sampling, testing, and reporting. (See ch. 2.)

Matters for Congressional Consideration

An industry-operated, risk-based system that integrates residue prevention, detection, and quality control from the farm through the slaughterhouse, established with FSIS' assistance and oversight, would be more effective than the current federal program. Therefore, the Congress may wish to direct FSIS to adopt such an approach while maintaining an oversight role to monitor the effectiveness of industry programs. To ensure that FSIS could effectively carry out these responsibilities, the Congress may also wish to provide FSIS with additional access to industry records and enforcement authority.

Agency Comments

GAO obtained written comments on a draft of this report from USDA, HHS, and EPA. GAO also obtained the views of officials from two industry trade groups that collectively represent over 80 percent of the meat and poultry industry. All three agencies and the industry trade groups fundamentally agreed that a process-oriented, risk-based approach that tries to prevent residue problems from occurring would be more effective than the current system that relies on limited testing of end products to detect residues

after the fact. USDA disagreed with GAO's conclusion on the reliability of the current program, stating that for individual animal species and compounds, the results may be reliable. However, GAO's main point was that since their actual reliability is unknown, these results should not be aggregated in a manner that suggests they are representative of the entire meat and poultry supply. USDA agreed on this point. HHS stated that the report took a narrow view of FDA's enforcement actions and cited the use of injunctions against repeat violators as an example of its preferred approach. GAO disagrees with HHS on this point because FDA's own data show that few investigations are actually done and that only 12 injunctions were obtained in 4 years even though almost 2,300 repeat violators were reported during that period. Changes were made throughout the report in response to technical comments provided by all three agencies. In addition, the agencies' comments are presented in their entirety, along with GAO's responses, in appendixes II, III, and IV. Industry endorsed the use of a process-oriented, risk-based system and noted that it was already moving in this direction. Industry's views are discussed in chapter 4.

Contents

Table

Abbreviations

ARS	Agricultural Research Service
CES	Compound Evaluation System
CSRS	Cooperative State Research Service
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FSIS	Food Safety and Inspection Service
GATT	General Agreement on Tariffs and Trade
HACCP	Hazard Analysis and Critical Control Point
HHS	Department of Health and Human Services
NRP	National Residue Program
RVIS	Residue Violation Information System
USDA	U.S. Department of Agriculture

Introduction

Modern agricultural practices—including the use of chemical fertilizers, pesticides, and animal drugs—have enabled farmers to produce a domestic food supply that is abundant, diverse, and available to the consumer at relatively low cost. While beneficial in many ways, these practices may leave chemical residues on or in food. The safety of these residues has concerned consumers, especially during the last 5 years. Chemical issues generally fall below biological hazards, such as microbial contamination, when public health issues are ranked by experts. While the health effects of biological hazards are usually immediate and acute, chemical hazards may take a lifetime to manifest themselves as disease or may produce genetic changes in the next generation. Therefore, each is recognized as a separate and important source of potential public health problems and must be dealt with appropriately within the context of a risk-based food safety program.

The federal government expends considerable effort and resources each year on programs designed to monitor and control the levels of chemical residues in the nation's food supply.[1] In fiscal year 1992, the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) spent about $30 million on its National Residue Program (NRP), the principal federal effort to prevent contamination from chemical residues in meat and poultry. Chemical residues can get into meat and poultry when animals are exposed to environmental contaminants, pesticides, or animal drugs used to prevent or treat illnesses and/or promote growth.

The National Residue Program

Established in 1967, the NRP is designed to detect, measure, reduce, and prevent potentially harmful residue levels of drugs, pesticides, and other chemicals in meat and poultry products destined for human consumption. Under the program, samples of domestic and imported meat and poultry are collected at slaughtering establishments and ports of entry throughout the United States and are analyzed for residues of animal drugs, pesticides, and other chemical contaminants. Each year, the NRP's results are presented in FSIS' Domestic Residue Data Book and are reported to the Congress as part of USDA's annual report on meat and poultry inspection. In calendar year 1992, meat and poultry samples were tested for a total of 56 different chemical compounds, covering 14 classes of animal drugs and

[1]FSIS carries out its meat and poultry inspection responsibilities under the Federal Meat Inspection Act, as amended (21 U.S.C. 601 et seq.) and the Poultry Products Inspection Act, as amended (21 U.S.C. 451 et seq.). In addition, under the Talmadge-Aiken Act of 1962 (7 U.S.C. 450), states may opt to perform their own inspections of meat and poultry slaughtering and processing at plants within their own borders. Such state inspections are performed in accordance with federal standards by state employees under cooperative agreement with FSIS. These plants are considered to be federally inspected and therefore may sell their products in interstate commerce.

pesticides. Overall, a total of 373,990 domestic and 18,171 import residue analyses were performed.[2]

FSIS' Compound Evaluation System (CES) is the primary basis for the NRP. This system is used to determine (1) whether a compound is likely to produce a potentially hazardous residue in meat and poultry, (2) how great a hazard the residue might produce—on a scale from A (high) to D (low), and (3) how likely humans are to be exposed to the residue—on a scale from 1 (likely) to 4 (unlikely). A "Z" designation is assigned to either (or both) the hazard and the exposure category if there is insufficient information to rank a compound. FSIS developed the CES in 1985 to focus NRP resources on the most potentially important residue problems. FSIS' analysis of these factors is based, in part, on such information as scientific assessments and other data obtained from the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) in the Department of Health and Human Services (HHS), as well as from other USDA agencies.

The CES ranking serves two primary purposes. First, the ranking is used to set priorities for the compounds to be included in the NRP for testing. Second, the ranking is used to set priorities for the compounds that need to have tests developed. The compounds selected for testing in the monitoring portion of the program must (1) leave a detectable residue in meat and poultry, (2) have regulatory limits (tolerances) for the given residues in meat and poultry, (3) have a CES ranking, and (4) have suitable regulatory test methods for detecting, quantifying, and confirming the residues in question.

Under the monitoring portion of the NRP, tissue samples are to be selected randomly from healthy-looking animals during the slaughtering process. These tissue samples are analyzed for chemical residues, and the results are used to develop profiles for given animal species/populations and chemical compounds on a national, annual basis. Monitoring, however, is not designed to stop meat and poultry containing potentially hazardous residues from reaching the food supply. The products tested under this program normally pass on to market before their test results are known.

Although the monitoring program is not designed to stop meat and poultry with potentially hazardous residues, producers identified as residue

[2]The multiple-residue methods used by FSIS will generally provide test results for a number of compounds within the same chemical family. Therefore, the total number of analyses reported each year significantly exceeds the number of meat and poultry samples actually selected for testing under the NRP.

violators during monitoring must submit a sample of their animals (up to 15) for preclearance testing before any more can be offered for food purposes. FSIS will continue to require preclearance testing until it is satisfied that the violator has demonstrated compliance with residue standards. Also, as animals go through the slaughtering process, FSIS inspectors identify ill-looking animals and animals with drug injection marks for individual enforcement testing. These animals do not enter the food supply until the results of residue testing are known. Individual enforcement testing is also conducted on animal species with suspected or known residue problems. For example, young calves (known as bob calves) have a history of drug residue problems and are therefore sampled more intensively.

Violators identified in any testing component of the NRP are notified by FSIS of their violation by letter, and copies of these letters are sent to EPA, FDA, and the states. Depending on the nature/seriousness of the violations, EPA and FDA may initiate investigative action and implement regulatory or educational efforts of their own with identified violators. Information on violations is also entered into FSIS' automated Residue Violation Information System to assist FSIS in identifying repeat violators. FDA also has access to this system.

Coordination With Other Agencies

While primarily responsible for the NRP and its day-to-day operations, FSIS depends on other agencies to provide regulatory limits for residues of chemical compounds, information, and support for the NRP's efforts. For example, EPA is responsible for assessing the potential health and environmental effects of pesticides marketed for use in the United States under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136 et seq.), and for establishing allowable levels for their residues in foods—including meat and poultry—under the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301 et seq.). Similarly, as part of its responsibilities under the Federal Food, Drug, and Cosmetic Act, FDA ensures the accuracy and integrity of safety and effectiveness data submitted by animal drug sponsors and establishes tolerances (or other regulatory limits) for animal drug residues, as well as for environmental contaminants, in foods, including meat and poultry. FDA is also responsible for testing for residues in fruits, vegetables, and other foods (except meat and poultry) and for taking enforcement action against violators of established residue regulatory levels. FSIS uses the regulatory levels established by EPA and FDA as the standards against which it tests

meat and poultry for pesticide, animal drug, and other residues under the NRP.

EPA and FDA also assist FSIS in attempting to identify the chemical compounds in use whose residues may present hazards to consumers of meat and poultry. For instance, EPA and FDA participate in an annual Surveillance Advisory Team meeting during which chemical compounds are recommended for inclusion in the NRP. FDA also participates with FSIS in the Interagency Residue Control Group, which deals with residue issues in general, including animal drug residues in meat and poultry. Also, both EPA and FDA are parties to a Memorandum of Understanding with FSIS to coordinate regulatory activities on pesticide, animal drug, and environmental contaminant residues in foods.

Objectives, Scope, and Methodology

In connection with an ongoing investigation of chemical residues in the U.S. food supply, the Chairman, Human Resources and Intergovernmental Relations Subcommittee, House Committee on Government Operations, asked GAO to examine whether (1) FSIS' NRP can assure the public that the nation's meat and poultry supply is free of potentially hazardous chemical residues and (2) program assistance from EPA and FDA is adequate to support FSIS' NRP needs. Also, as agreed with the Chairman's office, GAO examined the value of a different regulatory approach—one that requires industry to have residue prevention, detection, and control programs that are monitored by the federal government.

To address these objectives, we interviewed and obtained documentation from USDA, EPA, and FDA officials. We reviewed legislation, policies, procedures, regulations, and agency documents on meat and poultry inspection, as well as past reports by USDA's Office of Inspector General, the National Research Council, the Office of Technology Assessment, and the Congressional Research Service. We also visited one FSIS area office, one FSIS regional office, and one FSIS laboratory to discuss their activities under the NRP, and eight meat and poultry plants across the nation to determine how residue samples were taken.

To determine the extent to which assurances can be made on the basis of the NRP's results, we interviewed program officials in FSIS and obtained documentation on the universe of chemical compounds of concern for meat and poultry; the process for identifying, setting priorities for, and selecting specific compounds from that universe for testing under the NRP; and the availability of acceptable test methods for detecting those

compounds and/or their chemical by-products in meat and poultry. We also discussed test method development needs and issues with FSIS, the Agricultural Research Service, and the Cooperative State Research Service within USDA, and FDA.

We used generally accepted statistical standards to assess the adequacy of the NRP's sample size, the randomness of the program's sample selection, and the limitations of the program's results. We also compared the compounds selected for testing in calendar years 1989 through 1992 and their respective priority rankings with the number and rankings of chemical residues of concern identified by FSIS.

To determine whether the information and support provided by EPA and FDA meets the NRP's needs, we reviewed the Memorandum of Understanding among USDA, EPA, and FDA on activities for regulating residues from pesticides, drugs, and environmental contaminants that may adulterate meat and poultry; minutes from the Interagency Residue Control Group and the Surveillance Advisory Team on the NRP's operations, and information on the actions taken by EPA and FDA in response to FSIS' residue violation referrals. We also interviewed FSIS, EPA, and FDA officials on the NRP's process for selecting chemical compounds, assessing their risks, and/or developing methods of testing for them.

We obtained information on industry programs from interviews with industry trade officials, conferences, trade journals, and other publications. We also interviewed officials from the American Meat Institute and the National Broiler Council to obtain industry views on the need for industry-led, risk-based Hazard Analysis and Critical Control Point (HACCP) systems for residue prevention and control, as well as on the associated roles of industry and government under such an approach. Together, these two organizations represent over 80 percent of the meat and poultry industry.

We obtained written comments on a draft of this report from USDA, EPA, and FDA. These comments were summarized and incorporated into the report as appropriate and are presented in their entirety, along with GAO's responses, in appendixes II, III, and IV. We performed our work between August 1992 and July 1994 in accordance with generally accepted government auditing standards.

National Residue Program Is Not Comprehensive and Is Flawed

The NRP's test results cannot reliably be used to assure the public that the meat and poultry supply is free of potentially hazardous residues for two major reasons. First, the NRP's testing is not comprehensive—only a relatively small number of the chemical compounds identified as capable of leaving residues in meat and poultry are tested for each year. Second, there are flaws in the NRP's sampling methodology and implementation that may bias the results obtained and reported for the compounds that are tested. As a result, the information that USDA reports to the Congress each year may not present an accurate picture of the extent to which potentially hazardous residues exist in the meat and poultry supply.

Most Compounds Identified as Capable of Leaving Residues in Meat and Poultry Are Not Tested

The NRP's testing is adversely affected by many problems and does not include most of the compounds identified by FSIS as capable of leaving residues in meat and poultry. Over two-thirds of these compounds have yet to be evaluated by FSIS under its Compound Evaluation System (CES) to determine (1) the degree of hazard they may present to consumers of meat and poultry and (2) the priority they should receive under the NRP either in testing for their presence or in developing test methods for them, if needed. At the same time, tests are not conducted for the residues of some high-priority compounds because acceptable tests do not exist. Furthermore, residues of animal drugs used in an extra-label[1] manner may not always be detected under the NRP. Finally, imported meat and poultry are not tested for residues of heavy metals or unapproved and/or banned compounds even though such residues may be present in them.

Ranking Process Is Backlogged

Under the NRP, compounds identified as having the potential to leave residues in meat and poultry are evaluated and prioritized by FSIS under the CES to determine the relative hazard and exposure threat they present to consumers of meat and poultry. Then the compounds are assigned rankings. The CES rankings are important because FSIS uses them to set priorities for selecting and testing specific residues under the NRP and to start developing tests for high-priority compounds if acceptable tests are not available.[2] However, although 367 compounds have been identified by FSIS as potentially presenting residue concerns for meat and poultry, 240

[1]The use of an animal drug in a manner other than that specified on the FDA-approved label is called an extra-label use and is a violation of the Federal Food, Drug, and Cosmetic Act.

[2]According to FSIS' criteria, compounds having CES rankings of A-1 through A-3, B-1, B-2, and C-1 are considered as "high priority" and are to be selected for NRP testing—or for test development if an acceptable method of testing for the compound does not exist.

(almost two-thirds) had not been evaluated and assigned hazard and exposure rankings under the CES as of the 1993 NRP plan.

The CES ranking effort has become backlogged because (1) ranking chemical compounds according to hazard and exposure potential is inherently difficult and time-consuming and (2) FSIS has not dedicated the resources needed to complete the ranking in a timely fashion. An FSIS official in the Residue Evaluation and Planning Division told us that it can take as long as 5 months to rank a compound under CES, depending on the volume and currency of the scientific information available. However, at the time of our review, only three FSIS personnel were assigned to perform the CES rankings. Only six compounds were ranked for the 1992 NRP and three for the 1993 NRP. FSIS also intends to develop CES rankings for two compounds that were dropped from testing after no violations were found for them in 5 consecutive years.

In written comments on this report, USDA questioned the importance of testing many of the compounds currently included in the list of compounds considered for NRP testing. According to USDA, there is considerable duplication in the list; many unranked compounds are detected by the multi-residue test methods used for other compounds; some of the compounds are indistinguishable from compounds that naturally occur in animals; and many of the unranked compounds are no longer of concern for various reasons. This contention is inconsistent with FSIS' expressed intention to increase the resources dedicated to the CES ranking process so that 10 compounds can be ranked each year. If USDA is correct, then the list needs to be updated to remove compounds that are no longer considered important and to add any new compounds that should be considered for ranking. FDA and EPA together approve about 30 new compounds each year, many of which have agricultural uses. As a result, even after updating the list, FSIS may still take many years to rank the remaining compounds on the list.

Lack of Test Methods Limits Testing for Compounds

According to FSIS, for the agency to select a compound for testing during NRP monitoring, FSIS must be able to reliably detect its residue in meat and poultry using a multiple-residue test method—a test capable of simultaneously detecting several residues within the same chemical family.[3] However, tests developed by compound producers/sponsors to meet EPA's or FDA's approval requirements usually detect only the residue

[3]To be selected for monitoring testing, a compound should also have an established tolerance or other regulatory limit, as well as a high-priority CES ranking.

of the compound for which they are seeking approval in the commodity on which the compound is to be used. In these cases, FSIS must modify the approved test or develop a new test that is acceptable and practical for use in testing for the compound during NRP monitoring.

FSIS officials said that test development is time-consuming and resource-intensive, sometimes taking 18 months or more to complete for each compound. FSIS officials told us that FSIS laboratories cannot quickly address all NRP test development needs because of resource constraints and competing priorities, such as analyzing compounds for the NRP, analyzing microbiological hazards for FSIS,[4] and reviewing the performance of and the scientific standards used by private laboratories under contract to FSIS.

However, despite the importance of test development and the scarcity of resources available to develop tests, laboratory resources available for the NRP are not always applied to the highest-priority needs. For instance, of the 48 compounds that FSIS ranked as having high priority for testing in the 1992 NRP, 12[5] did not have tests that FSIS considered acceptable or practical. However, although 27 compounds were recommended for test method development during the period from 1993 through 1998, only 2 are high priority. Of the remaining 25 compounds, none meets FSIS' priority criteria for test development, and 21 have not been ranked under the CES.

Residues From Some Extra-Label Drug Uses May Not Be Detected

Any use or intended use of an animal drug on a food-producing animal in a manner other than that specified on the FDA-approved label is considered an extra-label use and a violation of the Federal Food, Drug, and Cosmetic Act. Veterinarians and others resort to extra-label drug use in order to treat or prevent the suffering and death of animals when approved products and dosages have proven ineffective or simply do not exist for the medical problem at hand. Because FDA believes that in some cases extra-label use may be the only effective treatment, FDA allows the practice when it is performed under a veterinarian's care and steps are taken to ensure that unsafe residue levels do not result.

[4]FSIS does not have a routine, statistically based monitoring program to test raw meat and poultry for microbiological hazards at individual plants. However, in fiscal year 1993, FSIS established a program to test about 3,000 samples for microbiological pathogens in steers and heifers. This program, if implemented annually, could further constrain the laboratory resources available to the NRP.

[5]In commenting on this report, USDA indicated that after issuing the 1992 NRP, it developed tests for 2 of the 12 high-priority compounds, was attempting to develop tests for 3 others, and no longer considered 1 other compound a concern because FDA had revoked its use.

Studies have shown extra-label use to be widespread, frequently occurring without a veterinarian's involvement. As a result, the time needed to ensure the dissipation of potentially harmful residues from animals treated in an extra-label manner is often not determined or followed. Furthermore, as FDA stated in its January 1992 task force report on extra-label use, "to compile a list of drugs which might be used in an extra-label manner would encompass nearly all drugs currently being marketed."[6] FDA is concerned about extra-label use that goes beyond the parameters of its discretionary enforcement policy because such use could endanger public health by exposing consumers to residues that have not been shown to be safe.

Compounds are primarily selected for NRP monitoring on the basis of the residues that are likely to result from their approved uses. However, some extra-label uses are detected under NRP monitoring when multi-residue test methods detect the residues of compounds not approved for use in the species tested or when testing for a given compound is extended to an unapproved species. Extra-label uses are also detected when particular compounds are targeted for testing under NRP exploratory programs. However, unless FSIS knows what compounds are being used in an extra-label manner, as well as how, where, and when they are being used, and specifically tests for those uses, some extra-label residues are likely to go undetected. Such information is not readily available to FSIS. It is therefore unlikely that the current system of testing animals at the time of slaughter could ever completely ensure that all residues from the extra-label use of animal drugs are detected in meat and poultry.

Imported Products Are Not Tested for Some Potential Hazards

Each year about 4 to 6 percent of the U.S. meat and poultry supply is imported from other nations. FSIS requires the countries exporting meat and poultry to the United States to test their products for residues under programs that are at least equal to the U.S. program.[7] FSIS also "reinspects"

[6]Report of the Enforcement Task Force (Extra-Label Use), Department of Health and Human Services, FDA (Jan. 17, 1992).

[7]In order to export meat and poultry to the United States, foreign countries must have inspection/residue detection programs that, after review, are deemed by FSIS to be at least equal to those of the United States. As part of the effort to ensure this, FSIS requires exporting nations to provide information about their agricultural practices, chemical compounds used and tested for, and residue testing program results. FSIS personnel also visit exporting nations each year to review laboratory capabilities and procedures and sample and perform residue testing at ports of entry to the United States on imported meat and poultry. This testing is actually a "reinspection" of products that have already been inspected and passed by the foreign country. A recent U.S. Court of Appeals decision (992 F.2d 1359 (5th Cir., 1993)), which is to be reheard before the full court, concluded that, for the purposes of the Poultry Products Inspection Act, foreign countries must have programs that are identical to, rather than at least equal to, U.S. programs.

samples of imported meat and poultry for residues when these products enter the United States to monitor the effectiveness of foreign residue testing. These efforts, however, do not encompass all potentially hazardous residues that may be in imported meat and poultry because FSIS' testing is generally limited to the same compounds tested for in domestic meat and poultry under the NRP. Hence, unless included in domestic testing, FSIS' import testing does not include (1) pesticide and animal drug compounds used by foreign nations that are not approved for or are banned from use in the United States and (2) heavy metal residues that exporting nations have detected as a potential problem.

According to FSIS, foreign nations must identify compounds used in agricultural production, including those that are not approved for or are banned from use in the United States, as part of the initial certification process that enables them to export meat and poultry to the United States. However, rather than test imported meat for unapproved and banned compounds, FSIS reviews the residue testing programs, test methods, and other safeguards used by these countries, as well as the test results, and if it is satisfied with these programs, it relies on them to ensure that no residues of unapproved or banned compounds are present in the meat and poultry exported to the United States. FSIS personnel in the Foreign Programs Division also told us that it would be difficult to test imports for these residues because the internal organs used for such tests are generally not exported with the meat; despite efforts to keep abreast of the compounds being used, FSIS does not have complete knowledge of these compounds; and tests are not available to detect many of them. FSIS officials also told us that testing imported meat and poultry for residues of compounds other than those tested for domestically could cause international trade problems. According to these officials, if FSIS tested for and found residues of unapproved or banned compounds in imported shipments and rejected them, the same treatment could be applied to U.S. exports, which may contain compounds approved for use in the United States but not in other countries.

With regard to heavy metal residues, from at least 1989 through 1992, five of the largest meat and poultry exporting nations to the United States have periodically reported to FSIS that their domestic testing found heavy metal residues in excess of their domestic standards. However, FSIS does not routinely test domestic or imported products for heavy metal residues because no U.S. regulatory limits have been established for them in meat

and poultry,[8] and there is no official basis for testing or taking action on them.

Domestic meat and poultry have periodically been "surveyed" under the NRP for heavy metal residues, and an FSIS study of several types of heavy metal residues published in 1992 concluded that, with the possible exception of lead and cadmium, the need to establish regulatory limits for domestic meat and poultry was questionable.[9] Nevertheless, the health hazards of heavy metals such as lead and cadmium are well known. In fact, the United States has acted in other areas to prevent the ingestion of these residues, banning the use of lead in gasoline and drinking water systems and of cadmium compounds in pesticides.[10] Restrictions have also been placed on the use of lead in paint and on utensils used for food and drink.

As a result of our inquiries, FSIS asked FDA to review FSIS' past findings on some heavy metal residues and assist FSIS in setting regulatory limits for those residues in animal tissues, should FDA determine that such limits are needed.[11] According to an FDA Programs and Environmental Policy Division official, FDA is currently developing risk-assessment information for FSIS on the heavy metal residue data referred to it, as requested. This official also said that while FDA would provide guidance and assistance, the actual establishment of regulatory limits for these residues in meat and poultry was an FSIS risk-management responsibility. However, in commenting on this report, the Department of Health and Human Services (HHS) stated that FDA is responsible for establishing regulatory limits for heavy metal residues if such limits are needed. HHS also stated that FDA could set action levels for such residues by issuing compliance policy guides, rather than following the more time-consuming process that requires public notice and comment for regulatory limits established under

[8]Official tolerances have been established for arsenic residues in cattle, swine, horses, and poultry.

[9]"Chemical Contaminants Monitoring: Trace Metals in Edible Tissues of Livestock and Poultry," AOAC International Journal, Vol. 75, (Nov. 4, 1992).

[10]The use of lead-based paint is restricted/banned under the Lead-Based Paint Poisoning Prevention Act, as amended (42 U.S.C. 4821 et seq.). Leaded gasoline is banned under the Clean Air Act, as amended (42 U.S.C. 7545 (k)(2)(D)). The use of lead in public water systems is banned under the Safe Drinking Water Act, as amended (42 U.S.C. 300g et seq.). The use of cadmium compounds in pesticides for use on golf course fairways and home lawns was banned by EPA on Aug. 19, 1987 (52 F.R. 31076).

[11]Under the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301 et seq.), FDA is responsible for approving and verifying the safety and effectiveness of animal drugs and medicated feeds and for establishing tolerances or other regulatory safety levels for animal drug residues and environmental contaminants in foods, including meat and poultry. FDA is also responsible for investigating and taking enforcement action against those who violate the residue standards it sets.

the Administrative Procedures Act (5 U.S.C. 553). However, action levels are not legally binding and can, and have been, successfully challenged.

According to FSIS program documentation, the purpose of the import testing program is to provide an independent check to ensure that foreign residue detection and control efforts are operating effectively. Although FSIS officials state that imported meat and poultry would be difficult to test without the internal organs typically used for residue testing, FSIS is able to test imported meat and poultry for compounds included in the domestic testing program and occasionally finds violative residues as a result. However, because FSIS does not test for unapproved and/or banned compounds, it cannot independently ensure that meat and poultry exported to the United States by nations using such compounds contain no residues of these compounds—as required by law. Under the legislation governing federal responsibilities for ensuring food safety, any food, domestic or imported, that contains any residue of a compound that has been banned or whose safety has not been determined and approved by the United States is considered to be adulterated and cannot enter the food supply. Furthermore, without testing imported meat and poultry for the residues of unapproved and/or banned pesticides and animal drugs that exporting nations are using, as well as for the heavy metal residues identified as a potential problem, FSIS cannot independently ensure that potentially hazardous levels of these residues are not entering the domestic meat and poultry supply through imported products.

Sampling and Reporting Flaws

The monitoring portion of the NRP may not provide reliable information on the occurrence of residue violations in specific animal populations on an annual, national basis because the NRP's sampling practices and subsequent analyses do not always conform to accepted statistical standards. We identified several problems with the NRP sampling methodology: (1) random selection procedures are not consistently followed; (2) climatic/geographic and seasonal adjustments are not made for all affected species; and (3) similar sampling rates are not used for all the species and compounds tested, which may cause the violation rates calculated by FSIS to be skewed. These sampling problems, when considered as a whole, raise questions about the validity of the test results obtained through the NRP's monitoring. Moreover, the program results that FSIS annually reports to the Congress are misleading because test results that were obtained by using dissimilar sampling rates are averaged to calculate "overall" violation rates, import test results are omitted altogether, and each year's program results are contrasted, without a

consistent basis of comparison, to imply year-to-year differences in the overall violation rate found.

Sample Selection Is Not Consistently Random

According to our observations of the selection of tissue samples at several of the larger U.S. slaughtering plants, as well as follow-up discussions with FSIS inspectors, samples are not always selected randomly. When the selection is not random, or if the samples are selected at a predictable time, the producer or the slaughterhouse may be able to predetermine which animals will be sampled and thereby undermine the accuracy of the random selection test results.

Although some FSIS inspectors had procedures for collecting random samples, they did not always follow them because of their workload and/or personnel shortages. For example, at some plants samples were not collected within the time required by the random program; at other plants, sampling was predictable—only in the morning or in the afternoon. Also, some samples were selected on the basis of individual judgment rather than random procedures (i.e., an inspector randomly selected an animal lot but arbitrarily selected animals from the lot). In addition, random sampling did not always occur according to a plan because, in some cases, the plant was not slaughtering the species to be sampled within the scheduled period. Recognizing the problems associated with collecting random samples, FSIS gives inspectors at federally inspected plants 7 days from the date scheduled to take the sample; as long as the sample is taken within the planned 7-day period, it is considered timely.

FSIS officials acknowledge that to the extent that some samples are not selected randomly, or the time of sampling is predictable, test results could be biased for some locations at given times. However, they point out that the samples tested for the NRP are collected on all species slaughtered, at numerous plants, in all regions, all year long, and they question the degree to which these problems affect the NRP's results overall.

Climatic/Geographic and Seasonal Adjustments Are Not Made

The validity of the sampling results may be diminished because FSIS does not adjust its sampling plan for climatic/geographic variations in the use of some compounds or the seasonal slaughter of some species. Climatic/geographic and seasonal considerations can be important for some of the species tested by FSIS. For instance, animal deworming compounds are used more frequently in warmer seasons and regions of the country than in colder seasons and regions. In addition, slaughter rates

for some of the species sampled and tested under FSIS' NRP monitoring plan can vary significantly by season. Furthermore, the use of animal drugs to promote and maintain animal health may be at its greatest during peak slaughter seasons.

FSIS officials said that making climatic/geographic adjustments for all species would increase program costs, and they questioned whether such adjustments would provide any significant additional information about the population sampled. These officials also said that animals are sometimes brought to slaughter plants from various geographic regions, and it would therefore be difficult to adjust sampling rates to compensate for the climatic/geographic use of compounds. Also, USDA stated, in commenting on this report, that sampling adjustments are made for some species when officials believe that they are warranted by variations in seasonal slaughter rates. USDA stated that such adjustments are not made for species whose seasonal slaughter rates do not differ greatly. USDA recognized that this could cause a "slight bias" in the test results but stated that this possibility must be balanced against the need to stabilize laboratory workloads, generate and distribute necessary forms, and attend to other concerns.

Nevertheless, to the extent that sampling rates are not adjusted to compensate for these factors, an overrepresentation of samples from off-seasons and an underrepresentation of samples from peak seasons can distort the test results for the species sampled.[12]

Small Sample Sizes and Different Sampling Rates May Skew Test Results

The sampling plan for the monitoring portion of the NRP does not ensure that FSIS can detect residue violations for all species tested with the same degree of reliability.[13] For example, FSIS generally tested enough samples of heavily slaughtered (major) species, such as beef cattle, to be 95-percent confident that residues in excess of established regulatory limits would be detected if they existed in 1 percent or more of the animals slaughtered. However, FSIS generally tested too few samples of less commonly slaughtered (minor) species, such as geese, to detect a residue problem with this same degree of confidence.

[12]The need to adjust meat and poultry sampling rates for seasonal and geographic factors was discussed in Food Safety and Inspection Service Meat and Poultry Inspection (MPI) Program, USDA, Office of Inspector General (38607-1-At, 1986).

[13]FSIS' random sampling program is designed to provide a 95-percent probability that at least one residue violation will be detected when 1 percent or more of the animal population sampled exceeds established regulatory limits. Exceptions are made for minor species.

In addition, when testing for a given compound, FSIS did not select samples at the same rate for each of the animal species tested. Also, it did not select samples to test for different compounds in the same animal species at the same rates. Consequently, the test results obtained may contain large sampling errors for the compounds and species tested.

Reporting of NRP Data

In reporting the NRP's domestic test results, FSIS combines and averages the test data it obtains on compounds from different species. In doing this, FSIS ignores differences in the sampling rates used for each compound/species pair. This approach is not methodologically sound and may bias the estimated violation rate. For example, as part of the NRP's monitoring for 1992, FSIS tested 294 bob calves and 256 sows for the presence of nine specific antibiotic residues and found four and zero violative samples, respectively (a 1.36-percent violation rate for bob calves and a 0.00-percent violation rate for sows). Under FSIS' methodology, the 1.36-percent violation rate is significant—a 1.00-percent violation rate indicates, at the 95-percent confidence level, that a residue problem exists in at least 1.00 percent of the population sampled. However, under FSIS' procedure, the "overall" violation rate for these two species is only 0.73 percent—less than significant. By averaging test results for the two species, the violation rate for bob calves is reduced, the rates for sows is increased, and the existence of an antibiotic residue problem for bob calves is masked. In fact, using this procedure, FSIS reported that it found an overall violation rate of 0.42 percent for antibiotic residues under its 1992 NRP monitoring program. However, results for nine antibiotics tested actually included violation rates as high as 1.36 percent for bob calves and 1.83 percent for market hogs.

Furthermore, residue problems disguised by potentially biased results are compounded when yearly residue data are used to determine an overall violation rate, which is then compared with previous years' data in order to imply a change in the overall violation rate found. By ignoring differences in the sampling rates used for each compound/species pair, FSIS calculates a potentially biased estimate of the overall yearly violation rate. Also, FSIS does not sample each compound/species at the same rate each year, so each year's result could be biased in a different direction. Therefore, FSIS has no statistically valid basis for comparing overall violation rates from one year to the other.

Finally, the results of testing imported meat and poultry are not included in program results, even though these foreign products constitute 4 to

6 percent of the U.S. meat and poultry supply and are tested for residues in the same way as domestic meat and poultry products are.

Using its annual test results, FSIS has made public statements suggesting that the incidence of potentially hazardous chemical residues in the meat and poultry supply are declining. For example, in its first briefing on NRP operations, FSIS reported that only 0.30 percent of the samples tested in its 1990 monitoring program showed illegal residue levels and that fewer violations were being found every year. Again, in a similar public briefing in June 1992, FSIS reported that only 0.26 percent of the samples tested in its 1991 monitoring program showed illegal residues, versus 0.30 percent in 1990, and stated that "the trend for the overall violation rate continues downward. We are moving ever closer to our goal of zero illegal residues in meat and poultry." In its 1992 report to the Congress, FSIS again stated that, for 1991, NRP monitoring had found residue violations in only 0.26 percent of the samples tested versus the 0.30 percent found in 1990. Given the problems discussed above, the data on which these statements were based are questionable. Furthermore, FSIS program officials agree that NRP monitoring data cannot be used to estimate the overall incidence of violative residues in the meat and poultry supply.

Conclusions

FSIS' ability to ensure that the most serious compounds of concern are being targeted and detected under the NRP is impaired by problems in several critical program areas. The majority of the chemical residues identified as being of potential concern to consumers of meat and poultry have yet to be ranked for testing and may not be ranked for many years, given the level of resources currently planned for this task. Also, lack of adherence to the NRP's established priority system further weakens the program because it causes scarce resources for testing and test development to be spent on compounds of questionable significance.

Furthermore, FSIS can do more to ensure that imported meat and poultry, which annually constitute about 4 to 6 percent of the U.S. meat and poultry supply, are free of the potential problem residues identified by exporting countries. In addition, shortcomings in the procedures used to sample meat and poultry, as well as the omission of test results obtained for foreign products, jeopardize the reliability of the program's results. While FSIS has used the NRP monitoring data to imply that there is a downward trend in the presence of potentially hazardous residue levels, program officials agree that the data cannot be used for that purpose.

We believe that fundamental changes need to be made to the basic regulatory approach now used by FSIS to ensure that potentially hazardous chemical residues are not in the nation's meat and poultry supply. These changes are discussed in detail in chapter 4 of this report. However, these changes will require congressional approval before they can be implemented. In the interim, improvements in the problem areas identified could make the NRP somewhat more effective.

Recommendations

To strengthen the NRP, the Secretary of Agriculture should direct the Administrator of FSIS to

- update the listing of compounds considered for NRP testing to ensure that resources are not expended on inconsequential compounds;
- provide the resources necessary to complete the ranking of the updated listing of NRP compounds within a reasonable time frame and ensure that high-priority needs are addressed first when plans for testing and test development are formulated for the NRP;
- modify port-of-entry residue testing for imported meat and poultry to include residues that the domestic testing of the exporting nation has shown to have high violation rates (such as heavy metals), as well as the banned and unapproved compounds that the exporting nation identifies as being used domestically, or require that the exporting nation have programs to test specifically for such residues prior to shipment;
- strengthen the NRP methodology by ensuring that statistically valid random sampling procedures are adhered to when meat and poultry samples are selected for residue testing, the effects of climatic/geographic and seasonal factors on slaughter rates and compound use are considered for the species sampled, adequate sample sizes are used for all of the species and compounds tested, and the sampling rates used for each species/compound pair are taken into account when analyzing the results.

The Secretary should also ensure that NRP data are not reported as representative of the meat and poultry supply in general, or as indicative of trends in the occurrence of potentially harmful chemical residues in meat and poultry.

We also recommend that, if regulatory limits for heavy metal residues are found to be needed, the Secretary of HHS ensure that the Commissioner of FDA establish such limits.

Agency Comments and Our Response

USDA questioned the value of FSIS' continuing to list compounds identified as being of concern for meat and poultry because, among other reasons, the list is outdated. At the same time, however, FSIS intends to apply additional resources to speed up the ranking process. If the list is outdated, FSIS should consider updating the list before expending further resources on ranking compounds on the list. Accordingly, we have changed our position to recommend that USDA update the list of compounds as a needed first step in the process of ranking the remaining compounds in a reasonable time frame.

In commenting on our recommendation that HHS and USDA work together to determine the need and set standards for heavy metals, HHS took the position that FDA was solely responsible for establishing tolerances for heavy metal residues, if needed. We agree and have therefore addressed our recommendation to the Secretary of HHS.

Additional Support From Other Agencies Is Needed to Enhance the NRP's Effectiveness

FSIS depends on other agencies, both outside and within USDA, to carry out portions of the NRP. However, these agencies are not able to meet all of FSIS' needs. For example, FSIS relies on EPA's and FDA's assistance to identify compounds whose residues may be found in meat and poultry and to set regulatory limits for these residues. However, thousands of agricultural chemicals are in use worldwide; information on them and on the residues they leave is not always complete; and new products are continually being introduced. Also, health and other concerns have been raised about some of the older compounds previously approved for use by EPA and FDA, as well as about the regulatory limits set for their residues in foods—including meat and poultry. EPA estimates that its efforts to reevaluate pesticide compounds will not be completed until 2006.[1] Although FDA has reevaluated some older animal drug compounds, its efforts are hampered by resource constraints and competing agency priorities. FSIS also must rely on FDA to take enforcement action against violators identified through the NRP. However, other priorities and limited resources have restricted FDA's enforcement actions against residue violators as well. Finally, FSIS has not fully used USDA research agencies to meet its test method development needs for the NRP. Because of these problems, the NRP is not as effective as it might otherwise be in preventing chemical residues from entering the meat and poultry supply.

Potentially Hazardous Compounds May Not Be Identified

Thousands of chemical compounds are used in agricultural production worldwide, and new chemical compounds are introduced each year. Despite the efforts of FSIS, EPA, and FDA to identify and evaluate the safety of compounds in use,[2] information about the universe of chemical compounds that could contaminate the meat and poultry supply is not complete.[3] Also, less complete information is generally available about

[1]Pesticides: Pesticide Reregistration May Not Be Completed Until 2006 (GAO/RCED-93-94, May 21, 1993).

[2]In addition to several past and present contract arrangements with outside data sources to develop data bases for the identification of chemical compounds in agricultural use, EPA, FDA, and USDA personnel meet annually as members of the Surveillance Advisory Team to identify compounds of concern to meat and poultry. Also, the Interagency Residue Control Group, primarily hosted by FDA and USDA, meets monthly to discuss residues from compounds and other issues of concern associated with food-producing animals. The Pesticide Residue Method Group, comprising scientific/technical personnel from EPA, FDA, and USDA, also meets periodically throughout the year to discuss pesticide issues.

[3]Pesticides: Limited Testing Finds Few Exported Unregistered Pesticide Violations on Imported Food (GAO/RCED-94-1, Oct. 6, 1993); Pesticides: Status of FDA's Efforts to Improve Import Monitoring and Enforcement (GAO/T-RCED-93-55, June 6, 1993); Food Safety: Difficulties in Assessing Pesticide Risks and Benefits (GAO/T-RCED-92-33, Feb. 26, 1992); Food Safety and Quality: FDA Needs Stronger Controls Over the Approval Process for New Animal Drugs (GAO/RCED-92-63, Jan. 17, 1992); EPA's Pesticide Import Program, EPA, Office of Inspector General (E1E67-06-0068-81660, Aug. 16, 1988).

chemical compounds used in foreign nations that may directly or indirectly introduce residues to meat and poultry.

The safety of previously approved compounds may also be called into question by more recent scientific information. For instance, many of the pesticide compounds that EPA approved in the past for domestic food uses on the basis of older, less stringent scientific standards have not yet been fully evaluated according to today's standards for their potential to cause cancer, reproductive disorders, birth defects, and environmental damage. The Congress mandated time frames for EPA to reevaluate these older pesticides. While some progress has been made, EPA's efforts to reevaluate and reregister these pesticide compounds according to newer, more rigorous standards have been hampered by resource constraints, data gaps, and the arduous nature of the reregistration process itself. Currently, about 15,000 food-use pesticide products await reassessment and reregistration. Meanwhile, the use of these compounds and the regulatory residue limits established for them will continue, although knowledge of their health and environmental effects is incomplete. EPA's primary focus is therefore on completing the reregistration process.

Similarly, FDA officials told us that some of the animal drugs previously approved under older scientific standards should be reevaluated. However, since FDA does not have the resources necessary to perform reevaluation as a separate effort, these compounds are reevaluated when approval is sought to allow their use on additional species or to apply them in a different manner. These officials also stated that while some of these compounds are no longer commonly used, others still in use have not been reevaluated.

Limited Enforcement Actions May Not Deter Future Violations

According to FSIS officials, the agency is limited in its ability to ensure compliance with the program's requirements because it does not have the authority to investigate and take enforcement action at the farm level—responsibilities currently assigned primarily to FDA. Under its individual enforcement testing program, FSIS can require a producer identified as having marketed animals containing residues in excess of established regulatory limits to bring in a sample of animals for "preclearance" testing before the producer can sell any more animals for food. However, FSIS cannot go to the farm and select the animals itself to ensure that the sample is representative of the producer's herd. In fact, FSIS frequently cannot ensure that the sample came from the producer's herd at all.

FSIS relies on EPA[4] and FDA to investigate the causes of residue violations. FSIS sends copies of the notification letters it sends to violators to EPA, FDA, and state authorities—both EPA and FDA use cooperative agreements with the states to assist them in investigative/enforcement efforts.[5] FDA is also notified of the violations found by FSIS through shared access to the automated Residue Violation Information System (RVIS) data base. FDA is most heavily involved in taking action on these referrals because FDA is responsible for investigating how residue violations occur at the farm level. Also, most of the residue violations found and referred for investigation by FSIS each year are from animal drugs rather than pesticide compounds. In 1992, only 26 EPA-related violations were detected and reported to EPA, while 4,325 animals found to contain residues that exceeded regulatory limits were reported to FDA for investigation.[6]

According to FDA's Compliance Program Guidance Manual, FDA is to conduct on-farm investigations for

- first-time violators when (1) the residue levels reported greatly exceed established regulatory limits—i.e., 10 times the established tolerance, (2) unapproved drug residues are detected in food animals, (3) residue violations are detected in the NRP monitoring program, and (4) violative residue levels are detected for approved drugs that are considered to pose a high risk to human safety;
- repeat violations; and
- incidents reported under the Contamination Response System.[7]

An FDA compliance officer told us that, given existing resource constraints, priorities must be set for investigation and enforcement. Therefore, FDA

[4]Although EPA investigates instances when pesticides may have been misused, the agency has no responsibility for enforcing pesticide tolerances. Enforcement is carried out by FSIS, FDA, and the states.

[5]Under EPA-funded cooperative agreements, the states are primarily responsible for taking investigative/enforcement action(s) in response to pesticide use violations. State agencies also report special incidents involving pesticide violations to EPA's regional offices, which in turn report them to headquarters. In addition to state efforts, for calendar years 1989 through 1993, FSIS referred a total of 120 residue violations to EPA.

[6]EPA's figures are on a calendar year basis, while the figures reported to FDA are on a fiscal year basis.

[7]The Contamination Response System is designed to facilitate quick regulatory response to residues that indicate a widespread contamination problem may exist (i.e., accidental contamination of livestock feed with industrial chemicals).

first investigates repeat violators,[8] residue violations that greatly exceed established regulatory limits, and residue violations of certain drugs that are of particular concern. Other cases are investigated by FDA and the states if and when resources are available.

While we do not question FDA's setting of priorities, many important investigations may not be getting done. In a January 17, 1992, enforcement task force report,[9] FDA itself stated that

> Even though illegal tissue residues are a concern of very high priority to the Center, we are not able to accomplish nearly as much as we should in this program area. For example, USDA reported illegal drug residues in 6,607 animals sampled in FY 89 and in 6,180 animals sampled in FY 90. FDA and State resources combined were able to conduct follow-up investigations in only 1,282 and 1,125 cases respectively.

A comparison between the violations reported and investigated for each of these 2 years indicates that FDA and the states were able to perform follow-up investigations for fewer than 20 percent of the residue violations reported. In responding to the task force report, FDA's Director, Center for Veterinary Medicine, said that an increase in resources for FDA's investigative and enforcement activities was "desperately" needed, but the prospects for receiving these increased resources in fiscal year 1993 were "bleak" and the prospects for fiscal year 1994 were unimproved. As a result, FDA planned to conduct only 826 investigations in fiscal year 1993, although FSIS refers more than 4,000 residue-violative animals to FDA for investigation each year.

Furthermore, FDA has limited enforcement powers. For example, FDA cannot impose civil penalties for residue violations and, like most other federal agencies, must refer cases warranting injunction or criminal prosecution to the Department of Justice.[10] During this review, FDA officials expressed concern that Justice was reluctant to prosecute these cases. However, in commenting on the report draft, HHS stated that "in recent years" the Department of Justice has been supportive of FDA's residue injunction recommendations.

[8]FSIS' Guidelines for Regional Residue Officers define a repeat violator as someone who, on one or more occasions, presents animals for slaughter for food purposes, which contain violative tissue residue concentrations of drugs, pesticides, or other chemical residues, within 12 months following the issuance of a FSIS violation notification letter. Also, a repeat violation can occur with a closed or open case for different residue and/or slaughter class or species, within the designated 12 months.

[9]Report of the Enforcement Task Force (Extra-Label Use), HHS, FDA, Jan. 17, 1992.

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

Table 3.1 shows the number of (1) animals with residue violations reported to FDA from RVIS for fiscal years 1989 through 1992, (2) repeat violators, (3) investigations initiated by FDA, and (4) different types of regulatory actions taken. These data were obtained from FDA's Center for Veterinary Medicine, Office of Surveillance and Compliance.

Table 3.1: Residue Violations Reported to FDA and Regulatory Actions Taken, Fiscal Years 1989-92

Residue violations and actions taken	FY 1989	FY 1990	FY 1991	FY 1992	Total
Violative animals reported in RVIS[a]	6,607	6,180	4,327	4,325	21,439
Repeat violators[b]	681	840	517	236	2,274
Investigations[c]	1,283	1,240	868	1,100	4,491
Warning letters	85	100	102	96	383
Injunctions/consent decrees	1	0	2	9	12
Citations	0	0	2	0	2
Prosecutions	0	0	1	0	1

[a]FDA generally bases investigations of violative animals on repeat violators and violations involving high residue levels.

[b]Starting in fiscal year 1991, the criteria were modified for identifying repeat violators—resulting in a decrease in the numbers reported.

[c]Fiscal year numbers may not include some investigations because of late reporting.

As table 3.1 shows, from fiscal years 1989 through 1992, there was only about a 20-percent chance overall that a residue violation referral would be investigated (4,491 investigations out of 21,439 referrals) and there was less than a 9-percent chance that a regulatory action would follow an investigation (398 regulatory actions out of 4,491 investigations). The data also show that if FDA did take action, there was better than a 96-percent chance overall that it would issue a regulatory warning letter (383 warning letters out of 398 regulatory actions). Thus, FDA tends to rely on issuing warning letters to residue violators. However, warning letters carry no penalties. Consequently, chronic violators can, and do, continue to sell contaminated animals without fear of penalty. In fact, FDA's data show that despite 2,274 repeat violations over the 4-year period, only 12 injunctions/consent decrees, 2 citations, and 1 prosecution were obtained against violators for the entire 4-year period.

Better Use of Other USDA Research Agencies Could Enhance Test Development for the NRP

According to FSIS officials, FSIS laboratories cannot meet all of the NRP's needs for test methods in a timely fashion because of resource constraints and competing priorities. These officials said that FSIS laboratories must also respond to a host of other requirements, such as performing analyses to support FSIS' chemical and microbiological testing programs and the certification of contract laboratories.

Although FSIS laboratories may be unable to meet the NRP's needs for test methods, additional research and development capability exists within USDA's Agricultural Research Service (ARS) and Cooperative State Research Service (CSRS).[11] However, FSIS has made little use of these additional resources to meet the NRP's needs for test development.

According to FSIS officials, ARS assists in developing test methods for the NRP by developing analytical methods for specific compounds and developing new technologies and methodologies that FSIS can use to develop multi-residue tests or apply to specific compounds.

However, for fiscal years 1989 through 1992, FSIS requested ARS to undertake only three projects on method development—all of which were still ongoing as of December 1993. Only one of these projects was for the actual development of test methods and involved two compounds. Furthermore, CSRS officials could not recall any instances when FSIS had asked them to develop test methods.

Agency Comments and Our Response

In commenting on a draft of this report, HHS said that informal activities, such as educational visits to violative producers, are frequently more effective than taking official regulatory action. HHS also said that, in other cases, warning letters were usually sufficient to correct a problem and cited a decline in the number of repeat violators as evidence to support this comment. We agree that educational efforts can be effective in gaining compliance. However, we do not agree that a decline in the number of repeat violators can be used as evidence of the effectiveness of issuing warning letters. This decline is a function of changes made in 1991 in the criteria for identifying repeat violators that excluded middlemen with trace-back systems from being counted as repeat violators.

HHS also commented that we were inaccurate in concluding from FDA's data that FDA investigates only a small number of the residue violations

[11]The current administration proposes combining the CSRS, ARS, the Extension Service, and the National Agricultural Library under the Agricultural Research and Education Service.

referred to it each year because several related violations may be covered by one investigation. This assertion may or may not be accurate; FDA was unable to provide data to support its claim.

An Integrated, Risk-Based Approach to Residue Prevention Would Better Ensure Food Safety

Even if FSIS corrected the NRP deficiencies previously discussed in this report, the program would still be faced with a fundamental difficulty under its current approach: reliance on testing thousands of end products at slaughter to ensure the residue safety of meat and poultry. Federal regulatory agencies, the food industry, and the international community have recognized that systemwide, risk-based, preventive approaches would do more to ensure food safety and are beginning to move in that direction. One such approach that has gained widespread acceptance is known as the Hazard Analysis and Critical Control Point (HACCP) system. This system employs scientific, risk-based principles to prevent, detect, and control various food safety hazards, including residues, throughout the entire production process.

FSIS is currently working with industry and others to design a risk-based HACCP system approach to ensure safer meat and poultry. At this time, FSIS has not decided on the roles and responsibilities for government and industry in detecting and controlling residues. Consumer groups' concerns about food safety and industry's concerns about additional government regulation under the new program also have to be addressed.

Current Approach Is Increasingly Infeasible

Currently, FSIS relies heavily on the day-to-day testing of meat and poultry products prior to retail marketing to ensure that they are free of potentially hazardous residues. But the effectiveness of this reactive approach is questionable, given the magnitude of the meat and poultry supply, the hundreds of chemical compounds of concern that need to be tested for, and the comparatively limited number and variety of tests that FSIS can perform by itself. Furthermore, the usefulness of this approach is likely to diminish even more because FSIS' current resources cannot keep pace with the industry's growth. For example, in line with federal initiatives to control spending, FSIS' staff resources have remained relatively constant since 1981. However, poultry production has continued to increase at 4 percent each year and is expected to continue to do so for at least the next several years. New chemical compounds also continue to enter the agricultural marketplace each year, adding to FSIS' already backlogged compound assessment, test development, and testing needs.

Risk-Based Approach Is Gaining Acceptance

There is a growing recognition that to more effectively guard against the potential hazards in today's food supply, inspection and testing programs need to be (1) based on scientific risk assessments and (2) integrated throughout the production cycle. In 1985, the National Academy of

Sciences recommended that risk-based inspection and testing be incorporated into the meat and poultry production cycle.[1] In June 1992, GAO reported that a uniform, risk-based inspection system was needed to ensure the safety of the food supply.[2] The HACCP system approach, developed in the 1960s, incorporates risk-based principles and is used by many in the meat and poultry industry. While the HACCP system's advantages and disadvantages are still debated, the approach is supported by the major trading partners of the United States under the General Agreement on Tariffs and Trade (GATT).

A Widely Accepted Scientific, Risk-Based Inspection System Originated in the 1960s

One scientific, risk-based approach to controlling microbiological, physical, and chemical residue food safety hazards—known as the HACCP system—has gained widespread acceptance by federal food safety agencies, many sectors of the domestic food industry, and the international community. The HACCP system approach evolved from Modes of Failure concepts designed to provide "absolutely" safe food for the 1960s manned space flight program. A major food processor successfully used the concept to fulfill its space program contract and subsequently adopted the HACCP system approach for use in all of its food operations. HACCP systems have since been established by other major food processors and retailers.

Under the HACCP system approach, producers and processors are responsible for designing and operating risk-based quality control systems for avoiding and/or detecting the presence of identified hazards and for meeting the established compliance criteria set for them throughout the production process. First, potential food safety hazards and critical points in the production process for controlling them are identified. Second, methods to control the identified hazards are developed, and compliance criteria are established for these control points. Third, the control points are then monitored against the established criteria to ensure effective implementation. When a control point is determined to be ineffective, the process is stopped and corrective actions are taken. Fourth, monitoring results and corrective actions are documented.

HACCP System Approach Is Used by Many in the Meat and Poultry Sector

Meat and poultry trade associations have recommended the HACCP system approach and have made model HACCP plans available to their membership. While the HACCP system approach has not been universally

[1]Meat and Poultry Inspection: The Scientific Basis of the Nation's Program (Washington, D.C.: National Academy Press, 1985).

[2]Food Safety and Quality: Uniform, Risk-based Inspection System Needed to Ensure Safe Food Supply (GAO/RCED-92-152, June 26, 1992).

adopted, voluntary programs, such as the following, are now in use throughout substantial portions of the industry to prevent, detect, and control chemical residues:

- With the support of the National Cattlemen's Association, beef producers have introduced the Beef Quality Assurance Program. Originally used for residue avoidance, this program has grown to include national producer education programs that deal with many facets of the beef industry, including microbiological concerns.
- The National Pork Producers Council reports that farmers in their organization have voluntarily implemented HACCP programs to avoid residue problems with their animals.
- The National Turkey Federation sponsors the Chemical Residue Avoidance Program for turkey products. This program educates farmers about residues, including the sources of various residues and the critical points at which they are introduced into the production process; establishes good manufacturing practices to avoid introducing residues during production; and advises the industry to test its products for drug residues before the products enter the marketplace.

The federal government has also assisted the food industry in establishing risk-based HACCP system programs to control various food safety threats, as in the following instances:

- USDA's Animal and Plant Health Inspection Service has established voluntary risk-based programs with egg producers in order to control Salmonella enteritidis in egg-laying flocks.
- Since 1973, FDA has regulated the production of low-acid canned foods under a mandatory HACCP-based system. In this instance, the HACCP system approach was successfully employed by the canning industry to control contamination from Clostridium botulinum, the bacterium that causes botulism. Under the program, the industry established the risk-based quality control and testing procedures necessary to ensure that its product is processed according to government-approved good manufacturing practices. FDA reviews the industry's program records and conducts limited testing to ensure that the programs operate effectively.
- FSIS has entered into voluntary, HACCP-type joint agreements with some individual producers in order to control recurring antibiotic and environmental contaminant residue problems with their animals.

Two other federal initiatives are also under way. Specifically, FDA is establishing a mandatory, risk-based HACCP program with the seafood

industry in order to better ensure the safety and quality of its products.[3] FSIS is currently working with the domestic meat and poultry industry and others to design a scientific, risk-based HACCP-type approach for use in controlling microbiological pathogens, chemical residues, and physical hazards.

Advantages and Disadvantages of HACCP Systems Are Often Debated

The cost-effectiveness of risk-based programs such as HACCP has often been debated. Detailed training is required for the personnel involved, and concerns have been voiced that this approach requires higher staffing levels, increased recordkeeping, and higher costs. But according to companies with pre-existing quality control systems, the HACCP system approach does not require additional personnel because any additional monitoring tasks can be integrated into the existing quality control functions throughout the manufacturing process. Furthermore, while additional training and recordkeeping costs may be associated with the approach, the benefits that such training and increased documentation provide also need to be considered. Companies that have implemented HACCP programs report that they incur fewer production problems.

The detailed documentation compiled under HACCP systems is also available to attest to the quality and safety of a product, should the need arise. For example, in one instance, a major food producer with a HACCP system was able to avoid a nationwide recall of its product because detailed program records proved to the satisfaction of regulatory agencies that accusations of contamination were unfounded.

Moreover, in comparison with risk-based HACCP systems that more comprehensively attest to the residue safety of a product, the present system of federal testing by itself may be too limited to offset public concerns in a publicized residue incident. For example, despite federal statements attesting to the residue safety of its products, the apple industry incurred large marketplace losses when consumer groups and the media publicized health concerns about the chemical Alar and its approved use on apples. Without internal programs to comprehensively attest to the residue safety of their products, apple growers lost millions of dollars—whether or not the chemical had been used on their product.[4]

[3]The National Marine Fisheries Service has had a voluntary HACCP program with the seafood industry since July 29, 1992.

[4]The apple industry was subsequently provided with approximately $15 million in federal assistance to help offset the losses it suffered from the Alar incident. Ultimately, Alar was voluntarily removed from the market by the manufacturer.

Similarly, federal residue testing only encompasses a small portion of the meat and poultry supply, and despite federal efforts, chemical residues remain a high concern for consumers.[5] Yet the welfare of the meat and poultry industry depends upon the consuming public's confidence in its products. One member of the 1993 World Congress on Meat and Poultry Inspection emphasized this point:[6]

> I would like to emphasize here that residue control is indispensable, not just by reason of the possible direct risk to public health when applying undesired substances during the fattening period, but also because of the indirect risk of plummeting sales resulting from possible consumer boycotts.[7]

Finally, the use of risk-based HACCP systems is supported by GATT, a multilateral organization that establishes rules for international trade. The 115 nations that subscribe to GATT—including the United States—together account for nearly 90 percent of all world trade. Most of the largest markets for U.S. exports—Japan, Europe, and Canada—are moving toward risk-based HACCP inspection systems. Since comparable food safety inspection systems are required between trading partners, these scientific, risk-based systems may soon become essential in order to remain competitive in international trade.

To obtain industry views on the need for industry-led, risk-based HACCP systems for residue prevention and control, we interviewed the American Meat Institute's Senior Vice President for Regulatory Affairs and Inspection Service Director, as well as the Technical Adviser for the National Broiler Council. Together, these two organizations represent over 80 percent of the meat and poultry industry. In essence, the officials from these organizations endorsed the use of risk-based HACCP system programs for residue prevention, detection, and control from the farm to the table. They said that much of the industry has already implemented HACCP-type residue prevention programs without the government's assistance. In their view, industry is much more effective at designing and implementing HACCP programs to address residue prevention than is government. These officials believed that the federal role under an industry-led HACCP

[5]In a 1993 nationwide survey commissioned by Public Voice for Food and Health Policy, 92 percent of the respondents expressed concern over chemicals and pesticides used to grow food.

[6]The World Congress on Meat and Poultry Inspection was sponsored by FSIS and hosted by Texas A&M University and met on October 10-14, 1993, at College Station, Texas. The Congress included international regulatory officials, government and academic scientists, and representatives of professional, trade, and consumer organizations.

[7]C.C.J.M. van der Meijs, D.V.M., Director, Veterinary Service, Ministry of Agriculture, Nature Management and Fisheries, The Hague, The Netherlands.

approach should be limited to identifying, evaluating, and setting regulatory standards for compounds presenting health-based concerns; developing tests; monitoring the industry's residue prevention programs to verify the programs' effectiveness; and conducting compliance activities. They also believed that the government would require access to industry records in order to effectively monitor industry programs, but they emphasized that such access should be strictly limited to the records necessary to evaluate the effectiveness of the residue prevention, detection, and control programs implemented by the industry. We generally concur with these industry views, including the need to protect proprietary business data.

Roles and Responsibilities for Residue Detection and Control Under HACCP Have Yet to Be Decided

Although FSIS has begun to move toward a mandatory risk-based HACCP system approach for meat and poultry inspection, it is currently unclear whether (1) HACCP programs will include requirements for chemical residue testing and (2) the federal government or the industry will have the primary responsibility for day-to-day residue testing.

Concerns also exist about how the government will implement the HACCP concept to meet its regulatory responsibilities for meat and poultry. Government inspectors are concerned that the concept will be used to justify reductions in personnel. Consumer groups are also concerned about the government's implementation of the HACCP concept, but they favor a preventive, rather than the present reactive, system of control. Also, according to meat and poultry trade representatives, the industry is concerned that HACCP may become yet another layer of regulation, on top of current requirements.

These concerns might be addressed by developing a HACCP model based on FSIS' oversight approach for testing imported meat and poultry products. This oversight program relies on the exporting countries to ensure that exported products meet U.S. standards. FSIS verifies that the foreign residue programs are equivalent to the U.S. program and performs limited residue testing at ports of entry to ensure that the foreign programs are operating effectively. Although we believe that FSIS needs to improve its procedure for selecting compounds to be tested for under that program (see ch. 2), the basic approach to residue testing under the program appears sound. Such an approach could be adopted by FSIS for domestic meat and poultry under the HACCP concept. However, for such an approach to work, the risk-based HACCP concept would have to be implemented universally by the industry, and FSIS would need access to the industry's

residue prevention, detection, and control program records in order to ensure that the industry's actions are adequate. These requirements are similar to the access that FDA now has to the canning industry's records under the low-acid canned food program. FSIS may also need more comprehensive enforcement authority in order to strengthen its ability to ensure compliance with established residue limits, particularly at the farm level (see ch. 3).

Conclusions

Federal resources to prevent, detect, and control chemical residues in meat and poultry cannot keep pace with the industry's growth. At the same time, many sectors of the industry have recognized that it is in their own best interest to ensure the residue safety of their products and to document that safety. A risk-based approach to food safety appears to have widespread acceptance as the best means of achieving these goals. Concurrently, the federal government is moving toward a risk-based HACCP system approach for ensuring safer meat and poultry. While many questions about implementing this approach remain, the general structure and approach used by FSIS under its current program to monitor chemical residues in imported meat and poultry might be used for domestic meat and poultry as well.

Matters for Congressional Consideration

To improve the prevention, detection, and control of chemical residues in the domestic meat and poultry supply and more efficiently use scarce regulatory resources, the Congress may wish to consider

- requiring FSIS to establish scientific, risk-based HACCP systems with the industry for residue prevention, detection, and control;
- having FSIS shift the primary responsibility for day-to-day residue prevention, detection, and control to the industry; and
- requiring FSIS to adopt a regulatory oversight role designed to ensure the effectiveness of the industry's efforts.

As part of these deliberations, the Congress may wish to consider whether additional authority should be provided to facilitate FSIS' access to the industry's residue prevention, detection, and control program records and to enhance FSIS' enforcement powers against violators.

Agency Comments

USDA and EPA agreed that a process-oriented, risk-based system would be more effective than the current system in preventing residue problems

before they occur. While HHS did not specifically endorse this point of view in its comments, FDA has previously endorsed such a system and has recently adopted it for seafood processors under its jurisdiction and has recently proposed that all parts of the food industry have such systems.

Compounds Included in the NRP's Monitoring From 1988-92 With No Residue Violations for 3 or More Consecutive Years

Compound	CES ranking: Ranked high[a]	CES ranking: Ranked low	CES ranking: Not ranked	Number of consecutive years in NRP monitoring with no violations (1988-92)	Included in 1993 NRP monitoring plan[b]
Albendazole	A-2			5	
Aldicarb		A-4		3	
Aldrin	A-3			5	X
Benomyl and metabolite		B-3		4	
Carbadox	A-3			4	X
Carbaryl	B-2			5	
Carbofuran and metabolite		C-3		5	
Carbophenothion			X	5	X
Chlordane	A-2			4[c]	X
2-chloro-1-(2, 4, 5-tri-chlorophenyl) vinyl dimethyl phosphate (stirophos)			X	5	X
Cyano (3-phenoxyphenyl) methyl-4-chloro-a (methylethyl) benzeneacetate (fenvalerate)		D-3		3	
Cypermethrin		B-3		3	
Endosulfan			X	4	X
Endrin	A-3			5	X
Erythromycin			X	4	X
Fenbendazole		B-3		5[d]	
Flucythrinate			X	3	
HCB	A-3			5	X
Lindane	A-2			5	X
Linuron	A-3			4	X
Methoxychlor		D-4		5	X
Oxfendazole			X	5[d]	
PCB		A-4		5	X
Permethrin	B-2			3	
Phosalone			X	4	X
Ronnel			X	5	X
Sulfachloropyridazine			X	5	X
Sulfaethoxpyridazine			X	5	X
Thiabendazole	B-2			5[d]	
Toxaphene	A-2			5	X

(continued)

Compound	CES ranking			Number of consecutive years in NRP monitoring with no violations (1988-92)	Included in 1993 NRP monitoring plan[b]
	Ranked high[a]	Ranked low	Not ranked		
Tylosin		D-2		5	X
Total compounds in each category	**12**	**9**	**10**	**31**	**19**

[a]FSIS considers compounds with CES rankings of A-1 through A-3, B-1, B-2, and C-1 to be high priority.

[b]According to FSIS criteria, compounds for which no residue violations are found after 3 or more consecutive years of testing are candidates for rotation out of the NRP's monitoring.

[c]Three violations were found in 1992 under individual enforcement residue testing.

[d]The Benzimidazole family of compounds was removed from the 1993 monitoring plan because no residue violations were found for these compounds in 3 to 5 consecutive years of previous testing. However, at the insistence of FDA, FSIS plans to expend effort to rank Cambendazole, Oxfendazole, and Febantel (another Benzimidazole) under CES in 1993 and include the compounds in the NRP's 1994 monitoring testing.

Comments From the U.S. Department of Agriculture

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20250

August 29, 1994

Mr. John W. Harman
Director, Food and Agriculture Issues
Resources, Community, and Economic
Development Division
U.S. General Accounting Office
Washington, DC 20548

Dear Mr. Harman:

Thank you for the opportunity to comment on your draft report RCED-94-158, FOOD SAFETY: USDA's Role Under the National Residue Program Should Be Reevaluated. We have enclosed detailed suggestions for clarifying or correcting portions of the report. We take particular note of GAO's observations concerning the opportunity the HACCP initiative provides for reexamining the residue control programs.

Ultimately HACCP systems should extend from the farm to the table and include the full range of chemical hazards to food safety, as well as microbiological and physical hazards. USDA has adopted a coordinated approach that includes the Food Safety and Inspection Service and other agencies that are involved with food safety and pathogen reduction.

Sincerely,

Patricia Jensen
Acting Assistant Secretary
Marketing and Inspection Services

Enclosure

AN EQUAL OPPORTUNITY EMPLOYER

Comments on GAO's Draft Report
FOOD SAFETY: USDA's Role Under the National Residue Program Should Be Reevaluated
(RCED-94-158)

See comment 1.

Now on p. 3.

Page 4, Last Paragraph:

Exporting countries do not report to FSIS high numbers of heavy metal residue violations in their meat. What they do report is levels of heavy metals in liver and kidney tissues that sometimes exceed tolerances of the respective countries. The U.S. imports very few, if any kidneys from foreign countries.

See comment 2.

Now on p. 5.

Page 6, First Paragraph:

The residues are not necessarily hazardous. "Violative" is a better word.

See comment 3.

Now on p. 11.

Page 12, Lines 61, 62, and 63:

These statements apply to the monitoring program only.

See comment 4.

Now on p. 12.

Page 12, Line 85, and Page 13, Line 86:

The word "surveillance" should be replaced with the words "individual enforcement."

See comment 5.

Now on p. 15.

Page 17, First Paragraph:

The testing program is not intended to be comprehensive. The resources required to test for every compound that might leave a residue would be appallingly high. In addition, a review of the results of the NRP will reveal that few residues were detected even at levels well below tolerances. The results of testing for all possibilities would be no more fruitful.

See comment 6.

Now on p. 15.

Page 17, Second Paragraph:

The "list of potential compounds" is not a considered list, rather it is a compendium based on a 1979 GAO report and suggestions from consumer groups, industry, other regulatory agencies and the scientific literature. It is unreasonable to test for everything which could get into meat. Some compounds are not only unlikely to occur, or if they do occur, they would be in non-toxic concentrations.

Also see comments for **Page 4, Last Paragraph**.

See comment 7.

Now on pp. 15 and 16.

Page 18, First Paragraph:

This report overemphasizes the significance of the 367 compounds in the "Compounds Considered" list. This list is exactly what it

says and that is a list of compounds to be considered. There is tremendous duplication throughout the list of the same compounds but in different formulations. An example of this is arsenic. At least seven different formulations of arsenic exist in the list.

Multi-residue tests which are currently in use by FSIS will pick up many of the compounds in the list that are not ranked. Since we can already detect the presence of these compounds we don't want to waste resources to rank them. For example, we have a multi-residue test that will determine the presence of members of the beta lactam family. Amoxicillin and cloxacillin are members of this family that are on the list and not ranked.

Some of the compounds on the list such as follicle stimulating hormone are naturally synthesized in the body of animals and humans. They are also formulated by companies to treat different conditions in animals. It is impossible to develop a test to differentiate between naturally occurring and the administered types. It would be a waste of time to rank these compounds.

Some of the compounds on the list which were of concern at the time the list was developed are now not of concern because of various reasons. For example, many of the compounds in the list we now know will not cause residues in animals consequently we do not waste time ranking them. An example of this is most of your non-chlorinated organophosphates such as malathion. We feel that we have ranked and tested for most of the compounds on this list which are of concern from the public health standpoint. The compounds we are truly interested in from the public health standpoint will vary from year to year depending on current scientific information.

See comment 8.

Page 18, Second Paragraph, Second Sentence:

Now on p. 16.

The word "Branch" should be replaced by the word "Division."

See comment 9.

Page 18, Second Paragraph, Third Sentence:

Now on p. 16.

At this time there are only two reviewers available for CES evaluations and they are not available full time. Eleven compounds were ranked between June 1993 and February 1994. Some compounds are being reranked due to changes in agricultural production practices and in pesticide use. In the past, private contractors have been hired to rank some of the compounds. This is a very expensive process and current budget restrictions will not allow us to pursue this approach.

See comment 10.

Now on p. 16.

Page 18, Third Paragraph:

There is no intention to rank all of the compounds on this list. FSIS has been extremely open and above board. The list comprises compounds suggested from all sources. These sources are not necessarily scientifically trained or knowledgeable. We have considered eliminating the list since it is not as useful to us as it once was.

See comment 11.

Now on p. 16.

Page 19, Footnote:

This statement only applies to the monitoring program.

See comment 12.

Now on p. 17.

Page 20:

The Planning Branch (PB) develops not only the yearly monitoring and surveillance programs, but also makes recommendations for the development of methods to the Chemistry Division (CD). CD develops a response, and some negotiation between PB and CD (with input from the Technical Service Laboratories (TSL)) leads to the acceptance of a smaller number of methods development projects than either CD or PB would like. Obviously, competition for limited resources within FSIS/S&T is a major barrier to developing more chemical methods and increasing the coverage of the NRP.

The report mentions 12 out of 48 compounds having high priority for testing which FSIS does not have chemical methods to detect. The report does not mention the fact that FSIS does have methods for 36 compounds.

Concerning the 12 compounds not having test methods, alachlor is being tested for this year. Gentian violet was tested for last year. FSIS has been working on a multiresidue method for 2,4,-D and metabolites, 2,4,5-T, and Silvex without much success. Also EPA has revoked the registration for Silvex and 2,4,5-T. This should change their rankings but because of a shortage of personnel the two toxicologists have not had time to rerank them. EPA also has recently stated that they are not concerned about residues of 2,4,-D in meat and meat products. Furazolidone has had its use revoked by FDA so we are not concerned about it anymore. One of the reasons its use was revoked is that no chemical method was available to determine its metabolites in tissue.

Therefore it is evident that very few of the 48 compounds are left to consider for developing methods.

The report mentions a" 5-year plan to develop tests." This supposed 5-year plan is found in a document on file which states clearly what is included is a list of recommendations about method development needs during the next 5 years.

See comment 13.

Section deleted.

See comment 14.

Now on pp. 17 and 18.

Page 20, Last Paragraph:

These criteria apply only to the monitoring program.

Page 21:

This report appears to focus too heavily on the relationship between the availability of a multi-residue method (MRM) and whether a low ranking compound is in the NRP. Since MRM's are usually based on some important common chemical feature, the existence of an MRM permits the NRP to include additional (and lower CES-ranked) compounds in monitoring or surveillance programs. That is, information on these additional compounds is obtained at no additional cost because they are isolated and detected by the same method as is used for a compound with a high CES ranking.

The absence of a MRM does not preclude a compound's placement in the NRP. The NRP often includes compounds which can be detected only through use of a specific method.

Extralabel drug use is considered many times when planning testing programs. Frequently we test multiple species rather than just the species the drugs are approved in.

Extralabel drug use has been considered with tranquilizers. We have ranked compounds such as xylazine and acepromazine which are tranquilizers with suspected misuse and are developing a chemical method to detect their presence.

Another compound suspected of extralabel use is clenbuterol. It is not approved for use in the U.S. This compound is used in human medicine and is approved in other countries, such as Canada, for horses. There have been rumors of use in our show animals and there are reports of confirmed misuse in Europe and as well as human toxic reactions to residues in meat. FSIS is currently running an exploratory program for clenbuterol. Concomitantly, FSIS is reranking clenbuterol in order to evaluate new literature from the last three years. Concern about this compound is real since up to 1,000 consumers in the European community have had significant reactions to residues of this compound.

FSIS is also currently running an exploratory project looking for a drug called Berenil which we suspect of being used illegally in Puerto Rico.

See comment 15.

Now on pp. 18-20.

Page 24:

Foreign countries exporting to the U.S. are required to have their own residue testing and control programs. This includes the testing and/or control of compounds not approved for use in

See comment 16.

Now on pp. 21-25.

the U.S. FSIS officials travel to these countries to inspect their laboratories and residue control programs.

See comments for **Page 4, Line 99**.

Pages 26-30: (SAMPLING AND REPORTING FLAWS RAISE QUESTIONS ABOUT THE NRP's RESULTS)

Occasionally, inspectors will not be able to take scheduled samples because a plant has closed or is not slaughtering at the time of the request. There is no reason to assume that this type of nonresponse would bias the finding of violations in a meaningful way. It would affect the resulting confidence level of the results in a way that can be measured and reported, but it would not necessarily be a source of systematic bias.

Inspectors have been trained in the use of random sample procedures. Perhaps increased training emphasizing the importance of using random procedures in selection of samples would help to alleviate occasional lapses in implementation of the random sampling procedures. In the future, residue samples may be scheduled through PASS (a computerized scheduling system), which should increase the inspectors' ability to take samples at the requested times.

There is no evidence to indicate that occasional lapses by different inspectors at different times and locations over the entire population of plants leads to a systematic bias in sample results. In any case, the sampling methodology of random sampling is valid.

If GAO observed intentional manipulation of animals in the plants to bias results, then corrective action by FSIS should be a high priority. However, it is questionable whether plants have the ability to predict which animals have chemical residues. Also, for most species there are millions of animals and hundreds of firms - on any given day most firms have a very small chance of being selected for a monitoring residue sample. Even if an inspector tended to take samples at predictable times, would it be cost effective for firms to change the order of animals being slaughtered on a daily basis knowing the chances that any single animal being selected is almost zero? Would continuous manipulation of animals by the firm go unnoticed by inspectors?

The domestic monitoring sampling program is designed to do the following for each of specific species/compound pairs: to detect (with a predetermined level of confidence) in the specific species the presence (at predetermined levels) of the specific residue. The sampling was NOT designed to provide an overall

estimate of the national level of all chemical residues occurring in the meat and poultry supply. Nor was the sampling designed to provide estimates for individual species/compound pairs with specified levels of precision.

Within a species/compound pair, the results of the sampling may be considered as representative of that entire subpopulation (species) for the compound in question, since the sample selection procedure is designed to approximate the selection of a simple random sample of animals.

Geographical and/or seasonal patterns in use of compounds does not affect the validity of the sample design of the domestic monitoring program, given that the sample design is based on an objective of detection with a certain level of confidence, not maximizing the probability of detection.

Adjustments in the sample selection process are made for those species where it is felt that variation in slaughter due to season warrants this adjustment. The purpose of this adjustment is to equalize the probability of selection of samples over the year.

However, sample sizes are distributed evenly throughout the year for species whose seasonal production do not differ greatly. This could cause a slight bias, however this possibility must be balanced against such concerns as stabilizing laboratory workloads and scheduling the generation and distribution of forms.

For each species/compound combination a determination has been made as to the level of confidence desired and the level of detection desired. The sample size is based on these parameters. Usually the goal is to be at least 95 percent confident of detecting a violative residue in the sample if 1 percent or more of the species population is truly violative. These parameters will differ for some of the species/compound pairs, depending upon certain factors. For example, for some of the minor species, economic burden on the limited number of plants may be a consideration. This does affect the level of detection and/or the confidence level for such species/compound pairs. This design is intentional, so that limited resources can be placed into major areas of concern.

A design that would sample all species and compounds at the same "rate" is not necessary for the program to be statistically "valid." Indeed, such a design would not meet the current statistical objective of the domestic monitoring program.

It is realized that calculating violation "rates" across categories with different sampling rates would require weighing of the sample results. But, as stated previously, estimating

combined percentages of violations is not the purpose of the domestic monitoring program. It is unclear for what purpose such estimates could be used.

See comment 17.

Now on p. 24.

Page 30, Last Paragraph:

In the Domestic Residue Data Book - National Residue Program 1992, the data presented in the results section do not show rates. The number of tests and violatives are listed by residue grouping and species/production class. Totals are shown by residue grouping, and a cumulative total section is also presented in the report. The residue and cumulative totals should be used only as an indication of work load and should not be used to derive overall violation rates. This data should not be summed over either species or residues to arrive at an "overall" violation rate.

Species violation rates across residues should not be combined even if the sampling "rates" were the same for species. Also, an overall violation rate (across species and residues) should not be calculated and then compared to previous years.

On Page iii of the Domestic Residue Data Book - National Residue Program 1992, FSIS does indicate an overall sample violation rate and compares it with the sample rates of the previous 2 years. This rate is not presented as a statistical estimate of a population violation rate; however, it should be omitted, since it appears that it is being interpreted as such.

As pointed out in the GAO report, overall comparisons across years using monitoring results would not be valid for a number of reasons. An example would include the fact that the compounds, as well as species, may change from year to year.

In summary, only violation rates for each species/compound pair should be calculated. These are statistically valid estimates of the corresponding population rates. These individual rates could be compared across species, residues or years. For example: The violation rate for sulfonamides in 1992 markets hogs was .9 percent compared to .4 percent for sows. However, although it is valid to make statistical comparisons using these individual rates, the sample sizes might not be sufficient to detect small differences at low prevalence levels.

FSIS is not concerned with actual rates but uses the Monitoring Program to identify if potential residue problems exist. For example it makes little difference whether one, two or three violations are found in a slaughter class with a sample size of 300. What is critical is that the large population this sample represents would appear to have violations exceeding 1 percent.

See comment 18.

Now on pp. 25 and 26.

Page 32 - CONCLUSIONS:

Again, the primary purpose of the residue monitoring portion of the NRP is designed to detect whether selected residues are present in animals. If reporting national level estimates is desired, then the sample design of the domestic monitoring program would have to be reevaluated and modified accordingly at significant expense.

Currently, the Domestic Residue Data Book presents data summaries of the domestic monitoring program without any inclusion of statistical estimates of violation rates and accompanying confidence intervals for the species/compound pairs represented. Although the sampling was not designed with this purpose in mind, this information could be included in the report. This would involve a change in reporting, but not necessarily any change in sample design.

See comment 19.

Now on pp. 26 and 27.

Pages 33 and 34 - RECOMMENDATIONS:

See comments for **Pages 18; 28-29**.

See comment 20.

Now on p. 28.

Page 35:

Because FSIS' resources are limited, the Agricultural Research Service (ARS), has been used in the past to supplement FSIS' methods development capabilities. ARS usually is interested in basic rather than applied research, and methods development is considered to be applied research. More recently, ARS has focused on general technologies that may be applied by other researchers to the analysis of a specific compound or a class of compounds. That approach can have a broad impact on the development of methods developed within FSIS or on contract, but will require either a longer time-line or additional resources.

See comment 21.

Now on pp. 28 and 29.

Page 36:

See comments on Pages 18-24.

The report mentions that thousands of chemical compounds are used in agricultural production worldwide. Most of these chemicals are of no concern as far as causing residues in meat and poultry. This is because animals do not come into contact with them. An example of this would be an insecticide, such as Temephos, which is approved for use in citrus fruits only. Because animals are not fed citrus fruits the chances of them coming into contact with this insecticide would be remote.

The following are GAO's comments on the U.S. Department of Agriculture's (USDA) letter dated August 29, 1994.

GAO's Comments

1. The specific animal tissues (or other animal media) that are selected for use in residue testing are typically those identified as being the most likely to hold the greatest concentration of the specific residues being tested for, and/or those for which acceptable test methods are available. Typically, animal liver, kidney, fat, or muscle tissue is used. However, foreign nations may also test animal feces and urine, depending on the residue involved. No matter which test is conducted, the primary purpose of the test is to gauge, from the results obtained, the likely level of residue present in the main product of slaughter—the meat. Our point in the report is that although exporting countries have been finding, through their testing, heavy metal residues in excess of their regulatory standards and have been reporting these results to the Food Safety Inspection Service (FSIS), FSIS is not routinely testing the meat imported from these nations to determine whether any health-based concerns exist. We modified our report's language to clarify our point on this issue.

2. No change was made in response to this comment.

3. This statement was attributed to the monitoring program.

4. "Individual enforcement" was substituted for "surveillance," as suggested.

5. USDA states in its comments that testing under the National Residue Program (NRP) is not intended to be comprehensive and that expending the "appallingly high" resources required for such comprehensive testing would not be "fruitful." Nevertheless, statements made by FSIS and other USDA officials in briefings, press releases, and reports to the Congress have implied that this testing is comprehensive. GAO takes the position that the program's results cannot be used to provide an overall national estimate of all chemicals occurring in the meat and poultry supply, partly because the testing performed is not comprehensive. Accordingly, no change has been made to the report in response to these comments.

6. In its comments, USDA downplays the significance of FSIS' "list of compounds considered," stating that the list is more of a compendium than a considered list. USDA also states that it would be unreasonable to test for everything that could get into meat. GAO is not suggesting that FSIS

test for everything that could enter the meat and poultry supply. However, FSIS' list of compounds considered—or compendium—was compiled from the input of consumer groups, industry, other regulatory agencies and from scientific literature. While this list may require updating, it still serves as an important starting point for assessing relative residue concerns, identifying residues most likely to have the greatest impact on public health, and marshalling NRP resources for testing and developing test methods. No change has been made to the report in response to this comment.

7. USDA states that the report overemphasizes the significance of the 367 compounds in the "compounds considered" list. According to USDA, there is tremendous duplication in the list; many unranked compounds are detected by the multi-residue tests used for other ranked compounds and therefore it would be a waste of resources to rank them; some of the compounds listed are indistinguishable from those naturally occurring in animals; and many of the unranked compounds are no longer of concern for various reasons. USDA also believes that most of the compounds on the list that are of concern to public health have been ranked and tested. Further on, USDA discounts the scientific credibility of some sources contributing to the list and says that consideration has been given to eliminating the list altogether because of its present limited usefulness. Nevertheless, the need for an increase in resources to complete the ranking process for listed compounds was emphasized by FSIS officials throughout this review and in USDA's written comments on this report as well. Furthermore, resources are currently being expended by FSIS to rank compounds on the listing, and 21 compounds yet to be ranked have been recommended for test method development during the 1993-98 time frame. On the basis of USDA's statements, GAO concludes that FSIS could be expending scarce program resources on ranking and developing tests for inconsequential compounds. Accordingly, in addition to incorporating USDA's comments on this issue, GAO is recommending that FSIS update its listing of compounds considered before any additional resources are expended on compound ranking or associated test method development.

8. The word "Branch" was changed to "Division," as suggested.

9. See comment 7.

10. See comment 7.

11. This footnote has been attributed to the monitoring program, as suggested.

12. USDA's comments on the subsequent status of the 12 high-priority compounds referred to as not having test methods as of the 1992 plan have been summarized and footnoted in chapter 2 of the report. Also, information about the NRP's test method development plans for 1993-98 is now depicted as "recommended" in response to USDA's comments.

13. This section of the report was deleted in response to USDA's comments.

14. The section of the report describing the relationship between multi-residue test methods and the inclusion of low-ranked compounds in the NRP was deleted in response to comments provided by USDA.

As stated in the report, compounds are primarily selected for NRP monitoring testing on the basis of the residues that are likely to result from their approved uses. However, some extra-label uses are detected when the multi-residue methods used incidentally detect residues of compounds not approved for the animal species being tested, or when testing for a given compound family is extended to an unapproved species. Statements in the report were modified to clarify this point.

USDA's comments about extra-label use and the exploratory program essentially illustrate what is said in the report. Therefore, no change has been made to the report in response to this comment.

15. Information on the requirements to be met by foreign nations and on FSIS' Foreign Program Operations was brought forward in the report in response to this comment. See also comment 1.

16. GAO does not dispute the validity of random sampling methodology. However, unless sampling performed is truly random, the possibility for bias does exist. Also, while GAO agrees with USDA that the sampling performed in the monitoring program was not designed to provide an overall national estimate of all chemical residues occurring in the meat and poultry supply, FSIS has, in fact, implied that the sampling can be used to do just that when the information obtained is presented. No changes have been made to the report in response to these comments.

In addition, while the results obtained for a specific species/compound pair might be considered representative, without a calculation of the

sampling error the violation rate obtained might be misinterpreted. For instance, the violation rate calculated from a sample may imply that no residue problem exists for a specific species/compound pair, but when the sampling error involved is considered, there might not be enough information to really know. This is particularly relevant to "minor" species for which the sample size is usually small. Furthermore, GAO questions the value of sampling compound/species pairs for minor species for which, because of the small sample size, the probability of detecting a violation is quite small. No changes have been made to the report in response to these comments.

Unless the sampling design ensures that geographic areas and/or seasons are not under/overrepresented, the differences in compounds used across these areas, by season, may bias the results of the sampling. For instance, if sampling for a compound predominantly used during the summer is performed evenly throughout the year, the level of residues for that compound could be underestimated. In response to these comments, language was added to the report to clarify USDA's position on seasonal adjustments.

The manner in which FSIS reports information on violations implies that the agency is presenting an overall violation estimate. Furthermore, although USDA states that the purpose of an overall estimate is unclear, FSIS has, in fact, used this information to show overall violation trends. In our opinion, the different sampling rates used for each compound/species pair should either be weighted properly in arriving at the estimate or the estimate should not be reported at all. No changes have been made to the report in response to these comments.

17. USDA's comments in this area essentially agree with GAO's statements in the report. However, rate comparisons for species/compound pairs should only be done if sampling errors are taken into account. Specifically, using the example provided by USDA, one could conclude that the 0.4-percent violation rate for sows was about half that for market hogs. However, if sampling errors were taken into account, any differences between these rates might be impossible to detect. No changes to the report were necessary in response to these comments.

18. If desired, a national estimate could be calculated, given the current sampling design, with no appreciable additional expense, if the sampling results were properly weighted using the sampling rates for each species/compound pair. However, the estimate would be representative

only for the species/compound pairs that had a chance of being sampled. The inclusion of statistical estimates and confidence intervals would also prove useful, since most readers will tend to interpret sampling results as universe estimates. No changes to the report were necessary as a result of these comments.

19.USDA's comments have been addressed on the appropriate pages.

20. According to USDA, FSIS' own resources for test method development are limited. FSIS has therefore asked the Agricultural Research Service to assist it in meeting its test method development needs. However, additional test method development assistance might also be obtained from the Cooperative State Research Service, but FSIS has not requested such assistance. No changes to the report were required as a result of these comments.

21. USDA contends that "most" of the thousands of chemical compounds used in agricultural production worldwide do not normally present residue concerns for meat and poultry. However, as GAO points out, some compounds that may present such residue concerns may not be known because the knowledge base about them is incomplete. Furthermore, depending on the specific scientific properties of the compound and its ability to persist in the environment, the insecticide "Temephos" in FSIS' example could well pose a residue problem. For instance, in an effort to keep down undergrowth in the orchard, food-producing animals might be allowed to graze around and beneath the treated citrus trees. The animals would thereby consume grasses and other vegetation that have been coincidentally sprayed or have otherwise absorbed the insecticide, and residues of the compound might be present in the meat of these animals. No changes were made to the report as a result of these comments.

Comments From the Department of Health and Human Services

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

DEPARTMENT OF HEALTH & HUMAN SERVICES — Office of Inspector General

Washington, D.C. 20201

AUG 8 1994

Mr. John W. Harman
Director, Food and
Agriculture Issues
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Harman:

Enclosed are the Department's comments on your draft report, "Food Safety: USDA's Role Under the National Residue Program Should Be Reevaluated." The comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely yours,

Michael Mangano
for June Gibbs Brown
Inspector General

Enclosure

See comment 1.

Now on p. 4 and pp. 28-32.

DEPARTMENT OF HEALTH AND HUMAN SERVICES COMMENTS ON THE GENERAL ACCOUNTING OFFICE (GAO) DRAFT REPORT "FOOD SAFETY: USDA'S ROLE UNDER THE NATIONAL RESIDUE PROGRAM SHOULD BE REEVALUATED"

GENERAL COMMENTS

The Department has reviewed the draft report and has the following comments.

1. Regulatory Actions by the Food and Drug Administration

Throughout the report, (particularly on pages 5 and 32-34), the GAO takes a narrow view of regulatory actions, implying that the only effective action to take is prosecution. In fact, the Food and Drug Administration's (FDA) experience demonstrates that compliance with regulations may be effected through informal activities such as educational visits to the violative producer or in-plant sampling. Thus, many changes are effected before official action becomes necessary. If a situation does require official action, issuance of a warning letter to the producers of violative products is usually sufficient to correct a problem. It should be noted that the incidence of repeat offenders is steadily declining.

In many cases where warning letters are not effective, FDA may obtain an injunction against the offender. From a public health perspective, injunctions are a critical part of FDA's regulatory measures. In order to comply with the terms of the injunction, and avoid the possibility of a contempt-of-court action (or other action), the producer under injunction must adopt practices designed to ensure that the potential for continued residue violations are minimized.

The FDA monitors implementation of injunctions, which may remain in effect for many years. Injunction has been FDA's action of choice because of the need to stop, as quickly as possible, the practices that may put the public health at risk. It should be noted that in recent years the Department of Justice has been generally quite supportive of FDA's residue injunction recommendations and the FDA has had considerable success against repeat violators. The Department believes that chronic violators are learning that they cannot continue to sell contaminated animals without fear of penalty. The report should acknowledge the effective use of all regulatory tools available to FDA.

The report states that FDA investigated only a small number of violations reported by the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS). This is not accurate. The report compares the number of residues found by FSIS with the number of investigations carried out by FDA. The number of residues found does not correlate directly to the number of investigations since FDA may include several FSIS-reported residues in one investigation because it appears they may be related to the same causal incident. As frequently happens, several reported residue findings could have been caused by the same producer or a cluster of residue events associated closely in time so they would be treated by FDA as one investigation.

The report also suggests that the FSIS reports of violations all have an equal "chance" of being investigated by FDA. This is not the case. Because of FDA's limited resources, it has established criteria for determining which cases should be investigated. The criteria serve as a screening tool to help FDA make the best use of its resources, i.e., find and correct the most significant violations. This system works very well in conjunction with the States' investigation programs.

See comment 2.

2. FDA's Authorities on Residues in Animals

Now on pp. 20 and 21.

The report creates the impression that FDA does not have the authority to regulate. To the contrary, FDA has clear jurisdiction to regulate contaminants in food under sections 402, 406, 408, and 409 of the Food, Drug, and Cosmetics Act (FDCA). See 21 C.F.R. Part 109. Contaminants in certain species (particularly mercury in swordfish) have been regulated through the use of action levels under section 402(a)(1). Thus, FDA has the authority to address unsafe contaminants in meat and poultry.

Although FDA may take the route of notice and comment rulemaking with respect to chemical contaminants, the FDA is not limited to this procedure. FDA also can set informal action levels through the issuance of compliance policy guides. This procedure puts the industry on notice that FDA is prepared to take action against a product that has residues exceeding the action level. FDA used this approach in regulating mercury in swordfish and in regulating aflatoxins. Tolerances or safe concentrations for drug residues are published when new animal drug applications are approved pursuant to section 512 of the FDCA.

See comment 3.

Now on p. 27.

GAO RECOMMENDATION

We also recommend that, if regulatory limits for heavy metal residues are found to be required, the Secretaries of Agriculture and Health and Human Services determine, through their respective legal counsels, whether the establishment of these limits in meat and poultry is an FSIS or FDA responsibility, and ensure that these limits are established.

HHS COMMENT

We concur. We will be pleased to work with the Secretary of Agriculture to determine both the need for regulatory limits and who should have the responsibility if limits are found to be needed. It should be noted that regulatory limits have been set on a case-by-case basis when the need arose. This may remain the best approach for providing appropriate consumer protection without expending scarce resources unnecessarily.

TECHNICAL COMMENTS

See comment 4.

Now on p. 5.

1. Regarding "Matters for Congressional Consideration" on Page 7: The report does not make it clear that the statutes governing meat and poultry, the FDCA, the Meat Inspection Act, and the Poultry Inspection Act, are not coextensive. This can cause problems, when, for example, FDA is aware of drug use that results in residues that are illegal under the FDCA but not under the Meat Inspection Act. This needs to be clarified.

See comment 5.

Now on pp. 15 and 16.

2. Page 18, first sentence (and other portions of the report): This paragraph does not adequately distinguish between potential contaminants. It would be helpful to break out the 367 compounds of concern, showing the number in each category.

See comment 6.

Now on p. 18.

3. Page 22, the last sentence of the first full paragraph should be amended to read: "FDA is concerned about extra-label use that goes beyond the parameters of its discretionary enforcement policy because it could ..."

See comment 7.

Now on pp. 20 and 21.

4. Pages 25-26: The statements about FDA's legal authority to regulate contaminants in food are not correct. FDA has clear jurisdiction to regulate contaminants in food under sections 402, 406, 408, and 409 of the FDCA. FDA has also regulated contaminants such as heavy metals through action levels under section (402)(a)(1). The FDA is not required to go through notice and rulemaking procedures in setting action levels, which are then

announced through the issuances of compliance policy guides.

See comment 8.

5. Page 35, eighth sentence: This sentence is not correct. FDA has the responsibility for taking regulatory action, and needs assistance from FSIS rather than the reverse.

Now on p. 28.

See comment 9.

6. Page 40, first full paragraph, third sentence: This statement is not correct. As of the past few years, the Department of Justice has been generally quite supportive of FDA's residue enforcement recommendations.

Now on pp. 31 and 32.

See comment 10.

7. Page 47: The statement regarding the National Milk Producers Federation and the American Veterinary Medical Association is misleading. The producer groups have adopted quality assurance programs, but these programs are not what is commonly regarded as a Hazard Analysis and Critical Control Point based system. Additionally, multiresidue screening tests are generally not used at the farm to monitor specific drug residues in milk.

Section deleted.

See comment 11.

8. As GAO noted in its report, a 1992 FSIS study of several types of heavy metal residues concluded that, with the exception of lead and cadmium, the need to establish regulatory limits for domestic meat and poultry is questionable. Yet, there is a strong implication in the report that such limits are needed. It should be noted that most heavy metals, even lead, do not concentrate in the muscle of land animals. The comparison of FDA's program for testing imported dishes for lead contaminants with the program for testing meat (page 25) is inappropriate. The dishes often are glazed with a lead-based glaze which under conditions of home use can leach into food repeatedly with each use and thus expose consumers to unacceptable levels of lead in their diets. This is far more likely to occur than lead residues in muscle tissue becoming high enough to create a hazard to the consumer.

Now on p. 20.

Reports of heavy metal contamination in recent years made by USDA to FDA under the Contamination Response System have been very rare. However, when residue reports from FSIS under this system have been received, they are given high priority for assignments to the FDA field offices because residues of these contaminants may be indicative of a widespread problem. Rapid investigation into the cause and scope is essential and is carried out under procedures outlined in a Memorandum of Understanding in effect among the USDA/FSIS, the Environmental Protection Agency, and FDA that pertains to such residues.

The following are GAO's comments on the Department of Health and Human Services' (HHS) letter dated August 8, 1994.

GAO's Comments

1. GAO recognizes that, depending on the receptiveness of the violative producer, informal activities such as educational visits to violative producers (residue testing in slaughter plants is a USDA/FSIS responsibility) may at times offer an effective alternative to other regulatory options for ensuring future compliance with regulations. However, the point of the discussion here is that, in many cases, the investigation necessary to adequately make such a determination in the first place often does not take place because of resource constraints. Furthermore, GAO does not agree that the FSIS residue violation data referred to FDA each year can be used to make inferences about the effectiveness of warning letters or a decline in the number of repeat offenders. According to FDA documents, the criteria for identifying repeat violators were changed in 1991 and this change resulted in a decline in the number of repeat violators.

HHS also states that "in many cases where warning letters are not effective," an injunction may be obtained against an offender. In addition, HHS says that injunctions have been FDA's "action of choice," the Department of Justice has been generally supportive of FDA's residue injunction recommendations "in recent years," and FDA has had considerable success against repeat violators. However, data obtained from FDA's Center for Veterinary Medicine, Office of Surveillance and Compliance, show that from fiscal years 1989 through 1992, only 12 injunctions/consent decrees were obtained against residue violators, despite a reported total of 2,274 repeat violators during this same period. Also, during this review FDA personnel told GAO that the Department of Justice required "coaxing" in order to get it to accept residue cases for prosecution, and in the minutes of the September 24, 1992, Interagency Residue Control Group meeting, an attending FDA official was reported to have stated that some U.S. attorneys and the Department of Justice are reluctant to take residue violation cases. Therefore, while FDA's experience with Justice may well have improved, the above data indicate that such improvement is less than "several" years old.

HHS also maintains that GAO is "not accurate" in reporting that FDA investigates only a small number of the residue violations that FSIS refers to it each year. HHS says that several referrals can frequently be covered under one investigation if the same producer is involved and/or if the violations appear to be related to the same causal incident. While this

argument appears plausible, it conflicts with the statements and data that FDA itself presented in its 1992 enforcement task force report. In this report, FDA states "Even though illegal tissue residues are a concern of very high priority to the Center, we are not able to accomplish nearly as much as we should in this program area. For example, USDA reported illegal drug residues in 6,607 animals sampled in fiscal year 1989 and in 6,180 animals sampled in fiscal year 1990. FDA and state resources combined were able to conduct follow-up investigations in only 1,282 and 1,125 cases respectively." GAO based its statements on these same data, as well as on similar information obtained for fiscal years 1991 and 1992 from FDA's Center for Veterinary Medicine, Office of Surveillance and Compliance. In an effort to reconcile this issue, GAO again contacted FDA's Office of Surveillance and Compliance. However, personnel in that office were unable to provide reliable data supporting the fact that FDA's current reporting system substantially understates the number of residue referrals investigated by FDA. We were told that current reporting systems do not track information in the manner that would be required or that could otherwise be used to estimate how much of an understatement might be involved.

HHS' comments on FDA's investigative and enforcement activities and GAO's position on them were summarized and incorporated into the report. Also, since the effectiveness of FDA's enforcement activities is currently the subject of an ongoing GAO review, HHS' comments on FDA's investigative and enforcement activities were forwarded for consideration during that review.

However, GAO does not agree that the report suggests that all FSIS' residue violation referrals have an equal chance of being investigated by FDA. In fact, FDA's statements about the impact of resource constraints on investigative and enforcement activities, the consequent need to set priorities for investigative/enforcement activities, and the criteria used to set these priorities are all presented in the report. Accordingly, no change has been made to the report in response to these comments.

2. GAO clearly notes in the report that, according to provisions of the Federal Food, Drug, and Cosmetic Act, FDA is responsible for establishing regulatory safety levels for environmental contaminants in meat and poultry. Statements in the report depicting controversy over this responsibility and the applicability to the process of public notice and comment rulemaking procedures emanate directly from FDA and FSIS personnel. Furthermore, while FDA has used action levels to regulate

contaminants in certain species—i.e., mercury in swordfish and aflatoxins in milk, grain, and peanuts—action levels are not legally binding because they are not established through public notice and comment procedures under the Administrative Procedures Act (5 U.S.C. 553). The regulatory use of action levels can therefore become cumbersome if these levels are challenged, since in order to enforce compliance FDA must prove, in each case, that the residue levels found would clearly be injurious to public health if the commodity involved were consumed. Also, FDA's use of action levels for aflatoxin was successfully challenged in court, requiring FDA to begin the public notice and comment process in order to establish legally binding regulatory limits. This section of the report was revised to incorporate HHS' position on this issue, as well as GAO's responses to HHS' comments.

HHS also attests to FDA's authority (and therefore responsibility) for establishing heavy metal residue standards in meat and poultry. GAO has therefore modified the report's recommendation on this issue and addressed it solely to the Secretary of HHS.

3. This recommendation has been modified in response to HHS' comments and has been directed to the Secretary of HHS alone (see comment 2).

4. GAO was unable to obtain clarification from HHS on how this comment relates to the report's matters for congressional consideration. Therefore, no changes were made in response to this comment.

5. FSIS has questioned the usefulness of its present listing of compounds of concern and the importance of the compounds contained in this listing. GAO is therefore now recommending that FSIS update the listing before any additional program resources are used to rank compounds and/or develop test methods for them. Hence, a detailed breakout of the present listing of compounds would not be useful, and no change has been made to the report.

6. This statement was modified as suggested.

7. See comment 2.

8. This statement was revised to say "FSIS must rely on FDA to take enforcement action. . . ."

9. See comment 1.

10. References to the National Milk Producers Federation, the American Veterinary Medical Association, and the Beef Residue Prevention Protocol program were deleted from the report.

11. Documentation obtained from FSIS clearly shows that FSIS has been concerned since at least October 1990 about the possible need for a regulatory limit for lead residues in meat and poultry, and because of these concerns, it has recently requested FDA's assistance in determining the need for such a limit, as well as for limits for other heavy metal residues (also see comments 2 and 3). Accordingly, no change has been made to the report in response to these comments.

References to FDA's program for testing imported dishes for lead were deleted from the report.

As stated in the report, with the exception of arsenic, there are no domestic regulatory limits for heavy metals in meat and poultry, and FSIS does not routinely test meat and poultry for heavy metal residues. Thus, reports of such residues in meat and poultry are likely to be "rare." Accordingly, no change was made to the report in response to this comment.

Comments From the Environmental Protection Agency

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AUG 16 1994

OFFICE OF
ADMINISTRATION
AND RESOURCES
MANAGEMENT

Mr. John W. Harman
Director, Food and Agriculture Issues
Resources, Community and Economic Development Division
U. S. General Accounting Office
Washington, D. C. 20548

Dear Mr. Harman:

I appreciate the opportunity to review and comment on the GAO draft report entitled Food Safety: USDA's Role Under the National Residue Program Should Be Reevaluated (GAO/RCED-94-158). Under separate cover, EPA staff provided GAO with detailed comments for consideration when preparing the final report.

This report examines the effectiveness of the U. S. Department of Agriculture's National Residue Program. In the report, GAO concludes that a risk-based approach to food safety is the best way to prevent, detect, and control chemical residues. We concur with this conclusion.

Again, thank you for the opportunity to comment on the draft report. I look forward to receiving the final report.

Sincerely,

Jallyanne Harper

for Jonathan Z. Cannon
Assistant Administrator
and Chief Financial Officer

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The following are GAO's comments on the Environmental Protection Agency's (EPA) letter dated August 16, 1994.

GAO's Comments

1. Technical comments provided by EPA under separate cover were incorporated into the report, as appropriate.

Major Contributors to This Report

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