United States Government Accountability Office

Report to the Ranking Member, Subcommittee on Environment and the Economy, Committee on Energy and Commerce, House of Representatives

October 2014

FOOD SAFETY

FDA and USDA Should Strengthen Pesticide Residue Monitoring Programs and Further Disclose Monitoring Limitations

October 2014

FOOD SAFETY

FDA and USDA Should Strengthen Pesticide Residue Monitoring Programs and Further Disclose Monitoring Limitations

GAO Highlights

Highlights of GAO-15-38, a report to the Ranking Member, Subcommittee on Environment and the Economy, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

From 1970 to 2007, hundreds of millions of pounds of pesticides were applied annually to U.S. food crops to protect them from pests. To protect consumers, EPA sets standards—known as tolerances—for pesticide residues on foods. FSIS monitors meat, poultry, and processed egg products to ensure they do not violate EPA's tolerances, and FDA monitors other foods, including fruits and vegetables. AMS gathers annual residue data for highly consumed foods, although not for enforcement purposes.

GAO was asked to review federal oversight of pesticide residues in food. This report examines (1) what FDA data show with respect to pesticide residue violations in the foods that it regulates; (2) what FSIS data show with respect to pesticide residue violations in the foods that it regulates; and (3) what AMS data show with respect to pesticide residue levels in fruits and vegetables. For each agency, GAO examined limitations, if any, in the agencies' monitoring of foods for pesticide residues. GAO analyzed FDA, FSIS, and AMS pesticide residue data, including their reliability, reviewed agency methods for sampling foods for testing, and interviewed agency officials.

What GAO Recommends

GAO recommends that FDA improve its methodology and FDA and USDA disclose limitations in their monitoring and data collection efforts. FDA said it will consider methodological changes and will disclose limitations. USDA agreed with GAO's recommendations.

View GAO-15-38. For more information, contact John Neumann at (202) 512-3841 or neumannj@gao.gov.

What GAO Found

The Food and Drug Administration's (FDA) most recent data from 2008 through 2012 show that pesticide residue violation rates in 10 selected fruits and vegetables were low, but FDA's approach to monitoring for violations, which targets commodities it has identified as high risk, has limitations. Among other things, GAO found that FDA tests relatively few targeted (i.e., non-generalizable) samples for pesticide residues. For example, in 2012, FDA tested less than one-tenth of 1 percent of imported shipments. Further, FDA does not disclose in its annual monitoring reports that it does not test for several commonly used pesticides with an Environmental Protection Agency (EPA) established tolerance (the maximum amount of a pesticide residue that is allowed to remain on or in a food)—including glyphosate, the most used agricultural pesticide. Although FDA is not required by law to select particular commodities for sampling or test for specific pesticides, disclosing this limitation would help meet Office of Management and Budget (OMB) best practices for conducting and reporting data collection and help users of the reports interpret the data. Also, FDA does not use statistically valid methods consistent with OMB standards to collect national information on the incidence and level of pesticide residues. FDA officials said that it would be costly to calculate national estimates for the foods it regulates because it would require a large number of samples for a wide array of products, but did not provide documentation on the cost of doing so or an assessment of the trade-offs of doing less targeting and more random sampling. Limitations in FDA's methodology hamper its ability to determine the national incidence and level of pesticide residues in the foods it regulates, one of its stated objectives.

For domestic and imported meat, poultry, and processed egg products, the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service's (FSIS) most recent available data from 2000 through 2011 show the agency found a low rate of pesticide residue violations, but its data had limitations. Specifically, for this period, FSIS did not test meat, poultry, and processed egg products for all pesticides with established EPA tolerance levels. Like FDA, FSIS is not required by law to test the foods it samples for specific pesticides, but disclosing this limitation in annual reports would meet OMB reporting best practices. Since 2011, FSIS has increased the number of pesticides it has tested for and samples it has taken and engaged with EPA on changes to FSIS's monitoring program to better provide EPA with data it needs to assess the risks of pesticides.

The most recent data from USDA's Agricultural Marketing Service's (AMS) annual survey of highly consumed commodities, including fruits and vegetables, show that, from 1998 through 2012, pesticide residue detections varied by commodity and were generally well below tolerance levels. EPA and others praise AMS's data collection efforts as providing valuable information on the incidence and level of pesticide residues in foods. In addition, while the sampling methodology used by AMS in the Pesticide Data Program meets many of OMB's best practices for conducting and releasing information to the public concerning a data collection effort, it does not meet several others, such as some principles of probability sampling that are important for ensuring that the data the agency collects are nationally representative. As AMS does not disclose these limitations in its annual monitoring reports, users of the data may misinterpret information in these reports and draw erroneous conclusions based on the data.

Contents

Tables

Figures

Abbreviations

AMS	Agricultural Marketing Service
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FSIS	Food Safety and Inspection Service
HHS	Department of Health and Human Services
MOU	Memorandum of Understanding
OMB	Office of Management and Budget
PREDICT	Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting
USDA	U.S. Department of Agriculture

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
Washington, DC 20548

October 7, 2014

The Honorable Paul D. Tonko
Ranking Member
Subcommittee on Environment and the Economy
Committee on Energy and Commerce
House of Representatives

Dear Mr. Tonko:

The domestic and international farmers, ranchers, and other agricultural producers who contribute to the U.S. food supply often use insecticides, herbicides, or other pesticides to protect their products from insects, weeds, fungi, and other pests. In some instances, food producers may use multiple pesticides in sequence or simultaneously. The U.S. Environmental Protection Agency (EPA) estimated that domestic farmers used over 680 million pounds of pesticides for agricultural purposes in 2007, the latest year for which EPA has national data.[1] While pesticides can protect agricultural products from pests, pesticide residues that remain on food may also harm consumers. For example, residues may affect human nervous and endocrine systems or be carcinogenic. To reduce the risk of harm from exposure to pesticides, federal regulations establish acceptable levels of residue on and in foods, including animal feed.

Three federal agencies—EPA, the U.S. Department of Agriculture (USDA), and the Food and Drug Administration (FDA)—regulate various aspects of pesticide chemical residues (pesticide residues). EPA regulates the amount of pesticide residues that can remain on or in food or animal feed. Specifically, EPA sets tolerances—the maximum amount of a pesticide residue that is allowed to remain on or in a food. By law, residue of pesticides for which EPA has not set a tolerance, or an exemption from a tolerance, is considered unsafe and therefore prohibited in foods. Although EPA does not have the authority to enforce the tolerances it sets, it coordinates with USDA and FDA, which have enforcement authority, on which pesticides to include in their monitoring

[1]EPA collected data on pesticide usage from a combination of public and private sources. EPA officials said the agency has not published more recent data in part because it has not had funds to purchase data from private sources.

and enforcement programs. Under its National Residue Program, USDA's Food Safety and Inspection Service (FSIS) monitors meat, poultry, and processed egg products for pesticide residue and takes enforcement actions if it finds pesticide residues that exceed EPA tolerance levels.[2] FDA monitors pesticide residues, among other things, in foods it inspects, including fruits, vegetables, dairy products, seafood, and spices. FSIS's and FDA's jurisdiction and monitoring and enforcement activities extend to both domestic and imported foods. In addition, USDA's Agricultural Marketing Service (AMS) implements the Pesticide Data Program in conjunction with state agencies to survey, on an annual basis, pesticide residues in fruits, vegetables, and other foods. The program provides EPA with the residue data it needs to assess potential dietary exposure to various pesticides. EPA uses these and other data to estimate exposure, assess risk, and make registration decisions for pesticide uses.[3]

In this context, you asked us to review the federal government's oversight of pesticide residue tolerances for food. This report examines (1) what FDA data show with respect to pesticide residue violations in the foods that it regulates and limitations, if any, in its efforts to monitor foods for pesticide violations; (2) what FSIS data show with respect to pesticide residue violations in the foods that it regulates and limitations, if any, in its efforts to monitor foods for pesticide violations; and (3) what AMS data show with respect to pesticide residue levels in fruits, vegetables, and other foods, and limitations, if any, in its efforts to gather and report that information.

To address these objectives, we analyzed residue data collected by FDA, FSIS, and AMS and reviewed the methods the agencies have used to

[2] In this context, meat products covered by FSIS inspection include those from cattle, sheep, swine, goats, horses, mules, and other equines. Poultry includes any domesticated bird. Processed egg products include any dried, frozen or liquid eggs, with or without added ingredients. Processed egg products do not include whole, unbroken eggs.

[3]Under the Federal Insecticide, Fungicide, and Rodenticide Act, EPA registers pesticides for distribution, sale, and use in the United States and prescribes labeling and other regulatory requirements to prevent unreasonable adverse effects on the environment. To obtain a registration, a company or person (registrant) must provide data in support of registration including tests made and results, flagging any potential adverse effects. If the registration is for a food use pesticide, the applicant must also submit a petition for all needed tolerances. EPA may register the pesticide and set a tolerance level for those pesticides used on food or animal feed, notify the registrant of deficiencies in the data or need for additional information, or reject the application.

collect those data. We analyzed FDA and AMS data on samples of domestic and imported fruits and vegetables—the categories of commodities most often tested by these two agencies—and FSIS data on meat, poultry, and processed egg products. To report what FDA data show with respect to residue violations, we examined data on violations it detected in 10 highly consumed fruit and vegetable commodities (selected commodities) for fiscal years 1993 through 2012, excluding 2004:[4] apples, bananas, broccoli, cantaloupe, green beans, lettuce, peaches, pears, potatoes, and sweet bell peppers. We chose to focus our analysis of pesticide residue violations detected by FDA over a 5-year period (for fiscal years 2008 through 2012) because rates based on a small number of samples are unstable.[5] We also present data on pesticide residue violations detected in the 10 commodities from 1993 through 2012 in appendix II. Those data include years in which FDA generally took larger sample sizes than it did from 2008 through 2012. In addition, we examined recent FDA data on violations in other imported foods.[6] To report what FSIS data show with respect to pesticide residue violations, we analyzed the agency's National Residue Program data for meat, poultry, and processed egg products from calendar years 2000 through 2011, the years for which FSIS's annual reports were available. To report what AMS data show with respect to pesticide residues in fruits and vegetables, we analyzed the agency's Pesticide Data Program test results for the same 10 commodities for which we analyzed FDA data. We selected these 10 commodities because they were the commodities AMS tested for most often since 1994.[7] Specifically, we analyzed AMS data from the 3 most recent years in which the agency tested each of the

[4]FDA was not able to provide us with test results from 2004 that were comparable in detail to the other years. Therefore, we could not include that year in our analysis of pesticide residue test results.

[5] By grouping data from the 5 most recent years available, we balance the desire to present recent data with the need to have enough samples to present violation rates. We also report the samples and violation counts for each of the 5 years separately in order to display the range of sample sizes and violation counts over these years.

[6]We examined data on imported commodities—including fruits and vegetables—FDA found to have high rates of pesticide tolerance violations in fiscal years 2007 through 2011.

[7]AMS began the Pesticide Data Program in 1991. However, AMS officials advised us to begin our analysis with data from 1994 because the data prior to that year are not in a comparable format.

10 commodities for calendar years 1998 through 2012.[8] In using the agencies' data, we evaluated the reliability of these data by reviewing or discussing the agencies' management controls to ensure its accuracy and completeness. As appropriate, we also reviewed the agencies' compliance with the Office of Management and Budget's (OMB) *Standards and Guidelines for Statistical Surveys*.[9] We found these data to be sufficiently reliable for purposes of reporting what the agencies have found regarding pesticide residues and residue violations in food, although, where discussed, we note limitations in the methods the agencies have used to collect these data. To examine the recent methods FDA and FSIS have used to detect pesticide residue violations, we reviewed appropriate agency policy directives, reports, and other documents to better understand the agencies' residue monitoring programs. In addition, we analyzed FDA's use of its risk-based tool for selecting imported foods for pesticide residue testing, known as Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT).[10] We interviewed officials in FDA's Center for Food Safety and Applied Nutrition who are responsible for developing strategies and policies for reducing health threats from contaminated food and officials from FDA's Office of Regulatory Affairs who are responsible for monitoring foods for pesticide residue and enforcing pesticide tolerances. We interviewed officials in FSIS's Office of Public Health Science who are responsible for managing the agency's National Residue Program for meat, poultry, and processed egg products. We also interviewed agency officials in AMS's Monitoring Programs Division who are responsible for managing the Pesticide Data Program. Within EPA, we interviewed officials in the Office of Pesticide Programs who are responsible for using data generated by FDA, USDA, and others to

[8] The years in which AMS tested samples are not the same for every commodity because AMS uses a staggered sampling schedule. According to AMS officials, highly consumed commodities are rotated into the program every 5 years and tested for a period of 2 consecutive years.

[9] OMB, *Standards and Guidelines for Statistical Surveys* (September 2006).

[10] FDA uses PREDICT to identify imported food samples for testing for pathogens and other contaminants, including pesticides. FDA also uses the tool to identify other products for review prior to admission into the country, such as medical devices and pharmaceutical drugs. The PREDICT tool is web-based and designed to help border inspectors monitor products, especially high-risk ones, at ports of entry. PREDICT uses historical data, patterns, and violations to generate a numerical score for FDA-regulated imported products.

assess health risks associated with exposure to pesticides. Appendix I provides a more detailed description of our objectives, scope, and methodology.

We conducted this performance audit from November 2012 to October 2014 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

This section provides information on trends in agricultural pesticide use in the United States; growth in the volume of foods imported into the country; and the potential human health effects of exposure to pesticide residues and key responsibilities that EPA, FDA, and USDA's FSIS and AMS have with respect to pesticide residues in food.

Trends in Agricultural Pesticide Use in the United States

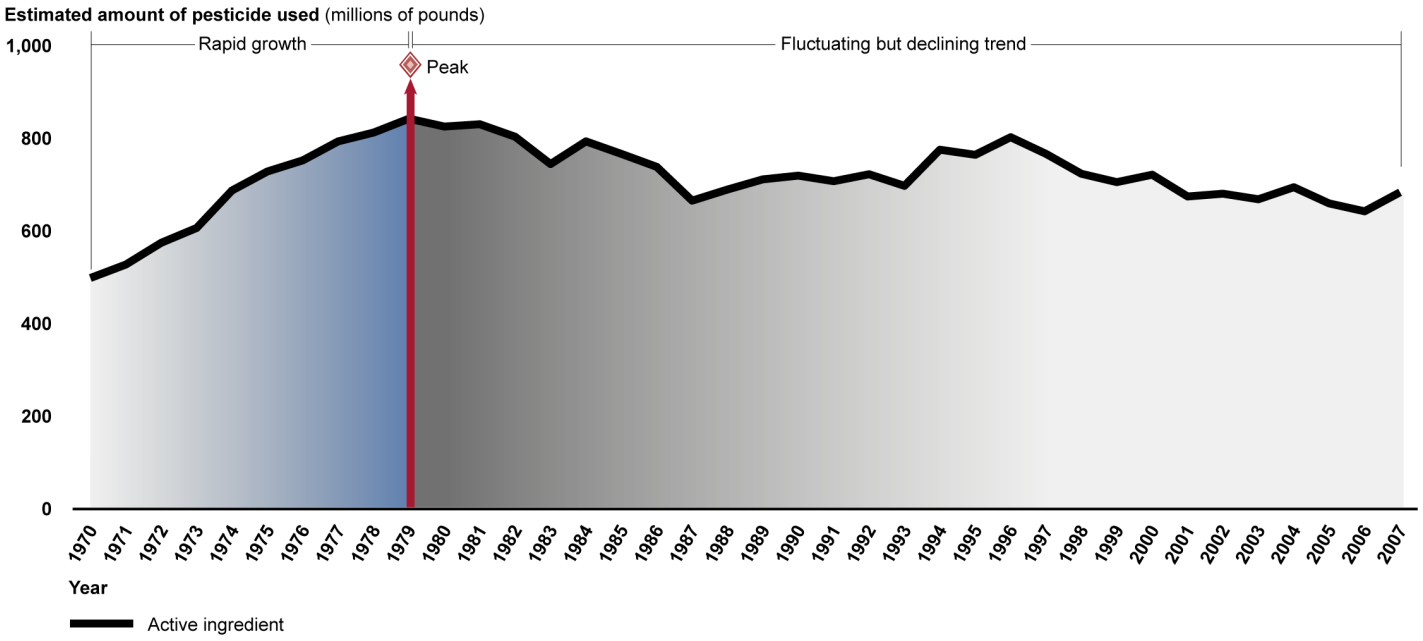
Conventional pesticide use in the U.S. agricultural sector grew from 1970 through 1979 and then generally trended downward through 2007 (see fig. 1).[11] According to a 2011 EPA report, the U.S. agricultural sector used an estimated 684 million pounds of conventional pesticides in 2007, the latest year for which the agency has published data.[12] This was an

[11]In this context, the term conventional pesticides includes herbicides (i.e., weed killers), plant growth regulators (i.e., chemicals used to alter the expected growth, flowering, or reproduction rate of plants), insecticides (i.e., chemicals used to kill insects and other arthropods), miticides (i.e., chemicals used to kill mites that feed on plants and animals), fungicides (i.e., chemicals used to kill fungi, including blights, mildews, molds, and rusts), nematicides (i.e., chemicals used to kill nematodes—microscopic, worm-like organisms that feed on plant roots), and fumigants (i.e., chemicals that produce gas or vapor intended to destroy pests in buildings or soil).

[12]EPA, *Pesticides Industry Sales and Usage: 2006 and 2007 Market Estimates*, Biological and Economic Analysis Division, Office of Pesticide Programs, Office of Chemical Safety and Pollution Prevention, Washington, D.C. 20460 (February 2011). According to EPA, neither it nor any other federal agency has a program devoted specifically to estimating the overall quantity of active ingredient used on an annual basis. EPA noted its report uses the best available information from the public domain and private marketing research companies (proprietary data sources). The numbers in EPA's report represent approximate values rather than precise values with known statistical properties.

increase from 643 million pounds in 2006, but well below the peak of 843 million pounds in 1979.

Figure 1: Estimated Number of Pounds of Conventional Pesticide Active Ingredients Used in U.S. Agricultural Sector, 1970 through 2007



Source: GAO analysis of Environmental Protection Agency data. | GAO-15-38

Note: The latest year for which EPA has published data on estimated pesticide usage is 2007. The figure depicts use of conventional pesticides only, excluding sulfur, petroleum oil, and other chemicals used as pesticides (e.g., sulfuric acid and insect repellents), wood preservatives, specialty biocides, and chlorine/hypochlorites. Active ingredient refers to the chemical or substance component of a pesticide product intended to kill, repel, attract, mitigate, or control a pest, or that acts as a plant growth regulator, desiccant, or nitrogen stabilizer. The term conventional pesticides includes herbicides (i.e., weed killers), plant growth regulators (i.e., chemicals used to alter the expected growth, flowering, or reproduction rate of plants), insecticides (i.e., chemicals used to kill insects and other arthropods), miticides (i.e., chemicals used to kill mites that feed on plants and animals), fungicides (i.e., chemicals used to kill fungi, including blights, mildews, molds, and rusts), nematicides (i.e., chemicals used to kill nematodes—microscopic, worm-like organisms that feed on plant roots), and fumigants (i.e., chemicals that produce gas or vapor intended to destroy pests in buildings or soil.)

As a group, the most commonly used pesticides have a variety of functions. In 2007, 13 of the top 25 pesticide active ingredients used in the agricultural sector were herbicides; 3 were fungicides; 3 were insecticides; 5 were fumigants; and 1 was a plant growth regulator.

According to EPA, the most used active ingredient in the U.S. agricultural sector from 2001 through 2007 was the herbicide glyphosate.[13] In 2007, glyphosate use reached 180 million to 185 million pounds. Other pesticides commonly used from 2001 through 2007 were the herbicide atrazine, the fumigant metam sodium, and the herbicide metolachlor-S.

EPA's 2011 report shows that, while the use of some pesticides has grown, others have declined. For example, the amount of organophosphate insecticides used in all sectors—including agriculture—declined more than 60 percent from 1990 through 2007, from an estimated 85 million pounds in 1990 to 33 million pounds in 2007.[14] Organophosphate use as a percentage of total insecticide use decreased from 70 percent in 1990 to 35 percent in 2007. These declines were the result, in part, of growing concerns over the toxicity of organophosphates. Some of the decline occurred after EPA increased its oversight of this class of pesticides in response to the Food Quality Protection Act of 1996 that included provisions to better ensure the health of infants and children from pesticide risks.[15]

The overall use of pesticides in agricultural settings is not necessarily indicative of the risk associated with those pesticides. A pound of one pesticide, for example, is not necessarily as toxic or potentially harmful to human health as a pound of another pesticide. Therefore, a total increase or decrease in the amount of pesticides used does not necessarily mean that total toxicity or risk has changed at the same rate. We were unable to find publicly available estimates of the overall toxicity or risk associated with the use of agricultural pesticides in the United States.

[13]Glyphosate is the active ingredient in certain "broad-spectrum" herbicides that are effective at killing a range of weeds but that may also kill the crop. The growth in glyphosate use is associated with the widespread planting of genetically engineered crops—such as corn and soybeans—that can tolerate being sprayed with glyphosate.

[14]According to EPA's website, organophosphates affect the nervous system by disrupting the enzyme that regulates acetylcholine, a neurotransmitter. Most organophosphates are insecticides. They were developed during the early nineteenth century, but their effects on insects, which are similar to their effects on humans, were discovered in 1932. However, organophosphates usually are not persistent in the environment.

[15]Pub. L. No. 104-170, 110 Stat. 1489.

Growth in the Volume of Imported Foods Regulated by FDA

The number of imported food shipments that FDA has responsibility for monitoring and testing has increased in recent years. We reported in September 2009 that the number of food "entry lines" that passed through U.S. ports and for which FDA had oversight authority nearly doubled in the previous 10 years to an estimated 9.5 million.[16] Since the issuance of our report, that number grew to about 9.7 million in 2012. The growth in the percentage of imported foods in the U.S. food supply has varied widely for different types of foods.[17]

While the overall growth in imported foods has enhanced consumer choice, it has also strained the resources of federal agencies responsible for monitoring food safety. Imported foods could pose pesticide risks that are different than those posed by domestically grown food if the exporting countries have different agricultural practices. For example, growers in other countries might use pesticides that are not registered for use in the United States and do not have an "import tolerance" that would allow residue of that pesticide on imported food.[18] FDA and USDA are responsible for ensuring the safety of imported food to the same extent as domestic food. If a food is found to have a pesticide in excess of an

[16]*GAO, Food Safety: Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food*, GAO-09-873 (Washington, D.C.: Sept. 15, 2009). An entry line is a unique shipment of imported products or items offered for admission into U.S. commerce. On the other hand, we use the term "lot" to indicate a unique quantity of a domestically grown product subject to FDA testing.

[17]According to USDA's Economic Research Service, the imported share of U.S. fruit and nut consumption grew from 28.1 percent in 1994 to 38.5 percent in 2009, while the imported share of U.S. vegetable consumption grew from 7.5 percent to 17.5 percent. From 1994 through 2009, seafood imports increased from about 56 percent to about 85 percent of the total amount consumed in the United States. In contrast, imported red meat, poultry, dairy, and egg products have generally remained constant as a percentage of the amount of U.S. consumption from 1994 through 2009.

[18]When no U.S. registration exists, interested persons may submit a petition requesting that EPA establish an import tolerance for a pesticide residue on a food or feed commodity, which will allow the food or feed treated with the pesticide in foreign countries to be imported into the United States. Therefore, the term "import tolerance" is used to refer to a residue tolerance that has been established for a pesticide for which there is no accompanying U.S. registration, but which meets U.S. food safety standards. Interested persons may also submit a petition requesting that EPA exempt a pesticide from the need for an import tolerance, which EPA may grant if it determines, among other things, that there is a reasonable certainty that no harm will result from aggregate exposure to the residue, including all anticipated dietary exposures and all other nonoccupational exposures for which there is reliable information.

import tolerance, or if no tolerance has been set, the food is considered unsafe and cannot enter commerce in the United States.

Potential Health Effects of Exposure to Pesticide Residues and Agency Responsibilities

According to EPA's website, the health effects of pesticides depend on the type of pesticide. Some, such as the organophosphates and carbamates, affect the nervous system. Others may irritate the skin or eyes; some may be carcinogens; and others may affect the hormone or endocrine systems in the body. Also, according to EPA's website, the specific health effects of a particular pesticide depends on the pesticide's toxicity and how much of it is consumed (i.e., exposure). EPA also notes that infants and children may be especially sensitive to health risks posed by pesticides.

EPA, FDA, and USDA's FSIS and AMS each have key responsibilities with respect to pesticide residues in food.

EPA Sets Pesticide Tolerances

The primary federal laws that govern how EPA regulates pesticides in the United States are the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA).[19] Under FIFRA and its implementing regulations,[20] EPA is to review applications for pesticide products and register those that it determines will meet FIFRA's statutory standards. Generally, unless it is registered with EPA for use on a particular commodity, a pesticide cannot be legally used on that commodity. Of particular relevance to EPA's review, if the use of a pesticide would result in a residue of the substance in or on food or animal feed, generally, EPA may not register that pesticide unless it can determine that the residue is "safe" as defined by FFDCA. Under FFDCA, with regard to a pesticide residue, safe means that EPA has determined, among other things, that there is a reasonable certainty that no harm will result from aggregate exposure to the residue, including all anticipated dietary exposures and all other nonoccupational exposures for

[19]7 U.S.C. §§ 136-136y, 21 U.S.C. §§ 301-399d; see specifically 7 U.S.C. § 136a, 21 U.S.C. § 346a. The Antimicrobial Regulation Technical Corrections Act of 1998 amended the definition of "pesticide chemical" in the FFDCA by, in part, excluding certain antimicrobial substances from the definition of pesticide chemical. Pub. L. No. 105-324, 112 Stat. 3035. Substances so excluded became subject to regulation by FDA as food additives. This report does not address antimicrobial substances that may be regulated by EPA as pesticide chemical residues or by FDA as food additives.

[20]7 U.S.C. § 136a; 40 C.F.R. pts. 152-180.

which there is reliable information. Nonoccupational exposures are those experienced by the general population, as opposed to those experienced by specific groups of pesticide users (i.e., occupational users), such as farm workers and pest control operators. EPA may establish a tolerance level—the maximum permissible pesticide residue in or on food or animal feed that is sold—that meets the FFDCA safety standard for a pesticide residue or may choose to grant a tolerance exemption if it determines that the exemption meets the FFDCA safety standard for a pesticide residue.[21]

EPA typically sets tolerances in response to a petition from the pesticide manufacturer to register the pesticide for use in association with a particular commodity.[22] For example, EPA has established a tolerance of 0.05 parts per million for the insecticide chlorpyrifos on cucumber and a tolerance of 1 part per million for the herbicide diuron on pears.[23] Tolerances for pesticides may differ depending on the commodity. For example, although the tolerance for chlorpyrifos is 1 part per million on cherries, it is 2 parts per million on radishes. According to EPA officials, the different tolerances reflect the agency's analysis of different chemical-specific and crop-specific agricultural practices and the expected residues that would result from those practices. From a regulatory perspective, it is also important to be aware of those situations in which EPA has not established a tolerance for a pesticide on a particular commodity. For example, although EPA has set a tolerance for diuron on pears, it has not set a tolerance for that herbicide on mushrooms, lettuce, or many other

[21]Registration of a pesticide is not, however, a prerequisite for establishing a tolerance. For example, EPA may establish a temporary tolerance to permit the experimental use of a nonregistered pesticide, or EPA may establish a tolerance for a pesticide residue resulting from the use of the pesticide in food or animal feed in a foreign country.

[22]Pesticide manufacturers go to some effort and expense to get a pesticide registered for a particular use. In light of this expense, they may choose not to seek registration for a pesticide to be used on all potential commodities if they do not expect the use on those commodities to be commercially significant. In 1963, the directors of state agricultural experiment stations began a program known as IR-4. The IR-4 program continues to this day, and with funding from USDA, land grant universities, and the agrochemical industry, works with EPA to register pesticides for use on commodities for which the manufacturer has not applied.

[23]Tolerances for residues in raw commodities apply to those same residues in processed commodities. If the residues in processed commodities are expected to exceed the residues in the raw commodity, a separate processed food tolerance is needed.

commodities. Therefore, residues of diuron are not permitted on those commodities.

FDA Monitors Most Foods for Pesticide Residue Violations

Under FFDCA, FDA is responsible for protecting the public health by ensuring that the food subject to its jurisdiction—including fruits, vegetables, dairy products, seafood, and spices—is safe, wholesome, sanitary, and properly labeled. In meeting its responsibility, FDA monitors pesticide residues, among other things, in foods it inspects. The agency's efforts include testing domestic and imported foods in interstate commerce for the presence of pesticide residues.[24] According to FDA's website, this responsibility entails annual oversight of more than $400 billion in domestic foods and about $50 billion in imported foods. FDA's *Compliance Program Guidance Manual* states that the agency's objectives are to (1) enforce pesticide residue tolerances in foods established by EPA and (2) determine the incidence and level of pesticide residues in domestic and imported foods.[25] FDA's guidance manual identifies pesticides and classes of pesticides but does not identify each pesticide for which the agency must test. FDA uses two broad categories of testing technology. One type of test—known as a multiresidue method—can detect many pesticides, and the other type—a selective residue method—can detect one specific pesticide. No one test can detect all possible pesticide residues.

FDA typically collects samples of domestic foods for testing close to the point of production in the distribution system, (i.e., from growers, packers, and distributors), while it collects imported foods for testing at the point of entry into U.S. commerce.[26] When testing raw commodities such as fruits and vegetables for pesticide residues, FDA conducts its tests on unwashed, whole (unpeeled) items. FDA also tests processed foods such as breakfast cereals and snack foods for pesticide residues.

[24]In addition, FDA monitors domestic and imported foods in interstate commerce for pathogens, natural toxins, heavy metals, and other contaminants.

[25]FDA, *Compliance Program Guidance Manual: Chapter 04—Pesticide and Chemical Contaminants*, 7304.004 (June 27, 2011).

[26]The amount (e.g., containers or pounds) of a commodity that FDA samples may vary by commodity. Two examples of amounts are one intact shipping case or a total of 20 pounds for fresh produce.

If FDA finds pesticide residues that exceed established tolerances for a specific commodity—or pesticide residues for which there are no established tolerances for that commodity—it may take a variety of enforcement actions. For example, FDA can refuse entry of food offered for import into the United States or seize foods in domestic commerce that exceed an EPA tolerance or are found to contain pesticide residues for which there is no tolerance. FDA may allow a food to be "reconditioned" or diverted to another use.[27] If FDA finds that an imported food has a pesticide residue violation, it may issue an "import alert" covering subsequent shipments of that product from the shipper or grower. FDA officials at ports of entry would then detain without physical examination any future shipments of that product from that shipper or grower unless the importer provides proof that the product did not contain residues of the pesticide(s) cited in the import alert in excess of the established tolerance. FDA may also issue an import alert for a food product from an entire country or geographic area. To be exempt from the alert, shippers or growers of a specific product from a specific location are asked to provide evidence that their products comply with EPA tolerances. FDA may also request that a company conduct a recall if it determines that domestic or imported foods that have entered the food supply have pesticide residues that violate established tolerances or are found to contain pesticide residues for which EPA has not established a tolerance. Generally, FDA has the authority to order a food recall if it would cause serious adverse health consequences or death to humans or animals and the company fails to voluntarily recall the product.

In December 2011, FDA completed the national rollout of PREDICT, a tool the agency expects will (1) improve import screening and targeting to prevent entry of goods that are adulterated,[28] misbranded or otherwise violate FDA standards (i.e., violative); and (2) expedite the entry of goods that do not violate FDA standards (i.e., nonviolative).[29] With PREDICT,

[27]One option would be to divert the product from food for human consumption to food for animal consumption if it would meet the established tolerance for animal food.

[28]Food is deemed to be adulterated under the Federal Food, Drug, and Cosmetic Act if, among other things, it bears or contains a pesticide chemical residue in excess of an established tolerance, or, when no tolerance exists, any residue is present and there is no exemption from the tolerance requirement granted.

[29]The tool is not specific to pesticide residues in food; FDA uses it for all types of products within its jurisdiction.

FDA gathers specific information about products, manufacturers, or growers, country of origin, and other factors to generate a risk score for each line in an entry. The higher the cumulative score, the greater the identified risk. FDA officials at ports of entry may use the risk scores and import alerts to make decisions about which products can be released into the country and which should receive further examination such as laboratory testing for pesticide residues. FDA does not use a similar tool for screening domestic foods for sampling. FDA's guidance directs its district offices to develop sampling plans that consider similar information, such as past violations, pesticide usage, and other information gathered by the district.

FDA also acquires data on particular commodity and pesticide combinations by conducting market basket surveys under its Total Diet Study. This annual survey is distinct from regulatory monitoring in that it determines pesticide residues in foods that are prepared and table-ready for consumption. The foods are washed, peeled, or cooked before analysis, simulating typical consumer handling. Each survey comprises about 300 different foods that represent the average U.S. consumer's diet, which FDA tests with methods that are 10 to 100 times more sensitive than FDA's regulatory monitoring procedures, meaning that they can detect much lower concentrations of residue. We did not examine the results of this study because its sample sizes for each commodity tested are small.[30]

FSIS Monitors Meat, Poultry, and Processed Egg Products for Pesticide Residue Violations

Under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, USDA's FSIS is responsible for examining and inspecting to prevent the distribution of adulterated food products. To meet this responsibility, FSIS, among other things, monitors meat, poultry, and processed egg products for pesticide residue.[31] FSIS executes this responsibility as part of its National Residue Program under which it randomly samples domestic and imported meat, poultry, and processed egg products to test for pesticides; veterinary drugs; and

[30]FDA typically tests four "market baskets" of each type of food per year. Each market basket is a composite of the food collected from three cities in one of four regions of the country. FDA surveys different cities from year to year.

[31]A meat, poultry, or egg product is considered adulterated under federal law if, among other circumstances, it bears or contains a pesticide chemical residue in excess of an established tolerance, or, when no tolerance exists, any residue is present and there is no exemption from the tolerance requirement granted.

environmental contaminants, such as heavy metals, that might find their way into these products destined for human consumption. FSIS takes samples of domestic products at slaughterhouses and processing facilities and samples imported products at ports of entry. In each case, FSIS tests products for pesticide residues at its Western Laboratory in California using the multiresidue method. On December 10, 2012, FSIS published a new policy stating that slaughterhouse and import establishments must maintain control of livestock products while awaiting the results of tests for contaminants.[32]

AMS Collects Data for Annual Survey of Pesticide Residues

USDA's AMS coordinates with state agencies to conduct an annual survey of pesticide residues in and on fruits, vegetables, and other food commodities known as the Pesticide Data Program. AMS does not conduct this survey to enforce EPA pesticide tolerances; rather, its primary purpose is to collect residue data that EPA uses to assess the dietary exposure associated with particular pesticides. However, FDA can review Pesticide Data Program data for possible violations and can use those data to inform its own enforcement program. In 2012, AMS decided that it would no longer collect residue data for beef, pork, and poultry products, with the expectation that FSIS would provide such data to EPA.

According to AMS documents, it uses random sample selection methods to obtain a statistically valid representation of the U.S. food supply. In recent years, the survey has annually tested domestic and imported samples of 20 to 30 commodities. The list of commodities tested changes from year to year and, over the history of the program, AMS has tested about 90 different types of food. In recent years, AMS has established cooperative agreements with about a dozen states to participate in the program. State officials, under the direction of AMS, collect foods at terminal markets[33] and distribution centers for large chain stores. Participation by the terminal markets and distribution centers in the program is voluntary. Depending on the commodity, the foods are tested for residue at either state or federal laboratories. Because AMS conducts

[32]The new policy does not apply to poultry. The FSIS policy stated that poultry did not need to be held from commerce pending negative test results because of (1) the significant number of poultry carcasses in a lot; (2) the economic effects of holding a lot; and (3) historically, FSIS has not seen contaminant problems (of any type) in poultry tested for residues.

[33]A terminal market is an organized wholesale market into which large quantities of agricultural produce, livestock, or other goods are shipped for distribution and sale.

residue testing to gather information for EPA to use in conducting risk assessments rather than for regulatory purposes, some of the foods are handled as AMS expects consumers to handle them. For example, fruits and vegetables may be washed, cored, or peeled before being tested.

FDA Data Show Low Rates of Pesticide Residue Violations, but FDA's Approach for Detecting Violations Has Limitations That Are Not Disclosed

FDA data for the 10 commodities we reviewed show the agency found low rates of pesticide residue violations as part of targeted (i.e., nongeneralizeable) monitoring for compliance and enforcement, but FDA's approach for detecting violations has limitations. Specifically, we found that FDA takes relatively few targeted samples to test for pesticide residue and detects what is likely to be a small percentage of the foods that have violative levels of residue.[34] Moreover, FDA does not disclose in its annual monitoring reports that it does not test for some commonly used pesticides that have established tolerances for many commodities. In addition, it is not clear to what extent FDA's recently implemented targeting tool for imported foods—PREDICT—helps the agency identify foods most likely to have pesticide residue violations. Furthermore, because FDA does not use statistically valid methods to gather residue data, it is not able to meet its objective to determine the incidence and level of pesticide residues in domestic and imported foods.

FDA Has Found Few Violations, and Violation Rates Have Varied Among the Foods It Tests as Part of Its Compliance and Enforcement Monitoring

From 2008 through 2012, FDA's compliance and enforcement monitoring program, which carries out one of the agency's objectives of enforcing pesticide residue tolerances in foods established by EPA, detected low rates of pesticide residue violations[35] among the targeted samples it tested of the 10 commonly consumed fruit and vegetable commodities we reviewed. We found that the violation rates among foods it tested varied by commodity. For example, over that 5-year period of time, FDA detected one or more residue violations in 0 to 1.9 percent of its samples of apples, bananas, broccoli, lettuce, and potatoes and detected one or

[34]FDA uses the term "sample" when reporting pesticide residue test results for domestic and imported foods. However, FDA clearly notes in its annual reports that it does not randomly select its samples. Therefore, the results of its samples are not meant to be used to generalize to a larger population of foods. Consequently, we use the term targeted sample to distinguish from more random sampling methods used by FSIS and AMS.

[35]A violation is either due to the presence in or on a commodity of a pesticide that exceeds the tolerance established by EPA (a violation of tolerance) or the presence of a pesticide for which EPA has not established a tolerance for that commodity (a violation of no tolerance).

more violations in 3.3 to 5.4 percent of its samples of cantaloupe, green beans, peaches, pears, and sweet bell peppers. Figure 2 provides data on the extent to which domestic and imported samples of the 10 selected commodities FDA tested had one or more violations from 2008 through 2012. The agency collected these data as part of its risk-based targeting, a selection method designed to target foods with a high risk of violation[36] rather than to estimate the incidence or prevalence of pesticide residues on all commodities; therefore, these data are not meant to be generalized to all foods the agency regulates.[37] FDA data also show that the agency generally found low rates of pesticide residue violations among its samples of the 10 selected commodities in the years from 1993 through 2007 and that the rates varied by commodity and year. See appendix II for a presentation of year-by-year results on sample and violation counts broken down by commodity, violation type, and origin for 1993 through 2012, with the exception of 2004.[38]

[36]Factors that affect risk-based targeting include the history of violations for particular commodities or places of origin.

[37]We present violation rates for a 5-year period rather than for individual years because rates based on a small number of samples are unstable. By grouping data from the 5 most recent years available, we balance the desire to present recent data with the need to have enough samples to present violation rates. We also report the samples and violation counts for each of the 5 years separately in order to display the range of sample sizes and violation counts over these years.

[38]As noted, FDA was not able to provide us with test results from 2004 that were comparable in detail to the other years. Therefore, we could not include that year in our analysis of pesticide residue test results.

Figure 2: Frequency and Rate That Domestic and Imported Targeted Samples of 10 Selected Commodities Had One or More Pesticide Residue Violations Detected by FDA, 2008 through 2012

Commodity	2008		2009		2010		2011		2012		Total (2008-2012)		
	Samples taken	Samples with one or more violations detected	Samples taken	Samples with one or more violations detected	Samples taken	Samples with one or more violations detected	Samples taken	Samples with one or more violations detected	Samples taken	Samples with one or more violations detected	Samples taken	Samples with one or more violations detected	Violation rate (percentage)
Apples	129	1	109	1	151	0	105	2	129	1	623	5	0.8%
Bananas	11	0	14	0	18	0	15	0	14	0	72	0	0.0%
Broccoli	81	1	58	0	72	2	63	1	34	0	308	4	1.3%
Cantaloupe	10	0	20	0	14	1	26	2	22	0	92	3	3.3%
Green beans	130	10	138	5	166	5	95	8	60	4	589	32	5.4%
Lettuce	82	1	103	2	58	0	41	0	5	0	289	3	1.0%
Peaches	44	0	43	0	55	6	37	2	43	2	222	10	4.5%
Pears	32	0	17	0	31	0	33	5	34	1	147	6	4.1%
Potatoes	122	1	69	2	116	5	91	0	82	2	480	10	2.1%
Sweet bell peppers	92	2	163	7	118	7	129	4	48	1	550	21	3.8%

Source: GAO analysis of Food and Drug Administration data. | GAO-15-38

Note: FDA may have detected more than one violation on a single sample. The violations represented in the figure are one of two types: violations of no tolerance and violations of tolerance. A violation of no tolerance means that FDA has detected residue of a pesticide on a commodity for which EPA has not established a tolerance. A violation of tolerance means that FDA has detected a pesticide residue that exceeds the EPA-established tolerance for that commodity. The violation rate presented in the table for each commodity represents the overall rate that FDA detected from fiscal years 2008 through 2012. FDA uses the term "sample" when reporting pesticide residue test results for domestic and imported foods. However, FDA notes in its annual pesticide monitoring reports that it does not randomly select its samples. Therefore, the results of its samples are not meant to be used to generalize to a larger population of foods. Consequently, we use the term targeted sample to distinguish from random sampling methods.

Our analysis also shows that FDA detected more than one violation in some samples of the 10 selected commodities. For example, from 2008 through 2012, of the 10 samples of potatoes with one or more violations detected (see fig. 2), FDA detected 24 residue violations as shown in figure 3. We also found that violations of no tolerance were the most common type of violation FDA detected in 7 of the 10 selected

commodities.[39] These violations occur when FDA detects a pesticide for which there is no established tolerance for the particular commodity on which it was found. For example, 38 of 41 violations detected in sweet bell peppers and 8 of 11 violations detected in peaches from 2008 through 2012 were violations of no tolerance. During the same period, FDA detected violations of established tolerances—instances in which the concentration of a pesticide residue exceeded the limit established by EPA—more frequently in its targeted samples of broccoli and potatoes. FDA detected no violations of either type in bananas in those years. See figure 3 for FDA's findings for the number of each of the two types of violations detected from 2008 through 2012 in the 10 selected commodities.

[39]Our analysis focuses on two types of violation; violations of no tolerance and violations of tolerance. FDA also may establish, as guidance, a nonbinding level, known as an action level, for an unavoidable residue of a cancelled pesticide that persists in the environment. From 2008 through 2012, FDA detected 7 instances among the 10 select commodities where an unavoidable residue level exceeded an action level for the commodity.

Figure 3: Total Number of Pesticide Residue Violations Detected by FDA in Targeted Samples of 10 Selected Commodities, by Violation Type, 2008 through 2012

Commodity	2008			2009			2010			2011			2012			Total (2008-2012)		
	Samples taken	No tolerance	Tolerance	Samples taken	No tolerance	Tolerance	Samples taken	No tolerance	Tolerance	Samples taken	No tolerance	Tolerance	Samples taken	No tolerance	Tolerance	Samples taken	No tolerance	Tolerance
Apples	129	2	2	109	1	0	151	0	0	105	2	0	129	1	0	623	6	2
Bananas	11	0	0	14	0	0	18	0	0	15	0	0	14	0	0	72	0	0
Broccoli	81	2	0	58	0	0	72	1	2	63	0	2	34	0	0	308	3	4
Cantaloupe	10	0	0	20	0	0	14	2	0	26	2	2	22	0	0	92	4	2
Green beans	130	22	0	138	11	0	166	6	1	95	14	0	60	6	0	589	59	1
Lettuce	82	1	0	103	2	0	58	0	0	41	0	0	5	0	0	289	3	0
Peaches	44	0	0	43	0	0	55	5	2	37	2	0	43	1	1	222	8	3
Pears	32	0	0	17	0	0	31	0	0	33	5	0	34	3	0	147	8	0
Potatoes	122	2	0	69	2	2	116	3	13	91	0	0	82	2	0	480	9	15
Sweet bell peppers	92	4	0	163	13	2	118	10	0	129	6	1	48	5	0	550	38	3

Violations detected, by type

Source: GAO analysis of Food and Drug Administration data. | GAO-15-38

Note: Figure 3 shows data on two types of violations. A violation of no tolerance means that FDA has detected residue of a pesticide on a commodity for which EPA has not established a tolerance. A violation of tolerance means that FDA has detected a pesticide residue that exceeds the EPA-established tolerance for that commodity. FDA uses the term "sample" when reporting pesticide residue test results for domestic and imported foods. However, FDA notes in its annual pesticide monitoring reports that it does not randomly select its samples. Therefore, the results of its samples are not meant to be used to generalize to a larger population of foods. Consequently, we use the term targeted sample to distinguish from random sampling methods.

As noted earlier, because FDA data on violations were derived from a sampling method designed to target foods with a high risk of violation, rather than from a statistically generalizable sample, FDA violation rates are not intended to be interpreted as reliable estimates of the actual rates of potential violations among these 10 commodities in the food supply. In addition, FDA typically collects its samples of domestic foods for testing close to the point of production (i.e., from growers, packers, and distributors) and collects its samples of imported foods for testing at the point of entry into U.S. commerce. In contrast, AMS tests foods that are further along the food supply chain—and, thus, closer to consumers—at terminal markets and distribution centers. AMS generally tests sample

sizes from 500 to 750 per commodity, which are considerably larger than FDA's sample sizes. The presence of a residue above a tolerance or for which there is no tolerance indicates a possible violation that FDA did not detect with its targeted sampling. Therefore, to further examine violation rates for the 10 selected commodities, we analyzed AMS data on these commodities that indicate the presence of pesticide residues in the food supply. AMS calls the residues it detects that exceed tolerances or for which there are no tolerances "presumptive tolerance violations." (It is also noteworthy that, unlike FDA's compliance and enforcement monitoring program, AMS tests commodities after preparing them as consumers are expected to do, such as washing, coring, or peeling fruits and vegetables. This practice is likely to reduce pesticide residues and lower the rate at which AMS finds presumptive tolerance violations.) We found that presumptive tolerance violation rates varied by several orders of magnitude across the 10 selected commodities and years tested. Specifically, for commodities with presumptive tolerance violations, the rates ranged from 0.14 percent on apples in 2001 to 19.47 percent on pears in 1998—a 139-fold difference. Table 1 shows the presumptive tolerance violation rates for the 3 most recent years in which AMS tested the 10 selected commodities for 1998 through 2012.[40] For example, as shown in table 1, the presumptive tolerance violation rate for peaches in 2008 was 9.1 percent.[41] If that violation rate prevailed (i.e., was a valid estimate of violations) for all peaches in that year, it would mean that about 9 out of 100 peaches consumed in that year would be expected to exceed the maximum permissible pesticide residue level for that fruit.

[40]AMS does not sample each commodity in each year. Therefore, the 3 most recent years for one commodity may not match the 3 most recent years for other commodities. The 3 most recent years of testing from 1998 through 2012 are shown in table 19 in appendix III.

[41]We estimate that the approximate margin of error was less than plus or minus 5 percentage points.

Table 1: Presumptive Tolerance Violation Rates for 10 Selected Commodities, Based on Agricultural Marketing Service (AMS) Data, Three Most Recent Years With Data Available for Each Commodity

Commodity	Third most recent year in which samples were taken	Violation rate (percentage) in that year	Second most recent year in which samples were taken	Violation rate (percentage) in that year	Most recent year in which samples were taken	Violation rate (percentage) in that year
Apples	2001	0.14%	2004	1.81%	2010	1.34%
Bananas	2002	1.38%	2006	4.45%	2012	0.00%
Broccoli	2001	0.56%	2002	0.41%	2007	4.76%
Cantaloupe	1999	2.53%	2004	0.67%	2011	0.14%
Green beans	2000	1.67%	2004	13.99%	2008	3.10%
Lettuce	2000	0.27%	2005	17.77%	2010	2.96%
Peaches	2001	15.31%	2007	9.19%	2008	9.09%
Pears	1998	19.47%	2004	6.88%	2010	0.94%
Potatoes	2001	1.09%	2002	2.16%	2009	2.28%
Sweet bell peppers	2000	3.52%	2003	3.51%	2010	1.34%

Source: GAO analysis of AMS Pesticide Data Program data. | GAO-15-38

Notes: The data indicate the percentage of samples with at least one violation for each of 3 years—not necessarily consecutive—from 1998 to 2012. In most instances, samples that AMS reported as having presumptive tolerance violations had only one presumptive tolerance violation. Sample sizes ranged from 370 for potatoes in 2002 to 831 for cantaloupe in 1999. Most sample sizes were from 720 to 740 per commodity. The margins of error for the violation rates for all 10 commodities were less than plus or minus 5 percentage points.

Although FDA's monitoring data from 2008 through 2012 show low pesticide residue violation rates across the 10 selected commodities we examined, FDA's test results also show that certain foods other than the 10 selected commodities had relatively high violation rates among the samples it tested. For example, in fiscal year 2011 (the most recent year for which the agency published its monitoring results), FDA reported violation rates among 24 imported food commodities that ranged from 10 to 75 percent (see table 2).[42] FDA analysis from other recent years also found other imported commodities with pesticide residue violation rates of at least 10 percent. For example, FDA found 13 such commodities in fiscal year 2007, 9 in 2008, 2 in 2009, and 15 in 2010.[43] Because FDA

[42]Commodities in this table had at least 20 samples analyzed and a violation rate of 10 percent or higher or had a minimum of 3 violations and a violation rate of 10 percent or higher.

[43]FDA published these data in its annual reports on pesticide monitoring. FDA did not publish this type of analysis of domestically grown foods.

collected these data for the purpose of compliance monitoring and enforcement, they represent the rate of violations that the agency detected through its targeted testing and are not valid estimates of the rate of violations in the foods that FDA regulates as they are not from statistically valid random samples. For example, if FDA tested targeted samples of apples because of the compliance history of apples, the rate of violations in those samples are not valid estimates of the rate of violations in all apples.

Table 2: Imported Food Commodities Analyzed by FDA with a Violation Rate of 10 Percent or Higher, Fiscal Year 2011

Commodity	Targeted samples analyzed (number)	Violations identified (number)	Violation rate (percentage)
Ginseng	12	9	75.0%
Capsicums (ground spice)	27	18	66.7%
Prickle pear	11	5	45.5%
Rice, basmati	13	5	38.5%
Raisins	9	3	33.3%
Bok choy	9	3	33.3%
Cilantro	9	3	33.3%
Papaya	69	20	29.0%
Capsicums (whole spice)	32	9	28.1%
Pear	18	5	27.8%
Tea	15	4	26.7%
Tea, chamomile	14	3	21.4%
Spinach	52	9	17.3%
Olives	24	4	16.7%
Serrano pepper	24	4	16.7%
Sweet potato	26	4	15.4%
Tomatillo	31	4	12.9%
Jalapeno pepper	120	15	12.5%
String beans	41	5	12.2%
Blackberries	68	8	11.8%
Red beet	48	5	10.4%
Leek	29	3	10.3%
Choyote	20	2	10.0%
Kale	20	2	10.0%

Source: FDA's annual report of its 2011 pesticide monitoring program. | GAO-15-38

Note: As of June 2014, the most recent year for which FDA had published an annual report containing this type of analysis of its test results was 2011. Commodities in this table had at least 20 samples analyzed and a violation rate of 10 percent or higher or had a minimum of 3 violations and a violation rate of 10 percent or higher. Caution should be used when interpreting rates based on a small number of samples (i.e., with a small denominator). For example, FDA took nine samples of raisins in 2011, and the violation rate of 33.3 percent would have changed by more than 10 percentage points if FDA had found one violation more or one less in the sample.

According to FDA's 2011 monitoring report, the commodities identified in table 2 may warrant special monitoring attention in the future because of the number or percent of violations detected in 2011. FDA also stated in its monitoring report that it typically uses multiple years of data as the basis for instructing field offices to increase their sampling of commodities that have a history of violations. At the same time, FDA noted that its pesticide residue monitoring program should not be viewed as random or statistical, meaning that the data presented in table 2 are not necessarily indicative of actual violation rates for those commodities.

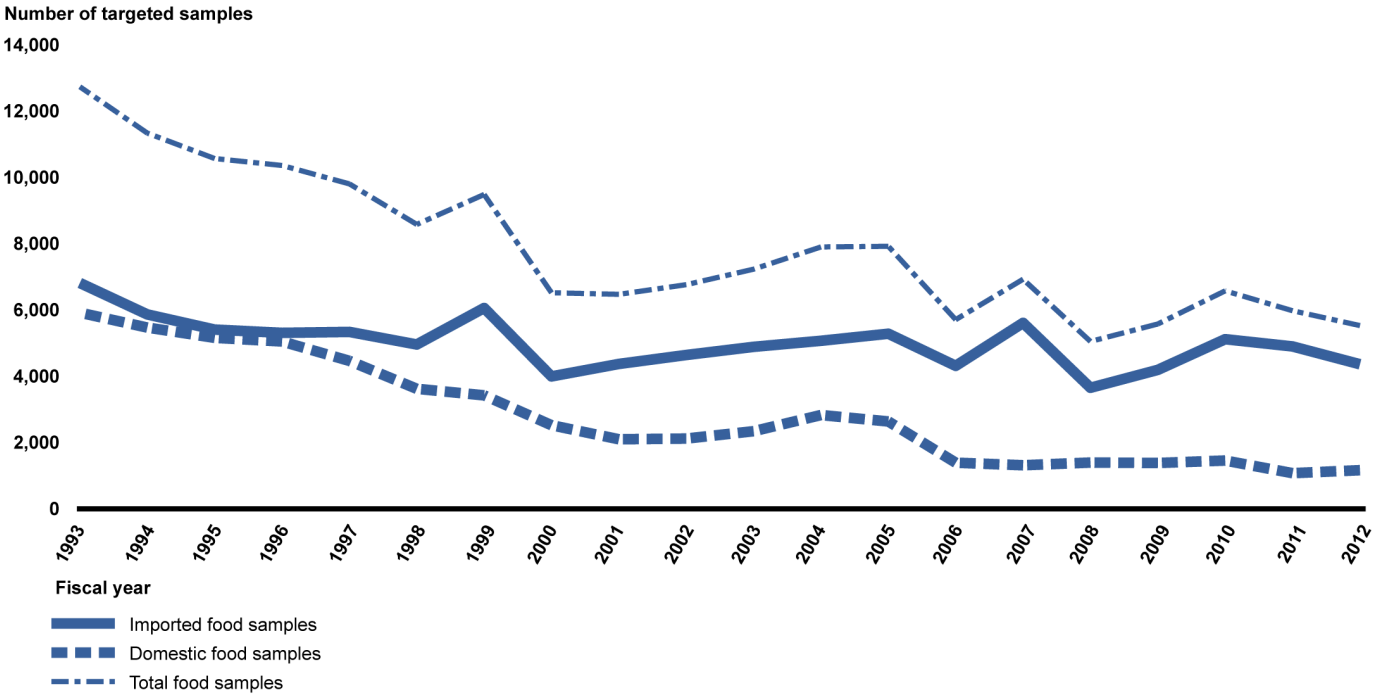
FDA's Approach for Detecting Pesticide Residue Violations Has Limitations

FDA's current monitoring approach has limitations that affect the agency's ability to detect pesticide residue violations. FDA takes relatively few targeted domestic and imported samples to test for pesticide residues. Additionally, FDA does not test for several widely used pesticides that have established tolerances for many commodities, meaning that it is unable to detect violations of those tolerances. Moreover, it is not clear to what extent FDA's recently implemented targeting tool for imported foods—PREDICT—helps the agency identify foods most likely to have pesticide residue violations.

FDA Takes Relatively Few Targeted Samples

The number of food samples FDA has tested for pesticide residues in recent years has been considerably smaller than what the agency tested in the early 1990s. FDA attributes this decrease in targeted samples, at least in part, to an increase in its testing for other types of contaminants, such as microbiological pathogens. In fiscal year 1993, FDA analyzed over 12,000 domestic and imported food samples for pesticide residues. That number declined in the subsequent years, reaching a low of about 5,000 in fiscal year 2008 followed by a small increase as of fiscal year 2012. Most of that decrease can be attributed to a reduction in the number of domestic food samples selected for testing. In the early to mid-1990s, FDA tested domestic and imported foods in roughly equal numbers. Throughout this period (i.e., fiscal years 1993 through 2012), the number of imported samples FDA tested for generally fluctuated from about 4,000 to about 7,000, while the number of domestic samples has declined from almost 6,000 to less than 1,200 (see fig. 4).

Figure 4: Total Number of Targeted Samples of Domestic and Imported Foods Tested for Pesticide Residues by FDA, Fiscal Years 1993 through 2012



Source: GAO analysis of Food and Drug Administration data. | GAO-15-38

FDA's targeted samples of imported and domestic foods likely represent a very small percentage of all foods that the agency regulates. For example, according to agency data for calendar year 2012, FDA tested 4,600 samples for pesticide residues—less than one-tenth of 1 percent—of the more than 9.7 million entry lines of imported foods that came through U.S. ports.[44] This equates to approximately 1 test out of every 2,100 entry lines. Likewise, FDA's samples of domestic foods likely represent a very small percentage of all domestic foods it regulates. In 2012, FDA tested 1,167 domestic samples for pesticide residue. However, these samples likely represented a smaller proportion of the domestic food supply than did the agency's samples of the imported food

[44]An entry line is a unique shipment or lot of a particular food by a particular shipper offered for admission into U.S. commerce at a particular place in time. FDA provided us data on imported entry lines of foods sampled in calendar year 2012 rather than fiscal year 2012 to assist our analysis of the agency's first full year of using PREDICT.

supply for 2012. This is because (1) most of the U.S. food supply is domestic and (2) FDA took about one-quarter as many domestic samples as imported samples in 2012. According to its recent annual reports, FDA has placed a greater emphasis on testing imported foods because it has found a higher percentage of imported samples with violations. Because FDA's sampling data are targeted and do not represent all foods that the agency regulates, it is not possible to use FDA's data to estimate how much of the foods it regulates contain violative levels of pesticides. As described above, however, AMS data (shown in table 1) on the presence of presumptive tolerance violations among the 10 commodities we reviewed indicate that, for some commodities, the frequency of violations that FDA does not detect could be relatively high.

FDA Does Not Disclose That It Does Not Test for Several Commonly Used Pesticides with Established Tolerance Levels in Foods

The multiresidue methods FDA uses to test commodities for pesticide residues cannot detect all pesticides with established tolerances, including six of the most commonly used pesticides in the United States, but the agency does not disclose pesticides that it does not test for, including these six. FDA is not required by law or regulation to select particular commodities for sampling or test for specific pesticides, but best practices in survey research, such as practices in OMB standards for designing and releasing to the public information concerning a data collection effort, call for, among other things, disclosure of conceptual limitations that could affect survey results. According to FDA's 2011 annual monitoring report, the agency's testing methods are able to detect the majority of the approximately 400 pesticides with established tolerances, as well as others without established tolerances, but certain commonly used pesticides that have established tolerances must be detected using selective residue testing methods that target the particular pesticide.[45] However, according to FDA officials, the agency does not regularly use selective residue testing methods because of their cost. Therefore, while there is no requirement that FDA test for all pesticides, and increasing the scope of its testing would require additional resources, FDA does not know the full extent to which tested commodities comply with established tolerances because the agency's testing methods cannot detect all pesticides with tolerances.

[45]In its 2011 summary of its monitoring program, FDA reported that it was able to detect 500 pesticides, including pesticides for which EPA had not established a tolerance. Pesticides that have established tolerance levels are registered for use on certain commodities.

We identified 6 pesticides that were among the 25 most commonly used pesticides in 2001, 2003, 2005, and 2007,[46] but that FDA has rarely, if ever, tested for in its regulatory monitoring program since 1993 because they generally require selective residue testing.[47] FDA does not disclose in its annual monitoring reports that it does not test for these pesticides. These 6 pesticides are glyphosate, 2,4-D, MCPA,[48] mancozeb, paraquat, and methyl bromide, all of which are registered for use on food or animal feed and have established tolerances.

- **Glyphosate:** According to a 2011 EPA report, glyphosate was the most commonly used agricultural pesticide in the United States in 2001, 2003, 2005, and 2007. Glyphosate is widely used on several major crops, particularly those that have been genetically engineered to tolerate it, such as corn and soybeans. EPA has established tolerances for glyphosate on over 170 food commodities. An official from EPA's Office of Pesticide Programs said that EPA asked AMS to conduct a onetime study of glyphosate residue, despite the costs, because FDA was not testing for it, it had widespread use, and likely widespread human exposure given the crops for which it was registered. Consequently, in 2011, a USDA laboratory tested 300 soybean samples for glyphosate and its metabolite, aminomethylphosphonic acid. USDA detected glyphosate residues in about 90 percent of the 300 soybean samples and the glyphosate metabolite in over 95 percent of the samples. The largest concentration of glyphosate USDA detected was 18.5 parts per million; thus, close to but not exceeding the tolerance of 20 parts per million. FDA officials cited two reasons FDA does not test for the herbicide. First, officials stated that glyphosate levels, if present in genetically engineered corn and soybeans, are likely to be reduced by the processing done to those foods. Second, according to FDA, the total start-up cost to implement selective residue methods for glyphosate at its six testing laboratories would be approximately $5 million. FDA officials stated the agency is evaluating the extent of the use of genetically engineered crops for human foods to determine

[46]EPA, *Pesticides Industry Sales and Usage: 2006 and 2007 Market Estimates*, Biological and Economic Analysis Division, Office of Pesticide Programs, Office of Chemical Safety and Pollution Prevention, Washington, D.C. 20460 (February 2011).

[47]FDA tests commodities for the other 19 most commonly used pesticides.

[48]MCPA is an abbreviation for 4-chloro-2-methylphenoxy acetic acid.

whether glyphosate should be added to its pesticide residue monitoring program.

- **2,4-D and MCPA:** FDA officials stated that, while the agency does not test for the pesticides 2,4-D and MCPA in its pesticide monitoring program, it does test for them in its Total Diet Study. EPA has established tolerances for both pesticides for dozens of food or animal feed commodities. According to agency officials, its Total Diet Study testing has never detected MCPA, but the agency has detected 2,4-D at low levels (below 5 parts per billion) in selected food items. However, as has occurred with glyphosate, the use of 2,4-D may increase if USDA deregulates the production of corn and soybeans genetically engineered to tolerate being sprayed with this herbicide.[49] According to FDA officials, testing for 2,4-D would also require a selective residue method that would cost approximately $5 million to implement throughout its laboratories. FDA officials stated the agency is evaluating the extent of the use of genetically engineered crops for human foods to determine whether 2,4-D should be added to its pesticide residue monitoring program. AMS's Pesticide Data Program rarely tested foods for 2,4-D or MCPA from 1998 through 2012.[50]

- **Mancozeb and paraquat:** FDA has not tested samples for the fungicide mancozeb or the herbicide paraquat, each of which would require selective residue testing. In explaining its reasons for not testing, FDA said that mancozeb degrades quickly and residues on food would likely be very low, and referred to an EPA assessment that paraquat posed minimal dietary risk. However, mancozeb has established tolerances for over 75 commodities, and paraquat has established tolerances for over 110 commodities. AMS's Pesticide Data Program did not test foods for mancozeb or paraquat from 1998 through 2012.

- **Methyl bromide:** FDA explained that it does not test for methyl bromide because it is a fumigant injected into the soil that dissipates or degrades before crops are planted and therefore, no residues

[49]As of June 2014, USDA was conducting a regulatory review of corn and soybean crops engineered to tolerate 2,4-D to determine whether they can be sold without regulation. Also, as of June 2014, EPA was conducting risk assessments to decide upon the approval of the proposed new uses of 2,4-D.

[50]AMS tested milk and grapes for 2,4-D and MCPA in 1998 and 2009, respectively.

would be expected in foods. However, methyl bromide also is used on crops in postharvest applications, and EPA has established tolerances for postharvest uses of the fumigant on about 90 commodities. AMS's Pesticide Data Program did not test foods for methyl bromide from 1998 through 2012.

Although FDA's last four annual monitoring reports state that the agency tests for the majority of pesticides with established tolerances, the reports do not disclose the pesticides with tolerances that the agency does not test for in its monitoring program. These annual monitoring reports identify the pesticides that the agency is capable of detecting in its monitoring program but do not identify which pesticides with tolerances it does not test for and the potential effect that not testing for those pesticides could have on its detection of violations, namely not detecting violations of those pesticides' tolerances. However, guidance from OMB directs agencies to meet certain standards when designing and releasing to the public information concerning a data collection effort—such as FDA's pesticide monitoring program—to help ensure and maximize the usefulness of information disseminated by the federal government.[51] For example, OMB directs agencies to produce survey documentation that includes those materials necessary to understand how to properly analyze data from each survey. Without awareness of this limitation (i.e., not disclosing the pesticides that have tolerances for which FDA does not test), users of the annual monitoring reports may not have accurate information and may misinterpret the results of the program, which, by not testing for certain pesticides, may be identifying fewer violations than occur.

[51]OMB, *Standards and Guidelines for Statistical Surveys* (September 2006). Although FDA's targeted samples are not intended to produce results with which to generalize, FDA uses and reports its targeted sampling data for statistical purposes. For example, it uses these data in deciding which future shipments or foods to target for monitoring, and it publishes these data in its annual monitoring reports. Therefore, OMB standards about presenting results and data are relevant to FDA's data collection effort.

The Effect of FDA's Targeting Tool on the Agency's Ability to Identify Foods at High Risk of Pesticide Residue Violations Is Unclear

Even as it has decreased the scope of its monitoring, in December 2011, FDA implemented PREDICT—a tool intended to improve import screening and targeting to prevent the entry of adulterated, misbranded, or otherwise violative goods. However, after the first full year of use in 2012, it was not clear what effect the tool has had on FDA's ability to identify foods at high risk of having pesticide residue violations.[52] According to FDA officials, the agency's employees do not rely solely on the risk information presented by PREDICT but can use their own judgment, or may be directed by FDA headquarters to inspect products that do not have high-risk scores.[53]

PREDICT generates a numerical risk score for each imported entry line based on the compliance history of the manufacturer, shipper, importer, consignee, and country of origin, as well as inherent health, safety, and other product-related variables. PREDICT ranks the risk score relative to all other scores generated in the previous 30 days. Entry lines with scores that are below the 60th percentile and not otherwise flagged may proceed into domestic commerce without further review. Entry lines with scores that are at or above the 60th percentile or otherwise flagged are held for review for an admissibility decision. An inspector then reviews this information, obtains additional documentation, if needed, and decides which lines to target for examination or sampling.

According to FDA officials, factors that inspectors consider when deciding whether to test a product other than the PREDICT risk score could include (1) knowledge of the compliance history of the firm or product that is not otherwise captured in the data systems accessed by PREDICT; (2) whether FDA had asked districts to target specific products for sampling

[52]We reported in September 2009 that FDA planned to begin deploying PREDICT on a district-by-district basis at all ports and for all FDA-regulated products (e.g., food, drugs, and medical devices) in September 2009 over a 6-week period. (See GAO-09-873. In March 2012, as part of a review of major FDA data systems, we noted that FDA fully deployed PREDICT at the end of December 2011. See GAO, *Information Technology: FDA Needs to Fully Implement Key Management Practices to Lessen Modernization Risks*, GAO-12-346 (Washington, D.C.: Mar. 15, 2012).

[53]According to FDA officials, entry reviewers are FDA employees trained to evaluate PREDICT scoring of imported shipments and verify the requirements for FDA-regulated products. After conducting the initial entry review, the entry reviewer forwards entries selected for further evaluation to the Investigations Branch where FDA inspectors coordinate the examination and sampling of selected shipments.

based on recent information about a product's known risk;[54] (3) FDA's pesticide program work plan;[55] (4) staff or equipment availability in the district and laboratories; and (5) other relevant information. However, FDA officials said that it was impossible to identify each inspector's rationale for selecting each individual product for sampling.

Because FDA's import sampling decisions are made on the basis of multiple sources of information (e.g., the inspector's judgment or specific direction from FDA headquarters) and not simply the PREDICT risk score, inspectors may select products for testing that do not have high risk scores. In 2012, over 9.7 million imported food entry lines entered the country. In general, FDA was more likely to select for testing those entry lines that had higher risk scores. For example, FDA tested 0.23 percent of the entry lines in the 90th percentile rank versus 0.01 percent of the entry lines in the 10th percentile. Overall, however, a cumulative total of about 25 percent of the entry lines tested in 2012 had risk scores below the 60th percentile (see table 3 for details).

[54]Such direction to districts to target specific products for sampling could include those with a high percentage of violations among tested samples in the past, such as targeted samples of ginseng, which, as shown in table 2, had a 75 percent violation rate in 2011.

[55]In 2009 and 2010, for example, FDA sent to its field offices a domestic and import sample collection schedule for the fiscal year. The schedules targeted specific foods, farms (for domestic), and countries (for imports) with a known history of illegal pesticide residues.

Table 3: FDA's Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) Scoring for Imported Food Entry Lines, Sampling Data, and Violation Rates in 2012

Percentile rank	Entry lines	Entry lines sampled	Cumulative percentage of entry lines sampled	Percentage of entry lines sampled	Violative entry lines	Violative entry lines as a percentage of entry lines sampled
0-9	2,164,855	214	4.7%	0.01%	9	4.2%
10-19	1,360,608	204	9.1%	0.01%	11	5.4%
20-29	1,175,780	193	13.3%	0.02%	18	9.3%
30-39	1,020,458	165	16.9%	0.02%	10	6.1%
40-49	772,975	163	20.4%	0.02%	14	8.6%
50-59	613,174	192	24.6%	0.03%	23	12.0%
60-69	723,304	614	38.0%	0.09%	43	7.0%
70-79	981,812	1,102	61.9%	0.11%	99	9.0%
80-89	409,475	577	74.4%	0.14%	43	7.5%
90-100	503,616	1,171	99.9%	0.23%	132	11.3%
No score[a]	21,896	5	100.0%	0.02%	3	60.0%[b]
Total	**9,747,953**	**4,600**	**100.0%**	**0.05%**	**405**	**8.8%**

Source: GAO analysis of FDA data. | GAO-15-38

Note: An entry line is a unique shipment of imported products or items offered for admission into U.S. commerce.

[a]FDA did not have PREDICT scores for all entry lines of imported foods in 2012.

[b]Rates based on a small number of samples (i.e., with a small denominator) may be less precise than rates based on a large number of samples. The percentile rank category of "no score" had five samples, and the violation rate of 60 percent would have changed by more than 20 percent if FDA had found one more or one less violation.

FDA's test results from 2012 show that, in some instances, the decisions of inspectors to test entry lines that had low-risk scores were justified when the agency found violations. However, high violation rates did not necessarily correspond with high-risk scores generated by PREDICT among the entry lines that FDA tested. FDA took a total of 4,600 samples of imported food entry lines in 2012, of which 405, or 8.8 percent, were violative because they contained pesticide residues in excess of established tolerance levels or for which no tolerance had been established. Although results cannot be generalized beyond FDA's PREDICT sample without a statistically valid, representative sample and it is difficult to reliably assess the relationship between PREDICT scores and violation rates without such a sample and, while this was the first year of PREDICT's implementation, FDA data show an inconsistent relationship between PREDICT scores and violation rates among the

sample of shipments that were tested. As depicted in table 3, the entry lines with the highest violation rate (12.0 percent) had risk scores in the 50th to 59th percentile and entry lines with the third highest violation rate (9.3 percent) had scores in the 20th to 29th percentile. Entry lines with risk scores in the 90th to 100th percentile had the second highest violation rate (11.3 percent). FDA data further show that the samples the agency tested with PREDICT scores below the 60th percentile had an overall violation rate (7.5 percent)[56] that was similar to the rate for entry lines with scores at or above the 60th percentile (9.2 percent).[57] This could suggest that PREDICT inconsistently identified entry lines with violations or it could suggest that factors other than PREDICT caused the agency to test entry lines that were at risk of a violation in spite of their lower PREDICT scores, or both. To reliably assess the effectiveness of PREDICT, therefore, the agency would need a statistically valid, representative sample of entry lines.

In addition, FDA did not test the vast majority of entry lines that had the highest PREDICT risk scores. In 2012, over 2.6 million entry lines scored above the 60th percentile, meaning that there was enough concern about these lines that FDA did not automatically allow them to proceed into commerce. Of those, FDA tested samples from 3,464 and did not test more than 500,000 of the 503,616 entry lines that had risk scores in the 90th to 100th percentile. This indicates that even if a system such as PREDICT is able to accurately identify high-risk foods, FDA's monitoring program is only capable of testing a small percentage of those foods for violations. FDA acknowledges that it is able to physically examine only a small percentage of imports and states that it is essential that screening and targeting be as effective as possible.

All 4,600 of the samples FDA tested in 2012 could have been selected from the more than 500,000 entry lines with a PREDICT risk score in the 90th to 100th percentile. However, FDA officials stated that there are several practical reasons why an inspector may not physically inspect and test a particular product falling within the highest percentile rank. For

[56]The overall violation rate for entry lines below the 60th percentile (7.5) is found by dividing the total number of violations (85) by the total number of entry lines sampled (1,131).

[57]The overall violation rate for entry lines in the 60th percentile and above (9.2) is found by dividing the total number of violations (317) by the total number of entry lines sampled (3,464).

example, a perishable product might cross a port of entry that temporarily lacks an available inspector. In addition, an inspector may not test a product with the highest percentile rank if the product already was subject to an Import Alert and could be detained without physical examination, or because the district recently tested a shipment of the same product from the same grower and found no violations. According to FDA officials, constraints on inspection staff and laboratory resources may also affect whether a product is tested.

FDA officials said that they were aware of the inconsistent relationship between PREDICT scores and detected violations in 2012 and were examining the issue in an ongoing, systemwide evaluation of PREDICT. In early 2013, FDA began an internal evaluation of PREDICT's overall effectiveness at identifying high-risk imported products; that effort was still ongoing as of July 2014. However, FDA's evaluation of PREDICT's effectiveness at targeting violative food products is hindered without having a statistically valid sample of foods that FDA regulates and that would serve as a baseline with which to compare PREDICT's results. OMB's standards on the professional principles and practices that federal agencies are directed to adhere to in all statistical activities[58] state that agencies must use generally accepted statistical methods, such as a probabilistic method that can provide estimates of sampling error, or justify statistically a nonprobability method that can measure the estimation error.[59] FDA's written plan for conducting its evaluation of PREDICT does not call for the agency to collect a statistically valid sample on the frequency of pesticide residue violations or provide the requisite justification. As discussed later in this report, according to FDA officials, calculating national estimates of pesticide violations for the entire food supply it regulates would be very expensive. However, without a statistically valid sample that would enable the agency to assess the reliability of PREDICT risk scores to indicate the presence of violations, FDA cannot derive a reliable estimate of the rate at which PREDICT is

[58]OMB, *Standards and Guidelines for Statistical Surveys* (September 2006). In part, this guidance directs that agency survey designs use generally accepted statistical methods, such as probabilistic methods that can provide estimates of sampling error. Any use of nonprobability sampling methods must be justified statistically and be able to measure estimation error.

[59]According to the OMB standards, the size and design of the sample must reflect the level of detail needed in tabulations and other data products, and the precision required of key estimates.

effectively identifying imported foods that contain violative levels of pesticide residues. Furthermore, because FDA uses PREDICT to identify risks among a wide range of products—not limited to foods—it is not clear the extent to which the scope of FDA's evaluation will enable it to address the effectiveness of PREDICT regarding pesticides specifically.

FDA Does Not Use Statistically Valid Methods to Gather Residue Incidence and Level Data for Its Pesticide Monitoring Program

In addition to the limitations in FDA's risk-based, targeted compliance and enforcement monitoring described above, FDA's monitoring program focuses on testing foods that have been targeted as part of monitoring for compliance and enforcement to the exclusion of determining the incidence and level of pesticide residues in domestic and imported foods. However, according to FDA's *Compliance Program Guidance Manual*, another of the agency's objectives is to determine the incidence and level of pesticide residues in domestic and imported foods. As we stated earlier, OMB standards provide guidance to agencies seeking to make estimates about populations, such as the incidence and level of pesticide residues in food.[60] Those standards state that agencies must select samples using generally accepted statistical methods, such as methods of probability sampling that can provide estimates of sampling error,[61] and any method that uses nonprobability sampling must be justified statistically and be able to measure estimation error. In addition, the size and design of the survey must reflect the precision required of key estimates. The OMB standards also address how agencies are to release information to the public, including information on limitations in the survey methodology. Determining the sufficient size and design of the sample would depend on what FDA wanted to know. If, for example, the agency wanted to know incidence and level of pesticide residues across all domestic and imported foods, it would need to design statistically valid random samples of those two broad categories of foods. If, on the other hand, FDA wanted to know about residue levels within particular commodities, it would need to design a survey of random samples of those commodities that meets statistical standards. FDA is not currently taking either of these approaches in its regulatory monitoring program. Finally, FDA's ability to evaluate the effectiveness of its targeted

[60]OMB, *Standards and Guidelines for Statistical Surveys* (September 2006).

[61]Sampling error refers to the variation in estimates from sample to sample due to sampling alone. Sampling error can often be reduced by drawing larger samples or using efficient sample design and analytical methods.

monitoring program (i.e., enforce pesticide residue tolerances in foods established by EPA) is limited because it has not determined the incidence and level of pesticide residues in the foods it regulates against which it can compare the results of its targeted compliance and enforcement monitoring.

In the early 1990s, FDA used statistically based samples of apples, pears, rice, and tomatoes to estimate the incidence and level of pesticide residues in those commodities. In each case, the agency took over 1,200 samples covering domestic and imported sources of the four commodities. Recent annual FDA monitoring reports indicate that the agency has not repeated this type of analysis because of resource constraints. In addition, to produce estimates for specific commodities in which it could be 95 percent confident, FDA documents have stated that the agency would need at least 800 imported and 800 domestic samples of each. Without designing and implementing a statistically valid sampling approach that would enable it to gather nationally representative incidence and level data for both domestically produced and imported foods, FDA is less able to determine the safety of the U.S. food supply and provide the users of its annual pesticide monitoring reports with reliable national estimates of the rate at which foods FDA regulates contain violative levels of pesticides. FDA officials said that calculating national estimates for the entire food supply it regulates would be very expensive because it would require a large number of samples for a wide array of products. The officials, however, did not provide estimates or documentation on the cost of a statistically valid sampling approach or whether they had assessed the trade-offs of doing less risk-based targeting and more random sampling.

FDA's focus on testing commodities that have been targeted as part of monitoring for compliance and enforcement to the exclusion of determining the incidence and level of pesticide residues in domestic and imported foods limits the agency's ability to make valid statements about violation rates for domestic and imported foods. FDA has stated in annual monitoring reports that imported foods it tested were more likely to have pesticide residue violations than domestic foods it tested. For example, in its summary of fiscal year 2011 test data, FDA stated that it found violative residues in 7.1 percent of the imported products it tested and 1.6 percent of the domestic products. For fiscal year 2010, FDA reported violative residues in 4.9 percent of imported products it tested and 1.9 percent of domestic products, and the rates were 4.0 and 1.4 for imported and domestic products it tested, respectively, in fiscal year 2009. FDA also reported the violation rates it found within certain categories of food;

namely, grains, fruits, vegetables, dairy, fish, and "other." For example, in 2011, FDA stated that the violation rate for domestic fruits it tested was 2.4 percent, and the rate for imported fruits was 6.9 percent. In making these statements, FDA considered both types of violations—those in which an established tolerance was exceeded and those in which a pesticide without an established tolerance was detected.

Determining whether these differences in violation rates represent underlying differences between domestic and imported commodities, however, is complicated by the fact that FDA does not collect data on violations using statistically valid samples, as described above. Therefore, based on standard statistical principles, it would not be valid or reliable to infer from the data that FDA collects through its targeted monitoring that imported commodities are more violative overall. These statistical principles suggest that it would be more valid to compare violation rates for a given commodity for imports to the same commodity for domestics—that is, an apples-to-apples comparison if violation rates are suspected to differ by commodity. Regardless, such a comparison would examine domestic and imported samples, whether by commodity or overall, selected in a statistically valid manner with sample sizes that are large enough and balanced enough to yield high levels of statistical confidence. The relatively small number of samples taken by FDA's monitoring program means that few, if any, commodities meet the sample size criteria in a single year, and no commodities were selected in the statistically valid method described above.

FDA's ability to evaluate how effectively its monitoring program detects and intercepts violative foods is also limited by the fact that it does not gather incidence and level data in a statistically valid manner, but only through a targeted sampling approach. The control activities standard under the federal standards for internal control call for agency management at the functional or activity level to compare actual performance with planned or expected results and analyze significant differences.[62] However, as discussed, FDA's pesticide monitoring program does not collect nationally representative data on the overall or commodity level rate of pesticide residue violations within the domestic and imported food supplies. As a result, FDA does not have

[62]GAO, *Standards for Internal Control in the Federal Government*, GAO/AIMD-00-21.3.1 (Washington, D.C.: November 1999).

representative data on such violations with which to compare the rate of violations detected through targeted pesticide monitoring. Depending on its level of precision, nationally representative data could also help FDA identify domestic or imported foods that are at a high risk of violating pesticide tolerances.

In addition to its targeted pesticide monitoring program, according to FDA reports, there are two sources of data on the overall incidence and level of pesticide residue in foods that FDA can use to quantify the presence of pesticide residue violations. However, these sources—FDA's Total Diet Study and AMS's Pesticide Data Program—have characteristics that affect their use in evaluating the effectiveness of FDA's targeted pesticide monitoring program. According to FDA, by its design, the Total Diet Study serves as an early warning system and is capable of detecting many more pesticide residues and at much greater sensitivity when compared with FDA's regulatory monitoring program. FDA's reports also state the agency relies on data from the Pesticide Data Program, which collects residue data on 20 to 30 commodities every year, with an emphasis on highly consumed commodities. Through December 2013, the program had gathered data on more than 90 commodities. And, in comparison to FDA's regulatory monitoring program, AMS's Pesticide Data Program is able to take considerably larger sample sizes.

While these two sources of data can help FDA identify emerging pesticide residue problems, because of their sampling methodologies, neither study can be used to directly and reliably evaluate the effectiveness of FDA's monitoring program across the domestic and imported food supplies. Although the Total Diet Study takes samples from a wide range of foods (i.e., over 270 different items composited from samples collected from three different cities), each study is only conducted four times each year. Therefore, specific foods are sampled only four times per year. The Pesticide Data Program tests large sample sizes but takes samples from relatively few commodities each year. In addition, both studies may first wash or peel foods before testing, simulating typical consumer handling. The Total Diet Study cooks some foods, including prepared foods containing multiple ingredients. These steps could reduce the detected concentration of pesticides. Without representative data on the presence of pesticide residue violations throughout the food supply, FDA cannot reliably evaluate the extent to which its monitoring program detects and intercepts violations at a rate greater than random chance.

FSIS Data for 2000 through 2011 Show Low Pesticide Residue Violation Rates for Meat, Poultry, and Processed Egg Products, but FSIS Did Not Disclose Limitations in the Data

Data from FSIS's National Residue Program for meat, poultry, and egg products (animal products) show a low rate of pesticide residue violations from 2000 through 2011. However, FSIS's approach for detecting violations during that period had limitations because the agency did not test these products for all pesticides with an established tolerance, and FSIS did not disclose those limitations in its annual pesticide monitoring reports. In addition, over that period, FSIS reduced the frequency with which it tested animal products for residues, a reduction in both the number of samples taken in a particular year and in the types of animal products tested. In 2011, in response to a USDA Office of Inspector General report, FSIS increased the number of pesticides that it tests for. In addition, according to agency officials, FSIS and EPA reached an informal agreement in May 2014 on changes to the National Residue Program that the agencies expect will make the data for residues in beef, pork, and poultry more useful for EPA in assessing potential dietary exposure and in determining pesticide risks to human health.

FSIS's National Residue Program Data for 2000 through 2011 Showed Low Violation Rates in Meat, Poultry, and Processed Egg Products, but Limitations in Its Data Are Not Disclosed

FSIS found a total of 30 pesticide residue violations out of nearly 55,000 random samples of domestic and imported meat, poultry, and processed egg products from 2000 through 2011.[63] In 3 of the 12 years we reviewed, FSIS found no pesticide violations, while in the other 9 years, it found from 1 to 8 violations. In each year in which it found violations, FSIS found them in far less than 1 percent of the animal products it tested. The 30 violations that FSIS found were distributed across 12 types of animal products known as production classes.[64] The production class with the greatest number of violations was boars/stags, with 13 violations for five different pesticides. All other production classes had 2 or fewer violations.

[63]All but 3 of the pesticide violations were in domestic products. The National Residue Program also occasionally found violations for other environmental contaminants, such as fire retardants, during this time period. In addition, the program found violative amounts of animal drugs such as antibiotics.

[64]Overall, FSIS tested 28 animal product types, or production classes; each production class was tested at least once during the period 2000 through 2011. They include horses, bulls, beef cows, dairy cows, heifers, steers, bison, bob veal, formula-fed veal, non-formula-fed veal, heavy calves, mature sheep, lambs, goats, market hogs, boars/stags, sows, roaster pigs, young chickens, mature chickens, young turkeys, mature turkeys, ducks, geese, ratites (which include ostrich and emu), squabs, rabbits, and processed egg products.

The 30 violations covered 14 separate pesticides for which FSIS found residues that either exceeded established tolerances or for which EPA had not established a tolerance.[65] The most common violation, which FSIS found six times, was for hexachlorobenzene.[66] According to EPA documents, hexachlorobenzene is no longer used but was commonly used into the 1960s as a pesticide, a fungicide, and for certain industrial purposes. It is still found in animal products because of its persistence in the environment. FSIS found other residue violations from 1 to 4 times from 2000 through 2011, including for the pesticides DDT[67] and chlordane that have been banned from use in the United States for about 40 years and 25 years, respectively, but are known to persist in the environment and can accumulate in plants ingested by animals. Although banned in the United States, DDT and chlordane may be used in other countries and, thus, have the potential to be in imported foods. While there is no EPA-established tolerance for DDT, EPA recommended an "action level" of 5 parts per million. EPA recommended an action level of 0.3 parts per million for chlordane. FSIS does not permit residues of DDT or chlordane above those levels.

FSIS also detected pesticides in some domestic and imported samples at levels that did not exceed established tolerances. The percentage of domestic samples with nonviolative detections declined over the time period we examined, from about 7 percent of about 7,500 samples in 2000 to 0.2 percent of about 1,900 samples taken in 2011. For imported samples, the percentage with nonviolative detections also declined, from about 6 percent of about 750 samples taken in 2001 to no detections in about 300 samples taken in 2011. The pesticide most frequently detected at nonviolative levels or below action levels was DDT. For example, in 2000, 371 of the 490 nonviolative detections in domestic products were of DDT. The decline in the rate of detections of pesticides at nonviolative or below action levels over this time period could be attributed to the

[65]Seven of the 30 violations exceeded established tolerances, and 22 were violations for which there was no established tolerance. One violation was for a pesticide identified by FSIS as a "chlorinated hydrocarbon." That term denotes a family of pesticides. We were not able to determine the specific name of the pesticide or whether it had an established tolerance.

[66]The other 13 named pesticides FSIS found at violative levels were carbaryl, chlordane, chlorfenvinphos, coumaphos, DDT, dieldrin, ethion, heptachlor, lindane, methoxychlor, mirex, permethrin, and piperonyl butoxide.

[67]DDT is the abbreviation for dichloro-diphenyl-trichloroethane.

possibility that persistent, but no longer used, pesticides such as DDT are less present in the environment. However, FSIS's approach may have underestimated violations from 2000 through 2011 as the agency (1) did not test meat, poultry, and processed egg products for all pesticides with established tolerance levels and (2) generally reduced the animal production classes tested for pesticide residue.

FSIS's National Residue Program Did Not Test Meat, Poultry, and Processed Egg Products for All Pesticides with Established Tolerance Levels

While FSIS's National Residue Program found relatively few pesticide tolerance violations from 2000 through 2011, its multiresidue testing method did not test meat, poultry, and processed egg products for all pesticides that had an established EPA tolerance. Therefore, the pesticides it tested for did not represent the full range of pesticides that might come in contact with meat, poultry, and processed egg products through direct application or through animal feed. In addition, FSIS's annual reports did not identify which pesticides with tolerances were not covered by the testing program.

According to FSIS documents, from 2000 through 2010, the agency increased its testing from about 20 to about 42 pesticides each year. In 2011, FSIS's guidance for its pesticide testing program called for a further increase to 55 pesticides. According to FSIS officials, the agency increased the number of pesticides it tested for in response to a recommendation in a 2010 report by USDA's Office of Inspector General[68] and requests from EPA's Office of Pesticide Programs. With the increase, FSIS tested for 9 of the 18 pesticides that are registered for direct use on food animals (see table 4).

[68]*FSIS National Residue Program for Cattle*, USDA Office of Inspector General, Audit Report 24601-08-KC (Mar. 25, 2010).

Table 4: Pesticides with Tolerances for Direct Use on Food Animals in the Food Safety and Inspection Service's (FSIS) August 2011, Pesticide Testing Guidance

Name of pesticide with established tolerance and registered for direct use on food animals	Included in FSIS's 2011 guidance for pesticide testing
Abamectin	No
Amitraz	No
Carbaryl	Yes
Chlorpyrifos	Yes
Coumaphos	No
Cyfluthrin	No
Cypermethrin	Yes
Diazinon	No
Dichlorvos	Yes
Diflubenzuron	Yes
Endosulfan	Yes
Lambda-Cyhalothrin	Yes
Malathion	No
Permethrin	Yes
Phosmet	No
Piperonyl butoxide	Yes
Pirimiphos-methyl	No
Pyrethrins	No

Sources: GAO analysis of EPA and FSIS documents. | GAO-15-38

Note: The pesticides in this table were registered by EPA for direct animal use as of February 2014.

In total, FSIS's 2011 program tested for 38 of the 191 pesticides that have established tolerances for both direct and indirect use on animals. In addition, FSIS tested for 17 pesticides that do not have established tolerances in animal products, bringing the number in its testing program to 55. The 17 pesticides without tolerances include some that may have been used in the past but now are banned or restricted in the United States. As of February 2014, there were 191 pesticides for which EPA had established residue tolerances in meat, poultry, and processed egg products, including 18 pesticides that are registered for direct use on

animals that produce these foods.[69] Other pesticides are registered for use on animal feed, and EPA has established tolerances for the meat, poultry, and processed egg products of the animals that might consume that feed.

As is the case with FDA, FSIS is not required by law or regulation to test the foods it samples for specific pesticides. However, OMB's standards for designing and releasing to the public information concerning a data collection effort also apply to FSIS's National Residue Program. In that regard, FSIS's annual reports do not meet OMB's best practices for statistical surveys because the agency does not disclose the pesticides with tolerances for which it does not test or the potential effect that its selection of pesticides could have on its results. Similarly, FSIS does not disclose the potential bias associated with its selection of production classes for testing. Such disclosure would be consistent with OMB standards for reporting limitations relevant to a data collection effort. By not providing this information, FSIS does not disclose conceptual limitations associated with its survey. Without information on these limitations and measures of sampling error (margin of error), users of the agency's annual monitoring reports may not have accurate information and may misinterpret the results of the program, which is identifying fewer violations for meat, poultry, and processed egg products than could occur.

[69]We did not attempt to determine the number and identity of each pesticide with established EPA tolerances for meat, poultry, and processed egg products in each year from 2000 through 2011. Instead, we performed our analysis using data on tolerances from February 2014 and acknowledge that the more recent data may include pesticides with tolerances that were established after 2011. We requested help from EPA in identifying pesticides with established tolerances for animal products. In turn, EPA requested that a contractor that manages data on registered pesticides query its database to provide information on tolerances as of February 2014. We determined that it would be unreasonably burdensome to request that the contractor also search for tolerances established for animal products for each year from 2000 through 2011. The data do not account for pesticides with EPA established tolerances for goat or horse products. After reviewing EPA tolerance regulations, we found that there were no pesticides with tolerances for goat or horse that did not also have a tolerance for another animal product. In light of that information, we did not request a separate query for goat or horse products.

From 2000 through 2011, FSIS Generally Reduced the Number of Samples and Animal Production Classes Tested for Pesticide Residue

In light of other priorities, from 2000 through 2009, FSIS reduced the number of domestic and imported samples taken from over 8,000 per year to less than 1,900 before increasing samples to more than 2,100 in 2010 and 2011.[70] The number of samples that FSIS tests of a particular production class affects the precision with which it can project its results across all of that class. According to FSIS annual reports, in 2006, the agency's goal was to test 230 to 300 samples from each production class to obtain results that were statistically meaningful. These reports indicate that testing sample sizes of 230 or 300 ensured FSIS a 90 percent or 95 percent probability, respectively, of detecting chemical residue violations if the violation rate is equal to or greater than 1 percent in the population being sampled. From 2006 through 2011, even with the general decline in the overall number of samples, FSIS's sample sizes for each production class tested generally exceeded 230. While FSIS did not decrease the sample size per production class, it did reduce the number of production classes it sampled. This led to a reduction in the total number of samples per year.

From 2000 through 2005, the agency tested as few as 19 to as many as 28 domestic production classes per year. However, from 2006 through 2011, FSIS tested 7 to 10 production classes per year. In addition, FSIS has not tested several production classes for pesticides for many years. For example, it has not tested ducks, geese, ratites (e.g., ostrich and emu), squabs, or rabbits since 2003, or young and mature turkeys and processed egg products since 2005. For the most part, the total U.S. consumption of these production classes is small; FSIS reports that all but young turkeys and processed egg products were each less than 1 percent of total meat, poultry, and processed egg products consumed in 2011.[71] As we said earlier, according to FSIS officials, in 2011 the agency

[70]FSIS continued to increase the number of samples it took after 2011, the end point of our analysis of violation data. In 2012, FSIS stated in its Residue Sampling Plan that it would increase its goal to 800 samples for each production class tested. FSIS explained that, by increasing the number of samples taken, it would increase its probability of finding a violation to greater than 99 percent, if the violation rate was equal to or greater than 1 percent in the population being sampled. In 2013, FSIS's 5,900 samples were spread across nine production classes, for an average of 656 per class, or about 144 less than its target of 800. FSIS officials said that to increase its sample size for each production class, the agency would have to decrease the number of production classes sampled in any 1 year.

[71]Young turkeys were about 5.2 percent, and processed egg products were about 4.7 percent of total meat, poultry, and processed egg products consumed in 2011, according to FSIS.

increased the number of pesticides it tested for in response to a recommendation in a 2010 report by USDA's Office of Inspector General and requests from EPA's Office of Pesticide Programs.

FSIS Has Engaged with EPA on Changes to the National Residue Program

FSIS has recently engaged with EPA on three types of changes to the National Residue Program that would enhance FSIS's collection and reporting of residue data. In addition to FSIS's use of the program's data for enforcing tolerances, EPA uses the data to assess potential dietary exposure in determining pesticide risks to human health. EPA also has used data on such residues in beef, pork, and poultry from AMS's Pesticide Data Program. However, AMS decided in 2012 to stop testing these commodities for pesticides, and EPA officials were concerned that FSIS's monitoring data would not be able to replace the AMS data and serve EPA's purposes.[72] Specifically, according to the Chief of EPA's chemistry and exposure branch, AMS's Pesticide Data Program (1) tested for a broader array of pesticides than FSIS has tested for in its National Residue Program, (2) was able to detect lower concentrations of the pesticides it tested for than FSIS has, and (3) made its data available to EPA in a more detailed format and in a timelier manner than FSIS has in its annual reports. Since AMS's decision that it would no longer include beef, pork, or poultry in its Pesticide Data Program, EPA has engaged in discussions with FSIS about ways that FSIS could enhance its National Residue Program to address these issues. Through these discussions, EPA and FSIS officials said they had reached some agreement concerning the pesticides for which FSIS tests, the residue detection levels FSIS can achieve, and the format and timing of the FSIS data as discussed below.

[72]According to the former Director of the Pesticide Data Program, AMS decided to stop testing meat and poultry samples (it had never tested processed egg products) after FSIS issued a *Federal Register* notice in July 2012, announcing its plan to modify and expand the National Residue Program. Specifically, FSIS announced it would begin using several multiresidue methods for analyzing samples for residues, including pesticide residues. According to the Director, it would be duplicative for both AMS and FSIS to conduct residue testing on meat and poultry using similar multiresidue methods, particularly as AMS does not have the authority to enter meat processing plants and had to rely on FSIS to obtain samples. The Director also noted that funding constraints led AMS to reduce the scope of the Pesticide Data Program by discontinuing its testing of meat and poultry.

Number of Pesticides for Which FSIS Tests

As reported in 2010 by USDA's Office of Inspector General and described to us by EPA officials, EPA has for years urged FSIS to increase the number of pesticides included in FSIS's National Residue Program.[73] Most recently, in April 2014, EPA provided FSIS with a document containing a list of 207 pesticides that AMS's Pesticide Data Program had tested for in beef, pork, and poultry but for which FSIS did not necessarily test in its National Residue Program. In the document, EPA indicated its priorities for which pesticides FSIS should include in its residue program. According to the EPA document, the agency used several criteria to develop its list of priorities, including whether AMS had previously detected these pesticides in samples and a measure of a pesticide's tendency to accumulate in fat. In May 2014, EPA and FSIS officials said they had reached agreement about the status of specific pesticides contained in EPA's priority list, such as whether FSIS tested for a specific pesticide or was in the process of adding this pesticide to its testing program. To add pesticides, FSIS must determine that its equipment is capable of detecting and accurately measuring individual pesticides in different types of animal tissue. According to the executive associate of FSIS's laboratories, the agency completed the process of validating the method needed to test for 88 pesticides in June 2014, and the agency's updated program guidance went into effect in July 2014. With that update to its program, as of July 2014, FSIS either tested or, according to agency program guidance, planned to start testing in July 2014 for 85 of the 207 pesticides on EPA's priority list.[74] However, as shown in table 5, many of the pesticides considered a priority by EPA are not in FSIS's current or planned testing program. For example, 13 of EPA's 32 "highest" priority and 27 of EPA's 41 "high" priority pesticides are not included. The Chief of EPA's chemistry and exposure branch in the Office of Pesticide Programs said that while he does not necessarily expect to see significantly more pesticide residue violations as a result of the expanded testing, data on additional pesticides—whether it shows the presence of residues or not—would help EPA refine its risk assessments. According to officials from both agencies, FSIS and EPA will continue to discuss how their priorities can be met with existing resource limitations.

[73]*FSIS National Residue Program for Cattle*, USDA Office of Inspector General, Audit Report 24601-08-KC (Mar. 25, 2010).

[74]According to FSIS's program guidance, the agency will test for three pesticides that are not on EPA's priority list, bringing the total number tested for to 88.

Table 5: Pesticides Tested for in Beef, Pork, and Poultry Included, or Planned for Inclusion, in the Food Safety and Inspection Service's (FSIS) National Residue Program, as of July 2014

EPA's priority	Pesticides in EPA's 2014 priority list	Pesticides in EPA's priority list planned for FSIS's National Residue Program in July 2014	Pesticides in EPA's 2014 priority list but not planned for FSIS's 2014 National Residue Program
Highest	32	19	13
High	41	14	27
Medium	51	17	34
Low	83	35	48
Total	**207**	**85**	**122**

Sources: EPA and FSIS data. | GAO-15-38

Note: According to FSIS's testing guidance, its testing program will include three pesticides that were not included in the Agricultural Marketing Service's Pesticide Data Program and, as a result, were not included in EPA's list of priorities.

Residue Detection Limits FSIS Can Achieve

In addition to discussing with FSIS the list of pesticides to include in the National Residue Program, EPA also has discussed changes in the limits of detection that FSIS can achieve for those pesticides. The executive associate of FSIS's laboratories said that because the agency's objective is to identify residue violations, rather than gather residue exposure data, it is not necessary that its testing methods be able to detect residues at levels well below the established tolerances. FSIS uses the term "minimum level of applicability" to refer to the lowest residue concentration that has been validated to be accurately and consistently reported by its testing method in a type of animal product. According to the executive associate, if a pesticide has an established tolerance, FSIS typically sets the minimum level of applicability at one-half of the tolerance. If there is no tolerance for a pesticide, FSIS sets the minimum level of applicability at five times the level of quantitation, which is the lowest concentration that its equipment can reliably measure. According to the Chief of EPA's chemistry and exposure branch, EPA expressed its concerns to FSIS that the relatively high FSIS minimum levels of applicability hampered EPA's ability to accurately estimate exposure to pesticide residues in food. That is because, according to the branch Chief, when FSIS reports that it did not detect any residue of a particular pesticide, EPA's practice has been to assume that the tested commodity had residue equaling one-half of the minimum level of applicability rather than no residue. To improve the precision of its risk assessments, EPA asked FSIS in August 2013 if it could lower its minimum level of applicability to one-tenth of the tolerance level for those pesticides that

have a tolerance for meat or poultry. However, in May 2014, the EPA branch Chief said that, after further review of FSIS's testing capabilities, EPA determined that, for the most part, FSIS's current minimum levels of applicability are adequate to meet EPA's needs. Further, according to agency officials, FSIS has agreed that, as its resources permit, it will look for ways to lower minimum levels of applicability on a case-by-case basis.

Format and Timing of FSIS Data

According to the Chief of EPA's chemistry and exposure branch, EPA's Office of Pesticide Programs wants to use FSIS data in its pesticide risk assessments but would need FSIS to make the data available to EPA in a more detailed format; in the past, the official said that EPA only received summary data from FSIS that were not adequate for its risk assessments. When EPA conducts risk assessments, according to the official, it must also make its source data fully available so that the public can review and analyze them. However, FSIS has not been making its source data similarly available to the public or EPA.

EPA officials also said that more timely access to FSIS's test results would enhance their risk assessment activities. They said that FSIS is required to publish data within 2 years of it being collected, whereas AMS provided EPA with data in about 9 months after it was collected. The USDA Inspector General's 2010 report on the National Residue Program also raised the issue of the time it took for data sharing and recommended that FSIS work with EPA and FDA to develop a formal plan with reasonable time frames to facilitate the exchange of residue testing data between the agencies. FSIS concurred with the recommendation saying that in conjunction with the other agencies it would include a formal plan for exchanging residue testing data in a draft Memorandum of Understanding (MOU) by March 2011. The draft MOU would revise a 1984 MOU between FSIS, AMS, EPA, and FDA that addresses a number of issues related to the agencies' regulatory activities concerning residues of drugs, pesticides, and environmental contaminants in foods, including the sharing of test results. As of May 2014, according to agency officials, the MOU for exchanging residue testing data had been drafted but had yet to be signed by the agencies' responsible officials.

In the meantime, EPA and FSIS officials said that after discussion the agencies agreed that FSIS will provide EPA with specific pesticide residue data, on a quarterly basis, in an electronic format starting in fiscal year 2015. EPA determined that the agreed-upon data will contain enough information for its pesticide risk assessments, and FSIS

determined that the data are not sensitive and can be released to the public.

AMS's Survey Data Show Pesticide Residues Vary by Commodity and Are Generally Well below Tolerance Levels, but Annual Reports Do Not Disclose Survey Limitations

For 10 highly consumed commodities, data from the most recent year in which they were tested by AMS's Pesticide Data Program show that the frequency with which pesticide residues were detected at any level and the average number of pesticides per sample varied by commodity and that the average levels of detected residues were well below the tolerance levels established by EPA.[75] However, there are limitations in AMS's survey methods. Specifically, while EPA officials and others have said that the Pesticide Data Program provides valuable information on the incidence and level of residues in foods, limitations in AMS's sampling methods may affect the usefulness of the data in making national estimates about the presence of pesticide residues in the food supply, and AMS does not disclose these limitations, reducing transparency regarding the agency's methods for collecting the data.

The Number of Pesticides per Sample Found by AMS's Pesticide Data Program Has Varied by Commodity

We analyzed pesticide residue data generated by AMS's Pesticide Data Program for 10 highly consumed and frequently sampled commodities and found that the average number of pesticide residues per sample ranged widely among the 10 commodities. In some of the instances, AMS detected only 1 pesticide residue, and in one commodity the agency found as many as 17 pesticide residues in a sample. According to AMS officials, these findings are due to inherent differences in commodities' vulnerability to pests and the resultant need to use pesticides to respond to varying pest pressures.

AMS's Pesticide Data Program cooperates with state agriculture departments and other federal agencies to annually collect, analyze, and report the type and concentration of pesticide residues on agricultural commodities in the U.S. food supply, with an emphasis on those commodities highly consumed by infants and children. The program typically takes approximately 500 to 750 samples each for about 20

[75]As discussed, AMS detected what it terms "presumptive tolerance violations" in some samples of the 10 selected commodities. Those were samples in which it found residues above an established tolerance or residues for which there was no established tolerance.

commodities each year.[76] We selected the 10 commodities that AMS sampled with the most frequency from 1994 through 2012: apples, bananas, broccoli, cantaloupe, green beans, lettuce, peaches, pears, potatoes, and sweet bell peppers. We then analyzed AMS's data for those commodities from the 3 most recent years in which the agency sampled them.[77] The years in which AMS tested samples are not the same for every commodity because AMS uses a staggered sampling schedule. According to AMS officials, the agency uses this schedule to provide current residue data for the most highly consumed commodities while using its resources efficiently; highly consumed commodities are rotated into the program every 5 years and tested for a period of 2 consecutive years.

Our analysis of AMS data shows that 9 of the commodities had residues in the vast majority of samples. For example, in 2008, about 96 percent of sampled peaches had at least one detected residue, and in 2010, about 99 percent of sampled apples had at least one detected residue. Only one of the commodities, cantaloupe, had pesticide residue detections in less than half (about 39 percent) of AMS's samples. Table 6 presents the percentage of samples with one or more detected pesticide residues in the most recent year of testing by AMS.

[76]AMS has developed Standard Operating Procedures for collecting samples. These procedures provide direction to state agency personnel in how to select and handle samples. For example, the procedures specify that the weight or volume of each sample must be within 20 percent of a specified amount, such as 3 pounds for small, low-weight commodities (e.g., mushrooms or tangerines) or 5 pounds for larger, high-weight commodities (e.g., cabbage or winter squash).

[77]We selected the commodities with the greatest number of sampling years in order to have a sufficient amount of data for our analysis. The earliest year we analyzed was 1998; the most recent year was 2012.

Table 6: Percentage of Samples with One or More Detected Pesticide Residues in the Most Recent Year of Testing by the Agricultural Marketing Service's (AMS) Pesticide Data Program

Commodity	Year of most recent testing	Percentage of samples with one or more detected residues
Apples	2010	99.19%
Bananas	2012	77.28%
Broccoli	2007	88.04%
Cantaloupe	2011	38.57%
Green beans	2008	69.91%
Lettuce	2010	85.47%
Peaches	2008	95.78%
Pears	2010	74.56%
Potatoes	2009	92.34%
Sweet bell peppers	2010	87.77%

Source: GAO analysis of AMS data. | GAO-15-38

Note: All margins of error for 95 percent confidence intervals are less than plus or minus 5 percentage points.

While the majority of AMS's samples of these commodities had at least one detected residue in recent years, our analysis found that there was substantial variation in the average number of pesticide residues detected in each sample. For example, AMS's most recent tests of these 10 commodities detected an average of 0.55 pesticides on cantaloupe samples in 2011, and an average of 5.2 pesticides on apples in 2010. AMS's most recent testing for the remaining 8 commodities found average pesticide detections within that range. Table 7 presents the average number of pesticides detected per sample in the most recent years of AMS's sampling of the 10 commodities.

Table 7: Average Number of Pesticides Detected per Sample in the Most Recent Year of Testing by the Agricultural Marketing Service's (AMS) Pesticide Data Program

Commodity	Year of most recent testing	Average number of pesticides detected per sample	Maximum number of pesticides detected in a single sample
Apples	2010	5.20	13
Bananas	2012	1.26	4
Broccoli	2007	1.69	6
Cantaloupe	2011	0.55	4
Green beans	2008	1.88	9
Lettuce	2010	3.44	13
Peaches	2008	3.50	10
Pears	2010	1.71	8
Potatoes	2009	1.88	8
Sweet bell peppers	2010	4.30	17

Source: GAO analysis of AMS data. | GAO-15-38

Note: All relative margins of error for 95 percent confidence intervals are less than plus or minus 11 percent of the numerical estimate itself.

For All Selected Commodities, Average Detected Residue Levels Have Been Well Below Tolerance Levels

In general, AMS's data show that, when pesticide residues were detected, they were at concentrations that were well below their established tolerances. We analyzed AMS's data for each of the 10 commodities to identify the four pesticide residues with the highest average concentration relative to each pesticide's tolerance.[78] Among the most recent AMS data for the 10 commodities, potatoes generally had the highest average concentration of residues relative to tolerance, but those concentrations were still low relative to the established tolerance level. Specifically, the average residue concentration as a percentage of tolerance for the top four pesticides detected in potatoes in 2009, ranged from an average of 0.94 percent for the pesticide boscalid to an average of 9.93 percent for the pesticide azoxystrobin. The residues AMS detected on the other 9 commodities generally had similar or lower average concentrations relative to their tolerances. In broccoli, for example, the four pesticides with the highest average residue

[78]We did not consider in this analysis those pesticides that AMS detected that did not have an established tolerance for that commodity.

concentrations averaged well below 1 percent of their tolerances in 2007. Table 8 presents the highest average pesticide residue concentration as a percentage of tolerance in the most recent year of AMS testing for all 10 commodities.

Table 8: Highest Average Pesticide Residue Concentration as a Percentage of Tolerance in the Most Recent Year of Testing by the Agricultural Marketing Service's (AMS) Pesticide Data Program

Commodity	Year of most recent testing	Pesticide with the highest concentration relative to tolerance	Average concentration of pesticide as a percentage of tolerance
Apples	2010	Thiabendazole	5.20%
Bananas	2012	Thiabendazole	0.66%
Broccoli	2007	Cyhalothrin	0.12%
Cantaloupe	2011	Dinotefuran	0.93%
Green beans	2008	Acephate	2.40%
Lettuce	2010	Cyhalothrin	0.60%
Peaches	2008	Fludioxonil	4.80%
Pears	2010	Pyrimethanil	2.85%
Potatoes	2009	Azoxystrobin	9.93%
Sweet bell peppers	2010	Thiamethoxam	2.80%

Source: GAO analysis of AMS data. | GAO-15-38

Note: All relative margins of error for the average concentration as a percentage of tolerance are less than plus or minus 40 percent of the numerical estimate itself, except for potato and broccoli, which are less than plus or minus 62 and 90 percent, respectively.

Because there have been improvements in the scope and precision of AMS's testing program and changes in EPA's established tolerances, AMS's residue data are not directly comparable over time. Since the start of the Pesticide Data Program in 1991, AMS's testing methods have improved in two ways that limit comparison of residue data over time. First, over the history of the program, the agency and its state partners have adopted improved testing methods that can reliably detect lower concentrations of residue. The ability to detect lower concentrations of residue has enabled AMS to reliably detect more residues in recent years than in earlier years. Second, with the new testing methods, AMS has added to the list of pesticides that are tested for each year. Additions to the list of pesticides that AMS tests for in a particular commodity have often led to additional detections. In addition, EPA has revised the established tolerances for particular pesticide and commodity

combinations. Changes in the tolerance established by EPA could affect calculations of residue concentration as a percentage of tolerance. For example, the same residue concentration found in year 1 and year 2 would represent different percentages of the tolerance if the tolerance were lowered or increased in the second year. We analyzed AMS's data using methods to control for these changes, and we found that doing so substantially affected the information regarding residue detections in each year. Appendix III provides further explanation of the methods we used in that analysis and our results.

AMS's Pesticide Data Program Provides Valuable Information but Does Not Disclose Survey Limitations

The Pesticide Data Program provides valuable information on residues that stakeholders find useful, but limitations in AMS's survey methods may affect the quality of program data and not disclosing these limitations in the program's annual reports reduces transparency regarding the survey methods used, and as a result, users may not have accurate information and may misinterpret the program's test results. In particular, AMS does not fully meet best practices in survey research, including some practices found in OMB standards, described above, on designing and releasing to the public information concerning a data collection effort. For example, AMS does not fully disclose in annual reports limitations in the Pesticide Data Program's survey methods that could lead to biased results and does not present measures of total survey error (sampling and nonsampling)[79] for estimates that result from a statistical survey, thereby diminishing users' ability to interpret the data.

EPA, FDA, and nongovernment stakeholders familiar with AMS's data have praised their value. Specifically, officials from EPA's Office of Pesticide Programs said that the results generally provide what they need for conducting assessments of pesticide risks. Furthermore, FDA officials said that they use the data to inform their own monitoring program, such as by increasing attention to commodities that were shown by AMS to have a history of residue problems. In addition, nongovernmental organizations and interested parties from the pesticide industry, academia, and a food safety organization, said that AMS's data are valuable and reliable. At the same time, EPA officials noted that AMS's survey may have sampling biases that could affect its results. For

[79]Total survey error is the difference between a population parameter (such as the mean, total, or proportion) and the estimate of that parameter based on the sample survey or census. It has two components: sampling error and nonsampling error.

example, officials from EPA's Office of Pesticide Programs said that AMS is limited by not having a complete record of all food distribution centers from which to draw samples or documentation on how centers that are not included in its records may differ from those that are included, if at all.[80] Officials from AMS noted that the agency relies on the participating states to seek cooperation from distribution centers. Officials from AMS also noted that the agency does not have the authority to require that distribution centers participate in the survey, as participation in the program is voluntary. In addition, they noted that no site selected from the list of volunteer centers has ever refused to participate.

The survey methods used by AMS in the Pesticide Data Program meet many best practices for meeting OMB's standards on designing and releasing to the public information concerning a data collection effort but do not meet several others, particularly those that are designed to ensure that the sample design will yield survey data that can form the basis of statistically valid estimates to represent a population of interest, in this case about the extent of pesticide residues in the U.S. food supply. AMS's surveys are based on some principles of statistically valid sample design—including random selection of distribution centers for which it has records within selected states that were invited and agreed to participate and commodities within those centers—and the laboratory tests of those commodities are based on scientifically established protocols for handling commodity samples and measuring pesticide concentrations. These are important quality assurance steps that are meant to select an unbiased sample of commodities in the food supply and to produce accurate residue detections on sampled items.

In addition, the program does not meet other best practices including those designed to provide the public with access to useful information. For example, AMS does not demonstrate the extent to which the commodities that it selects to sample (e.g., apples or pears) represent all commodities in the food supply or demonstrate the extent to which the distribution centers that participate represent all distribution centers in the country—an important limitation because the majority of states do not

[80]Sampling bias in this case implies that the food distribution centers under consideration are not representative of all food distribution centers.

participate in the program.[81] AMS also does not disclose whether, to accurately represent the U.S. food supply, samples selected from some distribution centers should be weighted differently than other samples because they were more or less likely to be selected or to correct for differences between the sample and the U.S. food supply. If pesticide residue concentrations on excluded commodities are significantly different from those on selected commodities or concentrations on commodities from participating distribution centers are significantly different from those in nonparticipating distribution centers, the Pesticide Data Program data may not accurately represent pesticide concentrations in the U.S. food supply. Without this information, users of the data may misinterpret AMS's annual monitoring reports and draw erroneous conclusions based on the data.

Conclusions

FDA and FSIS face a formidable task in monitoring and enforcing pesticide residue tolerances associated with thousands of pesticide and commodity combinations that play a critical role in food production by helping to minimize crop losses due to pests and weeds. As part of this task, FDA and FSIS are to determine that pesticide residues in food do not exceed established tolerances in order to ensure food safety and protect human health.

While there is no requirement that FDA or FSIS test for all the pesticides for which EPA has established a tolerance, OMB directs agencies to meet certain standards when designing and releasing information to the public concerning a data collection effort. FDA tests for the majority of pesticides that have established tolerances, but the agency does not disclose the pesticides with tolerances for which it does not test or the potential effect that not testing could have on its detection of violations. Such a disclosure would be consistent with OMB best practices for reporting limitations relevant to analyzing and interpreting results from a data collection effort. Our review found that FDA does not test for several commonly used pesticides, including glyphosate, or disclose the potential effects of not testing for these pesticides. In addition, while FSIS has recently increased the scope of its testing, the agency does not disclose that it does not test for specific pesticides that have tolerances for animal products or their

[81]AMS could not provide a quantitative assessment of the extent to which all distribution centers within participating states were invited to participate in the Pesticide Data Program.

feed or the potential effect of not testing for these pesticides. By not disclosing in their annual monitoring reports the pesticides that have tolerances for which they do not test and the potential effects of not testing for them, consistent with OMB best practices, users of the agencies' annual reports may not have accurate information and may misinterpret the results of the programs.

In addition, FDA's monitoring program focuses on testing commodities that have been targeted as part of monitoring for compliance and enforcement to the exclusion of determining the incidence and level of pesticide residues in imported and domestic foods—one of FDA's stated objectives. OMB standards direct agencies to use generally accepted statistical methods for collecting and reporting data. In this context, a generally accepted statistical method to obtain a valid estimate that represents a population would include either (1) testing a statistically valid sample of that population or (2) justifying statistically a nonprobability method that can measure the estimation error. According to FDA officials, calculating national estimates of pesticide violations for the entire food supply it regulates would be very expensive. However, FDA's focus on targeted samples limits the agency's ability to make valid national estimates about violation rates for imported and domestic foods since the targeted samples it collects cannot be the basis of statistically valid national estimates. Therefore, the annual pesticide monitoring reports do not reliably reflect the rate at which pesticide violations occur in the U.S. food supply, limiting their usefulness as a potential source of national estimates. Further, without reliable nationally representative data with which to evaluate how effective its targeted monitoring program is in identifying and intercepting violative foods, FDA cannot compare the rate of violations detected through the program with the overall rate of pesticide residue violations within the imported and domestic food supplies. Therefore, this limitation of testing only targeted commodities affects FDA's ability to evaluate the effectiveness of its PREDICT targeting tool and, ultimately, FDA's ability to reliably identify specific commodities that may be at high risk of violating pesticide residue tolerances is limited.

Finally, the sampling methodology used by AMS in the Pesticide Data Program meets many of the best practices for meeting OMB's standards on designing and releasing to the public information concerning a data collection effort, but it does not meet several others. For example, AMS does not disclose in the program's annual reports the potential effect of any bias associated with participating states or food distribution centers, or its selection of commodities, and does not report or direct data users

on how to obtain appropriate sampling error (margins of error) for estimates that result from a statistical survey, as called for by OMB's statistical survey standards. By not disclosing these potential sources of survey error, the agency's monitoring reports do not meet OMB best practices because they do not include all information necessary for users to analyze the data properly or to assess the quality of results, which may lead users to misinterpret AMS's annual monitoring reports and draw erroneous conclusions based on the survey data.

Recommendations for Executive Action

We are making five recommendations to the Secretary of Health and Human Services and four recommendations to the Secretary of Agriculture.

To better inform users of the annual monitoring report about the frequency and scope of pesticide tolerance violations, we recommend that the Secretary of Health and Human Services direct the Commissioner of FDA to disclose in the agency's annual pesticide monitoring program report which pesticides with EPA-established tolerances the agency did not test for in its pesticide monitoring program and the potential effect of not testing for those pesticides.

To gather and report reliable, nationally representative data on pesticide residue violations, we recommend that the Secretary of Health and Human Services direct the Commissioner of FDA to

- design and implement a statistically valid sampling methodology that would enable the agency, within existing resources, to gather nationally representative pesticide residue incidence and level data for both domestically produced and imported foods, or justify statistically the use of a nonprobability method that can measure the estimation error. In designing either approach, FDA should consider the extent to which the benefits exceed the costs; and
- report the nationally representative incidence and level data in its annual pesticide monitoring reports, including disclosing the limits of its chosen sampling methodology.

To evaluate and refine its targeted pesticide compliance and enforcement monitoring program, we recommend that the Secretary of Health and Human Services direct the Commissioner of FDA to use the incidence and level data to

- assess the effectiveness of FDA's targeted pesticide compliance and enforcement monitoring program, including its use of the PREDICT targeting tool for imported foods, by comparing the rate of violations detected through the program to the overall rate of pesticide residue violations within the domestic and imported food supplies; and
- identify any types of domestic and imported foods that are at high risk for pesticide residue tolerance violations to improve the ability of its targeted pesticide compliance and enforcement monitoring program to consistently identify food likely to have violations.

To better inform the public about the frequency and scope of pesticide tolerance violations, we recommend that the Secretary of Agriculture direct the FSIS Administrator to disclose in the agency's annual pesticide monitoring program report which pesticides with EPA-established tolerances the agency did not test for in its National Residue Program and the potential effect of not testing for those pesticides.

To better meet federal standards and best practices for statistical surveys, we recommend that the Secretary of Agriculture direct the AMS Administrator to provide better documentation of the survey methods used in its Pesticide Data Program in the program's annual reports by

- providing more complete information on the sampling methodology the agency uses, such as how it identifies and selects states, food distribution centers, and commodities for pesticide residue testing, and include measures of sampling error for reported estimates,
- reporting on the extent to which its survey covers commodities in the U.S. food supply and any limitations associated with its survey methodology; and
- describing methods users should employ to analyze the data, including obtaining margins of error for making generalizeable estimates of pesticide residues in commodities.

Agency Comments and Our Evaluation

We provided a draft of this report to the Department of Health and Human Services (HHS) on behalf of FDA, USDA, and EPA for review and comment. HHS and USDA provided written comments on the draft, which are presented in appendixes IV and V, respectively. Of the five recommendations that were directed to it, HHS agreed with two, neither agreed nor disagreed with two, and disagreed with one. In its written comments, USDA stated it generally agreed with the four recommendations that were directed to it and described actions it planned to take to address them. In an e-mail received on August 25, 2014, an

official from EPA's GAO Liaison Team stated that EPA had no comments on our report.

In its written comments, HHS said that it has already increased its monitoring of pesticide residues by taking actions consistent with our recommendations and discussed ways in which the agency has increased the scope of its testing program. In addition, HHS noted that FDA's food safety mission also includes protecting consumers against foodborne illnesses due to microbiological contamination and that the risk of microbiological contamination, rather than pesticide contamination, often drives the agency's decisions about using its limited resources. We appreciate FDA's efforts to increase the scope of its pesticide residue program and understand that it faces a difficult task in protecting consumers from many types of food contamination.

HHS disagreed with our first recommendation that FDA disclose in its annual pesticide monitoring program report which pesticides with EPA-established tolerances FDA did not test for and the potential effect of not testing for those pesticides. HHS said that future versions of FDA's annual report will clarify that not all pesticides with EPA-established tolerances were analyzed. However, HHS disagreed with naming the pesticides that were not assessed and said that FDA's annual report is intended to comply with requirements of the Pesticide Monitoring Improvements Act of 1988. HHS stated that in its annual report, FDA discloses all pesticides tested for within the report's annual scope, as required by the act, including many pesticides that do not have EPA-established tolerances. In addition, HHS said that it believes that disclosing pesticides for which FDA does not test would enable users to more easily circumvent the pesticide monitoring program.

We believe that OMB's guidelines for releasing information to the public concerning a data collection effort are also applicable to FDA's pesticide monitoring program, and based our recommendation on those guidelines.[82] OMB directs agencies to produce survey documentation that includes those materials necessary to understand how to properly analyze data from each survey. In our view, disclosing the pesticides that are not included in FDA's testing program would be consistent with OMB best practices for reporting limitations relevant to analyzing and

[82]OMB, *Standards and Guidelines for Statistical Surveys* (September 2006).

interpreting results from a data collection effort. With regard to HHS's comment that pesticide users might more easily circumvent the monitoring program if they knew which pesticides FDA did not test for, we note that a user seeking to circumvent the pesticide monitoring program could do so now by reviewing the list of pesticides FDA tested for that it publishes in its annual reports. We also note that HHS did not comment on whether or how FDA's future annual program reports would disclose the potential effects of not testing for certain pesticides that have EPA-established tolerances. We continue to believe that it is important for users of the annual reports to know the extent to which certain pesticides are excluded from testing and that the agency may be identifying fewer pesticide residue violations than are occurring. Thus, we continue to believe that FDA should fully implement the recommendation.

In its written comments, HHS said that FDA would investigate the feasibility and potential costs of implementing our second recommendation that the agency design and implement a statistically valid sampling methodology for its pesticide monitoring program. According to HHS, implementing a program for systematic statistical sampling would require additional resources or, given existing resources, a reduction in the variety of commodities that FDA would analyze annually. HHS added that AMS's Pesticide Data Program generates national statistically valid data that FDA uses to inform the risk value in PREDICT and which commodities to target for testing.

We welcome FDA's decision to investigate the feasibility of enhancing its monitoring program. Implementing a statistically valid sampling methodology would be necessary to attain the agency's objective to determine the incidence and level of pesticide residues in domestic and imported foods.[83] In our view, nationally representative data collected by FDA would provide a more accurate picture of the pesticide residue violation rate throughout the food supply and would also enable the agency to evaluate the monitoring program's effectiveness and refine its targeting efforts under PREDICT, topics addressed in our fourth and fifth recommendations. While we recognize the value provided by AMS's Pesticide Data Program, we note that the data generated by AMS were not intended to be used for the purpose of evaluating the effectiveness of

[83]FDA, *Compliance Program Guidance Manual: Chapter 04—Pesticide and Chemical Contaminants*, 7304.004 (June 27, 2011).

FDA's program. As we state in the report, AMS's Pesticide Data Program tests large sample sizes but takes samples from relatively few commodities each year and thus cannot be used to directly and reliably evaluate the effectiveness of FDA's monitoring program across the domestic and imported food supplies.

HHS did not commit to implementing our third recommendation that FDA report nationally representative incidence and level data in its annual reports, but did agree that FDA would disclose the limitations associated with its monitoring program in its annual reports. In its written comments, HHS explains that the FDA pesticide program is targeted in nature. As we state in the report, determining the incidence and level of pesticide residues in imported and domestic foods is one of FDA's stated objectives. However, FDA's focus on targeted samples limits the agency's ability to make valid national estimates about violation rates for imported and domestic foods since the targeted samples it collects cannot be the basis of statistically valid national estimates. Thus, we continue to believe that FDA should fully implement this recommendation.

HHS concurred with our fourth recommendation that FDA assess the effectiveness of its targeted pesticide compliance and enforcement monitoring program, including its use of PREDICT. HHS described FDA's ongoing effort to evaluate (1) the effectiveness of regulatory actions in preventing future violative shipments by reviewing incidences of repeat violations among growers, shippers, importers, consignees, dealers, filers, and harvesters over the past 3 years and (2) risks associated with PREDICT. While we welcome FDA's efforts to evaluate its program, we continue to believe that a comprehensive evaluation cannot be successfully completed without statistically valid data on the national incidence and level of pesticide residues.

Similarly, HHS generally concurred with our fifth recommendation that FDA identify any domestic and imported foods that are at high risk for pesticide residue tolerance violations to improve the ability of its targeted pesticide compliance and enforcement monitoring program to consistently identify foods likely to have violations. In its written comments, HHS said that FDA actively identifies and targets commodities that are at high risk for pesticide residue violations. We do not believe that FDA can be sure that it is targeting high risk commodities without statistically valid data on the incidence and level of violations in commodities.

In its written comments, USDA stated that it generally agreed with our findings and our four recommendations directed to the agency but wanted

to emphasize some of the differences in its agencies' missions with respect to monitoring pesticide residues. In response to our four recommendations, USDA said that

- FSIS will disclose in its annual pesticide monitoring program reports which pesticides with an EPA-established tolerance the agency did not test for in the National Residue Program and the potential effect of not testing for those pesticides. USDA also said that FSIS will continue to insert or remove pesticides from its testing program based on their public health importance and will continue discussions with EPA on the minimum level of applicability (i.e., the lowest valid residue concentration reported by a test method) for those pesticides tested by FSIS or those prioritized for testing by EPA;

- AMS plans to add a description of the sampling methodology employed for selecting states, food distribution centers, and commodities for inclusion in the Pesticide Data Program annual summary report and explore procedures for assessing the degree to which incompleteness in the sampling frame may lead to the potential for biased estimates;

- AMS plans to provide more information on its sampling methodology, program parameters, and inherent limitations in its methodology in the Pesticide Data Program annual summary report. AMS believes that the participating sites provide a reliable representation of all sites and will investigate methods for confirmation; and

- AMS will work to describe methods users can use to analyze Pesticide Data Program data and to improve the sampling methodology. Once developed, such methods and procedures will be included in the Pesticide Data Program annual summary report. USDA did not mention whether it would describe methods for users of the data to obtain margins of error, which we believe is important to help users analyze the data.

FDA also provided us with technical comments, which we incorporated as appropriate.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the appropriate

congressional committees, the Secretary of Agriculture, the Secretary of Health and Human Services, the Commissioner of FDA, the Administrator of EPA, and other interested parties. In addition, the report will be available at no charge on the GAO website at http://www.gao.gov.

If you or your staff members have any questions about this report, please contact me at (202) 512-3841 or neumannj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix VI.

Sincerely yours,

John Neumann
Acting Director, Natural Resources and Environment

Appendix I: Objectives, Scope, and Methodology

This report examines (1) what the Food and Drug Administration (FDA) data show with respect to pesticide residue violations in the foods that it regulates and limitations, if any, in its efforts to monitor foods for pesticide violations; (2) what the Food Safety and Inspection Service (FSIS) data show with respect to pesticide residue violations in the foods that it regulates and limitations, if any, in its efforts to monitor foods for pesticide violations; and (3) what the Agricultural Marketing Service (AMS) data show with respect to pesticide residue levels in fruits, vegetables, and other foods, and limitations, if any, in its efforts to gather and report that information.

To examine what is known about pesticide residue in food and violations of residue tolerances, we analyzed data from the FDA, the U.S. Department of Agriculture's (USDA) FSIS, and USDA's AMS. We evaluated the reliability of these data by reviewing or discussing the agencies' management controls to ensure the data's accuracy and completeness. As appropriate, we also reviewed the agencies' compliance with the Office of Management and Budget's (OMB) *Standards and Guidelines for Statistical Surveys*.[1] We found these data to be sufficiently reliable for purposes of making estimates of the extent of pesticide residues and residue violations in food, although where discussed we note limitations in the methods the agencies have used to collect these data.

FSIS is responsible for examining and inspecting meat, poultry, and processed egg products to ensure their safety. FDA is responsible for regulating to ensure the safety of virtually all other foods. AMS collects residue data on a wide range of foods for informational purposes. Much of our analyses of FDA's and AMS's residue test results focused on 10 selected fruit and vegetable commodities that are highly consumed in the United States.[2] We selected these 10 commodities because they were the commodities AMS tested for most often from 1994 through 2012 and for which the agencies had data sufficient for our purposes.

Our analysis of FDA's data for those commodities covered 1993 through 2012, and our analysis of AMS's data for the commodities collectively

[1]OMB, *Standards and Guidelines for Statistical Surveys* (September 2006).

[2]These 10 commodities were apples, bananas, broccoli, cantaloupe, green beans, lettuce, peaches, pears, potatoes, and sweet bell peppers.

spanned 1998 through 2012. We also analyzed FSIS's monitoring data from 2000 through 2011 to report information about pesticide residues found in meat, poultry, and egg products. For each agency, the data we analyzed were the most recent available at the time of our review. In addition, our analysis included a review of certain aspects of FDA's domestic and imported food inspection process, FSIS's National Residue Program, and the methodology AMS has used to gather residue data through its Pesticide Data Program.

FDA's Pesticide Residue Monitoring Program

Our review of FDA's pesticide residue monitoring program included an analysis of the agency's monitoring results, which are discussed in more detail in appendix II, as well as a review of its monitoring approach.

Analysis of FDA Data for Types and Origin of Pesticide Residue Violations

To examine pesticide residue violations in the foods that it regulates, we analyzed FDA's pesticide residue monitoring data from the years for which it had electronic data—1993 through 2012, excluding 2004.[3] FDA provided us with electronic files for those years containing pesticide residue data for all food commodities that it tested, but we focused our analysis on 10 commodities—apples, bananas, broccoli, cantaloupe, green beans, lettuce, peaches, pears, potatoes, and sweet bell peppers. We selected 10 commodities that AMS identified as being widely consumed in the U.S. diet and for which FDA and AMS had testing data during that time period. More specifically, we selected the 10 because they were the commodities that AMS had tested most often during the history of the Pesticide Data Program. The AMS program has tested over 90 commodities for pesticide residues, with an emphasis on commodities that are highly consumed by infants and children.[4] Typically, AMS tests commodities for a range of different pesticides about every 5 years for 2 years in a row.[5] AMS tested the 10 selected commodities in at least 8 years from the beginning of the program in 1991 through 2012. We used the same group of 10 commodities for our analysis of FDA and AMS data

[3]FDA was not able to provide us with test results from 2004 that were comparable in detail to the other years. Therefore, we could not include that year in our analysis of pesticide residue test results.

[4]In addition to raw commodities, AMS also tests processed commodities such as canned vegetables, frozen fruit, fruit juices, and baby foods.

[5]In some instances, AMS tested commodities for a specific subset of pesticides. For example, in 1999, AMS conducted two separate special pesticide residue tests for classes of pesticides known as organophosphates and carbamates in apples.

on pesticide residue violations to enable consistent presentations of the two agencies' results.

We analyzed the FDA data using Statistical Analysis System software to determine the types and origins of violations that the agency detected for each of the 10 commodities. There are two types of pesticide residue violations. In the first instance, FDA detects a pesticide residue in an amount that exceeds the tolerance that the Environmental Protection Agency (EPA) has established. That is known as a violation of tolerance. In the second instance, FDA detects the residue of a pesticide for which EPA has not established a tolerance for that particular commodity. That is known as a violation of no tolerance. In some cases, FDA may detect the residue of a pesticide that is no longer registered for any use in the United States but for which FDA (in consultation with EPA) has established a maximum residue level, or "action level," to account for the fact that the pesticide may persist in the environment for long periods of time after its use is discontinued.[6] If FDA detects residue that exceeds an action level, it considers, on a case-by-case basis, whether to take an enforcement action to remove the food from the market. We also identified whether the samples that FDA tested were from the United States (domestic) or imported from another country. Finally, we reviewed FDA annual reports from 2008 through 2012 to gather data on pesticide residue violations the agency detected in all foods that it sampled, including the origin of the foods FDA found to have residue violations.

Because FDA data on violations were derived from a sampling method designed, at least in part, to target foods with a high risk of violation, rather than from a statistically generalizable sample, FDA rates are not intended to be interpreted as reliable estimates of the actual violation rates among these 10 commodities in the food supply. Therefore, to determine violation rates for these commodities, we also analyzed AMS data that indicate the presence of residues that exceed tolerances and

[6]An action level specifies the level below which FDA exercises its discretion not to take enforcement action.

present these results with the limitations discussed in the report.[7] Specifically, we used Statistical Analysis System survey procedures to analyze AMS Pesticide Data Program data from 1998 through 2012 for the same commodities—where those data were available—to identify the rate at which AMS found residues that exceeded established tolerances or for which there were no tolerances. AMS refers to these situations as "presumptive tolerance violations." For this analysis, we used data from the 3 most recent years—from 1998 through 2012—in which AMS tested the 10 commodities. AMS tests particular commodities on a staggered schedule; the earliest year of data for one of the commodities was 1998. We were not able to reliably compare the rate at which AMS found violations in most domestically grown and imported commodities because of small or imbalanced sample sizes.

Review of FDA's Methods for Monitoring Pesticide Residue Violations

To examine limitations, if any, in FDA's efforts to monitor for pesticide residue violations, we reviewed FDA documents including FDA's annual pesticide monitoring reports, district work plans for sampling domestic commodities, guidance for sampling both domestic and imported commodities, and documentation related to the agency's import scoring system known as Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT). We interviewed agency officials from FDA's Center for Food Safety and Applied Nutrition and officials from FDA's Office of Regulatory Affairs who are responsible for developing strategies and policies for reducing health threats from contaminated food, monitoring foods for residue, and enforcing pesticide tolerances. These interviews included discussions about FDA violation data and the use of FDA's import review system PREDICT, including the agency's ongoing internal evaluation of that system. We visited FDA's Baltimore District Office to interview officials about how agency personnel monitor domestic and imported foods, as well as their use of PREDICT to target imported foods for testing because, among other things, it receives a large quantity of imported foods. We also analyzed the violation rates for imported foods relative to their PREDICT scores in 2012, the first full year in which FDA used the system nationwide, to determine the relationship

[7]We calculated margins of error for 95 percent confidence intervals for the AMS data and present them along with the estimates. However, as we described in this report, there are limitations in AMS's survey methods that lead us to have some concerns about using its data to make national estimates about the incidence and level of pesticide residues. Consequently, the results of our analyses are restricted to the samples taken by AMS for the 10 commodities we reviewed and are not meant to be generalized to the population of these commodities in the food supply.

between PREDICT scores and violations. In addition, we reviewed FDA's sampling methods and its reporting of sampling results relative to the direction and guidance contained in the OMB's *Standards and Guidelines for Statistical Surveys* and the *Standards for Internal Control in the Federal Government*, as well as other best practices in survey methodology.[8]

FSIS's Pesticide Residue Monitoring Program

Our review of FSIS's pesticide residue monitoring program included an analysis of the agency's monitoring results as well as a review of its monitoring approach.

Analysis of FSIS Data on Pesticide Residues in Meat, Poultry, and Processed Egg Products

To examine what FSIS has found with respect to pesticide residue violations in meat, poultry and processed egg products, we analyzed FSIS's monitoring data from 2000 through 2011 to identify the types and frequency of pesticide residues found in those commodities. Specifically, we analyzed pesticide residue test results from 2000 through 2011 published by the agency in its annual National Residue Program reports. Using data from FSIS's annual reports, we identified the number of samples that FSIS tested for residues each year, the number of pesticide residue violations it detected, the types of animal products—known as production classes—with violations, and the types of pesticides found. We also analyzed the annual reports to gather data on the frequency with which FSIS detected pesticide residues at levels below established tolerances.

Review of FSIS's Methods for Monitoring Pesticide Residue Violations

We analyzed the size and scope of the National Residue Program by reviewing FSIS's annual sampling plans from 2010 through 2013. Specifically, we gathered data from the annual plans on the number of samples FSIS planned to take of domestic and imported products and the production classes that it planned to sample. With respect to the scope of the program, we reviewed the sampling plans and agency guidance documents to identify which pesticides FSIS's testing methods were capable of detecting. The pesticides in FSIS's testing program included some for which EPA has established tolerances for animal products and

[8]OMB, *Standards and Guidelines for Statistical Surveys* (September 2006) and GAO/AIMD-00-21.3.1; American Association for Public Opinion Research, *Best Practices for Survey Research*, http://www.aapor.org//Best_Practices1.htm; and Federal Committee on Statistical Methodology, *Measuring and Reporting Sources of Error in Surveys* (July 2001).

others for which EPA has not established tolerances. Using information from EPA, we identified 18 pesticides that EPA has registered for direct use on animals. Using FSIS's guidance documents, we identified which of the 18 pesticides registered for direct use on animals can be, or is planned to be, detectable by FSIS's testing methods. We also reviewed FSIS's sampling methods and the agency's reporting of sampling results relative to the direction and guidance contained in OMB's *Standards and Guidelines for Statistical Surveys*, as well as other best practices in survey methodology.[9]

We also interviewed officials at EPA's Office of Pesticide Programs about EPA's use of FSIS data in conducting risk assessments of specific pesticides. In particular, we discussed the EPA officials' views on the adequacy of the FSIS data for EPA's risk assessment needs. We also discussed with these officials EPA's negotiations with FSIS on expanding the scope of the National Residue Program to test for more pesticides and to be able to detect lower concentrations of pesticides in beef, pork, and poultry. EPA officials provided us with a list of pesticides the agency had prioritized for FSIS to include in the National Residue Program. We compared EPA's priorities with FSIS's testing plans for 2014.

We also reviewed a 2010 report by USDA's Office of Inspector General on FSIS's residue program.[10] The report contains findings, conclusions, and recommendations that concerned, among other things, the scope of FSIS's residue monitoring. We interviewed FSIS officials to discuss the agency's response to recommendations in the Inspector General's report concerning the scope of the National Residue Program's testing methods.

AMS's Pesticide Data Program

Our review of AMS's pesticide residue monitoring program included an analysis of the agency's monitoring results, as well as a review of its monitoring approach.

[9]OMB, *Standards and Guidelines for Statistical Surveys* (September 2006) and GAO/AIMD-00-21.3.1; American Association for Public Opinion Research, *Best Practices for Survey Research*, http://www.aapor.org//Best_Practices1.htm; and Federal Committee on Statistical Methodology, *Measuring and Reporting Sources of Error in Surveys* (July 2001).

[10]*FSIS National Residue Program for Cattle*, USDA Office of Inspector General, Audit Report 24601-08-KC (Mar. 25, 2010).

Analysis of AMS Data on the Type and Number of Residues in 10 Selected Commodities

To examine what AMS has found with respect to pesticide residue levels, we analyzed residue data for the 10 selected fruit and vegetable commodities collected by the agency's Pesticide Data Program from 1998 through 2012. We evaluated AMS's sampling[11] and nonsampling[12] error according to best practices in survey research, including OMB' s *Standards and Guidelines for Statistical Surveys* as well as other best practices in survey methodology.[13] Using the AMS data for each of the 10 commodities, we estimated: (1) the number of unique detections of pesticide residue above the limit of detection on each sample; [14] (2) the average number of pesticide residues per sample; (3) the four residues with the highest average residue concentration relative to that commodity's pesticide tolerance; and (4) the number of presumptive tolerance violations.[15] Because the AMS data were collected through random samples, our estimates have sampling error. Although we found limitations with the AMS sampling methodology, as described in the report, in order to produce an estimate of the sampling error, we used survey procedures in Statistical Analysis System software to calculate confidence intervals associated with each of the estimates under assumptions about the sampling and nonsampling error. We calculated these estimates under the assumption that AMS data were taken from an equally weighted random sample, stratified by the state in which the distribution center is located. We provide the details of those sampling errors and confidence intervals where appropriate.

We conducted our analyses to characterize pesticide residue for the 10 commodities using the same data in two different ways. The first analysis

[11]Sampling errors are errors associated with survey estimates that are due to sampling some and not all of the units in the sampling frame.

[12]Nonsampling errors are errors in sample estimates that do not stem from sampling, such as coverage error, measurement error, or data processing error.

[13]OMB, *Standards and Guidelines for Statistical Surveys* (September 2006); American Association for Public Opinion Research, *Best Practices for Survey Research*, http://www.aapor.org//Best_Practices1.htm; and Federal Committee on Statistical Methodology, *Measuring and Reporting Sources of Error in Surveys* (July 2001).

[14]The limit of detection is the concentration of a residue that AMS could detect with accuracy.

[15]AMS gathers its Pesticide Data Program data in an effort to estimate residue levels in the food supply rather than for regulatory purposes, but information about findings of residues that exceed pesticide tolerances or for which there is no tolerance is available to FDA, FSIS, and EPA. AMS calls these findings "presumptive tolerance violations."

focused on the most recent AMS data available for each commodity. We presented the results of that analysis in the body of this report. The second analysis examined AMS data at different points in time. To accomplish this analysis, we took steps to control for variations in how AMS collected the data over time, as well as changes in EPA tolerances so that we could reliably compare data from one year to another. We refer to these data as restricted data. We briefly describe the reasons for those restrictions and our methods below and present the results of that analysis in appendix III.

Analysis of Restricted AMS Data at Different Points in Time

To provide additional information on what was detected in other recent points in time, we examined two additional periods for each of our 10 commodities. We identified the 3 most recent years of AMS data for our analysis of pesticide residue. Because AMS did not test each commodity each year, the 3 most recent years of data varied for each commodity. For example, the 3 most recent years of testing on apples were 2001, 2004, and 2010, and the 3 most recent years for bananas were 2002, 2006, and 2012.

To reliably compare the AMS data at different points in time, we accounted for changes in AMS's testing methods and EPA's established tolerances. In particular, comparing residues detected at different time points is complicated by the fact that the pesticides AMS tested for, the technology it used to detect residues, and the tolerances established by EPA for pesticides may change for particular commodity-pesticide combinations. To account for those changes, we developed methods for restricting the data so it could be compared at different time points for a limited set of pesticides, higher limits of detection, and a fixed set of tolerance levels.

More specifically, the first change to account for was that the number of pesticides for which AMS's Pesticide Data Program tested for increased over time as its methods became more sophisticated. The residue of a particular pesticide might have been present on samples of a commodity in each year we analyzed but could only be detected in the second or third year when more comprehensive testing methods included that pesticide. To account for increases in detections caused by an expansion in the number of pesticides AMS tested for, we included in our analysis only those pesticides AMS tested for in all 3 years. For example, AMS tested apples for 93, 175, and 184 pesticides in 2001, 2004, and 2010, respectively. The restricted list we used for our analysis consisted of the

83 pesticides that AMS tested apples for in each of these years and, therefore, excluded 10 from 2001, 92 from 2004, and 101 from 2010. By focusing on a common set of pesticides, our restricted analysis, while standardized across the years, does not include any changes that may have occurred in the pesticides that were not tested.

The second change to account for was that, as the technical capabilities of laboratories that test for pesticide residue have improved, AMS has been able to reliably detect increasingly lower concentrations of residue. As a result, a particular pesticide residue may have been present at low levels in all 3 years, but was only detectable in the most recent year because of improved technology. AMS's database includes the limit of detection for each pesticide, thereby indicating the concentration it can reliably detect. To account for increases in the ability to detect residues in later years, we used AMS's limit of detection for each pesticide to restrict the data. For our analysis of different points in time, we selected the highest limit of detection for each commodity-pesticide combination in the first year and applied this to our analysis of that commodity pesticide combination in the remaining 2 years. By focusing on this common set of limits of detection, our restricted analysis, while standardized across the years, does not include any changes that may have occurred in the limits of detection for particular pesticides.

The third change to account for was that EPA's established tolerance for a particular pesticide/commodity combination can change over time. Therefore, the concentration of pesticide residue as a percentage of tolerance could have changed because EPA changed the tolerance rather than because the concentration changed. To account for the effect that change in tolerance could have on our ability to compare the concentrations of pesticide residues relative to their tolerance in different years, we performed our analysis for each year using the tolerance that was in place for each pesticide/commodity combination in the first year of testing. By focusing on this common set of pesticide tolerances, our restricted analysis, while standardized across the years, does not include any changes that may have occurred in the tolerances for particular pesticides.

Analysis of Most Recent Unrestricted AMS Data

In the body of this report, we present our analysis of the most recent AMS data for the 10 selected commodities. In this analysis, we did not restrict the data with respect to the number of pesticides AMS tested for, the limit of detection it could achieve, or the EPA-established tolerance. We

identified the most recent year in which AMS had sampled the 10 commodities, and using those years' data, we conducted the same four types of analysis described above (1) the number of unique detections of pesticide residue above the limit of detection on each sample; (2) the average number of pesticide residues per sample; (3) the four residues with the highest average residue concentration relative to that commodity's pesticide tolerance; and (4) the number of presumptive tolerance violations. Because the AMS data were derived from a survey that contains sampling error, we calculated confidence intervals for each estimate to help us understand the reliability of these estimates.

For both the restricted and unrestricted methods of analysis, we were generally unable to use AMS's data to analyze pesticide residue detections separately by the place of origin of the 10 commodities we examined. AMS's files include data on whether the sampled commodities were grown domestically or imported, but there was not a sufficient and balanced number of both domestic and imported samples for reliable comparisons of the frequency or amount of residues detected. Nearly all sampled apples, bananas, broccoli, lettuce, and potatoes were from one type of origin (either imported or domestic), and green beans and pears had sample sizes that were larger (at least 90) in each group, but the differential between imported and domestic sample sizes was still of a magnitude greater than 4. Cantaloupe, peaches, and sweet bell peppers had larger numbers of both domestic and imported samples to more reliably analyze and report findings related to origin.

Review of Methods AMS Used to Collect Data on Pesticide Residue

To examine limitations, if any, in AMS's efforts to collect residue data, we compared the agency's methods and its reporting of those methods with standards established by OMB's *Standards and Guidelines for Statistical Surveys* as well as other best practices in survey methodology.[16] In particular, we evaluated AMS's survey practices for addressing components of coverage error, nonresponse error, and sampling error. We interviewed AMS officials regarding the agency's collection and reporting of Pesticide Data Program data. We also interviewed (1) a former AMS statistician who was involved in the initial design of the Pesticide Data Program about the survey methodology used for gathering

[16]OMB, *Standards and Guidelines for Statistical Surveys* (September 2006); American Association for Public Opinion Research, *Best Practices for Survey Research*, http://www.aapor.org//Best_Practices1.htm; and Federal Committee on Statistical Methodology, *Measuring and Reporting Sources of Error in Surveys* (July 2001).

the data and (2) EPA officials in the Office of Pesticide Programs about their use of the AMS data and their views on the data's reliability.

We conducted this performance audit from November 2012 to October 2014 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix II: Food and Drug Administration Pesticide Residue Monitoring Data for 10 Selected Commodities from 1993 through 2012

The Food and Drug Administration (FDA) tests domestically grown and imported foods for pesticide residues to determine their compliance with pesticide tolerances established by the Environmental Protection Agency (EPA). When FDA tests commodities for compliance with EPA's tolerances, it may find one or more violations. One type of violation occurs if FDA finds residue of a pesticide for which EPA has not established a tolerance for that commodity. Such residues are prohibited and constitute a violation of no tolerance. A second type of violation occurs if FDA finds residue that exceeds an established tolerance for that commodity. That is called a violation of tolerance. FDA also tests commodities for the residue of pesticides that are no longer registered by EPA for use but that may persist in the environment and for which FDA has established an "action level." If FDA detects residue of an unregistered pesticide that exceeds an action level, according to FDA officials, the agency considers, on a case-by-case basis, whether the presence of such a residue in or on food would require an enforcement action to remove the food from commerce.

As discussed in this report, FDA uses targeted methods for selecting domestic and imported foods for pesticide residue testing rather than a random selection method. The agency targets foods for testing on the basis of a variety of factors, including the compliance history of the food, grower, or country of origin; the importance of the food in the U.S. diet; and others. Because FDA uses targeted methods, the results only indicate the presence or absence of violations from among the foods that FDA chose to sample.

In addition in this report, we examined the results of FDA's testing of 10 commonly consumed fruits and vegetables from 2008 through 2012. The 10 commodities are apples, bananas, broccoli, cantaloupe, green beans, lettuce, peaches, pears, potatoes, and sweet bell peppers. Tables 9 through 18 present FDA data for the 10 commodities by year from 1993 through 2012. Specifically, the tables provide the number of samples of each commodity FDA tested, the number of samples FDA found to have at least one violation, and the number and type of violations found in each year.[1] Tables 9 through 18 also indicate whether the food was of domestic or imported origin. Because FDA may detect multiple violations

[1]Data on the third type of violation—action level violations—are shown in notes to the tables.

in a single sample, the total number of violations detected may exceed the number of samples with one or more violations.

Table 9: Results of FDA Pesticide Residue Tolerance Compliance Testing of Apples from 1993 through 2012, by Violation Type and Origin

	Number of samples		Samples with one or more violations		Number of violations of no tolerance		Number of violations of tolerance	
Year	Domestic	Imported	Domestic	Imported	Domestic	Imported	Domestic	Imported
1993	313	101	2	3	4	6	0	0
1994	85	36	1	1	0	1	4	0
1995	202	48	0	4	0	8	0	0
1996	217	59	6	0	8	0	0	0
1997	194	58	1	1	0	2	1	0
1998	219	55	1	0	1	0	0	0
1999	193	116	0	0	0	0	0	0
2000	214	50	1	1	4	2	0	0
2001	233	54	1	3	1	4	0	8
2002	167	38	0	1	0	4	0	0
2003	183	62	2	0	2	0	0	0
2005	142	32	0	2	0	5	0	0
2006	140	30	1	0	1	0	0	0
2007	136	40	0	1	0	1	0	2
2008	118	11	0	1	0	2	0	2
2009	91	18	0	1	0	1	0	0
2010[a]	123	28	0	0	0	0	0	0
2011	84	21	0	2	0	2	0	0
2012	104	25	1	0	1	0	0	0
Total	**3,158**	**882**	**17**	**21**	**22**	**38**	**5**	**12**

Source: GAO analysis of FDA data. | GAO-15-38

Note: Because FDA may detect multiple violations in a single sample, the total number of violations detected may exceed the number of samples with one or more violations. FDA was not able to provide us with test results from 2004 that were comparable in detail to the other years. Therefore, we could not include that year in our analysis of pesticide residue test results.

[a]Our analysis focuses on two types of violation; violations of no tolerance and violations of tolerance. FDA also may establish, as guidance, a nonbinding level, known as an action level, for an unavoidable residue of a cancelled pesticide that persists in the environment. FDA detected pesticide residues that exceeded action levels in two domestic and three imported apple samples in 2010, which are not shown in the table.

Table 10: Results of FDA Pesticide Residue Tolerance Compliance Testing of Bananas from 1993 through 2012, by Violation Type and Origin

	Number of samples		Samples with one or more violations		Number of violations of no tolerance		Number of violations of tolerance	
Year	Domestic	Imported	Domestic	Imported	Domestic	Imported	Domestic	Imported
1993	6	188	0	0	0	0	0	0
1994	2	281	0	2	0	8	0	0
1995	31	231	0	1	0	0	0	2
1996	9	251	0	0	0	0	0	0
1997	7	329	0	0	0	0	0	0
1998	5	158	0	0	0	0	0	0
1999	3	200	0	0	0	0	0	0
2000	2	294	0	1	0	4	0	0
2001	0	86	0	0	0	0	0	0
2002	0	76	0	0	0	0	0	0
2003	2	116	0	1	0	1	0	0
2005	1	24	0	0	0	0	0	0
2006	2	18	0	0	0	0	0	0
2007	0	41	0	0	0	0	0	0
2008	0	11	0	0	0	0	0	0
2009	1	13	0	0	0	0	0	0
2010	0	18	0	0	0	0	0	0
2011	0	15	0	0	0	0	0	0
2012	1	13	0	0	0	0	0	0
Total	**72**	**2,363**	**0**	**5**	**0**	**13**	**0**	**2**

Source: GAO analysis of FDA data. | GAO-15-38

Note: Because FDA may detect multiple violations in a single sample, the total number of violations detected may exceed the number of samples with one or more violations. FDA was not able to provide us with test results from 2004 that were comparable in detail to the other years. Therefore, we could not include that year in our analysis of pesticide residue test results.

Table 11: Results of FDA Pesticide Residue Tolerance Compliance Testing of Broccoli from 1993 through 2012, by Violation Type and Origin

	Number of samples		Samples with one or more violations		Number of violations of no tolerance		Number of violations of tolerance	
Year	Domestic	Imported	Domestic	Imported	Domestic	Imported	Domestic	Imported
1993	59	80	1	0	1	0	0	0
1994	23	68	0	0	0	0	0	0
1995	23	50	0	0	0	0	0	0
1996	26	36	0	0	0	0	0	0
1997	23	43	0	0	0	0	0	0
1998	13	39	0	0	0	0	0	0
1999	26	63	0	2	0	2	0	6
2000	14	36	0	0	0	0	0	0
2001[a]	24	33	2	0	1	0	4	0
2002	28	52	0	0	0	0	0	0
2003	27	45	0	0	0	0	0	0
2005	23	58	0	0	0	0	0	0
2006	12	43	1	0	0	0	2	0
2007	13	58	0	1	0	2	0	0
2008	13	68	0	1	0	2	0	0
2009	11	47	0	0	0	0	0	0
2010	13	59	0	2	0	1	0	2
2011	4	59	0	1	0	0	0	2
2012	7	27	0	0	0	0	0	0
Total	**382**	**964**	**4**	**7**	**2**	**7**	**6**	**10**

Source: GAO analysis of FDA data. | GAO-15-38

Note: Because FDA may detect multiple violations in a single sample, the total number of violations detected may exceed the number of samples with one or more violations. FDA was not able to provide us with test results from 2004 that were comparable in detail to the other years. Therefore, we could not include that year in our analysis of pesticide residue test results.

[a]Our analysis focuses on two types of violation; violations of no tolerance and violations of tolerance. FDA also may establish, as guidance, a nonbinding level, known as an action level, for an unavoidable residue of a cancelled pesticide that persists in the environment. FDA detected pesticide residue that exceeded an action level in one domestic sample of broccoli in 2001, which is not shown in the table.

Table 12: Results of FDA Pesticide Residue Tolerance Compliance Testing of Cantaloupe from 1993 through 2012, by Violation Type and Origin

	Number of samples		Samples with one or more violations		Number of violations of no tolerance		Number of violations of tolerance	
Year	Domestic	Imported	Domestic	Imported	Domestic	Imported	Domestic	Imported
1993	53	118	0	1	0	0	0	2
1994	64	57	0	9	0	11	0	6
1995	45	90	1	11	2	17	0	4
1996	75	106	3	12	7	24	0	0
1997	64	81	1	1	1	2	0	0
1998	26	63	0	5	0	8	0	2
1999	41	91	0	0	0	0	0	0
2000	18	44	0	0	0	0	0	0
2001	21	39	0	0	0	0	0	0
2002	22	49	0	0	0	0	0	0
2003	22	18	0	0	0	0	0	0
2005	44	4	0	0	0	0	0	0
2006	4	4	0	0	0	0	0	0
2007	18	8	1	0	3	0	0	0
2008	3	7	0	0	0	0	0	0
2009	17	3	0	0	0	0	0	0
2010	6	8	0	1	0	2	0	0
2011	4	22	0	2	0	2	0	2
2012	16	6	0	0	0	0	0	0
Total	**563**	**818**	**6**	**42**	**13**	**66**	**0**	**16**

Source: GAO analysis of FDA data. | GAO-15-38

Note: Because FDA may detect multiple violations in a single sample, the total number of violations detected may exceed the number of samples with one or more violations. FDA was not able to provide us with test results from 2004 that were comparable in detail to the other years. Therefore, we could not include that year in our analysis of pesticide residue test results.

Table 13: Results of FDA Pesticide Residue Tolerance Compliance Testing of Green Beans from 1993 through 2012, by Violation Type and Origin

	Number of samples		Samples with one or more violations		Number of violations of no tolerance		Number of violations of tolerance	
Year	Domestic	Imported	Domestic	Imported	Domestic	Imported	Domestic	Imported
1993	89	72	0	10	0	21	0	6
1994	135	100	1	15	2	28	0	4
1995	101	103	0	13	0	29	0	4
1996	120	60	0	3	0	7	0	0
1997	163	91	4	12	18	26	3	4
1998	98	144	1	14	2	34	0	2
1999	111	100	2	11	2	24	2	2
2000	124	73	0	10	0	25	0	0
2001	79	57	2	3	4	2	0	10
2002	83	80	1	7	2	11	0	4
2003	64	78	2	17	4	38	0	1
2005	78	114	1	19	1	36	0	0
2006	34	97	0	7	0	16	0	0
2007	28	116	2	3	4	5	0	0
2008	27	103	1	9	2	20	0	0
2009	34	104	1	4	1	10	0	0
2010	37	129	2	3	1	5	1	0
2011	37	58	1	7	1	13	0	0
2012	17	43	1	3	1	5	0	0
Total	**1,459**	**1,722**	**22**	**170**	**45**	**355**	**6**	**37**

Source: GAO analysis of FDA data. | GAO-15-38

Note: Because FDA may detect multiple violations in a single sample, the total number of violations detected may exceed the number of samples with one or more violations. FDA was not able to provide us with test results from 2004 that were comparable in detail to the other years. Therefore, we could not include that year in our analysis of pesticide residue test results.

Table 14: Results of FDA Pesticide Residue Tolerance Compliance Testing of Lettuce from 1993 through 2012, by Violation Type and Origin

	Number of samples		Samples with one or more violations		Number of violations of no tolerance		Number of violations of tolerance	
Year	Domestic	Imported	Domestic	Imported	Domestic	Imported	Domestic	Imported
1993	143	43	5	7	5	8	6	6
1994	70	37	5	0	8	0	0	0
1995	87	50	6	4	2	2	18	10
1996	80	45	2	1	1	2	6	0
1997[a]	67	27	1	0	1	0	0	0
1998	31	28	0	1	0	2	0	0
1999	35	47	0	2	0	12	0	0
2000	34	17	0	0	0	0	0	0
2001	23	22	0	3	0	8	0	2
2002	19	13	0	0	0	0	0	0
2003	49	6	3	1	5	2	0	0
2005	44	29	1	2	1	3	0	0
2006	38	7	1	0	4	0	0	0
2007	36	33	2	0	0	0	4	0
2008	54	28	1	0	1	0	0	0
2009	73	30	2	0	2	0	0	0
2010	35	23	0	0	0	0	0	0
2011	7	34	0	0	0	0	0	0
2012	3	2	0	0	0	0	0	0
Total	**928**	**521**	**29**	**21**	**30**	**39**	**34**	**18**

Source: GAO analysis of FDA data. | GAO-15-38

Note: Because FDA may detect multiple violations in a single sample, the total number of violations detected may exceed the number of samples with one or more violations. FDA was not able to provide us with test results from 2004 that were comparable in detail to the other years. Therefore, we could not include that year in our analysis of pesticide residue test results.

[a]Our analysis focuses on two types of violation; violations of no tolerance and violations of tolerance. FDA also may establish, as guidance, a nonbinding level, known as an action level, for an unavoidable residue of a cancelled pesticide that persists in the environment. FDA detected pesticide residue that exceeded an action level in one domestic sample of lettuce in 1997, which is not shown in the table.

Table 15: Results of FDA Pesticide Residue Tolerance Compliance Testing of Peaches from 1993 through 2012, by Violation Type and Origin

	Number of samples		Samples with one or more violations		Number of violations of no tolerance		Number of violations of tolerance	
Year	Domestic	Imported	Domestic	Imported	Domestic	Imported	Domestic	Imported
1993	135	63	7	0	4	0	8	0
1994	244	80	3	3	7	10	3	0
1995	200	52	2	2	2	6	1	0
1996	125	41	0	3	0	7	0	0
1997	162	33	2	1	2	2	3	0
1998	149	46	0	1	0	0	0	2
1999	130	27	0	0	0	0	0	0
2000	116	44	1	2	0	4	2	0
2001	85	26	4	1	9	1	1	0
2002[a]	96	43	2	1	1	0	0	3
2003	95	36	2	1	3	0	0	2
2005	80	16	2	0	0	0	8	0
2006	52	21	1	0	0	0	2	0
2007	36	16	1	0	1	0	0	0
2008	29	15	0	0	0	0	0	0
2009	35	8	0	0	0	0	0	0
2010	44	11	6	0	5	0	2	0
2011	20	17	2	0	2	0	0	0
2012	24	19	1	1	1	0	1	0
Total	**1,857**	**614**	**36**	**16**	**37**	**30**	**31**	**7**

Source: GAO analysis of FDA data. | GAO-15-38

Note: Because FDA may detect multiple violations in a single sample, the total number of violations detected may exceed the number of samples with one or more violations. FDA was not able to provide us with test results from 2004 that were comparable in detail to the other years. Therefore, we could not include that year in our analysis of pesticide residue test results.

[a]Our analysis focuses on two types of violation; violations of no tolerance and violations of tolerance. FDA also may establish, as guidance, a nonbinding level, known as an action level, for an unavoidable residue of a cancelled pesticide that persists in the environment. FDA detected pesticide residue that exceeded an action level in one domestic sample of peaches in 2002, which is not shown in the table.

Table 16: Results of FDA Pesticide Residue Tolerance Compliance Testing of Pears from 1993 through 2012, by Violation Type and Origin

	Number of samples		Samples with one or more violations		Number of violations of no tolerance		Number of violations of tolerance	
Year	Domestic	Imported	Domestic	Imported	Domestic	Imported	Domestic	Imported
1993	29	89	1	8	2	14	0	2
1994	53	106	0	20	0	35	0	4
1995	70	65	5	1	5	2	0	0
1996	69	61	0	1	0	0	0	2
1997	88	88	3	0	5	0	0	0
1998	49	44	1	0	1	0	0	0
1999	28	73	0	0	0	0	0	0
2000	72	63	0	0	0	0	0	0
2001	34	92	0	11	0	34	0	3
2002	40	45	0	2	0	2	0	0
2003	43	48	0	4	0	4	0	0
2005	33	34	4	1	4	2	0	0
2006	17	16	0	1	0	2	0	0
2007	20	28	7	4	7	7	0	0
2008	14	18	0	0	0	0	0	0
2009	9	8	0	0	0	0	0	0
2010	18	13	0	0	0	0	0	0
2011	15	18	0	5	0	5	0	0
2012[a]	18	16	1	1	3	0	0	0
Total	**719**	**925**	**22**	**59**	**27**	**107**	**0**	**11**

Source: GAO analysis of FDA data. | GAO-15-38

Note: Because FDA may detect multiple violations in a single sample, the total number of violations detected may exceed the number of samples with one or more violations. FDA was not able to provide us with test results from 2004 that were comparable in detail to the other years. Therefore, we could not include that year in our analysis of pesticide residue test results.

[a]Our analysis focuses on two types of violation; violations of no tolerance and violations of tolerance. FDA also may establish, as guidance, a nonbinding level, known as an action level, for an unavoidable residue of a cancelled pesticide that persists in the environment. FDA detected two action level violations in imported pears in 2012, which are not shown in the table.

Table 17: Results of FDA Pesticide Residue Tolerance Compliance Testing of Potatoes from 1993 through 2012, by Violation Type and Origin

	Number of samples		Samples with one or more violations		Number of violations of no tolerance		Number of violations of tolerance	
Year	Domestic	Imported	Domestic	Imported	Domestic	Imported	Domestic	Imported
1993	213	49	0	0	0	0	0	0
1994	192	26	0	0	0	0	0	0
1995	270	23	8	0	18	0	7	0
1996	234	78	2	0	4	0	0	0
1997[a]	174	20	2	0	0	0	0	0
1998[a]	142	26	5	4	4	8	0	0
1999[a]	116	38	3	0	3	0	0	0
2000	102	14	2	0	4	0	0	0
2001	142	15	6	0	0	0	12	0
2002	124	33	0	0	0	0	0	0
2003	98	55	1	3	2	14	0	0
2005	124	36	0	2	0	3	0	0
2006	88	28	0	4	0	12	0	0
2007	79	40	0	0	0	0	0	0
2008	82	40	0	1	0	2	0	0
2009	43	26	0	1	0	2	0	2
2010	76	40	3	2	1	2	11	2
2011	46	45	0	0	0	0	0	0
2012	56	26	0	2	0	2	0	0
Total	**2,401**	**658**	**32**	**19**	**36**	**45**	**30**	**4**

Source: GAO analysis of FDA data. | GAO-15-38

Note: Because FDA may detect multiple violations in a single sample, the total number of violations detected may exceed the number of samples with one or more violations. FDA was not able to provide us with test results from 2004 that were comparable in detail to the other years. Therefore, we could not include that year in our analysis of pesticide residue test results.

[a]Our analysis focuses on two types of violation; violations of no tolerance and violations of tolerance. FDA also may establish, as guidance, a nonbinding level, known as an action level, for an unavoidable residue of a cancelled pesticide that persists in the environment. FDA detected six action level violations in domestic potatoes in 1997, one in domestic potatoes in 1998, and one in domestic potatoes in 1999, which are not shown in the table.

Table 18: Results of FDA Pesticide Residue Tolerance Compliance Testing of Sweet Bell Pepper from 1993 through 2012, by Violation Type and Origin

	Number of samples		Samples with one or more violations		Number of violations of no tolerance		Number of violations of tolerance	
Year	Domestic	Imported	Domestic	Imported	Domestic	Imported	Domestic	Imported
1993	48	199	0	1	0	0	0	3
1994	43	230	1	10	0	23	2	6
1995	40	309	0	8	0	14	0	2
1996	80	251	0	1	0	0	0	2
1997	85	200	0	0	0	0	0	0
1998	29	176	0	6	0	8	0	2
1999	37	187	0	5	0	11	0	0
2000	21	139	0	5	0	12	0	0
2001	14	221	0	19	0	56	0	4
2002	14	276	0	20	0	77	0	4
2003	32	418	0	30	0	100	0	3
2005	47	235	0	8	0	9	0	3
2006	15	161	0	8	0	20	0	0
2007	12	200	2	8	4	16	0	4
2008	12	80	0	2	0	4	0	0
2009	19	144	0	7	0	13	0	2
2010	12	106	0	7	0	10	0	0
2011	21	108	0	4	0	6	0	1
2012	11	37	0	1	0	5	0	0
Total	**592**	**3,677**	**3**	**150**	**4**	**384**	**2**	**36**

Source: GAO analysis of FDA data. | GAO-15-38

Note: Because FDA may detect multiple violations in a single sample, the total number of violations detected may exceed the number of samples with one or more violations. FDA was not able to provide us with test results from 2004 that were comparable in detail to the other years. Therefore, we could not include that year in our analysis of pesticide residue test results.

Appendix III: Analysis of Pesticide Residues at Different Points in Time, Taking into Account Changes in Monitoring Methodologies and Pesticide Tolerances

To analyze pesticide residues in foods over time, we took into account changes in how agencies collected residue data and changes in pesticide tolerances. In this appendix, we discuss how changes in the Agricultural Marketing Service's (AMS) methods of testing foods for pesticide residues and in the Environmental Protection Agency's (EPA) established pesticide tolerances can affect the comparability of the residue data from AMS's Pesticide Data Program at different points in time. In particular, we found that changes to the set of pesticides AMS tested for, improvements in AMS's ability to detect smaller quantities of pesticide residue, and changes made by EPA to the established tolerance for a particular pesticide/commodity combination limited our ability to analyze residue data at different points in time.

To develop comparable measures for examining changes in residue detections at different points in time, we performed an analysis that focused on the set of pesticides; limits of detection, which is the concentration of a residue that AMS could detect with accuracy; and tolerances that were common to all years that we reviewed (1998 through 2012) for each particular commodity. The data that AMS collected in recent years were generally more extensive than the data the agency collected in earlier years because it added pesticides to its testing program and lowered its limits of detection for particular pesticides. In our analysis, we "restricted" the data on pesticides from recent years, meaning that we assumed that the older methods were still in use and, therefore, excluded more recent data that AMS collected with new methods. This allowed us, for the period of our review, to make comparisons between data on pesticide residues, limits of detection, and tolerances in effect during the earlier years. However, because the data collected in the earlier years were generally less extensive, it was not possible to estimate the residues that would have been detected in earlier years if the list of pesticides, limits of detection, and tolerances in effect in recent years had been in effect in those earlier years. Therefore, our analysis is able to provide a comparison at different points in time for only the restricted set of pesticides, assuming generally higher limits of detection. We are unable to assess changes at different points in time for pesticides that were added to the list of pesticides that AMS tested for in recent years or for concentrations of residues only detectable with more sensitive testing equipment that became available in recent years.

To analyze pesticide residue data at different points in time, we selected the 3 most recent years of AMS data for 10 commodities; apples, bananas, broccoli, cantaloupe, green beans, lettuce, peaches, pears,

potatoes, and sweet bell peppers. Due to AMS's staggered sampling schedule, it was not possible to select the same years for all 10 commodities. Table 19 shows the 3 most recent years in which AMS tested the 10 commodities for pesticide residue, from 1998 through 2012.

Table 19: Agricultural Marketing Service (AMS) Pesticide Data Program Data Selected for Analysis for the Most Recent 3 Years of Testing of the Commodity

Commodity	Year 1	Year 2	Year 3
Apples	2001	2004	2010
Bananas	2002	2006	2012
Broccoli	2001	2002	2007
Cantaloupe	1999	2004	2011
Green beans	2000	2004	2008
Lettuce	2000	2005	2010
Peaches	2001	2007	2008
Pears	1998	2004	2010
Potatoes	2001	2002	2009
Sweet bell peppers	2000	2003	2010

Source: AMS. | GAO-15-38

To restrict the data set, we identified three characteristics of AMS's testing that could have changed over time: (1) the list of pesticides that AMS tested for annually;(2) the concentration of a residue that AMS could detect with accuracy, or limit of detection; and (3) the tolerance established by EPA for a particular pesticide/commodity combination and against which the test results were measured to determine whether the residue exceeded that tolerance.

To restrict the list of pesticides, we refined the list of all pesticides for which AMS tested each commodity to only the pesticides that AMS tested that commodity for in each of the 3 years. For example, AMS tested apples for 93, 175, and 184 pesticides in 2001, 2004, and 2010, respectively. The restricted list we used for our analysis consisted of the 83 pesticides that AMS tested apples for in each of the 3 years and, therefore, excluded the remaining pesticides (i.e., 10 from 2001, 92 from 2004, and 101 from 2010).

To restrict the data with regard to limit of detection, we identified the highest level AMS used for a particular pesticide in the first of the 3 years it tested the commodity and used that value in our analyses for the

second and third years of testing as well.[1] For example, the highest limit of detection for the pesticide methomyl on cantaloupe was 0.032 parts per million in 1999. By 2011, the highest limit of detection for methomyl on cantaloupe had changed to 0.01 parts per million. We used the highest limit of detection for the methomyl/cantaloupe combination in 1999 in our analysis of all 3 years of restricted cantaloupe data.

To restrict the data with regard to EPA tolerances, we identified the tolerance for each pesticide/commodity combination in the first year and used that value in our analyses of the second and third years as well. For example, the tolerance for the pesticide methamidophos on green beans was 0.02 parts per million in year 2000; we used that tolerance in our analysis of residue data for green beans in 2004 and 2010 as well, even though by 2010 EPA had changed the tolerance to 3.0 parts per million. Restricting the tolerance only affects our analysis of the average concentration of residues relative to tolerance. It does not affect the analysis of the number of residues per sample or the average number of residues per sample. We note that our approach is limited by the fact that an EPA change to a tolerance may either increase it or decrease it. For the purposes of our analysis of pesticide residue concentrations as a percentage of tolerance over time in this appendix, we used the tolerance from the first year.[2]

Comparison of Restricted AMS Data Over Time

Using the data that we restricted to account for changes in pesticides tested for, limits of detection, and tolerances, we examined the residue data for each of the 10 commodities to determine the number of residues AMS detected over time and the pesticide residue with the highest average concentration relative to that pesticide's tolerance. For some commodities, there was little change in the number of detected residues at different points in time. For example, broccoli—one of the 10 commodities with relatively few detections—had an average of 0.2 pesticide residues per sample in 2001, 2002, and 2007 when the testing

[1]In some cases, variations in testing technology across laboratories in a given year meant that there were multiple limits of detection for one commodity in a year.

[2]Elsewhere in this report, we presented our analysis of the pesticide with the highest residue concentration as a percentage of tolerance for each of the 10 select commodities in the most recent year of AMS testing. For that analysis, we used the tolerance as established for that year.

methods used in 2001 were applied to those years.[3] Peaches—one of the commodities with more detected residues—averaged 3.6 residues per sample in 2001, 2.2 residues per sample in 2007, and 2.1 residues per sample 2008 when the methods used in 2001 were applied to each year. For the set of pesticides and limits of detection that were common across the 3 years, there was little change in the number of residues detected on most of the 10 commodities. Table 20 presents the average number of pesticide residues detected per sample for all 10 commodities, using restricted data from the 3 most recent years of AMS testing.

Table 20: Average Number of Pesticides Detected per Commodity Sample, Using Restricted Agricultural Marketing Service (AMS) Data for the Most Recent 3 Years of Testing

Commodity	Year 1	Year 2	Year 3
Apples	2.0[a]	1.8[f]	1.4[k]
Bananas	0.4[b]	0.3[g]	*0.3*[j]
Broccoli	0.2[a]	0.2[b]	0.2[i]
Cantaloupe	0.5[c]	0.6[f]	0.1[m]
Green beans	1.6[d]	1.6[f]	1.2[n]
Lettuce	0.5[d]	0.8[h]	0.5[k]
Peaches	3.6[a]	2.2[i]	2.1[l]
Pears	0.8[e]	0.5[f]	0.2[k]
Potatoes	1.1[a]	1.1[b]	1.0[o]
Sweet bell peppers	2.0[d]	1.7[j]	1.4[k]

Source: GAO analysis of AMS data. | GAO-15-38

Note: We analyzed AMS's data for those commodities from the 3 most recent years in which the agency sampled them, which are not the same for every commodity because AMS uses a staggered sampling schedule. We restricted the AMS data to account for changes in pesticides AMS tested for, the limits of detection AMS attained, and EPA-established tolerances. Averages for all years are based on data that have been restricted to the pesticides, limits of detection, and tolerances in effect during the first year. Unless otherwise indicated, all relative margins of error for 95 percent confidence intervals are less than plus or minus 10 percent of the value of those numerical estimates. Instances in which the relative margins of error are less than plus or minus 21 percent are shaded.

[a]The AMS testing year was 2001.

[3]We calculated margins of error for 95 percent confidence intervals for the AMS data and present them in table 20 below. However, as we described in this report, there are limitations in AMS's survey methods that lead us to have some concerns about using its data to make national estimates about the incidence and level of pesticide residues. Consequently, the results of our analyses are restricted to the samples taken by AMS for the 10 commodities we reviewed and are not meant to be generalized to the population of these commodities in the food supply.

[b]The AMS testing year was 2002.

[c]The AMS testing year was 1999.

[d]The AMS testing year was 2000.

[e]The AMS testing year was 1998.

[f]The AMS testing year was 2004.

[g]The AMS testing year was 2006.

[h]The AMS testing year was 2005.

[i]The AMS testing year was 2007.

[j]The AMS testing year was 2003.

[k]The AMS testing year was 2010.

[l]The AMS testing year was 2012.

[m]The AMS testing year was 2011.

[n]The AMS testing year was 2008.

[o]The AMS testing year was 2009.

We also analyzed the restricted AMS data to identify changes in the highest average concentration relative to that pesticide's tolerance at different points in time. In some commodities, there was little change over time. For example, the pesticide that AMS detected on bananas in Year 1 (2002) with the highest average concentration relative to its tolerance was imazalil at 2.4 percent relative to tolerance. We found that imazalil was also the pesticide with the highest average concentration relative to its tolerance in Year 2 (2006) at 0.9, and thiabendazole was the highest in Year 3 (2012) with 0.5 percent. Table 21 presents the pesticide with the highest average concentration relative to that pesticide's tolerance for each of the 10 commodities, using restricted data from the three 3 most recent years of AMS testing.

Table 21: Pesticide Residue with the Highest Average Concentration Relative to That Pesticide's Tolerance, Using Restricted Agricultural Marketing Service (AMS) Data

Commodity	Concentration as a percentage of tolerance in Year 1	Concentration as a percentage of tolerance in Year 2	Concentration as a percentage of tolerance in Year 3
Apples	5.8%	3.7%	3.5%
Bananas	2.4%	0.9%	0.5%
Broccoli	0.1%	<0.1%	**0.3%**
Cantaloupe	2.1%	3.2%	**0.5%**
Green beans[a]	135.2%	169.9%	137.0%
Lettuce	0.1%	11.0%	2.0%
Peaches	6.8%	7.6%	4.8%
Pears	2.3%	0.7%	**0.2%**
Potatoes	3.6%	4.6%	4.0%
Sweet bell peppers	**2.2%**	**1.4%**	1.5%

Source: GAO analysis of AMS data. | GAO-15-38

Note: We restricted the AMS data to account for changes in pesticides AMS tested for, the limits of detection AMS attained, and EPA-established tolerances. For the restricted data, all relative margins of error for 95 percent confidence intervals are less than plus or minus 40 percent of the value of the numerical estimates, with 10 exceptions. Five of the exceptions have relative margins of error that are less than plus or minus 86 percent and are shaded, while five have relative margins of error that are less than plus or minus 196 percent and are indicated in bold. For estimates with large relative margins of error, the particular value of the estimate should be interpreted with caution. Instead, for such estimates presented in this table, a more cautious interpretation is a general one: for the different time points we examined, the average concentration remained a small percentage of tolerance.

[a]The pesticide AMS detected with the highest concentration relative to its tolerance in green beans was methamidophos. In the first testing year shown, AMS frequently detected large concentrations of this pesticide, including seven presumptive tolerance violations. EPA subsequently raised the tolerance from 0.2 parts per million to 1 part per million, but the restricted data in the table do not reflect that or other changes in tolerance. Therefore, with respect to green beans, the table overstates the highest average concentration relative to the tolerance for methamidophos in the second and third years of testing.

Comparing Unrestricted AMS Pesticide Residue Data with Restricted AMS Data

We also compared the original, or unrestricted, data to the restricted data to determine the effect that the changes in pesticides tested for, limits of detection, and EPA tolerances had on our analysis. We found the number of residues detected and the concentrations detected as a percentage of tolerance in the 3 most recent years were generally higher when using unrestricted data than when using restricted data. We also found that, regardless of whether we used unrestricted or restricted data, when pesticide residues were detected, they were detected at low concentrations relative to their established tolerances.

Furthermore, we found that in the unrestricted AMS data set, the number of residues detected per commodity was higher when compared to the restricted data. We compared unrestricted AMS data to restricted AMS data for each of the 10 selected commodities to determine the effect of expanded testing methods on the number of pesticides detected in the most recent year. Broccoli is one commodity that shows that the enhanced testing methods, which were used in the most recent years, detected significantly more residues than the earlier testing methods. Using the restricted data, broccoli was one of the commodities least likely to have residues in test results that we examined. Specifically, 14 percent of the 720 individual samples of broccoli AMS tested in 2001 had detected residues, and about 20 and 17 percent of more than 735 samples had detected residues in 2002 and 2007, respectively.[4] Using the restricted data, we determined that AMS detected an average of 0.2 residues on sampled broccoli in 2001, 2002, and 2007. The results of our two methods of analysis for broccoli were not substantially different for the first 2 years; our analysis using the unrestricted AMS data found an average of 0.4 residues for sampled broccoli in 2001 and 2002. However, in 2007, the unrestricted AMS data show that broccoli samples had an average of 1.7 residues per sample with detected residues on more than 88 percent of broccoli samples.

If AMS's 2001 testing methods had persisted, a significant number of residues would not have been detected in 2007. Therefore, enhanced testing methods allowed for the detection of additional residues in 2007, but our analysis does not indicate whether these residues would have been detected in earlier years if these enhanced testing methods had been used in those years as well. Table 22 presents a comparison of unrestricted and restricted AMS data from the most recent year of AMS testing for all 10 commodities.

[4]The 95 percent margin of error for percent of samples with detected residues for each year is within plus or minus 5 percentage points.

Table 22: Comparison of the Average Number of Pesticides Detected per Sample, Using Restricted and Unrestricted Agricultural Marketing Service (AMS) Data from the Most Recent Year of Testing

Commodity	Restricted data	Unrestricted data
Apples[a]	1.4	5.2
Bananas[b]	**0.3**	1.3
Broccoli[c]	**0.2**	1.7
Cantaloupe[d]	**0.1**	0.5
Green beans[e]	1.2	1.9
Lettuce[a]	**0.5**	3.4
Peaches[e]	2.1	3.5
Pears[a]	**0.2**	1.7
Potatoes[f]	0.9	1.9
Sweet bell peppers[a]	1.4	4.3

Source: GAO analysis of AMS data. | GAO-15-38

Note: We restricted the AMS data to account for changes in pesticides AMS tested for, the limits of detection AMS attained, and EPA-established tolerances; unrestricted data do not account for those changes. For the restricted data, unless indicated, all relative margins of error for 95 percent confidence intervals are less than plus or minus 10 percent of the value of those numerical estimates. Five instances in which the relative margins of error are less than plus or minus 21 percent are shown in bold. For the unrestricted data, all relative margins of error are less than plus or minus 11 percent.

[a]The AMS testing year was 2010.

[b]The AMS testing year was 2012.

[c]The AMS testing year was 2007.

[d]The AMS testing year was 2011.

[e]The AMS testing year was 2008.

[f]The AMS testing year was 2009.

We also found that using unrestricted rather than restricted data produced somewhat different results regarding the pesticide with the highest average residue concentrations relative to tolerance, but that the average concentrations were also low relative to their established tolerances.[5] For example, the commodity with the pesticide with highest average concentration relative to its tolerance using the unrestricted data was potatoes, at 9.9 percent. That compared to 4.0 percent using the restricted data.

[5]We did not consider in this analysis those pesticides that AMS detected on samples of any of the 10 commodities but that do not have an established tolerance for that commodity.

Differences in the concentrations relative to tolerance between the two types of data could suggest that tolerances were lowered or that the unrestricted data set of pesticides included pesticides with higher concentrations relative to tolerance in later years that were not part of the restricted data set. It was beyond the scope of our review to determine which, if any, of these scenarios occurred for each commodity. However, green beans provided a clear example of the effect that a change in tolerance could have on our analysis. In 2000, the tolerance for the pesticide methamidophos on green beans was 0.2 parts per million. In that year, AMS detected residues in about 27 percent of its green bean samples, with residue concentrations averaging 135 percent of the tolerance. Those detections included seven presumptive tolerance violations for that pesticide. After 2000, EPA increased the tolerance for methamidophos on green beans to 1 part per million. Using the restricted data, which assumes that the first year tolerance of 0.2 parts per million continues into the second and third year, AMS detected residues with concentrations that averaged about 170 and 137 percent of that tolerance, respectively. However, using unrestricted data from 2004 and 2008 that accounted for the new tolerance of 1 part per million, we found that AMS detected residue concentrations averaging 3.4 percent and 0.9 percent of the tolerance for methamidophos, respectively. Table 23 presents the highest pesticide residue concentration as a percentage of tolerance in the most recent year of AMS testing for all 10 commodities using both unrestricted and restricted AMS data.

Table 23: Comparison of Restricted and Unrestricted Agricultural Marketing Service (AMS) Data for Pesticide Residue with the Highest Average Concentration Relative to That Pesticide's Tolerance for the Most Recent Year of Testing

	Concentration as a percentage of tolerance in most recent year	
Commodity	**Using restricted data**	**Using unrestricted data**
Apples[a]	3.5%	5.2%
Bananas[b]	0.5%	0.7%
Broccoli[c]	**0.3%**	**0.1%**
Cantaloupe[d]	**0.5%**	0.9%
Green beans[e]	136.8%	2.4%
Lettuce[a]	**2.0%**	0.6%
Peaches[e]	4.8%	4.8%
Pears[a]	**0.2%**	2.9%
Potatoes[f]	4.0%	**9.9%**
Sweet bell peppers[a]	**1.5%**	2.8%

Source: GAO analysis of AMS data. | GAO-15-38

Note: We restricted the AMS data to account for changes in pesticides AMS tested for, the limits of detection AMS attained, and EPA-established tolerances; unrestricted data do not account for those changes. For the restricted data, all relative margins of error are less than plus or minus 40 percent of the numerical estimate with five exceptions that have relative margins of error that are less than plus or minus 196 percent and are shown in bold. For the unrestricted data, all relative margins of error are less than plus or minus 40 percent with two exceptions that have relative margins of error that are less than plus or minus 90 percent and are shown in bold. For estimates with large relative margins of error, the particular value of the estimate should be interpreted with caution. Instead, for such estimates presented in this table, a more cautious interpretation is a general one: for the different time points we examined, with the exception of green beans, the average concentration remained a small percentage of tolerance.

[a]The AMS testing year was 2010.

[b]The AMS testing year was 2012.

[c]The AMS testing year was 2007.

[d]The AMS testing year was 2011.

[e]The AMS testing year was 2008.

[f]The AMS testing year was 2009.

Appendix IV: Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

SEP 19 2014

John Neumann, Acting Director
Natural Resources and Environment
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Mr. Neumann:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "FDA and USDA Should Strengthen Pesticide Residue Monitoring Programs and Further Disclose Monitoring Limitations" (GAO-15-38).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: FOOD SAFETY: FDA AND USDA SHOULD STRENGTHEN PESTICIDE RESIDUE MONITORING PROGRAMS AND FURTHER DISCLOSE MONITORING LIMITATIONS (GAO-15-38)

The Department appreciates the opportunity to review and comment on the draft Government Accountability Office (GAO) report.

HHS' food safety program is designed to safeguard public health from foodborne illness posed by foods that may contain pathogens, natural toxins, pesticides, and other contaminants. HHS has already increased its monitoring of pesticides residues by taking actions consistent with GAO's recommendations.

- Over the past five years, the U.S. Food and Drug Administration's (FDA's) pesticide regulatory program has grown to include testing for over 800 pesticides, making it among the most robust globally.
- FDA's testing scope includes numerous pesticides used around the world that have no U.S. tolerances. No-tolerance findings (the pesticide is detected and there is no established tolerance) comprise over 95% of the violations; they are a significant focus of the FDA analytical pesticide screening.
- This year, FDA approved investigation of a new screening technology/method that will further increase coverage to over 1000 pesticides when implemented.
- An Agency research project currently underway, *Development and Validation of a Single HPLC/MS Method to Detect Very Polar Pesticides in Produce*, could enable FDA to analyze glyphosate and its metabolites and other high-use herbicides like paraquat.
- For its Total Diet Study (TDS) FDA developed a method for detecting acid herbicides which include the widely used herbicide 2,4-D and 35 other herbicides. FDA plans to evaluate the new procedure for implementation in its pesticides program.
- FDA continues to collaborate with the Environmental Protection Agency, the United States Department of Agriculture (USDA) Pesticide Data Program (PDP), the USDA Food Safety and Inspection Service, and several state agencies with pesticide monitoring programs to leverage limited resources to maximize effectiveness and efficiencies.

In addition to the assessment of pesticide residue contamination, FDA's food safety mission also includes protecting the consumer against foodborne illness due to microbial contamination, a risk that often has immediate and fatal consequences. For that reason, FDA deploys its limited resources through targeted testing to achieve the greatest overall public benefit. This means that frequently the decision to test a food product is driven by the risk the product represents from a microbial contamination perspective, rather than from a pesticide contamination perspective.

GAO Recommendation

GAO recommends that FDA disclose in the agency's annual pesticide monitoring program report which pesticides with EPA-established tolerances the agency did not test for in its pesticides monitoring program and the potential effect of not testing for those pesticides.

1

HHS Response
In future versions of its annual report, FDA will clarify that not all pesticides for which EPA has established tolerances were analyzed, but disagrees with the recommendation to name the pesticides that were not assessed. The FDA annual Pesticide Report is intended to comply with the requirements set forth in 21U.S.C. 1401(b), authorized by the Pesticide Monitoring Improvement Act of 1988 (PMIA). FDA reports all pesticides tested for within the report's annual scope, as required by the PMIA, including many pesticides that do not have EPA-established tolerances. FDA believes that disclosing pesticides for which FDA does not test would enable users to more easily circumvent the pesticides monitoring program.

The FDA pesticide program is targeted in nature. It collects and tests food samples in a manner that makes the best use of available resources for the enforcement of U.S. pesticide residue tolerances. Due to resource limitations, FDA does not test foods it samples for all pesticides for which EPA has established tolerances. As indicated earlier, FDA has expanded the scope of its pesticide program significantly in the last several years and continues to investigate analytical methods to include as many pesticides as possible.

GAO Recommendation
GAO recommends that FDA design and implement a statistically-valid sampling methodology that would enable the agency, within existing resources, to gather nationally representative pesticide residue incidence and level data for both domestically produced and imported foods, or justify statistically the use of a non-probability method that can measure the estimation error.

HHS Response
FDA will investigate the feasibility and potential costs to develop and utilize a statistically-valid sampling methodology. To achieve sufficient precision for each food-pesticide combination, the design will necessarily require prioritized and strategic analysis of specific foods and pesticides. A program for systematic statistical sampling would require additional resources for FDA. Alternatively, given current resources and increasing food imports, this would imply a substantial reduction in the variety of commodities that FDA would analyze annually. In addition, the USDA PDP already administers a national statistically-valid sampling program, and FDA utilizes those data in its pesticide monitoring program to inform which commodities will be assigned a higher risk value for pesticides in PREDICT and which commodities we may target for sampling.

GAO Recommendation
GAO recommends that FDA report the national representative incidence and level data in its annual pesticide monitoring reports disclosing the limits of sampling methodology.

HHS Response
The FDA pesticide program is targeted in nature: it collects and tests food samples in order to most efficiently use available resources for the enforcement of U.S. pesticide residue tolerances in the context of its other food safety priorities. FDA will disclose the limitations of the data provided in future annual reports and, as noted above, will evaluate its sampling programs and the cost of implementing representative sampling.

GAO Recommendation
GAO recommends that FDA assess the effectiveness of FDA's targeted pesticide compliance and enforcement monitoring program including use of PREDICT.

HHS Response
HHS concurs with GAO's recommendation. FDA is currently reviewing incidences of repeat violations among growers, shippers, importers, consignees, dealers, filers, and harvesters over the past 3 years to assess the effectiveness of regulatory actions in preventing future violative shipments.

FDA is also evaluating risks associated with PREDICT, FDA's risk-based screening system for imports. Routine evaluation of FDA data (e.g., PREDICT, TDS, Warning Letters, Import Alerts) supplemented by other sources of intelligence (including EPA, the USDA PDP program, and pesticide use data) enhances PREDICT screening to improve risk-based targeting of products and better inform FDA on what pesticides to include in analytical procedures. FDA hosts monthly PREDICT Roundtables in order to discuss and develop PREDICT screening criteria. Additional identification of the most appropriate data can be used to refine PREDICT criteria for the pesticide program.

GAO Recommendation
GAO recommends that FDA identify any domestic and imported foods that are high risk for pesticide residue tolerance violations to improve the ability of its targeted pesticide compliance and enforcement monitoring program to consistently identify food likely to have violations.

HHS Response
HHS generally concurs with GAO's recommendation. FDA actively identifies and targets domestic and imported commodities that are at high risk for pesticide residue violations. The Agency uses available intelligence from other federal and state agencies along with pesticide usage data from other countries as well as other resources to adjust the sampling plan or to do special assignments as necessary.

Appendix V: Comments from the U.S. Department of Agriculture

United States Department of Agriculture

Office of the Secretary
Washington D.C. 20250

MEMORANDUM

TO: John Neumann
Acting Director, Natural Resources and Environment
Government Accountability Office

THROUGH: Edward Avalos
Under Secretary
Marketing and Regulatory Programs

FROM: Rex Barnes
Acting Administrator

SUBJECT: Response to GAO Audit Report (GAO-15-38)

Attached is the U.S. Department of Agriculture's response to the draft report titled "Food Safety: FDA and USDA Should Strengthen Pesticide Residue Monitoring Programs and Further Disclose Monitoring Limitations." USDA's Agricultural Marketing Service (AMS) was designated as the "lead agency" for this engagement, and accordingly prepared the attached response to the GAO's four recommendations, after consultation with the Food Safety Inspection Service (FSIS). Thank you for the opportunity to provide comments.

If you have any questions or need further information, please contact Frank Woods at 202-720-8836 or via e-mail Frank.Woods@ams.usda.gov.

Attachment

An Equal Opportunity Employer

U.S. Department of Agriculture
Statement of Action on the U.S. Government Accountability Office
Final Report GAO-15-38, "Food Safety: FDA and USDA Should Strengthen Pesticide Residue Monitoring Programs and Further Disclose Monitoring Limitations."

August 25, 2014

General Comments

USDA appreciates the opportunity to review the draft GAO report and generally agrees with the report's findings and recommendations, however, we would like to emphasize some of the differences in the agencies' missions with respect to monitoring pesticide residues. Specifically, the Agricultural Marketing Service (AMS) Pesticide Data Program (PDP) is informational and designed to provide specified information to EPA, whereas the Food Safety and Inspection Service (FSIS) program is regulatory in nature and is designed to protect public health. FSIS has a test and hold policy that requires establishments to hold product that is awaiting test results from entering commerce. Because the product is withheld from commerce, the policy requires a very prompt turnaround time for sample results from FSIS laboratories. FSIS operates under a 3-6 day turnaround time to report sample results to lessen the impact on industry. Other agencies do not have this time constraint of analyzing samples within days, which significantly impacts how FSIS manages its laboratory resources. In addition, violations in the FSIS testing program may require a recall or other enforcement action by the agency.

GAO Recommendation for USDA (page 54 of draft report):

To better inform the public about the frequency and scope of pesticide tolerance violations, we recommend that the Secretary of Agriculture direct the FSIS Administrator to disclose in the agency's annual pesticide monitoring program report which pesticides with EPA-established tolerances the agency did not test for in its National Residue Program and the potential effect of not testing for those pesticides.

USDA Response:

USDA agrees with this recommendation and will have the Food Safety and Inspection Service (FSIS) disclose in its annual pesticide monitoring program reports, which pesticides with EPA-established tolerances the agency did not test for in the National Residue Program and the potential effect of not testing for those pesticides. FSIS is expanding its pesticide testing capabilities and is working more closely with the EPA to provide them with more useful testing results and in a more timely manner. As noted in the report, in June 2014 FSIS completed validation studies to expand its current testing method to test for additional pesticides. The total count is now 88 pesticides, a significant increase from the number tested previously, which includes 19 pesticides of "Highest" priority to EPA, and 14 pesticides of "High" priority to EPA. FSIS laboratories began testing for the additional pesticides in July 2014. FSIS will continue to work off the priority list developed with EPA to insert or remove compounds from FSIS' testing programs based on their public health importance and will continue discussions with EPA on the minimum level of applicability for those pesticides tested by FSIS or those prioritized for testing

1

by EPA. Minimum level of applicability refers to the lowest residue concentration that has been validated to be accurately and consistently reported by a testing method in a type of animal product.

Additional GAO Recommendations for USDA (Page 54)

To better meet federal standards and best practices for statistical surveys, we recommend that the Secretary of Agriculture direct the AMS Administrator to provide better documentation of the survey methods used in its Pesticide Data Program in the program's annual reports by:

Recommendation: Providing more complete information on the sampling methodology the agency uses, such as how it identifies and selects states, food distribution centers, and commodities for pesticide residue testing, and include measures of sampling error for reported estimates.

USDA Response: USDA agrees that increasing transparency regarding Pesticide Data Program (PDP) survey methodology will reduce the potential for misinterpretation of the Agricultural Marketing Service (AMS) annual monitoring reports. AMS plans to add a description of the sampling methodology employed for site selection (including how states, food distribution centers/sites, and commodities are identified and selected) for inclusion in the PDP Annual Summary report. Additionally, AMS will explore procedures for assessing the degree to which incompleteness of the sampling frame may lead to the potential for biased estimates.

Recommendation: Report on the extent to which its survey covers commodities in the U.S. food supply and any limitations associated with its survey methodology, and

USDA Response: USDA agrees and AMS plans to provide more information on its sampling methodology, program parameters and inherent limitations in the PDP Annual Summary report. AMS believes that the participating sites provide a reliable representation of all sites and will investigate methods for confirmation. Sites that participate in PDP range from small family run businesses to large national chain distributors. It is important to note that PDP participation by sites is strictly voluntary and cannot be mandated. It is also important to note that expanding the number of states and sites that participate in PDP will incur additional costs.

Recommendation: Describe methods users should employ to analyze the data, including obtaining margins of error for making generalizable estimates of pesticide residues in commodities.

USDA Response: AMS routinely meets with the National Agricultural Statistics Service (NASS) to review PDP sampling methodology. AMS will work to describe methods users can use to analyze the data and to improve the sampling methodology. Once developed, such methods and procedures will be included in the PDP Annual Summary report.

Again, thank you for the opportunity to review and comment on this draft report. We look forward to working with you on future Department of Agriculture engagements.

2

Appendix VI: GAO Contact and Staff Acknowledgments

GAO Contact

John Neumann, (202) 512-3841 or Neumannj@gao.gov

Staff Acknowledgments

In addition to the individual named above, James R. Jones, Jr. (Assistant Director), Susan Baker, Kevin Bray, Mark Braza, Ross Campbell, John Delicath, Sheyda R. Esnaashari, Jason Trentacoste, and Sonya Vartivarian made key contributions to this report. Armetha Liles, Monica Savoy, and Kiki Theodoropoulos also made important contributions to this report.

Related GAO Products

Pesticide Safety: Improvements Needed in EPA's Good Laboratory Practices Inspection Program. GAO-14-289. Washington, D.C.: May 15, 2014.

Environmental Health: EPA Has Made Substantial Progress but Could Improve Processes for Considering Children's Health. GAO-13-254. Washington, D.C.: August 12, 2013.

Pesticides: EPA Should Take Steps to Improve Its Oversight of Conditional Registrations. GAO-13-145. Washington, D.C.: August 8, 2013.

Food Safety: FDA Can Better Oversee Food Imports by Assessing and Leveraging Other Countries' Oversight Resources. GAO-12-933. Washington, D.C.: September 28, 2012.

Information Technology: FDA Needs to Fully Implement Key Management Practices to Lessen Modernization Risks. GAO-12-346. Washington, D.C.: March 15, 2012.

Seafood Safety: FDA Needs to Improve Oversight of Imported Seafood and Better Leverage Limited Resources. GAO-11-286. Washington, D.C.: April 14, 2011.

Agricultural Chemicals: USDA Could Enhance Pesticide and Fertilizer Usage Data, Improve Outreach, and Better Leverage Resources. GAO-11-37. Washington, D.C.: November 4, 2010.

Food and Drug Administration: Overseas Offices Have Taken Steps to Help Ensure Import Safety, but More Long-Term Planning Is Needed. GAO-10-960. Washington, D.C.: September 30, 2010.

Food Safety: FDA Could Strengthen Oversight of Imported Food by Improving Enforcement and Seeking Additional Authorities. GAO-10-699T. Washington, D.C.: May 6, 2010.

Food Safety: Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food. GAO-09-873. Washington, D.C.: September 15, 2009.

Food Safety: Improvements Needed in FDA Oversight of Fresh Produce. GAO-08-1047. Washington, D.C.: September 26, 2008.

Agricultural Pesticides: Management Improvements Needed to Further Promote Integrated Pest Management. GAO-01-815. Washington, D.C.: August 17, 2001.