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United States Government Accountability Office
Washington, DC 20548

April 23, 2010

The Honorable Brad Miller
Chairman
Subcommittee on Investigations and Oversight
Committee on Science and Technology
House of Representatives

Subject: Food Safety: FDA Has Begun to Take Action to Address Weaknesses in Food Safety Research, but Gaps Remain

Dear Mr. Chairman:

The United States faces challenges to ensuring food safety. First, imported food makes up a substantial and growing portion of the U.S. food supply, with 60 percent of fresh fruits and vegetables and 80 percent of seafood coming from across our borders. In recent years, there has been an increase in reported outbreaks of foodborne illness associated with both domestic and imported produce. Second, we are increasingly eating foods that are consumed raw and that have often been associated with foodborne illness outbreaks, including leafy greens such as spinach. Finally, shifting demographics means that more of the U.S. population is, and increasingly will be, susceptible to foodborne illnesses. The risk of severe and life-threatening conditions caused by foodborne illnesses is higher for older adults, young children, pregnant women, and immune-compromised individuals. In January 2007 GAO designated federal oversight of food safety as a high-risk area needing urgent attention and transformation because of the federal government's fragmented oversight of food safety.¹

The Food and Drug Administration (FDA) is responsible for ensuring the safety of roughly 80 percent of the U.S. food supply—virtually all domestic and imported foods except for meat, poultry, and processed egg products—valued at a total of \$466 billion annually, as of June 2008. In 2007 the FDA Science Board, an advisory board to the agency, reported that science at FDA suffers from serious deficiencies. In addition, our prior reviews of FDA's food safety programs have identified gaps in scientific information, limiting FDA's ability to oversee food labeling, fresh produce, and dietary supplements. Further, as part of our recent review on the effectiveness of the strategic planning and management efforts of FDA, 67 percent of FDA managers reported, in response to a GAO survey, that updated scientific technologies or other tools would greatly help them to contribute to FDA's goals and responsibilities; however, only 36 percent of managers reported that FDA was making great progress

¹GAO, *High-Risk Series: An Update*, [GAO-07-310](#) (Washington, D.C.: January 2007).

in keeping pace with scientific advances.² In written comments responding to our survey, some managers stressed the need to increase and stabilize funding, recruit and retain top scientists, and make decisions on the basis of scientific evidence.

In this context, you asked us to examine ways in which FDA may use science to more effectively support its regulatory work and to inform the public about food content and safety. This report focuses primarily on FDA's (1) progress in addressing selected recommendations identified by the Science Board; (2) incorporation of scientific and risk analysis into its oversight of the accuracy of food labeling, fresh produce, and the safety of dietary supplements; and (3) a new computer screening tool that may improve its efforts to screen imports using a risk-based approach.

To assess FDA's progress in addressing selected science recommendations by the Science Board, we reviewed FDA documents, such as subsequent Science Board reports and updates; interviewed FDA officials from various centers and offices; and examined FDA's progress in addressing these selected science recommendations. To determine FDA's ability to incorporate science and risk analysis into its oversight, we reviewed our prior work on food labeling, fresh produce, and dietary supplements and updated the information where appropriate.³ (See enclosures I, II, III, and IV for highlights of our prior work.) To determine how FDA is using the Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting (PREDICT) to oversee the safety of imported food, we reviewed our September 2009 report on imported food safety, reviewed and summarized formal assessments of PREDICT conducted by FDA and its contractor, and spoke with FDA officials responsible for managing and implementing the screening tool to obtain their views.⁴ We also relied on our recent work assessing FDA's efforts to modernize its information technology.⁵

We conducted this performance audit from January 2010 to April 2010 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 during these reviews provides a reasonable basis for our findings and conclusions based on our audit objectives.

²The percentages represent survey responses of a "great extent" and "very great extent" and have a margin of error of plus or minus 10 percentage points or less. See GAO, *Food and Drug Administration: Opportunities Exist to Better Address Management Challenges*, [GAO-10-279](#) (Washington, D.C.: Feb. 19, 2010) for more information; and *Food and Drug Administration: 2009 FDA Managers Survey on Performance and Management Issues, an E-supplement to GAO-10-279*, [GAO-10-280SP](#) (Washington, D.C.: Feb. 2010) for survey results.

³GAO, *Dietary Supplements: FDA Should Take Further Actions to Improve Oversight and Consumer Understanding*, [GAO-09-250](#) (Washington D.C.: Jan. 29, 2009); *Food Safety: Improvements Needed in FDA Oversight of Fresh Produce*, [GAO-08-1047](#) (Washington, D.C.: Sept. 26, 2008); and *Food Labeling: FDA Needs to Better Leverage Resources, Improve Oversight, and Effectively Use Available Data to Help Consumers Select Healthy Food*, [GAO-08-597](#) (Washington, D.C.: Sept. 9, 2008).

⁴GAO, *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).

⁵GAO, *Information Technology: FDA Needs to Establish Key Plans and Processes for Guiding Systems Modernizations Efforts*, [GAO-09-523](#) (Washington, D.C.: June 2, 2009).

In Summary

FDA has begun to address selected Science Board recommendations. For example, FDA reported in May 2008 that it created the Office of Chief Scientist and, in May 2009, it added more responsibilities to the office to signal a new emphasis on regulatory science. According to the Acting Chief Scientist, his office plans to identify major scientific cross-cutting opportunities across FDA and to collaborate with other government agencies. However, gaps in scientific information have hampered FDA's oversight of food labeling, fresh produce, and dietary supplements. In addition, FDA's new computer tool—PREDICT—is designed to improve its risk-based import screening efforts by analyzing food shipments using criteria that include a product's inherent food safety risk and the importer's violative history, among other things, to estimate each shipment's risk. FDA has developed a draft performance measurement plan for evaluating the effectiveness of this risk-based approach.

Background

FDA's 2007 *Food Protection Plan* lays out the agency's framework for overseeing the safety of food and outlines three core elements—prevention, intervention, and response.⁶ Because no plan can prevent all food contamination, FDA reported that it is using a targeted, risk-based strategy that relies on statistical sampling and risk-detection tools, such as the development of PREDICT, to identify safety threats to imported food. In addition, according to FDA officials, a research coordinating committee was established to develop a collaborative research agenda that supports activities under prevention, intervention, and response. We reported that while the plan proposes positive first steps, the capacity to carry them out is critical and that FDA had provided few details on the resources and strategies required to implement its *Food Protection Plan*.⁷

Recognizing the important role FDA plays in overseeing food safety, among other things, FDA's Science Board reported in November 2007 that science at FDA suffers from serious deficiencies and is not positioned to meet current or emerging regulatory responsibilities.⁸ The report, entitled *FDA Science and Mission at Risk*, predicted that FDA will flounder and ultimately fail without a strong scientific foundation. Specifically, in the report, the Science Board found that FDA could not fulfill its mission because its scientific base had eroded and its scientific organizational structure was weak. Through its discussions with FDA staff, the Science Board identified consistent themes: (1) the need for an agencywide vision for the role of science; (2) the importance of possessing leading-edge skills in science and the importance of priorities for the science program; and (3) the need for coordinated maximization of science resources, oversight of program performance,

⁶U.S. Department of Health and Human Services, U.S. Food and Drug Administration, *Food Protection Plan: An Integrated Strategy for Protecting the Nation's Food Supply*, (Washington, D.C., November 2007).

⁷GAO, *Federal Oversight of Food Safety: FDA Has Provided Few Details on the Resources and Strategies Needed to Implement its Food Protection Plan*, [GAO-08-909T](#) (Washington, D.C.: June 12, 2008); and *Federal Oversight of Food Safety: FDA's Food Protection Plan Proposes Positive First Steps, but Capacity to Carry Them Out is Critical*, [GAO-08-435T](#) (Washington, D.C.: Jan. 29, 2008).

⁸FDA Science Board, Subcommittee on Science and Technology, *FDA Science and Mission at Risk*, (Washington, D.C., November 2007).

and an infrastructure to act on this vision. The Science Board found that scientific leadership at the center level was variable.⁹ The board made several science-related recommendations intended to address these weaknesses. Among other things, the Science Board recommended that FDA develop a new science organization to oversee agencywide goals and standards and play an oversight and accountability role.

FDA Has Begun to Address Selected Science Board Recommendations

FDA has taken some steps to implement the selected Science Board's recommendations we reviewed. For example, the board recommended that FDA rapidly centralize its science programs in order to appropriately inform the regulatory process. To this end, the board recommended that FDA establish the position of Chief Scientific Officer, as directed by the Food and Drug Administration Amendments Act of 2007. In May 2008 FDA established the Office of Chief Scientist, appointed its first chief scientist, and noted that this appointment signaled a new emphasis on the importance of science in the agency. In February 2009 the first chief scientist (1) released a scientific strategy for the agency that outlined the efforts FDA had initiated to ensure that the scientific base at FDA was effective and targeted to its regulatory responsibility; (2) called for FDA to work with academia and industry to support and amplify the scientific base that underpins FDA's regulatory decisions; and (3) stated that FDA needed strong support for science from within FDA and in partnership with others outside of FDA, such as academia and industry.¹⁰

The Science Board also found scientific gaps in areas that are important to developing the FDA centers' scientific knowledge. In particular, for the two centers that are primarily responsible for food safety, the board noted that it was crucial for both centers to develop the science needed to fulfill their mandated missions. The centers took the following actions:

- In response to the Science Board's request, the Center for Food Safety and Applied Nutrition (CFSAN)—which is responsible for ensuring that the nation's food supply is safe, sanitary, wholesome, and properly labeled—identified seven areas in which the scientific base needed to be strengthened through additional scientific expertise, additional resources, or the leveraging of outside expertise. For example, CFSAN identified the detection of foodborne viruses as an important area for further research. CFSAN has recently hired two virologists and two Commissioner's Fellows and is in the process of leveraging virology research through academic and inter-agency collaborations. The board had noted that the development of effective

⁹FDA's public health responsibilities are, among other things, to ensure the safety and effectiveness of medical products—drugs, biologics, and medical devices—marketed in the United States; ensure the safety of nearly all food products other than meat and poultry; and regulate tobacco products. FDA carries out these responsibilities through six regulatory product centers; its Office of Regulatory Affairs, which performs fieldwork, such as inspections and enforcement activities, on behalf of all the product centers; and its research arm, the National Center for Toxicological Research.

¹⁰Office of the Chief Scientist and Principal Deputy Commissioner, U.S. Food and Drug Administration, *Report on Status of Regulatory Science at FDA: Progress, Plans and Challenges* (Washington, D.C., February 2009).

prevention strategies is hampered by limited available scientific knowledge and resources devoted to the identification of these viruses.

- According to an August 2009 review of the Center for Veterinary Medicine (CVM)—which is responsible for the evaluation, approval, and surveillance of animal drugs, feed ingredients, and animal devices—the FDA Science Board noted the commitment to mission and quality science exhibited by the center’s leadership. For example, the review found that CVM had initiated an environmental scan to identify emerging scientific and technological issues related to CVM’s mission. The board also found that CVM has a well-developed internal consultative process for developing its 3-year research plan. However, the board noted that the consultative process was primarily internal and did not have key input from leading scientists and organizations in academia and industry. It further noted that, while CVM has some excellent researchers and scientists, the center as a whole lacks depth in critical positions and in subject matter experts, a vulnerability that is likely to become more acute as the demand for new experts in leading-edge science increases. Subsequently, CVM has instituted a workforce initiative which includes activities such as building alliances and partnerships with private and governmental groups, attending job fairs at universities and trade shows, and learning and development programs.

Furthermore, the Science Board recommended that FDA strengthen its collaboration across the centers and with other government agencies. The Acting Chief Scientist agreed with this recommendation. He told us that he plans to identify major scientific cross-cutting opportunities across the centers and to collaborate with other government agencies, such as the National Institutes of Health, and with research universities. The Acting Chief Scientist also cited the following as examples of ongoing science-related activities:

- The consolidation of state of the art laboratories in engineering and life sciences and co-location of FDA staff to facilitate scientific exchange and collaboration.
- The creation of the Commissioner’s Fellowship Program, whose fellows are to be trained in regulatory science and participate in targeted FDA research and policy activities.
- Partnerships across government, such as the FDA and Defense Advanced Research Projects Agency partnership to develop technologies for rapid detection of food pathogens.

We have reported on leading practices for effective strategic planning that could help organizations clarify priorities and communicate priorities to stakeholders.¹¹ These practices include establishing long-term strategic goals that support the organization’s mission and developing strategies that address key management challenges that threaten their ability to meet strategic goals. For strategic planning to

¹¹GAO, *Agencies’ Strategic Plans Under GPRA: Key Questions to Facilitate Congressional Review*, [GAO/GGD-10.1.16](#) (Washington, D.C.: May 1997).

be done well, organizations must involve their stakeholders; assess their internal and external environments; and align their activities, core processes, and resources to support mission-related outcomes. Leading practices also include developing results-oriented performance measures to gauge an agency's progress toward achieving its mission or strategic goals. When applying these measures, managers can collect and track performance information, which can then be used to guide decision making and improve results.

Gaps in Scientific Information and Risk Analysis Have Hampered FDA's Oversight of Food Labeling, Fresh Produce, and Dietary Supplements

Generally, FDA relies on available scientific research to inform regulatory decisions and considers the risk level of different food products when deciding where to focus resources. However, we found that FDA was hampered in its ability to carry out some food safety responsibilities—oversight of food labels, fresh produce, and dietary supplements—because it lacked certain scientific information. For food labels, we found that FDA's research on their accuracy, consumers' perceptions of them, and other labeling options was limited. For fresh produce, we found that gaps in scientific knowledge have limited FDA's efforts to integrate science and risk analysis into its oversight. Finally, for dietary supplements, we found that FDA lacked information to better identify safety concerns associated with dietary supplements.

FDA's Research Plans on Food Labeling Have Been Limited

Two-thirds of U.S. adults are overweight, and childhood obesity and diabetes are on the rise. In an effort to reverse these growing public health problems, the Department of Health and Human Services and the U.S. Department of Agriculture (USDA) issued dietary guidelines providing science-based dietary direction for consumers to limit their sugar, fat, and salt intake; eat more whole grains, fruits, and vegetables; and monitor portion size. Consumers who want to make healthy food choices look to food labels for information to help them eat better. Federal law prohibits food labeling that, among other things, is false or misleading or fails to list the amounts of certain nutrients.

The Nutrition Facts panel on a food product's label has important information for consumers about a product. This panel contains the serving size; the number of servings per container; the number of calories per serving; and the amount of certain nutrients, such as dietary fiber, vitamins, fat, and sodium. As we reported in September 2008, however, the nutrition information provided in the required Nutrition Facts panel may be inaccurate.¹² In addition, according to many stakeholders we interviewed—including key health, medical, and consumer organizations—consumers find the range of information on labels confusing and misleading. We identified three areas in which FDA's oversight contributes to inadequate labeling:

- *Accuracy of Nutrition Facts panel information.* FDA's research to determine the accuracy of nutrient information is limited and outdated and shows varying degrees of compliance. FDA has not conducted random sampling on

¹²GAO-08-597.

food labeling since 1996. While FDA found that most of the randomly selected products tested were within allowable ranges, compliance rates varied significantly for a few nutrients, such as vitamins A and C and iron. These variances are important because consuming too much or too little of certain vitamins and iron may impair health. FDA officials cited resource constraints and other priorities as reasons for not updating these studies and told us that FDA has no plans for future studies. In addition, from fiscal years 2000 through 2006, FDA conducted nonrandom sampling—collecting targeted samples to test for compliance with nutrition labeling regulations. FDA investigators often selected the nonrandom samples because of obvious labeling violations, such as a candy bar with a Nutrition Facts panel that did not identify any fat or sugar. About 21 percent and 28 percent, respectively, of the domestic and imported foods that were tested were in violation. One type of food with a high percentage of violations was infant formula. Of the 10 formula products sampled over the 7 years, 4 were in violation because they lacked the vitamins, minerals, or other nutrients required by law.

- *Misleading food labeling.* FDA does not have empirical research on consumer perceptions to support enforcement against misleading food labels. For example, stakeholders from health, medical, and consumer organizations reported that “whole grain” labels can be misleading because the product may contain little whole grain, “transfat free” products may still be high in saturated fat, and “natural” products may be highly processed. According to FDA officials, the agency generally does not enforce the prohibition against misleading food labeling because it lacks the resources to conduct the substantive, empirical research on consumer perceptions that it believes it would need to legally demonstrate that a label is misleading.
- *Options for a front-of-package nutrition labeling system.* As we reported, more collaborative research is needed to help FDA with its broad research agenda for evaluating options for a front-of-package nutrition labeling system. The National Academies’ Institute of Medicine, which is often called on to advise federal agencies on health issues, recommended that FDA and others increase research on the nutrition label and pointed out that manufacturers’ use of nutrition symbols underscores the need to improve strategies for using the food label as an educational tool. Our 2008 report noted that FDA’s broad research agenda on front-of-package symbol systems was ambitious and would likely require extensive resources over several years. FDA officials recently stated they will soon begin analyzing the data collected for its first studies. We recommended that FDA collaborate with other federal agencies and stakeholders to evaluate options for a simplified, empirically valid system that conveys overall nutritional quality and that mitigates labels that are misleading to consumers. FDA agreed with the need to evaluate the communication effects of nutrition symbols and presented a research agenda. In October 2009 the FDA Commissioner announced that the agency is drafting a proposed regulation to establish nutritional criteria that would have to be met by manufacturers’ front-of-package labels to ensure that consumers are not led to believe that foods are healthier than they are.

We recommended among other things that FDA (1) maintain data on labeling violations and the corrective actions taken in a searchable format; (2) analyze violation data in routine management reports; and (3) track regulatory meetings on labeling violations to assess whether they are an effective use of resources. Such data can help managers set priorities and allocate resources, such as for food safety research. FDA noted in its comments to this correspondence that it has implemented a process to issue, and post to its website, closeout letters when a firm has sufficiently addressed violations cited in a Warning Letter FDA had sent to the firm. While this appears to address part of our first recommendation, FDA did not indicate whether the closeout letters and other data on violations and corrective actions are in a searchable format. FDA commented that it has not taken actions to implement the other two recommendations.

Knowledge Gaps Make It Difficult for FDA to Integrate Science into a Risk-Based Approach to Oversee Fresh Produce

In recent years, there has been an increase in reported outbreaks of foodborne illness associated with both domestic and imported produce. In addition to harming human health, such outbreaks can undermine consumer confidence in the safety of the nation's food supply and have serious economic consequences. The importance of safe, fresh produce is growing because consumption has increased as both health experts and the U.S. government have encouraged Americans to eat fruits and vegetables as part of a healthy diet. As we reported in September 2008, FDA officials noted that gaps in science have impeded their ability to make some decisions on how to regulate fresh produce.¹³ For example, cattle are known carriers of *E. coli* O157:H7, but scientists do not fully know how *E. coli* is passed from animals to produce and thus cannot say how far cattle should be kept from a field of leafy greens. Furthermore, FDA lacked sufficient information to develop robust, science-based risk assessments that quantify the relative risks of consuming different types of produce. Lacking such information, FDA largely relied on qualitative information—such as the history of past outbreaks—to rank the risk levels of fresh produce.

We also found that FDA had taken limited steps to fill some of the science gaps. To fill some gaps, FDA conducts laboratory research on fresh produce commodities and their associated pathogens. For example, at the time of our review, FDA had a study underway to improve its understanding of how one type of *Salmonella* contaminated tomatoes. In response to recurring outbreaks of foodborne illness, FDA implemented ongoing multiyear initiatives to study farming practices and environmental conditions that could lead to the contamination of leafy greens and tomatoes. FDA also participates in four research centers in cooperation with academic institutions,¹⁴ but the Science Board noted that the overall output from these centers has been modest because of budget constraints. Finally, FDA directly funds projects carried out by other research institutions, but it had suspended this extramural research grant program in some recent years because it lacked resources.

¹³GAO-08-1047.

¹⁴Centers include the National Center for Food Safety and Technology at the Illinois Institute of Technology; the Joint Institute for Food Safety and Applied Nutrition at the University of Maryland; the National Center for Natural Products Research at the University of Mississippi; and the Western Center for Food Safety at the University of California, Davis, which was just established at the time of our review.

Because FDA's efforts address only some of its research needs, it relies heavily on the research of other federal agencies for scientific knowledge, such as USDA and the National Institutes of Health. However, it can be difficult to get other agencies to conduct research that meets FDA's needs, such as developing baseline data on contamination in lettuce in different regions and seasons. Such research would aid FDA's regulatory work but is extremely expensive to conduct. Therefore, gaps in science remain.

At the time of our review, FDA was (1) working with university researchers on a USDA-funded project that looked at options for reducing the risk of *E. coli* O157:H7 in leafy greens; (2) planning to strengthen its risk ranking of food commodities and pathogens, starting with fresh produce items; (3) planning to fund about \$1 million in extramural research on the safety of fresh produce; (4) developing a plan outlining priority research needs, including the safety of fresh produce; and (5) exploring ways to obtain voluntary access to proprietary data from producers for research purposes, such as fresh produce firms' testing records showing when they found *E. coli* O157:H7 or *Salmonella* in product samples. FDA noted in its comments to this correspondence that it has taken several steps to address science gaps in produce safety. These include forming a Produce Safety Staff within CFSAN and making progress in detecting or analyzing pathogens in produce, among other things.

To enhance FDA's oversight of the safety of fresh produce, we recommended that the agency develop a plan to identify research priorities and facilitate research related to fresh produce. FDA agreed with our recommendation and said that CFSAN and the agency were developing strategic plans for research, including fresh produce-related research. CFSAN's plan would identify regulatory research priorities that can be addressed through intramural and extramural research, as well as future research needs that cannot be addressed owing to resource limitations. FDA noted in its comments to this correspondence that it organizes and participates in meetings on fresh produce research. However, FDA provided no information specific to our recommendation whether they had developed a research plan. We also recommended that FDA identify approaches for obtaining testing and other information from industry members to inform its research agenda. FDA agreed with our recommendation, but it noted that the data and information from industry would further inform, rather than supplement, the agency's research agenda and would also be used in agency risk assessments associated with fresh produce. FDA officials told us that the agency is currently exploring the potential for FDA to access and use industry data and noted in its comments to this correspondence that it has worked with produce industry members to discuss wash water modeling data and is in contact with the Department of Defense to access the department's Procurement Produce Testing Data. Although, this appears to show progress in data sharing, it does not directly address our recommendation to identify broader approaches for attaining such information.

FDA Lacks Information to Identify Safety Concerns Associated with Dietary Supplements

According to a recent Centers for Disease Control and Prevention survey, more than half of all adults in the United States consume dietary supplements. From 1994 to 2008, the number of dietary supplements available to consumers increased from

about 4,000 to an industry estimate of 75,000. In addition, food products—such as fortified cereals and energy drinks—that contain added dietary ingredients are in the marketplace in unprecedented numbers, and consumers are expected to spend increasing amounts on these products over the next several years. However, unlike drugs, which require FDA’s premarket approval, dietary supplements are presumed safe under law unless FDA can establish significant or unreasonable risk. Once FDA has identified a safety concern, the agency’s ability to remove a product from the market is hindered by a lack of mandatory recall authority and the difficult process of demonstrating significant or unreasonable risk for specific ingredients.

In January 2009 we reported that FDA’s ability to identify safety concerns associated with dietary supplements is undermined by a lack of scientific information available for other regulated products, such as drugs.¹⁵ For example, it took FDA almost 10 years after issuing its first advisory about ephedra—a dietary supplement ingredient used to help in weight loss that had been implicated in thousands of adverse events and a number of deaths—to gather sufficient data to meet the statutory burden of proof for banning it from the market. Given the data limitations, the difficult process of establishing significant or unreasonable risk for dietary supplement ingredients with known safety concerns has raised doubts among some experts about FDA’s ability to adequately protect the public.

In the absence of scientific research, we recommended that FDA request authority to require dietary supplement companies to (1) identify themselves as a dietary supplement company as part of the existing registration requirements and update this information annually, (2) provide a list of their products and a copy of the labels and update this information annually, and (3) report all adverse events related to dietary supplements. In general, FDA agreed with our recommendations and commented that FDA’s ability to ensure the safety of dietary supplements could be improved if FDA had this type of information. As of April 10, 2010, FDA has not taken any action on this recommendation. However, FDA noted in its comments to this correspondence, that bills pending in Congress,¹⁶ if passed in their present form, would provide FDA with the authority to require dietary supplement companies to identify themselves as dietary supplement companies as part of the existing registration requirements. In addition, if passed in their present form, the bills would require dietary supplement companies to update information pertaining to their company annually.

FDA’s Risk-Based Approach to Better Target Imported Food Shows Promise, but Further Actions Are Needed

Owing in part to the volume of imported products it regulates (i.e., food, drugs, and medical devices), FDA physically examines only approximately 1 percent of imported food. However, FDA has spent about \$9 million and plans to spend an additional \$14 million developing PREDICT, its new computer screening tool, which uses criteria—such as a product’s violative history, country of origin, foreign facility inspections, or lack of a track record—to estimate the risk of imported food shipments and potentially improve the agency’s ability to target for inspection shipments of

¹⁵GAO-09-250.

¹⁶The Food Safety Enhancement Act (H.R. 2749) and the FDA Food Safety Modernization Act (S. 510).

imported products that are more likely to violate FDA's regulations.¹⁷ PREDICT generates a numerical risk score for all FDA-regulated products by analyzing importers' shipment information. According to FDA, after PREDICT estimates the risk that an imported food shipment poses, it either clears the shipment to proceed or alerts FDA officials that the shipment needs further review.

FDA's PREDICT 2007 pilot test suggested that PREDICT could enhance FDA's risk-based import screening efforts. According to FDA, PREDICT could potentially decrease the incidence of imported foodborne illnesses. However, although the PREDICT pilot produced positive results and demonstrated the tool's potential to improve import screening efforts, we recommended that the agency take further actions to help ensure that the tool is effective. In particular, we recommended that FDA develop a performance measurement plan to help ensure that PREDICT is effectively targeting high-risk imported food shipments for field and laboratory examinations. FDA agreed with our recommendation to develop a performance measurement plan and reported that a draft plan is currently in review to test the efficacy of PREDICT. Agency officials noted that they have to collect 6 to 9 months of data after deployment to conduct a proper review. The agency is currently deploying PREDICT on a district-by-district basis at all ports and for all FDA-regulated products. FDA noted in its comments to this correspondence that PREDICT is fully operational in the Los Angeles and New York districts, but due to technical problems FDA has not determined when the Seattle district will be deployed. In addition, FDA officials stated that a scheduled nationwide rollout this summer of PREDICT has been delayed primarily due to information technology infrastructure problems, such as server crashes and overloads, which are affecting FDA field data systems nationwide.

More broadly, we recently identified information technology management concerns that might hinder the rollout of FDA modernization projects such as PREDICT.¹⁸ Specifically, we reported that FDA does not have a final comprehensive strategic plan for information technology to coordinate and manage its numerous information technology initiatives and projects. FDA officials stated that the agency drafted a strategic plan, which includes PREDICT, for information management. Such a plan would provide a comprehensive picture of what the organization seeks to accomplish, identify the strategies it will use to achieve desired results, provide results-oriented goals and performance measures that permit it to determine whether it is succeeding, and describe interdependencies within and across projects so that these can be understood and managed.

Agency Comments

We provided FDA with a draft of this report for review and comment. FDA provided written comments which are presented in enclosure V. We incorporated updated information and technical comments as appropriate.

¹⁷GAO-09-873.

¹⁸GAO-09-523.

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 Commissioner of the Food and Drug Administration, and other interested parties. In addition, the report will be available at no charge on the GAO Web site at <http://www.gao.gov>.

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

Sincerely yours,

A handwritten signature in black ink that reads "Lisa Shames". The signature is written in a cursive style with a long horizontal stroke at the end.

Lisa Shames
Director, Natural Resources and Environment

Enclosures (6)

Enclosure I: Highlights from Food Safety: Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food (GAO-09-873)

September 2009



Highlights of GAO-09-873, a report to congressional committees

FOOD SAFETY

Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food

Why GAO Did This Study

Imported food makes up a substantial and growing portion of the U.S. food supply. To ensure imported food safety, federal agencies must focus their resources on high risk foods and coordinate efforts.

In this context, GAO was asked to (1) assess how Customs and Border Protection (CBP), the Food and Drug Administration (FDA), and the U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) are addressing challenges in overseeing the safety of imported food; (2) assess how FDA leverages resources by working with other entities, such as state and foreign governments; and (3) determine how FDA is using its Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting (PREDICT) system to oversee imported food safety. GAO analyzed CBP, FDA, and FSIS procedures, reports, and regulations and interviewed agency officials and key stakeholders.

What GAO Recommends

GAO recommends, among other things, that FDA seek authority from the Congress to assess civil penalties on firms and persons who violate FDA laws, and that the FDA Commissioner explore ways to improve the agency's ability to identify foreign firms with a unique identifier. CBP and FDA generally agreed with our recommendations. FSIS provided technical comments only.

View GAO-09-873 or key components. For more information, contact Lisa Shames at (202) 512-3841 or shamesl@gao.gov.

What GAO Found

CBP, FDA, and FSIS have taken steps to address challenges in ensuring the safety of the increasing volume of imported food. For example, CBP maintains the system that importers use to provide information to FDA on food shipments; FDA electronically reviews food imports and inspects some foreign food production facilities to prevent violative food from reaching U.S. shores; and FSIS employs an equivalency system that requires countries to demonstrate that their food safety systems provide the same level of protection as the U.S. system. However, gaps in enforcement and collaboration undermine these efforts. First, CBP's computer system does not currently notify FDA or FSIS when imported food shipments arrive at U.S. ports, although efforts are underway to provide this information to FDA for air and truck shipments. This lack of communication may potentially increase the risk that unsafe food could enter U.S. commerce without FDA review, particularly at truck ports. Second, FDA has limited authority to ensure importers' compliance with its regulations. Third, CBP and FDA do not identify importers with a unique number; as a result, FDA cannot always target food shipments originating from high risk importers. Finally, CBP faces challenges in managing in-bond shipments—those that move within the United States without formally entering U.S. commerce—and such shipments possibly could be diverted into commerce.

FDA generally collaborates with select states and foreign governments on imported food safety. FDA has entered into a contract, several cooperative agreements, and informal partnerships for imported food with certain states, and some state officials told GAO that they would like to collaborate further with FDA on food imports. However, citing legal restrictions, FDA does not fully share certain information, such as product distribution lists, with states during a recall. This impedes states' efforts to quickly remove contaminated products from grocery stores and warehouses. FSIS has begun to make available to the public a list of retail establishments that have likely received food products that are subject to a serious recall. FDA is also expanding efforts to coordinate with other countries. In particular, through its Beyond Our Borders initiative, FDA intends to station investigators and technical experts in China, Europe, and India, to provide technical assistance and gather information about food manufacturing practices to improve risk-based screening at U.S. ports.

According to FDA, PREDICT will analyze food shipments using criteria that include a product's inherent food safety risk and the importer's violative history, among other things, to estimate each shipment's risk. A 2007 pilot test of PREDICT indicated that the system improved FDA's ability to identify products it considers to be high risk while allowing a greater percentage of products it considers low risk to enter U.S. commerce without a manual review. However, FDA has not yet developed a plan to measure the system's performance, and GAO previously identified shortcomings in FDA's information technology modernization efforts. FDA plans to begin deploying PREDICT at all ports and for all FDA-regulated products in September 2009.

United States Government Accountability Office

Enclosure II: Highlights from Dietary Supplements: FDA Should Take Further Actions to Improve Oversight and Consumer Understanding (GAO-09-250)

January 2009



Highlights of GAO-09-250, a report to congressional requesters

DIETARY SUPPLEMENTS

FDA Should Take Further Actions to Improve Oversight and Consumer Understanding

Why GAO Did This Study

Dietary supplements and foods with added dietary ingredients, such as vitamins and herbs, constitute multibillion dollar industries. Past reports on the Food and Drug Administration's (FDA) regulation of these products raised concerns about product safety and the availability of reliable information. Since then, FDA published draft guidance on requirements for reporting adverse events—which are harmful effects or illnesses—and Current Good Manufacturing Practice regulations for dietary supplements. GAO was asked to examine FDA's (1) actions to respond to the new serious adverse event reporting requirements, (2) ability to identify and act on concerns about the safety of dietary supplements, (3) ability to identify and act on concerns about the safety of foods with added dietary ingredients, and (4) actions to ensure that consumers have useful information about the safety and efficacy of supplements.

What GAO Recommends

GAO recommends that the Secretary of Health and Human Services direct the Commissioner of the FDA to request additional authority to oversee dietary supplements, issue guidance on new dietary ingredients and to clarify the boundary between dietary supplements and foods with added dietary ingredients, and take steps to improve consumer understanding of dietary supplements. In commenting on this report, FDA generally agreed with GAO's recommendations.

To view the full product, including the scope and methodology, click on GAO-09-250. For more information, contact Lisa Shames at (202) 512-3841 or shamesl@gao.gov.

What GAO Found

FDA has made several changes in response to the new serious adverse event reporting requirements and has subsequently received an increased number of reports. For example, FDA has modified its data system, issued draft guidance, and conducted outreach to industry. Since mandatory reporting went into effect on December 22, 2007, FDA has seen a threefold increase in the number of all adverse event reports received by the agency compared with the previous year. For example, from January through October 2008, FDA received 948 adverse event reports—596 of which were mandatory reports submitted by industry—compared with 298 received over the same time period in 2007. Although FDA has received a greater number of reports since the requirements went into effect, underreporting remains a concern, and the agency has further actions planned to facilitate adverse event reporting.

FDA has taken some steps to identify and act upon safety concerns related to dietary supplements; however, several factors limit the agency's ability to detect concerns and remove products from the market. For example, FDA has limited information on the number and location of dietary supplement firms, the types of products currently available in the marketplace, and information about moderate and mild adverse events reported to industry. Additionally, FDA dedicates relatively few resources to oversight activities, such as providing guidance to industry regarding notification requirements for products containing new dietary ingredients. Also, once FDA has identified a safety concern, the agency's ability to remove a product from the market is hindered by a lack of mandatory recall authority and the difficult process of demonstrating significant or unreasonable risk for specific ingredients.

Although FDA has taken some actions when foods contain unsafe dietary ingredients, certain factors may allow potentially unsafe products to reach consumers. FDA may not know when a company has made an unsupported or incorrect determination about whether an added dietary ingredient in a product is generally recognized as safe until after the product becomes available to consumers because companies are not required to notify FDA of their self-determinations. In addition, the boundary between dietary supplements and conventional foods containing dietary ingredients is not always clear, and some food products could be marketed as dietary supplements to circumvent the safety standard required for food additives.

FDA has taken limited steps to educate consumers about dietary supplements, and studies and experts indicate that consumer understanding is lacking. While FDA has conducted some outreach, these initiatives have reached a relatively small proportion of dietary supplement consumers. Additionally, surveys and experts indicate that consumers are not well-informed about the safety and efficacy of dietary supplements and have difficulty interpreting labels on these products. Without a clear understanding of the safety, efficacy, and labeling of dietary supplements, consumers may be exposed to greater health risks associated with the uninformed use of these products.

United States Government Accountability Office

Enclosure III: Highlights from Food Safety: Improvements Needed in DFA Oversight of Fresh Produce (GAO-08-1047)

September 2008



Highlights of GAO-08-1047, a report to congressional requesters

FOOD SAFETY

Improvements Needed in FDA Oversight of Fresh Produce

Why GAO Did This Study

In recent years, both domestic and imported produce have been linked to reported outbreaks of foodborne illness. Contamination in produce is of particular concern because produce is often consumed raw. The Food and Drug Administration (FDA) has primary responsibility for ensuring the safety of both domestic and imported fresh produce. GAO was asked to examine (1) the resources FDA has spent on fresh produce safety and how it has allocated those resources, (2) the effectiveness of FDA's actions to oversee fresh produce safety, and (3) the extent to which FDA's planned actions to enhance fresh produce oversight address identified challenges. For this review, GAO analyzed FDA spending data and estimates and FDA activities data, reviewed FDA plans, and interviewed FDA officials and others.

What GAO Recommends

GAO recommends, among other things, that the Commissioner of FDA update its guidance on good agricultural practices and its regulations on current good manufacturing practice for food, and seek explicit authority from the Congress to adopt preventive controls for high-risk foods and authority for enhanced access to records.

FDA agreed with most of GAO's recommendations but believed that it had sought authority from the Congress. FDA should continue to take steps to obtain these authorities so that it can conduct its oversight responsibilities.

To view the full product, including the scope and methodology, click on GAO-08-1047. For more information, contact Lisa Shames at (202) 512-3841 or shamesl@gao.gov.

What GAO Found

While FDA has considered fresh produce safety a priority for many years, resource constraints and other work—including counterterrorism efforts and unplanned events such as foodborne illness outbreaks—have caused FDA to delay key produce safety activities. FDA has no formal program devoted exclusively to fresh produce and has not consistently and reliably tracked its fresh produce spending. Based on FDA estimates, FDA spent at least \$20 million and 130 staff years on fresh produce in fiscal year 2007—or about 3 percent of its food safety dollars and 4 percent of its food safety staff years. In addition, FDA had few staff dedicated solely to fresh produce safety. Moreover, FDA acknowledged that it has not yet been able to conduct certain fresh produce work crucial to understanding the incidence of contamination of produce by pathogens such as *E. coli* O157:H7 or *Salmonella*, because it has lacked the resources to either fund its extramural research grant program or perform some critical research internally. Finally, FDA delayed issuing final fresh-cut produce guidance at least 6 years because it had to shift staff to counterterrorism and outbreak investigation work.

FDA has provided limited oversight of domestic and imported fresh produce. For example, while FDA has issued guidance for industry on recommended practices for reducing the risk of contamination during the processing of fresh-cut produce, it has not issued regulations requiring firms to take action to prevent contamination, even though some industry groups would like it to do so. FDA's intervention efforts have also been limited. Specifically, domestic fresh produce firms were inspected infrequently. Furthermore, FDA examined less than 1 percent of the 7.6 million fresh produce lines imported from fiscal years 2002 through 2007. Finally, FDA has improved some elements of its emergency response by, for example, partnering with California on outbreak investigations. However, it faces challenges in tracing an outbreak involving fresh produce back to its source because produce is highly perishable and may no longer be available for testing. Also, when product is available, it may be unlabeled or mixed in packages containing products from multiple sources.

FDA has proposed changes through its *Food Protection Plan* that could significantly enhance its fresh produce oversight. However, the agency is still in the planning stages for several enhancements and has not provided specific information on strategies and resources, making it difficult to assess the likelihood of success. To help prevent contamination, FDA plans to update its existing guidance on good agricultural practices and regulations on current good manufacturing practice for food, and has identified a need for explicit authority to issue preventive safety regulations for high-risk foods and enhanced access to records. To enhance intervention efforts, FDA plans to use more rigorous risk-based criteria to target domestic firm inspections and is testing a new import screening software tool. To improve response efforts, FDA is examining best practices for tracing contaminated foods to their source.

United States Government Accountability Office

Enclosure IV: Highlights page from Food Labeling: FDA Needs to Better Leverage Resources, Improve Oversight, and Effectively Use Available Data to Help Consumers Select Healthy Foods (GAO-08-597)

September 2008



Highlights of GAO-08-597, a report to the Chair, Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, Committee on Appropriations, House of Representatives

Why GAO Did This Study

Two thirds of U.S. adults are overweight, and childhood obesity and diabetes are on the rise. To reverse these health problems, experts are urging Americans to eat healthier. Food labels contain information to help consumers who want to make healthy food choices. The Food and Drug Administration (FDA) oversees federal labeling rules for 80 percent of foods. GAO was asked to examine (1) FDA's efforts to ensure that domestic and imported foods comply with labeling rules, (2) the challenges FDA faces in these efforts, and (3) the views of key stakeholders on FDA actions needed to mitigate misleading labeling. GAO analyzed FDA data, reports, and requirements on food labeling oversight and compliance and interviewed agency and key stakeholder group officials.

What GAO Recommends

GAO is recommending actions for FDA to ensure that labeling office managers have the information they need to oversee compliance with labeling laws; ensure the public has timely access to information on labeling violations on FDA's public Web site; and better leverage resources to achieve its mission. In commenting on a draft of this report, FDA stated that the report raised important issues, and agreed, with qualifications, with some of GAO's recommendations, but did not comment on others.

To view the full product, including the scope and methodology, click on GAO-08-597. For more information, contact Lisa Shames at (202) 512-3841 or shamesl@gao.gov.

FOOD LABELING

FDA Needs to Better Leverage Resources, Improve Oversight, and Effectively Use Available Data to Help Consumers Select Healthy Foods

What GAO Found

FDA's oversight and enforcement efforts have not kept pace with the growing number of food firms. As a result, FDA has little assurance that companies comply with food labeling laws and regulations for, among other things, preventing false or misleading labeling. Specifically:

- FDA does not have reliable data on the number of labels reviewed; the number of inspections, which include label reviews, has declined. For example, of the tens of thousands of foreign food firms in over 150 countries, just 96 were inspected by FDA in 11 countries in fiscal year 2007—down from 211 inspections in 26 countries in 2001.
- FDA's testing for the accuracy of nutrition information on labels in 2000 through 2006 was limited. FDA could not provide data for 2007.
- Although the number of food firms in FDA's jurisdiction has increased, the number of warning letters FDA issued to firms that cited food labeling violations has held fairly steady.
- FDA does not track the complete and timely correction of labeling violations or analyze these and other labeling oversight data in routine reports to inform managers' decisions, or ensure the complete and timely posting of information on its Web site to inform the public.
- In addition to its official recalls database, FDA's Center for Food Safety and Applied Nutrition has continued to waste resources on a second recall database that FDA had agreed to eliminate in 2004, as GAO had recommended.

FDA has reported that limited resources and authorities challenge its efforts to carry out its food safety responsibilities—these challenges also impact efforts to oversee food labeling laws. FDA's *Food Protection Plan* cites the need for authority to, among other things, collect a reinspection user fee, accredit third-party inspectors, and require recalls when voluntary recalls are not effective.

Stakeholders from health, medical, and consumer groups identified actions they believe will mitigate misleading labeling and help consumers identify healthy food. Several stakeholders support a simplified, uniform front-of-package symbol system to convey nutritional quality to consumers. The United Kingdom, Sweden, and the Netherlands have developed voluntary nutrition symbols, while the European Commission has proposed requiring front-of-package labeling of key nutrients.

United States Government Accountability Office

Enclosure V: Comments from the Department of Health & Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

APR 9 2010

Lisa Shames, Director
Natural Resources and Environment
U.S. Government Accountability Office
441 G Street N.W.
Washington, DC 20548

Dear Ms. Shames:

Enclosed are comments on the U.S. Government Accountability Office's (GAO) report entitled: "Food Safety: FDA Has Begun to Take Action to Address Weaknesses in Food Safety Research, but Gaps Remain" (GAO-10-182R).

The Department appreciates the opportunity to review this report before its publication.

Sincerely,

A handwritten signature in black ink, appearing to read "Andrea Palm", written over a horizontal line.

Andrea Palm
Acting Assistant Secretary for Legislation

Enclosure

FDA's General Comments to GAO's Draft Report Entitled,
*Food Safety: FDA Has Begun to Take Action to Address Weaknesses in Food Safety Research,
but Gaps Remain- GAO 10-182R*

The Food and Drug Administration (FDA) appreciates the opportunity to review and comment on the Government Accountability Office's (GAO's) draft report.

Ensuring that foods are safe and secure is a vital part of the FDA mission, and FDA is committed to ensuring that the food supply in the United States continues to be among the safest in the world. To that end, the Commissioner of Food and Drugs, Margaret Hamburg, created the Office of Foods (OF) in August 2009, to lead a functionally unified FDA Foods Program and enhance the Agency's ability to meet today's great challenges and opportunities in food and feed safety, nutrition, and other critical areas. The FDA Foods Program, lead by the newly appointed Deputy Commissioner for Foods, includes three major operating units—the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine (CVM), and the foods-related activities of the Office of Regulatory Affairs (ORA). It also draws on the resources and expertise of FDA's National Center for Toxicological Research (NCTR) and key Office of the Commissioner staff offices. The new Office of Foods is responsible, on behalf of the Commissioner, for providing all elements of FDA's Foods Program leadership, guidance, and support to achieve the Agency's public health goals. The Office of Foods also is the focal point for planning and implementing the recommendations of the President's Food Safety Working Group and the new food safety authorities being considered by Congress.

The FDA Foods Program protects and promotes the health of humans and animals by

- ensuring the safety of foods for humans, including dietary supplements;
- ensuring the safety of animal feed and the safety and effectiveness of animal drugs;
- setting science-based standards for preventing foodborne illness and ensuring compliance with these standards;
- protecting the food and feed supply from intentional contamination; and
- ensuring that food labels contain reliable information that consumers can use to choose healthy diets.

A strong science-based foundation is vital to all of these areas and FDA recognizes that several of these areas – food labeling, fresh produce safety, dietary supplements, import safety, and information technology—are highlighted in this GAO report. FDA is taking steps to address public health concerns related to all of the areas identified in this report, as well as many others. In December 2009, the Commissioner of Food and Drugs and the Deputy Commissioner for Foods launched the “One Mission, One Program” Initiative, and charged FDA leadership with designing the future, unified Foods Program at FDA. Organized into ten core groups, they are addressing cross-cutting areas that affect more than one organizational element of the Foods Program. The groups are as follows:

- Preventive controls
- Risk-informed decision-making
- Inspection and compliance strategy
- Import safety
- Federal/state integration
- Incident preparedness and response
- Science, technology, and research integration

FDA's General Comments to GAO's Draft Report Entitled,
*Food Safety: FDA Has Begun to Take Action to Address Weaknesses in Food Safety Research,
but Gaps Remain- GAO 10-182R*

- Information systems
- Strategic communications
- Resource planning

FDA leadership is fully committed to transforming food safety to reflect President Obama's vision of a new food safety system – based on the core principles of the President's Food Safety Working Group: prioritizing prevention, strengthening surveillance and enforcement, and improving response and recovery – to protect the American public. Pending legislation, if enacted, would strengthen FDA's efforts in this regard. The legislation would also enable FDA to implement further preventative measures, such as by issuing new food safety regulations, and would provide mechanisms to help ensure such measures are appropriately implemented. The Food Safety Enhancement Act (H.R. 2749) as passed by the House and the pending food safety bill (S. 510) under consideration in the Senate illustrate the broad agreement on the general direction of the food safety reform toward an improvement of risk-based preventive controls to reduce foodborne illness as a major public health goal.

Consumer groups are fighting for improvements in the food safety system along with major sectors in the food industry; however, the efforts of the federal agencies and our state, local, tribal and territorial food safety partners will fall short unless Congress modernizes food safety laws to deal with the challenges of the 21st century and provides the necessary resources to sustain a modern integrated food safety system.

Food Labeling

GAO states that FDA has not taken any actions on GAO's recommendations that FDA (1) maintain data on labeling violations and the corrective actions taken in a searchable format; (2) analyze violation data in routine management reports; and (3) track regulatory meetings on labeling violations to assess whether they are an effective use of resources.

As resources permit, FDA will consider implementing a routine review of violation data to inform its compliance activities in the labeling area. FDA uses the Mission Accomplishments and Regulatory Compliance Services-Compliance Management System (MARCS-CMS) to track all enforcement work, including those that involve labeling. For the past two years, the system has included data on the specific charge used in an action. In addition to the information related to the actions, the system has an area to include the firm's responses. In October 2008, the system was expanded to include import actions.

To further provide transparency in FDA's enforcement actions, FDA implemented a process whereby it issues and posts a Warning Letter close out letter when a firm has sufficiently addressed deviations cited in a Warning Letter. This process began with Warning Letters issued on or after September 1, 2009. The close out letter to the firm is posted on FDA's website directly linked to the Warning Letter, including those issued for labeling violations. Although the Agency does not track regulatory meetings on labeling, it has been working diligently to mine its field data to best prioritize inspection and sampling work planning with respect to domestic and foreign firms and products. That process is continually being informed and refined. Complementing that effort with analyses of labeling and other data will further enhance efficiencies in our monitoring and surveillance program.

2

FDA's General Comments to GAO's Draft Report Entitled,
*Food Safety: FDA Has Begun to Take Action to Address Weaknesses in Food Safety Research,
but Gaps Remain- GAO 10-182R*

Fresh Produce

GAO states that it previously recommended that FDA develop a plan for identifying research priorities and facilitating research related to fresh produce. GAO also recommended that FDA identify approaches for obtaining testing and other information from industry members to inform its research agenda. GAO found that FDA has taken limited steps to fill some of the science gaps.

FDA believes that it has taken significant steps to address science gaps in produce safety. FDA offers the following list of activities in addition to the examples cited in the GAO draft report.

FDA formed the Produce Safety Staff (PSS) within CFSAN's Office of Food Safety in 2008. In 2008 and 2009 CFSAN recruited highly sought-after experts with extensive technical experience in produce safety from academia and industry to staff the PSS. The PSS is now comprised of seven permanent, and ten total staff members with science and regulatory expertise. FDA also hired a Senior Advisor on Produce Safety to advise the Agency on policies and programs affecting the safety of fresh produce. The role of the PSS is to assess produce safety hazards from farm to table, identify and address science gaps, and develop appropriate regulatory instruments to eliminate or mitigate hazards associated with fresh produce. PSS leadership had a significant role in the development of the CFSAN research strategic plan, which identifies and prioritizes produce safety knowledge gaps using the Carver+shock model, and links these needs with intramural and extramural research programs.

CFSAN has also devoted scientific resources and made progress in methods for pathogen recovery from produce, a significant obstacle to effective surveillance programs. Other examples of progress in addressing science gaps in produce safety include the following:

- Recent scientific accomplishments include the development and validation of a rapid molecular screening method for the detection of viable *Salmonella* directly from several high-risk produce commodities including tomatoes, spinach, and peppers (Jalapeno and Serrano). This accomplishment is significant because the new method detects only living *Salmonella*, by targeting short-lived RNA within *Salmonella* cells, avoiding potential false-positive results inherent to previous molecular methods. FDA scientists continue to develop, assess, and explore technologies for the detection of pathogens in produce both in the field and in the laboratory.
- FDA scientists, in collaboration with bioscience industry partners, developed and implemented a Pathogen Annotated Tracking Resource Network (PATRN) System to aid analysis of foodborne pathogens. PATRN is a transparent, web-based database system which captures both the global expertise and surveillance data on foodborne pathogens. This system is an important improvement in FDA intervention and response capabilities.
- FDA scientists developed and released for public health application a custom Affymetrix DNA microarray design (*E. coli-Shigella* GeneChip - ECSG) for identifying and discriminating strains of *Escherichia coli* and *Shigella* spp. This

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advanced methodology will significantly improve sample through-put and accuracy in the detection of contaminated food products.

- In collaboration with bioscience industry partners, FDA scientists developed a series of diagnostic detection assays in a self-contained biosensor system. The system allows for the specific targeting of *Salmonella* strains, and rapid (less than two hour) screening for key foodborne pathogens including *Salmonella*, *E. coli* O157:H7, *Listeria monocytogenes*, and all four groups of *Shigella*. The advantages of this system include its ability to detect multiple and minute amounts of pathogens directly from suspect foods, a significant improvement over conventional methods.
- FDA scientists determined the inactivation rate of hepatitis A virus in fresh produce. This knowledge is an important factor for risk assessments, and for improvement of detection methods for efficient source attribution.

FDA also organizes and participates in meetings to encourage and facilitate the sharing of research ideas and techniques and to minimize duplication of efforts. A summary of recent and future meetings are provided below:

- Leafy Greens Industry: Microbial Data Trends and Practices Symposium: FDA participated in a September 16, 2009 meeting sponsored by the University of California Davis Center for Produce Safety, Salinas, CA. This meeting brought together produce industry scientists and academic researchers to discuss on-going produce industry data gathering efforts and to explore means of data mining current industry data sets.
- Data Mining to Populate Produce Risk Assessment Models: A March 15, 2010, meeting was conducted with a national produce trade association to consider FDA access to industry microbiological testing data. Access to industry data would inform the CFSAN research agenda, augment CFSAN risk assessment modeling, and fill data gaps, such as:
 - i) Leafy greens / *E. coli* Predictive Risk Assessment (Research Triangle Institute contract)
 - ii) Produce Risk Ranking Tool
 - iii) Pilot of decision analysis tool to identify research needs for Leafy greens / *E. coli* (interagency risk consortium workshop)
 - iv) iRISK (online comparative risk assessment tool) pilot of 50 commodities/20 hazards under development and includes produce examples.
- Produce Microbial Testing: A March 16, 2010 meeting between a national produce trade association, a leading produce company, and FDA was held to discuss the utility and limitations of microbial testing in the fresh produce industry. Also discussed was the ability to access industry data sets.
- FDA CFSAN/United States Department of Agriculture Beltsville Agriculture Research Center (BARC) Science Day: A half-day meeting was conducted March 18, 2010, to assemble leading produce researchers from CFSAN and BARC to discuss on-going and future produce safety research.
- Produce Safety Research Summit: The FDA Western Center for Food Safety in collaboration with the University of California – Davis, Center for Produce Safety is

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planning a produce research summit for June 24, 2010. Industry, government and academic research leaders will identify and rank produce food safety priority research needs.

Furthermore, FDA continues to work with industry partners to share data:

- Wash Water Modeling: FDA has met on numerous occasions with a leading fresh-cut produce processor to discuss the company's wash water microbial risk model and the associated industry data set.
- Accessing U.S. Department of Defense (DOD) Procurement Produce Testing Data: DOD Logistics is a significant purchaser of fresh produce and routinely performs microbial testing of fresh produce for the presence of human pathogens. FDA is in contact with DOD to develop a data sharing agreement to allow FDA access to this database.

CFSAN's science program includes formal and informal relationships with academic institutions, other scientific organizations and research agencies. These interactions assist CFSAN and FDA in fulfilling its public health mission and expand the science-base upon which future regulatory programs are developed. The attached CY 2008 Annual CFSAN Leveraging Report reflects the contributions made by the consortia and leveraging partners during 2008 to FDA's mission.

Dietary Supplements

GAO reports that FDA has not taken any action on its recommendation that FDA request authority to require dietary supplement companies to identify themselves as a dietary supplement company as part of the existing registration requirements and update this information annually, provide a list of their products and a copy of the labels and update this information annually, and report all adverse events related to dietary supplements.

As noted in FDA's response to the 2009 GAO report on Dietary Supplements, FDA stated that although receiving all adverse events on dietary supplements could theoretically enhance our ability to detect signals of potential toxicity over time, we are uncertain whether, in practice, such information would advance the Agency's ability to identify unsafe dietary supplements or to do so quickly. FDA would develop an approach to reviewing all adverse events reports if Congress were to require such reporting.

The Food Safety Enhancement Act (H.R. 2749) as passed by the House and the pending food safety bill (S. 510) under consideration in the Senate would require food companies (including dietary supplement manufacturers) to renew their registrations annually and allow FDA to create new food registration categories, which could include one or more categories specific to dietary supplements. This legislation, if passed, would address GAO's recommendations that FDA require dietary supplement companies to identify themselves as dietary supplement companies and update registration information annually.

Enclosure VI: GAO Contact and Staff Acknowledgments

GAO Contact

Lisa Shames, (202) 512-3841 or shamesl@gao.gov

Staff Acknowledgments

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