



GAO

Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

February 16, 2010

Congressional Committees

Subject: *Food Irradiation: FDA Could Improve Its Documentation and Communication of Key Decisions on Food Irradiation Petitions*

According to the Centers for Disease Control and Prevention (CDC), pathogens such as *Salmonella*, *E. coli*, and *Listeria* cause an estimated 14 million cases of foodborne illnesses each year, resulting in about 60,000 hospitalizations and 1,800 deaths. Foodborne illness symptoms can range from mild gastroenteritis to life-threatening renal syndromes. The populations most susceptible to the more serious symptoms include very young children, individuals 60 years and older, pregnant women, and people who have a weakened immune system. In 2007, about 20 to 25 percent of the U.S. population was in this high-risk category. Moreover, consumers' vulnerability to foodborne illness is increasing as a result of changes in demographics, among other things. For example, older Americans will make up an estimated 20 percent of the U.S. population by 2015.

The pathogens that account for much of the most severe foodborne illness can be greatly reduced by subjecting food to ionizing radiation, also known as food irradiation. For example, irradiation can eliminate as much as 99.999 percent of *E. coli* 0157, *Listeria*, and *Campylobacter*. On the basis of extensive scientific studies and the opinions of experts, we reported in 2000 that the benefits of food irradiation outweigh the risks.¹ Moreover, many experts believe that irradiation can be effectively incorporated into an establishment's food safety program to further ensure the safety of the food against pathogens. Irradiation can also be used as a phytosanitary treatment where it is applied at low doses to safeguard natural resources by replacing fumigation or other chemical treatments to eliminate particular plant pests from fruits and vegetables imported into the United States.

Three federal agencies have primary responsibility for the oversight of food irradiation.² The Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS), which is responsible for ensuring that U.S. meat, poultry, and

¹GAO, *Food Irradiation: Available Research Indicates That Benefits Outweigh Risks*, [GAO/RCED-00-217](#) (Washington, D.C.: Aug. 24, 2000).

²Food irradiation facilities that use nuclear materials, such as cobalt-60, must meet the Nuclear Regulatory Commission's design, operating, management, training, and other requirements and are inspected yearly for compliance.

processed egg products are safe, wholesome, and properly labeled,³ reviews petitions to use irradiation on meat and poultry, as well as labels for use on irradiated products. USDA's Animal and Plant Health Inspection Service (APHIS), which is responsible for protecting the health and value of American agriculture and natural resources, ensures that products are properly irradiated to neutralize plant pests (render insects incapable of maturation or reproduction) and are appropriately labeled for entry and distribution in the United States.⁴ Finally, the Department of Health and Human Services' Food and Drug Administration (FDA) is responsible for ensuring that the nation's food supply—excluding meat, poultry, and processed egg products—is safe, wholesome, and properly labeled. FDA is authorized to review and approve petitions submitted by anyone for irradiation of a food product.⁵ The burden is generally on the individual or group that submits the petition to demonstrate that radiation can be used safely on the food product named in the petition under the proposed conditions of use. Since October 2000, FDA has approved two petitions and issued a partial response to a third that permits the use of irradiation on two food items; six petitions are still pending and under review.⁶ FDA is also responsible for administering federal food labeling requirements that prohibit labels that, among other things, are false or misleading.

Irradiation has been approved for several food products—for example, it was approved for meat and poultry more than 10 years ago. However, according to several industry estimates, the amount of food irradiated has been relatively steady or slowly increasing since 2000. Some industry officials believe that the labeling requirements for irradiated food products suggest to consumers that these foods are less than safe and thus deter the purchase of such products. In addition, Congress, in the 2002 Farm Bill, directed the Secretary of Health and Human Services, delegated to FDA, to reconsider its labeling requirements for irradiated foods. In April 2007 FDA proposed revising its labeling requirements for irradiated foods.

In this context, this report responds to your request for information on food irradiation. Our objectives were to determine (1) how FDA's current labeling requirements for irradiated food products compare with USDA's labeling requirements and how FDA's proposed changes to its requirements might impact the amount of food that is irradiated and (2) the extent to which FDA has effectively managed the petition review process for irradiated food. To determine how FDA's current labeling requirements for irradiated food products compare with USDA's

³In addition, the 2008 Farm Bill made catfish subject to mandatory inspection by USDA.

⁴APHIS also regulates phytosanitary irradiation of approved articles (e.g., fruits, vegetables, cut flowers, and foliage) either prior to or upon arrival into the United States. The articles may originate from foreign countries, Hawaii, Puerto Rico, or the U.S. Virgin Islands.

⁵Congress defined a food additive to include sources of radiation. Thus, irradiation is considered an adulterant unless carried out in the manner FDA has approved as safe. As such, petitions seeking new uses of irradiation are reviewed through FDA's food additive petition process.

⁶FDA approved a petition to irradiate seeds for sprouting on October 30, 2000, and molluscan shellfish on August 16, 2005. FDA also provided approval to irradiate fresh iceberg lettuce and fresh spinach on August 22, 2008, which was a partial response to a petition that covered a much larger scope.

labeling requirements and how FDA's proposed changes to its requirements might impact the amount of food that is irradiated, we reviewed FDA's and USDA's current labeling requirements and FDA's proposed revisions to its requirements. We also interviewed knowledgeable officials from FDA and USDA as well as representatives from the major industry and consumer advocacy groups. To determine the extent to which FDA has effectively managed the petition review process for irradiated food, we reviewed statutory and regulatory requirements for the petition review process, analyzed information on the six pending petitions, and interviewed officials from FDA and representatives from all of the organizations that filed the pending petitions. Enclosure I provides additional information on our scope and methodology.

We conducted this performance audit from April 2009 to February 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 provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Food irradiation is the process of exposing food products to ionizing radiation in order to, among other things, control foodborne pathogens. According to the International Atomic Energy Agency, 56 countries currently allow the irradiation of food products. The safety of irradiated foods has been extensively studied and has been endorsed by the World Health Organization, CDC, USDA, and FDA. Food is irradiated in facilities using gamma rays, X-rays, or electron beams as their source of ionizing radiation. Although the three work differently, the three types of ionizing radiation have the same effects on food. A more detailed explanation of the three types of irradiators is included in enclosure II.

Although no comprehensive information exists on the amount of food that is currently irradiated in the United States, several industry experts estimate that the amount of food irradiated has been relatively steady or slowly increasing since 2000. Since our 2000 report, use of irradiation has expanded to include ground beef and imported fruits.⁷ However, since 2000, poultry is no longer being irradiated and the amount of irradiated ground beef has likely declined, according to industry experts. The 2002 Farm Bill prohibited the Secretary of Agriculture from barring the use of safety technologies, which would include irradiation, in the National School Lunch Program.⁸ However, according to USDA officials, generally because of cost factors, no schools ever received any irradiated beef. Currently about 15 to 18 million pounds of ground beef are irradiated annually, most of which is sold through mail-order services, according to beef industry representatives. Experts believe that the lack of an increase in irradiated ground beef can be attributed to the low acceptance by the

⁷[GAO/RCED-00-217](#).

⁸The National School Lunch Program, administered by USDA's Food and Nutrition Service, is a federally assisted meal program operating in public and nonprofit private schools and residential care institutions throughout the United States. Schools that choose to take part in the lunch program get cash subsidies and donated commodities from USDA for each meal they serve.

general public and the high cost associated with irradiation. In contrast, use of irradiation for fruits and spices has increased. According to an industry source, the quantity of irradiated spices has increased recently because many spice processors have transitioned from ethylene oxide—a gas identified by the Environmental Protection Agency as a probable human carcinogen—to irradiation as an alternative treatment. However, according to a spice industry representative, the spice industry does not track information on the exact quantity of spices being irradiated. According to two companies that irradiate spices, however, they irradiated almost 88 million pounds of spices in 2008. According to APHIS officials, from 2007 through April 2009, about 9.5 million pounds of imported fruit—including guavas from Mexico, mangosteens from Thailand, and mangoes from India—were irradiated for phytosanitary purposes. In addition, according to an industry source, about 7 to 8 million pounds of purple sweet potatoes and other fruits grown in Hawaii are also irradiated annually to eliminate pests. A list of the food products that FDA has approved for irradiation is included in enclosure III.

FDA’s and USDA’s Current Labeling Requirements for Irradiated Foods Differ in Two Important Ways, and FDA’s Proposed Changes Could Potentially Increase the Amount of Food Irradiated

Although FDA’s and USDA’s labeling requirements for irradiated foods have some commonalities, they differ in important ways. The requirements are similar in that both agencies generally require that labels on irradiated foods packaged for retail sale include the international food irradiation symbol—the radura (see fig. 1)—and a statement disclosing that the food has been exposed to ionizing radiation.⁹ FDA and USDA also allow processors to add additional language to the labels to identify the source of the radiation and purpose of the treatment. However, FDA’s and USDA’s labeling requirements for irradiated foods differ in two important ways. First, labels on food products subject to FDA jurisdiction do not have to be reviewed and preapproved by FDA before marketing.¹⁰ Rather, the processor is responsible for properly labeling its products. In fact, FDA officials told us that they do not collect information on how irradiated foods are labeled and marketed. In contrast, USDA reviews and preapproves all labels before use on meat and poultry products and has denied label submissions that do not meet its requirements.¹¹ Second, FDA and USDA have different requirements when an irradiated ingredient is used in a multi-ingredient product. Specifically, FDA does not require the product’s ingredient list to disclose that a particular ingredient has been irradiated, while USDA generally does.

⁹Similar to the United States, select countries (such as Australia and member states of the European Union) also require a statement to disclose that the food product has been exposed to radiation on packages of irradiated foods sold at retail, but generally do not require the use of the radura symbol.

¹⁰However, FDA inspectors review labels on at least three products during each food safety inspection. For more information on FDA’s oversight of food labels, see GAO, *Food Labeling: FDA Needs to Better Leverage Resources, Improve Oversight, and Effectively Use Available Data to Help Consumers Select Healthy Foods*, [GAO-08-597](#) (Washington, D.C.: Sept. 9, 2008).

¹¹USDA has denied several label submissions that sought to state that electricity (instead of an electron beam) was used to irradiate the food. USDA also denied submissions that used the term “pasteurized.”

Figure 1: The International Food Irradiation Symbol—the Radura



Source: USDA.

Regarding FDA’s proposed changes to its labeling requirements, FDA, industry, and USDA officials we spoke with generally agree that changes to FDA’s current labeling requirements could increase the amount of food that is irradiated. As of December 2009, FDA officials stated they had completed a summary of the more than 32,000 public comments on its proposed changes. Furthermore, FDA officials said FDA is actively working to develop a final rule, but given FDA’s competing priorities and limited resources, officials do not know when it will be completed.

Specifically, FDA is proposing to eliminate the labeling requirements for irradiated foods in cases when the irradiation does not cause a material change in the food—that is, when irradiation does not alter the characteristics, such as nutritional property, ordinarily found in the food—or a material change in the consequences that may result from use of the food. FDA officials stated that manufacturers will be responsible for determining if a material change has occurred and whether the labeling is required. Ultimately, according to FDA officials, FDA may have to decide whether manufacturers have identified relevant material changes and appropriately applied the labeling requirements. However, FDA cannot provide a blanket statement on when to require labeling for irradiation or establish a set of criteria for defining a material change because these changes can vary depending on the type of food and the irradiation process. According to FDA’s proposal, several benefits could come out of the proposed rule. First, if consumers look more favorably on irradiated foods as a result of the proposed rule, the supply of such food may increase. Second, if retailers become more willing to carry relabeled irradiated products, consumers benefit from the added opportunity to buy these products. Third, if manufacturers believe that choosing the no-label option will lead to increased profits they may start using irradiation to enhance the safety of their products. Finally, the price of irradiated food could decline if more people buy the unlabeled products.

Industry representatives we spoke with agree that the quantity of irradiated foods could increase if the labeling requirements are eliminated. They noted that although irradiation is a potential preventive solution to food safety problems, no one will invest in the use of the technology if there is no demand for the products. They further said that a significant deterrent to the use of irradiation would cease to exist if

the labeling requirement is eliminated, which could result in the irradiation of more foods and enhanced food safety. Industry representatives also told us that, currently, industry will avoid using irradiation if another option is available to achieve similar results. For example, a spice industry representative stated that even though irradiation is the most effective technology to eliminate bacterial contamination in spices, a company will choose an alternative technology, such as steam sterilization, to treat spices packaged for retail sale in order to avoid the labeling requirements required for irradiated foods. According to an industry representative, if the labeling requirement for certain irradiated foods is eliminated, then spices sold at the retail level will likely experience the biggest immediate change because spice producers have indicated that they would like to move away from the use of gas technologies. For example, ethylene oxide is routinely used to sterilize spices. In addition, according to industry representatives, the change could reduce the logistical complexity for retailers that sell both irradiated and nonirradiated foods because separate product numbers and labels would no longer be required.

USDA officials also concurred that the proposal could change the amount of food irradiated and noted that the current labeling requirements are a deterrent to increasing the marketability and sale of these products. USDA officials told us that USDA follows FDA's lead with issues concerning the safety of irradiated foods. They also said any change in FDA's labeling requirements would impact USDA because there is a goal for federal agencies to have consistent regulations. Consequently, USDA would consider modifying its own labeling requirements for irradiated foods after FDA finalizes its proposed rule. However, USDA would have to go through its own rulemaking process before making any changes.

Consumer groups we spoke with are not embracing FDA's proposed rule and continue to support labeling requirements for irradiated foods. Since 1986, public comments have consistently supported labeling as a means to prevent consumer deception by informing consumers that the food has been exposed to radiation. In addition, consumer groups continue to believe consumers have a right to know if their food has been exposed to radiation so they can decide whether or not to purchase the food.

FDA Has Not Effectively Managed Its Review of Six Pending Petitions to Use Irradiation on Food

For the six currently pending food irradiation petitions, FDA has not met key statutory and regulatory time frames for the review of food additive petitions—which include petitions for new uses of irradiation on food—and has failed to consistently document its decisions about these petitions. Moreover, FDA has not communicated key information to the affected petitioners. As a result, FDA's petition review process lacks transparency and leads to misunderstandings and confusion among petitioners.

FDA is required to notify petitioners, within specified time frames, about certain decisions it has made regarding the petitions. For example, FDA regulations require that within 15 days of receiving a petition submission, FDA must notify the petitioner as to whether FDA will accept the petition and file it in the federal docket. However,

FDA did not do so for five of the six pending petitions.¹² In one instance, FDA notified a petitioner almost 3 months after receiving a petition submission that it could not be filed until the petitioner made certain changes. A requirement in statute provides that within 90 days of filing the petition, FDA is to notify petitioners if the study and investigation of the petition will take longer than 90 days.¹³ For five of the six petitions, FDA did not notify the petitioners. In fact, FDA notified only one petitioner that it needed an additional 90 days to complete the scientific review. Finally, FDA is required by statute to complete its petition review and issue an order within 180 days after filing the petition. Furthermore, FDA regulations require that FDA notify petitioners whether their petition has been approved or denied. We found that FDA did not complete its review within this time frame, or notify petitioners, in any of the six cases. In fact, the six petitions have been active and pending, on average, about 8.5 years—and some of them for about 10 years. FDA officials told us they believe the 180 day requirement is unrealistic for resolving petitions for the new uses of ionizing radiation on food, although FDA has never sought a change in the law. There are no reporting requirements once FDA surpasses the 180 day requirement for resolving such petitions. Enclosure IV provides additional information on the six pending petitions.

Although FDA regulations require, among other things, that recommendations and decisions of FDA officials be documented and that those recommendations and decisions reveal any significant controversies or differences of opinion and reveal their resolution, FDA's petition files contain little or no documentation of its decision-making on the six pending petitions, and in some cases fail to reveal the process FDA used to make decisions. As a result, FDA's reasons for some of its decisions are unclear, and the process it used to arrive at these decisions is not transparent. For example, FDA did not document a decision that negatively affected the timely review of two pending petitions to irradiate meat and poultry products. FDA officials told us that FDA made an administrative decision to review these two petitions at the same time that it reviewed a third petition for multi-ingredient food products to minimize the costs and time associated with rulemaking. However, FDA officials did not document the decision or the reason in the three petition files—all of which have now been pending for about 10 years. In 2001 FDA identified that furan—a colorless and volatile liquid—can form during the irradiation process.¹⁴ This discovery impacted FDA's food irradiation petition reviews because furan is considered possibly carcinogenic to humans through long-term exposure. However, FDA officials told us that they determined in 2003 that furan formation was not a safety concern with irradiated meat and poultry products. Nevertheless, FDA has not moved forward in reviewing the two petitions for meat and poultry products because they continue to be “linked” to the multi-ingredient petition, upon which FDA continues to have concerns regarding furan formation because different levels of furan are formed in different types of foods. FDA officials acknowledged that FDA's failure to revisit this administrative decision represented an oversight by FDA. They further noted that it is possible for FDA to move forward with its review of the petitions on the meat and

¹²For two petitions, FDA did not notify the petitioners that their petitions were filed. For the remaining three petitions, FDA notified the petitioners 20 to 37 days after receiving the petitions.

¹³21 U.S.C. § 348.

¹⁴Furan is also formed during traditional heat processing techniques, such as canning and cooking.

poultry products, but that FDA has not established a time frame to revisit its administrative decision and proceed with its review of these two petitions.

Finally, although FDA has acknowledged the need to provide clear, adequate, and timely information on its review process, FDA has not effectively communicated pertinent information to the six petitioners. As a result, FDA's petition review process is not transparent and creates confusion and misunderstandings. In addition, petitioners are not provided valuable information to help them better understand the status of their petition reviews and better respond to FDA changes in its review process. According to the six petitioners we spoke with, all believe they have fulfilled the technical requirements for a successful petition and that FDA does not have any outstanding data requirements. However, this is inconsistent with what FDA told us, which was that the identification of furan in 2001 completely changed the course of the irradiation petition review process. According to FDA, its research on furan is ongoing and likely will not conclude until sometime after 2013.¹⁵ This research includes FDA's overall Furan Action Plan as well as studies on total dietary intake of foods with potential for furan exposure.¹⁶ Consequently, FDA has halted approving food irradiation petitions where furan has been identified as a result of the irradiation process until the research on furan is complete. In addition, FDA has not systematically informed petitioners about key information, and officials are unable to provide a reason for this omission.

- When a petitioner requested an update on a petition that it had submitted in 2000, FDA officials orally advised the petitioner to modify the scope of the petition to irradiate crustaceans to exclude breaded and battered products because furan formation has been documented when these types of products are irradiated. Having complied by sending a letter to FDA requesting a scope change, the petitioner told us it believes FDA is proceeding with its review of the petition. However, officials at FDA told us FDA will not make a final decision until they have responded to relevant objections received in response to the final rule for irradiation of molluscan shellfish. FDA officials could not provide a time frame as to when it would be able to move forward with the crustacean petition and FDA has not communicated these issues to the petitioner.
- A second petitioner believes that a petition it submitted in 2002 to irradiate dietary supplements is actively under review because it has met FDA's requirements for providing all of the pertinent information and FDA has never requested any additional data. According to FDA officials, FDA is moving slower with the review of this petition, in part due to concerns about the broad scope of the petition and a lack of clarity regarding what specific dietary supplements could be included in this category. FDA said that they do not have data regarding how dietary supplements are used, and therefore cannot

¹⁵FDA told us it made a decision to move forward with its own research into furan because of the importance of the research to the public health and did not choose to place the responsibility on the petitioners to demonstrate the safety of furan.

¹⁶Canada and the European Union are also conducting research on the occurrence and formation of furan in foods and have not made any conclusions with respect to the human health risks related to consuming foods that contain furan.

begin to evaluate the possibilities with respect to the generation of furan in dietary supplement ingredients, or the possibilities for dietary exposure of different dietary supplements. However, FDA officials communicated none of these issues to the petitioner.

Most of the six petitioners have expressed concern or frustration with the length of time their petitions have been under review with little or no feedback from FDA. Petitioners also noted that FDA officials would not provide specific details when asked about the status of a petition. One petitioner said that FDA did not provide sufficient guidance on what it required to approve or deny a petition and that it seemed to use a “we’ll know it when we see it” approach. FDA officials acknowledged FDA has a responsibility to proactively communicate with the petitioners about the status of their petition, problems, and the need for additional data. However, the officials also noted that FDA staff are “not consultants” and that the petitioners, not FDA, are primarily responsible for making contact. FDA’s management of the petition review process appears to conflict with the objective of “maximizing the availability and clarity of information about the process for review of applications and submissions (including petitions, notifications, and any other similar forms of requests) made under [the Food and Drug Administration Modernization Act of 1997]” as articulated in that act and restated in FDA’s Plan for Statutory Compliance issued in November 1998.¹⁷

Conclusions

Pathogens such as *Salmonella* and *E. coli* continue to cause severe foodborne illness outbreaks, with the populations most susceptible to these illnesses growing in number. Subjecting food to ionizing radiation has been shown to not only be safe but to reduce pathogens in food by as much 99.999 percent. Despite the effectiveness of food irradiation, consumers are still unsure about its safety. In addition, according to several industry experts, the amount of food irradiated has been relatively steady or slowly increasing since 2000. While FDA is proposing changes to its labeling requirements for irradiated food that may increase the amount of food that is irradiated, it has not effectively managed its petition review process, which is the vehicle to potentially allow more food products to be irradiated. In addition, despite regulatory requirements, FDA has not documented pertinent decisions about its petition review process and has not communicated this information to the affected petitioners. These deficiencies limit the ability of petitioners to understand the actions FDA takes, the ability of petitioners to respond appropriately when FDA changes the requirements of the review process, and the transparency of the petition review process.

Recommendations for Executive Action

To more effectively manage its food irradiation petitions, we recommend that the Commissioner of the Food and Drug Administration direct the Office of Food Additive Safety to take the following two actions to be consistent with FDA regulations:

¹⁷FDA, *Regulatory Information: FDA Plan for Statutory Compliance*, (November 1998).

- document its key decisions in its administrative files; and
- communicate its key decisions to its petitioners and, for new petitions, the status of its decisionmaking, consistent with regulatory time frames.

Agency Comments

We provided the Departments of Agriculture and Health and Human Services with a draft of this report for their review and comment. USDA said that we accurately described the department's role within the context of the report and provided us with a technical comment that we incorporated. The Department of Health and Human Services, representing FDA, provided written comments and said that the draft raised legitimate issues regarding its management of the food irradiation petition process. FDA agreed with our recommendations and said that it had already begun to implement them. FDA's specific comments are presented in enclosure V.

As agreed with your offices, 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 of this report to the Commissioner of the Food and Drug Administration, the Secretary of Agriculture, appropriate congressional committees, and other interested parties. This report is also available at no charge on GAO's Web site at <http://www.gao.gov>.

If you or your staffs 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 correspondence. Key contributors to this report are listed in enclosure VI.



Lisa Shames
Director, Natural Resources and Environment

Enclosures (6)

List of Congressional Committees

The Honorable Henry A. Waxman
Chairman
The Honorable John D. Dingell
Chairman Emeritus
The Honorable Joe Barton
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Bart Stupak
Chairman
The Honorable Greg Walden
Ranking Member
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives

Enclosure I

Scope and Methodology

The three federal agencies that have primary responsibility for the oversight of food irradiation are (1) the Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS), (2) USDA's Animal and Plant Health Inspection Service (APHIS), and (3) the Department of Health and Human Services' Food and Drug Administration (FDA). To determine how FDA's current labeling requirements for irradiated foods compare with USDA's labeling requirements and how FDA's proposed changes to these requirements might impact the amount of food that is irradiated, we reviewed FDA and FSIS labeling regulations, relevant *Federal Register* notices, FDA's proposed changes to the labeling requirements, and obtained food irradiation labels submitted to USDA for review and approval. We also spoke with officials from FDA, FSIS, and APHIS and representatives from

- industry (Dairy Queen; Food Technology Service, Inc.; GrayStar, Inc.; Hawaii Pride; Omaha Steaks; RayFresh; Sadex Corporation; Sterigenics; STERIS Corporation; the Society of Plastics Industry; and Wegmans),
- trade associations (the American Meat Institute, the American Spice Trade Association, the Food Irradiation Processing Alliance, the Grocery Manufacturers Association, the International Food Information Council, the Minnesota Beef Council, the National Chicken Council, the National Fisheries Institute, the National Grocers Association, the North American Meat Processors Association, and the United Fresh Produce Association), and
- consumer advocacy groups (the Consumer Federation of America, the Center for Science in the Public Interest, and Food and Water Watch).

In addition, we interviewed food irradiation experts at Michigan State University, the University of California at Davis, and the state of Florida. We visited four irradiation facilities of the four major companies that irradiate meat and spices in Florida, Iowa, and New Jersey using different types of irradiators. We also visited the ports of Philadelphia and Newark/New York, which are primary points of entry for fruits and vegetables on the East Coast. At these ports, we observed Customs and Border Protection examinations of incoming shipments of fruits and vegetables. Finally, we spoke with representatives from Australia, Belgium, Canada, the European Union, France, Germany, Mexico, and Thailand to learn about food irradiation practices in other countries.

To determine the extent to which FDA has effectively managed the petition review process for food irradiation petitions, we reviewed FDA statutory and regulatory requirements for reviewing food additive petitions, which include irradiation petitions; analyzed data on the six pending food additive petitions to irradiate food products; and reviewed FDA files containing documentation on the management of those six pending irradiation petitions. We spoke with officials from FDA responsible for reviewing food additive petitions and the organizations that filed the six pending petitions to irradiate food products. We also spoke with one consumer advocacy

group that filed a citizen petition against a prior FDA decision to allow irradiation of meat. Although FDA receives numerous food additive petitions for such things as sweeteners and emulsifiers, the focus of our review was the six pending petitions dealing with ionizing radiation.

We conducted this performance audit from April 2009 to February 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 provides a reasonable basis for our findings and conclusions based on our audit objectives.

Enclosure II

Ionizing Radiation Processes

Food irradiation facilities use three types of ionizing irradiation: gamma rays, X-rays, and electron beams. These three types of ionizing radiation have the same effects, in that each process generally kills bacterial pathogens or neutralizes plant pests on food, but differ in how they work. Gamma irradiators use a radioactive source—either cobalt-60, most commonly, or cesium-137—as their source of ionizing radiation, while X-ray and electron beam irradiators electronically generate ionizing radiation without the use of radioactive material. The extent to which the radiation penetrates into food products depends on the type of food and the energy of the photons emitted by a gamma ray or X-ray source or particles emitted by an electron beam source.¹⁸ The penetration of electron beam radiation is relatively shallow, generally a few centimeters, while gamma rays and X-rays can penetrate much more deeply—for example, a half meter or more. Depending on the nature of the food, among other things, gamma radiation can take from 15 to 45 minutes, while electron beam radiation can take from several seconds to several minutes. X-ray radiation involves a substantial energy loss—generally greater than 90 percent—as the electrons are converted into X-rays. When food is irradiated, it does not come in contact with radioactive materials and, therefore, it remains free of radioactive contamination.

In total there are approximately 50 facilities in the United States that have irradiators. Of these only four facilities irradiate nonspice food products like meat and fruits. There are more than a dozen facilities that irradiate spices and these facilities generally also irradiate nonfood products like medical devices, such as surgical kits. In addition, the majority of the facilities that irradiate food are gamma irradiators and the vast majority of products that are irradiated are not food products. In addition, there appears to be no irradiators located at the same facility where the food products are processed. Irradiators can be expensive to purchase, with the total capital cost ranging from \$2 million dollars to several times that. According to an industry group, the capital costs of irradiation equipment are often seen as prohibitive.

¹⁸X-ray and gamma radiation sources generate photons, which are pure energy and contain no mass or weight. Electron beam radiation sources generate small particles of matter moving at high velocity; they carry energy due to the motion of these particles.

Enclosure III

Table 1: Food Products Approved for Irradiation in the United States

Food product	Agency and approval date	Purpose of irradiation	Maximum permitted dosage (kiloGray)
Dry or dehydrated enzyme preparations	Food and Drug Administration (FDA), June 10, 1985	Control of insects and micro-organisms	10.0
Pork carcasses or fresh nonheated processed cuts	FDA, July 22, 1985 United States Department of Agriculture (USDA), January 15, 1986	Control <i>Trichinella spiralis</i>	0.30 to 1.00
Fresh foods	FDA, April 18, 1986	Delay maturation	1.0
Food	FDA, April 18, 1986	Arthropod disinfestation	1.0
Dry or dehydrated aromatic vegetable substances	FDA, April 18, 1986	Microbial disinfection	30.0
Fresh, frozen uncooked poultry	FDA, May 2, 1990 USDA, September 21, 1992	Control foodborne pathogens	3.0
Refrigerated and frozen uncooked sheep, cattle, swine, and goat	FDA, December 3, 1997 USDA, December 23, 1999	Control foodborne pathogens and extend shelf-life	4.5 (refrigerated) 7.0 (frozen)
Fresh shell eggs	FDA, July 21, 2000	Reduction of <i>Salmonella</i>	3.0
Seeds for sprouting	FDA, October 30, 2000	Control microbial pathogens	8.0
Fresh or frozen molluscan shellfish	FDA, August 16, 2005	Control <i>Vibrio</i> bacteria and other foodborne pathogens	5.5
Fresh iceberg lettuce and fresh spinach	FDA, August 22, 2008	Control foodborne pathogens and extend shelf-life	4.0

Source: GAO presentation of information from 21 C.F.R. 179.26 and *Federal Register* notices.

Enclosure IV

Table 2: The Six Food Irradiation Petitions Pending Review With FDA

Petitioner	Federal Register date	Years in FDA review	Purpose for petition
United States Department of Agriculture's (USDA)–Food Safety and Inspection Service (FSIS)	December 21, 1999	10.0	Use of Ionizing Radiation on Unrefrigerated, Refrigerated, and Frozen Poultry Products (FAP 9M4696)
USDA–FSIS	December 22, 1999	10.0	Use of Ionizing Radiation on Unrefrigerated Meat Food Products (FAP 9M4695)
Grocery Manufacturers Association (formerly National Food Producers Association)	January 5, 2000	10.0	Use of Ionizing Radiation on Certain Refrigerated, Frozen or Dried Meat, Poultry, Fruit or Vegetable Products (FAP 9M4697)
National Fisheries Institute	February 6, 2001	8.9	Use of Approved Sources of Ionizing Radiation as a Physical Process to Reduce the Food Safety Risk in Consuming Crustaceans (FAP 1M4727)
STERIS Corporation	May 9, 2003	6.6	Use of Gamma Rays to Reduce Micro-organisms on Dietary Supplements (FAP 2M4741)
Sterigenics	November 30, 2004	5.0	Request Approval for Shelf Stable Foods Processed with Irradiation in Combination with Other Methods (FAP 3M4744)

Source: GAO analysis of Food and Drug Administration information.

Enclosure V

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

JAN 27 2010

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

Dear Ms. Shames:

Enclosed are the Departmental comments on the U.S. Government Accountability Office's (GAO) draft report entitled: "Food Irradiation: FDA Could Improve Its Documentation and Communication of Key Decisions on Food Irradiation Petitions" (GAO-10-309R).

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

Sincerely,

A handwritten signature in black ink, appearing to read "Andrea Palm", with a long horizontal flourish extending to the right.

Andrea Palm
Acting Assistant Secretary for Legislation

Enclosure

Comments from the Department of Health and Human Services

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES TO THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, FOOD IRRADIATION: FDA COULD IMPROVE ITS DOCUMENTATION AND COMMUNICATION OF KEY DECISIONS ON FOOD IRRADIATION PETITIONS (GAO-10-309R)

Introduction

The Food and Drug Administration (FDA) appreciates the opportunity to review and comment on the Government Accountability Office's (GAO's) draft report. FDA believes that the report raises legitimate questions regarding the agency's documentation of the record for pending petitions to permit irradiation of food and the timeliness of its communication with petitioners on the status of pending petitions. In addition, the report calls attention to the challenge that the FDA faces in balancing the need to protect an objective deliberative process and the need to maintain transparency for that process with the petitioner and the public. The agency agrees with the recommendations set forth in the report and has already made advances in implementing them.

Ionizing radiation used on foods (irradiation, or food irradiation) has been studied for over 100 years as a method for food processing and has been approved by FDA and government regulatory bodies in other countries for use to disinfect foods from arthropod pests, reduce levels of microbes that are implicated in foodborne illness, and also increase the shelf life and visual appeal of foods. Currently, most of the foods that are irradiated in the United States are: (1) spices that are added to processed foods, (2) imported fruits, and (3) a small quantity of meats from specialty food purveyors. Although its technical effects on food are well-known and understood, irradiation is not a widely-used technology.

The agency agrees with GAO's analysis of the potential public health benefits of more widespread use of food irradiation to reduce food contamination from bacterial pathogens, such as *Listeria monocytogenes*, *Escherichia coli* O157:H7 and *Salmonella* spp., and thereby reduce the number of illnesses from bacterial contamination. Irradiation can be a useful intervention as one element of a Hazard Analysis and Critical Control Points (HACCP) plan or other system of science-based preventive controls to ensure the safety of food. Irradiation is not, however, a substitute for a sound preventive control systems or current Good Manufacturing Practices that are employed to prevent, reduce, control, or eliminate food borne hazards that may occur during food production, processing, or storage.

One focus of GAO's report is the examination of the length of FDA's review of several food additive petitions for the irradiation of food. During its review of these food additive petitions, the agency discovered that irradiation, along with traditional thermal food processing technologies (e.g., baking, roasting, grilling), can produce furan, a byproduct that has been shown to be carcinogenic in rodents. The discovery of the potential for furan production raised valid safety questions for those petitions under review and for those uses of irradiation already approved by FDA. Review of the currently approved uses of irradiation has shown that furan is not produced at levels above the limit of detection in those foods when irradiated.

Comments from the Department of Health and Human Services

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES TO THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, FOOD IRRADIATION: FDA COULD IMPROVE ITS DOCUMENTATION AND COMMUNICATION OF KEY DECISIONS ON FOOD IRRADIATION PETITIONS (GAO-10-309R)

The Office of Food Additive Safety (OFAS, formerly the Office of Premarket Approval) within FDA's Center for Food Safety and Applied Nutrition (CFSAN) confirmed the presence of detectable furan in irradiated foods in the spring of 2001. FDA's public health priority after the initial furan discovery was to gain additional information from petitioners and from the agency's own research to address the overall safety of irradiated foods with respect to furan exposure. Since then, in an effort to understand the impact of furan on food safety, OFAS¹ has spent significant resources developing and examining information to better understand the formation and levels of furan in foods, and how this may affect the safety of the food supply. Additionally, the agency held a public meeting in June of 2004 to discuss the occurrence of furan in food. In September 2005, the agency published an action plan to help guide the agency's activities on the issue of furan in food. It is important to understand that FDA's furan data collection and evaluation were taking place in parallel to a larger but similar investigation of acrylamide produced in foods. The agency's charge to protect the health of consumers by eliminating or reducing exposures to chemicals of concern is a high priority. Although FDA does not consider furan a concern for currently approved uses of irradiation on food, the agency is continuing research to better understand and characterize the occurrence of furan in foods generally.

FDA agrees that transparency to the petitioner is critical for the petitioner to understand the basis for the agency's safety determinations and data needs. Although FDA acknowledges some deficiencies in informing petitioners of the status for some of the pending petitions in question, the agency believes that the petitioners have long been aware of the public health importance of understanding the issue of furan as it applies to processed foods. FDA attaches the highest importance to transparency of its review processes to the petitioner and the public, but the agency also must protect the objectivity of the deliberative process. In accordance with the agency's regulations, documents such as safety data that are provided by the petitioner are available for public review anytime after the petition has been filed. However, to protect the agency's deliberative process, and ensure that the decision is made in an objective manner, review documents generated by the agency are not available to the petitioner or the public until a final decision is made on the petitioned request. The agency's request(s) for additional information from a petitioner are generally distilled from review memoranda. In some cases, multiple reviews may be needed before communicating any deficiencies to the petitioner. At the conclusion of a petition review, review documents are generally referenced, as well as discussed, in the preamble to the agency's final rule.

Some of the petitions requesting additional uses of irradiation are quite broad in scope. Such petitions generally raise broader and more complex safety questions and can require more work than was initially anticipated if they contain insufficient information to address the complex questions being raised. Given the breadth of scientific issues raised

¹ Some staff formerly in the Office of Premarket Approval now work in CFSAN's Office of Research Science.

Comments from the Department of Health and Human Services

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES TO THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, FOOD IRRADIATION: FDA COULD IMPROVE ITS DOCUMENTATION AND COMMUNICATION OF KEY DECISIONS ON FOOD IRRADIATION PETITIONS (GAO-10-309R)

by these petitions, the review process has required more resources and has been substantially slower than anticipated.

Since the last GAO report² in October 2000, the agency has approved two petitions for the irradiation of additional foods (seeds for sprouting and molluscan shellfish). The agency also issued a partial response to a third petition that permits the use of irradiation on two produce products (fresh iceberg lettuce and fresh spinach). In addition to the partially-responded petition, the agency is currently reviewing five additional petitions that cover the use of irradiation in a broad range of foods.

In addition to reviewing food additive petitions for additional uses of irradiation, the agency is also responding to objections that have been submitted in response to final rules permitting the irradiation of certain foods. All final rules for the use of irradiation in foods have received objections to the new uses. The agency must balance its resources to respond both to pending petitions and to objections from published rules.

Another focus of GAO's report is FDA's current labeling requirements for irradiated foods and the changes FDA proposed in those requirements in 2007. Those changes would remove the requirement that the radura logo (the international symbol indicating a food has been irradiated) appear on the label of irradiated foods unless the irradiation had caused a material change in the food, or in the consequences that may result from the use of the food. FDA is aware that there are different opinions on the labeling of irradiated foods.

As reported by GAO in its draft report, industry representatives believe that the quantity of irradiated foods in the marketplace would increase if the current labeling requirements were eliminated, with potential benefits for food safety. GAO also reported that consumer groups support FDA's current labeling requirement and oppose any change. GAO notes that public comments from consumers to FDA have consistently supported labeling as a means to prevent consumer deception by informing consumers that food has been irradiated. According to GAO, consumer groups continue to believe that consumers have a right to know that their food has been exposed to irradiation so they can decide whether or not to purchase the food.

As noted in the 2007 proposed rule, FDA conducted consumer focus groups in 2001, primarily to assess whether the current radiation disclosure statement is perceived as a warning and thus, presumably, a deterrent to consumer acceptance of irradiated foods. The focus group data indicated that the majority of participants were uncertain about the safety, effectiveness, and appropriateness of irradiated food products and greatly desired more information. Most of the participants viewed alternate terms, such as "cold pasteurization" and "electronic pasteurization" as misleading, because such terms

² GAO, *Food Irradiation: Available Research Indicates That Benefits Outweigh Risks*, GAO/RCED-00-217 (Washington, D.C.: Aug. 24, 2000)

Comments from the Department of Health and Human Services

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES TO THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, FOOD IRRADIATION: FDA COULD IMPROVE ITS DOCUMENTATION AND COMMUNICATION OF KEY DECISIONS ON FOOD IRRADIATION PETITIONS (GAO-10-309R)

appeared to conceal rather than to disclose information. Participants in the focus groups did not see the current irradiation disclosure labeling as a warning, per se, because knowledgeable participants considered irradiation to be a positive safety attribute. Less knowledgeable participants, such as those who associated irradiation with things such as x-ray or radiation, wanted more information about the appropriateness of food irradiation. All participants in the focus groups agreed that irradiated foods should be labeled "honestly." (72 FR 16291 at 16293, April 4, 2007).

FDA continues to examine its policy and regulation on labeling of irradiated foods and will consider all points of view and all relevant information as it considers next steps in the rulemaking.

Response to Recommendations

GAO Recommendation 1

To more effectively manage its food irradiation petitions, GAO recommends that the Commissioner of the Food and Drug Administration direct the Office of Food Additive Safety to document its key decisions in its administrative files to be consistent with FDA regulations.

FDA Response

The agency agrees with this recommendation and has already taken steps to that end and to more effectively manage its food irradiation petitions. Specifically, OFAS has formed an irradiated foods team to oversee the administrative process for the review of irradiation petitions by documenting the ongoing status for management oversight and to oversee the documentation of key time points and decisions in the review process.

GAO Recommendation 2

To more effectively manage its food irradiation petitions, GAO recommends that the Commissioner of the Food and Drug Administration direct the Office of Food Additive Safety to communicate its key decisions to its petitioners and, for the new petitions, the status of its decision making, consistent with regulatory timeframes to be consistent with FDA regulations.

FDA Response

The agency agrees with this recommendation. Specifically, the agency has directed OFAS to communicate its key decisions and the status of its decision-making, consistent with regulatory timeframes. These decisions include notifying the petitioner of

Enclosure V

Comments from the Department of Health and Human Services

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES TO THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, FOOD IRRADIATION: FDA COULD IMPROVE ITS DOCUMENTATION AND COMMUNICATION OF KEY DECISIONS ON FOOD IRRADIATION PETITIONS (GAO-10-309R)

acceptance or non-acceptance of the petition. This recommendation will ensure the transparency of the food irradiation petition review process.

Enclosure VI

GAO Contact and Staff Acknowledgments

GAO Contact

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

Staff Acknowledgments

In addition to the contact named above, Jose Alfredo Gomez (Assistant Director), David Moreno (Analyst-in-Charge), Nancy Crothers, Diana Goody, Jessica Lotz, Alise Nacson, and Alex Winograd made key contributions to this report. Important contributions were also made by Kevin Bray, Cindy Gilbert, and Maria Stattel.