



Report to the Ranking Member,
Subcommittee on Labor, Health and
Human Services, Education, and Related
Agencies, Committee on Appropriations,
House of Representatives

March 2018

FOOD SAFETY

Federal Efforts to Manage the Risk of Arsenic in Rice

GAO Highlights

Highlights of [GAO-18-199](#), a report to the Ranking Member, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, Committee on Appropriations, House of Representatives

Why GAO Did This Study

Arsenic, an element in the earth's crust, can be harmful to human health and may be present in water and certain foods, such as rice. Rice may be more susceptible to arsenic contamination than other crops due to the flooded conditions in which it is typically grown. FDA and USDA work to address food safety risks. FDA's responsibilities for rice include regulatory and research programs; USDA's include research programs.

GAO was asked to review issues related to arsenic and rice. GAO examined (1) what NRC and recent key scientific reviews have reported about the effects of ingestion of arsenic on human health, (2) the extent to which FDA and USDA have managed the risk to human health from arsenic in rice, and (3) the extent to which FDA has coordinated with USDA and other federal agencies on actions to manage the risk. GAO analyzed a 2013 NRC report on inorganic arsenic, 14 reviews of scientific studies on the human health effects of ingesting arsenic published from January 2015 to June 2017, and agency documents; interviewed agency officials; and compared good practices with actions FDA and USDA took to manage risk and that FDA took to coordinate.

What GAO Recommends

GAO is making five recommendations, including that FDA develop a timeline for updating its risk assessment and finalizing its draft guidance and that FDA and USDA develop a coordination mechanism for developing methods to detect foodborne contaminants, including arsenic. FDA and USDA generally agreed with the recommendations.

View [GAO-18-199](#). For more information, contact Steve Morris at (202) 512-3841 or morriss@gao.gov.

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What GAO Found

The National Research Council (NRC) of the National Academy of Sciences, in 2013, and more recent key scientific reviews reported evidence of associations between long-term ingestion of arsenic and adverse human health effects, such as cardiovascular disease. Many of the studies NRC reviewed as part of its survey of the scientific literature examined the ingestion of arsenic in drinking water, but others looked at arsenic from all sources, including dietary sources such as rice. NRC stated that evidence suggests that food, particularly rice, may be a significant source of inorganic arsenic, the more toxic of the two forms of arsenic; however, consumption of rice and levels of arsenic in rice vary widely, making it difficult to estimate arsenic intake from rice. NRC identified stronger evidence for some health effects at higher levels of arsenic—defined by NRC as 100 parts per billion or higher in drinking water—than at lower levels, which are more common in the United States, and noted that research on the health effects of ingesting lower levels of arsenic is ongoing.

The Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) have taken actions to manage the risk of arsenic in rice to human health, including assessing the type and prevalence of health effects that may result from long-term ingestion of arsenic in rice. FDA also has taken action to publicly communicate and report on the risk. In 2016, FDA issued a risk assessment about the human health effects from long-term ingestion of arsenic in rice and draft guidance recommending industry not exceed a level of 100 parts per billion of inorganic arsenic in infant rice cereal. FDA noted it issued this guidance because infants face a higher risk owing to their less-varied diets. However, FDA has not updated the risk assessment, which was informed by a review of scientific studies published before February 2015, or finalized the draft guidance. In prior work, GAO has found that sharing risk information and incorporating stakeholder feedback can help organizations identify and better manage risks, as well as increase transparency and accountability to Congress and taxpayers. FDA officials stated that they may update the risk assessment based on newly-available information and consider public comments before finalizing the draft guidance. However, FDA officials could not provide a specific timeline for either. By developing such a timeline, FDA could help clarify when it will take action and improve the transparency of its decisions.

FDA coordinated with USDA and other federal agencies on actions to manage the risk of arsenic in rice to varying extents. For example, FDA and USDA coordinated on developing arsenic detection methods for rice to a limited extent, although both agencies have crosscutting strategic goals for developing detection methods for foodborne contaminants, including arsenic. GAO has noted in prior work that developing interagency mechanisms to coordinate crosscutting issues may reduce potentially duplicative efforts. FDA and USDA officials stated that they coordinated on an informal basis but have no mechanism for coordinating more formally. By developing a coordination mechanism, FDA and USDA could enhance their ability to use their resources efficiently and avoid potentially duplicative efforts.

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Abbreviations

ARS	Agricultural Research Service
CDC	Centers for Disease Control and Prevention
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FGIS	Federal Grain Inspection Service
HHS	Department of Health and Human Services
NIFA	National Institute of Food and Agriculture
NIH	National Institutes of Health
NRC	National Research Council
ppb	parts per billion
OMB	Office of Management and Budget
USDA	U.S. Department of Agriculture

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March 16, 2018

The Honorable Rosa L. DeLauro
Ranking Member
Subcommittee on Labor, Health and Human Services, Education, and
Related Agencies
Committee on Appropriations
House of Representatives

Dear Ms. DeLauro:

Arsenic, an element in the earth's crust, is present in the environment, including water, air, and soil, because of both natural occurrence and human activity. It exists in two general forms, organic and inorganic.¹ Both can be harmful to human health, but inorganic arsenic is generally considered to be the more toxic form.² Inorganic arsenic has been classified as carcinogenic to humans by the International Agency for Research on Cancer.³ According to the Department of Health and Human Services' (HHS) Agency for Toxic Substances and Disease Registry, exposure to arsenic generally occurs through contaminated groundwater and the ingestion of foods containing arsenic compounds.⁴ The Agency for Toxic Substances and Disease Registry identified rice as a predominant dietary source of arsenic.⁵ Partly because of the flooded conditions under which rice is typically grown, rice may be more

¹The organic form of arsenic consists of arsenic compounds that include carbon. The inorganic form of arsenic consists of arsenic compounds that include elements other than carbon.

²Most data reported for arsenic in food describe the levels of total arsenic (the sum of both forms). In this report, we use the term "arsenic" to refer to either total arsenic or inorganic arsenic only.

³The International Agency for Research on Cancer is the World Health Organization's agency that promotes international collaboration in cancer research. For additional information on its classifications, see International Agency for Research on Cancer, Agents Classified by the IARC Monographs, Volumes 1-120, accessed November 9, 2017, <http://monographs.iarc.fr/ENG/Classification/index.php>.

⁴Agency for Toxic Substances and Disease Registry, *Addendum to the Toxicological Profile for Arsenic* (Atlanta, GA: 2016).

⁵The Agency for Toxic Substances and Disease Registry noted that as a dietary source of arsenic, including inorganic arsenic, rice is second to seafood, which mostly contains the organic form of arsenic.

susceptible to arsenic contamination than other crops. In 2009, the European Food Safety Authority noted that exposure of infants to arsenic in rice products is a concern because such products are often used in foods for infants and because infants and young children have a higher food intake relative to their body weight than adults.⁶

The safety and quality of the U.S. food supply, both domestic and imported, are governed by a complex system stemming from at least 30 federal laws that are administered by 15 federal agencies. HHS's Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) are the principal agencies working to protect the food supply from risks, such as contamination. FDA is responsible for ensuring the safety of virtually all domestic and imported food products, with the exception of meat and poultry, processed egg products, and catfish, which are the responsibility of USDA's Food Safety and Inspection Service. Other agencies within USDA also play a role in food safety. For example, USDA's Agricultural Research Service (ARS) and National Institute of Food and Agriculture (NIFA) sponsor food safety research. In addition, the Environmental Protection Agency (EPA) has the statutory responsibility for, among other things, ensuring that the pesticides used on food crops do not endanger public health. EPA has been updating its assessment of the health hazards of inorganic arsenic in the Integrated Risk Information System—an important source of toxicity information for federal agencies. The National Research Council (NRC) of the National Academy of Sciences has reviewed EPA's approach to updating its toxicological assessment of inorganic arsenic and issued a report in 2013 that provided key guidance and a preliminary survey of the literature on inorganic arsenic.⁷

For more than 4 decades, we have reported on the fragmented federal food safety oversight system, which has caused inconsistent oversight, ineffective coordination, and inefficient use of resources. In January 2007, because of risks to the economy and to public health and safety, we added transforming federal oversight of food safety to our list of areas at high risk for fraud, waste, abuse, and mismanagement, or most in need of

⁶In this report, we use the term "rice" to encompass rice grain and products made with rice, such as infant rice cereal.

⁷National Research Council, Committee on Inorganic Arsenic, *Critical Aspects of EPA's IRIS Assessment of Inorganic Arsenic: Interim Report* (Washington, D.C.: National Academies Press, 2013).

transformation.⁸ In our February 2017 update to that list, we noted that HHS, USDA, and the Office of Management and Budget (OMB) have taken some positive steps to address fragmentation in the federal food oversight system but that additional steps are needed.⁹ In January 2017, to address ongoing fragmentation, we recommended that the Executive Office of the President, in consultation with relevant federal agencies and other stakeholders, develop a national strategy to improve the food safety oversight system.¹⁰ In addition, we have found shortcomings with FDA's oversight of seafood, dietary supplements, and other matters.¹¹ In 2012, we identified key issues to consider that could benefit interagency collaborative mechanisms, which may help reduce potentially duplicative, overlapping, and fragmented efforts.¹²

You asked us to review issues related to arsenic and rice. This report examines (1) what NRC and recent key scientific reviews have reported about the effects of ingestion of arsenic on human health, (2) the extent to which FDA and USDA have managed the risk to human health from arsenic in rice, and (3) the extent to which FDA has coordinated with USDA and other federal agencies on actions to manage the risk.

To determine what NRC and recent key scientific reviews have reported about the effects of ingestion of arsenic on human health, we analyzed NRC's 2013 report on inorganic arsenic and 14 reviews of the scientific literature published from January 2015 through early June 2017 on the human health effects of ingestion of arsenic. We identified the reviews by conducting a literature search of research databases, such as PubMed and Toxline, and selected English-language reviews that met certain

⁸GAO, *High-Risk Series: An Update*, [GAO-07-310](#) (Washington, D.C.: Jan. 31, 2007).

⁹GAO, *High-Risk Series: Progress on Many High-Risk Areas, While Substantial Efforts Needed on Others*, [GAO-17-317](#) (Washington, D.C.: Feb. 15, 2017).

¹⁰GAO, *Food Safety: A National Strategy Is Needed to Address Fragmentation in Federal Oversight*, [GAO-17-74](#) (Washington, D.C.: Jan. 13, 2017).

¹¹See, for example, GAO, *Imported Seafood Safety: FDA and USDA Could Strengthen Efforts to Prevent Unsafe Drug Residues*, [GAO-17-443](#) (Washington, D.C.: Sept. 15, 2017); *Dietary Supplements: FDA May Have Opportunities to Expand Its Use of Reported Health Problems to Oversee Products*, [GAO-13-244](#) (Washington, D.C.: Mar. 18, 2013); and *Imported Food Safety: FDA's Targeting Tool Has Enhanced Screening, but Further Improvements Are Possible*, [GAO-16-399](#) (Washington, D.C.: May 26, 2016).

¹²GAO, *Managing for Results: Key Considerations for Implementing Interagency Collaborative Mechanisms*, [GAO-12-1022](#) (Washington, D.C.: Sept. 27, 2012).

criteria, such as relying on human, rather than animal, studies. We assessed the scientific and statistical credibility, reliability, and methodological soundness of the reviews and excluded reviews for which we could not clearly determine the methodology.

To determine the extent to which FDA and USDA have managed the risk to human health from arsenic in rice, we examined relevant provisions in the Federal Food, Drug, and Cosmetic Act, as amended;¹³ the Federal Agriculture Improvement and Reform Act of 1996;¹⁴ and other laws, regulations, and policies. We also reviewed our prior work on enterprise risk management and used the essential elements for managing risk that it identified.¹⁵ We identified information on agency actions for managing the risk from arsenic in rice by collecting documentation and interviewing officials from FDA and USDA, and we reviewed the information in light of the requirements, policies, and elements. We assessed FDA's and USDA's reported actions to determine the extent to which each agency's actions aligned with the essential elements for managing risk. In assessing FDA's and USDA's actions against these essential elements, we used the terms "consistent" and "partially consistent" to reflect the extent to which each agency's actions aligned with an essential element. We also interviewed 17 stakeholders, including university researchers, representatives of a consumer organization, and representatives of the rice industry, including rice mills and farms, to obtain their views on the extent to which FDA's and USDA's actions managed this risk. We identified stakeholders based on suggestions from agency officials and other stakeholders; through our site visit to Arkansas' rice agricultural research and production areas and rice mills; and the stakeholders' unique perspective or qualifications, such as membership in the NRC Committee on Inorganic Arsenic. The views we obtained in these interviews are not generalizable to all university researchers or consumer or rice industry organizations but they provide illustrative examples of the views of such stakeholders.

¹³21 U.S.C. §§ 301, et seq.

¹⁴Pub. L. No. 104-127, 110 Stat. 888 (Apr. 4, 1996).

¹⁵GAO, *Enterprise Risk Management: Selected Agencies' Experiences Illustrate Good Practices in Managing Risk*, [GAO-17-63](#) (Washington, D.C.: Dec. 1, 2016). This report also identified good practices agencies are implementing that illustrate the essential elements of enterprise risk management.

To determine the extent to which FDA coordinated with USDA and other federal agencies on actions to manage the risk from arsenic in rice, we identified actions for which coordination would be expected. Specifically, we identified actions for which the agencies shared similar goals in their strategic plans or relevant expertise. For these actions, we examined whether FDA developed interagency collaborative mechanisms. We had previously reported that such mechanisms could facilitate coordination between agencies.¹⁶ We also examined whether FDA considered a key issue we had identified when implementing one of these mechanisms: to clarify the roles and responsibilities of participating agencies. We selected this key issue because it was relevant to the challenges FDA and the other agencies faced. See appendix I for a detailed description of our objectives, scope, and methodology.

We conducted this performance audit from December 2016 to March 2018 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

Forms and Distribution of Arsenic

Arsenic is a naturally occurring element that is widely distributed in the earth's crust in two general forms—organic and inorganic. It commonly enters the body through ingestion of food or water. Most data reported for arsenic in food describe the levels of total arsenic because analyses that provide information about the forms of arsenic present are more difficult to perform, and relatively few laboratories are able to perform these analyses. Data on the levels of specific forms of arsenic, however, are becoming increasingly important because, according to the Agency for Toxic Substances and Disease Registry, the two forms have different toxicities, with inorganic arsenic being considered the more toxic form. Further, foods may have different proportions of organic and inorganic arsenic as well as different levels of total arsenic. According to the European Food Safety Authority, plants generally contain low levels of both total and inorganic arsenic, but rice may contain significant levels of

¹⁶[GAO-12-1022](#).

total arsenic and inorganic arsenic. Levels of arsenic in groundwater, a major source of drinking water in many parts of the world, may be high in some areas; essentially all the arsenic in drinking water is inorganic arsenic.

The form and level of arsenic in rice may vary depending on the geographic region where rice is grown, conditions under which rice is grown, variety of the rice, and rice milling practices.¹⁷ In the United States—where, according to USDA, approximately 80 percent of the rice consumed domestically is grown—rice is primarily grown in six states: Arkansas, California, Louisiana, Mississippi, Missouri, and Texas. In 2016, the latest year for which USDA data were available, about 47 percent of the rice grown in the United States was grown in Arkansas, and about 21 percent was grown in California.¹⁸

The amount of arsenic rice absorbs varies by geographic region because of differing levels of arsenic in the soil and other factors. Arsenic levels in the soil vary both naturally and as a result of human activity. Natural processes that contribute to arsenic levels in the soil may include bedrock weathering, because arsenic is present in many rock-forming minerals. Human activities that contribute to arsenic levels in the soil may include the use of arsenic-based pesticides and animal drugs, the mining and smelting of metal, and coal combustion.¹⁹ Figure 1 shows the results of a 2013 U.S. Geological Survey sampling of soils to measure the levels of arsenic in the contiguous United States.²⁰ In addition, the figure shows the outlines of rice-growing counties based on 2016 data from USDA.

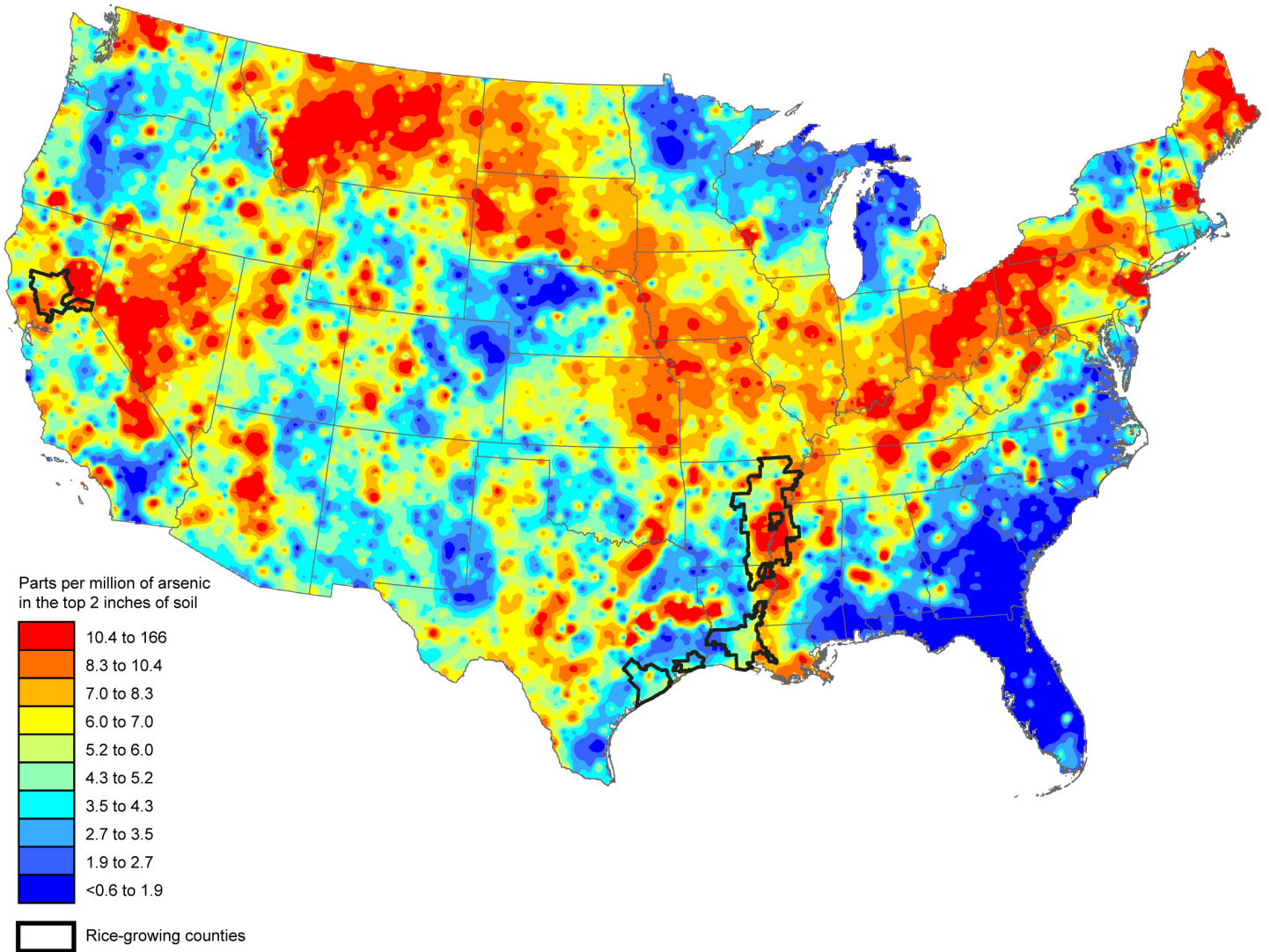
¹⁷Milling is the extent to which the hull, bran, and germ have been removed from the rice seed. White rice results from the removal of the hull and practically all of the germ and the bran layer.

¹⁸According to our analysis of USDA data, shares of domestic rice production in 2016 for the remaining four states were: Louisiana, 13 percent; Missouri, 7 percent; and Mississippi and Texas, 6 percent each.

¹⁹One arsenic-based pesticide, monosodium methanearsonate, is currently permitted for use on cotton and turf grass (i.e., golf courses, sod farms, and highway rights-of-way). In December 2015, FDA issued a final rule withdrawing the approval of the last remaining arsenic-containing animal drug approved for use in food-producing animals. 80 Fed. Reg. 78,970 (Dec. 18, 2015).

²⁰U.S. Geological Survey, *Geochemical and Mineralogical Data for Soils of the Conterminous United States* (Reston, VA: 2013). The 2013 data are the most recent available.

Figure 1: Levels of Arsenic in the Soil Surface of the Contiguous United States, with Rice-Growing Counties Outlined



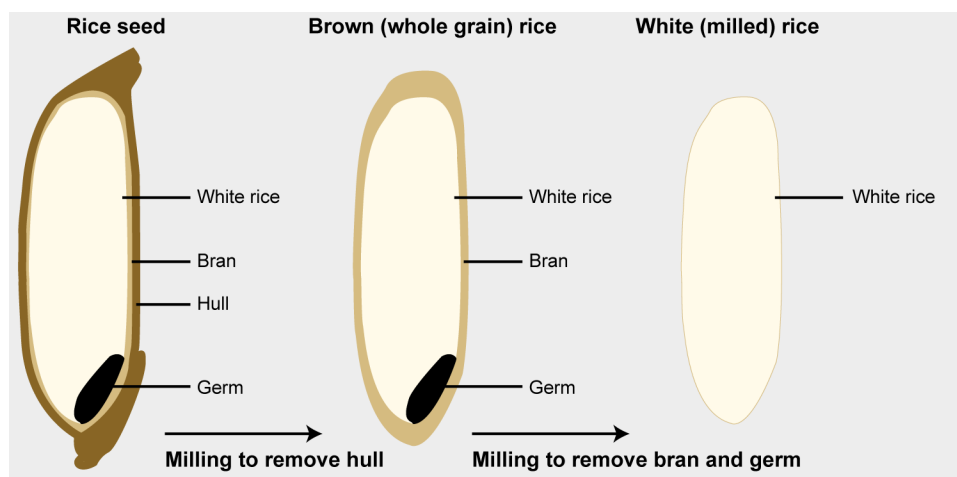
Source: Map from U.S. Geological Survey and GAO Analysis of USDA data. | GAO-18-199

Note: Rice-growing counties are identified by USDA's National Agricultural Statistics Service as the counties within the major rice-producing regions of the United States.

Compared to other plants, rice absorbs more arsenic from the environment, in part because of the physiology of rice. For example, rice may readily absorb certain compounds of arsenic because, among other reasons, these compounds are similar in size to compounds containing silicon, an essential nutrient for rice. The conditions under which rice is

grown may also cause it to absorb more arsenic than other plants. For instance, rice is often grown in flooded fields to control pests, grasses, and diseases, among other reasons. However, flooded conditions may promote the formation of arsenic compounds that may be easily absorbed by the rice plant. Even under the same growing conditions, some varieties of rice tend to have higher levels of arsenic in their grain, on average, than others, owing to a need for longer growing periods, among other factors. In addition, the concentrations of the two forms of arsenic may vary within the rice grain. While organic arsenic may be distributed throughout the rice grain, most of the inorganic arsenic is found in the bran layer. As seen in figure 2, the process of milling rice removes the bran layer; thus, levels of inorganic arsenic in white, or milled, rice may be lower than those in brown, or whole grain, rice.

Figure 2: Rice Grain Before and After Milling



Source: GAO adaptation of image from Riceland Foods. | GAO-18-199

Federal Agencies' Responsibilities for Rice

A number of federal agencies are responsible for ensuring the safety and quality of rice and for assessing the human health effects of ingestion of arsenic in rice. Within HHS, FDA has overall responsibility for implementing provisions of the Federal Food, Drug, and Cosmetic Act, as amended. Specifically, FDA is responsible for determining whether food, including rice, is deemed to be adulterated (i.e., whether it bears or contains any poisonous or deleterious substance that may render it injurious to health). Under its regulations, FDA may issue guidance to

establish a level of a contaminant that a food should not exceed.²¹ FDA would consider case-by-case whether a food that contains the contaminant is adulterated. For example, in 2013, FDA issued draft guidance for arsenic in apple juice, on the basis of its risk assessment that estimated the long-term cancer risk posed by inorganic arsenic. According to FDA, its Center for Food Safety and Applied Nutrition is responsible for regulatory and research programs that address the health risks associated with foodborne contaminants and is aided in this role by the Office of Regulatory Affairs, which is responsible for field-based activities such as inspections, sampling, and testing of regulated products. The Center for Food Safety and Applied Nutrition also conducts industry outreach and educates consumers, among other things.

Other agencies within HHS may also conduct research, collect data, and provide information on the health effects of arsenic. For example, the National Institutes of Health (NIH) sponsor research on the health effects of ingestion of arsenic. The Centers for Disease Control and Prevention (CDC) administer the National Health and Nutrition Examination Survey, which, among other things, collects data about diet and exposure to certain substances, such as arsenic. Under the Superfund Amendments and Reauthorization Act of 1986,²² the Agency for Toxic Substances and Disease Registry prepares toxicological profiles for certain hazardous substances, including arsenic.²³

Agencies within USDA conduct and sponsor research to advance food safety and to help farmers market rice and manage the risk of growing it. Within USDA, ARS and NIFA conduct and sponsor research, to, among other things, maintain an adequate, nutritious, and safe supply of food to meet human nutritional needs and requirements. NIFA also distributes capacity grants that support research and extension programs at land-

²¹FDA may establish such a level, referred to as an “action level,” when a contaminant cannot be avoided by good manufacturing practices and a technological or other change may be foreseeable. Such change may include anticipated improvements in good manufacturing practices or studies that may provide significant new toxicological or use data.

²²42 U.S.C. § 9604 (i)(3).

²³In 2007, the Agency for Toxic Substances and Disease Registry issued a peer-reviewed toxicological profile for arsenic and information regarding levels of significant human exposure and significant health effects. In 2016, it issued an addendum, providing a non-peer reviewed supplement of the scientific data that were published since the release of the profile in 2007.

grant universities, which provide science-based information to farmers. The Agricultural Marketing Act of 1946 authorizes the Federal Grain Inspection Service (FGIS) to establish quality standards,²⁴ including standards for rice.²⁵ FGIS also offers inspection services for rice farmers and processors upon request. The Risk Management Agency manages the Federal Crop Insurance Corporation, which offers crop insurance to farmers for over 100 different crops, including rice. For the 2018 crop year, the rice crop insurance provisions generally require that the rice be flood-irrigated (i.e., intentionally covered with water at a uniform and shallow depth throughout the growing season).²⁶

Other agencies play a role in managing the risk of arsenic. EPA regulates the presence of certain substances, such as arsenic, in drinking water under the Safe Drinking Water Act and conducts toxicological assessments.²⁷ In 2001, EPA issued a rule limiting the level of arsenic in drinking water to 10 parts per billion (ppb) to protect consumers from the health effects of long-term exposure.²⁸ Under its Integrated Risk Information System program, EPA conducts assessments that provide toxicity values—such as for increased cancer risk due to lifetime ingestion of a specified quantity of a substance. In accordance with congressional direction,²⁹ EPA submitted a plan for developing a draft assessment and preliminary assessment materials for inorganic arsenic to NRC for review. In 2013, NRC released an interim report, which provided guidance to EPA and included a preliminary survey of the scientific literature.³⁰ In addition, in accordance with Executive Order 13272, the Small Business Administration’s Office of Advocacy helps agencies assess the potential impacts of draft rules on small businesses—which could include members

²⁴7 U.S.C. § 1622(h)(1).

²⁵Federal Grain Inspection Service, *United States Standards for Rice* (Washington, D.C.: 2009).

²⁶The Federal Crop Insurance Corporation also offers a sprinkler irrigated endorsement that, if purchased, allows farmers to irrigate rice with sprinklers rather than with continuous flooding.

²⁷42 U.S.C. § 300g–1(b)(12)(A).

²⁸66 Fed. Reg. 6976 (Jan. 22, 2001). EPA defines chronic or long-term exposure as multiple exposures occurring over a significant portion of a lifetime.

²⁹H. Conf. Rpt. 112-331 (2012).

³⁰NRC has also previously issued reports in 1999 and 2001 to help evaluate the scientific validity of the risk assessment that EPA used in its rulemaking limiting arsenic in drinking water.

of the rice industry—small governmental jurisdictions, and small organizations.³¹

Entities outside of the federal government have recently proposed or established limits or guidance for arsenic in rice. For example, in 2017, the Codex Alimentarius, an international standard-setting body, published a code of practice that provides guidance for preventing and reducing arsenic contamination in rice, as well as communicating the risk to stakeholders.³² In 2014 and 2016, the Codex Alimentarius established a standard for inorganic arsenic of 200 ppb for white rice and 350 ppb for brown rice.³³ In 2015, the European Commission issued a regulation limiting inorganic arsenic in various rice-based foods, including limits of 200 ppb in white rice, 250 ppb in brown rice, and 100 ppb in rice destined for food for infants and young children.³⁴

Enterprise Risk Management

Enterprise risk management allows agencies to assess threats and opportunities that could affect the achievement of their goals. In a 2016 report, we updated our 2005 risk management framework to (1) reflect changes to OMB's Circular A-123, which requires agencies to implement enterprise risk management;³⁵ (2) incorporate recent federal experience; and (3) identify essential elements of federal enterprise risk management.³⁶ Beyond traditional internal controls, enterprise risk management promotes risk management by considering its effect across

³¹Executive Order 13272, *Proper Consideration of Small Entities in Agency Rulemaking* (Washington, D.C.: Aug. 13, 2002).

³²Codex Alimentarius, *Code of Practice for the Prevention and Reduction of Arsenic Contamination in Rice*, CAC/RCP 77-2017.

³³Codex Alimentarius, *General Standard for Contaminants and Toxins in Food and Feed*, Codex Standard 193-1995. The Codex Alimentarius standards are voluntary for nations but, according to the World Trade Organization, they are used as a benchmark for trade purposes. The World Trade Organization encourages reference to the standards in bilateral and multilateral trade agreements. Various federal agencies, including EPA, FDA, and USDA, participate in Codex Alimentarius activities.

³⁴Commission Regulation (EU) 2015/1006 of 25 June 2015, amending Regulation (EC) No 1881/2006 as regards maximum levels of inorganic arsenic in foodstuffs.

³⁵Office of Management and Budget, *Management's Responsibility for Enterprise Risk Management and Internal Control*, OMB Circular No. A-123 (July 15, 2016).

³⁶[GAO-17-63](#). See also GAO, *Risk Management: Further Refinements Needed to Assess Risks and Prioritize Protective Measures at Ports and Critical Infrastructure*, [GAO-06-91](#) (Washington, D.C.: Dec. 15, 2005).

the entire organization and how it may interact with other identified risks. Additionally, it also addresses other topics such as setting strategy, governance, communicating with stakeholders, and measuring performance, and its principles apply at all levels of the organization and across all functions—such as those related to managing the risk of arsenic in rice. The six essential elements of enterprise risk management that we identified in December 2016 are as follows:³⁷

- **Align risk management process with goals and objectives.** Ensure the process maximizes the achievement of agency mission and results.
- **Identify risks.** Assemble a comprehensive list of risks, both threats and opportunities, that could affect the agency’s ability to achieve its goals and objectives.
- **Assess risks.** Examine risks, considering both the likelihood of the risk and the impact of the risk to help prioritize risk response.
- **Respond to the risks.** Select risk treatment response (based on risk appetite), including acceptance, avoidance, reduction, sharing, or transfer.
- **Monitor risks.** Monitor how risks are changing and whether responses are successful.
- **Communicate and report on risks.** Communicate risks with stakeholders and report on the status of addressing the risks.

³⁷In this report, we used “risk management” rather than “enterprise risk management” because we examined FDA’s and USDA’s actions related to arsenic and rice, rather than their entire portfolio of activities related to food safety.

NRC and Recent Key Scientific Reviews Reported Evidence of Associations between Ingestion of Arsenic and Adverse Human Health Effects

NRC, in its 2013 report, and recent key scientific reviews reported evidence of associations between long-term ingestion of arsenic and adverse human health effects.³⁸ NRC identified stronger evidence of these associations at higher arsenic levels—defined by NRC as 100 ppb or higher in drinking water—than at lower levels, which are more common in the United States. NRC reported greater uncertainty regarding the associations with some health effects at lower levels of arsenic and noted that research on the health effects of ingestion of lower levels of arsenic is ongoing. Many of the studies on which NRC based its conclusions were focused on the ingestion of arsenic from drinking water, but other studies were based on arsenic from all sources, including dietary sources such as rice.³⁹ Further, NRC reported that evidence from CDC dietary surveys and related academic studies suggests that food, particularly rice, may be a significant source of inorganic arsenic, especially when arsenic levels in drinking water are lower; however, consumption of rice and levels of arsenic in rice vary widely, making it difficult to estimate arsenic intake from rice. NRC reported strong evidence of causal associations—that is, a potential cause and effect—between the long-term ingestion of arsenic from water or dietary sources, such as rice, and the following five health effects:

- **Skin diseases.**
 - **Skin lesions.** Skin lesions due to arsenic ingestion predispose a person to some skin cancers and may indicate increased

³⁸Studies report an association between exposure—for example, through ingestion—to a substance and a health effect if the occurrence of the health effect is significantly different between groups exposed to different levels of the substance. An association, however, does not necessarily mean that the exposure caused the health effect, but according to NRC, associations can help identify the hazards. The NRC report categorized health effects as follows: (1) strong evidence of causal association, (2) moderate evidence of association, and (3) limited but suggestive evidence of association. To categorize a health effect, according to the chair of the NRC committee that developed the report, the committee relied on nine factors such as strength and consistency. Health effects in the first category met all factors, those in the second met many of them, and those in the third met a few.

³⁹NRC reviewed 257 studies as part of its preliminary review of the scientific literature on the epidemiologic evidence related to the most affected organ systems. In certain studies, researchers estimated the ingested level of arsenic based on levels of arsenic measured in urine, hair, or toenails. In such cases, the arsenic may have originated in water or food. According to NRC, after ingestion, inorganic arsenic in drinking water is rapidly and almost completely absorbed, and there is evidence that arsenic in rice is likewise almost completely absorbed. We did not examine the individual studies cited by the NRC report.

susceptibility to other cancer and noncancer diseases. Skin lesions have a well-established dose-response relationship with arsenic in drinking water.⁴⁰

- **Skin cancer.** Arsenic is an established skin carcinogen, according to NRC. NRC stated that almost all published studies found evidence of an association between arsenic ingestion and nonmelanoma skin cancers.⁴¹
- **Lung cancer.** Arsenic from drinking water is an established lung carcinogen in humans, according to NRC. NRC cited studies conducted in Argentina, Chile, Japan, Taiwan, and the United States that reported associations between high levels of arsenic ingestion and lung cancer. NRC reviewed several studies that examined ingestion of lower levels of arsenic, some of which found evidence of an association, while others did not.⁴²
- **Cardiovascular disease.** NRC stated that many studies found a causal association between the ingestion of arsenic and cardiovascular disease and mortality. Studies suggest that the ingestion of lower levels of arsenic in drinking water and possibly in food is associated with cardiovascular disease, but additional evidence is needed to fully understand the relationship.
- **Bladder cancer.** Arsenic is an established bladder carcinogen in humans, according to NRC. NRC cited a 2012 assessment by the International Agency for Research on Cancer that indicated higher mortality from bladder cancer in populations that are exposed to high

⁴⁰A dose-response relationship, in this case, describes how the likelihood and severity of an adverse health effect (the response) is related to the amount and type of exposure to arsenic (the dose). NRC reported that, while some studies found that skin lesions occur only at high levels of arsenic, others found that lesions also occur at lower levels—that is, below 100 ppb of arsenic in drinking water.

⁴¹Some studies have found evidence that the risk of skin cancer increases with increasing levels of arsenic. Studies that examined ingestion of lower arsenic levels have generally been less conclusive, in part because of methodological limitations.

⁴²One study in Japan found evidence of an increase in lung cancer incidence with increased consumption of foods containing arsenic. In addition, one study in Chile suggests that ingestion of arsenic in utero or in early life increases the risk of lung cancer mortality, and a study in the United States found a relationship between increased urinary arsenic levels and lung cancer mortality.

levels of arsenic compared to those that are not based on studies in Argentina, Chile, and Taiwan.⁴³

NRC reported that there was moderate evidence of association between the long-term ingestion of various levels of arsenic from water or dietary sources such as rice, and adverse health effects, although some studies found evidence of an association and others did not. Adverse health effects include, for example, neurodevelopmental toxicity and pregnancy outcomes related to infant illness, disease, or injury.⁴⁴ NRC also reported that there was limited evidence of an association between the long-term ingestion of arsenic from water and dietary sources and adverse health effects, such as liver and pancreatic cancer and renal disease.

We analyzed 14 scientific reviews, published since NRC's 2013 report, from January 2015 through early June 2017, that generally have supported NRC's conclusions that long-term ingestion of arsenic is associated with the above-mentioned health effects. Two reviews reporting additional evidence related to cardiovascular disease suggested that there may be a threshold—an arsenic level below which there is no significant occurrence of cardiovascular disease.⁴⁵ However, one of these reviews noted that the number of studies they examined was small, among other limitations. Regarding lung cancer, another recent review proposed a dose-response relationship, which NRC identified as a gap in the understanding of this adverse health effect.⁴⁶ However, this review noted that the studies it included did not distinguish between the risk of lung cancer in smokers and non-smokers, which NRC reported may be a

⁴³Officials from the National Cancer Institute provided us with a 2016 study that found a dose-response relationship between bladder cancer and ingestion of drinking water with lower levels of arsenic in the United States.

⁴⁴NRC reported that there is increasing evidence that exposure to arsenic early in life, including during the prenatal and early childhood stages, when rice products are often ingested, can affect health early or later in life. During these more sensitive life stages, exposure may not necessarily be long-term.

⁴⁵D. Phung, D. Connell, S. Rutherford, and C. Chu. "Cardiovascular Risk from Water Arsenic Exposure in Vietnam: Application of Systematic Review and Meta-Regression Analysis in Chemical Health Risk Assessment," *Chemosphere*, vol. 177 (2017); and M.S. Sidhu, K.P. Desai, H.N. Lynch, L.R. Rhomberg, B.D. Beck, and F.J. Venditti. "Mechanisms of Action for Arsenic in Cardiovascular Toxicity and Implications for Risk Assessment," *Toxicology*, vol. 331 (2015).

⁴⁶S.H. Lamm, H. Ferdosi, E.K. Dissen, J. Li, and J. Ahn, "A Systematic Review and Meta-Regression Analysis of Lung Cancer Risk and Inorganic Arsenic in Drinking Water," *International Journal of Environmental Research and Public Health*, vol. 12, no. 12 (2015).

key confounding factor. The review also cited other limitations, including the small number of studies it used to model this relationship. See appendix II for additional information about the reviews we identified.

FDA and USDA Have Taken Actions to Manage the Risk to Human Health from Arsenic in Rice

FDA and USDA have taken actions to manage the risk to human health from arsenic in rice, including assessing the type and prevalence of health effects that may result from long-term ingestion. These efforts were generally consistent with the six essential elements for managing risk, which we have found could help agencies assess threats that could affect the achievement of their goals. Specifically, FDA has taken actions that were consistent with five of the six essential elements, including: (1) aligning risk management process with goals and objectives, (2) identifying risks, (3) assessing risks, (4) responding to the risks, and (5) monitoring risks. However, FDA has not fully taken action on the sixth element of communicating and reporting on risks. FDA issued a risk assessment in 2016 for public comment and a draft guidance limiting the levels of arsenic in infant rice cereal, but it has not updated or finalized these key documents. USDA has taken actions consistent with five of the six essential elements but has not taken actions to monitor the risk because of its more limited, nonregulatory role.

Aligning Risk Management Process with Goals and Objectives

FDA and USDA have aligned their actions to manage the risk to human health from arsenic in rice to goals in their strategic plans. According to FDA officials, FDA's actions align with three of the six goals identified in the 2015–2018 research strategic plan for FDA's Center for Food Safety and Applied Nutrition, including advancing diet and health research that contributes to the development of science-based policies and communication strategies.⁴⁷ Regarding USDA's actions, ARS officials stated that their research on arsenic in rice aligned with four goals in ARS's fiscal year 2012–2017 strategic plan, such as protecting food from pathogens, toxins, and chemical contamination during production,

⁴⁷Center for Food Safety and Applied Nutrition, *Science and Research Strategic Plan, 2015–2018*. These goals are as follows: Goal 2, develop and implement screening methods for use in field laboratories to improve the capacity for detection of chemical contaminants; Goal 4, integrate and apply modern toxicological approaches to support regulatory and public health decision making on chemical hazards in foods, dietary supplements, and cosmetics; and Goal 5, advance diet and health research that contributes to the development of science-based policies and communication strategies.

processing, and preparation.⁴⁸ NIFA officials stated that the research they sponsored on arsenic in rice aligned with one of the sub-goals in NIFA's fiscal year 2014–2018 strategic plan: to reduce the incidence of foodborne illness and provide a safer food supply.⁴⁹ FGIS officials provided documentation showing that their actions aligned with one of the goals in their fiscal year 2016–2020 strategic plan: provide the environment for fair and competitive market practices between agricultural producers and buyers.⁵⁰ FDA's and USDA's actions were consistent with the essential element of aligning risk management actions to their strategic plans.

Identifying Risks

Total Diet Study

The Food and Drug Administration's (FDA) Total Diet Study, which began testing for arsenic in 1991, is an ongoing program that monitors the levels of about 800 contaminants and nutrients in the average U.S. diet. To conduct the study, FDA buys, prepares, and analyzes about 280 kinds of foods and beverages from representative areas of the country and estimates the average amounts of contaminants and nutrients the entire U.S. population, some subpopulations, and each person consumes annually. The sampling plan calls for purchasing each type of food four times a year, each time in a different region. Within each region, FDA purchases each food product from three different stores and combines them into a composite sample, for a total of four estimates each year. FDA makes results of the study, from 1991 through 2015, available to the public in electronic form on its website.

Source: GAO analysis of FDA data. | GAO-18-199

FDA and USDA have taken actions to identify the risk of arsenic in rice. FDA has identified the risk of arsenic in rice through the Total Diet Study—an annual testing of contaminants and nutrients in food. As part of conducting the Total Diet Study, FDA collects samples of certain foods, including rice, and tests them for a variety of toxic chemicals, including total arsenic. From 2014 through 2015, the most recent years for which data are available, FDA tested six different categories of rice-based foods for arsenic.⁵¹ FDA officials told us that they identified arsenic in rice as a priority based, in part, on the results of the Total Diet Study, which indicated that rice had higher levels of arsenic compared to other foods. Some university researchers we interviewed stated that the Total Diet Study would be more helpful if it measured inorganic arsenic or had a more robust methodology. For example, one university researcher noted

⁴⁸Agricultural Research Service, *Strategic Plan FY 2012–FY 2017* (Washington, D.C.: 2016). These goals are as follows: Goal 1.1, enable Americans to make health-promoting, science-based dietary choices; Goal 1.2, protect food from pathogens, toxins, and chemical contamination during production, processing, and preparation; Goal 2.1, integrated, effective, and safe water resource management; and Goal 3.1, protect, expand, and enhance the United States' crop genetic resource base, increase scientific knowledge of crop genes, genomes, biological processes and systems, and deliver economically and environmentally sound technologies that improve the production efficiency, quality, health and value of the nation's crops.

⁴⁹National Institute of Food and Agriculture, *Strategic Plan, FY 2014–FY 2018* (2014).

⁵⁰Grain Inspection, Packers and Stockyards Administration, *Strategic Plan, FY 2016–2020*. In September 2017, the programs carried out by FGIS, formerly part of the Grain Inspection, Packers and Stockyards Administration, were realigned into USDA's Agricultural Marketing Service.

⁵¹FDA included three baby foods—turkey and rice; chicken and rice; and dry rice cereal, prepared with water—as well as cooked white enriched rice, crisped rice cereal, and meatless fried rice from restaurants that serve Chinese carry-out food.

that the number of samples in the Total Diet Study is not big enough to be nationally representative. FDA officials told us that starting with the fiscal year 2018 Total Diet Study, they plan to begin testing rice-based foods for inorganic arsenic, increase the number of samples they collect, and make other improvements to the sampling methodology.

USDA officials have taken actions to identify the risk of arsenic in rice through a variety of research programs. ARS officials told us that they have conducted research on arsenic in rice under four national programs: (1) plant genetic resources, genomics, and genetic improvement; (2) water availability and watershed management; (3) human nutrition; and (4) food safety. For example, ARS researchers are examining whether changes in soil chemistry as a result of organic or conventional management practices affect arsenic levels in rice. NIFA officials stated that NIFA sponsors research on arsenic in rice through formula-based grants to universities and through competitive grants, such as those offered through the Agriculture and Food Research Initiative.⁵²

To identify what research to undertake, ARS officials told us that they typically meet with industry to identify its highest priorities. For example, ARS officials from the Delta Water Management Research Unit in Arkansas stated that they started researching arsenic in rice after participating in a joint ARS-USA Rice Federation conference in 2012.⁵³ FGIS officials told us that contaminants such as arsenic may affect the quality of a grain, such as rice, and hence its value. They stated that they work closely with the grain industry to develop new standards and tests to meet industry's needs.

Assessing Risks

FDA and USDA have taken actions to assess the risk of arsenic in rice. In 2012, FDA published its current method to detect inorganic arsenic in

⁵²The Agriculture and Food Research Initiative is a competitive grant program that supports research, education, and extension activities in six priority areas. They include (1) plant health and production and plant products; (2) animal health and production and animal products; (3) food safety, nutrition, and health; (4) bioenergy, natural resources, and environment; (5) agriculture systems and technology; and (6) agriculture economics and rural communities.

⁵³USA Rice Federation is an organization that advocates for the U.S. rice industry, including rice farmers and millers.

rice.⁵⁴ FDA officials told us that this method, though useful, is time-consuming and expensive, and the agency continues to develop other methods to reduce cost and time. For example, in 2017, FDA developed another method to detect inorganic arsenic in wine and rice that takes less time than its current method.⁵⁵ FDA officials told us they have an ongoing research project on a field-deployable method based on a commercially-available digital arsenic test kit for detecting arsenic in drinking water called the Arsenator. In addition, FDA has been using laser ablation, the process of removing a material from a solid using a laser beam so that it can be measured, as a way to study arsenic distribution in rice.⁵⁶

From 2011 through 2014, FDA conducted targeted sampling of more than 1,400 rice-based foods—including rice, rice beverages, cereals, and snacks—for inorganic arsenic. This targeted sampling and a literature review of articles published before February 2015 informed a risk assessment of arsenic in rice that FDA issued for public comment in April 2016.⁵⁷ Specifically, the risk assessment used the results of the targeted sampling to identify levels of inorganic arsenic in rice and examined available scientific information to provide quantitative estimates of lung and bladder cancer risk—that is, the number of expected lung and bladder cancer cases per million people that may be attributable to long-term ingestion of inorganic arsenic in rice and a qualitative assessment of other adverse health effects. The risk assessment also analyzed alternative approaches to reducing the risk of arsenic in rice, such as instituting limits on the allowable level of arsenic in various rice-based

⁵⁴Food and Drug Administration, *Arsenic Speciation in Rice and Rice Products Using High Performance Liquid Chromatography-Inductively Coupled Plasma-Mass Spectrometric Determination*, Elemental Analysis Manual for Food and Related Products, 4.11 (2012).

⁵⁵Gray, Patrick, J., Courtney K. Tanabe, Susan E. Ebeler, and Jenny Nelson, “A Fast and Fit-for-Purpose Arsenic Speciation Method for Wine and Rice,” *Journal of Analytical Atomic Spectrometry*, vol. 32 (2017).

⁵⁶Laser ablation is used with an analytical instrument that can measure the material, such as an inductively-coupled plasma mass spectrometer.

⁵⁷Food and Drug Administration, Center for Food Safety and Applied Nutrition, *Arsenic in Rice and Rice Products Risk Assessment Report, Version Released for Public Comment* (March 2016). 81 Fed. Reg. 19,976 (Apr. 6, 2016). FDA conducted a literature review on arsenic levels in U.S. rice and infant rice cereal published up to October 2013 as well an update of articles published from October 2013 to February 2014 on cancer-related health effects and another update of articles published from October 2013 to February 2015 on noncancer health effects for pregnant women, infants, and children.

foods, limiting the amount and frequency of consumption of rice, and cooking practices.

FDA's actions have helped assess the risk of arsenic in rice, although some stakeholders we interviewed have identified limitations to FDA's actions. For example, one rice producer noted that because FDA's current detection method is time-consuming and expensive, it is not widely used—companies only use it when tests for total arsenic reveal that the levels exceed the limit for inorganic arsenic that their customers request. Some stakeholders noted that the evidence FDA used to assess the risk of the ingestion of low levels of arsenic, which may be more relevant for rice consumption, is more uncertain.

USDA agencies have also taken actions to assess the risk by conducting research to develop faster and less expensive methods to detect inorganic arsenic in rice. In 2016, ARS developed a method using hydride generation, which uses an acid to convert the inorganic arsenic into a gas that can be detected by an instrument. ARS officials stated that they have conducted research on the hydride generation method for more than 5 years and were able to further refine the method with funding from the Rice Foundation.⁵⁸ Stakeholders from the rice industry and a university researcher we interviewed noted that, while the hydride generation method is faster and cheaper than FDA's current detection method, it is too time-consuming and expensive for commercial purposes. For example, rice mills could not keep pace with trucks lining up to unload rice if they use the hydride generation method. However, ARS officials stated that researchers may use it if they need to analyze thousands of samples and are willing to trade off some accuracy for speed and cost. In addition, FGIS conducted some of its own development work on the Arsenator. Agency officials said that they began research on the Arsenator to help provide a rapid and inexpensive method of detecting inorganic arsenic at FGIS official testing locations that could include rice mills but have suspended their efforts because representatives of the rice industry have told them that these tests are not necessary.

Responding to the Risks

FDA and USDA have taken actions to respond to the risk of arsenic in rice. In 2016, FDA issued draft guidance, which proposed an action level, recommending that the rice industry not exceed a level of 100 ppb

⁵⁸The Rice Foundation sponsors research and education programs for the rice industry.

inorganic arsenic in infant rice cereal, and FDA has conducted research on cooking methods that may reduce arsenic. In its draft guidance, FDA stated that it used its risk assessment, among other considerations, to identify the level of inorganic arsenic in infant rice cereal.⁵⁹ FDA further noted that it selected 100 ppb because of the potential for human health risks associated with inorganic arsenic and because such a level is achievable with the use of current good manufacturing practices—specifically, selecting sources of rice or rice-derived ingredients with lower inorganic arsenic levels.⁶⁰ FDA officials told us that they focused on infant rice cereal because infants are at a higher risk of experiencing some of the health effects of ingesting inorganic arsenic, such as neurodevelopmental effects, and because the diet of infants is less varied than that of adults. FDA officials noted that the proposed guidance sets a limit for infant rice cereal that is generally consistent with the limit set by the European Commission and that other types of rice sold in the United States also generally meet the Codex Alimentarius standards.

University researchers and a group representing consumers we interviewed stated that FDA's draft guidance is a good first step, but that FDA should establish limits for arsenic in other rice products, such as rice crackers and other foods that children eat. FDA officials noted that the next most susceptible group would likely be toddlers and young children, but because their diet is more diverse than that of infants, rice-based foods make up a smaller portion of their diet. FDA requested public comments on certain aspects of the draft guidance, such as its feasibility, and noted that when it is finalized, it will represent FDA's current thinking on this topic. The public comments were due to FDA in July 2016, although FDA noted that the public may comment on its guidance at any time. University researchers and stakeholders from the rice industry we interviewed stated that FDA's draft guidance has become a de facto industry standard for infant rice cereal. In 2016, FDA also published research on the effect that cooking methods, such as cooking rice in

⁵⁹Food and Drug Administration, *Inorganic Arsenic in Rice Cereals for Infants: Action Level Guidance for Industry, Draft Guidance* (April 2016). 81 Fed. Reg. 19,976 (Apr. 6, 2016).

⁶⁰A level of 100 ppb is equivalent to 100 micrograms of arsenic per kilogram of rice. In setting this level, FDA used information about the health effects of ingesting various levels of arsenic, as well as information about rice consumption patterns and levels of arsenic in rice based on its sampling efforts.

excess water, may have on reducing the level of arsenic in rice.⁶¹ FDA officials told us that they provided advice to consumers on cooking methods that could reduce arsenic in rice on the FDA website but said FDA will not direct manufacturers to change the cooking instructions for rice because the alternative methods may reduce the nutritional value of the rice.⁶²

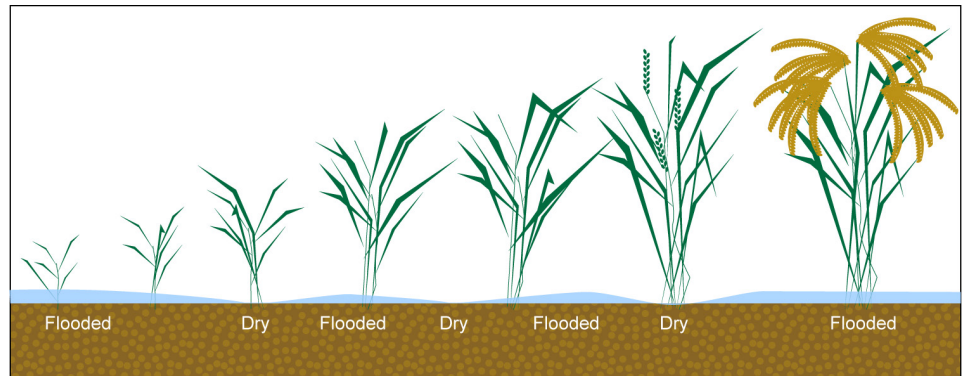
Within USDA, ARS and NIFA have sponsored published and ongoing research that can help respond to the risk, such as research on ways to reduce the uptake of arsenic by rice through new rice varieties, water management practices, and soil additives, as well as research on the genetic mechanisms underlying the uptake and transport of arsenic in the rice plant. For example, ARS has been conducting research on rice varieties that can improve yield and grain quality, including lower levels of arsenic, at the Dale Bumpers National Rice Research Center in Arkansas for more than 30 years. In 2016, university and ARS researchers published a study showing that growing rice using a water management practice called alternate wetting and drying could decrease the levels of arsenic.⁶³ Under this practice of growing rice, shown in figure 3 below, fields are periodically drained and re-flooded during the growing season.

⁶¹Gray, Patrick J., Sean D. Conklin, Todor I. Todorov, and Sasha M. Kasko, "Cooking Rice in Excess Water Reduces Both Arsenic and Enriched Vitamins in the Cooked Grain," *Food Additives and Contaminants: Part A*, vol. 33, no. 1 (2016).

⁶²Food and Drug Administration, *Questions & Answers: Arsenic in Rice and Rice Products*, accessed May 19, 2017, <https://www.fda.gov/Food/FoodbornellnessContaminants/Metals/ucm319948.htm>.

⁶³LaHue, Gabriel T., Rufus L. Chaney, Maria Arlene Adviento-Borbe, Bruce A. Linquist, "Alternate Wetting and Drying in High Yielding Direct-Seeded Rice Systems Accomplishes Multiple Environmental and Agronomic Objectives," *Agriculture, Ecosystems and Environment*, vol. 229 (2016).

Figure 3: Alternate Wetting and Drying Water Management Practice in Arkansas Rice Fields



Flooded rice field at ARS's Dale Bumpers National Rice Research Center, Arkansas



Dry field of rice at the University of Arkansas System Division of Agriculture

Source: GAO analysis of USDA data (art); GAO (photos). | GAO-18-199

Note: The U.S. Department of Agriculture's (USDA) Agricultural Research Service (ARS) and the University of Arkansas System Division of Agriculture, funded in part by USDA, conduct research on alternate wetting and drying, a water management practice illustrated above, to determine how to produce comparable rice yields to those from continuous flooding and reduce water use and levels of arsenic.

ARS officials stated that the alternate wetting and drying water management practice has been adopted to a limited extent in Arkansas, but pointed out that other benefits, such as reducing water use, may have been more influential to its adoption than the lowering of arsenic levels. They noted that there are a number of challenges that may preclude widespread use, including inadequate water-pumping capacity and the lack of crop insurance coverage for the practice. In addition, in 2015, university researchers and an ARS researcher, with a grant from NIFA, published a study on the effects of adding iron oxide to the soil on the

levels of arsenic in rice; they found that iron oxide resulted in significant reduction of arsenic for the two varieties of rice that the study examined.⁶⁴

Monitoring Risks

FDA, which is responsible for ensuring the safety of rice and rice-based foods, has taken actions to monitor the risk of arsenic in rice. USDA has not done so, because of its more limited, nonregulatory role. FDA has a compliance program designed to monitor over 1,400 products annually, including foods that are most likely to contribute to the dietary intake of toxic elements, among other contaminants.⁶⁵ In fiscal years 2015 and 2016, FDA monitored the risk of arsenic by assessing the levels in rice and rice-based foods under this compliance program, and FDA officials told us that they plan to continue to do so in fiscal years 2017 and 2018.⁶⁶ FDA officials told us that they generally test the rice for total arsenic but have recently analyzed some samples for inorganic arsenic based on factors such as the level of total arsenic found. FDA considers whether to conduct follow-up actions, including enforcement actions, on a case-by-case basis. As a result of its monitoring in 2016 and 2017 FDA considered, but did not take, two enforcement actions for arsenic in infant rice cereal. FDA officials stated that the inorganic arsenic level in one case was close to the 100 ppb limit and within the margin of error of the detection method, and in the second case, FDA determined during its follow-up to the initial sample that the manufacturer destroyed the remaining product.

USDA agencies have not monitored arsenic in rice. The Food Safety and Inspection Service is USDA's regulatory agency for food safety, but officials have told us they have not taken actions in this area because rice is not under the agency's jurisdiction. ARS maintains a food composition

⁶⁴Farrow, Eric, M., Jianmin Wang, Joel G. Burken, Honglan Shi, Wengui Yan, John Yang, Bin Hua, and Baolin Deng, "Reducing Arsenic Accumulation in Rice Grain through Iron Oxide Amendment," *Ecotoxicology and Environmental Safety*, vol. 118 (2015).

⁶⁵The Toxic Elements in Food and Foodware, and Radionuclides in Food Compliance Program focuses on sampling and analyzing foods that can be significant dietary sources of toxic elements for young children.

⁶⁶In fiscal year 2015, FDA tested eight samples of rice-based foods for arsenic; in fiscal year 2016, FDA tested 38 samples; and FDA officials provided plans to test 93 samples in fiscal years 2017 and 86 in fiscal year 2018. The samples include infant rice cereals; rice-based infant and toddler puffs and teething biscuits; and rice beverages, including those targeted to children.

database,⁶⁷ but it does not monitor rice for contaminants such as arsenic because, according to ARS officials, that is not the database's purpose. FGIS officials stated that they do not have an arsenic testing program for rice at this time. They told us that they considered establishing a testing program for rice intended for export at the request of the rice industry. However, FGIS officials stated that they suspended their efforts when industry determined that it did not need a testing program.

Communicating and Reporting on Risks

FDA and USDA have taken actions to communicate and report on the risk of arsenic in rice to the public. FDA has issued a risk assessment and draft guidance on arsenic in infant rice cereal, but it has not updated or finalized these documents. FDA's 2016 risk assessment report provides information about the risk from long-term ingestion of arsenic in rice, and its draft guidance on arsenic in infant rice cereal includes a link to an FDA website with information for consumers, including pregnant women and parents.⁶⁸ FDA has requested comments and received 22 public comments from 17 individuals and organizations on both documents. The comments have addressed a range of issues, including the methodology FDA used in its risk assessment; the 100 ppb limit and scope of the agency's draft guidance; and the effectiveness of the agency's communication to the public. However, FDA has not publicly issued versions of the guidance or the risk assessment that address these comments. In our prior work, we have found that sharing risk information and incorporating feedback from internal and external stakeholders can help organizations identify and better manage risks, as well as increase transparency and accountability to Congress and taxpayers.⁶⁹

In the risk assessment, FDA stated that it will provide an update after considering public comments and any newly-available information. For example, FDA officials told us that they plan to consider newly-available information, such as any updates to EPA's Integrated Risk Information System assessment for inorganic arsenic, and may update the risk

⁶⁷USDA National Nutrient Database for Standard Reference contains food composition data for over 8,800 food items and components, including nutrients such as fiber, minerals, protein, and vitamins.

⁶⁸FDA's website provides information to consumers and FDA's statement on testing and analysis of arsenic in rice and rice products. Food and Drug Administration, "Arsenic in Rice and Rice Products," accessed May 19, 2017, <https://www.fda.gov/Food/FoodbornellnessContaminants/Metals/ucm319870.htm>.

⁶⁹GAO-17-63.

assessment as a result. With regard to public comments, FDA officials told us that they do not intend to make any changes to the approach or findings of the risk assessment and that they are still considering whether to make changes to the draft guidance as a result of public comments. FDA officials stated that they are still reviewing comments and that, before publication, the guidance would have to undergo interagency review. FDA officials also stated that the agency is not required to provide a response to comments in the final guidance. Further, FDA officials stated that the agency does not need to finalize the guidance in order to sample foods for a contaminant or to take enforcement action when contamination may pose a health hazard.

Stakeholders we interviewed stated that updating the risk assessment and finalizing the draft guidance would improve FDA's communication of the risk. For example, some stakeholders we interviewed told us that the information used in the risk assessment—both regarding the health effects of arsenic and the levels of arsenic in rice—may need to be updated to incorporate the results of more recent research. Further, two stakeholders we interviewed—one representing the rice industry and the other representing consumers—noted that it is not clear to them what actions FDA can take based on the draft guidance. However, FDA officials could not give us a timeline for when they plan to update the risk assessment or finalize the guidance. By developing a timeline for updating the risk assessment on arsenic in rice to incorporate any newly-available information, FDA could help clarify when it will take action. Developing a timeline for finalizing the draft guidance on arsenic in infant rice cereal could also help FDA improve the transparency of its decisions—such as by clarifying the effectiveness of the draft guidance.

USDA has taken actions that can help communicate and report on the risk of arsenic in rice. ARS officials told us that they have communicated the results of their research on arsenic in rice in a number of ways, such as through presentations at conferences and through outreach to farmers, including in cooperation with extension programs at universities. For example, USDA researchers demonstrated automated irrigation systems that can be used for the alternate wetting and drying water management practice. In 2017, ARS researchers contributed to the development of a bulletin in conjunction with University of Arkansas researchers that contains recommended practices about irrigation methods that can

reduce the levels of arsenic in rice.⁷⁰ ARS officials told us that their communication efforts could help increase farmers' interest and adoption of methods they have researched. They also stated that they work with extension programs because these programs have good access to farmers.

FDA Coordinated Several Risk Management Actions with USDA and Other Federal Agencies to Varying Extents

FDA coordinated with USDA and other federal agencies on the actions to manage the risk of arsenic in rice for which coordination would be expected, to varying extents. FDA coordinated with USDA and several other federal agencies, including CDC, EPA, and NIH, on the development of the risk assessment and draft guidance on arsenic in infant rice cereal, but USDA raised concerns about the extent of the coordination. FDA and USDA coordinated to a limited extent to develop faster and less expensive methods to detect arsenic in rice.

FDA Coordinated Its Risk Assessment and Draft Guidance with Several Federal Agencies, but USDA Raised Concerns about the Extent of Coordination

FDA coordinated with several federal agencies on the development of the risk assessment and draft guidance on arsenic in infant rice cereal. According to FDA officials, in developing the risk assessment, FDA initially coordinated with EPA on two noncancer health effects—adverse pregnancy outcomes and developmental neurotoxicology effects in young children—to ensure consistency with the work EPA was doing to update its Integrated Risk Information System assessment for arsenic. When FDA completed the draft of the noncancer section of its risk assessment, the agency provided it to EPA and NIH's National Institute of Environmental Health Sciences for review. FDA incorporated comments from EPA and NIH in the risk assessment document, which EPA, CDC, and NIH subsequently reviewed. From December 2014 through June 2015, the risk assessment and draft guidance underwent HHS's clearance process. Through this process, CDC and NIH, along with HHS's Assistant Secretary for Legislation and its Office of the Assistant Secretary for Planning and Evaluation, reviewed the documents, and FDA revised the risk assessment and draft guidance to address their comments. CDC, EPA, and NIH officials told us that they were generally satisfied with FDA's coordination efforts and the extent to which FDA addressed their comments. For example, CDC officials said that the

⁷⁰University of Arkansas Division of Agriculture Research and Extension, *Rice Information: Using Alternate Wetting and Drying (AWD) Rice Flood Management* (July 2017).

agency provided FDA several rounds of comments, and by the end of the process, all of its comments had been considered.

OMB also chose to review FDA's risk assessment and draft guidance on arsenic in infant rice cereal through its interagency review process.⁷¹ According to FDA officials, as part of this process, which occurred from May 2015 through March 2016, FDA coordinated with EPA again, as well as with OMB's Office of Information and Regulatory Affairs and the U.S. Trade Representative within the Executive Office of the President, the Small Business Administration's Office of Advocacy, and USDA. Officials from the Small Business Administration's Office of Advocacy said that they were generally satisfied with the review process and characterized the outcome as typical in that some, but not all, of their suggested changes were accepted.⁷²

However, USDA officials raised concerns about FDA involving them too late in the coordination process and about the extent to which FDA addressed their comments. From May 2015 through July 2015, USDA conducted its first review of these documents and provided FDA with comments. USDA had offered to provide FDA with feedback on versions of the risk assessment on several occasions earlier in the process, but FDA did not accept USDA's offers, according to a USDA official. As discussed below, FDA chose to engage USDA later in the process.

In their comments, USDA officials expressed concerns regarding uncertainties and data limitations in the risk assessment and draft guidance on arsenic in infant rice cereal. USDA also raised questions about whether sufficient data on the link to adverse health effects existed to warrant the draft guidance. Furthermore, USDA stated that because the documents focus solely on rice, instead of addressing risks to the diet as a whole, FDA needs to share clear, consistent, and understandable messages with the public to alleviate fear and misunderstanding related to the risk posed by arsenic in rice. According to USDA officials, FDA did not adequately address their comments in the revised documents,

⁷¹According to OMB staff, OMB's Office of Information and Regulatory Affairs reviewed FDA's risk assessment and draft guidance using its authority to review significant agency guidance documents under Executive Order 12866, as clarified under OMB memorandum M-09-13 (Mar. 4, 2009), and a 2007 bulletin for agency good guidance practices (72 Fed. Reg. 16, pp. 3432-3440 (Jan. 25, 2007)).

⁷²OMB staff stated that FDA provided responses to comments and made revisions based on these comments throughout OMB's review.

including FDA's communication strategy. However, according to a senior USDA official, in its response to USDA's comments, FDA maintained that, overall, the comments it received from its external peer reviewers—five university researchers—were supportive of the risk assessment and that based on the peer review, FDA did not change its findings or conclusions. According to this USDA official, FDA also noted that there are insufficient data to accurately quantify the risk from arsenic in rice to pregnant women or children but that it decided moving forward with the draft guidance on arsenic in infant rice cereal would be prudent.

FDA and USDA did not agree on USDA's role in developing the risk assessment and the point at which they should begin coordinating on the risk assessment. FDA officials told us that FDA generally considers agencies' expertise in determining whether and when to include them in the development of risk assessments and related documents. FDA did not see USDA as having a role in developing the risk assessment; rather, FDA officials told us that they reached out to USDA after the risk assessment was drafted, when the agency began to consider how to reduce the levels of arsenic in rice during the growing process and the feasibility of industry meeting its draft guidance on arsenic in infant rice cereal. The officials said that FDA met with USDA officials on numerous occasions and invited them to attend additional meetings with various stakeholders. However, according to a senior USDA official, USDA has relevant scientific and technical expertise that should have played a role in developing the risk assessment. According to this official, if FDA had involved USDA earlier in the development process, FDA may have addressed USDA's comments to a greater extent.

We have shown in prior work that agencies can facilitate their collaborative efforts by developing a mechanism for interagency coordination, and a key issue to consider when developing such a mechanism is whether participating agencies have clarified their roles and responsibilities.⁷³ FDA officials stated that they were not aware of the existence of any mechanism for coordinating risk assessments of contaminants in food, including arsenic in rice, which among other things, could clarify the roles and responsibilities of participating agencies. FDA officials told us that they followed a 2002 report listing guiding principles when developing the risk assessment, but this report, which broadly applies to all foodborne contaminants, did not specify the process FDA

⁷³[GAO-12-1022](#).

should follow to coordinate its risk assessment.⁷⁴ However, our review of this 2002 report shows that it recommends that FDA encourage active participation and communication with other agencies and stakeholders and collaboration, when appropriate, as part of its risk assessment development process. Although FDA did reach out to USDA, those meetings were after the completion of the risk assessment. By developing a mechanism for working with relevant agencies to identify their roles and responsibilities for coordinating risk assessments of contaminants in food, including arsenic in rice, FDA could have better assurance that it fully utilizes the expertise of all participating federal agencies.

FDA and USDA Coordinated on Developing Methods to Detect Arsenic in Rice to a Limited Extent

FDA and USDA's FGIS and ARS coordinated on the development of detection methods to a limited extent. Officials from FDA and FGIS told us that they began to coordinate in March 2016, when they discovered, in the course of ongoing coordination in another area, that they were each working independently on developing a faster and less expensive detection method using the Arsenator. According to FDA officials, FDA became aware of FGIS's interest in developing methods to detect arsenic in rice during a Codex Alimentarius meeting that researchers from both agencies attended. Therefore, the avoidance of potentially duplicative effort occurred as a result of an informal discussion that occurred during this meeting. With regard to ARS, FDA officials told us that FDA did not coordinate with ARS on the development of the hydride generation method but that FDA used its own validated method to provide ARS with actual arsenic concentrations of samples to help ARS test its method. According to ARS officials, ARS did not coordinate with FDA or FGIS when developing its method on hydride generation. According to an FDA official, FDA did not coordinate the development of its current method to detect inorganic arsenic in rice, the faster method for wine and rice, or the laser ablation method with FGIS, ARS, or any other federal agency.

We have shown in prior work that many of the meaningful results that the federal government seeks to achieve, such as those related to protecting food and agriculture, require the coordinated efforts of more than one federal agency.⁷⁵ ARS officials told us that from their perspective, there was no reason to coordinate because ARS, FDA, and FGIS are trying to

⁷⁴Food and Drug Administration, Center for Food Safety and Applied Nutrition, *Initiation and Conduct of All 'Major' Risk Assessments within a Risk Analysis Framework* (2002).

⁷⁵[GAO-12-1022](#).

meet different needs with their research. Further, ARS officials told us that coordinating with FDA would blur the distinction between ARS's scientific role and FDA's regulatory role and may imply that ARS has regulatory responsibilities or expertise. However, all three agencies share a crosscutting strategic interest in developing methods for detecting foodborne contaminants, including arsenic in rice. The strategic plans for ARS and FDA's Center for Food Safety and Applied Nutrition include outcomes and strategies related to the development of detection methods for chemical contaminants or residues. Further, FGIS's strategic plan includes a strategy of developing innovative tests to measure grain quality, and according to FGIS officials, they have considered testing inorganic arsenic as part of measuring grain quality. According to FGIS officials, once they began coordinating with FDA on the Arsenator, they saw value in coordinating and did so for about 9 months before suspending work on the detection method.

We have noted in prior work that interagency mechanisms to coordinate programs that address crosscutting issues may reduce potentially duplicative efforts.⁷⁶ However, neither FDA nor USDA has such a mechanism to coordinate the development of methods to detect arsenic in rice or other methods to detect contaminants in food. FDA officials told us that the agency works with USDA research agencies on food safety in an informal manner, and USDA officials told us that they are not aware of any mechanism for coordination and that coordination with FDA generally occurs at the secretarial level because it cuts across a number of USDA agencies. Recently, we also found another example in which FDA and USDA did not coordinate in developing detection methods for other contaminants in foods. FDA and another USDA agency—the Food Safety and Inspection Service—did not coordinate in developing detection methods for drug residues in seafood.⁷⁷ By developing a mechanism to coordinate their crosscutting efforts to develop faster and less expensive methods for detecting contaminants in food, including arsenic in rice, FDA and USDA could enhance their ability to use their resources efficiently and avoid engaging in unnecessary and potentially duplicative efforts.

⁷⁶[GAO-12-1022](#).

⁷⁷[GAO-17-443](#). In that report, we recommended that FDA and USDA's Food Safety and Inspection Service coordinate and communicate in developing these methods.

Conclusions

NRC and key recent scientific reviews have indicated that long-term ingestion of arsenic may pose a significant risk to human health, and FDA and USDA have taken various actions to manage the risk to human health of arsenic in rice. Their actions are generally consistent with the essential elements we have identified for managing risk, which can help agencies assess threats that could affect the achievement of their goals. For example, both agencies have conducted research on arsenic detection methods, and FDA has issued for public comment a risk assessment on the human health effects from the long-term ingestion of arsenic in rice. In addition, according to FDA officials, because infants are at a higher risk of experiencing some of the health effects of ingesting arsenic, such as neurodevelopmental effects, and the diets of infants are less varied than that of adults, FDA issued a draft guidance regarding arsenic in infant rice cereal. However, FDA officials have not provided a specific timeline for updating the risk assessment in response to newly-available information or for finalizing the draft guidance for infant rice cereal in response to public comments. Both of these documents could help communicate to the public the risk of arsenic in rice, and updating or finalizing them could also help FDA demonstrate its commitment to increasing transparency and accountability by addressing public comments and clarifying its enforcement authority, among other things.

FDA coordinated the development and review of these key documents with several federal agencies, and these agencies were generally satisfied with FDA's coordination efforts. However, USDA raised concerns about being involved too late in the process and the extent to which its comments were addressed. By developing a mechanism for working with relevant agencies to identify their roles and responsibilities for coordinating risk assessments of contaminants in food, including arsenic in rice, FDA could better ensure that it fully utilizes their expertise. Furthermore, FDA and USDA coordinated on the development of arsenic detection methods to a limited extent. Developing a mechanism to coordinate their crosscutting efforts to develop methods to detect contaminants in food, including arsenic in rice, could help FDA and USDA manage their resources and avoid engaging in unnecessary and potentially duplicative efforts.

Recommendations for Executive Action

We are making a total of five recommendations, including four to FDA and one to USDA. Specifically:

- The Commissioner of FDA should develop a timeline for updating the risk assessment on arsenic in rice. (Recommendation 1)
- The Commissioner of FDA should develop a timeline for finalizing the draft guidance on arsenic in infant rice cereal. (Recommendation 2)
- The Commissioner of FDA should develop a mechanism for working with relevant agencies to identify their roles and responsibilities for coordinating risk assessments of contaminants in food, including arsenic in rice. (Recommendation 3)
- The Commissioner of FDA should work with USDA to develop a mechanism to coordinate the development of methods to detect contaminants in food, including arsenic in rice. (Recommendation 4)
- The Secretary of Agriculture should work with FDA to develop a mechanism to coordinate the development of methods to detect contaminants in food, including arsenic in rice. (Recommendation 5)

Agency Comments and Our Evaluation

We provided a draft of this report to EPA, HHS, OMB, and USDA for their review and comment. HHS and USDA provided written comments, which are summarized below and reproduced in appendix III and appendix IV, respectively. In addition, EPA, HHS, and USDA provided technical comments, which we incorporated as appropriate. OMB did not comment.

In its comments, HHS generally agreed with our findings and three of the four recommendations directed to it and partially agreed with the other recommendation. Specifically, HHS partially agreed with our first recommendation for FDA to develop a timeline for updating the risk assessment on arsenic in rice, noting that the evolving nature of science precludes it from committing to a specific timeline. We recognize that new scientific studies continue to add to the understanding of the risk of arsenic. However, we continue to believe that FDA should demonstrate its commitment to increasing transparency and accountability by developing a timeline to update the risk assessment, potentially in conjunction with finalizing the draft guidance on arsenic in infant rice cereal. Such an update may state that recent scientific studies or public comments have not resulted in a change to FDA's assessment of the risk.

HHS generally agreed with our findings about the actions it has taken to manage the risk from arsenic in rice and the extent of its coordination with USDA and other agencies. HHS noted that it anticipates developing a final guidance establishing an action level of 100 ppb of inorganic arsenic in infant rice cereal by the end of 2018, which will be consistent with our recommendation. HHS also noted that it will consider ways to enhance mechanisms—such as the Interagency Risk Assessment Consortium—to collaborate and coordinate in the development of risk assessments with agencies that have regulatory responsibility or specific expertise. Further, HHS stated that FDA agrees that a mechanism for better coordinating with USDA on the development of methods to detect contaminants in foods would be worthwhile. FDA will consider whether and how existing mechanisms, such as the Interagency Residue Control Group and the annual meeting with USDA's ARS and the Food Safety and Inspection Service on food safety research, could be used to improve collaboration with USDA on method development. HHS's plans to enhance or use existing interagency mechanisms may be responsive to our recommendations if they focus on enhancing coordination with other agencies that have expertise or similar goals in the areas of risk assessments and methods to detect foodborne contaminants.

In its comments, USDA generally agreed with our findings and the one recommendation we directed to it. Specifically, USDA generally agreed with our findings about the extent to which FDA coordinated with USDA on the development of methods to detect contaminants in food, including arsenic in rice. It also generally agreed with our recommendation that USDA work with FDA to develop a mechanism to do so and stated that the USDA Office of the Chief Scientist will facilitate this effort. Further, USDA noted that the Interagency Risk Assessment Consortium may be an appropriate mechanism for addressing GAO's recommendations. USDA's proposal has the potential to be responsive to our recommendation if it focuses on enhancing coordination with FDA regarding the development of detection methods for foodborne contaminants.

As agreed with your office, unless you publicly announce the contents earlier, we plan no further distribution of this report until 30 days from the report date. At that time, we will send copies to the appropriate congressional committees; the Secretaries of Agriculture and Health and Human Services; the Administrator of EPA; the Director of OMB; and other interested parties. In addition, the report will be available at no charge on the GAO website at <http://www.gao.gov>.

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

Sincerely yours,

A handwritten signature in black ink that reads "Steve D. Morris". The signature is written in a cursive, slightly slanted style.

Steve D. Morris
Director, Natural Resources and Environment

Appendix I: Objectives, Scope, and Methodology

This report examines (1) what the National Research Council (NRC) and recent key scientific reviews have reported about the effects of ingestion of arsenic on human health, (2) the extent to which the Food and Drug Administration (FDA) and U.S. Department of Agriculture (USDA) have managed the risk to human health from arsenic in rice, and (3) the extent to which FDA has coordinated with USDA and other federal agencies on actions to manage the risk. In this report, we use the term arsenic to refer to either total arsenic or inorganic arsenic. We use the term rice to encompass rice grain and products made with rice, such as infant rice cereal.

To determine what NRC and recent key scientific reviews have reported about the effects of ingestion of arsenic on human health, we analyzed NRC's 2013 report on inorganic arsenic and 14 reviews of the scientific literature published from January 2015 through early June 2017 on the human health effects of ingestion of arsenic.¹ We conducted a literature search of several research databases, such as PubMed and Toxline, to identify reviews that (1) were focused on the effects of ingestion of arsenic on human health; (2) were peer-reviewed; (3) relied on human, rather than animal, studies; (4) provided conclusions or summary statements related to more than one study, rather than just listing individual study findings; (5) included an abstract; and (6) were written in English. We assessed the scientific and statistical credibility, reliability, and methodological soundness of the reviews. We also contacted some of the authors for additional methodological information. Methodological information included, for example, criteria for selecting the studies used in the review; meta-analyses; or meta-regression approach.² It also included limitations that the authors cited for the studies they reviewed or for any analyses they conducted. We excluded articles for which we could not clearly determine the methodology. We also reviewed the authors' statements regarding conflicts of interest and determined that none of the articles should be excluded for this reason. We did not examine the references cited by these reviews as part of our analysis. We also did not

¹National Research Council, Committee on Inorganic Arsenic, *Critical Aspects of EPA's IRIS Assessment of Inorganic Arsenic: Interim Report* (Washington, D.C.: National Academies Press, 2013).

²Meta-analyses, including meta-regression, are statistical approaches that combine the results and pool the data from multiple, previous studies on a topic. These techniques allow researchers to draw conclusions and identify patterns that may not be apparent from individual studies.

examine the studies cited by the NRC. The studies we reviewed are listed in appendix II.

To determine the extent to which FDA and USDA have managed the risk to human health from arsenic in rice, we examined relevant provisions in the Federal Food, Drug, and Cosmetic Act, as amended;³ the Federal Agriculture Improvement and Reform Act of 1996;⁴ and other relevant laws, regulations, and policies. We also used the essential elements for managing risk as identified in our prior work on enterprise risk management.⁵ These include: (1) align the risk management process with goals and objectives, (2) identify risks, (3) assess risks, (4) respond to the risks, (5) monitor the risks, and (6) communicate and report on the risks. We identified information on agency actions for managing the risk from arsenic in rice by collecting documentation and interviewing officials from FDA and USDA and we reviewed the information in light of the requirements, policies, and elements. We assessed FDA's and USDA's reported actions to determine the extent to which each agency's actions aligned with these elements. In assessing FDA's and USDA's actions against these essential elements, we used the terms "consistent" and "partially consistent" to reflect the extent to which each agency's actions aligned with an essential element. A determination of "consistent" meant that the agency provided evidence that it had taken major actions in alignment with that essential element. A determination of "partially consistent" meant that the agency provided evidence that it had taken some actions in alignment with that essential element.

We also interviewed 17 stakeholders to obtain their views on the extent to which FDA's and USDA's actions managed the risk, including university researchers (academics) specializing in relevant fields such as epidemiology and soil chemistry, representatives of a consumer organization, and representatives of the rice industry, including rice mills and farms. We identified stakeholders based on suggestions from agency officials and other stakeholders; through our site visit in Arkansas' rice agricultural research and production areas and rice mills; and based on

³21 U.S.C. §§ 301, et seq.

⁴Pub. L. No. 104-127, 110 Stat. 888 (Apr. 4, 1996).

⁵GAO, *Enterprise Risk Management: Selected Agencies' Experiences Illustrate Good Practices in Managing Risk*, [GAO-17-63](#) (Washington, D.C.: Dec. 1, 2016). This report also identified good practices agencies are implementing that illustrate the essential elements of enterprise risk management.

the stakeholders' unique perspective or qualifications, such as membership in the NRC Committee on Inorganic Arsenic. The views we obtained from these interviews are not generalizable to all university researchers or consumer or rice industry organizations but they provide illustrative examples of the views of such stakeholders. Table 1 lists information about the 17 stakeholders we interviewed.

Table 1: Information about Selected Stakeholders

Stakeholder	Type of Stakeholder
1. Dr. Aaron Barchowsky, Department of Environmental and Occupational Health, University of Pittsburgh	Academic
2. Dr. Rebecca Fry, Gillings School of Global Public Health, University of North Carolina	Academic
3. Dr. Jarrod Hardke, Division of Agriculture, University of Arkansas	Academic
4. Dr. Brian Jackson, Department of Earth Sciences, Dartmouth College ^a	Academic
5. Dr. Margaret Karagas, Department of Epidemiology, Dartmouth College ^b	Academic
6. Dr. Keeve Nachman, Bloomberg School of Public Health, Johns Hopkins University	Academic
7. Dr. Ana Navas-Acien, Mailman School of Public Health, Columbia University	Academic
8. Dr. Angelia Seyfferth, Department of Plant and Soil Sciences, University of Delaware	Academic
9. Consumers Union	Consumer organization
10. Organic Trade Association	Rice industry
11. USA Rice Federation	Rice industry
12. Nestlé	Rice industry
13. Lundberg Family Farms	Rice industry
14. Producers Rice Mill, Inc.	Rice industry
15. Riceland Foods, Inc.	Rice industry
16. Vaught Farms, Inc.	Rice industry
17. Brantley Farming Company	Rice industry

Source: GAO analysis of data from selected stakeholders. | GAO-18-199

Notes:

^aDr. Jackson invited Dr. Tracy Punshon of Dartmouth College Department of Biological Sciences to join him in the interview. We incorporated her views as appropriate.

^bDr. Karagas invited Dr. Carolyn Murray of the Dartmouth Geisel School of Medicine to join her in the interview. We incorporated her views as appropriate.

To determine the extent to which FDA has coordinated with USDA and other federal agencies on actions to manage the risk to human health from arsenic in rice, we identified relevant actions and examined whether FDA developed interagency collaborative mechanisms, which we have previously reported could help to facilitate coordination between agencies.⁶ To identify actions for which the agencies shared similar goals in their strategic plans or relevant expertise and for which FDA would be expected to coordinate with USDA and other federal agencies, we reviewed relevant provisions in the Federal Food, Drug, and Cosmetic Act, as amended;⁷ the Federal Agriculture Improvement and Reform Act of 1996;⁸ other relevant laws, regulations, and policies; the current science and research strategic plan for FDA's Center for Food Science and Applied Nutrition and current strategic plans for USDA's Agricultural Research Service (ARS) and Federal Grain Inspection Service (FGIS); and information about the agencies' missions from their websites. These actions were the development of FDA's risk assessment and draft guidance on arsenic in rice and FDA's and USDA's efforts to develop detection methods for arsenic in rice. We interviewed FDA officials and reviewed documentation they provided to identify the other federal agencies and offices with which FDA coordinated the development and review of its risk assessment and draft guidance on arsenic in infant rice cereal and the development of methods for detecting arsenic in rice. These agencies and offices included ARS, the Centers for Disease Control and Prevention, the Environmental Protection Agency (EPA), FGIS, National Institutes of Health's National Institute of Environmental Health Sciences, the Department of Health and Human Services' Assistant Secretary for Legislation and Office of the Assistant Secretary for Planning and Evaluation, Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs, the Small Business Administration's Office of Advocacy, and the U.S. Trade Representative.

To determine the extent to which FDA coordinated its risk assessment and draft guidance on arsenic in rice with USDA and other federal agencies, we obtained and reviewed FDA's framework for conducting risk

⁶GAO, *Managing for Results: Key Considerations for Implementing Interagency Collaborative Mechanisms*, [GAO-12-1022](#) (Washington, D.C.: Sept. 27, 2012).

⁷21 U.S.C. §§ 301, et seq.

⁸Pub. L. No. 104-127, 110 Stat. 888 (Apr. 4, 1996).

assessments; reviewed agencies' comments on these documents;⁹ interviewed FDA officials regarding FDA's efforts to coordinate with other agencies; and interviewed officials from the Centers for Disease Control and Prevention; EPA; the National Institutes of Health; OMB; the Small Business Administration's Office of Advocacy; and USDA regarding the nature of their comments, their experiences coordinating with FDA, and the extent to which FDA addressed their comments.

To examine the extent to which FDA and USDA coordinated the development of arsenic detection methods, we obtained and reviewed documents, including those describing the detection methods that FDA, ARS, and FGIS have developed or have under development, and we interviewed officials from these agencies regarding their efforts to develop these methods and coordinate their development efforts. We also interviewed officials from these agencies to gather their views on the effectiveness of these coordination efforts. We then examined whether FDA had interagency collaborative mechanisms for the development of its risk assessment and draft guidance, and its efforts with USDA to develop arsenic detection methods. We also examined whether participating agencies clarified their roles and responsibilities. Our prior work identified this as a key issue for agencies to consider when implementing coordination mechanisms. We selected this practice because it was relevant to the challenges the agencies faced.

We conducted this performance audit from December 2016 to March 2018 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.

⁹USDA and EPA provided us with copies of their comments on FDA's risk assessment and draft guidance on arsenic in infant rice cereal.

Appendix II: Recent Reviews of the Health Effects of Ingestion of Arsenic

The following list identifies recent key reviews of the health effects of ingestion of arsenic that we analyzed.

Amadi, C.N., Z.N. Igweze, and O.E. Orisakwe. "Heavy Metals in Miscarriages and Stillbirths in Developing Nations." *Middle East Fertility Society Journal*, vol. 22, no. 2 (2017): 91-100.

Bardach, A.E., A. Ciapponi, N. Soto, M.R. Chaparro, M. Calderon, A. Briatore, N. Cadoppi, R. Tassara, and M.I. Litter. "Epidemiology of Chronic Disease Related to Arsenic in Argentina: A Systematic Review." *The Science of the Total Environment*, vol. 538, (2015): 802-16.

Karagas, M.R., A. Gossai, B. Pierce, and H. Ahsan. "Drinking Water Arsenic Contamination, Skin Lesions, and Malignancies: A Systematic Review of the Global Evidence." *Current Environmental Health Reports*, vol. 2, no. 1 (2015): 52-68.

Khanjani, N., A. Jafarnejad, and L. Tavakkoli. "Arsenic and Breast Cancer: A Systematic Review of Epidemiologic Studies." *Reviews on Environmental Health* (2017).

Lamm, S.H., H. Ferdosi, E.K. Dissen, J. Li, and J. Ahn. "A Systematic Review and Meta-Regression Analysis of Lung Cancer Risk and Inorganic Arsenic in Drinking Water." *International Journal of Environmental Research and Public Health*, vol. 12, no. 12 (2015): 15498-15515.

Mayer, J.E. and R.H. Goldman. "Arsenic and Skin Cancer in the USA: The Current Evidence regarding Arsenic-Contaminated Drinking Water." *International Journal of Dermatology*, vol. 55, no. 11 (2016): e585-e591.

Milton, A.H., S. Hussain, S. Akter, M. Rahman, T.A. Mouly, and K. Mitchell. "A Review of the Effects of Chronic Arsenic Exposure on Adverse Pregnancy Outcomes." *International Journal of Environmental Research and Public Health*, vol. 14, no. 6 (2017).

Phung, D., D. Connell, S. Rutherford, and C. Chu. "Cardiovascular Risk from Water Arsenic Exposure in Vietnam: Application of Systematic Review and Meta-Regression Analysis in Chemical Health Risk Assessment." *Chemosphere*, vol. 177 (2017): 167-175.

Quansah, R., F.A. Armah, D.K. Essumang, I. Luginaah, E. Clarke, K. Marfoh, S.J. Cobbina, et al. "Association of Arsenic with Adverse Pregnancy Outcomes/Infant Mortality: A Systematic Review and Meta-Analysis." *Environmental Health Perspectives*, vol. 123, no. 5 (2015): 412-21.

Robles-Osorio, M.L., E. Sabath-Silva, and E. Sabath. "Arsenic-Mediated Nephrotoxicity." *Renal Failure*, vol. 37, no. 4 (2015): 542-7.

Sidhu, M.S., K.P. Desai, H.N. Lynch, L.R. Rhomberg, B.D. Beck, and F.J. Venditti. "Mechanisms of Action for Arsenic in Cardiovascular Toxicity and Implications for Risk Assessment." *Toxicology*, vol. 331 (2015): 78-99.

Sung, T., J. Huang, and H. Guo. "Association between Arsenic Exposure and Diabetes: A Meta-Analysis." *BioMed Research International*, (2015).

Tsuji, J.S., M.R. Garry, V. Perez, and E.T. Chang. "Low-Level Arsenic Exposure and Developmental Neurotoxicity in Children: A Systematic Review and Risk Assessment." *Toxicology*, vol. 337, (2015): 91-107.

Von Stackelberg, K., E. Guzy, T. Chu, and B.C. Henn. "Exposure to Mixtures of Metals and Neurodevelopmental Outcomes: A Review." *Risk Analysis*, vol. 35, no. 6 (2015): 971-1016.

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

MAR 01 2018

Assistant Secretary for Legislation
Washington, DC 20201

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

Dear Mr. Morris:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "*Food Safety: Federal Efforts to Manage the Risk of Arsenic in Rice*" (GAO-18-199).

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

Sincerely,

A handwritten signature in blue ink that reads "Matthew D. Bassett".

Matthew D. Bassett
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED – FOOD SAFETY: FEDERAL EFFORTS TO MANAGE THE RISK OF ARSENIC IN RICE (GAO-18-199)

The U.S. Department of Health and Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report. The Food and Drug Administration (FDA) takes seriously its mandate to oversee the safety of domestic and imported foods, in part, through the monitoring of contaminants and the assessment of potential exposure and risk, especially for vulnerable populations. We have been testing for arsenic and other contaminants in foods for many years and using data from our monitoring activities to inform the development of interventions to minimize public health risk. As the draft report describes, based on the growing body of scientific evidence on the health risks associated with arsenic exposure and the FDA's testing of rice and rice products, we coordinated with U.S. Department of Agriculture (USDA) and other federal agencies to take steps to minimize the risk to public health. In FY 2016, following our many meetings with manufacturers of infant rice cereal and the publication of our draft guidance, we determined that only two out of 33 samples of infant rice cereal tested had inorganic arsenic levels above the proposed 100 ppb action level. As the draft report mentions, we believe our draft guidance is being used as the industry standard, and we are committed to finalizing it. FDA also is working on a proactive strategy to look broadly at toxic elements in foods, such as arsenic and lead, to be sure that our relatively limited resources are focused on areas where we could have the greatest public health impact.

We value GAO's recognition of the importance of collaborative mechanisms that facilitate coordination between the FDA, USDA, and other federal agencies to manage public health risks such as exposure to arsenic. As evidence of FDA's desire to enhance collaboration, in January, FDA and USDA announced a formal agreement to bolster coordination between the two agencies and aimed at making the oversight of food more efficient and effective in the areas of dual jurisdiction, produce safety, and biotechnology.¹ FDA also relies on ongoing collaborative and coordinating efforts in the areas of research, methods development, and risk assessments across HHS, USDA, and the Environmental Protection Agency. By coordinating and working together with other agencies in these areas, efficiencies can be achieved and each agency's specific food safety and scientific experience can be leveraged to strengthen the federal food safety system.

Recommendation 1

The Commissioner of FDA should develop a timeline for updating the risk assessment on arsenic in rice.

HHS Response

HHS partially concurs with GAO's recommendation.

The FDA is committed to using the best available science to inform and support policy decisions including regulatory actions and consumer messages on public health issues. A risk assessment approach is a useful means of transparently, systematically, and clearly addressing complex risk management questions to inform these decisions. The scope of a specific risk assessment is driven by the specific questions to be addressed. FDA's 2016 risk assessment, "Arsenic in Rice

¹<https://www.fda.gov/Food/InternationalInteragencyCoordination/DomesticInteragencyAgreements/ucm594371.htm>

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED – FOOD SAFETY: FEDERAL EFFORTS TO MANAGE THE RISK OF ARSENIC IN RICE (GAO-18-199)

and Rice Products Risk Assessment Report,” provided the scientific basis to support the regulatory actions and consumer messages. FDA continues to monitor the scientific literature to evaluate whether any new science would change the conclusions of the 2016 risk assessment, requiring FDA to update the risk assessment for the purpose of informing a change in FDA policy or consumer messages. Given the unpredictable, evolving nature of the science, however, we are unable to commit to any specific timeline. For example, and as noted in the draft report, we will continue to collaborate with EPA’s Integrated Risk Information System (IRIS) Program on their updated assessment of inorganic arsenic and will consider if EPA’s update would necessitate any changes to our risk assessment report correspondent with EPA’s findings.

Recommendation 2

The Commissioner of FDA should develop a timeline for finalizing the draft guidance on arsenic in infant rice cereal.

HHS Response

HHS concurs with GAO’s recommendation.

The FDA is committed to finalizing the draft guidance establishing an action level of 100 ppb for inorganic arsenic in infant rice cereal. FDA anticipates developing a final guidance by the end of 2018.

Recommendation 3

The Commissioner of FDA should develop a mechanism for working with relevant agencies to identify their roles and responsibilities for coordinating risk assessments of contaminants in food, including arsenic in rice.

HHS Response

HHS concurs with GAO’s recommendation.

The FDA will consider ways to enhance its mechanisms to collaborate and coordinate with other agencies in the development of risk assessments for which an agency has a regulatory responsibility and/or specific expertise. FDA has a long history of working collaboratively with other federal agencies with a food safety mission through the Interagency Risk Assessment Consortium. Established by presidential order in 1998, the Consortium is a technical resource for collaboration, efficient use of federal resources, and innovation among member agencies for the development and use of food safety risk assessments and related tools and research. FDA also will seek to enhance awareness of its ongoing risk assessments among other agencies and request they identify their roles and responsibilities with regard to these specific risk assessments.

Recommendation 4

The Commissioner of FDA should work with USDA to develop a mechanism to coordinate the development of methods to detect contaminants in food, including arsenic in rice.

HHS Response

HHS concurs with GAO’s recommendation.

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED – FOOD SAFETY: FEDERAL EFFORTS TO MANAGE THE RISK OF ARSENIC IN RICE (GAO-18-199)

The FDA continues to use formal groups/meetings, such as the Interagency Residue Control Group and the annual USDA Agricultural Research Service (ARS) and Food Safety and Inspection Service (FSIS) Food Safety Research meeting to coordinate and develop research projects. Additionally, collaborations among researchers developed through involvement with the national and international scientific community (e.g., Codex, AOAC International, and American Chemical Society) will continue to assist in the development and coordination of research. These informal collaborations were effectively leveraged in the development of both the Arsenator™ and hydride generation collaborative study. Even with these established and successful means of interaction, FDA agrees that a mechanism for better coordinating with USDA on development of methods to detect contaminants in foods would be worthwhile. FDA will consider whether and how these existing collaborations—such as the Interagency Residue Control Group, the annual meeting with USDA's ARS and FSIS on Food Safety Research, other cooperation and coordination groups—could be used to provide improved ways for collaborating with USDA on method development.

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



United States
Department of
Agriculture

Research
Education
Economics

Office
of the Under
Secretary

Room 214W
Jamie L. Whitten Building
Washington, DC 20250-0110

February 16, 2018

Mr. Steve D. Morris
Director, Natural Resources and Environment
United States Government Accountability Office
441 G Street NW.
Washington, D.C. 20548

Dear Mr. Morris:

The United States Department of Agriculture (USDA) appreciates the opportunity to review and provide comments on the draft Government Accountability Office (GAO) report to Congressional requesters GA0-18-199, "FOOD SAFETY: Federal Efforts to Manage the Risk of Arsenic in Rice" (March 2018).

The report was reviewed by the following USDA agencies: Federal Grain Inspection Service (FGIS), Agricultural Research Service (ARS), National Institute of Food and Agriculture (NIFA), Risk Management Agency (RMA), and the Office of the Chief Scientist (OCS). In general, USDA supports the GAO report.

USDA agrees with GAO, that FDA and USDA have taken important actions to manage the risk to human health from arsenic in rice. In particular, USDA ARS scientists and NIFA funded projects: 1) compared commercial rice cultivars for inorganic arsenic (iAs) accumulation in the grain for producers; 2) developed innovative water management practices that lower rice grain iAs levels for producers; 3) genetically mapped the genes responsible for iAs accumulation in rice for breeders; and, 4) developed a more rapid, lower cost method for detecting iAs levels in rice grain for industry.

The report has five recommendations for Executive Action that are addressed to FDA and USDA agencies. Recommendation 5 is specifically directed to USDA. The recommendations are:

- 1) The Commissioner of FDA should develop a timeline for updating the risk assessment on arsenic in rice.
- 2) The Commissioner of FDA should develop a timeline for finalizing the draft guidance on arsenic in infant rice cereal.
- 3) The Commissioner of FDA should develop a mechanism for working with relevant agencies to identify their roles and responsibilities for coordinating risk assessments of contaminants in food, including arsenic in rice.

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- 4) The Commissioner of FDA should work with USDA to develop a mechanism to coordinate the development of methods to detect contaminants in food, including arsenic in rice.
- 5) The Secretary of Agriculture should work with FDA to develop a mechanism to coordinate the development of methods to detect contaminants in food, including arsenic in rice.

USDA Response to GAO Recommendation 5.

The USDA is committed to strengthening the mechanisms for coordinating the development of methods to detect contaminants in food and associated risks with FDA, including arsenic in rice. Hence, the USDA Office of the Chief Scientist (OCS) will facilitate this effort, and provide the Secretary of Agriculture with annual progress reports on the coordination between USDA and FDA on the mitigation of iAs in rice. These actions support the January 30, 2018, formal Agreement U.S. Secretary of Agriculture Sonny Perdue and FDA Commissioner Scott Gottlieb, M.D. announced at the White House aimed at making the oversight of food more efficient and effective by bolstering coordination between the two agencies. The formal Agreement outlines efforts to increase interagency collaboration, efficiency and effectiveness on produce safety and biotechnology activities, while providing clarity to manufacturers.

For USDA, an important challenge in implementing the GAO recommendations (and the 2018 FDA-USDA agreement) is having a shared operational understanding of coordination. For example, the GAO statement that *"FDA and USDA did not agree on USDA's role in developing the risk assessment and the point at which they should begin coordinating on the risk assessment"* is accurate. Thus, USDA supports Recommendation 5, that USDA work with FDA to develop a mechanism for working together and coordinating research in these areas.

USDA recommends that USDA and FDA partner with the Interagency Risk Assessment Consortium (IRAC) in the coordination of GAO's recommendations. IRAC is a network of U.S. federal agencies with responsibilities and interests in developing food-safety risk-assessment tools or conducting or using food-safety risk assessments. IRAC was mandated by presidential order in 1998 to be a central coordinator and technical resource for collaboration, efficient use of federal resources, and innovation among these agencies.

For its part, the USDA ARS Food Safety Program will continue to hold its annual meeting to which FDA is invited, and participates. USDA ARS will also provide copies of the Food Safety Program annual meeting reports to Office of the Secretary for awareness. Research conducted on detection methods for residues is a major component within this meeting, including arsenic in rice. In addition, all USDA ARS Food Safety Research annual project reports are provided in an extensive document to regulatory agency stakeholders, including FDA, and will be provided to the Office of the Secretary for awareness.

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In addition, all USDA ARS and NIFA funded research undergoes external peer review and, where appropriate, requires agreement from regulatory stakeholders. For example, arsenic food safety research that included iAs detection methods development at Beltsville, MD, clearly notes involvement with FDA. Information on all USDA ARS and NIFA approved projects is available on the USDA ARS (<https://www.nal.usda.gov/fsrio>) and USDA NIFA (<https://nifa.usda.gov/>) Web sites.

Sincerely,



Chavonda Jacobs-Young, Ph.D.
Acting Deputy Under Secretary
Acting Chief Scientist, USDA

Appendix V: GAO Contact and Staff Acknowledgments

GAO Contact

Steve D. Morris, (202) 512-3841 or morriss@gao.gov

Staff Acknowledgments

In addition to the contact named above, Anne K. Johnson (Assistant Director), Ruth Solomon (Analyst in Charge), Kevin Bray, Stephen Cleary, Ellen Fried, Juan Garay, Rebecca Parkhurst, Beverly Peterson, Anne Rhodes-Kline, Sara Sullivan, Kiki Theodoropoulos, Sarah Veale, and Khristi Wilkins made key contributions to this report.

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