United States Government Accountability Office

Report to the Honorable Jon Tester, U.S. Senate

March 2016

GENETICALLY ENGINEERED CROPS

USDA Needs to Enhance Oversight and Better Understand Impacts of Unintended Mixing with Other Crops

GAO-16-241

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GAO Highlights

Highlights of GAO-16-241, a report to the Honorable Jon Tester, U.S. Senate

Why GAO Did This Study

Three agencies have primary responsibility for regulating GE crops and food in the United States: USDA, EPA, and FDA. USDA and industry groups estimate that at least 90 percent of many major commercial crops, such as corn and soybeans, are GE varieties. Proponents say GE crops offer greater pest resistance, use less labor-intensive processes to control weeds, and result in increased productivity to feed growing populations. Opponents cite a lack of consensus on impacts to agriculture, the environment, and human health.

GAO was asked to review oversight and information on GE crops. This report examines (1) steps EPA, FDA, and USDA have taken to regulate GE crops; (2) the data USDA has on the extent and impact of unintended mixing of GE and non-GE crops, and what steps have been taken to prevent such mixing; and (3) the extent to which USDA, EPA, and FDA provide information to the public on GE crops. GAO analyzed legislation, regulations, and agency policies and reports and interviewed agency officials and stakeholders, including representatives from the biotechnology and food industries and consumer, farm, environmental, and commodity groups.

What GAO Recommends

GAO recommends, among other things, that USDA set a timeline for updating its regulations and include farmers growing identity-preserved crops in its survey efforts to better understand the impacts of unintended mixing. USDA generally agreed with these recommendations.

View GAO-16-241. For more information, contact Steve D. Morris at (202) 512-3841 or morriss@gao.gov.

What GAO Found

The Environmental Protection Agency (EPA), Food and Drug Administration (FDA), and U.S. Department of Agriculture (USDA), have taken steps to regulate genetically-engineered (GE) crops (i.e., crops whose genetic makeup has been modified), but USDA has not updated its regulations to oversee GE crops derived from alternative technologies in which the GE crop developed contains no plant pest DNA. EPA regulates certain GE crops as part of its pesticide registration process. FDA, through its voluntary consultation process, works with companies that develop GE crops to consider food safety issues. EPA and FDA apply the same legal authorities and oversight processes to regulate GE and non-GE crops, regardless of how a GE crop was developed. Conversely, USDA's GE crop regulations pertain only to crops for which the donor, vector, or recipient of genetic material is a plant pest. In 2008, USDA took steps to update its regulations to capture GE crops developed with alternative technologies. However, in February 2015, USDA withdrew its proposed rule because, in part, the scope of this rule was not clear. USDA still intends to update its regulations, but has not established a timeline for doing so. GAO's body of work has shown that without milestones and interim steps it can be difficult for an agency to set priorities, measure progress, and provide management a means to monitor the agency's progress in promulgating a new rule. In addition, until a rule is finalized USDA will continue to lack regulatory authority to assess the potential risks, if any, posed by GE crops created with alternative technologies.

USDA has limited data on the extent and impact of unintended mixing of GE and non-GE crops, according to USDA officials and stakeholders. USDA officials said that the agency has generally not collected information on unintended mixing in past farmer surveys because no specific request had been made to obtain this information. In a 2012 report, the USDA Advisory Committee on Biotechnology and 21st Century Agriculture (AC21) recommended that the agency fund or conduct research, including quantifying actual economic losses (e.g., loss of a premium price for an organic crop), incurred by farmers as a result of unintended mixing. In its 2014 Organic Survey, USDA surveyed organic farmers on economic losses from unintended GE presence in their crops offered for sale. The survey results indicated that economic losses caused by unintended GE material in organic crops offered for sale exist, although at very small levels. However, USDA does not have similar data for farmers using non-GE seed and marketing their crops as identity-preserved (i.e., a specific genetic variety of a crop). USDA officials said identity-preserved crop acreage is significantly greater than organic crop acreage. Without including farmers growing identity-preserved crops in addition to those growing organic crops in its survey efforts, USDA is missing key information on the potential economic impacts of unintended mixing. Nonetheless, USDA has taken some steps to address unintended mixing, such as reviving AC21, as have farmers and the agribusiness industry.

USDA, EPA, and FDA provide varying degrees of information about their oversight of GE crops to the public. USDA and EPA regularly provide information and updates on actions relating to their oversight of GE crops on their websites and use a number of mechanisms to obtain public input on their actions. FDA provides information on GE crops relating to its consultation process.

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Abbreviations

AC21	Advisory Committee on Biotechnology and the 21st Century Agriculture
APHIS	Animal and Plant Health Inspection Service
BRS	Biotechnology Regulatory Services
DNA	deoxyribonucleic acid
EPA	Environmental Protection Agency
ERS	Economic Research Service
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FOIA	Freedom of Information Act
GE	genetically engineered
NASS	National Agricultural Statistics Service
OMB	Office of Management and Budget
PPA	Plant Protection Act
USDA	U.S. Department of Agriculture

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
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March 15, 2016

The Honorable Jon Tester
United States Senate

Dear Senator Tester:

Many large-scale commercial crops grown in the United States are predominantly genetically engineered (GE) varieties, that is, their genetic makeup has been modified through the use of modern biotechnology.[1] The U.S. Department of Agriculture (USDA) and industry groups estimate that over 90 percent of the corn, soybeans, and cotton and a substantial percentage of canola and sugar beets planted in the United States are GE varieties. Authoritative scientific bodies, such as the National Academy of Sciences, have issued reports stating that foods and food ingredients derived from GE crops pose no greater food safety risk than their non-GE counterparts.[2] Proponents of GE crops have cited a number of benefits, including a less labor-intensive process to control weeds, increased crop productivity to feed growing populations, and greater crop resistance to pests. Proponents also have said such crops contribute to more environmentally friendly food production by requiring less tilling of the soil, meaning less erosion and water use, and a reduced carbon footprint. Opponents have cited the lack of consensus on the potential impacts of GE crops on agriculture, the environment, trade, and human health. Among their concerns are the potential for insects and weeds to develop greater resistance to pesticides that are used in conjunction with a GE crop, the spread of GE pollen to non-GE crops and seed supplies, economic impacts from the potential disruption of domestic and international markets for non-GE crops and related foods, and possible human health risks associated with consuming foods derived from GE crops and the pesticides applied to them.

[1]Biotechnology is defined in this report as the use of organisms or cells to develop products that are technically, scientifically and clinically useful, and genetic engineering is a central focus. Modification through modern biotechnology involves recombinant DNA techniques, which involve recombining DNA, or the genetic or hereditary material in cellular organisms.

[2]Institute of Medicine and National Research Council of the National Academies, *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects* (Washington, D.C.: July 28, 2004).

Furthermore, as demand for foods derived from organic and non-GE ingredients has increased, so have concerns about the mixing of GE and non-GE crops and the unintended spread of genetic traits into the environment that might have unanticipated consequences for plants and animals. Some consumer groups have advocated for mandatory labeling of all foods containing ingredients derived from GE crops to allow consumers to know what is in their food. Opponents of labeling have said that such mandatory labeling would cause confusion among consumers and suggest a food safety risk that does not exist. Legislation has been introduced at both the federal and state levels relating to labeling of foods derived from GE ingredients. A number of bills have been introduced in the 114th Congress related to labeling foods containing ingredients derived from GE crops,[3] and, according to the National Conference of State Legislatures, lawmakers in more than 30 states have introduced legislation on GE labeling as of July 2015.

Three federal agencies have primary responsibility for regulating GE crops and food in the United States: USDA, the Environmental Protection Agency (EPA), and the Department of Health and Human Services's Food and Drug Administration (FDA). USDA is responsible for assessing whether GE crops pose a risk as "plant pests" that could directly or indirectly harm plants. To accomplish this, under the statutory authority of the Plant Protection Act, USDA regulates to detect, control, and prevent spread of plant pests including preventing the unintended release of regulated GE crops into the environment; such a release could occur when a developer tests the crop in a field trial. USDA may, upon finding that a crop does not pose a potential plant pest risk, grant a petition to deregulate the crop, meaning that it can be moved or released without agency oversight. EPA is responsible for regulating all pesticides, including those produced by plants that have been genetically modified to protect themselves from insects, bacteria, and viruses. USDA and, to a lesser extent, EPA exercise oversight of the thousands of field trials in which developers have tested new varieties of GE plants since 1987. FDA is responsible for ensuring the safety of most of the nation's food supply. With respect to GE crops, FDA encourages companies to

[3]For example, these bills include Genetically Engineered Food Right-to-Know Act, S. 511, 114th Cong. (2015); Genetically Engineered Food Right-to-Know Act, H.R. 913, 114th Cong. (2015); and Safe and Accurate Food Labeling Act of 2015, H.R. 1599, 114th Cong. (2015). Hearings have been held on this issue and H.R. 1599 was passed by the House in July 2015.

voluntarily submit safety data on new food or feed derived from GE crops before it is marketed.

Given the continued debate concerning the nature and extent of agricultural and environmental benefits and challenges of GE crops, as well as the related food safety assessment issues, you asked us to review the oversight of and information on GE crops. This report examines (1) the steps EPA, FDA, and USDA have taken to regulate GE crops, including those derived from alternative technologies; (2) the data USDA has on the extent and impact of unintended mixing of GE and non-GE crops, and what steps, if any, have been taken to prevent such mixing; and (3) the extent to which USDA, EPA, and FDA provide information to the public on GE crops they oversee. In this report, we define alternative technologies as those in which the GE crop developed contains no DNA of a plant pest, such as a bacterium or virus. This includes technologies in which a plant pest may have been used initially as part of the GE crop development process. It also includes technologies that do not use plant pests at all.

To determine how federal agencies have regulated GE crops derived from alternative technologies, we interviewed officials from USDA, EPA, and FDA, as well as representatives from 35 external stakeholder groups, using a standard set of questions. Stakeholders represented biotechnology, food industry, consumer, environmental, farm, and commodity producer groups and academia. They were identified during the course of our work and through the "snowball sampling" technique.[4] We selected these stakeholders to ensure that we captured a broad spectrum of views. We did not evaluate the underlying science, including the inherent safety or efficiency, of alternative GE technologies.

To examine what data, if any, exist on unintended mixing of GE and non-GE crops, we obtained USDA's strategic plans and reports, including USDA's 2012 Advisory Committee on Biotechnology and 21st Century Agriculture report with recommendations addressing the mixing of GE and non-GE crops. We also conducted a literature search and review to identify studies on the actual or potential impacts of GE crops on other

[4]In snowball sampling, the unit of analysis is a person. This methodology begins with an initial list of contacts, and asks each person interviewed to refer the interviewer to additional cognizant persons. The group of referred contacts (or "snowball") grows larger and then narrows as a group of individuals are identified frequently.

crops. We interviewed USDA officials who regulate, oversee, or set standards for cultivation, shipping, handling, and packing of major commodity crops, to determine the extent of USDA's role, if any, with respect to addressing the unintended mixing of GE and non-GE crops. We also interviewed stakeholders identified in our first objective to determine non-governmental roles in preventing the unintended mixing of GE and non-GE crops in the supply chain, from production to market, including the storage and shipping infrastructure. We did not review GE crops regulated under USDA's permit and notification field trial processes, or the extent to which these crops are affecting the supply chain, as USDA's Inspector General was reviewing these subjects at the time of our work.[5] Instead, the focus of our report is on those GE crops that have been deregulated and are available for commercialization. To determine the extent to which USDA, EPA, and FDA are providing the public with information on GE crops, we examined the extent to which that information is disseminated publicly in agency documents and on agency websites, interviewed agency officials, and examined any requirements and agency efforts to be transparent about how the agencies reached regulatory or policy decisions related to GE crops.

We conducted this performance audit from August 2014 to March 2016 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

Genetic engineering refers to a modern set of tools that can be used for precisely modifying the genetic makeup of crops, animals, or microorganisms in order to introduce, remove, or rearrange specific genetic material conferring desired traits. Genetic engineering techniques allow for faster development of new crop varieties, since the gene or genes for a given trait of interest can be readily incorporated into a plant or animal species to produce a new variety. GE varieties have been developed for many crops, plants, trees, and flowers. As of October 2015,

[5]U.S. Department of Agriculture, Office of Inspector General, *Controls Over APHIS' Introduction of Genetically Engineered Organisms*, 50601-0001-32 (Washington, D.C.: Sept. 22, 2015).

USDA had deregulated 118 GE plants, with corn, soybeans, and cotton being the most prevalent. Common classes of traits engineered into crops include insect resistance, herbicide tolerance, resistance to viruses, and other changes to enhance product quality. A number of different techniques can be used to modify organisms. To date, genetic engineering has relied extensively on the use of a particular bacterium to introduce traits into plants. To do this, developers remove the elements of the bacterium harmful to the plant, for example, and use the disarmed bacteria to insert new genetic material to facilitate the desired genetic change.[6] The bacterium used to introduce genes is not the only plant pest involved in genetic engineering. Small segments of DNA from plant viruses are sometimes inserted into GE crops to control the expression of genes of interest. Some of the bacteria and viruses used in genetic engineering to transfer genetic material into crops are defined as plant pests under USDA's regulations, meaning that they can directly or indirectly injure or cause disease or damage to plants.

In addition to bacterial transformation, it is possible to introduce genes with physical technologies. These technologies include particle bombardment (e.g., gene gun, or biolistics, where particles are coated with DNA containing the desired traits and shot into the target cells), and electroporation (the application of an electric current to a cell membrane in order to open a channel through which DNA may pass). Developers have also found many genetic sequences from plants that perform the same function as the aforementioned plant virus genes, that is, they control the expression of the introduced genes of interest. Thus, it is possible to produce genetically engineered plants that do not contain plant pest genetic sequences, according to USDA officials.

Alternative technologies, in particular genome editing technologies, have come into more widespread use. In many cases, crops produced using some of these alternative technologies cannot be distinguished from their non-GE counterparts. These alternative technologies tend to be more

[6]Most GE crops used a bacterium known as *Agrobacterium* to move genetic material into the crops. Genetic engineering became practical when scientists discovered that as part of its natural life cycle, *Agrobacterium* entered a plant cell and inserted some of its own DNA into the plant DNA. With this new genetic material, the plant produces enzymes and other material that benefit the bacterium. Human genetic engineering of crops became possible when scientists discovered it was possible to provide the genetic material *Agrobacterium* inserted into the plant instead of allowing *Agrobacterium* to insert its own genetic material.

precise and efficient. These technologies are distinguished by the use of artificial versions of nucleases, or "molecular scissors," that cut DNA at specific locations, which is a cornerstone of the newer genetic engineering technologies. Genome editing can be used to create deletions, substitutions, and gene insertions. These technologies also do not necessarily require use of a plant pest to introduce genetic changes.

GE and Non-GE Crops in the Supply Chain

GE crops may become unintentionally mixed with non-GE crops at various points in the supply chain, from production to market.[7] Cross-pollination is a natural process that some crops depend on for reproduction that can result in unintended mixing at the farm level when pollen from one crop fertilizes plants in a nearby field. For example, GE pollen may drift to a nearby non-GE field and fertilize those crops, and the resultant seeds and associated crops may have unintended GE traits when planted. This is especially true for cross-pollinated crops, such as corn, but much less true for a crop like soybeans that is primarily self-pollinated. But since corn pollen can move relatively long distances, and since corn plants naturally cross-pollinate, non-GE corn may be pollinated by GE corn if these crops are planted close enough to each other. Commingling is unintended mixing that occurs after crops are harvested, when GE crops or their residue accidentally come into contact with non-GE crops during transport, storage, handling, or processing. For example, if a railcar transports GE grains one day and then non-GE grains the next day, there is a chance that residual traces of the GE crop shipment could end up in the non-GE shipment. Since GE and non-GE crops are generally indistinguishable in appearance, it is difficult to prevent commingling without segregation methods. For purposes of this report, we are referring to both cross-pollination and commingling as unintended mixing.

The Advisory Committee on Biotechnology and 21st Century Agriculture (AC21) was originally established in 2003 and was charged with providing guidance to USDA on issues, identified by the Office of the Secretary, including examining the long-term impacts of biotechnology on the U.S. food and agriculture system and recommending how USDA might address those impacts. In 2011, the Secretary of Agriculture revived

[7]The National Institute of Standards and Technology has defined "supply chain" to mean a set of organizations, people, activities, information, and resources for creating and moving a product or service from suppliers to an organization's customers.

AC21 to address, among other things, what types of compensation mechanisms, if any, would be appropriate to address economic losses by farmers in which the value of their crops is reduced by unintended GE presence (unintended mixing of GE and non-GE materials), and what would be necessary to implement such mechanisms. Unintended mixing may result in economic losses by farmers, for instance, if pollen from a field of GE corn drifts and pollinates non-GE corn in a neighboring field and the resulting grain is harvested. In this case the non-GE farmer may receive a lower price for the crop or the shipment may be rejected by a buyer if the shipment exceeds a predetermined level of GE content. AC21 comprises of representatives from a cross-section of the agricultural community, including farmers, seed companies, food manufacturers, organic farming organizations, state government, biotechnology companies, and medical professionals.

AC21's recent focus has been to strengthen coexistence, meaning the ability of the agriculture sector to maintain different production systems. Coexistence specifically involves the concurrent cultivation of non-GE crops (e.g., conventional,[8] organic, and identity-preserved) and GE crops. AC21 defined identity-preserved crops as those of an assured quality in which the identity of the material is maintained from the germplasm or breeding stock to the processed food product on a retail shelf. Coexistence issues arise when the production-related activities of one farmer affect another farmer, potentially resulting in costs for the other farmer. Farmers could adopt measures to prevent mixing of GE and non-GE crops, such as using buffer zones between different crop types, which may result in smaller yields and additional costs because of the acreage taken out of production to create the buffer zone.

Key Statutes and Responsible Agencies Overseeing GE Crops

Three federal agencies share responsibility for overseeing GE crops—USDA, EPA, and FDA. Each agency has specific responsibilities for certain activities with GE crops, but not all of the agencies are necessarily involved in overseeing each activity or use of a GE crop. The agencies apply their general authorities under statutes that are relevant to each

[8]AC21 defined conventional crops as those produced from non-GE crop varieties that are not produced in compliance with the requirements of the Organic Foods Production Act of 1990 and that may be grown with the intent of entering the general commodity stream, in which case they may be mixed with GE varieties of the crop, if commercial GE varieties exist.

agency's responsibilities for overseeing GE crops specifically, as shown in table 1.

Table 1: Key Statutes Relevant to the Regulation of GE Crops

Statute	Relevance to the regulation of GE crops
Plant Protection Act	Authorizes the Secretary of Agriculture to regulate the importation or movement in interstate commerce of plants and articles, including GE crops that might introduce or disseminate a plant pest or noxious weed.
Federal Insecticide, Fungicide, and Rodenticide Act	Authorizes the EPA Administrator to register pesticides and regulate the distribution and use of nonregistered pesticides, which would include those genetically engineered into plants.
Federal Food, Drug, and Cosmetic Act	Authorizes the Secretary of Health and Human Services (delegated to FDA) to regulate food, animal feed, additives, and human and animal drugs, which would include those derived from biotechnology such as GE crops.

Legend: EPA = Environmental Protection Agency; FDA = Food and Drug Administration; GE = genetically engineered.
Source: GAO. | GAO-16-241

Under the Plant Protection Act (PPA), USDA is responsible for preventing the importation or dissemination of plant pests and noxious weeds into or within the United States. A noxious weed is any plant or plant product that can injure or cause damage to crops, livestock, interests of agriculture, public health, or the environment, among other things. USDA may prohibit or restrict the importation, entry, export, or movement in interstate commerce of, among other things, GE crops that might introduce or disseminate a plant pest or noxious weed.[9] Under its regulations, USDA allows individuals, including GE crop developers, to petition the agency to determine deregulated status for a GE crop if enough evidence has been collected showing that it poses no more of a plant pest risk than the equivalent non-GE crop, and it is not designated as a noxious weed. If USDA deregulates a GE crop, it is no longer subject to the restrictions of the plant pest provisions of the regulations relating to GE crops. However, USDA could later find the GE crop to be a plant pest or noxious weed on the basis of new data or analysis, and place restrictions on the importation, entry, export, or movement of the GE plant.

[9]See 7 C.F.R. pts 340, 360.

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is responsible for regulating the genetic materials engineered into a crop to produce pesticides that ward off insects, bacteria, and viruses, as well as the pesticidal substance that the crop ultimately produces.[10] These are known as plant-incorporated protectants.[11] As with conventional chemical or biological pesticides, EPA regulates the sale, distribution, and use of GE pesticides, and they must be registered before they are distributed or sold. In addition, EPA regulates the sale, distribution, and use of pesticides used in conjunction with GE crops engineered to be tolerant to those pesticides.

Under the Federal Food, Drug, and Cosmetic Act (FFDCA), FDA regulates to ensure the safety of most of the food supply, while USDA, under its authority, is responsible for the safety of meat, poultry, processed egg products, and catfish. FDA regulates to ensure the safety of foods and food products from plant sources, including food from GE crops, which must meet the same requirements as foods from non-GE crops. FDA also has in place a voluntary premarket consultation program and encourages developers of GE crops to consult with the agency before marketing their products.

[10]FIFRA defines a pesticide in part as any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.

[11]Plant-incorporated protectants are referred to in this report as GE pesticides.

EPA, FDA, and USDA Have Taken Steps to Regulate GE Crops, but USDA Has Not Updated Its Regulations to Oversee GE Crops Derived from Alternative Technologies

EPA, FDA, and USDA, generally have taken steps to regulate GE crops, including those derived from alternative technologies, but USDA has not updated its regulations to oversee all GE crops. EPA and FDA officials said that they apply the same legal authorities and oversight processes to regulate GE crops from alternative technologies that they do for other GE and non-GE crops, regardless of how they are derived. Conversely, USDA's regulations pertaining to GE crops address only GE crops for which the donor, vector, or recipient of genetic material is a plant pest. Although USDA proposed revising its regulations pertaining to the importation, interstate movement, and environmental release of certain genetically engineered organisms in 2008 to bring the regulations into alignment with the PPA and update the regulations in response to advances in genetic science and technology, it later withdrew its proposed rule. However, according to USDA officials, the agency needs to update its regulations to also subject GE crops that either do not use plants pests or use plant pests but do not result in plant pest DNA in the GE crop developed to the same restrictions and requirements as GE crops for which the donor, vector, or recipient of genetic material is a plant pest.

EPA and FDA Apply the Same Legal Authorities to Oversee GE Crops Derived from Alternative Technologies as They Do for Non-GE Crops and GE Crops from Other Technologies

EPA officials said that they regulate all pesticides, including those engineered into crops (GE pesticides) using the same legal authorities regardless of how they are derived, and FDA officials said that they apply the same legal authority to regulate GE crops from alternative technologies that they do for non-GE crops.[12] Accordingly, EPA uses the same oversight process to regulate GE pesticides engineered into crops using alternative technologies that it does for GE pesticides engineered into crops using other technologies. FDA's program to voluntarily work with companies to consider food safety issues is followed for any type of GE crop brought to FDA for consideration, regardless of the technology used to develop it, according to FDA officials.

EPA

EPA regulates a GE pesticide in a crop when it meets the definition of a pesticide under FIFRA and is intended for such use, regardless of how

[12]According to FDA officials, whether a GE crop variety is regulated under USDA's statutory authority has no bearing on whether food derived from the crop is regulated by FDA. FDA has statutory authority over food from all crop varieties, both GE and non-GE.

the pesticide was created or the technology used to develop it.[13] EPA officials stated that as new GE technologies are developed, many will eventually make their way to EPA for analysis and consideration as part of the pesticide registration process. For example, in May 2010 EPA registered a GE pesticide based on the plum pox virus. This pesticide was engineered into varieties of the European plum tree to give the tree the ability to resist the virus, which affects the quality of fruits and can leave infected trees unable to produce fruit. This GE pesticide was developed based on ribonucleic acid interference.[14] According to EPA officials, EPA considers this a pesticide because it was designed to defeat a virus, and therefore it mitigates a pest.[15] EPA officials said they will evaluate GE pesticides using alternative GE technologies on a case-by-case basis as they are brought to EPA for pesticide registration.

Before EPA can register a pesticide, a company must provide data demonstrating that the pesticide will not pose unreasonable risks to human health or the environment when used in accordance with widespread and commonly recognized practice. According to EPA documents and officials, when assessing the potential risks of pesticides—including those that are GE pesticides—EPA requires studies from applicants examining factors such as potential risks to human health, environmental fate and effects (e.g., potential for gene flow to non-GE crops), and the need for management plans to mitigate the potential development of pest (e.g., insect or weed) resistance in the field. EPA officials stated that they follow the process outlined in an internationally accepted guideline issued by the Codex Alimentarius Commission for risk

[13]Under EPA regulations, pesticides derived from GE crops are referred to as plant-incorporated protectants, which are pesticidal substances produced by plants and the genetic material necessary for the plant to produce the substance.

[14]Ribonucleic acid is found in all cells and transmits information from genes to the machinery the cell uses to produce proteins. Ribonucleic acid interference involves shutting down the expression of a gene by interrupting the transmission of the information from that gene by the ribonucleic acid. In the case of the European plum tree, the GE pesticide is a ribonucleic acid sequence that identifies the plum pox virus when it enters the plant and causes it to be degraded.

[15]In contrast, over 90 percent of the GE pesticides in crops EPA has reviewed are those containing genes that express a toxin from the soil bacterium *Bacillus thuringiensis (Bt)*. This toxin acts as a pesticide intended to ward off insect pests.

assessment when examining new genetic material that has been introduced into a plant.[16]

FDA

FDA regulates to ensure the safety of foods, including foods derived from GE crops, under the FFDCA and its implementing regulations. Foods derived from plant varieties developed through genetic engineering are subject to the same safety requirements as foods derived from non-GE crops. In May 1992, FDA established its policy regarding the review of GE foods in its *Statement of Policy: Foods Derived from New Plant Varieties*. This policy describes the kinds of assessments FDA recommends that companies perform to ensure that foods and feeds from new plant varieties are as safe as comparable foods and feeds already on the market, and otherwise do not raise regulatory concerns. In its 1992 policy, FDA stated that it was not aware of any information that showed foods from GE crops, as a class, were different from comparable foods in a meaningful or uniform way or that they have a different or greater safety concern than foods developed by non-GE plant breeding. FDA officials said that the basic principle as expressed in the agency's 1992 policy is that the traits and characteristics of foods should be the focus of safety assessments for new varieties of food crops, not the technologies used to develop them.[17] In addition, FDA has the authority under the FFDCA to seek an order to remove any food—including any foods derived from GE crops—from the market if the food is unsafe, or adulterated, under the law. FDA can also seek sanctions against those marketing such a food. According to documentation available on FDA's website, FDA's priority is to ensure that all foods, including those derived from GE crops, are safe and otherwise in compliance with the FFDCA and applicable regulations.

In 1995, FDA established a voluntary premarket consultation process, through which companies are encouraged to notify the agency before

[16]Codex Alimentarius Commission, *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (Codex Plant Guideline, CAC/GL 45-2003). The Codex Alimentarius Commission is a body that was established in November 1961 by the Food and Agriculture Organization of the United Nations, whose goals include protecting the health of consumers and ensuring fair practices in the international food trade. The Codex Alimentarius is a collection of internationally recognized standards, codes of practice, guidelines, and other recommendations relating to foods, food production, and food safety, and this guideline is considered the global standard for the safety assessment of foods derived from GE plants.

[17]According to FDA officials, the method by which food is produced or developed may in some cases aid in understanding the safety or nutritional characteristics of the finished food.

marketing a food produced from a GE crop and voluntarily submit a summary of the developer-performed safety assessment that, among other things, (1) identifies distinguishing attributes of new genetic traits, such as the source and function of the genetic material, the purpose of the modification, and the estimated concentration of the new material in food derived from the GE crop; (2) provides information regarding whether any new material in food made from the GE crop is known or suspected to be a toxin or allergenic, and the basis for concluding that the GE-derived food can be safely consumed; and (3) compares the composition or characteristics of GE-derived food to that of its non-GE counterpart with special emphasis on important nutrients and toxins that occur naturally in the food. FDA scientists then evaluate this safety assessment, which includes tests done by the developer, to determine whether it contains sufficient information to conclude that the developer has addressed all matters relevant to the safety and regulatory status of the GE food.[18] FDA officials said that such testing provides a way to detect undesirable traits at the developmental stage and defer marketing until any concerns are resolved. When FDA's team of scientists is satisfied with the developer's submission and has no further questions regarding safety or other regulatory issues based on the developer's information, the consultation is considered complete, and FDA provides a letter to the developer stating that it has no further questions. Although the consultation process is voluntary, according to FDA documentation and agency officials, it is the agency's experience that companies developing foods and feeds do not commercially market food or feed from their GE crops until they have received this letter or have satisfied any other agency requirement, if applicable.[19] As of November 2015, 108

[18]FDA officials said that their approach to safety assessments for foods derived from GE crops is consistent with the approach outlined in the guideline issued by the Codex Alimentarius Commission. The developer submissions FDA receives incorporate elements of the guideline, such as a molecular characterization and a safety assessment of the new substance.

[19]According to FDA officials, there can be cases where processes other than voluntary consultations are more appropriate or are required, such as a new dietary ingredient notification or submission of a food additive petition. A new dietary ingredient is one not marketed in the United States in a dietary supplement before October 15, 1994. A marketer of such an ingredient must submit information to FDA that a dietary supplement containing the new ingredient will be reasonably expected to be safe when used as intended. A food additive petition is submitted to FDA by a manufacturer or other sponsor to establish that a food additive is safe and accomplishes its intended use. Under this process, the safety of an additive does not need to be established with absolute certainty; instead, the regulations provide a science-based standard of safety, requiring a reasonable certainty that no harm will result from the intended use of an additive.

voluntary premarket consultations had been completed representing more than 150 different crop varieties, according to FDA's website and FDA officials, and FDA officials said they are not aware of any GE product intended for marketing that has not first gone through FDA's voluntary consultation process—that is, developers expected to consult with FDA prior to marketing have been doing so.

USDA's Regulations Do Not Allow for Assessment of GE Crops Derived from Alternative Technologies

According to USDA officials, USDA needs to update its regulations to assess certain potential plant and environmental health risks associated with GE crops derived from alternative technologies. According to USDA officials, USDA's regulations for GE crops do not capture the full authority to protect plant and environmental health provided by the PPA, and are not broad enough to allow USDA to restrict all GE crops that may pose a risk to plant health.

Under current regulations, USDA, through its Animal and Plant Health Inspection Service (APHIS), restricts the introduction and dissemination of GE crops for which the donor, vector, or recipient of genetic material is a plant pest, such as a bacterium or virus, until the agency assesses certain potential plant and environmental health risks and determines the regulated article does not pose a potential plant pest risk.[20] For example, a gene that confers resistance to the herbicide glyphosate that was sequenced from a bacterium has been used extensively to transform varieties of corn, soybean, and alfalfa crops, according to USDA officials. USDA also regulates any plant pests that have been genetically engineered. For example, USDA regulates the diamondback moth that has been engineered with genes that disrupt reproduction in this pest. This moth and its larvae are known pests for crops such as cauliflower, cabbage, and broccoli.

USDA regulates new GE crop varieties in field trials. During field trials, developers that are issued authorizations to release GE crop varieties through field trials must follow specific controls outlined in those authorizations to avoid unauthorized release or unintended mixing of GE and non-GE crops, among other things.[21] For example, if a developer

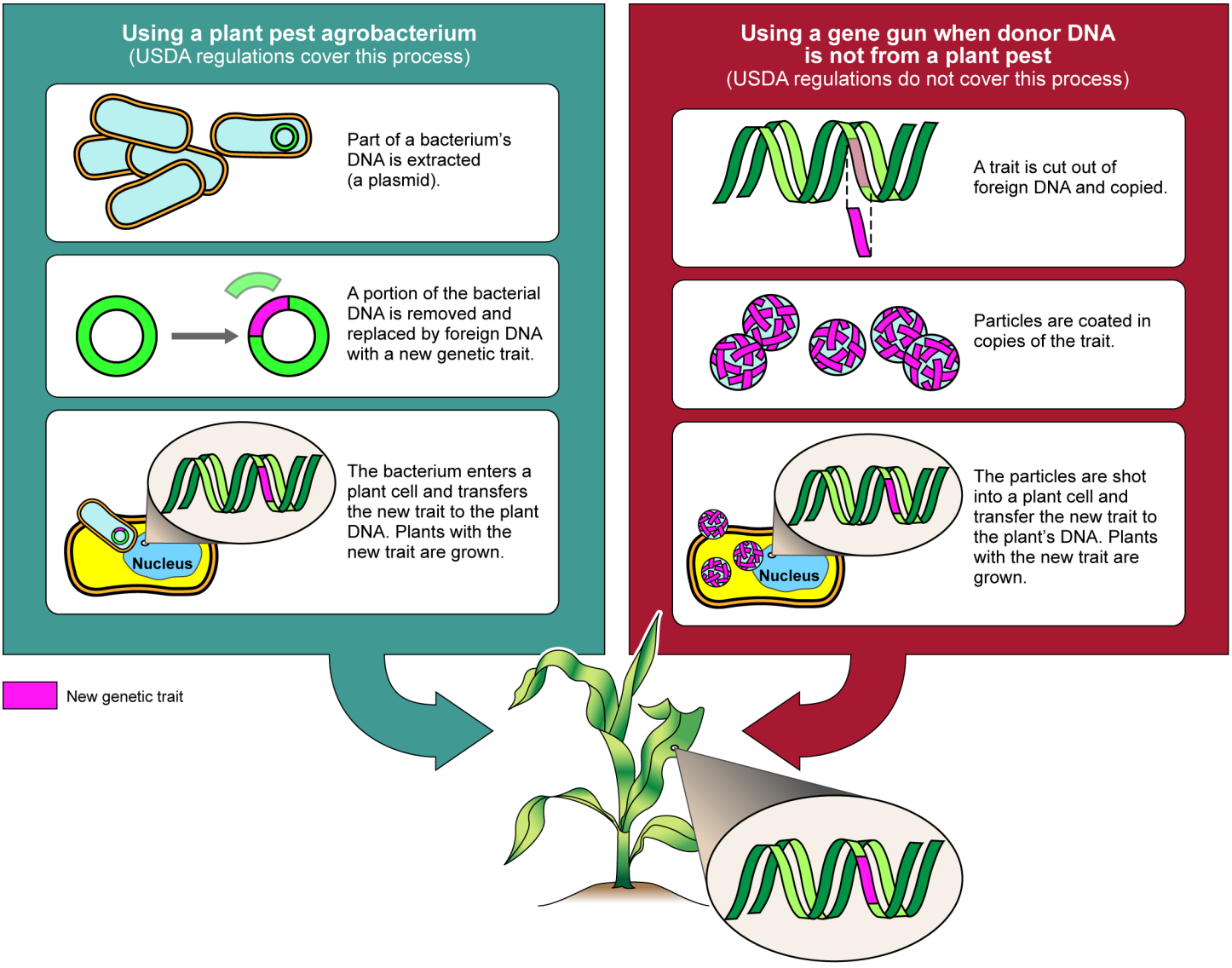
[20]According to its website, APHIS is charged with protecting and promoting U.S. agricultural health, including regulating genetically engineered organisms, to defend America's animal and plant resources from agricultural pests and diseases.

[21]USDA also performs crop testing on a limited, fee-for-service basis and validates GE crop testing methods.

inserted a trait that confers glyphosate tolerance into a type of grass using a plant pest, the developer would be required to submit a request for authorization to move or conduct outdoor plantings of this GE plant. Developers may petition USDA to deregulate their GE crops if they can demonstrate that these crops do not represent a plant pest risk. Commercialization of GE crops may follow deregulation. In contrast, if the developer engineered the grass conferring the same glyphosate tolerance, but did so by using a GE technology that did not involve a plant pest or did not result in plant pest DNA in the grass developed, the developer would not require an authorization, unless USDA later finds the GE crop to be a plant pest on the basis of new data or analysis. The reason, USDA officials said, is that the GE technology used to insert the desired trait did not involve use of a plant pest and no plant pests were otherwise used or inserted.[22] Although developers sometimes request authorization to conduct field trials of GE crops that do not meet the definition of a regulated article (e.g., because a plant pest was not used or a plant pest was used but no plant pest DNA was in the GE crop developed), USDA's regulations requiring an authorization are limited to situations where a plant pest was involved in the genetic engineering as a donor, vector, or recipient of genetic material, rather than on the potential risk to plant and environmental health associated with the plant and the introduced trait, as shown in figure 1.

[22]For example, the developer could have used the GE technology called biolistics, or a gene gun, which involves the use of a particle of heavy metal coated with DNA that is shot into the target cell.

Figure 1: Example of Genetic Engineering Technology with and without Use of a Plant Pest and the Extent of the U.S. Department of Agriculture's (USDA) Regulations



Source: GAO analysis of information from the U.S. Department of Agriculture. | GAO-16-241

Moreover, some GE crops developed using genetic engineering technologies that do not involve the use of a plant pest, or use a plant pest but do not result in plant pest DNA in the crop developed, could pose weediness risks, according to USDA officials. Specifically, there could be unintended cross breeding with a related wild plant species that could

make the new plant a noxious weed. For example, if a drought tolerance gene unintentionally moved from GE sorghum to Johnsongrass, a wild relative of sorghum, the resultant Johnsongrass could become a more aggressive or noxious weed in dry environments. According to USDA officials, a GE crop could be regulated using USDA's noxious weed authority under the PPA, but to date USDA has not done so.[23] This is because USDA's existing noxious weed regulations were not designed for crops, according to USDA officials.[24]

As of November 2015, USDA had received 44 letters of inquiry from GE crop developers asking whether their GE crops are subject to USDA regulations. As of that date, according to agency officials and USDA's website, USDA had determined that 30 of these GE crops are not subject to USDA regulations and 1 GE crop is subject to USDA regulations; the agency's responses to the remaining 13 letters were pending.[25] Most of these inquiries were for GE crops developed using technologies that did not involve a plant pest, or did involve the use of a plant pest but did not result in plant pest DNA in the crop developed, putting them beyond the

[23]The PPA defines plant pests and noxious weeds and provides USDA certain authorities, for example, to issue regulations prohibiting unauthorized movement of plant pests and to prohibit or restrict the importation, entry, exportation, or movement of any plant, noxious weed, or article to prevent the introduction or dissemination of a plant pest or noxious weed in the United States.

[24]USDA implements noxious weed authority under part 360 of title 7 of the *Code of Federal Regulations*. USDA officials said that the primary purpose of this regulation is to prevent the introduction of noxious weeds that are not currently found in the United States, and that this original purpose is different than how USDA would potentially use its noxious weed authority to oversee GE crops.

[25]To be subject to USDA's regulations, a GE crop must meet USDA's definition of a regulated article. A regulated article is any organism altered or produced through genetic engineering, if the donor organism, or vector or vector agent, belongs to a group of organisms that are or contain a plant pest, or is an unclassified organism or one whose classification is unknown, or any other organism or product altered or produced through genetic engineering determined to be, or when there is reason to believe it is, a plant pest. 7 C.F.R. § 340.1.

scope of USDA's regulations.[26] USDA officials said they expect the number of GE crops developed with alternative technologies that do not use a plant pest, or that use a plant pest but do not result in plant pest DNA in the crop developed, to increase in the future because these technologies are generally more efficient and precise than technologies using plant pests. For example, USDA officials observed that the plant science community is excited about what can be accomplished with the newest gene editing technologies, noting that such technologies can provide for GE crop development at greater speeds and lower costs.

In responding to the letters of inquiry from GE crop developers, USDA officials said that they consider information provided by the developer on the GE technology used, recipient crop, and introduced trait. If the inquiry is the first of its kind, USDA will work with various APHIS programs to ensure that they do not have plant health concerns for which other authorities could be used to protect plant health. While USDA may consider potential risks associated with the GE crop variety, its final response to the developer is solely focused on whether the GE crop is regulated and generally does not include information on the potential risks.[27]

[26]According to USDA officials, of the 30 inquiries to which USDA has responded, USDA determined that 16 did not use a plant pest, 12 were not regulated articles and thus not subject to USDA regulations but for reasons other than not using a plant pest, and 2 were not regulated despite being defined as regulated articles. For example, a developer made GE flowers overseas that were intended for import to the United States. Because the flowers were not intended for propagation—and cannot be propagated without tremendous human intervention—USDA determined that these were not regulated articles. Decisions on earlier inquiries were based strictly on whether the subject of the inquiry fell under part 340 of title 7 of the *U.S. Code of Federal Regulations*. More recently, for cases that did not fall under part 340, USDA officials said that APHIS has completed risk assessments in cases where a plant health risk was considered plausible and additional information was solicited from the developer to address the risk hypothesis formulated in the risk assessment.

[27]USDA officials said the agency responds to developers with letters containing five basic components: (1) an acknowledgment of receipt of the inquiry; (2) a citation for what constitutes a regulated article; (3) a short description of USDA's interpretation of the inquiry submitted; (4) a statement relating the inquiry to USDA's statutory authority; and (5) a statement asserting that risk from the GE crop may need to comply with other federal laws or regulatory oversight by other federal agencies such as EPA or FDA. Nevertheless, if APHIS believes that a reasonable risk may exist for the subject of the inquiry, APHIS will request additional information to address the risk before responding to the inquiry.

USDA Attempted to Update Its Regulations in 2008 and Is Considering Proposing Updated Regulations

In 2008, in part to respond to advances in genetic science and technology and address potential risks, if any, posed by GE crops developed through alternative technologies, USDA proposed a rule that included the possibility of using the noxious weed provisions of the PPA. These provisions would have expanded USDA's review to apply to new GE crop varieties that represent a potential noxious weed risk. According to USDA officials, the proposed rule was somewhat ambiguous with regard to what would be regulated and that created confusion for stakeholders. According to the proposed rule and USDA officials, a developer would talk to USDA if there was any doubt about whether the variety needed to be regulated. Although USDA took steps to update its regulations to capture any GE crop that may pose a risk to plant health, USDA ultimately withdrew the proposed rule in February 2015 because of issues raised by the public and industry, including a lack of clarity in several key aspects of the rule, according to USDA officials. For example, many of the public comments said that the proposed rule was not clear about what was to be included or excluded in USDA's regulatory scope and that USDA had not been sufficiently clear about how it would implement the proposed changes. In addition, according to USDA officials, commenters said they were unsure whether this was a voluntary process and did not know under what circumstances USDA would require regulation. In withdrawing the proposed rule, USDA decided that an updated proposed rule was needed, noting it wanted to engage stakeholders anew.

In February 2015, USDA officials said they were considering updating the regulations to address shortcomings in USDA's existing regulations and to take advantage of 28 years of experience regulating products of biotechnology to focus the program on those products that present a plant health risk, regardless of which technologies were used in their development. Executive Order 13563 states, among other things, that to facilitate the periodic review of existing regulations, agencies shall consider how best to promote retrospective analysis of rules that may be outmoded, ineffective, and insufficient, and to modify, streamline, expand, or repeal them in accordance with what has been learned.[28] In addition, an Office of Management and Budget (OMB) memorandum on this executive order states that agencies should explore how best to evaluate regulations in order to expand on those that work and to modify, improve, or repeal those that do not.[29] Candidates for reconsideration include rules

[28]Exec. Order No. 13,563, 76 Fed. Reg. 3821 (Jan. 21, 2011).

[29]Office of Management and Budget, *Improving Regulation and Regulatory Review*, OMB Memorandum M-11-10 (Washington, D.C.: 2011).

that new technologies or unanticipated circumstances have overtaken, according to this memorandum. Furthermore, a July 2015 Memorandum from the Executive Office of the President stated that advances in science and technology have dramatically altered the biotechnology landscape, referenced new technologies, and called on USDA, EPA, and FDA to, in part, formulate a long-term strategy to ensure that the Federal regulatory system is equipped to efficiently assess the risks, if any, associated with future products of biotechnology.

USDA is currently in the early stages of the process of considering updating its regulations. In May 2015, USDA hosted a series of webinars and began providing opportunities for the public to provide initial feedback on how the regulations might be improved. USDA also created a website devoted to stakeholder engagement regarding USDA's regulation of GE crops.[30] According to this website, the agency's intention is to use an open and robust policy dialogue to drive the development of a forward-looking rule that will provide a foundation for its future regulatory activities. As of June 2015, USDA had received comments from over 221,000 individuals from its stakeholder engagement efforts, according to USDA officials. Withdrawing the 2008 proposed rule allows USDA to discuss regulatory issues in ways that were not possible previously.[31] USDA officials said that they expect to publish a notice of intent and do a programmatic environmental impact statement in early 2016 to consider a number of alternatives for an updated proposed rule. The officials also said that USDA intends to publish a proposed rule no later than September 2016. However, USDA officials said that they do not have a timeline for finalizing a new rule.

Our body of work has shown that by setting implementation goals and a timeline, an organization builds momentum and can show progress from

[30]The agency established a docket available on Regulations.gov for public comment, which closed in June 2015. The public comments can be found online under "View All" in the Comments section at http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0036.

[31]Because of rules limiting ex parte communications with respect to active rule makings, publication of the 2008 proposed rule constrained USDA's ability to talk about alternatives with stakeholders, according to USDA officials. Ex parte rules can prevent unequal access or the perception of favoritism during the active rule-making period occurring after a new rule is proposed. According to USDA officials, withdrawing the proposed rule lifted this constraint, allowing APHIS to discuss regulatory issues in ways that were not possible while the proposal was in formal rulemaking.

day one, thereby helping ensure an initiative's successful completion.[32] In addition, our body of work has shown that timelines with milestones and interim steps can be used to show progress toward implementing efforts or to make adjustments to those efforts when necessary, and that without defined tasks and milestones, it is difficult for an agency to set priorities, use resources efficiently, measure progress, and provide management a means to monitor this progress.[33]

USDA officials noted that the process for finalizing a rule is challenging and would be difficult to do in the remaining time under the current administration. Although publishing the Notice, impact statement, and proposed rule in the coming months are good first steps, without setting a timeline, with milestones and interim steps, for updating its GE crop regulations, it will be difficult for the agency to set priorities, use resources efficiently, measure progress, and provide management a means to monitor the agency's progress in promulgating a new rule. In addition, until a rule is finalized, USDA will not be able to fully assess the potential risks to plant and environmental health posed by GE crops created with alternative technologies. Completing a new rule to update USDA's regulations is particularly important given that the number of GE crops developed with alternative technologies is expected to grow.

[32]GAO, *Streamlining Government: Key Practices from Select Efficiency Initiatives Should Be Shared Governmentwide*, GAO-11-908 (Washington, D.C.: Sept. 30, 2011). Also see GAO, *Results-Oriented Cultures: Implementation Steps to Assist Mergers and Organizational Transformations*, GAO-03-669 (Washington, D.C.: July 2, 2003).

[33]GAO, *Defense Health Care Reform: Actions Needed to Help Ensure Defense Health Agency Maintains Implementation Progress*, GAO-15-759 (Washington, D.C.: Sept. 10, 2015), and *Biobased Products: Improved USDA Management Would Help Agencies Comply with Farm Bill Purchasing Requirements*, GAO-04-437 (Washington, D.C.: Apr. 7, 2004).

USDA Has Limited Data on the Extent and Impact of Unintended Mixing of GE and Non-GE Crops, but Some Steps Have Been Taken to Address Such Mixing

USDA has limited data on the extent and impact of unintended mixing of GE and non-GE crops from production to market. Nonetheless, USDA has taken some steps to address unintended mixing of GE and non-GE crops. In addition, farmers and the agribusiness industry (i.e., industries associated with agricultural production and services, such as shipping and processing) have taken steps to address unintended mixing.

USDA Has Limited Data on the Unintended Mixing of GE and Non-GE Crops, Making It Difficult to Know the Extent and Economic Impact of Such Mixing

According to USDA officials and several stakeholders, USDA has limited data on the unintended mixing of GE and non-GE crops from production to market, making it difficult to know the extent of such mixing and the associated economic losses experienced by farmers. According to USDA officials, because GE crops on the market have been determined to be as safe as non-GE crops, are legal for farmers to cultivate, and are often destined for commingled commodity supplies, pollen movement between GE and non-GE crops on the market has been neither regulated nor tracked. In its 2012 report on enhancing coexistence, AC21 recommended that USDA fund or conduct research in a number of areas relevant to the promotion of coexistence in American agriculture, including quantification of actual economic losses incurred by farmers as a result of unintended GE presence (unintended mixing) and occurrences of these losses over time and in different geographic regions. Such research would enable USDA to gather more information on the extent and economic impact of the unintended mixing of GE and non-GE crops.

USDA officials identified two primary ways that the presence of GE crops can have an economic impact on farmers producing non-GE crops because of incurring additional costs: (1) by necessitating measures by farmers to prevent unintended mixing before harvest; and (2) through lost value on shipments rejected by grain-handling companies for exceeding contract specifications for allowable GE presence in a shipment after

harvest.[34] Measures farmers can take to prevent unintended mixing include using buffer zones, such as extra rows of alternative crops or empty space, intended to serve as a physical barrier between GE and non-GE crops, or planting crops at different times than neighboring crops to stagger the periods when each crop is pollinating. However, according to USDA officials and some stakeholders, these measures can result in decreased yields because of reduced acreage for production or a shorter growing season. USDA officials said assigning dollar values to preventive measures taken by farmers can be difficult and must consider geography, climate, or weather, which can differ substantially between areas. According to USDA officials, the cost of such preventive measures is generally factored into the contractual price for the non-GE crop as these measures may be required by the buyer.

In addition, USDA has limited data on the number of times crop shipments have been rejected because they have exceeded a specified level of unintended GE presence. Further, according to USDA officials and the AC21 report, data on the extent to which GE and non-GE crops are commingled within the supply chain are not available, in part, because these data are considered proprietary by grain-handling companies. Furthermore, there is limited public data on the contracted prices for non-GE crop supplies, further challenging efforts to develop economic loss information.[35]

USDA officials said that the National Agricultural Statistics Service (NASS) and the Economic Research Service (ERS) have generally not collected information on unintended mixing between GE and non-GE crops in past farmer surveys because no specific request had been made by other USDA agencies to obtain this information. NASS and ERS are the USDA agencies principally responsible for conducting farmer surveys. The NASS and ERS missions are, in part, to provide timely, accurate, and useful statistics in service to U.S. agriculture and to inform and enhance

[34]Unintended GE presence could result in an externality where some incurred costs of producing non-GE crops are not reflected in the market cost of these crops. An externality is a side effect or consequence of an industrial or commercial activity that affects other parties without being reflected in the cost of the goods or services involved. The presence of an externality may affect the optimal allocation of resources in a market, which may in turn establish a basis for a government role.

[35]According to USDA officials, public data on prices for non-GE crops with GE counterparts became available for the first time in September 2015, when USDA issued its first national weekly report containing non-GE prices for corn and soybeans.

public and private decision making on economic and policy issues, respectively. Further, according to NASS's strategic plan, NASS provides key statistical information and basic research essential for making informed policy decisions.[36] As part of an effort to obtain some information on unintended GE presence in non-GE crops, ERS included a related question in the 2010 Agricultural Resource Management Survey.[37] The results of this survey indicated that approximately 2.5 percent of organic corn farmers responding had shipments rejected by a buyer because of the presence of GE material. However, the survey did not ask these respondents to quantify all economic losses or indicate when such losses were incurred, and the survey asked only about corn crops.

In 2014, USDA's Organic Survey, administered by NASS, and partly in response to the AC21 recommendation to fund or conduct research on the quantification of economic losses incurred by farmers as a result of unintended GE presence, included a question asking organic farmers if they had experienced an economic loss because of unintended GE presence in their crops offered for sale, and if so, to quantify their three most recent losses.[38] The NASS survey data were released in September 2015, and showed the existence of economic losses because of unintended GE presence in non-GE crops, although at very small levels. According to USDA officials, the survey data estimate $6.1 million in economic losses because of unintended GE presence for organic farmers from 2011 to 2014, in comparison to billions of dollars in sales for organic

[36]U.S. Department of Agriculture, National Agricultural Statistics Service, *Strategic Plan for FYs 2010-2015* (Washington, D.C.: January 2011).

[37]The Agricultural Resource Management Survey is USDA's primary source of information on the financial condition, production practices, and resource use of America's farm businesses and the economic well-being of America's farm households. ERS added this question to the 2010 corn survey based, in part, on a gap identified by the National Research Council in its report, *Impact of Genetically Engineered Crops on Farm Sustainability in the United States* (Washington, D.C.: 2010), in which the council identified a lack of economic information on the specific costs of unintended mixing borne by producers who were not using biotechnology.

[38]According to a NASS official, organic surveys have been conducted three times. Referred to in 2008 as the Organic Production Survey, and in 2014 as the Organic Survey, these surveys were distributed to all organic producers including certified organic producers and organic producers exempt from certification. Referred to in 2011 as the Certified Organic Production Survey, it was sent only to certified organic producers. The organic surveys are conducted during the subsequent fiscal year; for example, the 2014 survey was conducted in fiscal year 2015. NASS anticipates administering the 2015 and 2016 surveys in fiscal year 2016 and fiscal year 2017, respectively. Any subsequent surveys in following years will depend on available funding, according to USDA officials.

farmers during this period.[39] In addition, of the estimated 14,093 organic farms, only an estimated 92 farms, or less than 1 percent, reported GE-related losses.[40]

USDA officials said that the results of the 2014 Organic Survey do not provide complete information on the economic impacts of unintended GE presence because, in part, the survey only included organic farmers, their direct marketplace losses, and their three most recent losses. According to USDA documentation, prior to fielding this survey, a number of USDA officials, including APHIS, ARS, ERS, and Office of the Secretary officials, as well as the Chair of USDA's Organic Working Group, noted that it would also be useful to collect information on other ancillary economic costs, such as the costs of reshipping and re-storing rejected shipments, as well as the costs associated with finding new buyers for rejected shipments.[41] However, for the 2014 Organic Survey, NASS officials said that NASS and other stakeholders decided to limit the number of questions on economic losses due to unintended GE presence given time constraints on deploying the survey, and because of space restrictions.[42] In addition, NASS officials we interviewed noted the content of the question was primarily directed by USDA's Risk Management Agency in light of AC21 discussions about the possibility of offering crop insurance coverage for losses associated with unintended GE presence. NASS officials said that adding additional questions on economic costs to future organic surveys might be possible, but would need to be considered in light of how a longer survey might affect farmer participation. They also said any changes to future surveys would have to be approved by OMB. Without more complete information on economic losses and other costs, USDA is missing an opportunity to better understand the economic impacts of unintended GE presence. As discussed, NASS's mission is, in part, to provide timely, accurate, and useful statistics in service to U.S. agriculture. Further, OMB guidance directs federal agencies to (1) periodically review information systems to determine how mission

[39]Regarding the reported estimated economic losses, the upper bound of the 95 percent confidence interval is $14.1 million, according to GAO analysis of NASS data.

[40]The 95 percent confidence interval for the number of farms that reported losses because of unintended GE presence is 60 to 124, according to GAO analysis of NASS data.

[41]The Organic Working Group is USDA's internal communications network concerning organic agriculture and markets.

[42]The 2014 Organic Survey was 16 pages long and included 52 questions, including a question on economic losses due to unintended GE presence.

requirements might have changed and whether the information continues to fulfill ongoing and anticipated mission requirements, and (2) ensure the information delivers the intended benefits to the agency and customers.[43] Although this guidance does not apply to USDA's survey efforts, it serves as an example of a best practice.

In addition to wanting more information on the losses sustained by organic farmers because of unintended GE presence, USDA officials said similar information is needed for non-organic producers who do not use GE seed varieties and who take preventive measures, such as buffer zones, to minimize the potential of GE crops affecting their crops. Further, these officials said that while they lack information on the number of nonorganic producers seeking to market their non-GE crop as identity-preserved (i.e., crops of a specific genetic variety, which might bring a higher price), the acreage planted with identity-preserved corn and soybeans is significantly greater than the acreage planted with organic versions of these crops. For example, they noted that the former numbers in the millions of acres, while the latter is in the hundreds of thousands of acres. Thus, these officials said that the potential economic impacts of the unintended presence of GE material in the crops of identity-preserved producers may be even greater than the impacts on organic producers. However, USDA currently has no efforts under way to survey these identity-preserved producers on this issue. Without including producers growing identity-preserved crops, in addition to producers growing organic crops, in its survey efforts, USDA lacks statistically-valid data needed to understand the full scope of the potential economic impacts from unintended GE presence.[44] In turn, without these data on these impacts, including the number of farmers and types of crops affected and the nature and extent of the associated economic losses, USDA is missing key information essential for making informed policy decisions on ways to better promote coexistence as called for by AC21.

[43]Office of Management and Budget, *Management of Federal Information*, OMB Circular No. A-130 Transmittal Memorandum #4 (Washington, D.C.: Nov. 28, 2000).

[44]USDA officials noted that non-GE, nonorganic farmers were not included in the 2014 Organic Survey as it only covers organic farmers, but that USDA may include questions on possible economic losses in the 2017 Census of Agriculture that would be sent to producers of all types. Historically, the cost of preventive measures in order to obtain a premium price has always been the responsibility of the farmer seeking the premium. The cost of these preventive measures is considered a required input for this production system and not a loss.

USDA Has Begun Taking Some Steps to Address the Unintended Mixing of GE and Non-GE Crops

USDA is not responsible for preventing the unintended mixing of GE material in non-GE and organic crops during cultivation and after these crops enter the supply chain, but has, nonetheless, taken some steps to focus on this issue. For example, the Secretary of Agriculture has made strengthening coexistence among different agricultural production methods a priority. However, USDA officials said that while there are many steps that USDA can take to help farmers produce crops that meet their customers' needs, segregating GE and non-GE crops is generally a private sector function.

As discussed, in February 2011, the Secretary of Agriculture reactivated AC21.[45] In reactivating AC21, USDA announced that it would take further steps to address the larger issue of coexistence between different types of production methods in U.S. agriculture.

In November 2012, after a number of public meetings and the solicitation of public comments, AC21 issued its report on enhancing coexistence, which made five broad recommendations for strengthening coexistence among different agricultural production methods, in particular between the production of GE and non-GE crops.[46] The recommendations were that USDA should

- fund or conduct research, such as the quantification of actual economic losses incurred by farmers as a result of unintended GE presence and occurrences of these losses over time and in different geographies;
- fund education and outreach initiatives to strengthen understanding of coexistence between diverse agricultural systems;
- develop mechanisms that foster crop stewardship and mitigate potential economic risks derived from unintended gene flow between

[45]AC21 met frequently from 2003 to 2008, examining the long-term impacts of biotechnology in agriculture and providing guidance to USDA on pressing individual issues, identified by the Office of the Secretary, related to the application of biotechnology in agriculture.

[46]USDA Advisory Committee on Biotechnology and 21st Century Agriculture, *Enhancing Coexistence: A Report of the AC21 to the Secretary of Agriculture* (Nov. 19, 2012).

crop varieties and promote and incentivize farmer adoption of appropriate stewardship practices;

- develop a plan for ongoing evaluation of commercially available non-GE and organic seed varieties and identification of market needs for producers serving GE-sensitive markets; and

- evaluate data gathered under the first recommendation regarding actual economic losses and in considering loss data, if warranted, implement a compensation mechanism to help address such losses.

Although NASS added the survey question on possible economic losses to the 2014 Organic Survey in part because of an AC21 recommendation, USDA officials stated that USDA may not have the authority to implement some of the other recommendations in the AC21 report. For example, these officials said that USDA currently does not have the authority to compensate farmers who experience losses because of the unintended presence of GE material in their non-GE crops. Some stakeholders we interviewed said that non-GE farmers, including organic farmers, may not be adequately compensated in the marketplace to cover losses resulting from the unintended mixing of GE and non-GE crops. Other stakeholders, however, said that these farmers chose to grow non-GE crops with the knowledge of the potential for unintended mixing with GE crops, balancing that risk against the higher prices they can get in the marketplace for non-GE crops, particularly organic crops.

In March 2015, USDA held an invitation-only workshop for selected farmer, nonprofit organization, academic, and other stakeholders, available through a webcast for the public to view, to obtain additional input on how to further advance understanding of agricultural coexistence.[47] After this workshop, USDA solicited public comments on key ongoing USDA initiatives, as well as proposed initiatives, in response to recommendations from AC21. Some of the ongoing initiatives include improving new crop insurance options for farmers not growing commodity crops,[48] eliminating an insurance premium surcharge for organic farmers,

[47]The workshop focused on the AC21 report recommendations related to (1) education and outreach, (2) developing a specific package of mechanisms that foster good crop stewardship and mitigate economic risks between crop varieties, and (3) promoting and incentivizing stewardship practices.

[48]Noncommodity crops include crops such as apples, bananas, broccoli, green beans, lettuce, peaches, pears, and potatoes.

supporting an organic seed finder database to help better understand the seed market and identify needs for increased sources of specific types of organic seed, and outreaching to the public on how to foster communication and collaboration to strengthen coexistence. Some of the proposed initiatives include the following:

- Developing a coexistence education and outreach strategy with the goal of getting farmers to understand and accept responsibility for both the biological and social consequences of their farming practices.
- Developing updated procedures and a plan for handling and prioritizing the evaluation of relevant germplasm stocks and developing cost-effective approaches for assessing unintended GE presence and mitigating that presence in those stocks.[49]
- Using USDA conservation programs, where applicable, to help finance farmers' measures to promote coexistence, such as creating buffer zones.

USDA does not have a timetable for the implementation of the AC21 report recommendations or any newer coexistence activities but has tracked the implementation of the ongoing initiatives closely, according to USDA's Office of the Secretary. USDA has begun implementation of nearly all recommended activities that it currently has the authority to implement. Some of the activities, for example, research recommendations, are long-term projects. USDA has indicated that it will be considering the 2014 Organic Survey data along with other economic information on coexistence it is gathering in deciding on additional future steps. USDA developed a document that describes its main coexistence activities in December 2015 and posted it on the AC21 webpage.

[49]The genes necessary for producing crops are contained in plant germplasm—the material in seeds or other plant parts that controls heredity.

Farmers and the Agribusiness Industry Have Taken Steps to Address Unintended Mixing

According to USDA officials and some stakeholders, farmers and the agribusiness industry generally take measures to minimize unintended presence of GE material in non-GE and organic crops through pollen flow during cultivation or unintended mixing in storage, shipping, and processing channels. Commodity group stakeholders described the current crop commodity system as one that handles grains, oilseeds, and other crops in bulk to keep the prices of food low.[50] They said the infrastructure was not built to address potential mixing of GE and non-GE crops, so the crops may be unintentionally mixed at multiple points in the supply chain. For example, GE and non-GE grain can be unintentionally mixed in rail cars, in barges, or at grain elevators because there generally is not a separate infrastructure for each type of grain. According to industry stakeholders we spoke with, even with these challenges, farmers and the agribusiness industry often take measures to keep GE and non-GE crops segregated to meet customer demand. These measures include the following:

- **Physical separation of crops**. Different crop types may be physically separated by buffer zones, and seed producers may use "pinning maps" to see the location of other reproductively similar seed crops being grown in their area.[51]

- **Temporal separation of crops**. Farmers may plant their crops earlier or later than surrounding farms to minimize pollination of their crops by nearby GE crops. In transit and processing, a grain elevator or other facility that handles both GE and non-GE crops might only accept GE or non-GE crops on certain days of the week to avoid unintended mixing.

- **Testing and inspection**. Buyers may test or inspect arriving shipments of non-GE crops to determine if there is GE material present.

[50]Oilseeds are grains primarily grown to be processed into edible or industrial oils. Common oilseeds grown in the U.S. include soybeans, peanuts, sunflower seeds, canola, and flax.

[51]Pinning maps may be used by farmers and seed companies to determine how best to preserve the genetic identity of their products. For example, farmers will mark on a map the fields where they intend to grow their crops, allowing other farmers in the same area to see what is being grown and where and thereby plan their fields accordingly.

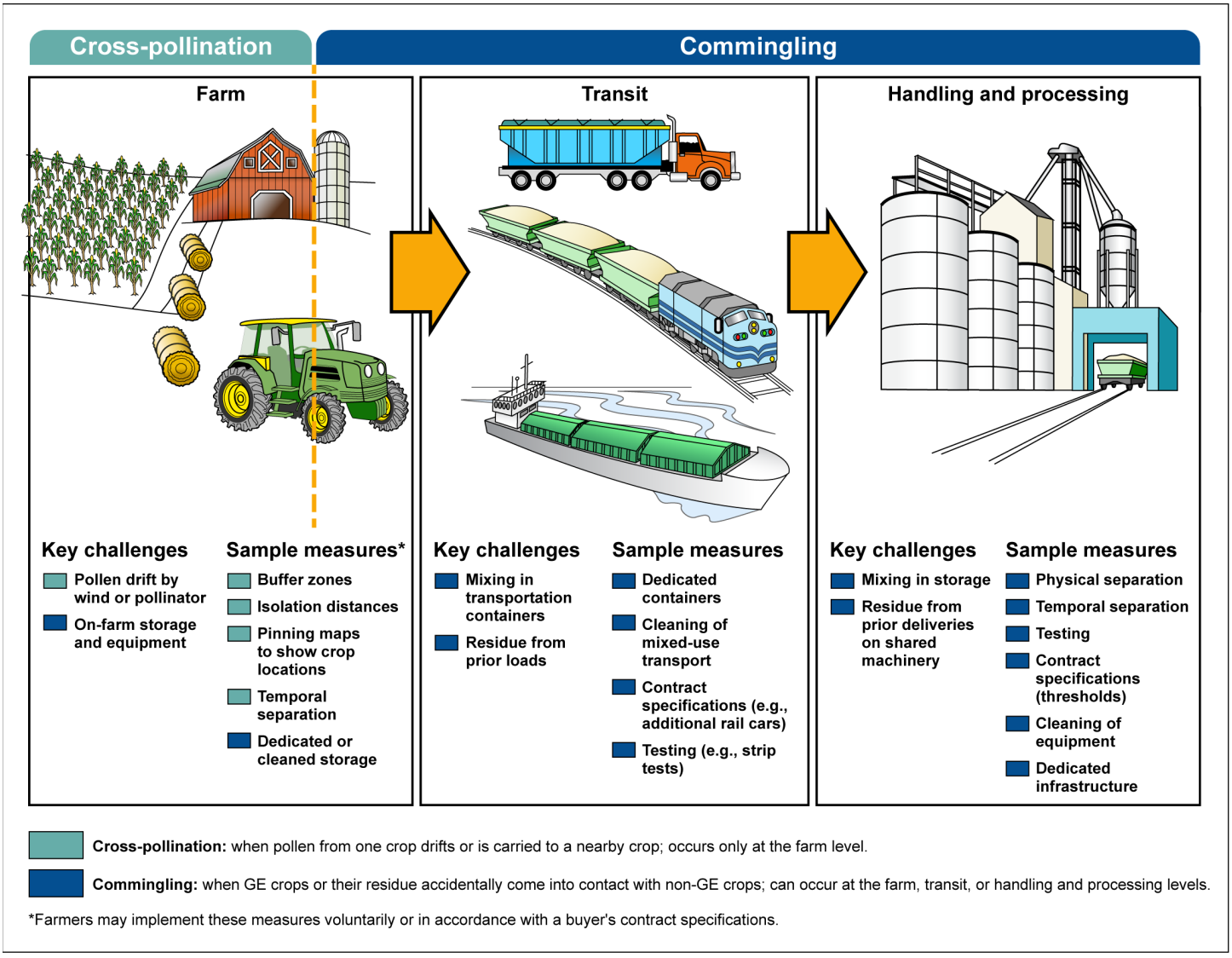
- **Tolerance levels and contract specifications**. Buyers, such as grain handlers, may have tolerance levels for GE content in non-GE shipments that they are willing to accept (e.g., less than 0.9 percent GE material). These tolerance levels are sometimes included in contract specifications between buyers and farmers. Contracts may also specify farm-level measures, including buffer zones, which are required by buyers in the contracts with farmers.

- **Cleaning of shared equipment and storage**. Farm-level, transit, and handling equipment and storage infrastructure may be cleaned on a regular schedule, or after its use for GE crops, to decrease the likelihood of unintended mixing with non-GE crops.

- **Dedicated infrastructure**. In some instances, growers, transporters, and processors may use distinct equipment and facilities to process non-GE crops separately from GE crops. Such infrastructure may include dedicated silos; transportation systems, including rail cars or containers; handling systems and grain elevators.

Figure 2 provides more information on measures to decrease unintended mixing of GE and non-GE crops.

Figure 2: Steps Taken by Farmers and the Agribusiness Industry to Decrease Unintended Mixing of Genetically Engineered (GE) and Non-GE Crops



Source: GAO analysis of information from the U.S. Department of Agriculture. | GAO-16-241

Some stakeholders said that many of the associated costs of these measures are passed on to consumers or others in the supply chain. For example, a grain handler would charge its customers a risk premium for a non-GE crop shipment, and companies will determine risk premiums based on the frequencies that crops are above the acceptable level of GE material present and if a crop is sourced from a location where a lot of GE

crops are cultivated. Stakeholders said that companies would otherwise not be able to absorb these costs unless the end-use consumers—for example, those buying organic or non-GE foods—are willing to pay a higher amount and take on the additional costs associated with these measures.

Stakeholders disagree on who should be held responsible for any financial losses caused by unintended mixing of GE and non-GE crops and how to go about maintaining coexistence. Some stakeholders suggest that non-GE crop farmers receive a premium price, which would help to cover the higher production costs (e.g., costs of preventive measures) and risks of unintended mixing. Others suggest that GE crop farmers are responsible for the unintended presence of GE material in neighboring non-GE and organic crops and should be liable for any related financial losses on the neighboring farms. USDA officials and some stakeholders have said that each production type has its associated production costs and risks, and it is an individual farmer's business decision as to which production type to choose, taking into account these factors.

USDA, EPA, and FDA Provide Varying Degrees of Information to the Public about Oversight of GE Crops

USDA, EPA, and FDA provide varying degrees of information to the public about their oversight of GE crops. USDA and EPA generally provide detailed information and updates on actions relating to their oversight of GE crops through their websites, live forums, and other means of communication, including *Federal Register* notices. FDA provides information to the public on its voluntary premarket consultation process for GE crops. (See app. II for more detail on the information that the three agencies provide to the public about their oversight of GE crops.) In addition, USDA and FDA have different roles and approaches in labeling food that might contain GE ingredients. USDA certifies organic products, which are intended to be non-GE. Companies also can hire USDA to evaluate if their products are meeting company-specified non-GE standards. FDA maintains that there is no food safety reason to label GE foods (see app. III on USDA and FDA labeling; app. IV provides information on stakeholder perspectives and legislative actions on the labeling of foods derived from GE ingredients).

All Three Agencies Provide Information to the Public about GE Crops

USDA

According to USDA's APHIS strategic plan for fiscal years 2015 to 2019,[52] USDA will use traditional communication tools, including publications, public service announcements, and newer technologies, to reach its stakeholders, partners, and customers. In addition, USDA regularly provides information and updates on actions and meetings on its website relating to its oversight of GE crops and other GE organisms, and offers opportunities for public input. For example, APHIS's Biotechnology Regulatory Services (BRS), which is responsible for implementing USDA regulations for certain GE crops that may pose a risk to plant health, holds annual public stakeholder meetings that are open to all interested parties to foster engagement in and ensure transparency of BRS's regulatory activities.[53] USDA also routinely informs the public about its actions related to oversight of GE crops through notices in the *Federal Register*, and maintains a list of all open and previous relevant *Federal Register* notices on its website. For example, USDA notified the public via the *Federal Register* a month in advance of its 2-day workshop on coexistence so that the public could listen in by telephone or webcast, and USDA shared information on how listeners could provide comments after the workshop. USDA also uses the *Federal Register* to alert the public to the availability of preliminary determinations and related assessments for new GE crops for which developers are seeking nonregulated status to commercialize these crops. In addition, APHIS has made educating the public about biotechnology an area of emphasis in its strategic plan for fiscal years 2015 to 2019.

EPA

According to EPA officials, the agency has made it a policy priority to increase engagement with the public on GE technologies and their applications using a variety of platforms. For example, EPA's Office of Pesticide Programs has an outreach program that is responsible for communicating to the public—through trade publications, media, and an EPA e-mail distribution list that has about 11,000 subscribers—all of EPA's actions on regulatory decision making regarding pesticides. On its website, EPA provides updates on actions related to oversight of GE crops, including pesticide registrations such as those intended for use with GE crops. As part of these updates, EPA made its predecision

[52]U.S. Department of Agriculture, *Safeguarding the Health and Value of American Agriculture Since 1972: Strategic Plan 2015-2019* (Washington, D.C.: January 2015).

[53]An archive of the annual stakeholder meetings and other BRS information, such as proposed rules or changes, as well as agendas, associated documents, and presentations for most meetings, is available on the BRS website.

rationale for the registration of the pesticide Enlist Duo, an herbicide intended for use on some herbicide-tolerant GE crops, available for public comment. EPA officials also cited other ways the agency provides information to the public with respect to its GE crops oversight. For example, the agency maintains a list of pending pesticide registration decisions that are open for public comment in a docket on its website with links to the respective comment pages for these pesticides on Regulations.gov.

FDA

FDA officials said that the agency has developed more consumer-friendly information on foods derived from GE crops, which is made available on FDA's website, including a question-and-answer web page on foods derived from GE crops and the text of FDA congressional testimonies on its oversight of foods derived from GE crops. In addition, FDA maintains a biotechnology web page that includes FDA's 1992 policy statement and makes recommendations about what kinds of assessments companies can perform to help determine that GE plant varieties are just as safe as their non-GE counterparts. The FDA web page also includes guidance documents for industry, including consultation procedures under FDA's 1992 policy statement, information on recommended premarket notification concerning foods from GE plants, and guidance for industry on voluntary labeling whether foods have or have not been derived from GE plants. FDA officials stated that this information is generally targeted to a more technical audience as opposed to the general public. FDA officials also stated that the agency has developed more consumer-friendly information on biotechnology and GE plants on its website.

According to FDA officials, FDA does not post developer submissions, including the safety and nutritional assessments of the GE crop submitted and the supporting data, on its website. In addition, these officials said the agency does not post information on consultations that were withdrawn before finalization or the reasons they were withdrawn, including any FDA concerns. However, FDA officials said that the safety and nutritional assessments are available in accordance with FDA's public information regulations and administration policies, and that FDA proactively publishes a summary of the consultation at the conclusion of each

consultation.[54] FDA officials stated that interested parties are able to obtain the developer submissions and related data that are not trade secrets or confidential commercial information from the agency by submitting Freedom of Information Act (FOIA) requests.[55] Stakeholders expressed varying perspectives on FDA's voluntary premarket consultation process. For example, some stakeholders noted the difficulty of going through the FOIA process to access the underlying data, and the lack of a public comment period or public notice prior to a consultation's completion.[56] FDA provides information on the voluntary premarket consultation process on its website, including submission date and developer name; the type of GE crop submitted; the trait being genetically engineered into the crop (e.g., insect resistance); the intended use (e.g., human food or animal feed); and whether the product required EPA review (when a plant-incorporated protectant, i.e., pesticide, is produced). Some stakeholders also said that FDA's final response letters and related notes to the file do not demonstrate what FDA has done to analyze the companies' claims; the agency posts on its website the date and text of final response letters to the developers of GE crops marking the

[54]According to FDA officials, since voluntary premarket consultations began in January 1995, 5 consultations were withdrawn because of FDA concerns. Of these 5 consultations, 3 were withdrawn after FDA expressed concerns about the technical information and organization of the submissions, 1 was better suited for FDA's New Dietary Ingredient consultation process, and 1 was withdrawn after FDA expressed concerns about human consumption of the particular protein resulting from the genetic engineering. Separately, 34 initial consultations between FDA and developers preparing for the voluntary premarket consultation process did not move forward for reasons related to developer, rather than FDA, concerns. For example, a developer may have discovered that a plant did not develop as expected and thus decided not to move forward with the product and the voluntary premarket consultation process.

[55]FOIA establishes a legal right of access to government information on the basis of the principles of openness and accountability in government. 5 U.S.C. § 552. FDA may not lawfully release trade secret and confidential commercial information to the public, except under specific circumstances. See 5 U.S.C. § 552(b)(4); 18 U.S.C. § 1905; see also 21 C.F.R. §§ 20.20, 20.61.

[56]According to FDA officials, FDA's process is a voluntary consultation process and FDA is not required to solicit public comments on consultation evaluations. However, FDA has sought public comments on other things, such as its 1992 statement of policy on food from new plant varieties, and in 2001 and 2006 when FDA released a proposed rule and guidance related to its program for foods from GE plants, respectively. The 2001 proposed rule would have required that developers submit a scientific and regulatory assessment of food derived from GE crops 120 days before these foods were marketed. The 2006 guidance describes procedures for the early food safety evaluation of new non-pesticidal proteins produced by new plant varieties, including those from GE plants.

completion of the consultations.[57] FDA officials said that information on the voluntary premarket consultation is often of a highly technical nature, and if FDA were to post this information, the agency would have to evaluate what information in the submission may lawfully be disclosed, revise the electronic files to make them more accessible under section 508 of the Rehabilitation Act of 1973,[58] and then review the material to ensure its accuracy before posting, a process that would take considerable staff time. For this reason, FDA officials said that providing the underlying data and further detail on a voluntary consultation in response to an occasional FOIA request is more efficient.

USDA and FDA Approaches to Labeling GE Food Ingredients

USDA and FDA have different roles in labeling food that might contain GE ingredients. As a result, the agencies differ in their approach to providing information to the public on GE food ingredients and the labeling of GE food ingredients.

USDA

USDA currently provides information to the public about the GE content of a food product through two programs: USDA's National Organic Program and its Process Verified Program. The Organic Foods Production Act of 1990 directs the Secretary of Agriculture to establish a national organic certification program. Under the National Organic Program, a program managed by USDA's Agricultural Marketing Service, products can receive a USDA organic seal if they meet specific national standards. USDA develops the standards for organically produced agricultural products to assure consumers that products with the USDA organic seal meet consistent, uniform standards. According to USDA officials, the Process Verified Program was started in 1999 and is conducted on a fee-for-service basis by USDA's Agricultural Marketing Service. Exercising its authority under the Agricultural Marketing Act of 1946, the Agricultural Marketing Service serves as a third-party auditor, physically visits a site, and verifies that a company's processes meet standards that a company sets for itself. Companies, such as grain handlers or poultry, pork, and cattle producers and processors, submit their processes to USDA for verification. According to USDA officials, the Process Verified Program

[57]We did not evaluate FDA's final response letters against specific criteria as part of this review.

[58]Under section 508 of the Rehabilitation Act of 1973, as amended, federal agencies are required to make their electronic and information technology accessible to people with disabilities. This requirement applies to all federal agencies when they develop, procure, maintain, or use electronic and information technology, unless it would pose an undue burden on the agency. 29 U.S.C. § 794d.

allows consumers to be assured that what they are buying adheres to the company's standards when they see USDA's process verified seal on packaging.

FDA

FDA regulates food labeling and enforces prohibitions against misbranded foods. According to FDA documentation and agency officials, FDA applies the same labeling principles to foods regardless of whether they are derived from GE or non-GE sources. The agency maintains it has no basis for concluding that foods derived from GE sources differ from their non-GE counterparts in any meaningful or uniform way solely based on their method of production, and therefore there is no basis for requiring labeling that indicates a food was developed through GE techniques.

FDA provides information on its website about why foods from GE plants are not currently required to be labeled to inform consumers about how the food was produced. The agency acknowledges on its website that there is strong consumer interest in knowing whether foods were produced using GE methods and that FDA supports voluntary labeling, maintaining that such statements must be truthful and not misleading. FDA finalized guidance to industry in November 2015 on voluntary labeling indicating whether foods have or have not been derived from GE plants.[59] This guidance contains nonbinding recommendations, and states that labeling by manufacturers on a wholly voluntary basis regarding whether a food was or was not bioengineered is acceptable to FDA, provided that such labeling is truthful and not misleading. In addition, the guidance states that FDA encourages food manufacturers to ensure that labeling terminology concerning the use of modern biotechnology in the production of food or its ingredients be accurate and consistent and that the integrity and meaning of scientific terminology be preserved to help ensure clear communication in food labeling. The guidance also states that a manufacturer that claims that a food product or its ingredients, including foods such as raw agricultural commodities, are GE or not GE should substantiate that the claim is truthful and not misleading. The guidance provides methods a manufacturer may use to substantiate the claim, including documentation of handling practices and procedures (those with control over growing, harvesting, storing, and distribution should consider appropriate recordkeeping to document

[59]Food and Drug Administration, *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants* (College Park, Md.: November 2015).

whether foods are or are not produced using genetic engineering including segregation procedures).

Conclusions

GE crops make up more than 90 percent of major U.S. crops such as corn, soybeans, and cotton. USDA, FDA, and EPA are responsible for regulating GE crops in the United States, with USDA generally ensuring that GE crops do not pose risks to plant and environmental health. Historically, USDA oversight has focused on GE crops that were created using plant pests, such as a bacterium or virus. In recent years, USDA has received an increasing number of inquiries from GE crop developers regarding whether their GE varieties—created using alternative technologies that either did not involve the use of a plant pest or did involve the use of a plant pest but did not result in plant pest DNA in the crop developed—are subject to USDA regulations. USDA acknowledges that its regulations overseeing GE crops have not kept pace with these technological developments and do not cover all GE crops. In February 2015, USDA withdrew its 2008 proposed rule that sought to revise its regulations regarding the importation, interstate movement, and environmental release of certain genetically engineered organisms to bring the regulations into alignment with the PPA and update the regulations in response to advances in genetic science and technology. USDA officials said that USDA intends to publish a proposed rule no later than September 2016 but that they do not have a timeline for finalizing an updated rule. Publishing a notice of intent, programmatic environmental impact statement, and proposed rule in the coming months are good first steps, but without setting a timeline, with milestones and interim steps, for updating its GE crop regulations, it will be difficult for the agency to set priorities, use resources efficiently, measure progress, and provide management a means to monitor the agency's progress in promulgating a new rule. In addition, until a rule is finalized, USDA will continue to lack regulatory authority to fully assess the potential risks, if any, to plant and environmental health posed by GE crops created with alternative technologies, in particular those that either do not use plant pests or use plant pests but do not result in plant pest DNA in the crop developed.

Furthermore, USDA has limited data on unintended mixing of GE and non-GE crops, making it difficult for USDA to identify the extent and impact of the unintended mixing. The Secretary of Agriculture reactivated AC21, which has prioritized the promotion of agricultural coexistence. In its 2012 report on enhancing coexistence, AC21 recommended that USDA should fund or conduct research that would enable USDA to gather more information on the extent and economic impact of unintended mixing. USDA's 2014 Organic Survey was an important first

step to gather data on the economic losses experienced by non-GE farmers, but the data collected do not provide complete information on economic impacts caused by unintended mixing of GE and non-GE crops. Without collecting additional information in future organic surveys, such as the costs of reshipping and re-storing shipments rejected because of unintended GE presence, as well as the costs associated with finding new buyers for such shipments, USDA is missing an opportunity to better understand the economic impacts of unintended GE presence. In addition, USDA does not have data on economic losses because of unintended GE presence for non-GE producers other than for organic producers who seek to market their crops as identity-preserved. Without collecting similar data from producers of identity-preserved crops, USDA lacks statistically valid data needed to understand the full scope of potential economic impacts from unintended GE presence. In turn, without these data, including the number of farmers and types of crops affected and the nature and extent of economic losses, USDA is missing key information essential for making informed policy decisions on ways to better promote coexistence as called for by AC21.

Recommendations for Executive Action

We are making three recommendations to the Secretary of Agriculture.

To improve USDA's ability to oversee GE crops, we recommend that the Secretary of Agriculture direct the Administrator of APHIS to develop a timeline, with milestones and interim steps, for updating its existing regulations to cover GE crops developed with alternative technologies that either do not use plant pests or use plant pests but do not result in plant pest DNA in the crop developed.

To improve USDA's ability to better understand the economic impacts of unintended mixing of GE and other crops, we recommend that the Secretary of Agriculture take the following two actions:

- Direct the Administrator of NASS to work with all relevant USDA stakeholders, including APHIS and the Organic Working Group, to determine what additional information should be sought in future organic surveys, such as the costs of reshipping and re-storing shipments rejected because of unintended GE presence, as well as the costs associated with finding new buyers for such shipments.

- Direct the Administrator of NASS to include producers, growing identity-preserved crops, in addition to organic producers in USDA's survey efforts.

Agency Comments and Our Evaluation

We provided a draft of this report to USDA, EPA, and the Department of Health and Human Services for review and comment. USDA provided written comments, which are reproduced in appendix V. USDA said that it generally agreed with the report's recommendations. EPA and the Department of Health and Human Services did not provide written comments. USDA and the Department of Health and Human Services's FDA also provided technical comments that we incorporated as appropriate.

Concerning our first recommendation in the draft report, to develop a timeline, with milestones and interim steps, for updating its existing regulations to cover GE crops developed with newer technologies that do not depend on the use of plant pests, USDA said that it agreed, in part, with the recommendation. Specifically, USDA said it had developed an internal timeline for outlining key milestones and interim steps, all with associated target dates, for updating the regulations that cover GE organisms. While USDA may have such a timeline now, it did not provide us with this timeline during the course of our work. In addition, USDA stated USDA's proposed regulations are being developed to address products of biotechnology, regardless of laboratory technique used to create or modify the genome. Thus, the intention of the proposed rule currently in development (as well as the 2008 proposed rule) is the overall protection of plant health through regulation of GE organisms that may pose a plant pest or noxious weed risk, with no relation to the technology used to develop the GE organism. In response to USDA's comments, we modified our recommendation so that instead of discussing GE crops developed with newer technologies that do not depend on the use of plant pests, the recommendation discusses GE crops developed with alternative technologies that either do not use plant pests or use plant pests but do not result in plant pest DNA in the crop developed.

Concerning our second recommendation, that NASS work with all relevant USDA stakeholders, including APHIS and the Organic Working Group, to determine what additional information should be sought in future organic surveys, such as the costs of reshipping and re-storing shipments rejected because of unintended GE presence, as well as the costs associated with finding new buyers for such shipments, USDA stated that it agreed. Specifically, USDA stated that NASS works with all relevant stakeholders to determine what information is needed for future organic surveys. For example, USDA said that since the 2014 Organic Survey, NASS has held a series of meetings with APHIS officials and the

Chair of USDA's Organic Working Group to discuss the 2014 Organic Survey results and how to move forward with future survey questions. USDA stated that the most recent of these meetings was held in January 2016 and that at the conclusion of this meeting, NASS, APHIS, and the chair of the working group vowed to keep meeting as well as to bring more stakeholders into the discussions, which will ensure that future organic surveys and related surveys involving GE related questions will have the necessary attention to obtain data, such as the need to better understand the economic impacts of unintended mixing of GE crops. Such actions, if taken, would address our recommendation.

Concerning our third recommendation, that NASS include producers growing identity-preserved crops, in addition to organic producers in USDA's survey efforts, USDA did not indicate whether it agreed or disagreed. USDA stated that NASS's overall survey programs currently include identity-preserved crops and conventional and organic producers. USDA described the sample design for its survey programs, specifically that the design includes area and list frames, and their definitions. However, the point of this recommendation is that NASS should survey producers growing identity-preserved crops regarding their potential economic losses from unintended GE presence, as is being done for organic producers. As we noted in the report, U.S. acreage planted to identity-preserved crops is significantly greater than that planted to organic crops; yet, little is known about the economic costs to identity-preserved farmers of unintended mixing. Until NASS surveys producers growing identity-preserved crops on these potential economic costs, USDA will continue to lack statistically valid data needed to understand the full scope of potential economic impacts from unintended GE presence.

While USDA stated that it generally agrees with our recommendations, it also stated that it takes issue with five themes that are repeated throughout the report. Specifically, USDA states that it is concerned that the intent of its current efforts to update the regulations is misstated; the intent of the 2008 proposed rule is misstated; plant pest and newer technologies are inappropriately conflated; newer technologies are presented as inherently more risky; and the 'Am I Regulated?' inquiries are presented as escaping regulation because they were developed using newer technologies.

USDA further clarified its position on these five themes, stating first that its current intention for updating its biotechnology regulations remains the same as it was in 2008: to protect plant health from plant pests and noxious weeds regardless of the method to transform the organism. In

this regard, USDA said that in several places in our report we incorrectly state that that 2008 proposed rule was intended to capture newer technologies. We do not say that the intent of the 2008 proposed rule or USDA's current efforts to update its biotechnology regulations is to capture new technologies. However, we do say that underlying USDA's efforts to update its regulations is the goal of subjecting new GE crops developed with newer (now alternative) technologies to a more comprehensive assessment of potential risks before commercialization of these new crops. As discussed, GE crops developed with the use of a plant pest are subject to a comprehensive assessment of their potential risks before the crops can be commercialized. Such assessments are not required, under USDA's biotechnology regulations, for GE crops developed with alternative technologies. As a result, there is a gap in USDA's current regulatory coverage that the agency has been seeking to close for more than 10 years, starting with the development of the 2008 proposed rule and continuing with its current efforts to update its biotechnology regulations.

In addition, USDA stated that we used the phrase "newer technologies that do not involve a plant pest" several times and that this phrase incorrectly conflates the use of newer technologies with the use of a plant pest component when there are older technologies (e.g., biolistics) that do not involve a plant pest and newer technologies that do (e.g., TALENS). USDA stated that its statutory authority is to prevent the introduction and dissemination of plant pests and noxious weeds in the United States, and as such, it may regulate any GE organism which "the Administrator determines is a plant pest or has reason to believe is a plant pest" and may regulate, as necessary, any plant that poses a risk as a noxious weed. We acknowledge that some newer technologies, such as TALENS, involve the use of a plant pest, and some older technologies, such as biolistics, do not. However, we note that while TALENS involves the use of a plant pest in developing a new GE crop, no plant pest DNA remains in the crop developed. Thus, that crop is not subject to USDA's biotechnology regulations unless USDA later learns, after the crop has been commercialized, of a plant pest or noxious weed concern. It is that distinction we were trying to draw with our use of "newer technologies," that is, those technologies that result in a new GE crop that is not subject to USDA regulation under its biotechnology regulations. In this regard, during our work USDA, EPA, and FDA officials told us that the field of biotechnology is rapidly evolving with the introduction of new GE organisms and new and emerging technologies that do not depend on the use of a plant pest. In light of USDA's comments, we have revised the report to substitute the use of "alternative technologies" for "newer technologies." Further, we have revised the report to define alternative

technologies as those in which the GE crop developed contains no plant pest DNA. This would include technologies such as TALENS that use a plant pest, and those technologies that do not use a plant pest at all.

Moreover, USDA also stated that the draft report implies that some of the newer technologies are inherently more risky and that USDA has no reason to believe that newer technologies, such as gene editing, are riskier or present any new risks, as compared to older technologies. USDA stated that it concludes, as did the Office of Science and Technology Policy in 1986 when it issued the Federal Coordinated Framework for the Regulation of Biotechnology, that potential risk of a GE organism is derived from the characteristics of the GE organism itself and the environment in which it is introduced and not from the technology that was used for the GE organism. We disagree that we have characterized newer (now alternative) technologies as inherently more risky. Instead the report discusses the potential risks of new GE crops developed with these technologies that are not subject to USDA's biotechnology regulations. For example, these crops are not subject to USDA's permit and notification requirements, the conduct of confined field trials, or the submission of detailed information for review by USDA scientists. Further, under USDA's regulations, developers of new GE crops developed using alternative technologies do not need to petition USDA to "deregulate" their product before commercializing it. However, in light of USDA's concern, we have revised the report to further qualify "potential risks" by adding "if any" after this phrase. We also have revised the report to make clear that we are focusing on those new GE crops in which the crop contains no plant pest DNA, regardless of whether the technology employed used a plant pest or not.

Finally, USDA said the report gives the incorrect impression that many of the 'Am I Regulated?' inquiries from GE crop developers escape USDA regulations because they were developed using newer (now alternative) technologies. USDA stated that most inquiries to date concern GE plants developed with biolistics, which is an older technology, and that for those inquiries where it determined that the organism in question was not a regulated article, it first concluded that there was no reason to believe the organism presented a plant pest risk. As discussed, we have made changes to the report defining alternative technologies as those in which the GE crop developed contains no plant pest DNA. This includes technologies where a plant pest may have been used initially as part of the GE crop development process. It also includes technologies that do not use plant pests at all in the development of a GE crop. Further, while USDA may conclude there is no reason to believe the organism covered by an inquiry presents a plant pest risk, that conclusion is not based on a

comprehensive assessment (e.g., the conduct of confined field trials and the submission of detailed information for review by USDA scientists) of the potential risks of that organism (i.e., a new GE crop). As discussed, under USDA's current biotechnology regulations, only those new GE crop varieties developed with and containing plant pest DNA are subject to a comprehensive USDA assessment of potential risks before commercialization, and it is this regulatory gap, at least in part, that USDA seeks to close in updating its biotechnology regulations. At present, only after commercialization of a GE crop created with an alternative technology, can USDA, if it becomes aware of a possible plant pest risk or noxious weed risk, take regulatory action.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to the appropriate congressional committees, the Secretary of Agriculture, the Secretary of Health and Human Services, the Commissioner of the Food and Drug Administration, the Administrator of the Environmental Protection Agency, the Director of the Office of Management and Budget, and other interested parties. In addition, the report will be available at no charge on GAO's website at http://www.gao.gov.

If you or your staff have any questions concerning 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 make key contributions to this report are listed in appendix VI.

Sincerely yours,

Steve D. Morris
Director, Natural Resources and Environment

Appendix I: Objectives, Scope, and Methodology

We reviewed federal oversight and information on genetically engineered (GE) crops. Our objectives were to examine (1) the steps the U.S. Department of Agriculture (USDA), Environmental Protection Agency (EPA), and Food and Drug Administration (FDA) have taken to regulate GE crops, including those derived from alternative technologies; (2) what data USDA has on the extent of unintended mixing of GE and non-GE crops, and what steps, if any, have been taken to prevent such mixing; and (3) the extent to which USDA, EPA, and FDA provide information to the public on GE crops they oversee. In this report, we define alternative technologies as those in which the GE crop developed contains no DNA of a plant pest, such as a bacterium or virus. This includes technologies in which a plant pest may have been used initially as part of the GE crop development process. It also includes technologies that do not use plant pests at all.

In general, to achieve our objectives, we interviewed officials or obtained documentation from USDA, EPA, and FDA. We also interviewed nonfederal stakeholders, including biotechnology, food industry, consumer, environmental, farm, and commodity group representatives, and those from academia. Industry and commodity groups included the Agricultural Retailers Association, American Seed Trade Association, American Soybean Association, American Sugarbeet Growers Association, Association of Official Seed Certifying Agencies, Biotechnology Industry Organization, Cargill, Clarkson Grain, Grocery Manufacturers Association, National Corn Growers Association, National Grain and Feed Association, North American Export Grain Association, and Organic Seed Growers and Trade Association. Consumer groups included the Center for Food Safety, Center for Science in the Public Interest, Institute for Responsible Technology, Consumers Union, and Organic Consumers Association. In addition, we interviewed officials from the American Association for the Advancement of Science, American Farm Bureau Federation, Biology Fortified, Environmental Working Group, Food & Water Watch, Genetic Literacy Project, National Association of State Departments of Agriculture, National Conference of State Legislatures, National Family Farm Coalition, National Organic Coalition, and the Non-GMO Project, as well as six academics who are agricultural economists studying the potential economic impacts of GE

crops. We identified the academics through a literature review, as well as through the "snowball sampling" technique.[1]

More specifically, to determine how federal agencies regulate GE crops derived from alternative technologies, we interviewed agency officials from USDA, EPA, and FDA, as well as representatives of 35 external, nonfederal stakeholders, generally using a standard set of questions. We took several steps to identify external, nonfederal stakeholders to interview for our work. First, we considered those stakeholders interviewed by GAO for our 2008 report related to GE crops and whether they conduct work in the areas related to this engagement.[2] Second, we identified individuals through literature reviews. Third, we used the snowball method—where each stakeholder was asked to propose or recommend additional stakeholder groups for GAO to interview. We selected the 35 stakeholders to ensure that we captured a broad spectrum of views on GE crop issues. Findings from the interviews of this sample of stakeholders cannot be generalized to those we did not speak to. We additionally gathered information from the National Academy of Sciences, including publicly available information from three public meetings and 10 webinars associated with the academy's ongoing study on GE crops. We did not evaluate the underlying science behind alternative GE technologies or the scientific basis of regulatory decisions related to GE crops made by USDA, EPA, and FDA.

To examine what data, if any, exist on unintended mixing of GE crops and non-GE crops, we obtained USDA's strategic plans and reports, including USDA's Advisory Committee on Biotechnology and 21st Century Agriculture reports with recommendations addressing options to minimize the mixing of GE and non-GE crops. We also interviewed USDA officials who regulate, oversee, or set standards for cultivation, shipping, handling, and packing of major commodity crops, to determine the extent of USDA's role, if any, with respect to addressing the unintended mixing of GE and non-GE crops. Further, we interviewed stakeholders identified in our first objective to determine nongovernmental roles in preventing the

[1]In snowball sampling, the unit of analysis is a person. This methodology begins with an initial list of cases and asks each person interviewed to refer the interviewer to additional cognizant persons. The group of referred cases (or "snowball") grows larger and then narrows as a group of individuals are identified frequently.

[2]GAO, *Genetically Engineered Crops: Agencies Are Proposing Changes to Improve Oversight, but Could Take Additional Steps to Enhance Coordination and Monitoring*, GAO-09-60 (Washington, D.C.: Nov. 5, 2008).

unintended mixing of GE and non-GE crops in the supply chain. We also conducted a literature search to identify and review studies on the actual or potential impact of GE crops on other crops. We did not review GE crops regulated under USDA's permit and notification field trial processes, or the extent to which these crops are affecting the supply chain, as USDA's Inspector General was reviewing these subjects.[3] The USDA Inspector General issued this report in September 2015.[4] Instead, the focus of our report is those GE crops that have been deregulated and are available for commercialization.

To determine the extent to which USDA, EPA, and FDA are providing the public with information on GE crops, we interviewed agency officials and reviewed agency documentation regarding how these agencies reached regulatory or policy decisions related to GE crops, and examined the extent to which that information is disseminated publicly, for example on the agencies' websites. We also interviewed stakeholders identified in our first objective to determine their perspective on the adequacy of the agencies' provision of information on GE crops to the public. To examine USDA and FDA approaches to labeling GE food ingredients, we reviewed relevant laws and agency guidance and interviewed agency officials on applicable programs. Specifically, at USDA, we reviewed documents and interviewed officials with respect to USDA's National Organic Program and Process Verified Program. At FDA, we reviewed FDA documentation and written statements from FDA officials on the agency's labeling principles. The documentation included FDA's 1992 *Statement of Policy: Foods Derived from New Plant Varieties*, and its 2015 guidance to industry on voluntary labeling indicating whether foods have or have not been derived from GE plants.

We conducted this performance audit from August 2014 to March 2016 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.

[3]We also addressed this issue in our 2008 report (GAO-09-60).

[4]U.S. Department of Agriculture, Office of Inspector General, *Controls Over APHIS' Introduction of Genetically Engineered Organisms*, 50601-0001-32 (Washington, D.C.: Sept. 22, 2015).

Appendix II: Further Detail on USDA, EPA, and FDA Efforts to Provide Information to the Public on Their Oversight of GE Crops

This appendix discusses the efforts of three agencies—the U.S. Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA)—to provide information to the public on the oversight of genetically engineered (GE) crops.

USDA

USDA's Animal and Plant Health Inspection Service's (APHIS) strategic plan for fiscal years 2015 to 2019 includes education and outreach efforts to ensure that GE organisms do not pose plant pest risks when released into the environment and as an alternative to rulemaking.[1] According to the plan, USDA will use traditional communication tools, including publications and public service announcements, in addition to newer technologies to reach its stakeholders, partners, and customers, and plans to expand its use of technology. Further, APHIS's Biotechnology Regulatory Services (BRS) 2015 to 2018 strategic plan states that USDA will use high-quality analysis in decision making and will strengthen risk assessment models to focus on GE organisms that pose a risk to plant health. USDA will also seek to keep stakeholders aware of its regulatory actions.

USDA regularly makes efforts to provide information relating to its oversight of GE crops and to offer opportunities for public input. For example:

- APHIS's BRS, which is responsible for implementing USDA regulations for certain GE crops that may pose a risk to plant health, holds annual public stakeholder meetings that are open to all interested parties to foster engagement and transparency in BRS's regulatory activities.[2]
- BRS makes available on its website all letters of inquiry from GE crop developers asking whether their GE crops are subject to USDA regulations, as well as BRS's response to each inquiry.

[1]U.S. Department of Agriculture, *Safeguarding the Health and Value of American Agriculture Since 1972: Strategic Plan 2015-2019* (Washington, D.C.: January 2015).

[2]An archive of the annual stakeholder meetings and other BRS information such as proposed rules or changes, as well as agendas, associated documents, and presentations for most meetings, is available on the BRS website.

- BRS makes available on its website a list of all pending and completed petitions submitted by developers to receive a determination on whether their new GE crops are likely to pose a plant pest risk and therefore would be regulated and provides links to supporting documentation, including guidance for submitting a petition, the developer's initial petition, BRS's preliminary assessment, and BRS's final assessment and decision.[3]

- BRS has posted to its website an online video explaining how USDA regulates biotechnology.

- USDA sought public input through the *Federal Register* on how to foster communication and collaboration between farmers to strengthen coexistence following the release of the Advisory Committee on Biotechnology and 21st Century Agriculture report in 2012.[4]

EPA

EPA officials stated that the agency has a significant interest in being transparent and assuring the public that the federal government is taking all measures necessary to ensure human and environmental safety. These officials said that EPA provides updates on its actions related to GE crops, including making its predecision rationale for pesticide registrations, available for public comment. For example:

- During the registration process for the pesticide Enlist Duo, an herbicide intended for use on some herbicide-tolerant GE crops, EPA made its assessments of the pesticide and its rationale for regulating the pesticide available for public comment for 30 days. According to agency officials, EPA extended the comment period on this pesticide for an additional 30 days and evaluated public comments before making a final registration decision. EPA then notified the public about which changes the agency had made in response to public comments.

[3]Documents associated with USDA's final assessments and decisions may include, for example, plant pest risk assessments or decision documents to comply with the National Environmental Policy Act, such as final environmental assessments or findings of no significant impact.

[4]78 Fed. Reg. 65960 (2013). USDA requested public input during a 60-day comment period, and subsequently extended the comment period for an additional 60 days.

- EPA occasionally convenes a Scientific Advisory Panel to provide independent scientific advice on a wide range of health and safety issues related to pesticides, including those related to GE crops, and information such as archived transcripts from the panel's meetings are made publicly available on EPA's website.[5]

- EPA's Office of Pesticide Programs has an outreach program that is responsible for communicating to the public all of EPA's actions on regulatory decision making regarding pesticides. Through this program, EPA disseminates information through trade publications, media, and an EPA e-mail distribution list that has about 11,000 subscribers. According to EPA officials, the outreach program also employs press releases and is increasing its use of social media tools to engage the public on newer platforms.

FDA

FDA officials stated that the agency has developed more consumer-friendly information on foods derived from GE crops. This information, made available on FDA's website, includes a question-and-answer web page on foods derived from GE crops, a 2013 statement on labeling of foods from GE crops, a consumer update on FDA's role in regulating the safety of foods from GE crops, and the text of FDA congressional testimonies on its oversight of foods derived from GE crops.

Information on FDA's voluntary premarket consultation process available on the agency's website includes

- submission date and developer name;

- the type of GE crop submitted;

- the trait being genetically engineered into the crop (e.g., insect resistance);

- intended use (e.g., human food or animal feed);

[5]The Scientific Advisory Panel is generally composed of biologists, statisticians, toxicologists and other experts who provide independent scientific advice to EPA on a wide range of health and safety issues related to pesticides.

- whether the product required EPA review (when a plant-incorporated protectant, i.e., pesticide, is produced);
- FDA's "note to the file" summarizing FDA's evaluation of the information submitted by the developer and the consultation's outcome;[6] and
- the date and text of FDA's final response letter, also called a "no further questions" letter, to the developer, that marks the completion of the consultation.

Additional information about voluntary premarket consultations that is not otherwise trade secret or confidential commercial information may be obtained through a Freedom of Information Act (FOIA) request, according to FDA documentation and officials.[7] From September 2002, the earliest date for which FDA maintains digital internal records on FOIA requests, through July 2015, FDA received at least one FOIA request for 22 (39 percent) of the 56 voluntary premarket consultations completed during that time.[8] FDA officials stated that although developers generally note that their submissions typically do not contain very much trade secret or confidential commercial information, some companies request that their information not be published on the Internet. Further, FDA officials noted that this information is often of a highly technical nature and if FDA were to post this information, these officials said FDA would have to evaluate what information in the submission may lawfully be disclosed, revise the electronic files to make them more accessible under section 508 of the

[6]The note to the file provides more detailed summaries and explanations of several elements of the information submitted by developers after the completion of a voluntary consultation. Examples include more detailed explanations of the intended effect of the new genetic trait, summaries of the developer's synopsis of the study's design, summaries of the developer's compositional analyses, and a high-level description of the developer's findings.

[7]FOIA establishes a legal right of access to government information on the basis of the principles of openness and accountability in government.

[8]FDA officials said that they did not have data on the number of FOIA requests received regarding the agency's voluntary premarket consultations since such consultations began in January 1995 through September 2002.

Rehabilitation Act of 1973,[9] and then review the material to ensure its accuracy before posting, a process that would take considerable staff time. Noting that their staff already face a number of competing priorities, these officials questioned whether routinely preparing companies' detailed data for posting on FDA's website was a good use of staff time, especially since these data can be obtained by FOIA request.

[9]Under section 508 of the Rehabilitation Act of 1973, as amended, federal agencies are required to make their electronic and information technology accessible to people with disabilities. This requirement applies to all federal agencies when they develop, procure, maintain, or use electronic and information technology, unless it would pose an undue burden on the agency. 29 U.S.C. § 794d.

Appendix III: USDA and FDA Approaches to Labeling GE Food Ingredients

The U.S. Department of Agriculture (USDA) and Food and Drug Administration (FDA) have different roles in the regulation of food labeling, including the labeling of foods that might contain genetically engineered (GE) ingredients, based on their respective statutory authorities. As a result, the agencies differ in their approach to providing information to the public on GE food ingredients and the labeling GE food ingredients.

USDA's National Organic Program and Process Verified Program

USDA currently provides information to the public about the GE content of a food product through two programs: USDA's National Organic Program and its Process Verified Program.

The Organic Foods Production Act of 1990 directs the Secretary of Agriculture to establish a national organic certification program. Under the National Organic Program, a program managed by USDA's Agricultural Marketing Service, products can receive a USDA organic seal if they meet specific national standards. USDA develops the standards for organically produced agricultural products to assure consumers that products with the USDA organic seal meet consistent, uniform standards. Specifically, according to USDA's policy and regulations, USDA's National Organic Program establishes standards for organic certification, which forbids the use of GE methods, among other things, in the production of organic crops. Products bearing the USDA organic seal have received a process-based certification, in addition to other national standardized factors set by USDA's National Organic Program required to attain organic status. USDA's National Organic Program standards for certified organic crops prohibit the use of sewage sludge, synthetic fertilizers, synthetic pesticides, and genetic engineering. Meat and poultry products that qualify as USDA organic may make a "Non-Genetically Engineered" claim based on their organic certification. However, the USDA organic seal itself does not bear the term non-GE. In addition, the National Organic Program requires that certifying agents conduct residue testing from a minimum of 5 percent of operations that they certify.

According to USDA officials, the Process Verified Program was started in 1999 and is conducted on a fee-for-service basis by USDA's Agricultural Marketing Service. Exercising its authority under the Agricultural Marketing Act of 1946, the Agricultural Marketing Service serves as a third-party auditor, physically visits a site, and verifies that a company's processes meet standards a company sets for itself. According to USDA

documentation and officials, these processes include, for example, how crops are grown or how livestock are raised, and whether the products are handled and processed according to specific guidelines.[1] Companies, such as grain handlers or poultry, pork, and cattle producers and processors, submit their processes to USDA for verification. According to USDA officials, the Process Verified Program allows consumers to be assured that what they are buying adheres to the company's standards when they see USDA's process verified seal on packaging. The USDA website includes the process points for all companies for which the Agricultural Marketing Service has completed process verifications and displays what standards USDA used to audit the company's process or processes. For example, the Agricultural Marketing Service has done process verifications to evaluate whether a company is feeding poultry a vegetarian diet, is not treating its livestock with antibiotics, or is handling grains in accordance with specific contract specifications (e.g., that they are segregating the grains in a way that satisfies a contract).

USDA's Agricultural Marketing Service completed its first process verification for a non-GE process in May 2015. It allowed a company to market its raw organic corn and soybeans by saying they were produced using a process intended to result in a product with GE content below a specific threshold.[2] The company's claim was that its non-GE process results in corn and soybeans that do not exceed 0.9 percent GE content. According to agency officials, USDA's program verified the company's process for the crops, although it did not address the content of any final products.

USDA officials stated that there has to be transparency if a food processor is going to use the USDA Process Verified Program seal. For example, the packaging of soy milk produced from non-GE process-verified soybeans would have to specify that it was made from non-GE soybeans, but could not imply that the final product, which includes other ingredients, had been produced in accordance with the same non-GE standards, unless those were also process verified by USDA.

[1]USDA posts companies' specific guidelines online. USDA's Process Verified Program seal on food packaging bears language directing consumers to USDA's website to view that company's specific guidelines and what the company does to meet those standards.

[2]Certified organic products are already produced in accordance with a process that prohibits use of GE seeds, although not all non-GE products are organic.

USDA officials stated that other companies have approached USDA about potentially pursuing their own non-GE process verification. These officials said that USDA will continue to operate the program by evaluating companies' processes against the companies' own standards because USDA officials do not have the statutory authority to define what is a universal non-GE process standard. These officials stated that setting a government standard for what constitutes a non-GE food or process would probably require legislative action by Congress.

FDA Maintains There Is No Basis for Requiring GE Labeling

FDA regulates food labeling and enforces prohibitions against misbranded foods. According to FDA documentation and agency officials, FDA applies the same labeling principles to foods regardless of whether they are derived from GE or non-GE sources. The agency maintains it has no basis for concluding that foods derived from GE sources differ from their non-GE counterparts in any meaningful or uniform way solely based on their method of production, and therefore there is no basis for requiring labeling that indicates a food was developed through GE techniques. Further, according to its 1992 policy on GE foods,[3] FDA maintains that it has no basis to conclude that as a class, foods developed with GE techniques present any different or greater safety concern than foods developed by non-GE plant breeding. According to FDA officials, scientific studies, information, and data FDA has reviewed since it issued its 1992 policy, including data and information evaluated through its voluntary premarket consultation process, reflect this same conclusion.

FDA provides information on its website about why foods from GE plants are not currently required to be labeled to inform consumers about how the food was produced. The agency acknowledges on its website that there is strong consumer interest in knowing whether foods were produced using GE methods and that FDA supports voluntary labeling, maintaining that such statements must be truthful and not misleading. FDA finalized guidance to industry in November 2015 on voluntary labeling indicating whether foods have or have not been derived from GE plants.[4] This guidance contains nonbinding recommendations and states

[3]Food and Drug Administration, *Statement of Policy: Foods Derived from New Plant Varieties* (Washington, D.C.: May 1992).

[4]Food and Drug Administration, *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants* (College Park, Md.: November 2015).

that labeling by manufacturers on a wholly voluntary basis regarding whether a food was or was not bioengineered is acceptable to FDA, provided that such labeling is truthful and not misleading. In addition, the guidance states that FDA encourages food manufacturers to ensure that labeling terminology concerning the use of modern biotechnology in the production of food or its ingredients be accurate and consistent and that the integrity and meaning of scientific terminology be preserved to help ensure clear communication in food labeling. In addition, according to the guidance

- if a food derived from GE plants is significantly different from its traditional counterpart such that the common or usual name or existing statement of identity no longer adequately identifies or describes the new food, the name of the new food must be changed to a term that accurately identifies or describes the new food;

- if a GE food or one of its constituents differs from its traditional counterpart regarding how the food is used or the consequences of its use (for example, if the GE food behaves differently than its traditional counterpart when used in a comparable way, such as in frying or canning), a statement must be made on the label to describe the difference(s) in use or the consequence(s) of its use; and

- if a food derived from GE plants contains an allergen that consumers would not expect to be present in the food based on the name of the food, the presence of that allergen must be disclosed on the label.

The guidance also states that a manufacturer that claims that a food product or its ingredients, including foods such as raw agricultural commodities, are GE or not GE should substantiate that the claim is truthful and not misleading. The guidance provides methods a manufacturer may use, including documentation of handling practices and procedures (those with control over growing, harvesting, storing, and distribution should consider appropriate recordkeeping to document whether foods are or are not produced using genetic engineering, including segregation procedures), use of certified organic food (compliance with USDA's requirements can be used to support food labeling claims about the production of food without the use of genetic engineering), and the use of validated test methods (to confirm the presence of bioengineered material in food derived from GE plants).

Appendix IV: Stakeholder Perspectives and Legislative Actions on Labeling of Foods Derived from GE Ingredients

Stakeholders we interviewed have differing views with respect to labeling of foods derived from genetically engineered (GE) ingredients. Proponents of mandatory GE labeling, including some consumer rights groups, argued that consumers have a right to know what is in their food. They also said that mandatory GE labeling would allow members of the public to make more informed decisions about what they purchase and consume. In addition, some proponents said mandatory GE labeling would be a low-cost way for companies to better inform consumers. For example, an analysis requested by the Consumers Union in 2014 estimated the cost of introducing such a national standard,[1] if passed on to consumers through higher prices, would be less than $10 per family each year.[2] Some opponents of GE labeling suggested that labeling foods containing GE ingredients—particularly without a demonstrated food safety risk—would confuse or unnecessarily alarm consumers. They estimated the costs of mandatory GE labeling could be as much as $400 to over $800 per family each year, as companies pass the costs on to consumers of changing packaging or switching to non-GE suppliers to avoid a label. However, some stakeholders said that a federal standard for GE labeling would promote clarity for consumers and prevent inconsistent policies. For example, one stakeholder said that if no national standard is imposed, states may act on their own, resulting in a system with policies that differ from state to state, creating confusion, negative impacts on interstate commerce, and additional costs for consumers as product packaging and labeling would have to be tailored to each individual state.

A number of bills were introduced in the 114th Congress related to labeling foods containing GE ingredients. A bill titled “Genetically Engineered Food Right-to-Know Act” was introduced in the Senate and House in February 2015, among other things, to establish a consistent and enforceable standard for labeling of foods produced using genetic

[1]According to its website, Consumers Union is the policy and action division of Consumer Reports.

[2]Andrew Dyke and Robert Whelan. *GE Foods Labeling Cost Study Findings* (Portland: ECONorthwest, Sept. 12, 2014). This analysis of existing studies found that the median cost that might be passed on to consumers by companies if mandatory GE labeling was enacted would be $2.30 per person annually, or $9.20 for a family of four.

engineering.[3] A bill titled "Safe and Accurate Food Labeling Act of 2015" was introduced in the House in March 2015 that would effectively prohibit mandatory labeling of GE foods, including any state-level labeling requirements.[4] That legislation would make FDA's voluntary premarket consultation process mandatory, establish a USDA certification for non-GE foods similar to the current National Organic Program, and preempt any state-level legislation requiring GE labeling.

As of July 2015, according to the National Conference of State Legislatures, various bills were introduced in more than 30 states since 2011 to address GE labeling at the state level. Some bills proposed a mandatory labeling system, under which a product containing any GE ingredients must be labeled as such. Other proposals involved a voluntary labeling system that would set labeling standards for products that do not contain GE ingredients and, in some cases, implement a system for verifying and labeling products as non-GE.[5] As of July 2015, three states had passed mandatory labeling laws for food products made from GE ingredients. Vermont enacted legislation in May 2014, which requires mandatory labeling of all GE foods beginning July 1, 2016. In addition, Connecticut and Maine enacted legislation in June 2013 and January 2014, respectively, on mandatory labeling of GE food products. Connecticut's law will go into effect when four other states adopt similar legislation, including at least one state bordering Connecticut, and the combined population of northeast states adopting such legislation must exceed 20 million. Maine's law requires five contiguous states, including Maine, to pass a law requiring GE labeling before its law will go into effect.

[3]For example, these bills include Genetically Engineered Food Right-to-Know Act, S. 511, 114th Cong. (2015); Genetically Engineered Food Right-to-Know Act, H.R. 913, 114th Cong. (2015); and Safe and Accurate Food Labeling Act of 2015, H.R. 1599, 114th Cong. (2015). Several hearings have been held on this issue and H.R. 1599 was passed by the House in July 2015.

[4]Safe and Accurate Food Labeling Act of 2015, H.R. 1599, 114th Cong. (2015). This bill was passed by the House in July 2015.

[5]At least one third-party, nongovernmental sector effort has been established to label non-GE products. One organization provides fee-for-service testing of a food product's individual ingredients, and if they meet the organization's threshold of no more than 0.9 percent GE content, the food product can bear a non-GE seal.

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

United States Department of Agriculture

Office of the Secretary
Washington, D.C. 20250

FEB 22 2016

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

Dear Mr. Morris:

Thank you for providing the United States Department of Agriculture (USDA) the opportunity to comment on the Government Accountability Office's (GAO) Draft Report "Genetically Engineered Crops: USDA Needs to Enhance Oversight and Better Understand Impacts of Unintended Mixing with Other Crops" (16-241). We have provided some overall comments, and have addressed the three Recommendations made to the Secretary of Agriculture.

Since 1986, the U.S. regulatory system has thoroughly reviewed and brought many new genetically engineered (GE) agricultural products to market. We have great confidence in the safety of the many GE crops reviewed and approved by the U.S. regulatory system.

While we generally agree with the GAO Recommendations, USDA takes issue with five themes that are repeated throughout the report. Specifically, USDA is concerned that the intent of current USDA efforts to update the regulations is misstated; the intent of the 2008 proposed rule is misstated; plant pest and newer technologies are inappropriately conflated; newer technologies are presented as inherently more risky; and the 'Am I Regulated?' inquiries are presented as escaping regulation because they were developed using newer technologies.

USDA provides additional clarity on these five themes:

USDA's current intention for updating the USDA biotechnology regulations remains the same as it was in 2008: to enhance our ability to protect plant health from plant pest risk and from noxious weed risk. This intention is not based on the technology used to develop the GE plants. In several places, the GAO report states that the 2008 proposed rule was intended to capture newer technologies. This is not correct. As stated above, just like in our 2008 proposed rule, the proposed rule currently in development is intended to enhance USDA's ability to protect plant health. USDA is updating its biotechnology regulations to protect plant health from plant pests and noxious weeds regardless of the method to transform the organism.

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The phrase "newer technologies that do not involve a plant pest" is used several times. This phrase incorrectly conflates use of newer technologies with use of a plant pest component. There are older technologies that do not involve a plant pest (e.g., biolistics) and there are newer technologies that do involve a plant pest (e.g., TALENs). USDA's statutory authority is to prevent the introduction and dissemination of plant pests and noxious weeds in the United States, and as such, USDA may regulate any GE organism which "the Administrator determines is a plant pest or has reason to believe is a plant pest" and may regulate, as necessary, any plant that poses a risk as a noxious weed.

The GAO report implies that some of the newer technologies are inherently more risky. USDA has no reason to believe that newer technologies, such as gene editing, are riskier or present any new risks, as compared to older technologies. USDA concludes, as did the Office of Science and Technology Policy in 1986 when it issued the Federal Coordinated Framework for the Regulation of Biotechnology, that potential risk of a GE organism is derived from the characteristics of the GE organism itself and the environment in which they are introduced and not from the technology that was used for the GE organism.

And lastly, the report gives the incorrect impression that many of the 'Am I Regulated?' inquiries from GE crop developers escape USDA regulations because they were developed using newer technologies. In fact, most inquiries to date concern GE plants developed with biolistics, which is an older technology. For those inquiries where we determined that the organism in question was not a regulated article, we first concluded that there was no reason to believe the organism presented a plant pest risk. This USDA scientific review and evaluation of submitted inquiries demonstrates USDA's commitment to safeguarding plant health.

GAO Recommendation

To improve USDA's ability to oversee GE crops, GAO recommends that the Secretary of Agriculture direct the Administrator of APHIS to develop a timeline, with milestones, and interim steps, for updating its existing regulations to cover GE crops developed with newer technologies that do not depend on the use of plant pests.

USDA Response

USDA agrees in part with this Recommendation. USDA has developed an internal timeline for outlining key milestones and interim steps, all with associated target dates, for updating the existing regulations that cover GE organisms. USDA's proposed regulations are being developed to address products of biotechnology, regardless of laboratory technique used to create or modify the genome. Thus, the intention of the proposed rule currently in development (as well as the 2008 proposed rule) is the overall protection of plant health through regulation of

GE organisms that may pose a plant pest or noxious weed risk, with no relation to the technology used to develop the GE organism.

GAO Recommendation

To improve USDA's ability to better understand the economic impacts of unintended mixing of GE and other crops, GAO recommends that the Secretary of Agriculture direct the Administrator of NASS to work with all relevant USDA stakeholders, including APHIS and the Organic Working Group, to determine what additional information should be sought in future Organic Surveys, such as the costs of re-shipping and re-storing shipments rejected because of unintended GE presence, as well as the costs associated with finding new buyers for such shipments.

USDA Response

USDA agrees with this Recommendation. NASS works with all relevant stakeholders to determine what information is needed for future organic surveys. Throughout the data collection and processing phases of the 2014 Organic Survey, NASS worked with APHIS officials concerning the data and data quality in regards to the GE-related question. Since then, NASS has held a series of meetings with APHIS officials, as well as the Chair of the OWG, to discuss the 2014 Organic Survey results and how to move forward with future questions. The most recent of these meetings was held in early January 2016. At the conclusion of the January 2016 meeting, and in an effort to remain collaborative, NASS, APHIS, and the Chair of the OWG vowed to keep meeting as well as to bring more stakeholders into the discussions. This will ensure that future Organic Surveys and related surveys involving GE related questions will have the necessary attention to obtain data, such as the need to better understand economic impacts of unintended mixing of GE crops.

GAO Recommendation

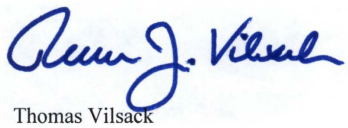
To improve USDA's ability to better understand the economic impacts of unintended mixing of GE and other crops, GAO recommends that the Secretary of Agriculture direct the Administrator of NASS to include producers growing identity-preserved crops, in addition to organic producers in USDA's survey efforts.

USDA Response

NASS' overall survey programs currently includes identity-preserved crops, and conventional and organic producers. The sample design for our programs includes two different frames: area and list frames. The area frame is defined as the entire land mass of the United States and ensures complete coverage of the U.S. farm population. The list frame is a roster of known

farmers and ranchers and includes a profile of each operation indicating the size of the operation and what commodities have historically been produced. Data from the area and list frame samples are expanded and combined using multiple-frame statistical methodology which ensures that all farms are represented in the summary totals and that each farm is included only once. These samples are designed to produce estimates at the State and/or U.S. levels only.

Thank you for your report on genetically engineered crops. Please feel free to contact us if you have any questions.



Thomas Vilsack
Secretary

Appendix VI: 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, James R. Jones, Jr. (Assistant Director), Cheryl Arvidson, Kevin S. Bray, Barbara El Osta, Cindy Gilbert, Adrian Pavia, Caitlin Rice, Aaron Shiffrin, and Kiki Theodoropoulos made key contributions to this report.

Related GAO Products

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