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# STATEMENT OF

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## BEFORE THE

## COMMITTEE ON AGRICULTURE, NUTRITION AND FORESTRY

## UNITED STATES SENATE

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Good morning, Chairman Roberts, Ranking Member Stabenow, and members of the Committee. I am Dr. Susan Mayne, Director of the Center for Food Safety and Applied Nutrition at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). Thank you for the opportunity to be here today to discuss FDA's regulatory program for foods derived from genetically engineered (GE) sources.[1]

Over the last 20 years, FDA has reviewed and evaluated data and information on more than 150 GE plant-derived foods, ranging from herbicide-tolerant soybeans to canola oil with a modified fatty acid profile. In a 1992 policy statement on foods derived from new plant varieties (including GE plant varieties), FDA stated that the Agency was not aware of any information showing that foods derived by these methods (i.e., genetic engineering) differ from other foods in any meaningful or uniform way or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding. This 1992 statement and its scientific underpinnings still reflect FDA's current thinking about foods derived from GE plants and, based on our evaluations, we are confident that foods from genetically engineered sources in the U.S. marketplace today are as safe as their conventional counterparts.

**BACKGROUND**

The selection and genetic improvement of plants for agricultural use has been going on for

[1] Foods derived from genetically engineered sources are also referred to as biotech, bioengineered, and genetically modified (GM) foods. Because from a scientific perspective, the term "genetic modification" means the alteration of the genotype of an organism using any technique, new or traditional, and therefore also encompasses plants altered through methods such as conventional breeding and selection, FDA uses the term "genetically engineered," or "GE," to distinguish organisms that have been modified using genetic engineering (also known as modern biotechnology) from those modified through traditional breeding.

thousands of years, although plant breeding as a science only began in the late 1800s. Typically, plant breeding has involved crossbreeding and hybridization, in which two related plants are cross-fertilized, and the resulting offspring have characteristics of both parent plants. In the breeding process, however, many undesirable traits often can appear in addition to the desirable ones. Some of those undesirable traits can be eliminated through additional breeding, which is time-consuming. Breeders can then further select and reproduce the offspring that have the desired traits. Many of the foods that are already common in our diet are obtained from plant varieties that were developed using conventional genetic techniques of breeding and selection. Hybrid corn, nectarines (which could be considered genetically altered peaches), and tangelos (a genetic hybrid of a tangerine and grapefruit) are all examples of such breeding and selection.

Today, by inserting one or more specific genes into a plant, scientists are able to produce a plant with new characteristics. These techniques give scientists the ability to isolate specific genes of interest and introduce them and their corresponding traits into plants without simultaneously introducing undesirable genes and traits. This can reduce the time-consuming process of breeding out undesired genes and traits when developing a new variety. Genetic engineering also expands the range of new proteins and other substances that can be introduced into plants.

Any genetic modification technique, including both conventional methods and genetic engineering, could change the composition of a food in a manner relevant to food safety. However, FDA has well-established scientific procedures for evaluating the safety of such new substances, and our guidelines help developers identify these issues and address such concerns prior to marketing. It is important to note that the kinds of testing typically conducted by

developers of a GE food crop to ensure that their foods meet applicable requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) also address food safety concerns. This testing provides a way to detect undesirable traits at the developmental stage and defer marketing until any concerns are resolved. FDA expects developers of foods derived from GE plants to analyze the composition of the foods from their new crop varieties to ensure that any changes compared to the food's conventionally derived counterpart are appropriately considered and addressed before marketing such foods.

As part of our review and analysis, we consider whether any newly introduced protein is likely to be allergenic or toxic and whether levels of important nutrients or anti-nutrients have been changed in a way that is relevant to food safety or nutrition. We also consider whether any newly introduced protein requires premarket approval as a food additive. Later in my testimony, I will describe the Agency's rigorous premarket consultation process and discuss in more detail how it helps us ensure the safety of foods derived from GE plants.

**COORDINATED FRAMEWORK FOR THE REGULATION OF BIOTECHNOLOGY**

FDA regulates foods from GE sources in conjunction with the U.S. Department of Agriculture (USDA) and the Environmental Protection Agency (EPA) under the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework), adopted by the agencies in 1986[2] and updated in 1992.[3] The Coordinated Framework provides a comprehensive Federal regulatory policy for ensuring the safety of biotechnology products. While the current

[2] 51 FR 23302, June 26, 1986

[3] 57 FR 6753, February 27, 1992

regulatory system for biotechnology products effectively protects health and the environment, advances in science and technology since 1992 have altered the product landscape. In addition, the complexity of the array of regulations and guidance documents developed by the three primary Federal agencies with jurisdiction over biotechnology products can make it difficult for the public to understand how the safety of biotechnology products is evaluated, and navigating the regulatory process for these products can be challenging, especially for small companies.

In light of these circumstances, on July 2, 2015, the Executive Office of the President (EOP) issued a Memorandum to FDA, EPA and USDA on modernizing the regulatory system for biotechnology products. The EOP Memorandum directs the agencies to implement certain specified activities, both in the near term and long term, including:

1. Establish an inter-agency biotechnology working group that includes representatives from EPA, FDA, USDA, and the EOP. The working group will implement activities identified below and will prepare an annual report of its activities for public dissemination.
2. Update the Coordinated Framework to clarify current roles and responsibilities of the agencies that regulate the products of biotechnology, after input from the public.
3. Develop a long-term strategy to ensure that the Federal regulatory system is equipped to assess the safety of future biotechnology products, to include a plan for periodic horizon-scanning assessments of new biotechnology products; identify any needed changes to authorities, regulations, or policies necessary to improve the agencies' abilities to assess potential risks; and increase transparency and streamline their

regulatory processes.

4. Conduct external independent assessments every five years to identify future products of biotechnology and to evaluate whether such products pose new risks.

Efforts are underway to implement the activities described in the memorandum. Subsequent to the issuance of the EOP Memorandum, an inter-agency working group, with representatives from the EPA, FDA, USDA, and the EOP, has been established within the Emerging Technologies Interagency Policy Coordination Committee to implement the activities described in the EOP Memorandum.

Under the auspices of the National Science and Technology Council, this interagency group issued a Request for Information (RFI) in the *Federal Register* to solicit data and information, including case studies, that can inform the development of the proposed update to the Coordinated Framework and the development of a long-term strategy consistent with the objectives described in the EOP Memorandum.[4]

FDA is hosting the first of three public meetings to be held across the country as part of the effort described in the EOP Memorandum. Under the auspices of the National Science and Technology Council, the FDA, along with the Office of Science and Technology Policy, EPA, and USDA, is holding this meeting to inform the public about the activities described in the EOP Memorandum; invite oral comments from interested parties; and provide information about how to submit written comments, data, or other information to the docket. This first public

[4] 80 FR 60414, October 6, 2015

meeting will be held on October 30, 2015, at the FDA campus in Silver Spring, Maryland. Information received at and after this public meeting and in response to the RFI will be used by FDA and others in the inter-agency working group as we update the Coordinated Framework and develop the long-term strategy.

We are committed to and look forward to working with the EOP, USDA, and EPA to implement the activities described in the EOP Memorandum. The Agency anticipates that this effort will further enhance the transparency and predictability of FDA's existing regulatory processes.

## FDA'S LEGAL AND REGULATORY FRAMEWORK PERTAINING TO FOODS DERIVED FROM GE PLANTS

FDA regulates the safety of foods, including foods derived from GE plants, under the FD&C Act and other applicable laws and regulations. Under the FD&C Act, FDA is also responsible for enforcement with respect to unlawful pesticide chemical residues in foods. Foods, such as fruits, vegetables, grains, and their byproducts, derived from plant varieties developed through genetic engineering, are subject to the same safety and labeling requirements as foods derived from non-GE plants. The Agency has broad authority to initiate regulatory action if a product fails to meet the requirements of the FD&C Act, as discussed in more detail below. FDA relies primarily on two sections of the FD&C Act to ensure the safety of foods and food ingredients, including those that are produced using genetic engineering:

The adulteration provisions of section 402(a)(1) [21 U.S.C. 342(a)(1)]. Under this post-market authority, FDA has the power to remove a food from the market (or sanction those marketing the food) if the food poses a risk to public health. It is important to note that the FD&C Act places a

legal duty on developers, manufacturers, and distributors to ensure that the foods they market to consumers are safe and comply with all legal requirements.

The food additive provisions of section 409 [21 U.S.C. 348]. Under this section, a substance that is intentionally added to food is a food additive, unless the substance is generally recognized as safe (GRAS) or is otherwise excluded (e.g., a pesticide, the safety of which is overseen by EPA). The FD&C Act requires premarket approval of any food additive, regardless of the technique used to add it to food. Use of an unapproved food additive renders the food unsafe and subject to the adulteration provisions in 402(a)(2)(C) of the FD&C Act.

FDA's *Statement of Policy: Foods Derived from New Plant Varieties*[5] explains how existing legal requirements apply to plant-derived food products developed using the tools of biotechnology. The policy was designed to answer questions about these products and to assist developers, prior to marketing, to meet their legal duty to provide safe and wholesome foods to consumers. The basic principle of the policy is that the traits and characteristics of the foods should be the focus of safety assessment for all new varieties of food crops, no matter which techniques are used to develop them.

Under FDA policy, a substance that would be a food additive if it were added during traditional food manufacturing is also treated as a food additive if it is introduced into food through genetic engineering of a food crop. Section 409 requires premarket approval of any food additive and, thus, requires premarket approval of any substance intentionally introduced via genetic

[5] 57 FR 22984, May 29, 1992, accessible at *http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096095.htm*

engineering that is not GRAS.

Examples of substances intentionally introduced into food that would not be considered GRAS and, therefore, would be reviewed as food additives include those that have unusual chemical functions, have unknown toxicity, or would be new major dietary components of the food. In general, substances intentionally added to or modified in food via genetic engineering to date have been proteins and fats that are, with respect to safety, similar to other proteins and fats that are commonly and safely consumed in the diet. Therefore, these substances have not been subject to the food additive approval process. In our experience with foods derived from GE plants to date, we have approved only one substance as a food additive for human consumption—an enzyme produced by an antibiotic resistance gene (kanamycin). Under the food additive approval process for use in animal food, we have approved the use of two substances (kanamycin and gamma linolenic acid), and another is currently under review.

**VOLUNTARY PREMARKET CONSULTATION PROCESS**

Food growers, manufacturers, and distributors are responsible for taking the steps necessary to ensure that their food products marketed in the United States are safe. To help developers of foods derived from GE plants comply with their obligations under the FD&C Act and FDA regulations, the Agency encourages them to participate in a voluntary consultation process with FDA prior to commercial distribution. The goal of the voluntary premarket consultation process is to ensure that any safety or other regulatory issues associated with food from the new plant variety are resolved *prior* to commercial distribution. Although the premarket consultation is voluntary, in our experience, most developers utilize this pathway. FDA also retains the

authority to regulate and ensure the safety of foods derived from new plant varieties under existing adulteration and misbranding provisions of the FD&C Act.

The results of FDA's consultations are public information and are available on the Agency's website. Since the consultation process was created, developers of GE plants (which include private companies, academic institutions, and government agencies) have completed the process more than 100 times as they sought to introduce plants representing more than 150 different crop varieties into the U.S. market. These evaluations have included varieties of potato, apple, soybean, corn, cotton, canola, papaya, alfalfa, creeping bent grass, plum, sugar beet, wheat, rice, cantaloupe, flax, squash, and radicchio, with traits such as herbicide tolerance, insect resistance, virus resistance, altered ripening, altered nutritional profiles, altered plant fertility, and altered plant growth properties, and resistance to browning. Where the traits are pesticidal, FDA directs developers to work with EPA, which evaluates the safety of pesticides and sets tolerances for their presence in food, which are then enforced by FDA.

Typically, the consultation begins early in the product development stage, well before it is ready for market. Developers meet with FDA scientists to describe the product they are developing. In response, the Agency advises the company on what tests would be appropriate for the developer to assess the safety of the new food.

After the studies are completed, a summary of the data and information on the safety and nutritional assessment are provided to FDA for review. The Agency evaluates the information for all relevant food safety hazards, including potential unintended effects on plant composition

and nutritional properties, since plants may undergo changes other than those intended by the developers. For example, FDA scientists evaluate data and information to ensure that the newly expressed compounds are safe for food consumption and that there are no allergens new to the food, no increased levels of natural toxicants or anti-nutrients, and no reduction of important nutrients.

The safety assessment approach FDA applies during its evaluation of consultation submissions is consistent with the approach laid out in the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003), established by the Codex Alimentarius Commission, a food standard-setting body established by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO).

Some examples of the information evaluated by FDA include:

- The name of the food and the crop from which it is derived;
- The uses of the food, including both human food and animal feed uses;
- The sources, identities, and functions of introduced genetic material and its stability in the plant;
- The purpose or intended technical effect of the modification and its expected effect on the composition and characteristic properties of the food or feed;
- The identity and function of any new substances introduced by the genetic material, including an estimate of its concentration;
- A comparison of the composition and/or characteristics of food derived from the GE

plant variety to that of food derived from the parental variety or other commonly consumed varieties with special emphasis on important nutrients, anti-nutrients, and toxicants that occur naturally in the food;

- Information on whether the genetic modification altered the potential for the food derived from the GE plant variety to induce an allergic response; and
- Other information relevant to the safety and nutritional assessment of the food derived from the GE plant variety.

These examples are not meant to be exhaustive, but are sufficiently broad so as to provide FDA with an indication of any safety or other regulatory issues that may require additional investigation. This flexibility allows FDA's consultation program to ask the necessary questions to understand any uncertainties that may exist concerning safety or other attributes of the food in order to ensure the safety and lawfulness of food from a new plant variety.

If FDA scientists have questions about the safety data, the developer may, for example, provide more detailed answers or conduct additional studies. Participation in the process is voluntary, although as previously noted, most, if not all, developers participate in this process and it provides for a rigorous food safety evaluation. It is common for FDA to request additional data and information or clarification about the data and information submitted by the developer. This iterative process makes for a rigorous safety evaluation. FDA considers a consultation to be complete only after all safety and other legal issues have been resolved. The final consultation phase and review of the firm's safety assessment generally takes 1-2 years, depending on the complexity of the consultation. The premarket consultation process is working well and protects

public health by helping FDA ensure that firms are making market-entry decisions in compliance with the law.

**LABELING OF FOODS DERIVED FROM GE SOURCES**

FDA also regulates the labeling of food under the FD&C Act. Section 403 of the Act [21 U.S.C. 343] sets forth labeling requirements for foods subject to the FD&C Act. In general, all foods, whether produced using genetic engineering or not, are subject to these labeling requirements. Section 403(a)(1) establishes that a food is misbranded if its labeling is false or misleading in any particular. Section 201(n) provides, in relevant part, that labeling is misleading if, among other things, it fails to reveal facts that are material in light of representations made or suggested in the labeling, or material with respect to consequences that may result from the use of the food under the conditions of use prescribed in the labeling, or under such conditions of use as are customary or usual.

In its 1992 Policy Statement, FDA explained that it found no basis to conclude that foods derived from new plant varieties developed using genetic engineering techniques, as a class, differ from other foods in any meaningful or uniform way or pose any different or greater safety concern than foods developed by traditional plant breeding. Therefore, the use of genetic engineering in the development of a food is normally not, by itself, material information within the meaning of section 201(n) of the FD&C Act. Scientific studies, information, and data FDA has reviewed since then, including data and information evaluated through the voluntary premarket biotechnology consultation process, reflects the same conclusion.

As set forth in the 1992 Policy, absent a material fact or difference in a food derived from a GE source, sections 403(a)(1) and 201(n) of the FD&C Act do not require additional labeling indicating that the food has been developed through genetic engineering. Federal courts have held that this interpretation of sections 403(a)(1) and 201(n) of the FD&C Act is entitled to deference. Further, courts have held that consumer desire to know such information is not, by itself, sufficient to require such labeling. FDA may require additional labeling for foods derived from GE sources, just as we would for non-GE foods that have been genetically modified through conventional methods such as plant breeding, when the genetic change results in a material difference in the food, such as a difference in nutritional content of the food (e.g., altered fatty acid profile) or a difference in functional characteristics of the food (e.g., suitability for frying). In general, it is the difference (e.g., not suitable for frying) and not the fact that the product was produced using genetic engineering that must be disclosed in the labeling. For example, oil from genetically engineered soybeans with increased levels of oleic acid is required to be labeled "high oleic soybean oil" so that consumers know that the nutritional properties of the oil are different from those of traditional soybean oil. We note that the Agency has received two Citizen Petitions regarding the labeling of genetically engineered foods. We are currently reviewing those petitions and considering the issues presented.

We recognize and appreciate that many consumers are interested in knowing whether their food is produced using genetic engineering. Currently, food manufacturers may indicate through voluntary labeling whether foods have or have not been developed through genetic engineering, provided that such labeling is truthful and not misleading. The Agency is supportive of such voluntary labeling and, in 2001, issued draft guidance to industry to help food manufacturers

who wish to voluntarily provide such information in food labeling to help ensure that such labeling is truthful and not misleading. FDA received more than 155,000 comments on the draft guidance. The Agency has considered the comments we received and is currently revising the draft guidance with the goal of publishing a final guidance document to assist food manufacturers who want to provide such labeling statements.

**GE ANIMALS**

FDA regulates GE animals under the new animal drug provisions of the FD&C Act and the Agency's implementing regulations. Because the genetic material, or recombinant DNA (rDNA) construct as integrated into the DNA of the target animal is intended to affect the structure or function of that animal, the rDNA construct meets the definition of a drug under the FD&C Act. The new animal drug approval process provides a rigorous review for such products.

The FD&C Act generally requires sponsors to demonstrate the safety and effectiveness of a new animal drug for the proposed conditions of its use prior to marketing. For new animal drugs that are intended for use in food-producing animals, FDA's evaluation of safety includes not only an evaluation of target animal safety, but also an evaluation of food safety. In addition, FDA must comply with the requirements of the National Environmental Policy Act prior to taking any actions, such as approval of an application.

In January 2009, FDA issued a final guidance for industry on the regulation of GE animals. The guidance explains the process by which FDA is regulating GE animals and provides a set of recommendations to help producers of GE animals meet their responsibilities under the law.

As the company has publicly noted, FDA is currently reviewing a new animal drug application related to AquAdvantage Salmon, an Atlantic salmon developed by AquaBounty Technologies, Inc., which is genetically engineered to reach market size more quickly than its non-GE counterpart. In December 2012, the Agency made its draft environmental assessment (EA) and a preliminary finding of no significant impact (FONSI) available for public comment. The draft EA and preliminary FONSI are the Agency's initial assessment of the potential impacts of the proposed product on the environment of the United States under the specific conditions proposed by the sponsor. FDA received over 35,000 comments on the draft EA and preliminary FONSI. We are reviewing these comments in order to determine whether any changes in the draft EA or additional analysis are warranted.

On September 19-20, 2010, the Agency held a public meeting of its Veterinary Medicine Advisory Committee (VMAC), a former body comprised of independent outside experts who advised FDA on scientific, technical, and policy matters, to discuss AquAdvantage Salmon. The presentations made by Agency experts, the transcript of that meeting, the Chair's report, and VMAC documents containing detailed information on the review process are all posted on FDA's website for public review. At the public meeting, the Agency did not indicate any preliminary views or determination on the product application. It did, on the safety question, provide a preliminary indication, noting that based on the data and information available at that time, food from AquAdvantage Salmon appears to be as safe to eat as non-GE farm-raised Atlantic salmon. FDA will make a final food safety determination before reaching any final decision on whether to approve the new animal drug application for AquAdvantage Salmon.

We also note that in the event that the new animal drug application for this product is approved the Agency will provide information to the public regarding any labeling of food from AquAdvantage Salmon.

**CONCLUSION**

FDA's voluntary premarket consultation process provides for a rigorous food safety evaluation foods derived from GE plants. As a result of these premarket consultations, we are confident that foods derived from GE plants in the U.S. marketplace today are as safe as their conventional counterparts. The Agency, in cooperation with EPA and USDA, will continue its oversight of new and emerging foods produced using genetic engineering and will be vigilant in ensuring the safety and integrity of the food supply.

Thank you for the opportunity to discuss FDA's regulation of foods derived from GE sources. I am happy to answer any questions you may have.