

**NATIONAL ENVIRONMENTAL POLICY ACT DECISION
AND
FINDING OF NO SIGNIFICANT IMPACT**

**Okanagan Specialty Fruits
Events GD743 and GS784**

**United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services**

The United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) has developed this decision document to comply with the requirements of the National Environmental Policy Act (NEPA) of 1969, as amended, the Council of Environmental Quality's (CEQ) regulations implementing NEPA, and the USDA APHIS' NEPA implementing regulations and procedures. This NEPA decision document, a Finding of No Significant Impact (FONSI), sets forth APHIS' NEPA decision and its rationale. Comments from the public involvement process were evaluated and considered in developing this NEPA decision.

In accordance with APHIS procedures implementing NEPA (7 CFR part 372), APHIS has prepared an Environmental Assessment (EA) to evaluate and determine if there are any potentially significant impacts to the human environment from a determination on the regulated status of a petition request (APHIS Number 10-161-01p) by Okanagan Specialty Fruits (OSF) for their genetically engineered apple Events GD743 and GS784 (hereafter referred to as GD743 and GS784 apples) which are resistant to enzymatic browning. This EA has been prepared in order to specifically evaluate the effects on the quality of the human environment that may result from approving the petition seeking nonregulated status for GD743 and GS784 apples. The EA assesses alternatives to a determination of nonregulated status of GD743 and GS784 apples and analyzes the potential environmental and social effects that result from the proposed action and the alternatives.

Regulatory Authority

“Protecting American agriculture” is the basic charge of APHIS. APHIS provides leadership in ensuring the health and care of plants and animals. The agency improves agricultural productivity and competitiveness, and contributes to the national economy and the public health. USDA asserts that all methods of agricultural production (conventional, organic, or the use of genetically engineered (GE) varieties) can provide benefits to the environment, consumers, and farm income.

Since 1986, the United States government has regulated genetically engineered (GE) organisms pursuant to a regulatory framework known as the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) (51 FR 23302, 57 FR 22984). The Coordinated Framework, published by the Office of Science and Technology Policy, describes the comprehensive federal regulatory policy for ensuring the safety of biotechnology research and

products and explains how federal agencies will use existing Federal statutes in a manner to ensure public health and environmental safety while maintaining regulatory flexibility to avoid impeding the growth of the biotechnology industry. The Coordinated Framework is based on several important guiding principles: (1) agencies should define those transgenic organisms subject to review to the extent permitted by their respective statutory authorities; (2) agencies are required to focus on the characteristics and risks of the biotechnology product, not the process by which it is created; (3) agencies are mandated to exercise oversight of GE organisms only when there is evidence of “unreasonable” risk.

The Coordinated Framework explains the regulatory roles and authorities for the three major agencies involved in regulating GE organisms: USDA’s APHIS, the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA).

APHIS is responsible for regulating GE organisms and plants under the plant pest provision in the Plant Protection Act of 2000 (PPA), as amended (7 USC §§ 7701 *et seq.*) to ensure that they do not pose a plant pest risk to the environment.

The FDA regulates GE organisms under the authority of the Federal Food, Drug, and Cosmetic Act (FFDCA). The FDA is responsible for ensuring the safety and proper labeling of all plant-derived foods and feeds, including those that are genetically engineered. To help developers of food and feed derived from GE crops comply with their obligations under Federal food safety laws, FDA encourages them to participate in a voluntary consultation process. The FDA policy statement concerning regulation of products derived from new plant varieties, including those genetically engineered, was published in the Federal Register on May 29, 1992 (57 FR 22984-23005). Under this policy, FDA uses what is termed a consultation process to ensure that human food and animal feed safety issues or other regulatory issues (e.g., labeling) are resolved prior to commercial distribution of bioengineered foods.

The EPA regulates plant-incorporated protectants under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA also sets tolerance limits for residues of pesticides on and in food and animal feed, or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug and Cosmetics Act (FFDCA) and regulates certain biological control organisms under the Toxic Substances Control Act (TSCA). The EPA is responsible for regulating the sale, distribution, and use of pesticides, including pesticides that are produced by an organism through techniques of modern biotechnology.

Regulated Organisms

The APHIS Biotechnology Regulatory Services’ (BRS) mission is to protect America’s agriculture and environment using a dynamic and science-based regulatory framework that allows for the safe development and use of GE organisms. APHIS regulations at 7 Code of Federal Regulations (CFR) part 340, which were promulgated pursuant to authority granted by the PPA, as amended (7 United States Code (U.S.C.) 7701-7772), regulate the introduction (importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is no longer subject to the plant pest provisions of the PPA or to the regulatory requirements of 7 CFR part 340 when APHIS determines that it is unlikely to pose a plant pest risk. A GE organism is considered a regulated article if the donor organism, recipient

organism, vector, or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation (7 CFR 340.2) and is also considered a plant pest. A GE organism is also regulated under Part 340 when APHIS does not have information to determine if the GE organism is unlikely to pose a plant pest risk.

A person may petition the agency that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, is no longer regulated under the plant pest risk provisions of the PPA or the regulations at 7 CFR part 340. The petitioner is required to provide information under §§340.6(c)(4) related to plant pest risk that the agency may use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest risk provisions of the PPA when APHIS determines that it is unlikely to pose a plant pest risk.

APHIS' Response to Petition for Nonregulated Status

Under the authority of the plant pest provisions of the PPA and 7 CFR part 340, APHIS has issued regulations for the safe development and use of GE organisms. As required by 7 CFR 340.6, APHIS must respond to petitioners who request a determination of the regulated status of GE organisms, including GE plants such as GD743 and GS784 apple. When a petition for nonregulated status is submitted, APHIS must make a determination if the GE organism is unlikely to pose a plant pest risk. If APHIS determines, based on its Plant Pest Risk Assessment (PPRA), that the genetically engineered organism is unlikely to pose a plant pest risk, the genetically engineered organism is no longer subject to the plant pest provisions of the PPA and 7 CFR part 340.

OSF has submitted a petition (APHIS Number 10-161-01p) to APHIS seeking a determination that their genetically engineered apples GD743 and GS784 are unlikely to pose a plant pest risk and, therefore, should no longer be a regulated article under regulations at 7 CFR part 340.

GD743 and GS784 Apples

GD743 and GS784 apples are engineered to be resistant to enzymatic browning. The “nonbrowning” phenotype of events GD743 and GS784 were developed by inserting a polyphenol oxidase (PPO) suppression sequence derived from apple. This nonbrowning trait reduces the need for anti-browning agents on cut fruit, and minimizes shrinkage caused by harvest and postharvest damage (OSF, 2012b). GD743 and GS784 apples will be used as direct replacements for their untransformed conventional counterparts in situations where the nonbrowning trait is considered desirable, such as in fresh-cut produce products, prepared apple slices, and the manufacturing of juice. They will also be used in conventional breeding efforts to produce new apple cultivars that are resistant to enzymatic browning (OSF, 2012b).

Coordinated Framework Review

Food and Drug Administration

GD743 and GS784 apples are within the scope of the FDA policy statement concerning regulation of products derived from new plant varieties, including those produced by genetic engineering. OSF initiated the consultation process with FDA for the commercial distribution of GD743 and GS784 apples and submitted a safety and nutritional assessment of food and feed derived from GD743 and GS784 to the FDA on May 30, 2011 (OSF, 2012b).

Environmental Protection Agency

The EPA has authority over the use of pesticidal substances and plant-incorporated protectants (PIPs) under the FIFRA as amended (7 USC §136, *et seq.*) and the FFDCA (21 USC §301, *et seq.*). APHIS considers the EPA's regulatory assessment when assessing potential impacts that may result from a determination of nonregulated status of a GE organism.

As GD743 and GS784 apples do not express any pesticidal properties, the EPA has no FIFRA review authority over this apple product. However, if GD743 and GS784 apples provides for a change in use of registered herbicides, the EPA would review proposed label changes relating to these new herbicide uses. But OSF does not indicate any change in herbicide use associated with GD743 and GS784 apples that would differ from that currently registered for other apples.

Scope of the Environmental Analysis

Although a determination of nonregulated status of GD743 and GS784 apples would allow for new plantings of GD743 and GS784 apples anywhere in the U.S., APHIS primarily focused the environmental analysis to those geographic areas that currently support apple production. A determination of nonregulated status of GD743 and GS784 apples is not expected to increase apple production, either by its availability alone or accompanied by other factors. To determine areas of apple production, APHIS used data from the National Agricultural Statistics Service (NASS) to determine where apples are produced in the U.S. (USDA-NASS, 2012b). In 2011, the United States total commercial apple bearing acreage was 330,600 acres. Historically, Washington, New York, and Michigan are the largest producers of apples. Approximately 40% of the nation's apples acres are in Washington. New York and Michigan together account for about one fourth of the U.S. apple acres. The majority of commercial apple production is marketed as fresh fruit valued at over \$2.38 billion. Processed fruit production is valued at \$338 million dollars (USDA-NASS, 2012b).

Public Involvement

On July 13, 2012, APHIS published a notice in the Federal Register (77 FR pages 41362-41363, Docket no. APHIS-2012-0025) announcing the availability of the OSF petition for a 60-day public review and comment period. Comments were required to be received on or before September 11, 2012. All comments were carefully analyzed to identify new issues, alternatives, or information. A total of 72,745 comments were received from individuals during the comment period, of which 70,737 were form letters. Comment documents may be viewed at <http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;dct=PS;D=APHIS-2012-0025>.

Most comments received were in form letters from individuals expressing an opinion of general opposition to GE food, the belief that GE crops harm the environment, or the belief that

GE crops are not beneficial to farmers. Many of the comments also objected to APHIS publishing multiple dockets for review on the same day. The form letter expressed a concern that there were too many dockets published on the same day. It also referenced other open dockets and potential effects from the use of the subjects of those petitions. These issues are outside the scope of the EA. The issues related to the OSF GD743 and GS784 apple petition which were raised in these comments are addressed in the EA; the issues raised included:

- Potential economic impacts on the US apple industry and market
- The socioeconomic impacts of mixing GD743 and GS784 apples in various apple markets
- Potential economic impacts on export markets.
- Concern that cross-pollination between GE and organic or conventional apple crops will affect sales for growers of these crops.
- GD743 and GS784 cross pollination with other apple varieties including native crabapples
- The effects of GD743 and GS784 on the physical environment
- The effects of GD743 and GS784 on biological organisms including Threatened and Endangered Species
- Potential for weakened plant defenses and increased susceptibility to disease or infection from PPO suppression
- Human health effects from consuming GE crops
- Concerns about the non-browning trait masking flaws or disease in the fruit
- Concerns about the nutritional, quality, and food safety of GD743 and GS784 apples

On November 8, 2013, APHIS published a notice in the Federal Register (78 FR 67100-67101, Docket no. APHIS-2012-0025) announcing the availability of the EA and PPRA for a 30-day public review period. On December 31, 2013 the comment period was reopened for an additional 30 days (78 FR 79658-79659, Docket no. APHIS-2012-0025). During the comment period, APHIS received a total of 105,971 comments of which 100,976 were form letters. APHIS also received 8 comments with a total of 461,311 signatures opposed to approval of the petition. Comment documents may be viewed at: <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0025>. No new issues, alternatives, or new information were identified in any of the comments received by APHIS. Responses to comments are included as an attachment to this Finding of No Significant Impact.

Major Issues Addressed in the EA

The issues considered in the EA were developed based on APHIS' determination that certain genetically engineered organisms are no longer subject to the plant pest provisions of the PPA and 7 CFR part 340, and for this particular EA, the specific petition seeking a determination of nonregulated status for GD743 and GS784 apples. Issues discussed in the EA were developed by considering public concerns as well as issues raised in public comments submitted for other environmental assessments of genetically engineered organisms, concerns raised in lawsuits, as well as those issues that have been raised by various stakeholders. These issues, including those regarding the agricultural production of apples using various production methods, and the

environmental food/feed safety of genetically engineered plants, were addressed to analyze the potential environmental impacts of GD743 and GS784 apples.

The EA describes the alternatives considered and evaluated using the identified issues. The following issues were identified as important to the scope of the analysis (40 CFR 1508.25):

Socioeconomic and Cultural Resource Considerations:

- Agricultural Production of Apples
- Domestic Commerce
- Organic Apple Production
- Foreign Trade

Environmental Considerations:

- Soil Quality
- Water Resources
- Air Quality
- Climate Change
- Animal Communities
- Plant Communities
- Microorganisms
- Biological Diversity

Human Health Considerations:

- Public Health
- Worker Safety

Livestock Health Considerations:

- Animal Feed/Livestock Health

Alternatives that were fully analyzed

The EA analyzes the potential environmental consequences of a determination of nonregulated status of GD743 and GS784 apples. To respond favorably to a petition for nonregulated status, APHIS must determine that GD743 and GS784 apples are unlikely to pose a plant pest risk. Based on its PPRA (USDA-APHIS, 2013), APHIS has concluded that GD743 and GS784 apples are unlikely to pose a plant pest risk. Therefore, APHIS must determine that GD743 and GS784 apples are no longer subject to 7 CFR part 340 or the plant pest provisions of the PPA. Two alternatives were evaluated in the EA: (1) no action and (2) determination of nonregulated status of GD743 and GS784 apples. APHIS has assessed the potential for environmental impacts for each alternative in the Environmental Consequences section of the EA.

No Action: Continuation as a Regulated Article

Under the No Action Alternative, APHIS would deny the petition. GD743 and GS784 apples and progeny derived from GD743 and GS784 apples would continue to be regulated articles under

the regulations at 7 CFR part 340. Permits or notifications acknowledged by APHIS would still be required for introductions of GD743 and GS784 apples and measures to ensure physical and reproductive confinement would continue to be implemented. APHIS might choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from the unconfined cultivation of GD743 and GS784 apples.

This alternative is not the preferred alternative because APHIS has concluded through a PPRa that GD743 and GS784 apples are unlikely to pose a plant pest risk (USDA-APHIS, 2013). Choosing this alternative would not satisfy the purpose and need of making a determination of plant pest risk status and responding to the petition for nonregulated status.

Preferred Alternative: Determination that GD743 and GS784 Apples are No Longer Regulated Articles

Under this alternative, GD743 and GS784 apples and progeny derived from GD743 and GS784 apples would no longer be regulated articles under the regulations at 7 CFR part 340. GD743 and GS784 apples are unlikely to pose a plant pest risk (USDA-APHIS, 2013). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of GD743 and GS784 apples and progeny derived from these events. The preferred alternative best meets the purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the PPA. Because the agency has concluded that GD743 and GS784 apples are unlikely to pose a plant pest risk, a determination of nonregulated status of GD743 and GS784 apples is a response that is consistent with the plant pest provisions of the PPA, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework.

Alternatives Considered but Rejected from Further Consideration

APHIS assembled a list of alternatives that might be considered for GD743 and GS784 apples. The agency evaluated these alternatives, in light of the agency's authority under the plant pest provisions of the PPA, and the regulations at 7 CFR part 340, with respect to environmental safety, efficacy, and practicality to identify which alternatives would be further considered for GD743 and GS784 apples. Based on this evaluation, APHIS rejected several alternatives. These alternatives are discussed briefly below along with the specific reasons for rejecting each.

1. Prohibit any GD743 and GS784 Apples from Being Released

In response to public comments that stated a preference that no GE organisms enter the marketplace, APHIS considered prohibiting the release of GD743 and GS784 apples, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that GD743 and GS784 apples are unlikely to pose a plant pest risk (USDA-APHIS, 2013).

In enacting the PPA, Congress found that

[D]ecisions affecting imports, exports, and interstate movement of products regulated under [the Plant Protection Act] shall be based on sound science...§402(4).

On March 11, 2011, in a Memorandum for the Heads of Executive Departments and Agencies, the White House Emerging Technologies Interagency Policy Coordination Committee developed broad principles, consistent with Executive Order 13563, to guide the development and implementation policies for oversight of emerging technologies (such as genetic engineering) at the agency level. In accordance with this memorandum, agencies should adhere to Executive Order 13563, and, consistent with that Executive Order, the following principle, among others to the extent permitted by law when regulating emerging technologies:

“[D]ecisions should be based on the best reasonably obtainable scientific, technical, economic, and other information, within the boundaries of the authorities and mandate of each agency”

Based on the PPRA (USDA-APHIS, 2013), and the scientific data evaluated therein, APHIS concluded that GD743 and GS784 apples are unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of GD743 and GS784 apples.

2. Approve the petition in part

The regulations at 7 CFR 340.6(d)(3)(i) state that APHIS may “approve the petition in whole or in part.” For example, a determination of nonregulated status in part may be appropriate if there is a plant pest risk associated with some, but not all lines described in a petition. Because APHIS has concluded that GD743 and GS784 apples are unlikely to pose a plant pest risk, (USDA-APHIS, 2013), there is no regulatory basis under the plant pest provisions of the PPA for considering approval of the petition only in part.

3. Isolation Distance between GD743 and GS784 Apples and Non-GE Apple Production and Geographical Restrictions

In response to public concerns of gene movement between GE and non-GE plants, APHIS considered requiring an isolation distance separating GD743 and GS784 apples from conventional or specialty apple production. However, because APHIS has concluded that GD743 and GS784 apples are unlikely to pose a plant pest risk (USDA-APHIS, 2013), an alternative based on requiring isolation distances would be inconsistent with statutory authority under the plant pest provisions of the PPA and regulations in 7 CFR part 340.

APHIS also considered geographically restricting the production of GD743 and GS784 apples based on the location of production of non-GE apple in organic production systems or production systems for GE-sensitive markets in response to public concerns regarding possible gene movement between GE and non-GE plants. However, as presented in APHIS’ PPRA for GD743 and GS784 apples, there are no geographic differences associated with any identifiable plant pest risks for GD743 and GS784 apples (USDA-APHIS, 2013). This alternative was rejected and not analyzed in detail because APHIS has concluded that GD743 and GS784 apples do not present a plant pest risk, and will not exhibit a greater plant risk in any geographically restricted area. Therefore, such an alternative would not be consistent with APHIS’ statutory authority under the plant pest provisions of the PPA and regulations in Part 340 and the biotechnology regulatory policies embodied in the Coordinated Framework.

Based on the foregoing, the imposition of isolation distances or geographic restrictions would not meet APHIS’ purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency’s authority under the plant pest provisions of the PPA. However, individuals might choose on their own to geographically isolate their non-GE production systems from GD743 and GS784 apples or to use isolation distances and other management practices to minimize gene movement between apple orchards.

4. Requirement of Testing for GD743 and GS784 Apples

During the comment periods for other petitions for nonregulated status, some commenters requested that USDA require and provide testing for GE products in non-GE production systems. APHIS notes that there are no nationally established regulations involving testing, criteria, or limits of GE material in non-GE systems. Such a requirement would be extremely difficult to implement and maintain. Additionally, because GD743 and GS784 apples are unlikely to pose a plant pest risk (USDA-APHIS, 2013), the imposition of any type of testing requirements is inconsistent with the plant pest provisions of the PPA, the regulations at 7 CFR part 340 and biotechnology regulatory policies embodied in the Coordinated Framework. Therefore, imposing such a requirement for GD743 and GS784 apples would not meet APHIS’ purpose and need to respond appropriately to the petition in accordance with its regulatory authorities.

Environmental Consequences of APHIS’ Selected Action

The EA contains a full analysis of the alternatives to which we refer the reader for specific details. The following table briefly summarizes the results for each of the issues fully analyzed in the Environmental Consequences section of the EA.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Meets Purpose and Need and Objectives	No	Yes
Unlikely to pose a plant pest risk	Satisfied through use of regulated field trials	Satisfied – risk assessment (USDA-APHIS, 2013)
Socioeconomic and Cultural		

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Agricultural Production of Apple	Total commercial apple bearing acreage has declined since 2002 while total apple utilized production has been relatively unchanged since 2007. Based on apple production trends and projections, apples will continue to be a major fruit crop in the U.S. for the foreseeable future.	Unchanged from No Action Alternative
Domestic Commerce	The majority of commercial apple production is marketed as fresh fruit. Of the approximately 9.3 billion pounds of utilized apple production, fresh fruit production accounted for 2.38 billion dollars and processed fruit production for 338 million dollars. In 2011 about 1% of the total apple crop was used for fresh sliced apples. The majority of processed apples are used for juice or cider.	Unchanged from No Action Alternative
Organic Apple Production	Specialty crop growers employ practices and standards for production, cultivation, and product handling and processing to ensure that their products are not pollinated by or commingled with conventional or GE crops. Organic apples are one of the top three organic fresh fruits purchased.	Unchanged from No Action Alternative

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Foreign Trade	The U.S. produces approximately 16% of the global apple export market. U.S. apples and apple products will continue to play a role in global apple production, and the U.S. will continue to be a supplier in the international market.	The foreign trade impacts associated with a determination of nonregulated status of GD743 and GS784 apples are anticipated to be similar to the No Action alternative however, import of each specific trait requires separate application and approval by the importing country.
Environment		
Soil Quality	Agronomic practices such as crop type, tillage, and pest management can affect soil quality. Growers will adopt management practices to address their specific needs in producing apples.	Unchanged from No Action Alternative
Water Resources	The primary cause of agricultural non-point source pollution is increased sedimentation from soil erosion, which can introduce sediments, fertilizers, and pesticides to nearby lakes and streams. Agronomic practices such as crop nutrient management, pest management, and conservation buffers help protect water quality from agricultural runoff	Unchanged from No Action Alternative

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Air Quality	Agricultural activities such as burning, tilling, harvesting, spraying pesticides, and fertilizing, including the emissions from farm equipment, can directly affect air quality. Aerial application of herbicides may impact air quality from drift, diffusion, and volatilization of the chemicals, as well as motor vehicle emissions from airplanes or helicopters.	Unchanged from No Action Alternative
Climate Change	Agriculture-related activities are recognized as both direct sources of greenhouse gases (GHGs) (e.g., exhaust from motorized equipment) and indirect sources (e.g., agriculture-related soil disturbance, fertilizer production)	Unchanged from No Action Alternative
Animal Communities	Apple orchards may be host to many animal and insect species. Many of these animals are typically considered pests and may be controlled by the use of integrated pest management strategies.	Unchanged from No Action Alternative

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Plant Communities	<p>Apple is a labor intensive, highly managed crop. Members of the plant community that adversely affect apple cultivation may be characterized as weeds. Weed control is an important aspect of apple cultivation. Apple growers use production practices to manage weeds in and around orchards. Apples are an outcrossing species, requiring cross pollination from a different commercial variety or crab apple species. Pollination efficiency decreases rapidly with distance between pollen sources so cross pollination with native crab apples would be unlikely.</p>	Unchanged from No Action Alternative
Microorganisms	<p>The apple orchard is a highly managed environment which incorporates integrated pest management (IPM) strategies. IPM programs are tailored to specific areas of the country; however, nearly every IPM program specifically addresses the most common diseases of apple.</p>	Unchanged from No Action Alternative
Biological Diversity	<p>The biological diversity in apple orchards is highly managed and may be lower than in the surrounding habitats.</p>	Unchanged from No Action Alternative
Human and Animal Health		

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Human Health/ Worker Safety	<p>The average U.S. consumer ate an estimated 47.6 pounds of fresh apples and processed apple products in 2011. The apple orchard is a highly managed environment which incorporates the use of agricultural chemicals. Pesticides are used on most apple acreage in the US. The EPA’s Worker Protection Standard (WPS); 40 CFR Part 170.1, <i>Scope and Purpose</i>) requires employers to take actions to reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers. The WPS contains requirements for pesticide safety training, notification of pesticide applications, use of personal protective equipment, restricted entry intervals following pesticide application, decontamination supplies, and emergency medical assistance.</p>	<p>OSF data demonstrates that the composition of GD743 and GS784 apples does not substantially differ from conventional apple varieties. OSF submitted a safety and nutritional assessment of food and feed derived from GD 743 and GS 784 to the FDA on May 30, 2011. FDA is presently evaluating the submission.</p> <p>OSF’s studies demonstrate no differences in morphological characteristics and agronomic requirements between GD743 and GS784 apples and other apple varieties. OSF demonstrates in its petition that the agronomic inputs required to cultivate GD743 and GS784 apples are functionally equivalent to those required for conventional apple. Accordingly, the health and safety protocols currently employed by farm workers in the cultivation of apple do not require changes to accommodate the cultivation of GD743 and GS784 apples.</p> <p>Therefore, human health and worker safety issues associated with the agricultural production of GD743 and GS784 apples would remain the same as those under the No Action Alternative.</p>

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Animal Feed	Some whole apples or apple pieces may be fed to domestic animals, but the majority of apple feed products are derived from the byproducts of manufacturing.	OSF submitted a safety and nutritional assessment of food and feed derived from GD 743 and GS 784 to the FDA on May 30, 2011. FDA is presently evaluating the submission. A compositional analysis concluded there were no biologically meaningful differences identified between GD743 and GS784 apples and other varieties. Therefore this is unchanged from the No Action Alternative.
Other Regulatory Approvals		
U.S.	OSF submitted a safety and nutritional assessment of food and feed derived from GD 743 and GS 784 to the FDA on May 30, 2011. FDA is presently evaluating the submission.	OSF submitted a safety and nutritional assessment of food and feed derived from GD 743 and GS 784 to the FDA on May 30, 2011. FDA is presently evaluating the submission.
CFIA	Regulatory submissions for product approvals were made to Health Canada and the Canadian Food Inspection Agency (CFIA) on December 7, 2011. CFIA is presently evaluating the submission.	Regulatory submissions for product approvals were made to Health Canada and the CFIA on December 7, 2011. CFIA is presently evaluating the submission.
Compliance with Other Laws		
CWA, CAA, EOs	Fully compliant	Fully compliant

Finding of No Significant Impact

The analysis in the EA indicates that there will not be a significant impact, individually or cumulatively, on the quality of the human environment as a result of this proposed action. I agree

with this conclusion and therefore find that an EIS need not be prepared. This NEPA determination is based on the following context and intensity factors (40 CFR 1508.27).

Context - The term “context” recognizes potentially affected resources, as well as the location and setting in which the environmental impact would occur. This action has potential to affect conventional and organic apple production systems, including surrounding environments and agricultural workers; human food and animal feed production systems; and foreign and domestic commodity markets.

In 2011, the United States total commercial apple bearing acreage was 330,600 acres. Historically, Washington, New York, and Michigan are the largest producers of apples. Approximately 40% of the nation’s apples acres are in Washington. New York and Michigan together account for about one fourth of the U.S. apple acres. The majority of commercial apple production is marketed as fresh fruit valued at over \$2.38 billion. Processed fruit production is valued at \$338 million dollars (USDA-NASS, 2012b). A determination of nonregulated status of GD743 and GS784 apples is not expected to directly cause an increase in agricultural acreage devoted to apple production. The availability of GD743 and GS784 apples will not change cultivation areas for apple production in the U.S., and there are no anticipated changes to the availability of GE and non-GE apple varieties on the market.

Intensity – Intensity is a measure of the degree or severity of an impact based upon the ten factors. The following factors were used as a basis for this decision:

1. *Impacts that may be both beneficial and adverse.*

A determination of nonregulated status of GD743 and GS784 apples will have no significant environmental impact in relation to the availability of GE, conventional, and organic apple varieties. As discussed in Chapter 4 of the EA, a determination of nonregulated status of GD743 and GS784 apples is not expected to directly cause an increase in agricultural acreage devoted to apple production. Based on the data provided by OSF for GD743 and GS784 apples (OSF, 2012b), APHIS has concluded that the availability of GD743 and GS784 apples will not change the cultivation areas for apple production in the U.S., and there are no anticipated changes in the availability of apple varieties on the market. A determination of nonregulated status of GD743 and GS784 apples could add another apple variety to the apple market, but is not expected to change the market demands for apples or apples produced using organic methods. As of 2011, there were 377 certified organic farms (with over 13,000 harvested acres) that produced approximately 300 million pounds of organic apples. The total gross value of sales was reported from 371 farms, for a total of 286 million pounds of organic apples valued at just over 122 million USD (USDA-NASS, 2012a).

2. *The degree to which the proposed action affects public health or safety.*

A determination of nonregulated status of GD743 and GS784 apples would have no significant impacts on human or animal health. Compositional tests conducted by the petitioner indicate that GD743 and GS784 apples are compositionally similar to other commercially available apples (OSF, 2012b). OSF initiated the consultation process with FDA for the commercial distribution of GD743 and GS784 apples and submitted a safety and nutritional assessment of food and feed derived from GD743 and GS784 apples to

the FDA in May 2011. FDA is presently evaluating the submission. Based on the assessment of laboratory data provided by OSF (OSF, 2012b) in the submitted petition and an analysis of the scientific literature (USDA-APHIS, 2013), APHIS has concluded that a determination of nonregulated status of GD743 and GS784 apples would have no adverse impacts on human or animal health.

3. *Unique characteristics of the geographic area such as proximity to historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas.*

There are no unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas that would be adversely impacted by a determination of nonregulated status of GD743 and GS784 apples. The common agricultural practices that would be carried out under the proposed action will not cause major ground disturbance; do not cause any physical destruction or damage to property, wildlife habitat, or landscapes; and do not involve the sale, lease, or transfer of ownership of any property. This action is limited to a determination of nonregulated status of GD743 and GS784 apples. The product will be deployed on agricultural land currently suitable for production of apple, will replace existing varieties, and is not expected to increase the acreage of apple production. This action would not convert land to nonagricultural use and therefore would have no adverse impact on prime farm land. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to GD743 and GS784 apples including the use of EPA registered pesticides. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate potential impacts to the human environment. In the event of a determination of nonregulated status of GD743 and GS784 apples, the action is not likely to affect historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas that may be in close proximity to apple production sites.

4. *The degree to which the effects on the quality of the human environment are likely to be highly controversial.*

The effects on the quality of the human environment from a determination of nonregulated status of GD743 and GS784 apples are not highly controversial. Although APHIS received public comments opposed to a determination of nonregulated status of GD743 and GS784 apples, this action is not highly controversial in terms of size, nature or effect on the natural or physical environment. As discussed in Chapter 4 of the EA, a determination of nonregulated status is not expected to directly cause an increase in agricultural acreage devoted to apple production. The availability of GD743 and GS784 apples will not change cultivation areas for apple production in the U.S., and there are no anticipated changes to the availability of apple varieties on the market. A determination of nonregulated status GD743 and GS784 apples would add a GE apple variety to the conventional apple market and is not expected to change the market demands for GE apple or apples produced using organic methods. A determination of nonregulated status of GD743 and GS784 apples will not result in changes in the current agronomic practices of planting, fertilizer application/use, cultivation, pesticide application use. The effect of GD743 and GS784 apples on wildlife or biodiversity is not different than that of other

apple varieties currently used in conventional agriculture in the U.S. During the public comment period, APHIS received comments opposing a determination of nonregulated status of GD743 and GS784 apples. Many of these public comments expressed a general opposition to genetically modified organisms (GMOs) or GE crops and the domestic regulatory process surrounding GE plants; perceived negative effects on public and animal health, biodiversity, and the environment; and a lack of consideration regarding organic production systems and the public right to choose non-GE containing food products. No new issues, alternatives or substantive new information were identified in any of the comments received by APHIS. APHIS has addressed comments in the response to public comments document attached to this FONSI based on scientific evidence found in peer-reviewed, scholarly, and scientific journals.

5. *The degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks.*

Based on the analysis documented in the EA, the possible effects on the human environment are well understood. The effects of the proposed activities are not highly uncertain and do not involve unique or unknown risks on the natural or physical environment. As discussed in Chapter 4 of the EA, a determination of nonregulated status of GD743 and GS784 apples is not expected to directly cause an increase in agricultural acreage devoted to apple production. The availability of GD743 and GS784 apples will not change cultivation areas for apple production in the U. S. and there are not anticipated changes to the availability of apple varieties on the market. A determination of nonregulated status of GD743 and GS784 apples will not result in changes in the current agronomic practices of planting, fertilizer application/use, cultivation, pesticide application use. Agronomic characteristics and cultivation practices required for GD743 and GS784 apples are indistinguishable from practices used to grow other apple varieties. The effect of GD743 and GS784 apples on wildlife or biodiversity is no different than that from other apple varieties currently used in conventional agriculture in the U.S. As described in Chapter 2 of the EA, well established management practices, production controls, and production practices (conventional and organic) are currently being used in apple production systems in the U.S. Therefore, it is reasonable to assume that farmers, who produce conventional apples, GD743 and GS784 apples, or produce apples using organic methods, will continue to use these reasonable, commonly accepted best management practices for their chosen systems and varieties during agricultural apple production. Therefore, the impacts are not highly uncertain, and do not involve unique or unknown risks.

6. *The degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration.*

A determination of nonregulated status for GD743 and GS784 apples would not establish a precedent for future actions with significant effects or represent a decision in principle about a future decision. Similar to past regulatory requests reviewed and approved by APHIS, a determination of nonregulated status will be based on whether an organism is unlikely to pose a plant pest risk pursuant to the regulatory requirements of 7 CFR part 340. Each petition that APHIS receives is specific to a particular GE organism and undergoes this independent review to determine if the regulated article poses a plant pest

risk. Under the authority of the plant pest provisions of the PPA and 7 CFR part 340, APHIS has issued regulations for the safe development and use of GE organisms. As required by 7 CFR 340.6, APHIS must respond to petitioners who request a determination of the regulated status of GE organisms, including GE plants such as GD743 and GS784 apples. When a petition for nonregulated status is submitted, APHIS must make a determination if the GE organism is unlikely to pose a plant pest risk. If APHIS determines, based on its Plant Pest Risk Assessment, that the genetically engineered organism is unlikely to pose a plant pest risk, the genetically engineered organism is no longer subject to the plant pest provisions of the PPA and 7 CFR part 340. APHIS regulations at 7 CFR part 340, which were promulgated pursuant to authority granted by the PPA, as amended (7 United States Code(U.S.C.) 7701-7772), regulate the introduction (importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is no longer subject to the plant pest provisions of the PPA or to the regulatory requirements of 7 CFR part 340 when APHIS determines that it is unlikely to pose a plant pest risk. A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation (7 CFR 340.2) and is also considered a plant pest. A GE organism is also regulated under Part 340 when APHIS has reason to believe that the GE organism may be a plant pest or APHIS does not have enough information to determine if the GE organism is unlikely to pose a plant pest risk. A person may petition the agency that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, is no longer regulated under the plant pest provisions of the PPA or the regulations at 7 CFR part 340. The petitioner is required to provide information under §340.6(c)(4) related to plant pest risk that the agency may use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA when APHIS determines that it is unlikely to pose a plant pest risk.

7. *Whether the action is related to other actions with individually insignificant but cumulatively significant impacts.*

No significant cumulative effects were identified through this assessment. The EA discussed cumulative effects on apple management practices, human and animal health, and the environment and concluded that such impacts were not significant. A cumulative effects analysis is provided in Chapter 5 of the EA. In the event APHIS reaches a determination of nonregulated status of GD743 and GS784 apples, APHIS would no longer have regulatory authority over these apples. APHIS has not identified any significant impact on the environment which may result from the incremental impact of a determination of nonregulated status of GD743 and GS784 apples when added to past, present, and reasonably foreseeable future actions.

8. *The degree to which the action may adversely affect districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places or may cause loss or destruction of significant scientific, cultural, or historic resources.* A determination of nonregulated status of GD743 and GS784 apples will not adversely impact cultural resources on tribal properties. Any farming activities that may be taken by

farmers on tribal lands are only conducted at the tribe's request; thus, the tribes have control over any potential conflict with cultural resources on tribal properties. A determination of nonregulated status of GD743 and GS784 apples would have no impact on districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places, nor would they likely cause any loss or destruction of significant scientific, cultural, or historic resources. This action is limited to a determination of nonregulated status of GD743 and GS784 apples. Standard agricultural practices for land preparation, planting, irrigation, and harvesting would be used on these agricultural lands including the use of EPA registered pesticides. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate impacts to the human environment. A determination of nonregulated status of GD743 and GS784 apples is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected under the National Historic Preservation Act. In general, common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or audible elements to areas in which they are used that could result in effects on the character or use of historic properties. For example, there is potential for audible effects on the use and enjoyment of a historic property when common agricultural practices, such as the operation of tractors and other mechanical equipment, are conducted close to such sites. A built-in mitigating factor for this issue is that virtually all of the methods involved would only have temporary effects on the audible nature of a site and can be ended at any time to restore the audible qualities of such sites to their original condition with no further adverse effects. Additionally, these cultivation practices are already being conducted throughout the apple production regions. The cultivation of GD743 and GS784 apples does not inherently change any of these agronomic practices so as to give rise to an impact under the NHPA.

9. *The degree to which the action may adversely affect the endangered or threatened species or its habitat that has been determined to be critical under the Endangered Species Act of 1973.*

As described in Chapter 6 of the EA, APHIS has analyzed the potential for effects from a determination of nonregulated status of GD743 and GS784 apples on federally listed threatened and endangered species (TES) and species proposed for listing, as well as designated critical habitat and habitat proposed for designation, as required under Section 7 of the Endangered Species Act. After reviewing possible effects of a determination of nonregulated status of GD743 and GS784 apples, APHIS has concluded that a determination of nonregulated status of GD743 and GS784 apples would have no effect on federally listed TES and species proposed for listing, or on designated critical habitat or habitat proposed for designation.

10. *Whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment.*

The proposed action would be in compliance with all federal, state, and local laws. Because the agency has concluded that GD743 and GS784 apples are unlikely to pose a plant pest risk, a determination of nonregulated status of GD743 and GS784 apples is a response that is consistent with the plant pest provisions of the PPA, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated

Framework. OSF initiated the consultation process with FDA for the commercial distribution of GD743 and GS784 apples and submitted a safety and nutritional assessment of food and feed derived from GD743 and GS784 apples to the FDA to on May 30, 2011 (OSF, 2012b). FDA is presently evaluating the submission.

GD743 and GS784 apples are compositionally similar to currently available apples on the market, with the exception of the nonbrowning trait. Agronomic characteristics and cultivation practices required for GD743 and GS784 apples are indistinguishable from practices used to grow other apple varieties. There are no other Federal, state, or local permits that are needed prior to the implementation of this action.

NEPA Decision and Rationale

I have carefully reviewed the EA prepared for this NEPA determination and the input from the public involvement process. I believe that the issues identified in the EA are best addressed by selecting Alternative 2 (Determination that GD743 and GS784 apples are No Longer Regulated Articles). This alternative meets APHIS' purpose and need to allow the safe development and use of genetically engineered organisms consistent with the plant pest provisions of the PPA.

As stated in the CEQ regulations, "the agency's preferred alternative is the alternative which the agency believes would fulfill its statutory mission and responsibilities, giving consideration to economic, environmental, technical and other factors." The preferred alternative has been selected for implementation based on consideration of a number of environmental, regulatory, and social factors. Based upon our evaluation and analysis, Alternative 2 is selected because (1) it allows APHIS to fulfill its statutory mission to protect America's agriculture and environment using a science-based regulatory framework that allows for the safe development and use of genetically engineered organisms; and (2) it allows APHIS to fulfill its regulatory obligations. As APHIS has not identified any plant pest risks associated with GD743 and GS784 apples, the continued regulated status of GD743 and GS784 apples would be inconsistent with the plant pest provisions of the PPA, the regulations codified at 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework. For the reasons stated above, I have determined that a determination of nonregulated status of GD743 and GS784 apples will not have any significant environmental effects.

for James L. Buchholz
Michael J. Firko

5/28/2014

Date

Deputy Administrator

Biotechnology Regulatory Services

References

OSF (2012) "Petition for Determination of Nonregulated Status: Arctic™ Apple (Malus x domestica) Events GD743 and GS784." Okanagan Specialty Fruits Inc.

USDA-APHIS (2013) "Draft Plant Pest Risk Assessment for Okanagan Specialty Fruits Inc.'s Non-browning Apple (Malus x domestica) Events GD743 and GS784. ." http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml.

USDA-NASS (2012a) "2011 Certified Organic Production Survey." USDA-NASS.

USDA-NASS "QuickStats Apple Production." http://quickstats.nass.usda.gov/results/5C1F4B04-F71C-33D9-B9AD-D12243A17C0B?pivot=short_desc.

Response to Public Comments on GD743 and GS784 Apples

Summary of comments received

On July 13, 2012, APHIS published a notice in the Federal Register (77 FR pages 41362-41363, Docket no. APHIS-2012-0025) announcing the availability of the Okanagan Specialty Fruits (OSF) petition for a 60-day public review and comment period. Comments were required to be received on or before September 11, 2012. All comments were carefully analyzed to identify new issues, alternatives, or information. A total of 72,745 comments were received from individuals during the comment period, of which 70,737 were form letters.

On November 8, 2013, APHIS published a notice in the Federal Register (78 FR 67100-67101, Docket no. APHIS-2012-0025) announcing the availability of the draft Environmental Assessment (EA) and plant pest risk assessment (PPRA) for a 30-day public review period. On December 31, 2013 the comment period was reopened for an additional 30 days (78 FR 79658-79659, Docket no. APHIS-2012-0025). During the comment period, APHIS received a total of 105,971 comments of which 100,976 were form letters. APHIS also received 8 comments with a total of 461,311 signatures opposed to approval of the petition. Comment documents may be viewed at: <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0025>. Most comments received were in form letters or from individuals expressing an opinion of general opposition to genetically engineered (GE) food, the belief that GE crops harm the environment, or the belief that GE crops are not beneficial to farmers. Several comments also referenced other open dockets and potential effects from the use of the subjects of those petitions. These issues are outside the scope of the EA. Several specific issues related to the GD743 and GS784 apple EA were, however, identified from the public comments. These were organized into categories and addressed below. No new issues, alternatives, or new information were identified in any of the comments received by APHIS. Responses to comments are included as an attachment to this Finding of No Significant Impact.

Issue 1

Several commenters expressed the view that APHIS's decision lacked a basis in sound science, and suggested that APHIS had relied on the applicants' analysis and data and had ignored high-quality data and information stating that "data used in the conclusions of the reports are from the petitioner" and lacked "independent, third-party exploration."

APHIS Response

APHIS disagrees with the suggestion that it failed to base its analysis on sound science. APHIS' analysis and decision within the PPRA regarding the plant pest risk posed by GD743 and GS784 apples is based on the best available scientific and technical information. APHIS used sound science to inform its regulatory decision regarding the plant pest risk of GD743 and GS784 apples, and has concluded that GD743 and GS784 apples are unlikely to pose a plant pest risk. APHIS carefully reviewed the information provided by the petitioner and others and considered all other relevant information sufficient to make the determination on the regulated status of GD743 and GS784 apples. APHIS carefully considered the possible environmental impacts of

the proposed product, and is satisfied that the EA developed for GD743 and GS784 apples is adequate and sufficient.

In the EA, APHIS has considered opposing views, has reviewed data submitted by those who supported or opposed the determination of nonregulated status, and has not relied on biased information. APHIS has included an analysis of each of the alternatives and evaluated and used the best available information from various sources, including peer-reviewed scientific literature that was reviewed and incorporated into APHIS' analysis. APHIS relied on a variety of sources to support its analysis of the potential impacts of a determination of nonregulated status for GD743 and GS784 apples. These sources include, but are not limited to the OSF petition, technical reports, and peer-reviewed literature.

Issue 2

A number of commenters indicated that the USDA should complete an EIS on this decision stating that “APHIS must prepare a full EIS in order to comply with NEPA’s mandate to prepare an EIS where an agency action may significantly impact the environment.”

APHIS Response

APHIS has prepared the EA to consider the potential environmental effects of the proposed action and the reasonable alternative to that action, the no action alternative, consistent with NEPA requirements (40 CFR parts 1500-1508, 7 CFR 1b, and 7 CFR part 372). This EA has been prepared in order to specifically evaluate the potential effects on the quality of the human environment that may result from the determination of nonregulated status of GD743 and GS784 apples. Based on the EA, APHIS concludes that the determination of nonregulated status of GD743 and GS784 apples would not cause significant impacts on the environment and therefore, APHIS does not need to prepare an EIS before deregulating this product.

Issue 3

Several commenters asserted that GD743 and GS784 apples are unnecessary as there are many methods to prevent browning without using GE. Many commenters noted that browning could be prevented by reducing temperature and oxygen levels, utilizing modified atmosphere packaging, or applying edible coatings, or applications of lemon juice, ascorbic acid, citric acid, malic acid, and EDTA. Other commenters noted that there are already apple varieties, which resist browning after cutting.

APHIS Response

While alternative methods to prevent browning are valid, APHIS did not evaluate these methods in this assessment because the use of these methods is not within the scope of this EA or the APHIS regulatory decisions in response to a petition for nonregulated status for GD743 and GS784 apples. This decision does not prevent apple processors from choosing the method to prevent browning that they wish to employ. The EA has been prepared in order to specifically evaluate the potential effects on the quality of the human environment that may result from a determination of nonregulated status of GD743 and GS784 apples.

Issue 4

Concerns were raised in the comments in regard to effects of GD743 and GS784 apples upon non-target animals including pollinizing insects and fruit eating animals. Specifically commenters noted, “The report includes no specific studies of the relation of the genetically engineered apple to bees and other pollinators.”

Several commenters took exception to APHIS’ use of the fact that food and feed safety data on GD743 and GS784 apples and the FDA assessment process to support the idea that ingestion of GD743 and GS784 apples will have no impacts on wild animals: According to the commenter, APHIS should not “equate the nutritional assessment with food quality and safety for wild animals” because “animals eating fruit do not have the same nutritional requirements as humans.”

APHIS Response

The EA has reported on the safety of GD743 and GS784 apples in the environmental consequences and cumulative impacts sections under various headings, including those on animals, plants, biodiversity, microbes and human health. Based upon information and analysis presented in the petition, PPRA, and EA, APHIS has not identified any potential for harm to the environment from GD743 and GS784 apples.

As noted in the EA, apple trees rely on cross-pollination for successful fruit set; Numerous species of bees, flies, beetles, and wasps, feed on apple blossom pollen and nectar and serve as pollinators of apple trees (Ladurner *et al.*, 2004; Gardner and Ascher, 2006). Foraging honey bees and other pollinators would come into contact with GD743 and GS784 apple pollen. GD743 and GS784 apples were developed by inserting a polyphenol oxidase (PPO) suppression transgene derived from apple. The transgene is designed to simultaneously suppress expression of four members of the apple PPO gene family. The gene product is a chimeric, sense-silencing RNA rather than a functional protein or new enzyme (USDA-APHIS, 2013). The sense-silencing RNA responsible for the nonbrowning trait in GD 743 and GS784 apples is designed to specifically target the PPO genes in apple and it is highly unlikely that there would be an effect on PPO genes in non-related organisms such as insects or other types of non-target organisms. Nucleic acids are a normal part of every living organism and do not have toxic or allergenic properties. Further, nucleic acids are considered to be “generally recognized as safe” (GRAS) by the U.S. Food and Drug Administration (FDA) (US-FDA, 1992). The only gene product produced by GD743 and GS784 apples, is the NptII protein. Non-target organisms will only be exposed to non-toxic RNA and the NptII protein that has previously been reviewed by FDA in consultations for other biotechnology plant products (US-FDA, 1998), therefore there is virtually no potential for adverse effects to non-target organisms. .

Under the Coordinated framework, FDA has primary responsibility for ensuring the safety of food and animal feed. APHIS uses this and other information from the scientific literature in its assessment. OSF indicated that they have submitted a safety and nutritional assessment of food and feed derived from GD743 and GS784 to the FDA on May 30, 2011 (OSF, 2012b). FDA is presently evaluating the submission. Data submitted by OSF demonstrates that the composition

of GD743 and GS784 apples does not substantially differ from conventional apple varieties (OSF, 2012b).

APHIS evaluated in the EA, OSF's data on agronomic performance, disease and insect susceptibility, and compositional profiles of GD743 and GS784 apples (OSF, 2012b). APHIS analysis indicates no significant differences between GD743 and GS784 apples and non-transgenic counterparts that would be expected to cause either a direct or indirect adverse effect on non-target organisms. Field trials conducted over a 10 year period with GD743 and GS784 apples have not shown any observable significant differences between GD743 and GS784 apples and non-transgenic controls. Because of this, there is no scientific reason to expect that the transformed GD743 and GS784 apples would have a negative impact on non-target organisms. Insect population diversity represents one measure of general impacts, and there were no differences observed at various times during development of the crop. In the absence of any observable acute stresses or impacts, there is no reason to presume that long term impacts would be expected, nor that a need exists to monitor for them. APHIS has carefully considered the possible environmental impacts of the proposed action, and is satisfied that the EA prepared by APHIS is adequate and sufficient.

Issue 5

APHIS received a number of comments on the issues related to the perceived health effects of consuming GE crops. Several commenters noted links between “birth defects, high infant mortality rates, and sterility in hamsters, rats, and livestock fed genetically engineered soy and corn” while others noted studies indicating “harm to the liver, kidneys, digestive and immune systems as well as other health problems” in rats fed GE crops. Other commenters cited a study on mice that “showed that mice that were fed GE soybeans had impaired embryonic development.”

APHIS Response

In regard to the human health concerns raised by commenters related to the consumption of GE crops and products. As noted by the National Research Council (NRC), unexpected and unintended compositional changes arise with all forms of genetic modification, including both conventional breeding and genetic engineering (NRC, 2004). The NRC also noted at the time, no adverse health effects attributable to genetic engineering had been documented in the human population. Reviews on the nutritional quality of GE foods have generally concluded that there are no significant nutritional differences in conventional versus GE plants for food or animal feed (Faust, 2002; Flachowsky *et al.*, 2005).

APHIS notes that many studies have been done on the effect of feeding GE plants to animals, including long-term studies and multiple generation studies. For example, Ricoch (Ricoch, 2012) examined data from animal feeding studies and 60 recent GE vs. non-GE crop lines comparisons, including 33 long-term animal feeding studies, 16 of which spanned multiple generations. The comparisons showed that GE transformation has less impact on plant expression and composition than conventional plant breeding. Ricoch (Ricoch, 2012) noted that no new safety concerns were raised in any of the feeding studies, including the multigenerational studies and long-term studies.

Similarly, Snell (Snell *et al.*, 2012) reviewed data from 12 long-term animal feeding studies of durations >90 days to up to 2 years, and 12 multigenerational studies (from 2 to 5 generations). No statistically significant differences were observed on animal health parameters when compared with control animals.

With regard to the general safety of the apples themselves, under the FFDCA, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled. Food and feed derived from GE apple must be in compliance with all applicable legal and regulatory requirements. GE apple for food and feed may undergo a voluntary consultation process with the FDA prior to release onto the market. Although a voluntary process, thus far all applicants who wish to commercialize a GE variety that will be included in the food supply have completed a consultation with the FDA. In a consultation, a developer who intends to commercialize a bioengineered food meets with the agency to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food and then submits to FDA a summary of its scientific and regulatory assessment of the food. The FDA evaluates the submission and responds to the developer by letter (US-FDA, 2013).

Compositional tests conducted by the petitioner indicate that GD743 and GS784 apples are compositionally similar to other commercially available apples (OSF, 2012b). OSF initiated the consultation process with FDA for the commercial distribution of GD743 and GS784 apples and submitted a safety and nutritional assessment of food and feed derived from GD743 and GS784 apples to the FDA on May 30, 2011 (OSF, 2012b). FDA is presently evaluating the submission. As discussed in Section 4.5 of the EA, based on APHIS' review of field and laboratory data and scientific literature provided by OSF (OSF, 2012b), and safety data available on other GE crops, APHIS has concluded that a determination of nonregulated status of GD743 and GS784 apples would have no significant impacts on human health.

Issue 6

A number of commenters expressed concerns that the nonbrowning trait in GD743 and GS784 apples will disguise inferior fruit quality, noting that “the color change serves as an important signal to people when a sliced apple is not fresh” and that the apples will “fool people into thinking that they are buying fresh apples when they are not.”

APHIS Response

The nonbrowning phenotype of GD743 and GS784 was developed by inserting a polyphenol oxidase (PPO) suppression sequence derived from apple. When apples containing the inserted gene are subjected to mechanical damage, such as slicing or bruising, the apple flesh does not brown as an untransformed apple does (OSF, 2012b). GD743 and GS784 apples resist enzymatic browning, which is separate from the discoloration that comes from meaningful damage or decay. The decomposition that renders an apple unsightly and inedible primarily occurs due to fungi and bacteria, and this secondary browning or decomposition will happen with GD743 and GS784 apples (OSF, 2012a). Furthermore, OSF's pest and disease field data and post-harvest rot data (OSF, 2012b) confirm that the apple disease that can affect fruit quality were detectable in both the GE and non-GE apples and are not masked by the non-browning phenotype (USDA-APHIS, 2013).

Issue 7

Several commenters expressed concerns related to labeling of GE crops and specifically GD743 and GS784 apples. A number of commenters noted that “The public has the right to choose whether to eat GMO or not” and that not labeling GD743 and GS784 apples as GE would not allow consumers to make informed decisions.

APHIS Response

APHIS did not evaluate labeling of GE food in this assessment because it is not within the scope of this EA or the APHIS regulatory authority. The EA has been prepared in order to specifically evaluate the potential effects on the quality of the human environment that may result from a determination of nonregulated status of GD743 and GS784 apples.

Issue 8

Several commenters expressed concerns regarding the nutritional qualities of GD743 and GS784 apples. A number of commenters raised concerns that GD743 and GS784 apples will not be properly digested, stating that since “the apple resists oxidation then it will probably resist digestion as well” and that “genetically modified foods are harmful because our bodies do not recognize them and does not know what to do with them.” Other commenters were concerned that removing polyphenols would reduce nutritional value stating “Polyphenols are shown to regulate the absorption of glucose in the digestive tract. Removing the polyphenols from apples will turn a healthy food into a less healthy one.”

APHIS Response

GD743 and GS784 apples are genetically engineered to suppress the polyphenol oxidase gene. Polyphenol oxidase is responsible for the “breaks down” phenolics; therefore suppressing the PPO gene results in higher amounts of phenolics. OSF data demonstrates that the composition of GD743 and GS784 apples do not substantially differ from conventional Golden Delicious and Granny Smith apple varieties (OSF, 2012b). Composition characteristics evaluated by OSF in these comparative tests include moisture, protein, fat, carbohydrates, ash, calories, dietary fiber, sugar profile, minerals, vitamins, antioxidant capacity, and phenolics (OSF, 2012b).

The main nutrients in apple are sugar, dietary fiber, potassium, phenolic antioxidants and, to a lesser extent, vitamin C. To establish that the new cultivars are nutritionally equivalent to their parent cultivars, apples from apple events GD743 and GS784 and the control Golden Delicious and Granny Smith were subjected to nutritional and proximate analysis, and measured for total phenolic and water-soluble oxygen radical absorbance capacity (ORAC) (OSF, 2012b). Analysis found no significant changes in proximates, dietary fiber or potassium content. Variation between apple events GD743 or GS784 and their respective controls was not significant, and all values fell within the expected norms provided by USDA’s National Nutrient Database for Standard Reference for apple (USDA Nutrient Databank identifier 09003) (OSF, 2012b). The apple events GD743 and GS784 demonstrated elevated vitamin C, likely due to the high phenolics that are characteristic of the nonbrowning apple. Apple events GD743 and GS784 are nutritionally equivalent to their parent varieties and may even have higher phenolic compound content and stability (OSF, 2012b). OSF indicated that they have submitted a safety and

nutritional assessment of food and feed derived from GD743 and GS784 apples to the FDA on May 30, 2012 (OSF, 2012b) who has authority over food safety of this product. FDA is presently evaluating the submission.

Issue 9

A number of commenters expressed concerns that no long term studies have been conducted and that “ten years of study is not enough time to evaluate a perennial crop like an apple tree.”

APHIS Response

The data collected from field trials conducted by OSF are typical of what apple breeders do in the development process of new apple varieties and in many instances go well beyond. The years of field trials and data collected are sufficient for APHIS evaluation.

Issue 10

Concerns were raised in regards to the impacts of GD743 and GS784 apples on organic or specialty apple crops. A number of comments focused on “the potential impact on organic farming from contamination by GD743 and GS784 apples.” One often repeated assertion was that “the burden of preventing contamination was being placed entirely on organic growers for borders and pollination control strategies” and that “consumer expectations” of organic products are not the same the National Organic Standard. Comments were critical of “APHIS’s conclusion that organic farmers wishing to avoid transgenic contamination should isolate their farms, create physical barriers and buffer zones, and delay or stagger planting so that neighbors’ GE crops do not contaminate theirs.” Many commenters stated that “the options proposed by APHIS Environmental Assessment are inappropriate for apples and are not crop-specific coping strategies.”

APHIS Response

The essential dynamics relating to the principals of coexistence of conventional apple and organic apple production would not change by the determination of nonregulated status of GD743 and GS784 apples. Although producing a particular crop for a specific market and meeting the specifications for growing a product to be marketed might be characterized by some as a "burden", this burden is intrinsic to plant production in general and growers have, for decades, been successfully growing crops bearing different traits and often on adjoining fields despite the method by which traits were introduced (conventional breeding or recombinant DNA technology). Studies of coexistence of major GE and non-GE crops in North America and the European Union (EU) have demonstrated that there has been no significant introgression of GE genes, and that GE and non-GE crops are coexisting with minimal economic effects (Brookes and Barfoot, 2004a; 2004b; Gealy *et al.*, 2007).

The U.S. Department of Agriculture's Advisory Committee on Biotechnology and 21st Century Agriculture (AC21) has released a final set of recommendations on enhancing coexistence among different crop production methods (USDA, 2012). The AC21 presented its report to Agriculture Secretary, Tom Vilsack, to be used as guidance to enhance working relationships among farmers growing different types of crops, specifically GE- and non-GE crops. The

committee also made recommendations to the USDA emphasizing education, stewardship and good neighbor -to-neighbor communications. The report indicates that technological innovations and market diversity have become key drivers of increased productivity and product quality for all forms of American agriculture.

However, ultimately organic producers are obligated to manage their operations to avoid unintentional contact with excluded methods. A number of techniques have been developed in order to maintain the concept of coexistence and to prevent cross-pollination. Isolation distances between fields help to minimize the effects of pollen flow. In addition to spatial isolation, growers can use reproductive isolation to minimize or eliminate cross-pollination (i.e. plant varieties with different maturity dates) or stagger planting dates (to obtain different flowering stages), with a minimum of three to four weeks difference between the planting of their crop and neighboring crop. For apple, the primary strategies would include sufficient isolation distance, use of border rows and restricted use of commercial bee hives. OSF has proposed a stewardship plan which includes these strategies. These strategies along with farmer communication can be successfully used to minimize the effects of pollen-mediated gene flow.

APHIS acknowledges that the public may have varying perceptions of the term "organic" and the term often may take on different meanings in the context of advertising, cultural values, pharmaceuticals, chemistry, food, agriculture and contemporary thought as expressed in literature and media. To accommodate the need for an appropriate food standard, the USDA established the National Organic Program (NOP), under the Organic Foods Protection Act and established the National Organic Program regulations. In the U.S., only products produced using specific methods and certified under the USDA's Agricultural Marketing Service (AMS) National Organic Program'(NOP) definition of organic farming can be marketed and labeled as "organic" (USDA-AMS, 2010). The NOP prohibits the use of excluded methods in organic operations.

Although the National Organic Standards prohibit the use of excluded methods, they do not require testing of inputs or products for the presence of excluded methods. Under the NOP, certifying agents attest to the ability of organic operations to follow a set of production standards and practices that meet the requirements of the Act. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of the National Organic Standards (USDA-AMS, 2010). The unintentional presence of the products of excluded methods will not affect the status of an organic product or operation when the operation has not used excluded methods and has taken reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan. As noted by Ronald and Fouche (Ronald and Fouche, 2006), "While 100% purity (zero tolerance for any undesired components) is very difficult to attain for any agricultural commodity, standard procedures involving spatial separation, border rows, planting dates, maturity dates, cleaning of equipment, and post-harvest handling have traditionally been able to provide products that meet the production burden of supplying products for diverse market requirements."

Because these apples will be planted on limited acreage in commercial apple groves, cross-pollination from these trees to other apple orchards will be limited to those that are in adjoining areas. Therefore organic growers who wish to reduce the likelihood of pollination from GD743

or GS784 may need to discuss their needs with neighboring orchards to incorporate pollination control strategies in their organic plans.

Major buyers of organic commodities have allowances for a certain percentage of GE traits. While some buyers may require testing for unintentional GE-trait content, this is one of the costs that presumably makes organic products more costly at purchase, and for which the grower is reimbursed. It is not likely that organic farmers or other farmers who choose not to plant transgenic varieties will be significantly impacted by the commercial use of GD743 or GS784 apples. APHIS therefore finds no basis of a burden being imposed, of burden shifting, or an increased burden being placed upon other farmers as a result of the determination of nonregulated status of GD743 or GS784 apples.

Issue 11

A number of comments raised the concern that PPO suppression could lead to GD743 and GS784 apples being more susceptible to disease and pests. Several commenters stated that “the PPO enzyme is also involved in a plant’s natural defense against pests and pathogens” and that PPO suppression “could negatively affect a plant’s ability to defend itself against pests.” Other commenters were concerned that “decreased resistance to pests or disease would likely lead to an increase in the use of pesticides or fungicides.”

APHIS Response

OSF evaluated how GD743 and GS784 events performed in the field with respect to control fruit. Pest and disease characteristics were monitored, and data was collected that would help to analyze if these events were less, equal or more susceptible to pest and diseases than control fruit (OSF, 2012b). If PPO were involved in pest and disease resistance, through a role in the hypersensitivity response, then one might expect a systematic increase in the sensitivity of PPO suppressed GD743 and GS784 to a wide variety of agents. OSF did not observe such a change in phenotype in their field observation of GD743 and GS784 (OSF, 2012b). Standard orchard practices were sufficient to prevent pests and diseases in GD743 and GS784 and no additional control measures were required (OSF, 2012b). GD743 and GS784 are expected to be no more susceptible to the same plant pathogens and insect pests as their conventional apple cultivars GD and GS (USDA-APHIS, 2013). Standard orchard practices will be used to control for disease and pests in GD743 and GS784 as they would in non-GE orchards.

Issue 12

Several concerns were raised in regards to the use of RNAi-mediated gene suppression techniques. Several commenters raised the concern that “the RNA interference technique used to create these apples could silence more than just the intended genes” and could “cause unpredicted off-target effects.” The other concern raised was that the PPRA used outdated information in making the assessment of the RNAi techniques used with commenters noting that APHIS should not be “basing conclusions on 15-year-old studies.”

APHIS Response

RNA interference (RNAi) is an RNA-based mechanism that changes endogenous gene expression in eukaryotes including plants, insects, fungi, nematodes, and mammals. RNAi-mediated gene suppression generally requires sequence homology of at least 90% between the silencing construct and the target sequence to be successful and even higher degrees of homology over 21-23 nucleotide stretches (Sharp, 2001). A complementarity between siRNAs (Short interfering RNA) and their target RNA sequences is necessary for an effective and efficient gene silencing. Short interfering RNA-mediated silencing of non-target genes, termed off-target effects (OTE), often appears to be caused by silencing genes homologs to the targeted gene and/or other genes sharing partial sequence complementarity or similarity to the si-RNA (Jackson *et al.*, 2003).

The potential unintended effects in biotech crops (e.g., compositional or agronomic changes) are important factors in the evaluation of crop safety assessment process (Cellini *et al.*, 2004). RNAi induced changes could be manifested in compositional or phenotypic changes in the genetically modified plant (Parrott *et al.*, 2010). OTE may also induce compositional and phenotypic changes and they can be compared to the intended phenotype and compared to the parental type or control. In GD743 and GS784 only the intended phenotypes were observed and the compositional and agronomic/phenotypic analysis revealed that it does not have any other unintended or off target effects other than the intended or desired phenotype in the GE apples.

Recently Jim Carrington an expert on RNAi, say “There is no confirmed evidence in the scientific literature, that associates consumption of plant-derived RNA molecules of any kind with any hazards in humans, other mammals, or domesticated animals” (Carrington, 2014). It is not likely that the gene silencing in the GD743 and GS784 events would contribute to silencing of other genes or off target affects.

Issue 13

A number of commenters expressed concerns regarding GD743 and GS784 apple trees expressing resistance to kanamycin. Commenters stated that “The genetic engineering process includes insertion of *nptII* gene from *E. coli*” and that the insertion of this gene “allows the transformed apple tissue to grow on a medium containing the antibiotic kanamycin but confers no benefit to the apple plant.” Commenters noted that “every cell of every GE apple tree, including the fruit and the tree roots, will show resistance to kanamycin.” These commenters were also concerned that “eating an Arctic Apple could transfer the gene for kanamycin resistance into your digestive system leading to the bacteria in the human digestive system to develop kanamycin resistance.” They also note that this “transfer has been demonstrated with GE soy.” The other concern raised was that the kanamycin resistance “can also spread to bacteria on the plant and in the soil making controlling diseases of special concern like fireblight in orchards much more difficult.”

APHIS Response

As noted in the OSF petition in addition to the PPO suppression transgene, the *nptII* gene from the *E. coli* has been introduced into apple to be used as a selectable marker (OSF, 2012b). This gene confers resistance to kanamycin in plants (Fraley *et al.*, 1986). NptII is an enzyme that inactivates the antibiotic kanamycin thereby allowing cells containing this gene to grow on

medium containing kanamycin. As part of a study of clonal stability of the Arctic™ Apple transgene, it was shown that the *nptII* gene, as expressed by nopaline synthase promoter (*PNOS*), did not result in detectable amounts of the NptII protein accumulating in mature fruit of GD743 and GS784 (OSF, 2012b). OSF measured the accumulation of NptII protein in leaf and mature fruit samples. In leaf, expression levels for the NptII enzyme were found to range from 2.6 to 8.4 ng/g fresh tissue in GD743 with an average of 5.0 ng/g and to range from 0.7 to 8.4 ng/g fresh tissue in GS784 with an average of 3.8 ng/g (OSF, 2012b). In fruit, expression levels for the NptII enzyme were found to range from 0.0 to 0.4 ng/g fresh tissue in GD743 with an average of 0.1 ng/g and to range from 0.0 to 0.5 ng/g fresh tissue in GS784 with an average of 0.1 ng/g (OSF, 2012b). The NptII protein expressed in mature fruit of GD743 and GS784 fall within the range of the controls. NptII is a common protein found in genetically engineered plants that have been widely planted across the U.S. and in other countries. No issues related to health or environmental safety has been noted to date. APHIS has determined in the PPRA that the presence of the *nptII* gene will have no significant environmental impacts (USDA-APHIS, 2013). Mature fruit of GD743 and GS784 does not contain detectable levels of NptII protein (OSF, 2012b).

With regard to concerns that GD743 and GS784 could confer kanamycin resistance to the bacteria in the human digestive system or other non-target organisms, FDA has evaluated horizontal gene transfer related to the use of antibiotic resistance marker genes, and concluded that the likelihood of transfer of antibiotic resistance genes from plant genomes to microorganisms in the gastrointestinal tract of humans or animals, or in the environment, is remote (US-FDA, 1998).

Issue 14

Concerns were raised in regards to the effects of GD743 and GS784 apples on domestic apple markets. Several commenters noted that “Negative publicity around the genetically engineered apple could also impact buying patterns for organic and conventional apples” as “people unsure of whether their apple is GMO or not will turn away from apples completely.” Other commenters noted that several “apple grower groups have already voiced their disapproval of these genetically engineered apples, including the California Apple Commission, the U.S. Apple Association, Northwest Horticultural Council, British Columbia Fruit Growers Association and others.”

APHIS Response

The adoption of GD743 and GS784 apples would add another apple variety to the market. All GD743 and GS784 apples will be sold under the Arctic™ brand name. This brand name will be used in a range of venues, including point-of-sale literature, price look-up code stickers on the apples and all forms of retail packaging, to identify Arctic™ fruit (OSF, 2012b). The apple industry has the advantage over the field crop industry in the fact that cultivars are already segregated and packed in lots. It is OSF’s intent that traceability will be maintained for all Arctic™ Apple cultivars from field to retail and foodservice outlets (OSF, 2012b). Regardless, APHIS does not base its decisions under 7 CFR part 340 regulations on consumer acceptance but rather whether the new GE organism poses a risk as a plant pest under the plant pest provisions of the PPA.

Issue 15

Concerns were raised in regards to the impacts of GD743 and GS784 apples on apple exports. Several commenters noted that many foreign markets do not accept GE products and that “GMO apples may contaminate nearby organic and conventional apple orchards and could potentially cause valuable export markets to reject U.S. grown apples as happened in the past when wheat and rice crops were found to be contaminated by GMOs.” Commenters also noted that “the cost of tracing and separating Arctic apples to avoid contamination of non-GE apple products and its effects on exports are not evaluated in OSF’s petition and must be considered.”

APHIS Response

Global sensitivities to GE products, including international restrictions on import of GE products and inability of the petitioner to gain approval for cultivation or importation, will continue to impede trade with those countries. These challenges to international trade in GE products are already in place. Restrictions on international trade in GE products, including GD743 and GS784 apples, are unlikely to change with a determination of nonregulated status of GD743 and GS784 apples.

As discussed in Section 4.2.2 – Domestic Commerce, in the EA, the apple fruit from a non-GE apple tree cannot be contaminated by transgenic pollen, since the flesh of the fruit develops from the receptacle, or base of the flower, which is not genetically modified, as opposed to the seed (OSF, 2012b). The flesh of the apple fruit retains the genetic identity of the tree it grows on, and is in no way altered by the genetic identity of the pollen that fertilizes the flower. During pollination with transgenic pollen, the genetic modification will only be present in the seed. But the probability of such seeds occurring is low, since only a tiny quantity of the large amount of pollen arriving on the stigma will germinate and only one pollen grain will fertilize the ovum (Hanke, 2003). It is important to note that because apple trees are an outcrossing species, any apple seeds that are produce will be hybrids and would have characteristics of both parents. In the case of GD743 and GS784, only a portion of the seeds would carry the transgene responsible for the non-browning trait.

As noted above in the response to Issue 14, GD743 and GS784 apples will be labeled with the Arctic™ brand name (OSF, 2012b). The apple industry has the advantage over the field crop industry in the fact that cultivars are already segregated and packed in lots. It is OSF’s intent that traceability will be maintained for all Arctic™ Apple cultivars from field to retail and food service outlets (OSF, 2012b).

Issue 16

A number of commenters expressed the concern that APHIS had “failed to consult” on the potential effects on threatened and endangered species and their critical habitats, as required under Section 7 of the Endangered Species Act (ESA), and that “APHIS must prove” its determination of nonregulated status of GD743 and GS784 apples will neither jeopardize any species nor harm any critical habitat anywhere the crop may be grown. Further, commenters stated that APHIS failed to consider species that may be present in the area of the proposed releases.

APHIS Response

APHIS disagrees with this comment. As required under Section 7 of the ESA, APHIS considered the potential for effects from the proposed determination of nonregulated status for GD743 and GS784 apples on federally listed threatened and endangered species and species proposed for listing, as well as effects on designated critical habitat and habitat proposed for designation. Because apples are grown in all 50 states and U.S. territories, APHIS considered possible effects on all listed species as well as all species proposed for listing (USFWS, 2014a; 2014b). After analyzing the potential for any effect, APHIS concluded that the determination of nonregulated status for GD743 and GS784 apples will have no effect on federally listed threatened and endangered species and species proposed for listing, as well no effect on designated critical habitat and habitat proposed for designation. APHIS has not identified any stressor associated with GD743 and GS784 apples that could affect the reproduction, numbers, or distribution of a listed TES or species proposed for listing. Therefore, consultation with, or the concurrence of, the USFWS and/or NMFS is not required.

Issue 17

A commenter stated that APHIS did not have enough information to assess factors such as weediness potential, a determination of where the new transgene and its products (if any) are produced in the plant and their quantity; agronomic characteristics such as susceptibility to pests and pathogens; and impacts on the environment; whether there are known toxicants; and whether the GE plant is a host to any TES, among other information.

APHIS Response

APHIS disagrees with this commenter on all of these points. Information provided by the applicant indicated that there is no increased weediness; there are no changes in agronomic characteristics; no toxicants produced; and no impacts on the environment. The only gene product produced is the neomycin phosphotransferase II (NptII protein), and that protein has previously been reviewed by FDA in consultations for other biotechnology plant products (US-FDA, 1998). NptII is a common protein found in a number of genetically engineered plants that have been widely planted across the U.S. and in other parts of the world. In every case, no issues related to health or environmental safety have been noted (APHIS petitions 08-315-01p, 04-337-01p, 04-264-01p, 01-137-01p, 01-206-02p, 01-206-01p, 95-352-01p, 96-051-01p, 95-045-01p, and 94-308-01p)(USDA-APHIS, 2014). Lastly, a review of the USFWS species list indicates there are no listed species or species proposed for listing that would use apple as a host plant to complete any portion of their lifecycle. Further, under the ESA, agencies are required to use the best available information when conducting their effects analysis. Agencies are not required to conduct research to fill possible gaps in data. However, in this case APHIS had adequate information available to determine that GD743 and GS784 apple trees are no different than other apple varieties currently grown.

Issue 18

Concerns were raised that APHIS failed to adequately assess impacts to TES. APHIS assumed incorrectly that composition analysis of the fruit would also apply to other parts of the apple tree, and failed to consider consumption of these other parts by TES animals.

APHIS Response

APHIS disagrees with this comment. APHIS considered the possibility that production of GD743 and GD784 apples may affect TES and critical habitat. To start this process, APHIS obtained information on listed species and species proposed for listing in all areas where apples could be grown. APHIS then considered the threats that could be posed to these species that would be different than threats posed from current apple varieties. To assess effects on plants and critical habitat, APHIS considered agronomic properties of the plant including weediness potential. For animals, APHIS considered effects of consumption by TES. All information known about GD743 and GD784 apples indicates that there would be no changes in agronomic properties and there would be no harm to any animal that would feed on these apples, including all plant parts. The commenter may have the mistaken belief that APHIS relied on the composition equivalency of the apple fruit to justify no effect from consumption of other parts of the apple tree. This is incorrect. APHIS came to this conclusion because there no reason to expect consumption of any part of the GD743 and GD784 apple plants to cause harm. The only differences between GD743 and GS784 apples and other apple varieties is the polyphenol oxidase suppression sequence that is derived from apple and prevents enzymatic browning of the fruit, and the expression of the NptII protein that provides resistance to kanamycin. The applicant provided data to demonstrate that these changes are expressed in fruit and leaves; parts of the plant most likely to be consumed by TES. Although data is not available for expression in other parts of the plant such as bark, twigs and roots, these parts are less likely to be consumed, and even if expressed in these plant parts, there are no hazards expected from the suppression of polyphenol oxidase or the expression of NptII.

Issue 19

Commenters raised the concern that APHIS claims that apple trees do not host any TES, without comment on whether unmanaged trees were considered, or how “host” was defined. It is likely that trees growing outside of cultivation and in abandoned orchards will interact with a wider array of wild organisms that may include TES. Abandoned apple trees and cultivated trees growing in proximity to forests and other wild areas have been shown to have higher insect diversity, including insects that move in from surrounding wild areas. Arthropods on abandoned apple trees in South Moravia, Czech Republic, include some that are endangered. Non-intensively managed apple orchards in Great Britain are home to endangered species, including fungi and insects, and management plans are being promoted specifically to protect those endangered species. In the U.S., apple trees from old homesteads and abandoned orchards are being intentionally maintained for wildlife, and may be used by TES.

APHIS Response

APHIS agrees that use of the term “host” in the EA could be misinterpreted. The meaning of the term “host” as used in the TES analysis of the EA refers to the use of the apple plant by another organism to complete a portion of its lifecycle. It does not refer to incidental feeding by a generalist herbivore. The effects of consumption were addressed separately. The possibility of

TES feeding on abandoned apple trees from old homesteads or abandoned orchards is not an issue. Pollination from GD743 and GD784 apples to abandoned trees would not change the genetic make-up of the abandoned tree, or its fruit flesh (edible portion of the apple). Additionally, if future orchards containing GD743 and GD784 apple were abandoned, there would be no effect on TES that may feed on the trees or fruit because there are no hazards associated with consumption of GD743 and GD784 apple fruit or plant parts.

Issue 20

Commenters expressed the concern that APHIS failed to properly consider and disclose its obligations to migratory birds. Specifically, Executive Order 13186 requires federal agencies to develop and implement a Memorandum of Understanding (MOU) with the FWS to promote the conservation of migratory bird populations. Further, that APHIS did not adequately assess impacts to migratory birds, and that APHIS did not consider the permitting requirements that allow the “take” of a migratory bird under certain activities, none of which include the types of activities discussed in the EA, and therefore no take of even a single migratory bird is allowed.

APHIS Response

APHIS disagrees with the commenter. First, as required by Executive Order 13186, APHIS has in place a signed MOU with the FWS (APHIS-USFWS, 2012). Second, APHIS has considered its obligations under the Migratory Bird Treaty Act and acknowledged in the EA that migratory birds may nest in or around these trees and may forage for insects and weed seeds as well. APHIS came to the conclusion that granting nonregulated status to GD743 and GD784 apples would have no impact on any migratory birds because there is nothing different between GD743 and GD784 apple trees and trees of other apple varieties, with the exception of the polyphenol oxidase suppression sequence that is derived from apple and prevents enzymatic browning of the fruit. The applicant provided data to demonstrate the compositional equivalency of GD743 and GD784 apples and other apple varieties currently grown. GD743 and GD784 apples do not produce novel proteins and there is no scientific reason to believe there would be any changes to any other parts of the plant. There would be no effect from consumption of GD743 and GD784 apple plant parts because there is nothing different between the plant parts of these varieties and plant parts of other apple varieties already in production. Further, there is no reason to suspect that migratory birds would interact with trees of GD743 and GD784 apples any differently than any other apple tree.

Issue 21

Several commenters raised the issue that many foreign governments have banned GE products, stating “80 countries ban GMO including Russia and China” and note that “26 countries from Europe” also ban or partially ban GE.

APHIS Response

APHIS acknowledges that foreign governments have their own requirements for GE approval that are independent and separate from the U.S. approval process. APHIS cannot rely on assessments from other countries for our own regulatory process.

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