

Okanagan Specialty Fruits Petition (10-161-01p) for Determination of Non-regulated Status of ArcticTM Apple Events GD743 and GS784

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ACRONYMS AND ABBREVIATIONS

AIA	Advanced Informed Agreement
AOSCA	American Organization of Seed Certifying Agencies
APHIS	Animal and Plant Health Inspection Service
BRS	Biotechnology Regulatory Services (within USDA–APHIS)
CAA	Clean Air Act
CBD	Convention on Biological Diversity
CEQ	Council on Environmental Quality
CFIA	Canadian Food Inspection Agency
CFR	Code of Federal Regulations (United States)
CH₄	methane
CO	carbon monoxide
CO₂	carbon dioxide
CWA	Clean Water Act
DNA	deoxyribonucleic acid
DRT	Drift Reduction Technology
EA	Environmental Assessment
EDTA	Ethylenediaminetetraacetic acid
EIS	Environmental Impact Statement
EO	Executive Order
EPA	U.S. Environmental Protection Agency
ESA	Endangered Species Act of 1973
EU	European Union
FDA	U.S. Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FFP	Food, Feed, or Processing
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FQPA	Food Quality Protection Act
FR	Federal Register
GD	Golden Delicious
GE	Genetically Engineered
GHG	Greenhouse Gas
GMO	Genetically Modified Organism

ACRONYMS AND ABBREVIATIONS

GS	Granny Smith
IPCC	Intergovernmental Panel on Climate Change
IPM	Integrated Pest Management
IPPC	International Plant Protection Convention
ISPM	International Standard for Phytosanitary Measure
LMO	Living Modified Organisms
MOU	Memorandum of Understanding
N₂O	nitrous oxide
NAAQS	National Ambient Air Quality Standards
NABI	North American Biotechnology Initiative
NAPPO	North American Plant Protection Organization
NEPA	National Environmental Policy Act of 1969 and subsequent amendments
NHPA	National Historic Preservation Act
NMFS	National Marine Fisheries Service
NO₂	nitrogen dioxide
NPS	Non-point Source
NRC	National Research Council
O₃	ozone
OECD	Organization for Economic Cooperation and Development
OPP	Office of Pesticide Programs
ORAC	Oxygen Radical Absorbance Capacity
OSF	Okanagan Specialty Fruits
Pb	Lead
PIP	Plant Incorporated Protectants
PM	Particulate Matter
PPA	Plant Protection Act
PPO	polyphenol oxidase
PPRA	Plant Pest Risk Assessment
PRA	pest risk analysis
RSPM	Regional Standards for Phytosanitary Measures
SIP	State Implementation Plan
SO₂	sulfur dioxide

ACRONYMS AND ABBREVIATIONS

SOC	Soil Organic Carbon
SSA	Sole Source Aquifer
TES	Threatened and Endangered Species
TSCA	Toxic Substances Control Act
U.S.	United States
USC	United States Code
USD	United States Dollars
USDA	U.S. Department of Agriculture
USDA-AMS	Agricultural Marketing Service
USDA-ARS	Agricultural Research Service
USDA-ERS	U.S. Department of Agriculture-Economic Research Service
USDA-FAS	U.S. Department of Agriculture-Foreign Agricultural Service
USDA-NASS	U.S. Department of Agriculture-National Agricultural Statistics Service
USDA-NOP	U.S. Department of Agriculture-National Organic Program
USDA-NRCS	Natural Resource Conservation Service
USFWS	United States Fish and Wildlife Service
WPS	Worker Protection Standard for Agricultural Pesticides

1 PURPOSE AND NEED

1.1 Background

Okanagan Specialty Fruits Inc. (OSF) of Summerland, BC submitted petition 10-161-01p to the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) in June 2010 seeking a determination of nonregulated status for Arctic™ apple events GD743 and GS784 that are resistant to enzymatic browning. The petition was deemed complete by APHIS in February 2012. GD743 and GS784 apples are currently regulated under 7 CFR part 340. Interstate movements and field trials of GD743 and GS784 apples have been conducted under permits issued or notifications acknowledged by APHIS since 2003. These field trials were conducted in the top two growing regions within the U.S., including the states of Washington and New York. Data resulting from these field trials are described in the OSF's GD743 and GS784 apple petition (OSF, 2012) and analyzed for plant pest risk in the APHIS Plant Pest Risk Assessment (PPRA) (USDA-APHIS, 2013).

The petition stated that APHIS should not regulate GD743 and GS784 apples because they do not present a plant pest risk. In the event of a determination of nonregulated status, the nonregulated status would include GD743 and GS784 apples, any progeny derived from crosses between GD743, GS784, and conventional apple, and crosses of GD743 and GS784 with other biotechnology-derived apples that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act.

1.2 Purpose of Product

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. 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, but rather remains its original color. This nonbrowning trait reduces the need for antibrowning agents on cut fruit, and minimizes losses caused by harvest and postharvest damage (OSF, 2012).

Browning reduces apple quality by causing detrimental flavor and nutritional changes that limit apple's fresh-market, fresh-cut, and processing applications. Brown bruises are a significant cause of reduced grade for fresh-market apples for growers and of lost value for retailers (OSF, 2012). 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, 2012).

1.3 Coordinated Framework Review and Regulatory Review

Since 1986, the United States (U.S.) 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, 1986; 57 FR 22984, 1992). 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 Animal and Plant Health Inspection Service (APHIS), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA).

USDA-APHIS

APHIS regulations at 7 Code of Federal Regulations (CFR) part 340, which were promulgated pursuant to authority granted by the Plant Protection Act (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 information to determine if the GE organism is unlikely to pose a plant pest risk.

A person may petition the agency for a determination 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 340. Under § 340.6(c)(4), the petitioner must provide information 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.

Environmental Protection Agency

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. The EPA regulates plant incorporated protectants (PIPs) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*) and certain biological control organisms under the Toxic Substances Control Act (TSCA) (15 U.S.C. 53 *et seq.*). Before planting a crop containing a PIP, a company must seek an experimental use permit from EPA. Commercial production of crops containing PIPs for purposes of seed increases and sale requires a FIFRA Section 3 registration with EPA.

Under FIFRA (7 U.S.C. 136 *et seq.*), EPA regulates the use of pesticides, and requires registration of all pesticide products for all specific uses prior to distribution for sale. EPA examines: the ingredients of the pesticide; the particular site or crop on which it is to be used; the amount, frequency, and timing of its use; storage and disposal practices. Prior to registration for a new use for a new or previously registered pesticide, EPA must determine through testing that the pesticide does not cause unreasonable adverse effects on humans, the environment, and non-target species when used in accordance with label instructions. EPA must also approve the language used on the pesticide label in accordance with 40 CFR part 158. Once registered, a pesticide may only be legally used in accordance with directions and restrictions on its label. The overall intent of the label is to provide clear directions for effective product performance, while minimizing risks to human health and the environment. The Food Quality Protection Act (FQPA) of 1996 amended FIFRA, enabling EPA to implement periodic registration review of pesticides to ensure they are meeting current scientific and regulatory standards of safety and continue to have no unreasonable adverse effects (US-EPA, 2011a).

EPA also sets tolerances (maximum residue levels) or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug, and Cosmetic Act (FFDCA). A tolerance is the amount of pesticide residue that can remain on or in food for human consumption or animal feed. Before establishing pesticide tolerance, EPA is required to reach a safety determination based on a finding of reasonable certainty of no harm under the FFDCA, as amended by the FQPA. FDA enforces the pesticide tolerances set by EPA.

Food and Drug Administration

FDA regulates GE organisms under the authority of the FFDCA (21 U.S.C. 301 *et seq.*). The FDA published its policy statement concerning regulation of products derived from new plant varieties, including those derived from genetic engineering, in the *Federal Register* on May 29, 1992 (57 FR 22984, 1992). Under this policy, FDA implements a voluntary consultation process to ensure that human food and animal feed safety issues or other regulatory issues, such as labeling, are resolved before commercial distribution of bioengineered food. This voluntary consultation process provides a way for developers to receive assistance from FDA in complying with their obligations under Federal food safety laws prior to marketing.

More recently, in June 2006, FDA published recommendations in “Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal

Proteins Produced by New Plant Varieties Intended for Food Use” (US-FDA, 2006). This establishes voluntary food safety evaluations for new non-pesticidal proteins produced by new plant varieties intended to be used as food, including bioengineered plants. Early food safety evaluations help make sure that potential food safety issues related to a new protein in a new plant variety are addressed early in development. These evaluations are not intended as a replacement for a biotechnology consultation with FDA, but the information may be used later in the biotechnology consultation.

1.4 Purpose and Need for this APHIS Action

As noted in the previous section any party can petition APHIS to seek a determination of nonregulated status for a GE organism that is regulated under 7 CFR 340. As required by 7 CFR 340.6, APHIS must respond to petitioners that 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 determine if the GE organism is unlikely to pose a plant pest risk. 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.

APHIS must respond to the petition from Okanagan Specialty Fruits requesting a determination of nonregulated status for GD743 and GS784 apples. APHIS has prepared this draft Environmental Assessment (EA) to consider the potential environmental effects of an agency determination of nonregulated status for GD743 and GS784 apples. This action is consistent regulations for the NEPA established by the Council of Environmental Quality’s (CEQ), and the USDA APHIS NEPA-implementing regulations and procedures (40 CFR parts 1500-1508, 7 CFR part 1b, and 7 CFR part 372). This EA has been prepared in order to specifically evaluate the effects on the quality of the human environment¹ that may result from a determination of nonregulated status for GD743 and GS784 apples.

1.5 Public Involvement

APHIS routinely seeks public comment on EAs prepared in response to petitions seeking a determination of nonregulated status of a regulated GE organism. APHIS does this through a notice published in the *Federal Register*. On March 6, 2012, APHIS published a notice² in the *Federal Register* advising the public that APHIS is implementing changes to the way it solicits public comment when considering petitions for determinations of nonregulated status for GE organisms to allow for early public involvement in the process. As identified in this notice, APHIS will publish two separate notices in the *Federal Register* for petitions for which APHIS prepares an EA. The first notice will

¹ Under NEPA regulations, the “human environment” includes “the natural and physical environment and the relationship of people with that environment” (40 CFR §1508.14).

² This notice can be accessed at: <http://www.gpo.gov/fdsys/pkg/FR-2012-03-06/pdf/2012-5364.pdf>

announce the availability of the petition, and the second notice will announce the availability of APHIS' decision making documents. As part of the new process, with each of the two notices published in the *Federal Register*, there will be an opportunity for public involvement:

1.5.1 First Opportunity for Public Involvement.

Once APHIS deems a petition complete, the petition will be made available for public comment for 60 days, providing the public an opportunity to raise issues regarding the petition itself and give input that will be considered by the Agency as it develops its EA and PPRA. APHIS publishes a notice in the *Federal Register* to inform the public that APHIS will accept written comments regarding a petition for a determination of nonregulated status for a period of 60 days from the date of the notice. This availability of the petition for public comment will be announced in a *Federal Register* notice.

1.5.2 Second Opportunity for Public Involvement.

Assuming an EA is sufficient, the EA and PPRA are developed and a notice of their availability is published in a second *Federal Register* notice. This second notice follows one of two approaches for public participation based on whether or not APHIS decides the petition for a determination of nonregulated status is for a GE organism that raises substantive new issues:

Approach 1. For GE organisms that do not raise substantive new issues.

This approach for public participation is used when APHIS decides, based on the review of the petition and our evaluation and analysis of comments received from the public during the 60-day comment period on the petition, that the petition involves a GE organism that does not raise new biological, cultural, or ecological issues because of the nature of the modification or APHIS' familiarity with the recipient organism. After developing its EA, finding of no significant impact (FONSI), and PPRA, APHIS publishes a notice in the *Federal Register* announcing its preliminary regulatory determination and the availability of the EA, FONSI, and PPRA for a 30-day public review period.

If APHIS determines that no substantive information has been received that would warrant APHIS altering its preliminary regulatory determination or FONSI, substantially changing the proposed action identifies in the EA, or substantially changing the analysis of impacts in the EA, APHIS' preliminary regulatory determination becomes final and effective upon public notification through an announcement on its website. No further *Federal Register* notice is published announcing the final regulatory determination.

Approach 2. For GE organisms that raise substantive new issues not previously reviewed by APHIS.

A second approach for public participation is used when APHIS determines that the petition for a determination of nonregulated status is for a GE organism that raises substantive new issues. This could include petitions involving a recipient organism that has not previously been determined by APHIS to have nonregulated status or when APHIS determines that gene modifications raise substantive biological, cultural, or ecological issues not previously analyzed by APHIS. Substantive issues are identified by APHIS based on our review of the petition and our evaluation and analysis of comments received from the public during the 60-day comment period on the petition.

APHIS solicits comments on its draft EA and draft PPRA for 30 days through the publication of a *Federal Register* notice. APHIS reviews and evaluates comments and other relevant information, then revises the PPRA as necessary and prepares a final EA. Following preparation of these documents, APHIS approves or denies the petition, announcing in the *Federal Register* the regulatory status of the GE organism and the availability of APHIS' final EA, PPRA, NEPA decision document (either a FONSI or NOI to prepare an EIS), and regulatory determination.

Enhancements to public input are described in more detail in the [*Federal Register*](#) notice³ published on March 6, 2012.

APHIS has determined that this EA will follow Approach 2. The issues discussed in this EA were developed by considering the public concerns, including public comments received in response to the *Federal Register* notice (77 F.R. 41362-3) announcing the availability of the petition (i.e., the first opportunity for public involvement previously described in this document), as well as issues noted in public comments submitted for other EAs of GE organisms, and concerns described in lawsuits and expressed by various stakeholders. These issues, including those regarding the agricultural production of apple using various production methods and the environmental and food/feed safety of GE plants, were addressed to analyze the potential environmental impacts of GD743 and GS784.

The public comment period for OSF's GD743 and GS784 apple petition closed on September 11, 2012. At its closing, a total of 72,745 public comments were submitted to the docket. The majority of the comments expressed a general dislike of the use of GE organisms or, were form letters sent to all of the dockets which were open at the time that this docket was open. 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 this EA. The issues that were raised in the public comments which were related to the OSF GD743 and GS784 apple petition 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.

³ This notice can be accessed at: <http://www.gpo.gov/fdsys/pkg/FR-2012-03-06/pdf/2012-5364.pdf>

- 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

APHIS evaluated these raised issues and the submitted documentation. APHIS has also included a discussion of these issues in this EA.

1.6 Issues Considered

The list of resource areas considered in this draft EA were developed by APHIS through experience in considering public concerns and issues raised in public comments submitted for this petition and other EAs of GE organisms. The resource areas considered also address concerns raised in previous and unrelated lawsuits, as well as issues that have been raised by various stakeholders for this petition and in the past. The resource areas considered in this EA can be categorized as follows:

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

2 ALTERNATIVES

This document 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 are unlikely to pose a plant pest risk. Based on its PPRA (USDA-APHIS, 2013), APHIS has concluded that GD743 and GS784 are unlikely to pose a plant pest risk. Therefore, APHIS must determine that GD743 and GS784 are no longer subject to 7 CFR part 340 or the plant pest provisions of the PPA.

Two alternatives are evaluated in this EA: (1) no action and (2) determination of nonregulated status of GD743 and GS784. APHIS has assessed the potential for environmental impacts for each alternative in the Environmental Consequences section.

2.1 No Action Alternative: 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 issued 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.

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

Under this alternative, GD743 and GS784 apples and progeny derived from them would no longer be regulated articles under the regulations at 7 CFR part 340. GD743 and GS784 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. This 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 Plant Protection Act. 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.

Under this alternative, growers may have future access to GD743 and GS784 apples and progeny derived from these events if the developer decides to commercialize GD743 and GS784 apples.

2.3 Alternatives Considered But Rejected from Further Consideration

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

2.4 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 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 PPA] 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 agencies in the development and implementation of policies for oversight of emerging technologies such as GE that included the following guidance:

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

Consistent with this guidance and based on the findings and scientific data evaluated for the PPRA (USDA-APHIS, 2013), APHIS concluded that GD743 and GS784 are unlikely to pose a plant pest risk. Therefore, there is no basis in science for prohibiting the release of GD743 and GS784.

2.5 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 both GD743 and GS784 are unlikely to

pose a plant pest risk, there is no regulatory basis under the plant pest provisions of the PPA for considering approval of the petition only in part.

2.6 Isolation Distance between GD743 and GS784 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 other 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 the 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 based on the location of production of non-GE apples 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' plant pest risk assessment for GD743 and GS784, there are no geographic differences associated with any identifiable plant pest risks for GD743 and GS784 (USDA-APHIS, 2013). This alternative was rejected and not analyzed in detail because APHIS has concluded that GD743 and GS784 do not pose a plant pest risk, and will not exhibit a greater plant pest 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. Individuals might choose on their own to geographically isolate their non-GE apple production systems from GD743 and GS784 or to use isolation distances and other management practices to minimize gene movement between apple orchards.

2.7 Requirement of Testing for GD743 and GS784

During the comment periods for other petitions for nonregulated status, some commenters requested USDA to require and provide testing for GE products in non-GE production systems. However, because GD743 and GS784 do not pose a plant pest risk (USDA-APHIS, 2013), testing requirements are 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 would be inconsistent with APHIS' purpose and need to respond appropriately to the petition in accordance with its regulatory authorities.

2.8 Comparison of Alternatives

Table 1 presents a summary of the potential impacts associated with selection of either of the alternatives evaluated in this EA. The impact assessment is presented in Section 4 of this EA.

Table 1. Summary of issues of potential impacts and consequences of alternatives.

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		
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

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
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
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

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
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
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	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.	Unchanged from No Action Alternative
Microorganisms	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.	Unchanged from No Action Alternative
Biological Diversity	The biological diversity in apple orchards is highly managed and may be lower than in the surrounding habitats.	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	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) (EPA, 1992); 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.	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. 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. 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.

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

3 AFFECTED ENVIRONMENT

The Affected Environment Section provides a discussion of the current conditions of those aspects of the human environment potentially impacted by a determination of nonregulated status of GD743 and GS784. For the purposes of this EA, those aspects of the human environment are: socioeconomic and cultural resources, apple production areas, the physical environment, biological resources, public health, and animal feed.

3.1 Socioeconomic and Cultural Resources

3.1.1 Agricultural Production of Apples

Apples are grown in all 50 states. People may grow apples in their backyards, small orchards or in larger production settings. In 2011, the U.S. total commercial apple bearing acreage was 330,600 acres (Table 2)(USDA-NASS, 2012b). Historically, Washington, New York, and Michigan are the largest producers of apples. Approximately 44% 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 (Figure 1) (USDA-NASS, 2012b).

Table 2. Commercial apple bearing acreage in U.S. States, 2011

State	Bearing Apple Acreage	State	Bearing Apple Acreage	State	Bearing Apple Acreage
Washington	146,000	Massachusetts	4,000	Missouri	1,800
New York	42,000	Wisconsin	3,800	Maryland	1,750
Michigan	34,000	Maine	3,100	Indiana	1,700
Pennsylvania	21,000	Vermont	2,800	Utah	1,400
California	17,500	Idaho	2,600	Colorado	1,300
Virginia	11,800	Minnesota	2,450	Arizona	1,200
North Carolina	6,900	Illinois	2,200	Iowa	1,000
West Virginia	4,900	Connecticut	2,100	Tennessee	800
Ohio	4,300	New Hampshire	1,900	Rhode Island	300
Oregon	4,100	New Jersey	1,900	Total	330,600

Source: (USDA-NASS, 2012b)

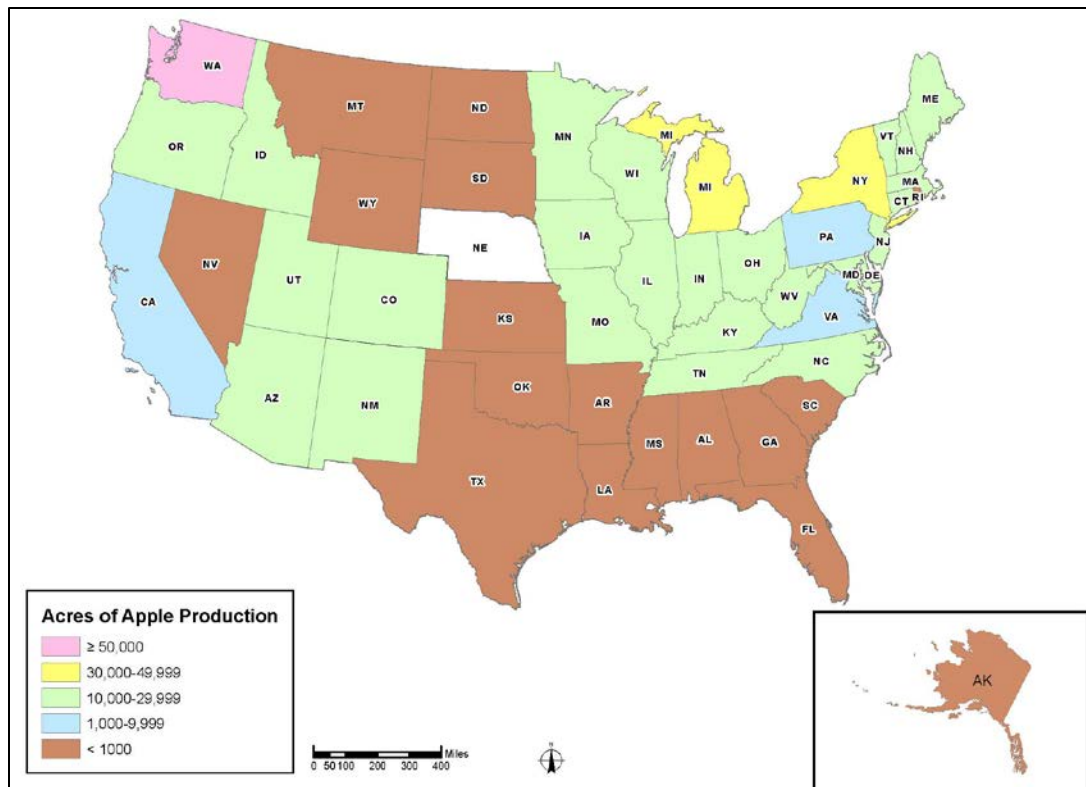


Figure 1. Acres of Apples Produced.

3.1.2 Domestic Commerce

In 2011, 330,600 acres of apples were cultivated in the United States, yielding approximately 9.3 million pounds at a value of 2.7 billion U.S. dollars (USDA-NASS, 2012b). 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).

Apples are processed into products such as juice, sauce, fresh slices, canned and frozen products. 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 (USDA-NASS, 2012b). Crunch Pak®, the largest sliced apple producer in the United States, produces more than a billion apple slices a year and has tripled their sales in just four years (Crunch Pak, 2012). According to a Reuter's estimate, approximately 10 % of McDonald's Corporation 2010 sales were from Happy Meals. In 2012, McDonald's Corporation announced that it would include a quarter cup of apples in every Happy Meal. Previously, apple slices with Happy Meals was an option. Currently, McDonald's Corporation is the leading food service user of apple slices (Karst, 2012).

Processing steps used in the production of apple slices are similar to the steps used for processing apples for apple sauce. As in apple sauce production, apples are dumped, washed, graded, peeled, and cored; however unlike apple sauce production, sliced apples packs generally consists of a single cultivar rather than a mix or blend of cultivars (Barrett et al., 2005). Surface discoloration is one of the most common quality defects of

fresh cut fruit and significantly contributes to the decreased shelf life of fresh cut fruit. When apples are peeled and cut, apple cells are broken and enzymes called polyphenol oxidases (PPOs) are released and come in contact with other molecules in the apple cell. When this happens, apple flesh discoloration or enzymatic browning occurs. Both physical and chemical methods can be used to prevent enzymatic browning. Physical methods that can be used are reducing temperature and oxygen levels, utilizing modified atmosphere packaging, or applying edible coatings. The most common chemical control method used for enzymatic browning is the application of ascorbic acid. Other chemical agents used are citric acid, malic acid, and EDTA. Along with enzymatic browning flesh texture is another common concern with fresh cut apples. Apples are typically treated with heat prior to slicing and with a chemical calcium solution after slicing to help maintain the texture of the fresh cut apple (Barrett et al., 2005)

3.1.3 Organic Apple Production

In the United States, 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, 2010a). Organic certification is a process-based certification, not a certification of the end product; the certification process specifies and audits the methods and procedures by which the product is produced.

The organic sector is rapidly growing both in the U.S. and the European Union (EU). Together, consumer purchases in these two regions made up 95 percent of estimated world retail sales of organic food products in 2003 (Dimitri and Oberholtzer, 2005). In 2009, world retail sales of organic products were estimated to be on the order of \$54.9 billion (USD), up from \$50.9 billion in 2008 (Organic Monitor, 2006).

In reporting the results of their annual manufacturer survey, the Organic Trade Association (Organic Trade Association, 2011) reports that U.S. organic food sales were estimated to be \$26.7 billion USD in 2010. Sales in 2010 represented 7.7 percent growth over 2009 sales. Experiencing the highest growth in sales during 2010 were organic fruits and vegetables, up 11.8 percent over 2009 sales. Organic fruits and vegetables represented over 11 percent of all U.S. fruit and vegetable sales (Organic Trade Association, 2011). Organic food and beverage sales represented approximately 4 percent of overall food and beverage sales in 2010 (Organic Trade Association, 2011).

As of 2011, there were 377 certified organic farms (13,363 harvested acres) that produced a total of 300 million pounds of organic apples. The total gross value of sales was reported from 371 farms, for a total of 286million pounds of organic apples valued at 122 million USD (USDA-NASS, 2012a). Organic apples are one of the top three organic fresh fruits purchased. The value of fresh organic apple sales in 2011 was 114 million USD compared to organic apples for processing valued at just under 8 million USD (USDA-NASS, 2012a). Washington State has the largest organic apple production in the United States followed by California and Arizona (USDA-NASS, 2012a). Climate is the primary reason the majority of organic apple production takes place in these states. The

relatively dry climate of Washington reduces the levels of pest and disease incidence for both conventional and organic apples compared to the more humid East coast states.

3.1.4 Foreign Trade

The United States produces approximately 16 percent of the global apple export market (USDA-FAS, 2012). Major apple exports for the U.S. are fresh apples and apple juice. As of 2011, the largest importer of U.S. fresh apples was Mexico, followed by Canada and India (USDA-FAS, 2012). The largest importer of U.S. apple juice is Canada with Japan and Mexico following (USDA-FAS, 2012). In 2011, the U.S. exported 833,000 metric tons of apples (USDA-FAS, 2012).

3.2 Physical Environment

3.2.1 Soil Quality

Soil consists of solids (minerals and organic matter), liquids, and gases. This body of inorganic and organic matter is home to a wide variety of fungi, bacteria, and arthropods, as well as the growth medium for terrestrial plant life (USDA-NRCS, 2004). Soil is characterized by its layers that can be distinguished from the initial parent material due to additions, losses, transfers, and transformations of energy and matter (USDA-NRCS, 1999). It is further distinguished by its ability to support rooted plants in a natural environment. Soil plays a key role in determining the capacity of a site for biomass vigor and production in terms of physical support, air, water, temperature moderation, protection from toxins, and nutrient availability. Soils also determine a site's susceptibility to erosion by wind and water, and flood attenuation capacity.

Soil properties change over time; temperature, pH, soluble salts, amount of organic matter, the carbon-nitrogen ratio, numbers of microorganisms and soil fauna all vary seasonally, as well as over extended periods of time (USDA-NRCS, 1999). Soil texture and organic matter levels directly influence its shear strength, nutrient holding capacity, and permeability. Soil taxonomy was established to classify soils according to the relationship between soils and the factors responsible for their character (USDA-NRCS, 1999). Soils are organized into four levels of classification, the highest being the soil order. Soils are differentiated based on characteristics such as particle size, texture, and color, and classified taxonomically into soil orders based on observable properties such as organic matter content and degree of soil profile development (USDA-NRCS, 2010). The Natural Resources Conservation Service (NRCS) maintains soil maps on a county level for the entire U.S. and its territories.

There are a multitude of organisms associated with soils, ranging from microorganisms to larger organisms, such as worms and insects. The microbial populations of the soil encompass an enormous diversity of bacteria, algae, fungi, protozoa, viruses, and actinomycetes (filamentous bacteria) (Doran et al., 1996). The extent of the diversity of microorganisms in soil is seen to be critical to the maintenance of soil health and quality. Microorganisms in soil are critical to the maintenance of soil function in both natural and managed agricultural soils because of their involvement in such key processes as soil structure formation; decomposition of organic matter; toxin removal; and the cycling of

carbon, nitrogen, phosphorus, and sulfur (Garbeva et al., 2004; USDA-NRCS, 2004). In addition, certain microbial organisms may contribute to the protection of the root system against soil pathogens (Garbeva et al., 2004).

3.2.2 Water Resources

The principal law governing pollution of the nation's water resources is the Federal Water Pollution Control Act of 1972, better known as the Clean Water Act (CWA). The Act utilizes water quality standards, permitting requirements, and monitoring to protect water quality. The EPA sets the standards for water pollution abatement for all waters of the U.S. under the programs contained in the CWA, but, in most cases, gives qualified states the authority to issue and enforce permits. Drinking water is protected under the Safe Drinking Water Act of 1974 (Public Law 93-523, 42 U.S.C. 300 *et seq.*).

Surface water in rivers, streams, creeks, lakes, and reservoirs supports everyday life through the provision of water for drinking and other public uses, irrigation, and industry. Surface runoff from rain, snowmelt, or irrigation water can affect surface water quality by depositing sediment, minerals, or contaminants into surface water bodies. Surface runoff is influenced by meteorological factors such as rainfall intensity and duration, and physical factors such as vegetation, soil type, and topography.

Groundwater is the water that flows underground and is stored in natural geologic formations called aquifers. It sustains ecosystems by releasing a constant supply of water into wetlands and contributes a sizeable amount of flow to permanent streams and rivers. Based on 2005 data, the largest use of groundwater in the U.S. is irrigation, representing approximately 67.2% of all the groundwater pumped each day (McCray, 2009). In the U.S., approximately 47% of the population depends on groundwater for its drinking water supply. The EPA defines a sole source aquifer (SSA) as an aquifer that supplies at least 50% of the drinking water consumed in the area overlying the aquifer. An SSA designation is one tool to protect drinking water supplies in areas where there are few or no alternative sources to the groundwater resource. There are 77 designated SSAs in the U.S. and its territories (US-EPA, 2011b).

Unlike a point source which is a "discernible, confined and discrete conveyance", nonpoint source (NPS) pollution comes from many diffuse sources. Rainfall or snowmelt moving over the ground, also known as runoff, picks up and carries away natural and human-made pollutants, creating NPS. The pollutants may eventually be transported by runoff into lakes, rivers, wetlands, coastal waters and ground waters. Agricultural NPS pollution includes animal wastes, fertilizers, and pesticides. Surface water may be contaminated by agricultural sediments transported by erosion that may also include pesticides, fertilizers, and sometimes fuel and pathogens. Agricultural practices that introduce contaminants into the groundwater include fertilizer and pesticide application, spilled oil and gasoline from farm equipment, nitrates, and pathogens from animal manure.

NPS pollution is the leading source of water quality impacts on rivers and lakes, the second largest source of impairments to wetlands, and a major contributor to groundwater

contamination (US-EPA, 2005). Management practices that contribute to NPS pollution include the type of crop cultivated, plowing and tillage, and the application of pesticides, herbicides, and fertilizers. The primary cause of NPS pollution is increased sedimentation in surface waters following soil erosion (US-EPA, 2005). The major contribution to groundwater contamination derives from agricultural areas (nitrogen inputs from fertilizer and manure) and is influenced by regional environmental factors such as precipitation and soil characteristics (US-EPA, 2003). Nutrients in excess are listed as the second cause of impairment in lakes, reservoirs, and ponds, with agriculture listed as the third most probable source of the impairment (US-EPA, 2012d).

Agricultural pollutants released by soil erosion include sediments, fertilizers, and pesticides that are introduced to area lakes and streams when they are carried off of fields by rain or irrigation waters (US-EPA, 2005). Increase in sediment loads to surface waters can directly affect fish, aquatic invertebrates, and other wildlife maintenance and survival. It also reduces the amount of light penetration in water which directly affects aquatic plants. Indirectly, soil erosion-mediated sedimentation can increase fertilizer runoff, thereby increasing nutrient loading and facilitating higher water turbidity, algal blooms, and oxygen depletion (US-EPA, 2005). Extension scientists suggest over fertilization should be avoided preventing loss of fruit quality, nutrient leaching into groundwater, risk of ground water pollution with nitrates and risk of estuary pollution from nitrates and phosphates (Carroll and Robinson, 2006). Preservation and conservation of water and soil resources must be maximized and non-point-source pollution must be minimized (Carroll and Robinson, 2006).

3.2.3 Air Quality

The Clean Air Act (CAA) requires the maintenance of National Ambient Air Quality Standards (NAAQS). The NAAQS, developed by the EPA to protect public health, establish limits for six criteria pollutants: ozone (O_3), nitrogen dioxide (NO_2), carbon monoxide (CO), sulfur dioxide (SO_2), lead (Pb), and inhalable particulates (coarse particulate matter [PM] greater than 2.5 micrometers and less than 10 micrometers in diameter [PM_{10}] and fine particles less than 2.5 micrometers in diameter [$PM_{2.5}$]). The CAA requires states to achieve and maintain the NAAQS within their jurisdiction. Each state may adopt requirements stricter than those of the national standard and each is also required by EPA to prepare a State Implementation Plan (SIP) containing strategies to achieve and maintain the national standard of air quality within the state. Areas that violate air quality standards are designated as non-attainment areas for the criteria pollutant(s), whereas areas that comply with air quality standards are designated as attainment areas. Emissions contributing to greenhouse gases (GHG) associated with global warming are discussed in Subsection 3.2.4, Climate Change.

3.2.4 Climate Change

Climate change represents a statistical change in global climate conditions, including shifts in the frequency of extreme weather. Agriculture is recognized as a direct (e.g., exhaust from equipment) and indirect (e.g., agricultural-related soil disturbance) source of greenhouse gas (GHG) emissions. The EPA has identified carbon dioxide (CO_2),

methane (CH₄), and nitrous oxide (N₂O) as the most important GHGs contributing to climate change. While each of these gases occurs naturally in the atmosphere, human activity has significantly increased the concentration of these gases since the beginning of the industrial revolution. The level of human produced gases accelerated even more so after the end of the Second World War, when industrial and consumer consumption expanded greatly. With the advent of the industrial age, there has been a 36% increase in the concentration of CO₂, 148 % in CH₄, and 18 % in N₂O (US-EPA, 2012b).

Many agricultural activities affect air quality, including smoke from agricultural burning, machinery, and N₂O emissions from the use of nitrogen fertilizer (Hoeft et al., 2000; Aneja et al., 2009; US-EPA, 2012b). The EPA report, Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990-2010 (US-EPA, 2012b), examines the agricultural contribution to climate change and possible mitigation measures. APHIS refers to this report for further discussion of the agricultural effects on climate change.

Although agriculture may influence climate change, climate change, in turn, potentially affects agriculture. In response to climate change, the current range of weeds and pests of agriculture may increase (Field et al., 2007). Current agricultural practices will be required to change in response to these changes in the ranges of weeds and pests of agriculture (Field et al., 2007).

Climate change potentially may provide a positive impact to agriculture in general. The Intergovernmental Panel on Climate Change (IPCC) predicts that potential climate change in North America may result in an increase in crop yield by 5-20% for this century (Field et al., 2007). However, this positive impact will not be observed across all growing regions as certain areas of the US are expected to be negatively impacted because the available water resources may be reduced substantially (Field et al., 2007). Note that the extent of climate change effects on agriculture is highly speculative. Nevertheless, North American production is expected to adapt to climate change impacts with improved cultivars and responsive farm management (Field et al., 2007).

3.3 Biological Resources

3.3.1 Animal Communities

Vertebrate Animals

Apple orchards attract wildlife by providing food, cover, and nesting areas. The bark, buds, twigs, and fruit are used by a variety of wildlife (Wilson, 2006). Beavers, porcupines, rabbits, raccoons, voles, mice, deer, woodchucks, foxes, fishers, bobcats, coyotes, squirrels, black bears, and a variety of birds are known to feed on apple trees and apples and can cause damage to apple trees (Wilson, 2006; Cornell, 2012). Birds such as quail nest in the grassy understories of apple orchards, while songbirds and mourning doves nest in the fruit trees (Palmer and Bromley, 1992).

Invertebrate Animals

A wide variety of invertebrates inhabit apple orchards, including beneficial as well as pest species. Insects commonly considered pests of apples include American plum borer, aphids, apple maggot, codling moth, Comstock mealybug, cutworm, dogwood borer, European apple sawfly, European corn borer, green fruitworms, internal lepidopterans, Japanese beetles, lacanobia fruitworm, lesser appleworm, mullein plant bug, Oriental fruit moth, oystershell scale, plum curculio, potato leafhopper, San Jose scale, sparganothis fruitworm, spider mites, spotted tentiform leafminer, stink bugs, tarnished plant bug, variegated leafroller, western flower thrip, white apple leafhopper (McVay et al., 1996; Bessin, 2003; Carroll and Robinson, 2006; WSU, 2010).

3.3.2 Plant Communities

Surrounding Landscapes and Other Vegetation in Apple Orchards

Apple orchards may be bordered by other agricultural crops or by woodlands, hedgerows, rangelands, or pasture/grassland areas. These surrounding plant communities may occur naturally or they may be managed for the control of soil and wind erosion. The vegetation adjacent to an apple orchard is often dependent on the geographic region where the orchard is located.

Apples as a Weed or Volunteer

As noted in the PPRA (USDA-APHIS, 2013), apple is a highly domesticated fruit tree species, and cultivated varieties of apple in the U.S. are not listed as weeds (Muenscher, 1980) or as Federal noxious weeds (7 CFR part 360⁴; (USDA-NRCS, 2012). GD743 and GS784 do not exhibit characteristics that would cause them to be weedier than other golden delicious and granny smith apples.

Volunteer plants originating from seed in apple orchards are very rare due to orchard management practices, such as herbicide treatment of the tree row and mowing of the alley between rows. Animals, such as bears, mice, and squirrels, can carry fruit containing seed or seeds away from cultivated areas. Apples are often discarded by travelers on roadways, or in compost piles. Seeds distributed in this way can result in seedling trees. Such cultivated apple-tree seedlings can be persistent; the species has escaped cultivation and naturalized in southern Canada, in the eastern USA, and from British Columbia south to California (Little, 1979). However, *M. domestica* typically occurs in commercial orchard plantings, as fruit trees in gardens or pastures. It is not common to find wild seedling trees; therefore, weediness is not thought to be a widespread problem.

3.3.3 Soil Microorganisms

Soil microorganisms play a key role in soil structure formation, decomposition of organic matter, toxin removal, nutrient cycling, and most biochemical soil processes (Garbeva et al., 2004). They also suppress soil-borne plant diseases and promote plant growth (Doran et al., 1996). The main factors affecting microbial population size and diversity include

⁴ http://www.aphis.usda.gov/plant_health/plant_pest_info/weeds/downloads/weedlist-2010doc.pdf

soil type (texture, structure, organic matter, aggregate stability, pH, and nutrient content), plant type (providers of specific carbon and energy sources into the soil), and agricultural management practices (crop rotation, tillage, herbicide and fertilizer application, and irrigation) (Garbeva et al., 2004). Plant roots, including those of apples, release a variety of compounds into the soil creating a unique environment for microorganisms in the rhizosphere. Microbial diversity in the rhizosphere⁵ may be extensive and differs from the microbial community in the bulk soil (Garbeva et al., 2004).

Apple scab is considered the most economically destructive disease of apples worldwide. Apple scab is caused by the fungal pathogen *Venturis inaequalis*. Although there are scab resistance varieties, many susceptible varieties such as McIntosh and Red Delicious are widely grown due to consumer preference (Wilcox, 2013). Apple scab is more likely to cause severe damage in climates that have cool, damp weather in the spring as opposed to areas with warm, drier climates. The fungus usually overwinters in fallen leaves. In the spring airborne ascospores are distributed by wind and wind driven rain (Vaillancourt, 2000). Apple scab is difficult to control and requires as many as 12 fungicide applications a growing seasons to limit the spread and damage of the disease. Management of apple scab in susceptible varieties is aimed at preventing a primary infection in the spring. Early infection can result in poor fruit set and an increase in the amount of the fungal inoculum in the orchard. Both preventative and curative fungicides are applied to control apple scab. Preventative fungicides are used to prevent infection and curative fungicides are used to treat infections that have been identified. Fungicides to control apple scab are applied every 5 -10 days on average depending on whether it is early in the season or late in the season. In addition to fungicide applications, methods such as pruning, clearing leaf litter from the orchard floor and/or treating leaves prior to drop or fallen leaves with urea are also useful (Vaillancourt, 2000).

Fire blight is a devastating bacterial disease of apples and several other rosaceous species. In the U.S., the yearly economic losses due to fire blight and control are estimated at 100 million USD (Norelli et al., 2009; Gardiner et al., 2012). The disease is caused by the infection of the apple tree with the bacteria *Erwinia amylovora*. The bacteria overwinter in cankers on the apple tree. When conditions are favorable, the bacteria will multiply. Occurrence and severity of the disease can vary from year to year depending on the level of bacteria present in the orchard, weather conditions, cultivar selection, and age of the trees. Fire blight disease can infect most parts of the apple tree. Insects, particularly pollinating insects, spread the bacteria throughout the orchard via blossoms. Several strategies such as weather monitoring, pruning, selection of resistant cultivars, and chemical/ antibiotic applications are used to control fire blight disease in the orchard (Steiner, 2000). Programs such as Maryblyt (Steiner and Lightner, 1992) and Cougarblight (Smith, 1999) are used to forecast when conditions are favorable for a fire blight incidence to occur and facilitate the efficient and effective implementation of

⁵ The rhizosphere is defined as subsoil area in the root zone of plants in which plant roots compete with the invading root systems of neighboring plants for space, water, and mineral nutrients, and interact with soil-borne microorganisms, including bacteria, fungi, and insects feeding on the organic material in the soil T. S. Walker, H. P. Bais, E. Grotewold and J. M. Vivanco, "Root Exudation and Rhizosphere Biology," *Plant physiology* 132.1 (2003)..

antibiotic application. Timely application of the antibiotic streptomycin or oxytetracycline is critical in controlling fire blight. Currently the organic apple growers are allowed to use streptomycin or oxytetracycline for fire blight control. Use of these antibiotics in organic apple production is scheduled to be phased out in October 2014 (WSUTFRE, 2013).

3.3.4 Biological Diversity

Biodiversity refers to all plants, animals, and microorganisms interacting in an ecosystem (Wilson, 1988). Agricultural biodiversity has been defined to include genetic diversity of the crops through and including the natural biodiversity of the surrounding ecosystem (see, e.g., (Carpenter, 2011). APHIS focuses its analysis of biological diversity at the ecosystem level, that aspect of the environment potentially impacted by the determination of nonregulated status of various GE crops. In this case, biodiversity refers to the ability of a highly managed ecosystem, such as an apple orchard, to support species that do not contribute directly to crop production but represent important components of the biological landscape. Such species include species affecting pollination (e.g., bees, butterflies) and control of insect pests; important avian (e.g., songbirds) and mammalian (e.g., small mammals) wildlife; and the plant community.

3.4 Public Health

Public health concerns related to GE apples focus primarily on human consumption of apples and apple products, animal consumption of apples and apple products as related to and the potential changes in crop composition associated with the introduced trait, and the indirect effect on human health and worker safety from laborers' exposure to agricultural chemicals.

3.4.1 Food and Feed

In 2011, the average U.S. consumer ate an estimated 15.4 pounds of fresh-market apples and 32.2 pounds of processed apples, for a total of 47.6 pounds of fresh apples and processed apple products (USDA-ERS, 2012). In 2011 more than 60% of apple production in the United States was marketed as fresh fruit (USDA-NASS, 2012b). The remaining apple production is marketed as processed fruit such as fruit juice, cider, sauce, canned, fresh apple slices, and dried fruit products (USDA-ERS, 2010b). In 2011, 138.4 million pounds of apples were marketed as fresh apple slices valued at over 26 million USD (Karst, 2012; USDA-NASS, 2012b).

Recent research suggests that apples may promote better health and help maintain a healthy weight. Compared to many other fruits and vegetables, apples contain relatively low amounts of Vitamin C, but are a rich source of other antioxidant compounds (Boyer and Liu, 2004). Apples are an excellent source of dietary fiber, which helps regulate bowel movements and may reduce the risk of colon cancer, help prevent heart disease and promote weight loss. Apples are also cholesterol-free, and their high fiber content helps control high cholesterol levels by preventing cholesterol absorption, and are nutrient dense for their low calorie content like most fruits and vegetables (Sharma, 2005).

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. Several wastes from apple processing, including pulp, peels, and cores, are suitable animal feeds (NRC, 1983). Apple pomace has feeding values similar to grass silage for wintering beef cattle (NRC, 1983). Between 25 to 35 percent of the fresh weight of the apple is retained in the pomace after pressing and is often mixed with alfalfa or corn for feeding (NRC, 1983).

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 any GE crop must be in compliance with all applicable legal and regulatory requirements. GE organisms for food and feed may undergo a voluntary consultation process with the FDA prior to release onto the market. Although a voluntary process, applicants who wish to commercialize a GE variety that will be included in the food supply invariably complete 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. This process includes: 1) an evaluation of the amino acid sequence introduced into the food crop to confirm whether the protein is related to known toxins and allergens; 2) an assessment of the protein's potential for digestion; and 3) an evaluation of the history of safe use of the protein in food. FDA evaluates the submission and responds to the developer by letter. OSF indicated that they have submitted a safety and nutritional assessment of food and feed derived from GD 743 and GS 784 to the FDA on May 30, 2011 (OSF, 2012). FDA is presently evaluating the submission. Additionally, regulatory submission for GD743 and GS784 was submitted to Health Canada and the Canadian Food Inspection Agency (CFIA) on December 7, 2011 (OSF, 2012).

As noted by the National Research Council (NRC), unexpected and unintended compositional changes arise with all forms of genetic modification, including both conventional hybridizing and genetic engineering (NRC, 2004). The NRC also noted that at the time, no adverse health effects attributed 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).

The apple orchard is a highly managed environment which incorporates the use of agricultural chemicals. Pesticide use is common on most apple acreage in the US. Most of the major apples producing states/regions have guidelines for commercial apple orchard production and management. Each orchard/ apple production plan typically includes guidelines that address integrated pest management practices (Carroll and Robinson, 2006; Moulton and King, 2008; Donohue et al., 2011; Walgenbach, 2012).

The widespread and common use of pesticides may result in small amounts (called residues) in or on apples and apple products. To ensure safety of the apple food supply, the EPA regulates the amount of each pesticide that may remain in or on foods. These limits, called tolerances, are established to ensure food safety and are the result of the

EPA making a safety finding that “the pesticide can be used with reasonable certainty of no harm.” (US-EPA, 2013). This finding of reasonable certainty of no harm is obligated under the FFDCA, as amended by the Food Quality Protection Act of 1996 (FQPA). In addition, the FDA and the USDA monitor foods for pesticide residues and work with the EPA to enforce these tolerances (see (USDA-AMS, 2013). In setting pesticide tolerances, the EPA generally will consider (US-EPA, 2013):

- The toxicity of the pesticide and its break-down products;
- How much the pesticide is applied to the crop and how often; and
- How much of the pesticide (i.e., the residue) remains in or on food by the time it is marketed and prepared.

3.4.2 Worker Safety

Worker hazards in farming are common to all types of agricultural production, and include hazards of equipment and plant materials. Pesticide application represents the primary exposure route to pesticides for farm workers. Workers engaged in apple production may encounter insecticides, herbicides, fungicides or fertilizers that may pose a worker health or safety risk unless used in accordance with the EPA -established agriculture-specific requirements in the Worker Protection Standard (WPS) (40 CFR Part 170) that protect workers from the hazards of chemical exposure. The WPS offers protections to more than two and a half million agricultural workers who work with pesticides at more than 560,000 workplaces on farms, forests, nurseries, and greenhouses. 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. The Occupational Safety and Health Administration requires all employers to protect their employees from hazards associated with agricultural chemicals. The EPA pesticide registration process, however, involves the design of use restrictions that if followed have been determined to be protective of worker health.

4 ENVIRONMENTAL CONSEQUENCES

4.1 Assumption used in analysis

This analysis of potential environmental consequences addresses the potential impact to the human environment from the alternatives analyzed in this EA. Potential environmental impacts from the No Action Alternative and the Preferred Alternative for GD743 and GS784 apples are described in detail throughout this section.

In this section APHIS focuses the analysis on commercial apple production because GD743 and GS784 are intended for commercial production for the fresh cut apple market. Based on APHIS' PPRA, GD743 and GS784 are not more weedy or more susceptible to diseases of apple than other commercially available apple varieties.

Although the preferred alternative would allow for new plantings of GD743 and GS784 anywhere in the U.S., APHIS will limit the environmental analysis to those areas that currently support apple production. To determine areas of apple production, APHIS used data from the USDA-NASS 2011 Noncitrus Fruits and Nuts Report (USDA-NASS, 2012b).

4.2 Socioeconomic and Cultural Resources

Apple agriculture can affect socioeconomic resources such as the domestic economy, international trade economy, and the social environment. This section describes key current issues within each of these topics.

4.2.1 Agricultural Production of Apple

No Action Alternative: Agricultural Production of Apple

Apple is a highly managed crop. Best management practices are commonly accepted, practical ways to grow apples, regardless of whether the apple farmer is using organic practices or conventional practices with non-GE or GE varieties. These management practices consider choices to use certain varieties, irrigation practices, pesticides, fertilizer use and other growing practices to contain costs, increase production, ease maintenance requirements, and to meet market demand. Over the years, apple production has resulted in well-established management practices that are available through local Cooperative Extension Service offices and their respective websites. The National Information System for the regional Integrated Pest Management (IPM) Centers publishes crop profiles for major crops on a state-by-state basis. These crop profiles provide production guidance for local growers, including recommended practices for specific pest control. Crop profiles for many of the apple production states can be reviewed at www.ipmcenters.org/cropprofiles/index.cfm.

An apple tree is a composite tree that consists of a scion grafted onto a rootstock. The rootstock is the bottom portion of the tree that supports the scion, and the scion is the top portion of the tree that produces the desired fruit variety. Apples trees are outcrossing species that require cross pollination. Due to the nature of the outcrossing of apple fruit

trees, the seeds produced by an apple will be a hybrid of the tree that produced the fruit and the tree that was used for pollination. The resulting characteristics of the fruit and even the vegetative portions of the plant may not resemble those of the parent trees (Crasweller, 2005). Therefore, apple trees are clonally propagated rather than grown from seed. Furthermore, popular apple varieties such as ‘Red Delicious’ have numerous varietal mutants or sports. These sports can arise through random genetic mutations. If the genetic mutation gives rise to a unique and desirable phenotype, then the genetic mutation could be maintained and marketed through clonal propagation. Apple producing orchards are typically established from trees purchased from a fruit tree production nursery. Commercial nursery workers propagate new apple trees for planting. Production of an apple tree ready for planting takes several years.

Orchard establishment and management involve careful consideration of site characteristics and apple tree selection. Growers choose site locations in an environment that protects the tree from climactic conditions as well as has suitable soil quality. Commercial apple orchards are typically 10 or more acres. Deciding on which apple varieties to grow is an important aspect of orchard planning. Factors such as the cultivars and rootstocks selected will determine tree spacing, training, and pest and disease management; however the overarching decision is driven by marketing strategy and consumer preference (Roper and Frank, 2004). It is necessary to select a combination of rootstock/scion that can be effectively managed and provides long term fruit production. The rootstock controls trees size; therefore rootstock selection is most important when determining tree spacing. Selecting a rootstock that is resistant to diseases and pests is also an important consideration when selecting a rootstock. Dwarfing rootstocks make apple tree management easier because of the smaller size of the apple tree and facilitates pest and disease management, pruning, thinning, and harvesting from the ground level (Moulton and King, 2008).

Another important consideration is the choice of pollinizer trees. Bloom time is critical when choosing pollinizer trees. If the pollinizer tree’s bloom time does not overlap at the same time as the selected variety, then pollination will not occur. Ideally, pollinizers should not be placed more than 100 feet away and approximately 10% of the orchard trees should be pollinizers (Roper and Frank, 2004)). Various strategies are used to provide pollen sources. Interspersing pollinizer trees, grafting branches of pollinizer cultivars onto the tree that requires a pollen source, or planting rows of pollinizer trees systematically throughout the orchard are some common strategies used for providing pollen sources (Warmund, 1996; Schotzko and Granatstein, 2005). Pollinizer trees can be other compatible apple varieties or crabapples. Crabapples are often used as pollinizers as they are smaller and easier to manage, flower profusely, and reduce confusion about which fruit to pick at harvest time (Penn State, 2012) . It is important to note that because apple trees are an outcrossing species, any apple seeds that are produced will be hybrids and would have characteristics of both parents. In the case of GD743 and GS784 apples, a portion of the seeds would carry the transgene responsible for the non-browning trait. GD743 carries two copies of the transgene while GS784 carries four copies (OSF, 2012). Therefore three quarters of the GD743 seeds would carry at least one copy of the transgene and 15/16 of the seeds of GS784 would carry at least one copy of the transgene.

Apples are grown in all 50 states. In 2011, the United States total commercial apple bearing acreage was 330,600 acres (USDA-NASS, 2012b). Historically, Washington, New York, and Michigan have been the largest apple producing states in the country. These three states alone account for approximately 67% of the total commercial apple bearing acreage in the country (USDA-NASS, 2012b). Total commercial apple bearing acreage has declined since 2002 while total apple utilized production has been relatively unchanged since 2007 (Figures 2 and 3).

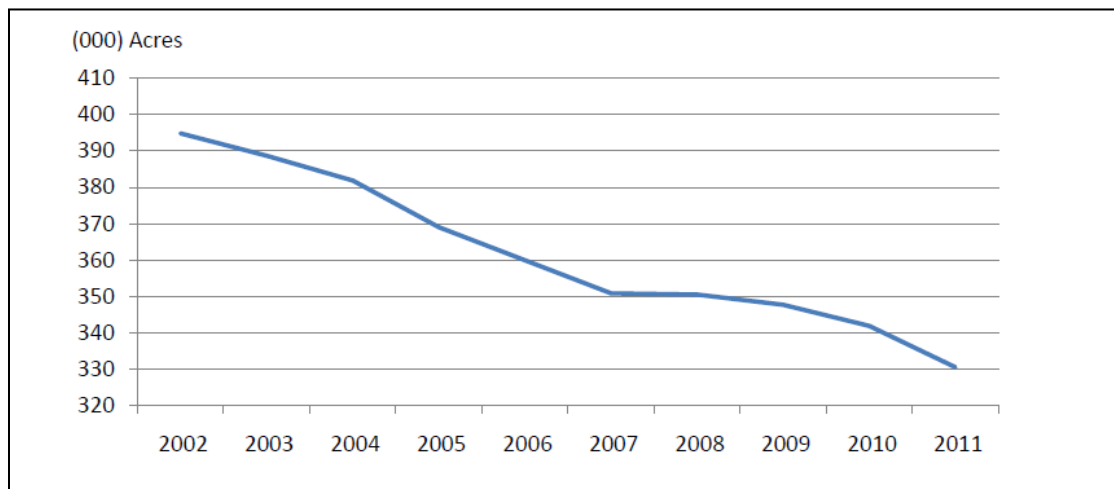


Figure 2. Commercial Apple Bearing Acreage-United States: 2002-2011 (USDA-NASS, 2012b).

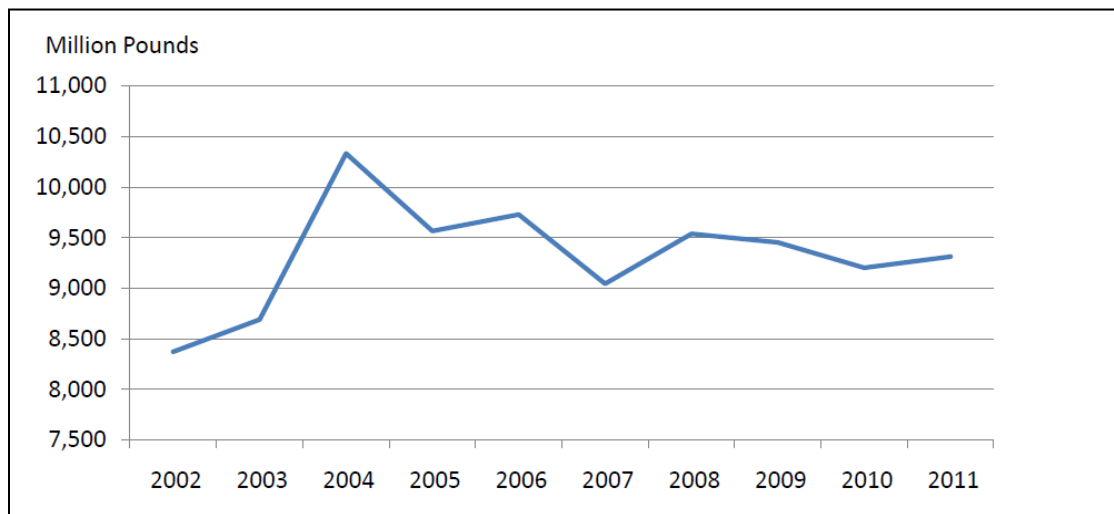


Figure 3. Commercial Apple Utilized Production- United States: 2002-2011 (USDA-NASS, 2012b).

The trend of an increase in apple production per acre can be accounted for by a number of factors such as, cultural practices to reduce biannual bearing, planting of high density orchards, and integrated pest management strategies (USITC, 2010). Apple production has remained relatively stable since 2005. The upward trend in apple production in 2004 can be contributed to a bumper crop (USITC, 2010). While apple production for the fresh

market has seen a slight increase from 2004 – 2008, apples utilized for processing decreased from 2004 - 2008 mainly due to the increase in importation of apple juice concentrate from China (USITC, 2010).

Based on apple production trends and projections, apples will continue to be a major fruit crop in the U.S. for the foreseeable future. The current agronomic practices utilized in apple production are likely to continue under the No Action Alternative.

Preferred Alternative: Agricultural Production of Apple

Under the Preferred Alternative, a determination of a nonregulated status of GD743 and GS784 apples is unlikely to change the agricultural production of apples as described in the No Action alternative.

OSF's studies demonstrate that agronomic characteristics and cultivation practices required for GD743 and GS784 apples are indistinguishable from practices used to grow other apple varieties (OSF, 2012). None of the BMP currently employed for apple production are expected to change if GD743 and GS784 apples are no longer subject to the regulatory requirements of 7 CFR Part 340 or the plant pest provisions of the PPA. A determination of a nonregulated status of GD743 and GS784 apples is unlikely to expand apple acreage. Accordingly, the potential impacts on agricultural production of GD743 and GS784 apples resulting from management practices associated with the No Action and Preferred Alternative are the same.

4.2.2 Domestic Commerce

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 valued at over 2.72 billion USD, fresh fruit production accounted for 2.38 billion dollars and processed fruit production for 338 million dollars (Table 3). Apples are processed into products such as juice, sauce, fresh slices, canned and frozen products. 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 (USDA-NASS, 2012b).

Table 3. Apple production and value by use 2011.

USE	Quantity (million pounds)	Value (US dollars)
Fresh	6.2771	2,384,586,000
Canned	1138.7	129,242,450
Juice/ Cider	1278.4	125,283,200
Frozen	255.5	32,320,750
Dried	153.5	17,192,000

Fresh slices	138.4	26,434,400
Other	71.0	7,313,000

Source: (USDA-NASS, 2012b)

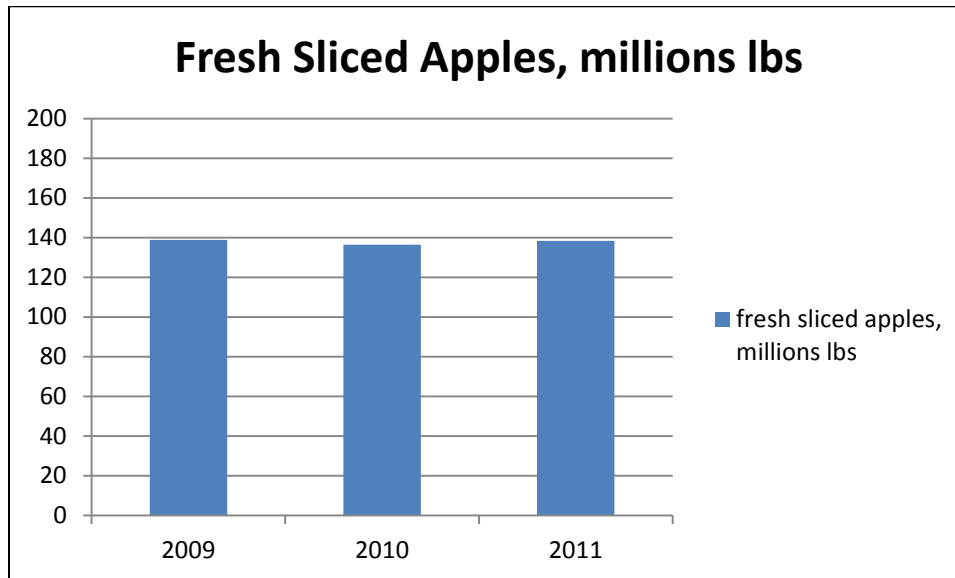


Figure 4. Fresh Sliced Apples 2009-2011 (USDA-NASS, 2012b).

Preferred Alternative: Domestic Commerce

A determination of nonregulated status of GD743 and GS784 apples is not expected to adversely impact domestic commerce. The adoption of GD743 and GS784 apples would add another apple variety to the market. OSF has estimated a total planted area of 4,000 acres or about 1.2 percent of total U.S. apple plantings over the first 10 years (OSF, 2012). OSF anticipates that apples, being a perennial crop of 20 or more years before replanting, will have a much slower adoption and introduction curve than annual crops (OSF, 2012).

OSF's studies demonstrate that agronomic characteristics and cultivation practices required for GD743 and GS784 apples are indistinguishable from practices used to grow other apple varieties (OSF, 2012). 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, 2012). 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.

GD743 and GS784 apples have the potential to improve fruit processing capabilities for maintaining the quality and shelf life of apples for processing and the snack food market. There also is an inherent reduction in food processing costs associated with a reduction in fruit browning and in providing alternatives to conventional technologies to prevent browning. If growers adopt GD743 and GS784 apple varieties and take advantage of the niche market, local farm economics may improve.

All GD743 and GS784 apples will be sold under the Arctic™ brand name. This brand name will be utilized 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, 2012). 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, 2012). Under the Preferred Alternative, trends related to domestic commerce are unlikely to be substantially different than what would occur in the No Action Alternative.

4.2.3 Organic Apple Production

No Action Alternative: Organic Apple Production

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, 2010a). Organic certification is a process-based certification, not a certification of the end product; the certification process specifies and audits the methods and procedures by which the product is produced.

In accordance with NOP, an accredited organic certifying agent conducts an annual review of the certified operation's organic system plan and makes on-site inspections of the certified operation and its records. Organic growers must maintain records to show that production and handling procedures comply with USDA organic standards.

The NOP regulations preclude the use of excluded methods. The NOP provides the following guidance under 7 CFR Section 205.105:

...to be sold or labeled as "100 percent organic", "organic" or "made with organic (specified ingredients or group(s))," the product must be produced and handled without the use of...

- (a) Synthetic substances and ingredients,...
- (e) Excluded methods...

Excluded methods are then defined at 7 CFR Section 205.2 as:

A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.

Organic farming operations, as described by the NOP, are required to have distinct, defined boundaries and buffer zones to prevent unintended contact with excluded methods from adjoining land that is not under organic management. Organic production operations must also develop and maintain an organic production system plan approved by their accredited certifying agent. This plan enables the production operation to achieve and document compliance with the National Organic Standards, including the prohibition on the use of excluded methods. (USDA-AMS, 2010a).

Common practices organic growers may use to exclude GE products include planting only organic seed, planting earlier or later than neighboring farmers who may be using GE crops so that the crops will flower at different times, and employing adequate isolation distances between the organic fields and the fields of neighbors to minimize the chance that pollen will be carried between the fields (NCAT, 2003). 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. 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, 2010a). The current NOP regulations do not specify an acceptable threshold level for the adventitious presence of GE materials in an organic-labeled product. 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 (Ronald and Fouche, 2006; USDA-AMS, 2010a).

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). Organic apples are one of the top three organic fresh fruits purchased. The value of fresh organic apple sales in 2011 was 114 million USD compared to organic apples for processing valued at 8 million USD (USDA-NASS, 2012a). Washington State has the largest organic apple production in the United States followed by California and Arizona (USDA-NASS, 2012a). Climate is the primary reason the majority of organic apple production takes place in these states. The relatively dry climate of Washington reduces the levels of pest and disease incidence for both conventional and organic apples compared the more humid east coast states.

Preferred Alternative: Organic Apple Production

Organic farmers will not be substantially affected by a determination of nonregulated status of GD743 and GS784 apple. Organic apple producers would not be able to adopt GD743 and GS784 varieties since these varieties would be considered excluded methods as defined at 7 CFR Section 205.2. It is important to note that the current NOP regulations do not specify an acceptable threshold level for the presence of GE materials in an product labeled organic (USDA-ERS, 2010a). 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 (Ronald and Fouche, 2006; USDA-AMS, 2010b). 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 GD 743 or GS784 may need to discuss their needs with neighboring orchards to incorporate pollination control strategies in their organic plans.

4.2.4 Foreign Trade

No Action Alternative: Foreign Trade

The United States produces approximately 16 percent of the global apple export market (USDA-FAS, 2012). In 2011, the US exported 833,000 metric tons of apples including approximately 826,000 metric tons of fresh apples and 35,000 kiloliters of apple juice valued at 941 million and 34 million USD respectively (USDA-FAS, 2012). As of 2011, the largest importer of U.S. fresh apples was Mexico, followed by Canada and India (USDA-FAS, 2012). The largest importer of US apple juice is Canada with Japan and Mexico following (USDA-FAS, 2012). Over the past 5 years fresh apple exports have seen a slight increase (see Figure 5). However, apple juice exports have seen a decline largely due to an increase in apple juice imported from China (USITC, 2010).

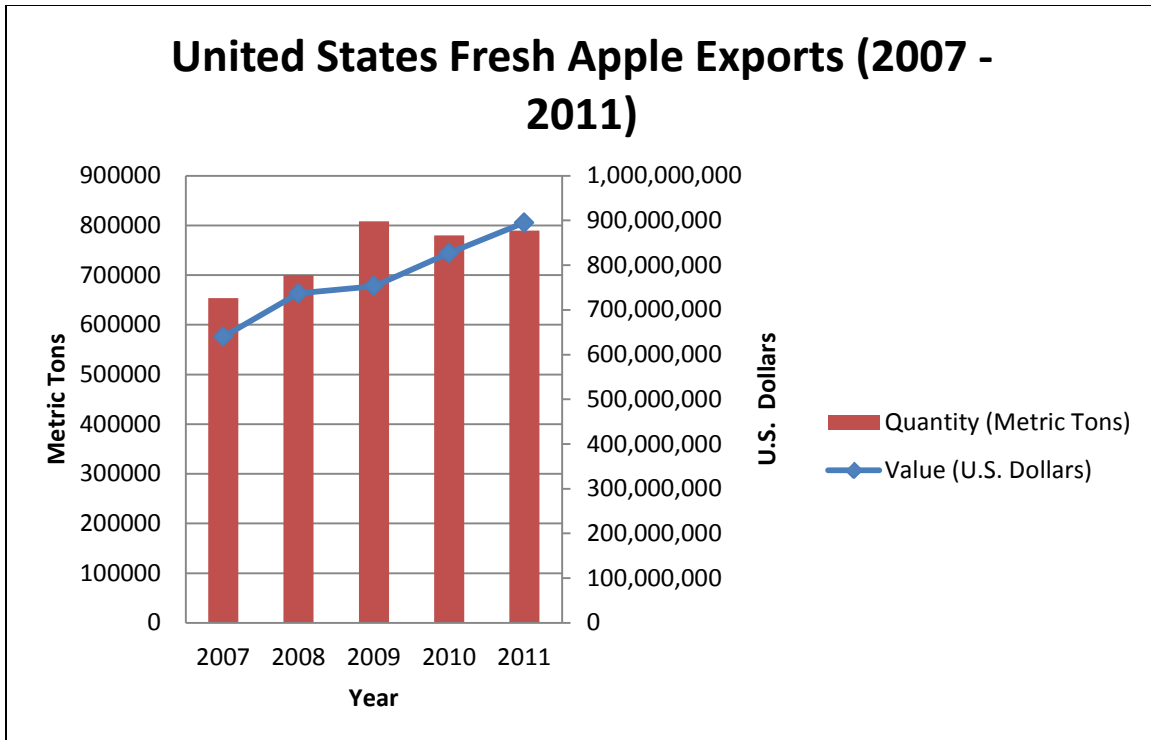


Figure 5. U.S. Fresh Apple Exports (2007-2011) (USDA-FAS, 2012).

Preferred Alternative: Foreign Trade

A determination of nonregulated status of GD743 and GS784 apples is not expected to adversely impact foreign trade. To the extent that adoption of GD743 and GS784 apples add another apple variety to the market, its introduction may enhance US competitiveness in global markets. As noted above in section 4.2.2, Domestic Commerce, GD743 and GS784 apples will be labeled with the Arctic™ brand name (OSF, 2012). It is OSF's intent that traceability will be maintained for all Arctic™ Apple cultivars from field to retail and food service outlets (OSF, 2012).

OSF anticipates that apples, being a perennial crop of 20 or more years before replanting, will have a much slower adoption and introduction curve than annual crops (OSF, 2012). The foreign trade impacts associated with a determination of nonregulated status of GD743 and GS784 apples are not expected to change from the No Action Alternative.

4.3 Physical Environment

4.3.1 Soil Quality

No Action Alternative: Soil Quality

Apples are cultivated in a wide variety of soils across the United States (see, e.g., Apple Crop Profiles provided at <http://www.ipmcenters.org/cropprofiles/GetCropProfiles.cfm>). Apples are typically grown in highly managed orchard environments of 10 acres or more. It takes approximately 4 – 6 years for an apple tree to produce fruit. Site preparation for

orchard establishment should include a crop rotation out of apples for at least one year. Planting a cover crop in the year before orchard establishment and incorporating the cover crop into the soil will improve soil organic matter content, suppress replant disease, weeds, and, depending on cover crop species, reduce nematodes (Carroll and Robinson, 2006). Organic matter is probably the most vital component in maintaining quality soil. Improving organic matter content of the soil helps maintain soil moisture and nutrients, is instrumental in maintaining soil stability and structure, reduces the potential for erosion, reduces non-point-source pollution from leached chemical fertilizers, provides energy for microorganisms, improves infiltration and water holding capacity, and is important in nutrient cycling, cation exchange capacity⁶, and the breakdown of pesticides (Doran et al., 1996; USDA-NRCS, 1996; Carroll and Robinson, 2006). Apples need a variety of nutrients, such as nitrogen, phosphorus, potassium, sulfur, magnesium, calcium, boron, iron, zinc, manganese and copper, at various levels (Spectrum). These nutrients may be deficient in poor, weathered soils, sandy soils, alkaline soils, or soils excessively high in organic matter. As with proper nutrient levels, soil pH is critical for apple development. Apples grow best in soil that is slightly acidic (pH 5.0 to 7.5); soil with a pH that is too high negatively affects yield (USDA-NRCS, 2013).

Land management practices for apple cultivation can affect soil quality. Living cover can protect against erosion, provides habitat and substrate for soil organisms, and increases soil organic residue inputs (Doran et al., 1996). Permanent grass sod or other cover crops are typically planted between the tree rows to minimize soil erosion, increase soil aeration and permeability, and support equipment movement through the orchard during wet weather (Walgenbach, 2011).

Preferred Alternative: Soil Quality

OSF's studies demonstrate that agronomic characteristics and cultivation practices required for GD743 and GS784 apples are indistinguishable from practices used to grow other apple varieties (OSF, 2012). A determination of nonregulation for GD743 and GS784 apples is not expected to change the management practices currently employed for apple production. Accordingly, the potential impacts on soil quality of GD743 and GS784 apples resulting from management practices associated with the No Action and Preferred Alternative are the same.

4.3.2 Water Resources

No Action Alternative: Water Resources

Apple trees must receive sufficient water to survive summer months (Roper and Frank, 2004). This water demand is met by a combination of natural rainfall, stored soil moisture, and supplemental irrigation during the growing season. Irrigation can supplement natural rainfall to provide the optimum water needs of the tree. Trees must be supplied with adequate soil moisture to ensure balanced growth and high quality fruit

⁶ Cation exchange capacity is the ability of soil anions (negatively charged clay, organic matter and inorganic minerals such as phosphate, sulfate, and nitrate) to adsorb and store soil cation nutrients (positively charged ions such as potassium, calcium, and ammonium).

(Carroll and Robinson, 2006). For orchards in full production it is very important for good fruit quality and size to be sure there is plenty of water available during the period (July–September) when the fruit is maturing (Moulton and King, 2008). Irrigation is most beneficial for young trees, which do not have extensive root systems and cannot explore large volumes of soil to get water. Each young tree requires about 5 gallons of water per week (Roper and Frank, 2004). Over-irrigation constitutes a leaching potential for nitrates or other easily leached products applied to the orchard (Smith, 2001).

In Michigan, very few orchards receive supplemental irrigation as the fruit growing areas receive an average of 27 inches of rainfall per year (Donohue et al., 2011). The soils are generally sandy loam to loam soils with good drainage (Donohue et al., 2011). By contrast, in an average growing season in the northeast, rainfall is usually less than required for optimal tree performance during critical periods of tree establishment and growth (Robinson et al., 2013). Washington apples are grown in a moderate, marine-influenced, desert climate, where scant rainfall occurs in the winter months. The dry, sunny growing-season weather gives growers the advantage of low disease pressure, but requires them to irrigate regularly (Smith, 2001).

The EPA considers water resources, groundwater, surface water and drinking water, and potential contamination of water resources, when registering a pesticide under FIFRA. Precautions to protect water resources, including aquatic animals and plants, if required, are provided on the pesticide label.

Preferred Alternative: Water Resources

Under the Preferred Alternative, no changes to water resources is anticipated from a determination of nonregulated status of GD743 and GS784 apples when compared to the no action alternative. OSF's studies demonstrate no differences in morphological characteristics and agronomic requirements between GD743 and GS784 apples and other apple varieties (OSF, 2012). A determination of nonregulated status of GD743 and GS784 apples is not expected to change the management practices currently employed for apple production. Accordingly, the potential impacts on water quality of GD743 and GS784 apples are expected to be the same under the Preferred Alternative as under the No Action Alternative.

4.3.3 Air Quality

No Action: Air Quality

All agricultural practices have the potential to cause negative impacts to air quality. Agricultural emission sources include smoke from agricultural burning, tillage, heavy equipment emissions, pesticide drift from spraying, and indirect emissions from carbon dioxide and nitrous oxide emissions from the use of nitrogen fertilizer and degradation of organic materials (USDA-NRCS, 2006b; Aneja et al., 2009; US-EPA, 2012b).

Conservation practices, including the use of cover crops such as permanent grass sod or other cover crops planted between the tree rows, help to decrease dust generation and

tractor emissions. Cover crops planted between tree rows physically serve to hold the soil in place, thereby decreasing airborne soils and pesticide drift in wind-eroded soils.

Preferred Alternative: Air Quality

Under the Preferred Alternative, a determination of nonregulated status of GD743 and GS784 apples would not change the impacts to air quality compared to the No Action Alternative.

OSF's studies demonstrate no differences in morphological characteristics and agronomic requirements between GD743 and GS784 apples and other apple varieties (OSF, 2012) and is not likely to change land acreage or any cultivation practices for apple production. It is expected that similar agronomic practices commonly utilized in commercially available apple varieties would also be used by growers of GD743 and GS784 apples. Accordingly, a determination of a nonregulated status of GD743 and GS784 apples is unlikely to change the use of agricultural practices with the potential to affect air quality from what is currently practiced. Based on this information, the potential impacts on air quality are expected to be the same under the Preferred Alternative as under the No Action Alternative.

4.3.4 Climate Change

No Action Alternative: Climate Change

Agriculture is recognized as a direct (e.g., exhaust from equipment) and indirect (e.g., agricultural-related soil disturbance) source of greenhouse gas (GHG) emissions. Agriculture, including land-use changes for farming, is responsible for an estimated 6.3% of total GHG emissions in the United States (US-EPA, 2012b). U.S. agriculture may influence climate change through various facets of the production process (Horowitz and Gottlieb, 2010). The major sources of GHG emissions associated with crop production are soil N₂O emissions, soil CO₂ and CH₄ fluxes, and CO₂ emissions associated with agricultural inputs and farm equipment operation (Adler et al., 2007; US-EPA, 2012b). Over the twenty-year period of 1990 to 2009, total emissions from the agricultural sector grew by 8.7%, with 7% of the total U.S. GHG emissions in 2009 generated from this sector (US-EPA, 2012b).

As discussed in Subsection 2.3.4 – Climate Change, these common agronomic practices contribute to GHG emissions, including tillage, cultivation, irrigation, pesticide application, fertilizer applications, and use of agriculture equipment. In comparison to field crops, apple cultivation potentially has fewer impacts on climate change. Apples are grown on few acres (330,600 acres) when compared to all U.S. cropland (442 million acres) (USDA-ERS, 2006) accounting for less than 0.1 percent of agricultural land use. Apple management does not require tillage and cultivation each year since apples are a perennial crop of 20 or more years before replanting, as such apples will have a much lower impact on climate change than annual crops.

While agricultural activities may affect climate change, the converse is also true; climate change may affect agriculture. Climate change potentially may provide a positive impact

to agriculture in general. The Intergovernmental Panel on Climate Change (IPCC) predicts that potential climate change in North America may result in an increase in crop yield by 5-20% for this century (Field et al., 2007). However, this positive impact will not be observed across all growing regions as certain areas of the US are expected to be negatively impacted because the available water resources may be reduced substantially (Field et al., 2007). Note that the extent of climate change effects on agriculture is highly speculative.

Freshwater and groundwater resources will be affected by climate change across the U.S., but the nature of the vulnerabilities varies from region to region (Field et al., 2007). In certain regions including the Columbia River and Great Lakes, surface and/or groundwater resources are intensively used for often competing agricultural, municipal, industrial and ecological needs, increasing potential vulnerability to future changes in timing and availability of water.

Over-allocated water systems, such as the Columbia River, that rely on capturing snowmelt runoff, will be especially vulnerable. With climate change, projected annual Columbia River flow changes relatively little, but timing of runoff shifts markedly toward increased winter and early spring flows and reduced summer and autumn flows (Karl et al., 2009). Loss of water availability in summer would exacerbate conflicts, over water. The challenges of managing water in the Columbia River basin will likely expand with climate change due to changes in snowpack and seasonal flows (Field et al., 2007; Karl et al., 2009).

A changing climate has a high likelihood of lowering net basin supplies and water levels for the Great Lakes Basin (Mortsch and Alden, 2003; Karl et al., 2009). Higher temperatures will mean more evaporation and hence a likely reduction in the Great Lakes water levels between 1 and 2 feet (Mortsch and Alden, 2003; Karl et al., 2009). Lower water levels in the Great Lakes are likely to influence many sectors, with multi-dimensional, interacting impacts.

Preferred Alternative: Climate Change

As described in Section 4.2.1, the range and area of U.S. apple production is not likely to expand under the Preferred Alternative. As described in the OSF petition (OSF, 2012) and APHIS PPRA (USDA-APHIS, 2013), GD743 and GS784 apples requires management strategies identical to those for conventional apple production, thus precluding changes in agricultural activities that may affect climate change, such as machine usage and fertilizer application. Collectively, because the range, area, and agronomic practices of apple are unlikely to change following a determination of nonregulated status of GD743 and GS784 apples, the agricultural impacts of apple cultivation on climate change are also unlikely to change under the Preferred Alternative.

4.4 Biological Resources

4.4.1 Animal Communities

No Action Alternative: Animal Communities

Apple orchards may be host to many animal and insect species. Mammals and birds may use apple orchards and the surrounding vegetation for food and habitat throughout the year. Invertebrates can feed on apple trees or fruit or prey upon other insects living on apple trees as well as in the vegetation surrounding apple orchards.

The types and numbers of birds that inhabit apple orchards may vary regionally and seasonally. Birds may cause problems for apple producers. On many farms or orchards bird damage is minimal, and growers can choose to ignore the problem or just take the loss into account as a cost of management. For other growers, problems from birds can be substantial, resulting in large portions of the fruit crop being consumed or damaged. Bird species commonly observed causing damage to apple orchards include (Tobin, 1989; Brittingham and Falker, 2010):

- American crow (*Corvus brachyrhynchos*);
- American robin (*Turdus migratorius*);
- American goldfinch (*Carduelis tristis*);
- Blue jays (*Cyanocitta cristata*);
- Cedar waxwing (*Bombycilla cedrorum*);
- European starling (*Sturnus vulgaris*);
- House finch (*Carpodacus mexicanus*);
- Common grackle (*Quiscalus quiscula*);
- House sparrow (*Passer domesticus*);

Common methods of reducing or preventing bird damage to apple orchards include the use of exclusion methods (netting), repellants, and harassment or scare tactics (Carroll and Robinson, 2006; Brittingham and Falker, 2010; Cooley et al., 2012).

Depending on the region, a variety of mammals may also utilize apple orchards. For the most part, herbivorous and omnivorous mammals feed on the apples themselves, but may also consume other parts of the apple tree (Wilson, 2006). Porcupines, beavers, mice, rabbits, and deer will consume bark of apple trees; deer will also consume buds; beaver, deer, and rabbits will consume twigs and leaves; and deer, fox, fisher, porcupines, bobcats, coyotes, squirrels, black bears, and other mammals will consume the fruit (Wilson, 2006).

Three species of voles cause significant economic damage by feeding on apple trees in commercial orchards. Meadow voles (*Microtus pennsylvanicus*), pine voles (*M. pinetorum*), and Montane voles (*Af. montanus*). Both meadow and pine voles are major pests in apple orchards throughout the eastern half of the country. Montane voles are of concern to orchardists in valleys of the Columbia River and its tributaries in eastern

Washington State (Tobin and Richmond, 1993). Voles damage trees by gnawing the trunks and roots of the tree.

Common methods of reducing or preventing damage to apple orchards from mammals include the use of exclusion or barrier methods, repellants, habitat modification, harassment or scare tactics, and population control (Tobin and Richmond, 1993; Carroll and Robinson, 2006; Cooley et al., 2012).

A wide variety of invertebrates inhabit apple orchards, including beneficial as well as pest species. For apple production facilities, much effort is expended in trying to eradicate pest insects from their apples (McVay et al., 1996; Bessin, 2003; Carroll and Robinson, 2006; WSU, 2010). Numerous insects and related arthropods perform a wide range of valuable functions; they pollinate plants, contribute to the decomposition and processing of organic matter, control of pests and diseases, maintenance of soil structure, detoxification of contaminants, and cycle soil nutrients (Gardner and Ascher, 2006; Ruiz et al., 2008; Shelton, 2012). Arthropods may also feed upon insects and mites that are considered to be pests. Some of these beneficial predatory species common in apple orchards include the lady beetles (family Coccinellidae), syrphid flies (Syrphinae), tachinid flies, lacewings (chrysopidae), true bugs (Hemiptera), parasitoids (hymenoptera and Diptera), and predatory mites (UNH, 2004; Cornell, 2012; Shelton, 2012)).

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). Apple trees rely on cross-pollination for successful fruit set, making pollinating insects extremely valuable (Gardner and Ascher, 2006). The most widely used insect for fruit pollination is the European honey bee (Park et al., 2010). While honey bees are important, they are certainly not the only crop pollinators. Native bees play an important role in crop pollination (Park et al., 2010). Relying on a single pollinator, such as the European honey bee, for pollination may pose increasing risk. Research suggests that wild bees are increasingly contributing to apple pollination (Park et al., 2012). Pollination studies have shown that wild bees can be more effective pollinators than honey bees on a per-visit basis, meaning they do not need to be as abundant as honey bees to provide the same level of pollination (Park et al., 2012).

Potential impacts to animal communities associated with apple cultivation are not expected to change in the No-Action Alternative.

Preferred Alternative: Animal Communities

Under the Preferred Alternative, potential impacts to animal communities are not anticipated to be different compared to the No Action Alternative. Potential impacts to animal communities arise from any changes in agronomic inputs associated with the crop modification and direct exposure to the GE crop and its products.

OSF has presented the results of field trials which demonstrate that GD743 and GS784 apples do not require any changes to agronomic inputs when compared with conventional

apples (OSF, 2012). Land use and agricultural production of apple under the Preferred Alternative is likely to continue as currently practiced. Consequently, any impact to animal communities as a result of apple production practices under the Preferred Alternative are expected to be the same as the No Action Alternative.

Consumption of GD743 and GS784 apples is unlikely to substantially affect non-target organisms, such as mammals, birds, or insects. OSF data demonstrates that the composition of GD743 and GS784 apples does not substantially differ from conventional apple varieties (OSF, 2012). 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, 2012). FDA is presently evaluating the submission. There is no evidence that animal exposure to GD743 and GS784 apples would have any effect or be any less attractive as food, refuge, cover and nesting sites as non GE varieties of apples.

Collectively, because the range, area, and agronomic practices of apple are unlikely to change following a determination of nonregulated status of GD743 and GS784 apples, the impacts of apple cultivation on animal communities are also unlikely to change under the Preferred Alternative.

4.4.2 Plant Communities

No Action Alternative: Plant Communities

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. Failure to control weeds in new apple orchards is the single greatest limiting factor to orchard establishment (Kamas et al.). An effective weed control program is the result of successfully integrating sound management strategies that includes timely applications of herbicide, weed surveillance, weed monitoring throughout the life of the orchard, planting ground covers, and mechanical cultivation (Kamas et al.; Roper, 2005; Carroll and Robinson, 2006; Pfeiffer, 2011). Ground cover, often including an under-tree herbicide strip, is the weed management system most commonly used in orchards (Cornell, 2012). The goal of ground cover is to reduce soil erosion and nutrient runoff that contaminates surface water sources and to minimize the use of herbicides (Carroll and Robinson, 2006). Plants commonly used as ground covers in orchards include slow growing grasses such as fescues and ryegrasses, herb mixtures, and legumes such as alfalfa, clover, and trefoil (Roper, 2005; Carroll and Robinson, 2006; Cornell, 2012; Granatstein et al., 2012). Herbicides are generally used to manage groundcover around tree trunks and in that portion of the under-tree area that is difficult to mow (Cornell, 2012).

Apples are self-incompatible, meaning a tree's own pollen will not produce fertilized seeds or fruit, therefore nearly all apple cultivars require cross pollination for consistent fruit set and yield (Dennis, 2003; Schneider et al., 2005; Park et al., 2012). Because all trees within a variety are clones (i.e. genetically identical), pollen must move across varieties (Park et al., 2012). This can be achieved by either planting multiple varieties in an orchard or using native crab apples. Ornamental crab apples can be used as pollinizers

in orchards, with trees planted in hedgerows. This avoids the need for having more than one commercial cultivar in an orchard and simplifies harvest (Dennis, 2003).

Preferred Alternative: Plant Communities

Under the Preferred Alternative, potential impacts to plant communities are not anticipated to be different compared to the No Action Alternative.

OSF has presented the results of field trials which demonstrate that GD743 and GS784 apples do not require any changes to agronomic inputs when compared with conventional apples (OSF, 2012). Growers are already managing orchards to control for competing plant life and surrounding areas that could provide pest and disease reservoirs using treatments and controls. There would be no change in herbicide use or patterns.

Apple is a highly domesticated fruit tree species, and cultivated varieties of apple in the U.S. are not listed as weeds (Muenscher, 1980) or as Federal noxious weeds (7 CFR part 360; (USDA-NRCS, 2012). Volunteer plants originating from seed in apple orchards are very rare due to orchard management practices, such as herbicide treatment of the tree row and mowing of the alley between rows. GD743 and GS784 apples do not display or possess any weedy characteristics, and thus, are not expected to behave as a weed (USDA-APHIS, 2013).

Land use and agricultural production of apple under the Preferred Alternative is likely to continue as currently practiced. Consequently, any impact to plant communities as a result of apple production practices under the Preferred Alternative is the same as the No Action Alternative.

4.4.3 Microorganisms

No Action Alternative: Microorganisms

The soil microbial community is an integral ecosystem component that may provide and sustain critical ecological processes. Nutrient cycling, establishing soil structure contributing to plant growth, metabolism of deleterious components are all dependent on the microbial constituents. The health and growth of these microbes may be influenced by many processes and conditions in agriculture, such as the crop cultivated, tillage, herbicide and fertilizer application, and irrigation (Garbeva et al., 2004).

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: apple scab, fireblight, and powdery mildew as well as the most common insect pests of apple which include codling moth, apple maggot, plum curculio, aphids, mites, redbanded leaf roller, and tentiform leaf miners (MacHardy, 2000; Beckerman, 2006; McCamant, 2007). While viral diseases can infect apple, primarily through the use of infected grafting wood, the use of certified budwood programs has had a significant impact on reducing the spread of viral diseases of apple (WSU, 2010). Effective management of diseases and pests in commercial apple varieties is especially important

since the majority of the top marketed apple varieties are susceptible to one or more of the major diseases of apple (Table 4).

Table 4. Disease Ratings for the top five apple varieties produced in the United States.

Apple varieties*	Apple Scab	Fireblight	Juniper rusts	Powdery mildew
Red Delicious	S	R	VS	MR
Gala	VS	VS	R—S	MS
Golden delicious	S	S	S	VS
Granny Smith	S	VS	R	VS
Fuji	S	VS	R—VS	R

*Top five conventional (USAA, 2011) and organic varieties (Slattery et al., 2011)

S-susceptible, R-resistant, VS-very susceptible, MR-moderately resistant

Source: (Beckerman, 2006; Slattery et al., 2011; USAA, 2011)

Preferred Alternative: Microorganisms

OSF has presented the results of field trials which demonstrate that GD743 and GS784 apples do not require any changes to agronomic inputs when compared with conventional apples (OSF, 2012). Growers are already managing orchards to control for fungal and insect borne diseases using treatments and controls. There would be no change in IPM programs that specifically addresses the most common diseases.

Because the agronomic practices of apple are unlikely to change following a determination of nonregulated status of GD743 and GS784 apples, the impacts of apple cultivation on microorganisms are also unlikely to change under the Preferred Alternative.

4.4.4 Biodiversity

No Action Alternative: Biodiversity

All plants, animals and microorganisms interacting in an ecosystem contribute to biodiversity (Wilson, 1988). In agriculture, biodiversity contributes to critical functions such as pollination, genetic introgression, biological control, nutrient recycling, and other important processes. Significant impacts on any of these functions could require costly management (Altieri, 1999). Concerns regarding the potential impacts to biodiversity associated with the introduction of GE crops (and crops in general) include the loss of diversity, which can occur at the crop, farm, and/or landscape scale (Carpenter, 2011).

Species diversity and abundance in apple agro-ecosystems may differ among conventional, GE, and organic production systems. Relative to any natural ecosystem, species abundance and richness will generally be less in intensively managed agro-ecosystems. The degree of biodiversity in an agro-ecosystem depends on four primary characteristics: 1) diversity of vegetation within and around the agro-ecosystem; 2) permanence of various crops within the system; 3) intensity of ecosystem management;

and 4) extent of isolation of the agro-ecosystem from natural areas of native vegetation (Altieri, 1999; USDA-NRCS, 2002). Agricultural land subject to intensive farming practices, such as that used in crop production, generally has low levels of biodiversity compared with adjacent natural areas.

Orchard management practices, including a range of practices incorporated in integrated pest management plans can be adopted which increase habitat preservation and plant biodiversity as well as reducing the amount of pesticides used (Palmer and Bromley, 1992; Carroll and Robinson, 2006; Cooley et al., 2012). Reduced pesticide use has a direct positive effect on wildlife by reducing the direct exposure of birds, mammals, and fish to pesticides. Indirect benefits include less alteration of suitable wildlife habitat and an available food supply of insects for insectivores (Palmer and Bromley, 1992).

Preferred Alternative: Biodiversity

Under the Preferred Alternative, cultivation, management, and land-use decisions related to GD743 and GS784 apples are not different from conventional apple varieties. Agronomic practices associated with apple production such as cultivation, irrigation, pesticide application, fertilizer applications and agriculture equipment would be unchanged. Animal and plant species that typically inhabit apple orchards will continue to be affected by currently used management plans and systems, which include the use of mechanical, cultural, and chemical control methods. The consequences of current agronomic practices associated with apple production on the biodiversity of plant and animal communities are unlikely to be altered.

Consequently, any impact to biodiversity as a result of apple production practices under the Preferred Alternative is likely to be identical to the No Action Alternative.

4.5 Public Health

4.5.1 Food and Feed

No Action Alternative: Food and Feed

In 2011, the average U.S. consumer ate an estimated 15.4 pounds of fresh-market apples and 32.2 pounds of processed apples, for a total of 47.6 pounds of fresh apples and processed apple products (USDA-ERS, 2012). In 2011 more than 60% of apple production in the United States was marketed as fresh fruit (USDA-NASS, 2012b). The remaining apple production is marketed as processed fruit such as fruit juice, cider, sauce, canned, fresh apple slices, and dried fruit products (USDA-ERS, 2010b). In 2011, 138.4 million pounds of apples were marketed as fresh apple slices valued at over 26 million USD (Karst, 2012; USDA-NASS, 2012b).

Recent research suggests that apples may promote better health and help maintain a healthy weight. Compared to many other fruits and vegetables, apples contain relatively low amounts of Vitamin C, but are a rich source of other antioxidant compounds (Boyer and Liu, 2004). Apples are an excellent source of dietary fiber, which helps regulate bowel movements and

may reduce the risk of colon cancer, help prevent heart disease and promote weight loss. Apples are also cholesterol-free, and their high fiber content helps control high cholesterol levels by preventing cholesterol absorption, and are nutrient dense for their low calorie content like most fruits and vegetables (Sharma, 2005).

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. Several wastes from apple processing, including pulp, peels, and cores, are suitable animal feeds (NRC, 1983). Apple pomace has feeding values similar to grass silage for wintering beef cattle (NRC, 1983). Between 25 to 35 percent of the fresh weight of the apple is retained in the pomace after pressing and is often mixed with alfalfa or corn for feeding (NRC, 1983).

The apple orchard is a highly managed environment which incorporates the use of agricultural chemicals. Pesticide use is common on most apple acreage in the US. Most of the major apples producing states/regions have guidelines for commercial apple orchard production and management. Each orchard/ apple production plan typically includes guidelines that address integrated pest management practices (Carroll and Robinson, 2006; Moulton and King, 2008; Donohue et al., 2011; Walgenbach, 2012).

The widespread and common use of pesticides may result in small amounts (called residues) in or on apples and apple products. To ensure safety of the apple food supply, the EPA regulates the amount of each pesticide that may remain in or on foods. These limits, called tolerances, are established to ensure food safety and are the result of the EPA making a safety finding that “the pesticide can be used with reasonable certainty of no harm.” (US-EPA, 2013). This finding of reasonable certainty of no harm is obligated under the FFDCA, as amended by the Food Quality Protection Act of 1996 (FQPA). In addition, the FDA and the USDA monitor foods for pesticide residues and work with the EPA to enforce these tolerances (see (USDA-AMS, 2013). In setting pesticide tolerances, the EPA generally will consider (US-EPA, 2013):

- The toxicity of the pesticide and its break-down products;
- How much the pesticide is applied to the crop and how often; and
- How much of the pesticide (i.e., the residue) remains in or on food by the time is it marketed and prepared.

Preferred Alternative: Food and Feed

OSF’s studies demonstrate no differences in morphological characteristics and agronomic requirements between GD743 and GS784 apples and other apple varieties (OSF, 2012). Agronomic practices associated with apple production such as cultivation, irrigation, pesticide application, fertilizer applications and agriculture equipment would continue unchanged.

Food and feed derived from GE apple must be in compliance with all applicable legal and regulatory requirements. 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, 2012).

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 (GD) and Granny Smith (GS) were subjected to nutritional and proximate analysis, and measured for total phenolic and water-soluble oxygen radical absorbance capacity (ORAC) (OSF, 2012). 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, 2012). 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 parents and may even have improved phenolic compound content and stability (OSF, 2012).

GE organisms for food and feed may undergo a voluntary consultation process with the FDA prior to release onto the market. 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, 2012). FDA is presently evaluating the submission. The potential impacts to food and feed are expected to be the same under the Preferred Alternative as under the No Action Alternative.

4.5.2 Worker Health and Safety

No Action Alternative: Worker Health and Safety

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, and changes in acreage, crops, or farming practices can affect the amounts and types of pesticides used and thus the risks to workers. Most of the major apples producing states/regions have guidelines for commercial apple orchard production and management. Each orchard/apple production plan typically includes guidelines that address orchard establishment and management, IPM, and postharvest production practices (Carroll and Robinson, 2006; Moulton and King, 2008; Donohue et al., 2011; Walgenbach, 2012).

EPA's WPS (40 CFR Part 170) was published in 1992 to require actions to reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers. The WPS offers protections to more than two and a half million agricultural workers who work with pesticides at more than 560,000 workplaces on farms, forests, nurseries, and greenhouses. 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. Worker safety precautions and use restrictions are noted clearly on pesticide registration labels. Growers are required to use pesticides consistent with the application instructions provided on the EPA-approved pesticide labels. These restrictions provide instructions as to the appropriate levels of personal protection required for agricultural workers. These may include instructions on personal protective

equipment, specific handling requirements, and field reentry procedures (see, e.g., (Carroll and Robinson, 2006; Cornell, 2012).

Preferred Alternative: Worker Health and Safety

Under the Preferred Alternative, cultivation practices and corresponding worker exposures to agronomic inputs are unlikely to change. 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 (OSF, 2012). 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.

Based on these findings, APHIS has determined that approval of a petition for nonregulated status of GD743 and GS784 apples will not impact worker safety.

5 CUMULATIVE IMPACTS

5.1 Assumptions Used for Cumulative Impacts Analysis

Cumulative effects have been analyzed for each environmental issue assessed in Section 4, Environmental Consequences. The cumulative effects analysis is focused on the incremental impacts of the Preferred Alternative taken in consideration with related activities including past, present, and reasonably foreseeable future actions. In this analysis, if there are no direct or indirect impacts identified for a resource area, then APHIS assumes there can be no cumulative impacts. Where it is not possible to quantify impacts, APHIS provides a qualitative assessment of potential cumulative impacts.

APHIS considered the potential for GD743 and GS784 apples to extend the range of apple production and affect the conversion of land to agricultural purposes. OSF's studies demonstrate that agronomic characteristics and cultivation practices required for GD743 and GS784 apples are indistinguishable from practices used to grow other apple varieties (OSF, 2012; USDA-APHIS, 2013). This implies that its cultural requirements would neither differ from those of other apples nor change the areas in which apple is currently cultivated. If the petition is approved, GD743 and GS784 apples could replace other commercially available apple varieties without requiring cultivation of new, natural lands. As such, land use changes associated with approving the petition for nonregulated status to GD743 and GS784 apples are not expected to be any different than those associated with the cultivation of other apple cultivars. Therefore, although the preferred alternative would allow for new plantings of GD743 and GS784 apples to occur anywhere in the U.S., APHIS focused the analysis of cumulative impacts on the areas in the U.S. that currently support apple production.

Potential reasonably foreseeable cumulative effects are analyzed under the assumption that growers have used in the past and would continue to use reasonable, commonly accepted best management practices (BMPs) for their chosen system and varieties during apple production. APHIS recognizes, however, that not all growers will use such BMPs. Thus, the cumulative impact analysis will also make the assumption that not all growers would do so. APHIS assumes growers of GD743 and GS784 apples will adhere to the EPA-registered uses and EPA-approved labels for all pesticides applied to apples.

5.2 Past and Present and Reasonably Foreseeable Actions

In the preceding analysis, the potential impacts from approving the petition for nonregulated status to GD743 and GS784 apples were assessed. The potential impacts under the Preferred Alternative for all the resource areas analyzed were the same as those described for the No-action Alternative.

The Preferred Alternative is not expected to directly cause a measurable change in agricultural acreage or area devoted to apple cultivation in the U.S. (see Subsection 4.2.1, Agricultural Production of Apple). Because GD743 and GS784 apples are another apple variety that is agronomically and compositionally similar to other commercially available apple varieties, it is expected GD743 and GS784 apples would replace other similar

varieties without expanding the acreage or area of apple production. OSF has estimated a total planted area of 4,000 acres or about 1.2 percent of total U.S. apple plantings over the first 10 years (OSF, 2012). There are also no anticipated changes to the availability of non-GE apple varieties on the market.

. As described above, organic growers use common practices to maintain the organic status of their apples including employing adequate isolation distances between the organic orchard and the orchards of neighbors to minimize the chance that pollen will be carried between the orchards. Given the importance of maintaining varietal traits and consumer recognition and preference for specific apple varieties, the separation of production and processing of apples by varieties have been utilized by growers, packers and retailers in the United States market to satisfy consumer preference and demand. Availability of another apple variety, such as GD743 and GS784 apples, under the Preferred Alternative, is not expected to impact the organic production of apple any differently than other apple varieties currently being grown.

Approving the petition for a determination of nonregulated status to GD743 and GS784 apples is not expected to result in changes to current apple cropping practices. Studies conducted by OSF demonstrate that agronomic characteristics and cultivation practices required for GD743 and GS784 apples are indistinguishable from practices used to grow other apple varieties (OSF, 2012; USDA-APHIS, 2013). Consequently, no changes to current apple cropping practices associated with the adoption of GD743 and GS784 apples are expected (see Subsection 4.2.1, Agricultural Production of Apple).

Based on the information described in Subsection 4.2.2 – Domestic Commerce, APHIS concludes that a determination of nonregulated status of GD743 and GS784 apples will have no foreseeable adverse cumulative effects on domestic commerce. Similar Golden Delicious and Granny Smith varieties are already on the market. GD743 and GS784 apples have the potential to improve fruit processing capabilities for maintaining the quality and shelf life of apples for processing and the snack food market and also improve the economics of fruit processing and consumer nutrition. There also is an inherent reduction in food processing costs associated with a reduction in fruit browning and in providing alternatives to conventional technologies to prevent browning. Based on these factors, no net negative cumulative impacts on domestic economics have been identified associated with the cultivation of GD743 and GS784 apples. If growers adopt GD743 and GS784 apple varieties and take advantage of the niche market, local farm economics may improve.

Current and historic economic evidence indicates that apple production in the United States has decreased since 2004 as a result of greater international competition. This trend may continue and shift apple production acreage in the United States to alternative cropping or pasture, which may affect other markets and trade. As noted in Subsection 4.2.4 – Foreign Trade, OSF's commercial launch of the GD743 and GS784 apples, although limited, has the potential for the creation of a niche market and in a small way supporting the continuation of apple production in the United States. However, for these apples to be sold in export markets, approvals in the destination country must have been obtained. So these apples may have little influence on apple exports. Based on these

factors, APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action that would have a negative impact on foreign trade.

Approving the petition for a determination of nonregulated status to GD743 and GS784 apples would have the same impacts to water, soil, air quality, and climate change as that of apple varieties currently available. Agronomic practices that have the potential to impact soil, water and air quality, and climate change would not change because GD743 and GS784 apples are agronomically similar to other apple varieties. Because of its similarity to other varieties of apple, adoption of GD743 and GS784 apples is expected to replace other similar cultivars without changing the acreage or area of apple production that could impact water, soil, air quality, and climate change.

The impacts of the Preferred Alternative to animal and plants communities, microorganisms, and biodiversity would be no different than that experienced under the No-action Alternative. GD743 and GS784 apples are both agronomically and compositionally similar to other apple varieties. Thus, it would not require any different agronomic practices to cultivate, and does not represent a safety or increased weediness risk that is any different from other currently available apples.

There are no differences in the potential for gene flow and weediness under the Preferred Action Alternative. Outcrossing and weediness are addressed in the PPRA (USDA-APHIS, 2013) GD743 and GS784 apples are similar to other apple varieties. The risk of gene flow and weediness of GD743 and GS784 apples is no greater than that of other apple varieties.

Food and feed derived from GE apple must be in compliance with all applicable legal and regulatory requirements and may undergo a voluntary consultation process with the FDA prior to release onto the market to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food. GD743 and GS784 apples are expected to have no toxic effect to human health or livestock. OSF submitted a safety and nutritional assessment of food and feed derived from GD743 and GS784 to the FDA on May 30, 2011 (OSF, 2012). FDA is presently evaluating the submission. No change in food and feed safety is expected to occur under the Preferred Alternative.

In summary, the potential cumulative effects regarding past and present actions combined with the Preferred Alternative have been analyzed, and no changes from the current baseline under the No-action Alternative would occur.

5.3 Cumulative Impacts Summary

In summary, the potential for impacts of GD743 and GS784 apples would not result in any changes to the resources areas when compared to the No-action Alternative. No cumulative effects are expected from approving the petition for nonregulated status for GD743 and GS784 apples, when taken in consideration with related activities, including past, present, and reasonably foreseeable future actions.

6 THREATENED AND ENDANGERED SPECIES

The Endangered Species Act (ESA) of 1973, as amended, is one of the most far-reaching wildlife conservation laws ever enacted by any nation. Congress, on behalf of the American people, passed the ESA to prevent extinctions facing many species of fish, wildlife and plants. The purpose of the ESA is to conserve endangered and threatened species and the ecosystems on which they depend as key components of America's heritage. To implement the ESA, the U.S. Fish & Wildlife Service (USFWS) works in cooperation with the National Marine Fisheries Service (NMFS), other Federal, State, and local agencies, Tribes, non-governmental organizations, and private citizens. Before a plant or animal species can receive the protection provided by the ESA, it must first be added to the Federal list of threatened and endangered wildlife and plants.

A species is added to the list when it is determined by the USFWS/NMFS to be endangered or threatened because of any of the following factors:

- The present or threatened destruction, modification, or curtailment of its habitat or range;
- Overutilization for commercial, recreational, scientific, or educational purposes;
- Disease or predation;
- The inadequacy of existing regulatory mechanisms; and
- The natural or manmade factors affecting its survival.

Once an animal or plant is added to the list, in accordance with the ESA, protective measures apply to the species and its habitat. These measures include protection from adverse effects of Federal activities.

Section 7 (a)(2) of the ESA requires that Federal agencies, in consultation with USFWS and/or the NMFS, ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. It is the responsibility of the Federal agency taking the action to assess the effects of their action and to consult with the USFWS and NMFS if it is determined that the action "may affect" listed species or critical habitat. To facilitate APHIS' ESA consultation process, APHIS met with the USFWS from 1999 to 2003 to discuss factors relevant to APHIS' regulatory authority and effects analysis for petitions for nonregulated status, and developed a process for conducting an effects determination consistent with the Plant Protection Act of 2000 (Title IV of Public Law 106-224). This process is used by APHIS to assist the program in fulfilling their obligations and responsibilities under Section 7 of the ESA for biotechnology regulatory actions.

The APHIS regulatory authority over GE organisms under the PPA is limited to those that are actual or suspected plant pests, or those that cannot adequately be assessed for plant pest risk potential consistent with 7 CFR §340.1 because of insufficient information. After completing a PPRA, if APHIS determines that GD743 and GS784 apples do not pose a plant pest risk, then the Agency would no longer have legal

justification to regulate them under the plant pest provisions of the PPA described in 7 CFR §340. Therefore, APHIS would have to make a determination that the article is no longer regulated. As part of its EA analysis, APHIS analyzed the potential impacts of GD743 and GS784 apples on the environment, including those that might affect TES and critical habitat. As part of this process, APHIS thoroughly reviews GE product information and data to inform the ESA effects analysis and, if necessary, the biological assessment. For each transgene(s)/transgenic plant the following information, data, and questions are considered by APHIS:

- A review of the biology, taxonomy, and weediness potential of the crop plant and its sexually compatible relatives;
- Characterization of each transgene with respect to its structure and function and the nature of the organism from which it was obtained;
- A determination of where the new transgene and its products (if any) are produced in the plant and their quantity;
- A review of the agronomic performance of the plant including disease and pest susceptibilities, weediness potential, and agronomic and environmental impact;
- Determination of the concentrations of known plant toxicants (if any are known in the plant);
- Analysis to determine if the transgenic plant is sexually compatible with any threatened or endangered plant species (TES) or a host of any TES; and
- Any other information that may inform the potential for an organism to pose a plant pest risk.

In following this review process, APHIS, has evaluated the potential effects that a determination of nonregulated status of GD743 and GS784 apples may have, if any, on Federally-listed TES and species proposed for listing, as well as designated critical habitat and habitat proposed for designation. Based upon the scope of the EA and production areas identified in the Affected Environment section of the EA, APHIS obtained and reviewed the USFWS list of TES species (listed and proposed) for all 50 states where apple is produced from the USFWS Environmental Conservation Online System (USFWS, 2013). Prior to this review, APHIS considered the potential for GD743 and GS784 apples to extend the range of apple production and also the potential to extend agricultural production into new natural areas.

OSF's studies demonstrate that agronomic characteristics and cultivation practices required for GD743 and GS784 apples are essentially indistinguishable from practices used to grow other apple varieties (OSF, 2012; USDA-APHIS, 2013). Although GD743 and GS784 apples may be expected to replace other varieties of apple currently cultivated, APHIS does not expect the cultivation of GD743 and GS784 apples to result

in new apple acres to be planted in areas that are not already devoted to apple production. Accordingly, the issues discussed herein focus on the potential environmental consequences of approval of the petition for nonregulated status of GD743 and GS784 apples on TES species in the areas where apples are currently grown.

APHIS focused its TES review on the interaction between TES and GD743 and GS784 apples, including the potential for sexual compatibility and the ability to serve as a host for a TES. APHIS does not have authority to regulate the use of any pesticide, fungicide or herbicide that may be used in apple production.

6.1 Potential Effects of the Cultivation of Event GD743 and GS784 Apples on TES

Based on the information submitted by the applicant and reviewed by APHIS, GD743 and GS784 apples are agronomically, phenotypically, and biochemically comparable to conventional apple (OSF, 2012). OSF has presented results of agronomic field trials for GD743 and GS784 apples. The results of these field trials demonstrate that there are no differences in agronomic practices between GD743 and GS784 and conventional apples (OSF, 2012). The common agricultural practices that would be carried out in the cultivation GD743 and GS784 apples are not expected to deviate from current practices, including the use of EPA-registered pesticides. OSF anticipates that apples, being a perennial crop of 20 or more years before replanting, will have a much slower adoption and introduction curve than annual crops (OSF, 2012). OSF has estimated a total planted area of 4,000 acres or about 1.2 percent of total U.S. apple plantings over the first 10 years (OSF, 2012). The products are expected to be deployed on agricultural land currently suitable for production of apple, will be cultivated only as specialty apples, are not expected to substantially replace existing varieties, and are not expected to increase the acreage of apple production.

Apples are cultivated in all 50 states, and are an important fruit crop for a number of States within the United States. Accordingly, the issues discussed herein focus on the potential environmental consequences of approval of the petition for nonregulated status of GD743 and GS784 apples on TES species and critical habitat in the areas where apples are currently cultivated. As discussed in Subsection 4.2.1 – Agricultural Production of Apples, APHIS has determined that GD743 and GS784 apples are unlikely to extend the range of apple production. Moreover, new acreage is not expected to be developed to accommodate the cultivation of events GD743 and GS784. APHIS obtained and reviewed the USFWS list of TES species (listed and proposed) for all 50 states where apple is produced from the USFWS Environmental Conservation Online System (USFWS, 2013).

6.2 Potential Effects GD743 and GS784 Apples on TES

Threatened and Endangered Plant Species

The agronomic data provided by OSF were used in the APHIS analysis of the weediness potential for GD743 and GS784 apples and further evaluated for the potential to impact

TES. Agronomic studies conducted by OSF tested the hypothesis that the weediness potential of GD743 and GS784 apples is unchanged with respect to conventional apple (OSF, 2012; USDA-APHIS, 2013). No differences were detected between GD743 and GS784 apples and conventional apple in growth, reproduction, or interactions with pests and diseases (USDA-APHIS, 2013). Apple is a highly domesticated fruit tree species, and cultivated varieties of apple in the U.S. are not listed as weeds (Muenscher, 1980) or as Federal noxious weeds (7 CFR part 360; (USDA-NRCS, 2012), nor is it listed as an invasive species by major invasive plant data bases. GD743 and GS784 are not likely to become weedier than their non-GE apple counterparts (USDA-APHIS, 2013). The introduced genes are not likely to increase weediness or fitness in wild relatives of apple (USDA-APHIS, 2013). APHIS has concluded the approval of the petition for nonregulated status of GD743 and GS784 apples does not present a plant pest risk, does not present a risk of weediness, and does not present an increased risk of gene flow when compared to other currently cultivated apple varieties. Based on the agronomic field data and literature survey on apple weediness potential, GD743 and GS784 apples are unlikely to affect TES as a troublesome or invasive weed (USDA-APHIS, 2013).

APHIS evaluated the potential of GD743 and GS784 apples to cross with a listed species. As discussed in Sections 3.3.2 and 4.4.2 – Plant Communities, and in the analysis of Apple as a Weed or Volunteer, APHIS has determined that there is no risk to unrelated plant species from the cultivation of GD743 and GS784 apples. The cultivated apple is a member of Rosaceae, the rose family consisting of about 100 genera with more than 2,000 species. The genus *Malus*, which includes the cultivated apple and crab apple contains about 25 species with its center of diversity in central Asia, but native or naturalized species are found in Europe, Asia and western China (Way et al., 1990). The majority of apples are self-incompatible, meaning a tree's own pollen will not produce fertilized seeds or fruit, therefore nearly all apple cultivars require cross pollination using another cultivar or a specialized crab-apple for consistent fruit set and yield (Dennis, 2003; Schneider et al., 2005; Park et al., 2012). As discussed in Section 4.2.1 – Agricultural Production of Apple, cultivated apples are generally propagated by grafting (Crasweller, 2005). A mature apple tree can produce numerous seeds during its annual cycle and survive for a number of years producing a multitude of seed. However for reasons discussed in Section 3.3.2 – Plant Communities, the probability of an individual apple seed developing into a mature tree is very small and volunteer plants originating from seed in apple orchards are very rare in such a managed environment (Roper, 2005; Carroll and Robinson, 2006; Cornell, 2012). After reviewing the list of threatened and endangered plant species in the U.S., APHIS determined that GD743 and GS784 apples would not be sexually compatible with any listed threatened or endangered plant species proposed for listing, as none of these listed plants are in the same genus nor are known to cross pollinate with species of the genus *Malus*.

A number of *Malus* species are native or naturalized in the United States (Little, 1979), and include: *Malus angustifolia* (southern crab apple); *Malus coronaria* (sweet crab apple); *Malus fusca* (Oregon crab apple); *Malus ioensis* (prairie crab apple); *Malus platycarpa*, thought to be a hybrid between cultivated apple and native species of crab apple (McVaugn, 1943); *Malus x domestica* (apple); *Malus x soulardii* (Soulard crab), a hybrid of *ioensis x domestica*; *Malus baccata* (Siberian crab apple); and *Malus prunifolia*

(pear leaf apple). Four species of crab apples are native to North America, the Pacific Crab (*Malus fusca*); and three species closely related to *Malus fusca* (Hosie, 1979). The introduced species *Malus baccata* and *Malus prunifolia*, have escaped from cultivation but are not naturalized. Research has found no introgression of cultivated apple genes to native *Malus* species of North America (Dickson et al., 1991). Cultivated apple can be artificially cross-pollinated to produce hybrids with many if not all crab apple species (Warmund, 1996; Roper and Frank, 2004), but the fertility and ecological fitness of such possible hybrids hasn't been well described.

After reviewing the list of threatened and endangered plant species in the U.S., APHIS determined, based on the agronomic field data, literature survey on apple weediness potential, and that there are no TES sexually compatible with apple, that GD743 and GS784 apples will have no effect on threatened or endangered plant species.

Threatened and Endangered Animal Species

Threatened and endangered animal species that may be exposed to the gene products in GD743 and GS784 apples would be those TES that inhabit apple orchards and feed on GD743 and GS784 apples. To identify potential effects on threatened and endangered animal species, APHIS evaluated the risks to threatened and endangered animals from consuming GD743 and GS784 apples or other parts of the apple tree. 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. Additionally, wildlife may use apple orchards as a food source, consuming parts of the tree, the fruit, or insects that live on the trees. However, most animals including TES generally are found outside of highly managed orchards.

OSF submitted a safety and nutritional assessment of food and feed derived from GD743 and GS784 to the FDA on May 30, 2011 (OSF, 2012). FDA is presently evaluating the submission.

GD743 and GS784 apples present minimal risk to TES consuming this crop. As discussed in Subsection 4.7, Animal Feed, there is no difference in the composition and nutritional quality of GD743 and GS784 apples compared with conventional apples (OSF, 2012); no expected hazards are associated with its consumption. OSF has presented data on the food and feed safety of GD 743 and GS 784 apples, evaluating the agronomic and morphological characteristics of GD 743 and GS 784 apples, including compositional and nutritional characteristics as compared to a conventional apple variety (OSF, 2012). Composition characteristics evaluated in these comparative tests include moisture, protein, fat, carbohydrates, ash, calories, dietary fiber, sugar profile, minerals, vitamins, antioxidant capacity, and phenolics (OSF, 2012). As discussed in Sections 4.6 and 4.7 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 (NDB) identifier 09003) (OSF, 2012). The apple events GD743 and GS784 demonstrated significantly higher levels of vitamin C as compared to the control cultivars. This

elevated level of vitamin C was likely due to the fact that the fruit tested was cut, put in bags, and put on ice, leaving the fruit flesh exposed for as long as 24 hours prior to testing (OSF, 2012). This resulted in some PPO-driven fruit browning within the control fruit. Despite elevated levels of vitamin C in events GD743 and GS784, these levels fell within, or very close to, the published range for apple (OSF, 2012). Evidence provided here is consistent with the concept that Arctic™ Apple cultivars GS743 and GS784 are nutritionally equivalent with their parent cultivars, prior to slicing. While after slicing, GD743 and GS784 retain their original phenolic content, whereas GD and GS suffer the loss of phenolic compounds, and possibly vitamin C, through the action of PPO (OSF, 2012).

Apple events GD743 and GS784 are nutritionally equivalent to their parents and may even have improved phenolic compound content and stability (OSF, 2012). The results presented by OSF show that there was no effect of the Arctic™ Apple trait on the composition of the apples, and no biologically-meaningful differences between GD743 or GS784 apples and their non-GE counterparts. Therefore, based on these analyses, APHIS concludes that consumption of GD743 and GS784 apples or plant parts (seeds, leaves, stems, pollen, or roots) would have no effect on any listed threatened or endangered animal species or animal species proposed for listing.

After reviewing the possible effects of allowing the nonregulated environmental release of GD743 and GS784 apples, APHIS has not identified any stressor that could affect the reproduction, numbers, or distribution of a listed TES or species proposed for listing. APHIS also considered the potential effect of a determination of nonregulated status of GD743 and GS784 apples on designated critical habitat or habitat proposed for designation, and could identify no differences from effects that would occur from the production of other apple varieties. Apple is not considered a particularly competitive plant species and is not listed in the U.S. as a noxious weed species by the Federal government (7 CFR part 360; (USDA-NRCS, 2012), nor is it listed as an invasive species by major invasive plant data bases. Apple does not serve as a host species for any listed species or species proposed for listing. Consumption of GD743 and GS784 apples by any listed species or species proposed for listing will not result in a toxic or allergic reaction. Based on these factors, APHIS has concluded that approval of the petition for nonregulated status of GD743 and GS784 apples, and the corresponding environmental release of this apple variety will have no effect on listed species or species proposed for listing, and would not affect designated habitat or habitat proposed for designation. Because of this no effect determination, consultation under Section 7(a)(2) of the Act or the concurrences of the USFWS or NMFS are not required.

7 Consideration of Executive Orders, Standards, and Treaties Relating to Environmental Impacts

7.1 Executive Orders with Domestic Implications

The following executive orders require consideration of the potential impacts of the Federal action to various segments of the population.

- ***Executive Order (EO) 12898 (US-NARA, 2010), "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,"*** requires Federal agencies to conduct their programs, policies, and activities that substantially affect human health or the environment in a manner so as not to exclude persons and populations from participation in or benefiting from such programs. It also enforces existing statutes to prevent minority and low-income communities from being subjected to disproportionately high and adverse human health or environmental effects.
- ***EO 13045, "Protection of Children from Environmental Health Risks and Safety Risks,"*** acknowledges that children may suffer disproportionately from environmental health and safety risks because of their developmental stage, greater metabolic activity levels, and behavior patterns, as compared to adults. The EO (to the extent permitted by law and consistent with the agency's mission) requires each Federal agency to identify, assess, and address environmental health risks and safety risks that may disproportionately affect children.

The No Action and Preferred Alternatives were analyzed with respect to EO 12898 and EO 13045. Neither alternative is expected to have a disproportionate adverse effect on minorities, low-income populations, or children.

Based on the information submitted by the applicant and reviewed by APHIS, GD743 and GS784 apples are agronomically, phenotypically, and biochemically comparable to conventional apple except for the nonbrowning trait expressed in GD743 and GS784 apples. 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 (GD) and Granny Smith (GS) were subjected to nutritional and proximate analysis, and measured for total phenolic and water-soluble oxygen radical absorbance capacity (ORAC) (OSF, 2012). 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 (NDB) identifier 09003) (OSF, 2012). 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 parents and may even have improved phenolic compound content and stability (OSF, 2012). This nutritional analysis establishes the safety of GD743 and GS784 apples and their products to humans, including minorities, low-

income populations, and children who might be exposed to them through agricultural production and/or processing. No additional safety precautions would need to be taken.

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, 2012). FDA is presently evaluating the submission.

Based on these factors, a determination of nonregulated status of GD743 and GS784 apple is not expected to have a disproportionate adverse effect on minorities, low-income populations, or children.

The following executive order addresses Federal responsibilities regarding the introduction and effects of invasive species:

EO 1311 (US-NARA, 2010), “Invasive Species,” states that Federal agencies take action to prevent the introduction of invasive species, to provide for their control, and to minimize the economic, ecological, and human health impacts that invasive species cause.

Apple is not listed in the U.S. as a noxious weed species by the Federal government (7 CFR part 360; (USDA-NRCS, 2012), nor is it listed as an invasive species by major invasive plant data bases. Volunteer plants originating from seed in apple orchards are very rare due to orchard management practices, such as herbicide treatment of the tree row and mowing of the alley between rows. Any volunteers that may become established are easily managed using standard weed control practices. Animals, such as bears, mice, and squirrels, can carry fruit containing seed or seeds away from cultivated areas. Apples are often discarded by travelers on roadways, or in compost piles. Seeds distributed in this way can result in seedling trees. Such cultivated apple-tree seedlings can be persistent; the species has escaped cultivation and naturalized in southern Canada, in the eastern USA, and from British Columbia south to California (Little, 1979). However, *M. domestica* typically occurs in commercial orchard plantings, as fruit trees in gardens or pastures. It is not common to find wild seedling trees; therefore, weediness is not thought to be a widespread problem. Non-engineered apples are widely grown in the U.S. Based on historical experience with these varieties and the data submitted by the applicant and reviewed by APHIS, GD743 and GS784 apple trees are sufficiently similar in fitness characteristics to other apple varieties currently grown and are not expected to become weedy or invasive.

The following executive order requires the protection of migratory bird populations:

EO 13186 (US-NARA, 2010), “Responsibilities of Federal Agencies to Protect Migratory Birds,” states that federal agencies taking actions that have, or are likely to have, a measurable negative effect on migratory bird populations are directed to develop and implement, within two years, a Memorandum of Understanding (MOU) with the Fish and Wildlife Service that shall promote the conservation of migratory bird populations.

Migratory birds may be found in apple orchards. A variety of birds are known to feed on apple trees and apples and can cause damage to apple trees (Wilson, 2006; Cornell, 2012). Birds such as quail nest in the grassy understories of apple orchards, while songbirds and mourning doves nest in the fruit trees (Palmer and Bromley, 1992). Birds may also forage for insects and weed seeds found in and adjacent to apple orchards. As discussed in Sections 4.6.1 and 4.7, data submitted by the applicant has shown no difference in compositional and nutritional quality of GD743 and GS784 apples compared with other conventional apple (OSF, 2012). GD743 and GS784 apples are not expected to be allergenic, toxic, or pathogenic in mammals since the transgene derived for PPO suppression is derived from apples so no new proteins are expressed in the apples (OSF, 2012). Based on APHIS' assessment of GD743 and GS784 apples, it is unlikely that a determination of nonregulated status of GD743 and GS784 apples would have a negative effect on migratory bird populations.

7.2 International Implications

EO 12114 (US-NARA, 2010), “Environmental Effects Abroad of Major Federal Actions” requires federal officials to take into consideration any potential environmental effects outside the U.S., its territories, and possessions that result from actions being taken.

APHIS has given this EO careful consideration and does not expect a significant environmental impact outside the U.S. in the event of a determination of nonregulated status of GD743 and GS784. All existing national and international regulatory authorities and phytosanitary regimes that currently apply to introductions of new apple cultivars internationally apply equally to those covered by an APHIS determination of nonregulated status under 7 CFR part 340.

Any international trade of GD743 and GS784 subsequent to a determination of nonregulated status of the product would be fully subject to national phytosanitary requirements and be in accordance with phytosanitary standards developed under the International Plant Protection Convention (IPPC, 2010). The purpose of the IPPC “is to secure a common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control” (IPPC, 2010). The protection it affords extends to natural flora and plant products and includes both direct and indirect damage by pests, including weeds.

The IPPC establishes a standard for the reciprocal acceptance of phytosanitary certification among the nations that have signed or acceded to the Convention (172 countries as of March 2010). In April 2004, a standard for PRA of living modified organisms (LMOs) was adopted at a meeting of the governing body of the IPPC as a supplement to an existing standard, International Standard for Phytosanitary Measure No. 11 (ISPM-11, Pest Risk Analysis for Quarantine Pests). The standard acknowledges that all LMOs will not present a pest risk and that a determination needs to be made early in the PRA for importation as to whether the LMO poses a potential pest risk resulting from the genetic modification. APHIS pest risk assessment procedures for genetically engineered organisms are consistent with the guidance developed under the IPPC. In

addition, issues that may relate to commercialization and transboundary movement of particular agricultural commodities produced through biotechnology are being addressed in other international forums and through national regulations.

The *Cartagena Protocol on Biosafety* is a treaty under the United Nations Convention on Biological Diversity (CBD) that established a framework for the safe transboundary movement, with respect to the environment and biodiversity, of LMOs, which include those modified through biotechnology. The Protocol came into force on September 11, 2003, and 160 countries are Parties to it as of December 2010 (CBD, 2010). Although the U.S. is not a party to the CBD, and thus not a party to the Cartagena Protocol on Biosafety, U.S. exporters will still need to comply with those regulations that importing countries which are Parties to the Protocol have promulgated to comply with their obligations. The first intentional transboundary movement of LMOs intended for environmental release (field trials or commercial planting) will require consent from the importing country under an advanced informed agreement (AIA) provision, which includes a requirement for a risk assessment consistent with Annex III of the Protocol and the required documentation.

LMOs imported for food, feed, or processing (FFP) are exempt from the AIA procedure, and are covered under Article 11 and Annex II of the Protocol. Under Article 11, Parties must post decisions to the Biosafety Clearinghouse database on domestic use of LMOs for FFP that may be subject to transboundary movement. To facilitate compliance with obligations to this protocol, the U.S. Government has developed a website that provides the status of all regulatory reviews completed for different uses of bioengineered products (NBII, 2010). These data will be available to the Biosafety Clearinghouse.

APHIS continues to work toward harmonization of biosafety and biotechnology consensus documents, guidelines, and regulations, including within the North American Plant Protection Organization (NAPPO), which includes Mexico, Canada, and the U.S., and within the Organization for Economic Cooperation and Development (OECD). NAPPO has completed three modules of the Regional Standards for Phytosanitary Measures (RSPM) No. 14, *Importation and Release into the Environment of Transgenic Plants in NAPPO Member Countries* (NAPPO, 2009).

APHIS also participates in the *North American Biotechnology Initiative (NABI)*, a forum for information exchange and cooperation on agricultural biotechnology issues for the U.S., Mexico, and Canada. In addition, bilateral discussions on biotechnology regulatory issues are held regularly with other countries including Argentina, Brazil, Japan, China, and Korea.

7.3 Compliance with Clean Water Act and Clean Air Act

This EA evaluated the potential changes in apple production associated with a determination of nonregulated status of GD743 and GS784 apples (Section 4.2) and determined that the cultivation of GD743 and GS784 apples would not lead to the increased production or acreage of apple in U.S. agriculture. The nonbrowning trait conferred by the genetic modification to GD743 and GS784 apples would not result in

any changes in water usage for cultivation. As discussed in Section 4.4.2 and 4.4.3, there are no expected negative impacts to water resources or air quality associated with GD743 and GS784 apple production. Based on these analyses, APHIS concludes that a determination of nonregulated status of GD743 and GS784 apples would comply with the CWA and the CAA.

7.4 Impacts on Unique Characteristics of Geographic Areas

A determination of nonregulated status of GD743 and GS784 apples is not expected to impact unique characteristics of geographic areas such as park lands, prime farmlands, wetlands, wild and scenic areas, or ecologically critical areas.

OSF has presented results of agronomic field trials for GD743 and GS784 apples. The results of these field trials demonstrate that there are no differences in agronomic practices between GD743 and GS784 and conventional apples. The common agricultural practices that would be carried out in the cultivation GD743 and GS784 apples are not expected to deviate from current practices, including the use of EPA-registered pesticides. The product is expected to be deployed on agricultural land currently suitable for production of apple, will be cultivated only as a specialty apple, is not expected to replace existing varieties, and is not expected to increase the acreage of apple production.

There are no proposed major ground disturbances; no new physical destruction or damage to property; no alterations of property, wildlife habitat, or landscapes; and no prescribed sale, lease, or transfer of ownership of any property. This action is limited to a determination of nonregulated status of GD743 and GS784 apples. This action would not convert land use to nonagricultural use and, therefore, would have no adverse impact on prime farmland. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of fruit would be used on orchard lands planted to GD743 and GS784 apples, including the use of EPA-registered pesticides. The Applicant's adherence to EPA label use restrictions for all pesticides is expected to mitigate potential impacts to the human environment.

Based on these findings, including the assumption that EPA label use instructions are in place to protect unique geographic areas and that those label use instructions are adhered to, a determination of nonregulated status of GD743 and GS784 is not expected to impact unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas.

7.5 National Historic Preservation Act (NHPA) of 1966 as Amended

The NHPA of 1966 and its implementing regulations (36 CFR 800) require Federal agencies to: 1) determine whether activities they propose constitute "undertakings" that have the potential to cause effects on historic properties and 2) if so, to evaluate the effects of such undertakings on such historic resources and consult with the Advisory Council on Historic Preservation (i.e., State Historic Preservation Office, Tribal Historic Preservation Officers), as appropriate.

APHIS' proposed action, a determination of nonregulated status of GD743 and GS784 is not expected to adversely impact cultural resources on tribal properties. Any farming activity that may be taken by farmers on tribal lands would only be conducted at the tribe's request; thus, the tribes would have control over any potential conflict with cultural resources on tribal properties.

APHIS' Preferred Alternative 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 it likely cause any loss or destruction of significant scientific, cultural, or historical resources. This action is limited to a determination of non-regulated status of GD743 and GS784.

APHIS' proposed action is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected under the NHPA. In general, common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or noise 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 increased noise on the use and enjoyment of a historic property during the operation of tractors and other mechanical equipment 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 is not expected to change any of these agronomic practices that would result in an adverse impact under the NHPA.

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