

# **NATIONAL ENVIRONMENTAL POLICY ACT DECISION**

## **AND**

### **FINDING OF NO SIGNIFICANT IMPACT**

Okanagan Specialty Fruits Inc.

Request for Extension of Determination of Non-regulated Status for Non-Browning Artic® Fuji Apple (16-004-01p)

United States Department of Agriculture

Animal and Plant Health Inspection Service

Biotechnology Regulatory Services

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

Okanagan Specialty Fruits Inc. (hereafter referred to as OSF), of British Columbia, Canada submitted a request (APHIS Number 16-004-01p) to APHIS on March 7, 2016 for extension of a determination of nonregulated status under 7 CFR 340 for a genetically engineered (GE) apple, NF872 'Artic® Fuji' (hereafter referred to as NF872 apple). A person may request that APHIS extend a determination of nonregulated status to other organisms pursuant to 7 CFR §340.6(e)(2) of the regulations. Such a request shall include information to establish the similarity of the unregulated antecedent organism and the regulated articles. A GE organism is no longer subject to the plant pest provisions of the Plant Protection Act (PPA) and the regulatory requirements of 7 CFR part 340 when APHIS determines that it is unlikely to pose a plant pest risk.

APHIS reviewed and analyzed the information submitted in the extension request by OSF (OSF, 2016) and has concluded that the NF872 apple, which is genetically engineered to be resistant to enzymatic browning, is similar to the antecedent organisms 'Artic® Golden Delicious' (GD743 apple) and 'Artic® Granny Smith' (GS784 apple) that were identified in the 10-161-01p petition and deregulated in 2015 (77 FR 41362-41363). Based on its Plant Pest Risk Assessment (PPRA) for OSF's apple events GD743 and GS784, APHIS has concluded in its Plant Pest Risk Similarity Assessment (PPRSA) that NF872 apple is unlikely to pose a plant pest risk (USDA-APHIS, 2016).

In accordance with APHIS' NEPA implementing procedures (7 CFR part 372), APHIS completed an Environmental Assessment (EA) and FONSI that analyzed the potential impacts to

the human environment from a determination on the regulated status of the antecedents GD743 and GS784 apples in 2015 (77 FR 41362-41363). APHIS carefully examined the NEPA documentation completed for GD743 and GS784 apples, including comments received from the public involvement process and concluded that the OSF extension request for a determination of nonregulated status of NF872 apple encompasses the same scope of environmental analysis and regulatory decision as GD743 and GS784 apples. This conclusion is based on:

- NF872 apple expresses the same GEN-03 binary plasmid as GD743 and GS784 apples;
- NF872 apple expresses the same resistance to enzymatic browning as GD743 and GS784 apples;
- NF872 apple does not exhibit any additional traits beyond what is expressed in GD743 and GS784 apples;
- the affected environment, issues and alternatives described and analyzed in the existing NEPA documentation for GD743 and GS784 apples are applicable to the extension request of NF872 apple;
- no new alternatives have been identified that are relevant to this regulatory action;
- no substantive new issues and impacts on the human environment have been identified that are relevant to this regulatory action; and
- APHIS is not aware of any substantive new information that would warrant alteration of the existing NEPA documentation for GD743 and GS784 apples, including the proposed action or analysis of impacts in the EA.

Based on the similarity of NF872 apple to the antecedent organisms GD743 and GS784 apples, the existing NEPA documentation completed for GD743 and GS784 apples is being used to evaluate and determine if there are any potentially significant impacts to the human environment from APHIS' response to OSF's extension request for a determination of nonregulated status pursuant to 7 CFR part 340 of NF872 apple.

### **Regulatory Authority**

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

In 1986, the Office of Science and Technology Policy (OSTP) issued the Coordinated Framework for the Regulation of Biotechnology (CF), which describes the comprehensive Federal regulatory policy for ensuring the safety of biotechnology products (51 FR 23302, 1986). Since 1986, the Environmental Protection Agency (EPA), Food and Drug Administration (FDA) and USDA has regulated GE organisms consistent with this regulatory framework. The CF 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; and, (3) agencies are mandated to exercise oversight of GE organisms only when there is evidence of “unreasonable” risk.

APHIS’ authority to regulate GE organisms and plants derives from the plant pest provisions in the PPA of 2000, as amended (7 USC § 7701 *et seq.*). APHIS regulates GE organisms to ensure that they do not pose a plant pest risk based on requirements in 7 CFR part 340.

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

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

### **Regulated Organisms**

The APHIS Biotechnology Regulatory Services’ (BRS) mission is to protect America’s agriculture and environment using a dynamic and science-based regulatory framework that allows for the safe development and use of GE organisms. APHIS regulations at 7 CFR part 340, which were promulgated in 1987 pursuant to authority granted by the Federal Plant Pest Act and further consolidated pursuant to the PPA, as amended (7 United States Code (U.S.C.) 7701-7772), regulate the introduction (importation, interstate movement, or release into the environment) of certain GE organisms. A GE organism is no longer subject to the plant pest provisions of the PPA and 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, or if the Administrator believes the GE organism is a plant pest .

## **APHIS' Response to an Extension Request for Nonregulated Status**

A person may request that APHIS extend a determination of nonregulated status to other organisms pursuant to §340.6(e)(2) of the regulations. Such a request shall include information to establish the similarity of the antecedent organism and the regulated articles in question. A GE organism is no longer subject to the plant pest provisions of the PPA or the regulatory requirements of 7 CFR part 340 when APHIS determines that it is unlikely to pose a plant pest risk.

OSF submitted an extension request (16-004-01p) to APHIS seeking a determination that NF872 apple is unlikely to pose a plant pest risk and, therefore, should no longer be a regulated article pursuant to regulations at 7 CFR part 340. APHIS reviewed and analyzed the information submitted in the extension request by OSF and has concluded that NF872 apple is similar to the antecedent organisms GD743 and GS784 apples and therefore, based on the Plant Pest Risk Similarity Assessment (PPRSA), APHIS has concluded that NF872 apple is unlikely to pose a plant pest risk (USDA-APHIS, 2016).

### **NF872 Apple**

OSF has developed NF872 apple (*Malus x domestica*), a new cultivar that has been genetically modified to be resistant to enzymatic browning. The “nonbrowning” phenotype of NF872 apple, and the antecedent events (GD743 and GS784 apples) were developed by inserting a polyphenol oxidase (PPO) suppression sequence derived from apples. 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 anti-browning agents on cut fruit and minimizes losses caused by harvest and postharvest damage (OSF, 2012).

According to the request, upon commercialization, NF872 apple will be sold as ‘Artic® Fuji’. NF872 apple will be used as a direct replacement for its untransformed conventional counterpart (Fuji apple) in situations where the nonbrowning trait is considered desirable, such as in fresh-cut produce products, prepared apple slices, and the manufacturing of juice. NF872 apple will also be used in conventional breeding efforts to produce new apple cultivars that are resistant to enzymatic browning (OSF, 2016). Fuji is the fifth most popular cultivar in the United States.

In 2005, five NF872 apple trees were planted in New York, two of which were used as the experimental control (OSF, 2016). The field trials for NF872 were conducted in New York state, one of the top two growing regions within the United States (OSF, 2016). Details regarding and data resulting from these field trials are described in the revised request for extension for NF872 apple (16-004-01p)(OSF, 2016).

## **Coordinated Framework Review**

### *Food and Drug Administration*

NF872 apple falls within the scope of the 1992 FDA's policy statement concerning regulation of products derived from new plant varieties, including those developed through biotechnology (FDA, 1992). OSF intends to submit a voluntary safety and nutritional assessment of NF872 apple to the FDA's Center for Food and Safety and Applied Nutrition (CFSAN) for a review of details to compositional analyses as a component of the food and feed safety of NF872 apple (OSF, 2016).

### *Environmental Protection Agency*

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

As NF872 apple and the antecedent organisms GD743 and GS784 apples do not express any pesticidal properties, the EPA has no FIFRA review authority over this apple product. However, if NF872 and the antecedent events GD743 and GS784 provide for a change in use of registered herbicides, the EPA would review proposed label changes relating to these new herbicide uses. No change from current herbicide use associated with NF872 apple is expected, and has not occurred for the antecedents GD743 and GS784 apples.

## **Scope of the Environmental Analysis**

Based on its similarity to the antecedent organisms, GD743 and GS784 apples, APHIS has concluded that the OSF extension request for a determination on the regulated status for NF872 apple encompasses the same scope of environmental analysis as GD743 and GS784 apples. APHIS reviewed and analyzed the information submitted in the extension request by OSF (OSF, 2016) and has concluded that NF872 apple is similar to the antecedent organisms, GD743 and GS784 apples, and, therefore, based on its PPRA for GD743 and GS784 apples (USDA-APHIS, 2014b), APHIS has concluded that NF872 apple is unlikely to pose a plant pest risk (USDA-APHIS, 2016). Although a determination of nonregulated status pursuant to 7 CFR 340 of NF872 apple would allow for new plantings of NF872 apple anywhere in the United States, APHIS primarily focused the environmental analysis on those geographic areas that currently support apple production. Similar to the antecedent organisms GD743 and GS784 apples, a determination of nonregulated status of NF872 apple is not expected to increase apple production, either by its availability alone or accompanied by other factors, or cause an increase in overall apple acreage. To determine areas of apple production, APHIS used data from the National Agricultural Statistics Service to determine where apple is produced in the United States. Apples are grown in all 50 states. People may grow apples in their backyards, small

orchards or in larger production settings. In 2014, the U.S. total commercial apple bearing acreage was 321,880 acres (USDA-NASS, 2015). Historically, Washington, New York, and Michigan are the largest producers of apples. Approximately 44% of the nation's apple acres are in Washington. New York and Michigan together account for about one quarter of the U.S. apple acres (USDA-NASS, 2015).

### **Public Involvement**

APHIS is not aware of any substantive new information that would warrant alteration of the existing NEPA documentation for the antecedent apples, including the proposed action or analysis of impacts in the EA since the completion of the public involvement process for GD743 and GS784 apples. APHIS has not received any additional information or comments from the public specifically directed at the GD743 and GS784 apple petition (10-161-01p), PPRA or NEPA documentation since a determination of non-regulated status was announced on February 18, 2015 (FR.Vol-80, No.32).

On August 12, 2016 APHIS published a notice in the Federal Register (81 FR 53396 -53398, Docket no. APHIS-2016-0043) announcing the availability of the draft Okanagan Specialty Fruits' NF872 Apple Extension Request Finding of No Significant Impact (FONSI) for a 30-day public review and comment period. Comments were required to be received on or before September 12, 2016. All comments were carefully analyzed to identify new issues, alternatives, or information. A total of 628 comments were received subsequent to the preliminary FONSI publication. The commenters expressed disagreement with GE crops in general, but did not include any further information. One comment indicated that APHIS failed to address possible effects associated with the use of clustered regularly interspaced short palindromic repeats (CRISPR) to develop the event NF872 apple. APHIS disagrees with this comment. The CRISPR Cas 9 (or other DNA endonuclease enzyme) technology mentioned in this comment was not used to develop the event NF872 apple, nor was it used in the development of the antecedent events GD743 and GS784 apples. The NF872 apple and the antecedent events were developed by Agrobacterium-mediated transformation with the binary plasmid GEN-03 (OSF, 2016). Therefore, an analysis of CRISPR technology is not within the scope for assessing potential environmental impacts associated with NF872 apple. Several specific issues related to NF872 apple were previously addressed in the EA for the antecedent events GD743 and GS784 apples, however APHIS reviewed one additional comment addressed below.

No new issues, alternatives, or new information were identified in any comments received by APHIS. Responses to previous comments are included in the EA for antecedent events GD743 and GS784 apples.

Comment documents may be viewed at:

<https://www.regulations.gov/docket?D=APHIS-2016-0043>.

In preparing this FONSI for NF872 apple, APHIS carefully reviewed and took into consideration all public input that was received during the public involvement process that was completed for the antecedent apples. On July 13, 2012, APHIS published a notice in the Federal Register (77 FR 41362-41363, Docket no. APHIS-2012-0025) announcing the availability of the OSF petition (10-161-01p). APHIS solicited comments on the petition for 60 days ending on September 11, 2012, in order to help identify potential environmental and interrelated economic issues and impacts that APHIS may determine should be considered in our evaluation of the petition. APHIS received 1,939 comments on the petition. Several of those comments included electronic attachments consisting of documents of many identical or nearly identical letters, for a total of 72,745 comments. Issues raised during the comment period included concerns regarding marketing and economic impacts; cross-pollination; and health, nutrition, and food safety. APHIS decided, based on its review of the petition and its evaluation and analysis of the comments received during the 60-day public comment period on the petition, that the petition involves a new crop trait or raises substantive new issues.

On November 8, 2013, APHIS published a notice in the Federal Register (78 FR 67100-67101, Docket no. APHIS-2012-0025) announcing the availability of the APHIS PPRA and Draft EA for public review and for a 30-day comment period, ending December 9, 2013. In a notice published in the Federal Register on December 31, 2013 (78 FR 79568-79569, Docket No. APHIS 2012-0025), APHIS reopened the comment period on the Draft EA and the PPRA for an additional 30 days, ending on January 30, 2014, indicating that comments would be considered if received between December 10, 2013 and the date of the notice. APHIS solicited comments on the Draft EA, the PPRA, and whether or not apple events GS784 and GD743 are likely to pose a plant pest risk. APHIS received 105,971 comments during the comment period, of which 100,976 were form letters. The majority of the comments expressed general opposition to APHIS making a determination of nonregulated status of GE organisms. Issues raised during the comment period included concerns regarding potential impacts on human and animal health and nontarget organisms and economic impacts on apple growers. APHIS addressed the issues raised during the comment period and provided responses to comments as an attachment to the GS784 and GD743 apple FONSI.

As part of the public process for this request, APHIS published a notice in the Federal Register announcing its preliminary regulatory determination and the availability of the PPRSA, preliminary FONSI, and preliminary determination for a 30-day public review period. At the close of the comment period, no substantive information was received that would warrant substantial changes to the APHIS analysis or determination, the Agency's preliminary regulatory determination will become effective upon public notification through an announcement on the APHIS website and in an announcement to more than 18,000 members of the BRS Stakeholder Registry. No further Federal Register notice will be published announcing the final regulatory determination.

## **Major Issues Addressed in the FONSI**

APHIS has concluded that the OSF extension request for a determination of nonregulated status pursuant to 7 CFR part 340 of NF872 apple encompasses the same scope of environmental analysis as GD743 and GS784 apples. APHIS is not aware of any substantive new issues that may impact the human environment associated with NF872 apple that were not considered in the previous NEPA analysis completed for a determination on the regulated status of a petition request for the antecedent apples. The potential impacts of nonbrowning apples on the agricultural production of apple, the physical environment, animal and plant communities, public health, animal feed, socioeconomics, and threatened and endangered species remain unchanged when compared to those presented in the Final EA and FONSI for GD743 and GS784 apples. Therefore, APHIS is using the same issues identified and analyzed in the existing NEPA documentation for the antecedent apples to evaluate and determine if there are any potentially significant impacts to the human environment from a determination on the regulated status of an extension request by OSF for NF872 apple.

The issues considered in the analysis of GD743 and GS784 apples were developed based on APHIS' determination that certain GE organisms are no longer subject to the plant pest provisions of the PPA and 7 CFR part 340, and for this particular EA, the specific petition seeking a determination of nonregulated status for the antecedent apples. Issues discussed in the EA were developed by considering issues raised in public comments submitted for other EAs of GE organisms, issues raised in lawsuits, as well as those issues that have been raised by stakeholders. These issues, including those regarding the agricultural production of apples using various production methods, and the environmental food/feed safety of GE plants were analyzed to determine the potential environmental impacts of NF872 apple.

APHIS developed the list of resource areas considered in its analysis from issues raised in public comments submitted for other EAs of GE organisms. These same issues have been determined by APHIS to be relevant to APHIS' authority actions associated with antecedent events GD743 and GS784 apples. The following issues were identified as important to the scope of the analysis (40 CFR 1508.25) and can be categorized as follows:

### **Socioeconomic 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:**

- Livestock Health/Animal Feed

In addition, APHIS also considered potential cumulative impacts relative to these issues, potential impacts on threatened and endangered species (TES), as well as adherence of the proposed action to Executive Orders, and environmental laws and regulations to which the action may be subject.

#### **Alternatives that were analyzed**

APHIS has concluded that the OSF extension request for a determination of nonregulated status of NF872 apple encompasses the same scope of environmental analysis and regulatory decision as GD743 and GS784 apples; that is, a determination of nonregulated status pursuant to 7 CFR part 340. APHIS reviewed and analyzed the information submitted in the extension request by OSF (OSF, 2016), and has concluded that NF872 apple is similar to the antecedent apples, and therefore, based on its PPRA for GD743 and GS784 apples (USDA-APHIS, 2014c), APHIS has concluded that NF872 apple is unlikely to pose a plant pest risk (USDA-APHIS, 2016). The comparison of characteristics of NF872 apple to the antecedent apples indicates that NF872 apple expresses the same GEN-03 binary plasmid, and resistance to enzymatic browning as the antecedent events GD743 and GS784, and NF872 apple does not exhibit any additional traits beyond what is expressed in the antecedent apples. Therefore, the proposed action identified in the existing NEPA documentation completed for GD743 and GS784 apples (10-161-01p) is being used to evaluate APHIS' action associated with a determination of nonregulated status of NF872 apple.

Based on the similarity to the antecedent GD743 and GS784 apples, APHIS has concluded that all the alternatives identified in the EA for GD743 and GS784 apples are relevant to APHIS' regulatory actions associated with NF872 apple, and therefore, are being used in their entirety. APHIS is not aware of any new alternatives that are relevant to APHIS' decision on the regulatory status of NF872 apple that were not considered in the previous NEPA analysis for

GD743 and GS784 apples. Therefore, APHIS is using the same alternatives, including the proposed action, identified and analyzed in the existing NEPA documentation completed for GD743 and GS784 apples to evaluate and determine if there are any potentially significant impacts to the human environment from a determination of nonregulated status of NF872 apple.

#### ***Alternatives described in the existing EA for GD743 and GS784 apples***

The EA analyzes the potential environmental consequences of a determination of nonregulated status of GD743 and GS784 apples. To respond favorably to a petition for nonregulated status, APHIS must determine that GD743 and GS784 apples are unlikely to pose a plant pest risk. Based on its PPRA (USDA-APHIS, 2014c), APHIS has concluded that GD743 and GS784 apples are unlikely to pose a plant pest risk. Therefore, APHIS must determine that GD743 and GS784 apples are no longer subject to 7 CFR part 340 or the plant pest provisions of the PPA. Two alternatives were evaluated in the EA: (1) no action and (2) determination of nonregulated status of GD743 and GS784 apples. APHIS assessed the potential for environmental impacts for each alternative in the “Environmental Consequences” section of the EA.

#### **No Action: Continuation as a Regulated Article**

Under the No Action Alternative, APHIS would deny the petition. GD743 and GS784 apples and progeny derived from GD743 and GS784 apples would continue to be regulated articles pursuant to the regulations at 7 CFR part 340. Permits or notifications acknowledged by APHIS would still be required for introductions of GD743 and GS784 apples and measures to ensure physical and reproductive confinement would continue to be implemented. APHIS might choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from the unconfined cultivation of GD743 and GS784 apples.

This alternative is not the preferred alternative because APHIS has concluded through a PPRA that GD743 and GS784 apples are unlikely to pose a plant pest risk (USDA-APHIS, 2014c) indicating this alternative would not satisfy the purpose and need for making a determination of plant pest risk status and responding to the petition for nonregulated status.

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

Under this alternative, GD743 and GS784 apples and progeny derived from them would no longer be regulated articles pursuant to the regulations at 7 CFR part 340. GD743 and GS784 apples are unlikely to pose a plant pest risk (USDA-APHIS, 2014c). Authorizations issued by APHIS would no longer be required for introductions of GD743 and GS784 apples and progeny derived from these events. The Preferred Alternative (i.e., a determination of nonregulated status of GD743 and GS784 apples) is not expected to increase apple production, either by its availability alone or associated with other factors, or result in an increase in overall acreage of GE apple. Potential impacts would be similar to the No Action Alternative. Because the agency

has concluded that GD743 and GS784 apples are unlikely to pose a plant pest risk, a determination of nonregulated status of GD743 and GS784 apples is a response that is consistent with the plant pest provisions of the PPA, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework.

### **Alternatives Considered but Rejected from Further Consideration**

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

#### **1. Prohibit the Release of GD743 and GS784 Apples**

APHIS considered prohibiting the release of GD743 and GS784 apples, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that GD743 and GS784 apples are unlikely to pose a plant health risk (USDA-APHIS, 2014c).

In enacting the PPA, Congress found that:

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

On March 11, 2011, in a Memorandum for the Heads of Executive Departments and Agencies, the White House Emerging Technologies Interagency Policy Coordination Committee developed broad principles, consistent with Executive Order 13563, to guide the development and implementation policies for oversight of emerging technologies (such as genetic engineering) at the agency level (76 FR 3821-3823, 2011). In accordance with this memorandum, agencies should adhere to Executive Order 13563, and, consistent with that Executive Order, the following principle, among others to the extent permitted by law when regulating emerging technologies, states that:

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

Based on the PPRA (USDA-APHIS, 2014c) and the scientific data evaluated therein, APHIS concluded that GD743 and GS784 apples are unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of OSF apple events GD743 and GS784.

#### **2. Approve the Petition in Part**

The regulations at 7 CFR 340.6(d) (3)(i) state that APHIS may “approve the petition in whole or in part.” For example, a determination of nonregulated status in part may be appropriate if there is a plant pest risk associated with some, but not all lines described in the extension request. Because APHIS has concluded that GD743 and GS784 apple events are unlikely to pose a plant pest risk (USDA-APHIS, 2014c) there is no regulatory basis pursuant to the plant pest provisions of the PPA for considering approval of the petition only in part.

### 3. Isolation Distance between GD743 and GS784 apple events and Non-GE Apple Production and Geographical Restrictions

Because APHIS has concluded that GD743 and GS784 apple events are unlikely to pose a plant pest risk (USDA-APHIS, 2014c) an alternative based on requiring isolation distances would be inconsistent with the statutory authority pursuant to the plant pest provisions of the PPA and regulations in 7 CFR part 340.

In response to public concerns of gene movement between GE and non-GE plants, APHIS considered requiring an isolation distance separating GD743 and GS784 apples from conventional or specialty apple production. APHIS also considered geographically restricting the production of GD743 and GS784 apples 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’ PPRA for GD743 and GS784 apples, there are no geographic differences associated with any identifiable plant pest risks for GD743 and GS784 apples (USDA-APHIS, 2014c). This alternative was rejected and not analyzed in detail because APHIS has concluded that GD743 and GS784 apples 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 pursuant to the plant pest provisions of the PPA and regulations in 7 CFR 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 pursuant to the plant pest provisions of the PPA. However, individuals might choose on their own to geographically isolate their non-GE production systems from GD743 and GS784 apples or to use isolation distances and other management practices to minimize gene movement between apple orchards.

### 4. Requirement of Testing for GD743 and GS784 apples

During the comment periods for other petitions for nonregulated status, some commenters requested that USDA require and provide testing for GE products in non-GE production systems. APHIS notes that there are no nationally-established regulations involving testing, criteria, or

limits of GE material in non-GE systems. Such a requirement would be extremely difficult to implement and maintain. Additionally, because GD743 and GS784 apples do not pose a plant pest risk (USDA-APHIS, 2014c), the imposition of any type of testing requirements is inconsistent with the plant pest provisions of the PPA, the regulations at 7 CFR part 340 and biotechnology regulatory policies embodied in the Coordinated Framework. Therefore, imposing such a requirement for GD743 and GS784 apples would not meet APHIS' purpose and need to respond appropriately to the petition in accordance with its regulatory authorities.

### **Environmental Consequences of APHIS' Selected Action**

Based on the similarity of the antecedent events GD743 and GS784 apples to NF872 apple (USDA-APHIS, 2016), APHIS has concluded that the previous analysis of impacts completed for GD743 and GS784 apples is relevant to APHIS' regulatory actions associated with responding to the OSF extension request for NF872 apple. The potential impacts of NF872 apple on agricultural production of apple, physical environment, animal and plant communities, public health, animal feed, socioeconomics, and threatened and endangered species are identical to those presented in the Final EA and FONSI for GD743 and GS784 apples and therefore are being used in their entirety to evaluate APHIS' action associated with a determination of nonregulated status of NF872 apple. The EA for GD743 and GS784 apples (USDA-APHIS, 2014a) contains a full analysis of the alternatives to which we refer the reader for specific details. The following table briefly summarizes the results for each of the issues fully analyzed in the Environmental Consequences section of the EA.

<b>Attribute/Measure</b>	<b>Alternative A: No Action</b>	<b>Alternative B: Determination of Nonregulated Status</b>
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, 2014c)
<b>Socioeconomic and Cultural</b>		
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,	Unchanged from No Action Alternative

	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.	
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.
<b>Environment</b>		
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 producing apples.	Unchanged from No Action Alternative
Water Resources	The primary cause of agricultural non-point source pollution is increased sedimentation from soil erosion, which can introduce sediments, fertilizers, and pesticides to nearby lakes and streams. Agronomic practices such as crop nutrient management, pest management, and conservation buffers help protect water quality from 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 (IPM) strategies.	Unchanged from 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. 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 IPM strategies. IPM programs are tailored to specific areas of the country; however, nearly every	Unchanged from No Action Alternative.

	IPM program specifically addresses the most common diseases of apple.	
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.
<b>Human and Animal Health</b>		
Human Health/ Worker Safety	<p>The average U.S. consumer ate an estimated 47.6 pounds of apple products in 2011 (USDA-APHIS, 2014a). The apple orchard is a highly managed environment which incorporates the use of agricultural chemicals. Pesticides are used on most apple acreage in the United States. The EPA's Worker Protection Standard (WPS), 40 CFR Part 170.1, (<i>Scope and Purpose</i>), requires employers to take actions to reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers. The WPS contains requirements for pesticide safety training, notification of pesticide applications, use of personal protective equipment, restricted entry intervals following pesticide application, decontamination supplies, and emergency medical assistance.</p>	<p>OSF submitted a safety and assessment of food and feed derived from GD743 and GS784 apples to the FDA on May 30, 2011. On March 16, 2015, the FDA concluded that based on the information provided by OSF, there were no safety or regulatory issues under the Food Drug and Cosmetic Act that would require further evaluation at the time of their conclusion (FDA, 2015).</p> <p>OSF's studies demonstrate no differences in morphological characteristics and agronomic requirements between GD743 and GS784 apples and other apple varieties. OSF demonstrates in its petition that the agronomic inputs required to cultivate GS784 and GD743 apples are functionally equivalent to those required for conventional apple. Accordingly, the health and safety protocols</p>



		<p>currently employed by farm workers in the cultivation of apples do not require changes to accommodate the cultivation of GS784 and GD743 apples.</p> <p>Therefore, human health and worker safety issues associated with the agricultural production of GS784 and GD743 would remain the same as those under the No Action Alternative.</p>
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.	<p>OSF submitted a safety and nutritional assessment of food and feed derived from GD743 and GS784 to the FDA on May 30, 2011. On March 16, 2015, the FDA concluded that based on the information provided by OSF, there were no safety or regulatory issues under the Food Drug and Cosmetic Act that would require further evaluation at the time of their conclusion (FDA, 2015). Therefore this is unchanged from the No Action Alternative.</p>
<b>Other Regulatory Approvals</b>		
United States	<p>OSF submitted a safety and nutritional assessment of food and feed derived from GD743 and GS784 to the FDA on May 30, 2011.</p> <p>On March 16, 2015, the FDA concluded that based on the information provided by OSF, there</p>	OSF submitted a safety and nutritional assessment of food and feed derived from GD743 and GS784 to the FDA on May 30, 2011.

	were no safety or regulatory issues under the Food Drug and Cosmetic Act that would require further evaluation at the time of their conclusion (FDA, 2015).	On March 16, 2015, the FDA concluded that based on the information provided by OSF, there were no safety or regulatory issues under the Food Drug and Cosmetic Act that would require further evaluation at the time of their conclusion (FDA, 2015).
Canadian Food Inspection Agency (CFIA)	Regulatory submissions for product approvals were made to Health Canada and CFIA on December 7, 2011. On March 20, 2015, the CFIA approved the unconfined release into the environment for GD743 and GS784 apples (CFIA, 2015).	Regulatory submissions for product approvals were made to Health Canada and CFIA on December 7, 2011. On March 20, 2015, the CFIA approved the unconfined release into the environment for GD743 and GS784 apples (CFIA, 2015).
<b>Compliance with Other Laws</b>		
Clean Water Act, Clean Air Act, Executive Orders	Fully compliant	Fully compliant

### Finding of No Significant Impact

Based on the analysis of impacts in the Final EA for GD743 and GS784 apples (USDA-APHIS, 2014a) and the similarity of NF872 apple to these antecedent apples, a determination of nonregulated status pursuant to 7 CFR 340 of NF872 apple will not have a significant impact, individually or cumulatively, on the quality of the human environment. This NEPA determination is based on the following context and intensity factors (40 CFR 1508.27):

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

In 2014, the United States total commercial apple bearing acreage was 321,880 acres (USDA-NASS, 2014d). Historically, Washington, New York, and Michigan are the largest producers of

apples. Approximately 40% of the nation's apple acres are in Washington. New York and Michigan together account for about one fourth of the U.S. apple acres (USDA-NASS, 2012). The majority of commercial apple production is marketed as fresh fruit valued at over \$2.5 billion (USDA-NASS, 2014c). Processed fruit production is valued at \$272 million (USDA-NASS, 2014b).

A determination of nonregulated status of NF872 apple is not expected to directly cause an increase in agricultural acreage devoted to apple production. The availability of NF872 apple will not change cultivation areas for apple production in the United States, and there are no anticipated changes to the availability of GE and non-GE apple varieties on the market.

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

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

A determination of nonregulated status pursuant to 7 CFR part 340 for NF872 apple will have no significant environmental impact in relation to the availability of GE, conventional, organic or specialty apple varieties. Based on the discussions in Chapter 4 of the EA for GD743 and GS784 apples (USDA-APHIS, 2014a) and its similarity to the antecedent events GD743 and GS784 apples, a determination of nonregulated status of event NF872 apple is not expected to directly cause an increase in agricultural acreage devoted to apple production, or those apple acres devoted to apple cultivation. The availability of NF872 apple will not change cultivation areas for apple production in the United States and there are no anticipated changes to the availability of GE and non-GE apple varieties on the market. A determination of nonregulated status of NF872 apple could add another GE apple variety to the conventional apple market but is not expected to change the market demands for GE apple or apples produced using organic methods or specialty systems. As of 2014, there were 868 certified and exempt organic farms (with 16,245 harvested acres) that produced approximately 562 million pounds of organic apples. The total gross value of sales was reported from 844 certified organic farms, for a total of approximately 482 million pounds of organic apples valued at just over \$248 million (USDA-NASS, 2014a).

Based on data provided by OSF for NF872 apple (OSF, 2016), APHIS has concluded that the availability of NF872 apple would not alter the agronomic practices, locations, or current production practices.

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

A determination of nonregulated status of NF872 apple would have no significant impacts on human or animal health under either alternative. FDA and EPA reviewed the antecedent apples and determined that the products met the agencies' review criteria for

approval. The non-browning trait has been successfully cultivated in the antecedents, with no evidence of human health impacts.

Public health concerns associated with the use of GE apple, such as NF872 apple, and GE apple products focus primarily on human and animal (livestock) consumption of GE food and feed commodities. Non-GE apple varieties, both those developed for conventional use and for use in organic production systems, are not routinely required to be evaluated by any regulatory agency in the United States for human food or animal feed safety prior to release in the market. Pursuant to the FFDCA, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and labeled properly. As a GE product, however, food and feed derived from NF872 apple 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, thus far all applicants who have wished to commercialize a GE variety that would be included in the food supply have completed a consultation with the FDA. In such 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 in food (Hammond and Jez, 2011). FDA evaluates the submission and responds to the developer by letter with any concerns it may have or additional information it may require. Several international agencies also review food safety associated with GE-derived food items, including the European Food Safety Agency and the Australia and New Zealand Food Standards Agency. OSF intends to provide the FDA with comprehensive event specific information on the identity, function, and characterization of the genes for NF872 apple.

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

There are no unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas that would be adversely impacted by a determination of nonregulated status pursuant to 7 CFR part 340 of NF872 apple. Similar to the antecedent apples, the common agricultural practices that would be carried out under the proposed action will not cause major ground disturbance; do not cause any physical destruction or damage to property, wildlife habitat, or landscapes; and do not involve the sale, lease, or transfer of ownership of any property. This action is limited to a determination of nonregulated status of NF872 apple. The

product will be deployed on agricultural land currently suitable for production of apple, will replace existing varieties, and is not expected to increase the acreage of apple production. This action would not convert land to nonagricultural use and therefore would have no adverse impact on prime farm land. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted with NF872 apple, including the use of EPA registered pesticides. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate potential significant impacts to the human environment. In the event of a determination of nonregulated status of NF872 apple, the action is not likely to affect historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas that may be in close proximity to apple production sites.

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

The impacts on the quality of the human environment from a determination of nonregulated status pursuant to 7 CFR part 340 of NF872 apple are not highly controversial. Although there is some opposition to a determination of nonregulated status of NF872 apple, this action is not highly controversial in terms of size, nature or effect on the natural or physical environment. As discussed in Chapter 4 of the EA for GD743 and GS784 apples (USDA-APHIS, 2014a), a determination of nonregulated status is not expected to directly cause an increase in agricultural acreage devoted to apple production. The availability of NF872 apple will not change cultivation areas for apple production in the United States, and there are no anticipated changes to the availability of apple varieties on the market. A determination of nonregulated status of NF872 apple could add another apple variety to the apple market and is not expected to change the market demands for apples produced using organic methods. A determination of nonregulated status of NF872 apple will not result in changes in the current practices of planting, fertilizer application/use, cultivation, or pesticide application use. The impact of NF872 apple on wildlife or biodiversity is not different than that of other apple varieties currently used in conventional agriculture in the United States.

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

Based on the analysis documented in the EA for apple events GD743 and GS784 (USDA-APHIS, 2014a) and their similarity to NF872 apple, the possible impacts on the human environment from a determination of nonregulated status pursuant to 7 CFR part 340 of NF872 apple are well understood. The impacts of the proposed activities are not highly uncertain and do not involve unique or unknown risks on the natural or physical environment. As discussed in Chapter 4 of the EA for GD743 and GS784 apples (USDA-

APHIS, 2014a), a determination of nonregulated status of NF872 apple is not expected to directly cause an increase in agricultural acreage devoted to apple cultivation. A determination of nonregulated status of NF872 apple will not result in changes in the current practices of planting, fertilizer application/use, cultivation, or pesticide application use. Agronomic characteristics and cultivation practices required for NF872 apples are indistinguishable from practices used to grow other apple varieties. The impacts of NF872 apple on wildlife or biodiversity is no different than that from other apples produced in conventional agriculture in the United States. As described in Chapter 2 of the EA for GD743 and GS784 apples (USDA-APHIS, 2014a), well-established management practices, production controls, and production practices (conventional and organic) are currently being used in apple production systems in the United States. Therefore, it is reasonable to assume that farmers, who produce conventional apple varieties, NF872 apple, or produce apples using organic methods, will continue to use these reasonable, commonly accepted best management practices for their chosen systems and varieties during agricultural apple production.

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

A determination of nonregulated status for NF872 apple would not establish a precedent for future actions with significant impacts or represent a decision in principle about a future decision. Similar to past regulatory requests reviewed and approved by APHIS, a determination of nonregulated status will be based on whether an organism is unlikely to pose a plant pest risk pursuant to the regulatory requirements of 7 CFR part 340. Each petition that APHIS receives is specific to a particular GE organism and undergoes this independent review to determine if the regulated article poses a plant pest risk.

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

Based on the similarity of GD743 and GS784 apples to NF872 apple, no significant cumulative impacts were identified. The EA reviewed cumulative impacts of GD743 and GS784 apples on apple management practices, human and animal health, and the environment and concluded that such impacts were not significant (USDA-APHIS, 2014a). A cumulative impacts analysis is included for each environmental issue analyzed in Chapter 4 of the EA for GD743 and GS784 apples (USDA-APHIS, 2014a). In the event APHIS reaches a determination of nonregulated status of NF872 apple, APHIS would no longer have regulatory authority over this apple. In the event of a determination of nonregulated status of NF872 apple, APHIS has not identified any significant impact on the environment which may result from the incremental impact of a determination of

nonregulated status of NF872 apple when added to past, present, and reasonably foreseeable future actions.

8. *The degree to which the action may adversely affect districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places or may cause loss or destruction of significant scientific, cultural, or historic resources.*

Based on the similarity of the antecedent apples to NF872 apple, a determination of nonregulated status pursuant to 7 CFR part 340 of NF872 apple will not adversely impact cultural resources on tribal properties. Any farming activities that may be taken by farmers on tribal lands are only conducted at the tribe's request; thus, the tribes have control over any potential conflict with cultural resources on tribal properties. A determination of nonregulated status of NF872 apple would have no impact on districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places, nor would they likely cause any loss or destruction of significant scientific, cultural, or historic resources. This action is limited to a determination of nonregulated status of NF872 apple. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on these agricultural lands including the use of EPA registered pesticides. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate impacts to the human environment. A determination of nonregulated status of NF872 apple is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected pursuant to the National Historic Preservation Act. In general, common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or audible elements to areas in which they are used that could result in impacts on the use and enjoyment of a historic property when common agricultural activities take place. Additionally, cultivation practices are already being conducted throughout the apple production regions. The cultivation of NF872 apple does not inherently change any of these agronomic practices so as to give rise to an impact pursuant to the National Historic Preservation Act.

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

As described in Chapter 6 of the EA for GD743 and GS784 apples (USDA-APHIS, 2014a) APHIS has analyzed the potential for effects from a determination of nonregulated status pursuant to 7 CFR part 340 of GD743 and GS784 apples on federally listed threatened and endangered species and species proposed for listing, as well as designated critical habitat and habitat proposed for designation, as required pursuant to Section 7 of the Endangered Species Act. After reviewing possible effects of a determination of nonregulated status of NF872 apple, APHIS has determined that a

determination of nonregulated status of NF872 apple would have no effect on federally listed threatened and endangered species and species proposed for listing, or on designated critical habitat or habitat proposed for designation.

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

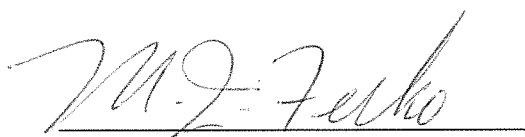
The proposed action would be in compliance with all Federal, State, and local laws. Because the agency has concluded that NF872 apple is unlikely to pose a plant pest risk, a determination of nonregulated status of NF872 apple is a response that is consistent with the plant pest provisions of the PPA, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework. There are no other Federal, State, or local permits that are needed prior to the implementation of this action.



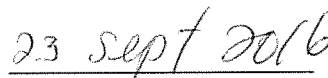
## NEPA Decision and Rationale

I have carefully reviewed the existing NEPA documentation completed for GD743 and GS784 apples, including input from the public involvement process. Based on APHIS' conclusion that NF872 apple encompasses the same scope of environmental analysis and regulatory decision as GS784 and GD743 apples; that is, a determination of nonregulated status pursuant to 7 CFR part 340, I conclude the issues identified and analyzed in the existing NEPA documentation for GD743 and GS784 apples are relevant to this regulatory action and best addressed by extending a determination of nonregulated status to NF872. This regulatory action meets APHIS' purpose and need to allow the safe development and use of GE organisms consistent with the plant pest provisions of the PPA and pursuant to 7 CFR part 340.

As stated in the CEQ regulations, "the agency's preferred alternative is the alternative which the agency believes would fulfill its statutory mission and responsibilities, giving consideration to economic, environmental, technical and other factors." The Preferred Alternative (a determination of nonregulated status of NF872 apple) has been selected for implementation based on consideration of a number of environmental, regulatory, and social factors. Based upon our evaluation and analysis, this alternative is selected because (1) it allows APHIS to fulfill its statutory mission to protect America's agriculture and environment using a science-based regulatory framework that allows for the safe development and use of GE organisms; and (2) it allows APHIS to fulfill its regulatory obligations. As APHIS has not identified any plant pest risks associated with NF872 apple, the continued regulated status of NF872 apple would be inconsistent with the plant pest provisions of the PPA, the regulations codified at 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework. For the reasons stated above, I have determined that a determination of nonregulated status of NF872 apple will not have any significant environmental impacts.



Michael Firko, Ph.D.  
APHIS Deputy Administrator  
Biotechnology Regulatory Services  
U.S. Department of Agriculture



Date

## Citations

Coordinated Framework for Regulation of Biotechnology 1986. Pub. L. Stat. June 26.

76 FR 3821-3823 (2011) "Executive Order 13563 of January 18, 2011 Improving Regulation and Regulatory Review."

"Plants Evaluated for Environmental and Livestock Feed Safety." CFIA. 2015. Last Accessed: 5/13/16  
[http://www.inspection.gc.ca/active/scripts/database/pntvcn\\_submitdb.asp?lang=e&crops=15&company=31&trait=all&events=all](http://www.inspection.gc.ca/active/scripts/database/pntvcn_submitdb.asp?lang=e&crops=15&company=31&trait=all&events=all).

FDA (1992) "Statement of Policy - Foods Derived from New Plant Varieties." Register, FDA Federal. Last Accessed: 02/03/16  
<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096095.htm>.

FDA (2015) "Biotechnology Consultation Note to the File BNF No. 000132." US-FDA.  
<http://www.fda.gov/Food/FoodScienceResearch/GEPlants/Submissions/ucm436168.htm>.

FR.Vol-80 (No.32) "Notice of Decision "

Hammond, BG and Jez, JM (2011) "Impact of food processing on the safety assessment for proteins introduced into biotechnology-derived soybean and corn crops." *Food and chemical toxicology : an international journal published for the British Industrial Biological Research Association*. 49 (4): p 711-21. <http://www.ncbi.nlm.nih.gov/pubmed/21167896>.

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

OSF (2016) "Revised Application for an Extension of the Determination of Non regulated Status for Non-Browning Arctic® Apple (10-161-01p): Transformation Event NF872 "

USDA-APHIS (2014a) "Final EA for Okanagan Specialty Fruits Petition (10-161-01p) for Determination of Non-regulated Status of Arctic™ Apple Events GD743 and GS784."

USDA-APHIS (2014b) "Okanagan Specialty Fruits Inc.'s Petition (10-161-01p) for Determination of Non-regulated Status of Non-browning Arctic™ Apple Events GD743 and GS784 Plant Pest Risk Assessment (PPRA)."

USDA-APHIS (2014c) "PPRA for Okanagan Specialty Fruits Inc.'s Petition (10-161-01p) for Determination of Non-regulated Status of Non-browning Arctic™ Apple Events GD743 and GS784."

USDA-APHIS (2016) "PPRSA- Preliminary Extended Determination of Nonregulated Status for Okanagan Specialty Fruits Non-Browning Arctic Apple (10-161-01p)."

USDA-NASS (2012) "Noncitrus Fruits and Nuts 2011 Summary." Last Accessed: 5/13/16

USDA-NASS (2014a) "All Organic Apples Harvested and Value of Sales - Certified and Exempt Organic Farms: 2014."

USDA-NASS (2014b) "Apple Processing Production 2014." Last Accessed: 5/13/16  
<https://quickstats.nass.usda.gov/results/8CBA3493-B406-36ED-934C-EC56A26E1501>.

USDA-NASS (2014c) "Fresh Market Apple Production." Last Accessed: 5/13/16  
<https://quickstats.nass.usda.gov/results/75C52136-B02E-396B-9198-60FBA75BEE77>.

USDA-NASS "USDA-NASS Data for 2014." [https://quickstats.nass.usda.gov/results/5C1F4B04-F71C-33D9-B9AD-D12243A17C0B?pivot=short\\_desc](https://quickstats.nass.usda.gov/results/5C1F4B04-F71C-33D9-B9AD-D12243A17C0B?pivot=short_desc).

USDA-NASS "United States Apple Production." [https://quickstats.nass.usda.gov/results/5C1F4B04-F71C-33D9-B9AD-D12243A17C0B?pivot=short\\_desc](https://quickstats.nass.usda.gov/results/5C1F4B04-F71C-33D9-B9AD-D12243A17C0B?pivot=short_desc).



USDA-APHIS (2014c) "PPRA for Okanagan Specialty Fruits Inc.'s Petition (10-161-01p) for Determination of Non-regulated Status of Non-browning Arctic<sup>TM</sup> Apple Events GD743 and GS784."

USDA-APHIS (2016) "PPRSA- Preliminary Extended Determination of Nonregulated Status for Okanagan Specialty Fruits Non-Browning Arctic Apple (10-161-01p)."

USDA-NASS (2012) "Noncitrus Fruits and Nuts 2011 Summary." Last Accessed: 5/13/16

USDA-NASS (2014a) "All Organic Apples Harvested and Value of Sales - Certified and Exempt Organic Farms: 2014."

USDA-NASS (2014b) "Apple Processing Production 2014." Last Accessed: 5/13/16  
<https://quickstats.nass.usda.gov/results/8CBA3493-B406-36ED-934C-EC56A26E1501>.

USDA-NASS (2014c) "Fresh Market Apple Production." Last Accessed: 5/13/16  
<https://quickstats.nass.usda.gov/results/75C52136-B02E-396B-9198-60FBA75BEE77>.

USDA-NASS "USDA-NASS Data for 2014." [https://quickstats.nass.usda.gov/results/5C1F4B04-F71C-33D9-B9AD-D12243A17C0B?pivot=short\\_desc](https://quickstats.nass.usda.gov/results/5C1F4B04-F71C-33D9-B9AD-D12243A17C0B?pivot=short_desc).

USDA-NASS "United States Apple Production." [https://quickstats.nass.usda.gov/results/5C1F4B04-F71C-33D9-B9AD-D12243A17C0B?pivot=short\\_desc](https://quickstats.nass.usda.gov/results/5C1F4B04-F71C-33D9-B9AD-D12243A17C0B?pivot=short_desc).

