

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

J.R. Simplot Company

V11 Snowden Potatoes with Low Acrylamide Potential and Reduced Black Spot

United States Department of Agriculture

Animal and Plant Health Inspection Service

Biotechnology Regulatory Services

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

J.R. Simplot Company submitted a request on May 19, 2015, for extension of a determination of nonregulated status (15-140-01p) under 7 CFR 340 for a genetically engineered (GE) potato, Snowden potato variety event SPS-00V11-6, (hereafter referred to as V11 potato). A person may petition the agency that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, is no longer regulated under the plant pest provisions of the Plant Protection Act (PPA) and the regulations at 7 CFR 340. A person may request that APHIS extend a determination of nonregulated status to other organisms under §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 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 reviewed and analyzed the information submitted in the extension request by Simplot (15-140-01p) (Simplot, 2015) and has concluded that V11 potato is similar to the 3 antecedent events (E12, F10, and J3, hereinafter referred to as the antecedent potatoes) as well as the other 7 previously deregulated events (E24, F37, J55, J78, G11, H37, and H50) in the 13-022-01p petition, and therefore, based on its Plant Pest Risk Assessment for the antecedent potatoes (USDA-APHIS, 2013), APHIS has concluded that V11 potato is unlikely to pose a plant pest risk (USDA-APHIS, 2015). J.R. Simplot refers to V11 and the previously de-regulated 10 events collectively as "Innate<sup>TM</sup>" potatoes.

The petition for the previous 10 events (13-022-01p) received a determination of non-regulated status from APHIS on November 10, 2014 (78 FR 25942-25943). The antecedent potatoes in the 13-022-01p petition were developed through *Agrobacterium*-mediated transformation of potato internode explants of 5 different varieties: Ranger Russet, Russet Burbank, Atlantic, variety G and variety H (Simplot, 2013). In accordance with §340.6(e)(2), Simplot requests this

determination of nonregulated status of the original Innate™ potato events be extended to the V11 event and any progeny derived from crosses of V11 with conventional potato, and any progeny derived from crosses of V11 potato with other transgenic potato varieties that have received a determination of nonregulated status, no longer be considered regulated articles under 7 CFR Part 340. V11 is currently regulated under 7 CFR part 340. Interstate movements and field trials of V11 have been conducted under APHIS approved authorizations from 2011 through 2014 in 9 states: Florida, Idaho, Michigan, Wisconsin, Nebraska, Washington, Pennsylvania, New York, and Oregon. Data resulting from these field trials are described in the request for extension (Simplot, 2015).

The binary plasmid vector pSIM 1278 of Innate™ potato is designed to silence four different genes in the potato: asparagine synthetase-1 (*Asn1*), polyphenol oxidase-5 (*Ppo5*), potato phosphorylase L (*PhL*) and the starch-associated R1 gene (*RI*) (Simplot, 2013). The suppression of *Asn1* is anticipated to result in potatoes with reduced free asparagine, and the suppression of *PhL* and *RI* is anticipated to result in potatoes with a lower content of reducing sugars (Simplot, 2013; USDA-APHIS, 2013). The gene targets of these four silencing constructs have been well-studied in potato and/or other plant species (USDA-APHIS, 2013). Similar to antecedent potatoes, V11 potato is currently targeted for the potato processing industry, producers, and potato consumers (Simplot, 2015). V11 potato is expected to enhance quality by reducing the severity of black spot in potatoes and achieving the traditional golden brown colors required by most French fry or potato chip customers. A chief attribute associated with the V11 potato is expected to be greater economic benefits for growers and processors (Simplot, 2015).

In accordance with APHIS procedures implementing NEPA (7 CFR part 372), APHIS completed an Environmental Assessment (EA) and NEPA Decision/FONSI that analyzed the potential impacts to the human environment from a determination on the regulated status of a petition request (APHIS-2012-0067) by Simplot for the antecedent potatoes in 2013 (78 FR 25942–25943). The EA assessed alternatives to a determination of nonregulated status under 7 CFR 340 of the antecedent potatoes and analyzed the potential environmental impacts that result from the proposed action and the alternatives. APHIS has carefully examined the existing NEPA documentation completed for the antecedent potatoes and has concluded that the Simplot extension request for a determination of nonregulated status of V11 potato encompasses the same scope of environmental analysis as the antecedent potatoes for the following reasons:

- The V11 potato expresses the same phenotype and traits, as well as the conclusions of the molecular, agronomic, phenotypic, and compositional assessments as the antecedent potatoes;
- The V11 potato was produced by transforming the potato variety Snowden with the same DNA and method that were used for the antecedent potatoes;
- The V11 potato does not exhibit any additional traits beyond what is expressed in the antecedent potatoes;
- The extension request for V11 potato encompasses the same regulatory action as the antecedent potatoes potato, that is a determination of nonregulated status under 7 CFR part 340;
- The affected environment, issues and alternatives described and analyzed in the existing NEPA documentation for the 10 antecedent organisms is applicable to the extension request of V11 potato;

- No new alternatives have been identified that are relevant to this regulatory action;
- No substantive new environmental or social issues and impacts have been identified that are relevant to this regulatory action;
- APHIS is not aware of any substantive new information that would warrant alteration of the existing NEPA documentation for V11 Potato, including the proposed action or analysis of impacts in the EA; and
- As with the antecedent potatoes, APHIS has not identified any stressor that would affect the reproduction, numbers or distribution of any threatened or endangered species or their critical habitat.

Based on its similarity to the antecedent potatoes, the Simplot extension request for V11 potato has been subject to the previous NEPA review completed for the antecedent potatoes. Therefore, the existing Environmental Assessment completed for previously antecedent potatoes is being used to evaluate and determine if there are any potentially significant impacts to the human environment from APHIS' response to Simplot's extension request for a determination of nonregulated status under 7 CFR 340 of V11 potato.

### **Regulatory Authority**

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

Since 1986, the United States government has regulated genetically engineered (GE) organisms pursuant to a regulatory policy framework known as the Coordinated Framework for the regulation of Biotechnology (Coordinated Framework) (51 FR 23302, 57 FR 22984). The Coordinated Framework, published by the Office of Science and Technology Policy, describes the comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products and explains how federal agencies will use existing Federal statutes in a manner to ensure public health and environmental safety while maintaining regulatory flexibility to avoid impeding the growth of the biotechnology industry. The Coordinated Framework is based on several important guiding principles: (51 FR 23302) 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 (51 FR 23302) agencies are required to exercise oversight of GE organisms only when there is evidence of “unreasonable” risk.

The Coordinated Framework explains the regulatory roles and authorities for the three major agencies involved in regulating GE organisms: USDA's APHIS, the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA). APHIS is responsible for regulating GE organisms and plants under the plant pest provisions in the PPA of 2000, as amended (7 USC §§7701 *et seq.*) to ensure that they do not pose a plant pest risk.

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

The EPA (US-EPA, 2011a) regulates plant-incorporated protectants under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA also sets tolerance limits for residues of pesticides on and in food and animal feed, or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug and Cosmetics Act (FFDCA) and regulates certain biological control organisms under the Toxic Substances Control Act (TSCA). The EPA is responsible for regulating the sale, distribution, and use of pesticides, including pesticides that are produced by an organism through techniques of modern biotechnology.

## **Regulated Organisms**

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

A person may petition the agency that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, is no longer regulated under the plant pest risk provisions of the Plant Protection Act and the regulations at 7 CFR 340. The petitioner is required to provide information under §340.6(c)(57 FR 22984) related to plant pest risk that the agency may use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest risk provisions of the PPA when APHIS determines that it is unlikely to pose a plant pest risk.

## **APHIS' Response to Application for an Extension of Nonregulated Status Under 7 CFR 340**

As required by 7 CFR 340.6, APHIS must respond to petitioners who request that nonregulated status of an antecedent organism(s), such as the previously deregulated Innate™ potatoes, be extended to a similar organism such as the V11 potato. When a request for an extension of nonregulated status is submitted, APHIS must make a determination if the GE organism is similar to an antecedent organism which has previously been determined is unlikely to pose a plant pest risk. If APHIS determines based on its Plant Pest Risk Assessment (PPRA) of the antecedent organism that the genetically engineered organism identified in the extension request is unlikely to pose a plant pest risk, the genetically engineered organism is no longer subject to the plant pest provisions of the PPA and 7 CFR part 340.

In accordance with §340.6(e)(2), Simplot requests APHIS' determination of nonregulated status for the antecedent potatoes be extended to V11 potato and any progeny derived from crosses of V11 potato with conventional potato, and any progeny derived from crosses of V11 potato with other transgenic potato varieties that have received a determination of nonregulated status, no longer considered regulated articles under regulations at 7 CFR Part 340. The antecedent organisms from petition 13-022-01p identified in the extension request for V11 potato are events E12, F10, and J3 of Innate™ potato. The petition (13-022-01p) for the 10 Innate™ potato events received a determination of nonregulated status from APHIS on November 10, 2014 (78 FR 25942-25943).

## **V11 Potato**

Simplot has developed V11 potato as a low acrylamide potential and reduced black spot potato. V11 potato and the antecedent events E12, F10, and J3, as described in petition 13-022-01p (Simplot, 2013) were generated through *Agrobacterium tumefaciens*-mediated transformation of conventional potato. The T-DNA insert for the V11 potato is pSIM1278 T-DNA. The pSIM1278 insert contains two separate silencing cassettes that are each delineated by a 14-bp deletion of the left border and 3-bp deletion of the right border regions (Simplot, 2015). A comparison of characteristics of the antecedent potato events and V11 potato is summarized in of this document.

The antecedent potatoes and V11 all contain a DNA insert from plasmid pSIM1278 which is derived from potato genomic DNA and is designed to silence four different genes in the potato: asparagine synthetase-1 (*AsnI*), polyphenol oxidase-5 (*Ppo5*), potato phosphorylase L (*PhL*) and the starch-associated R1 gene (*RI*). The change is intended for the benefit of potato consumers, producers, and processors (Simplot, 2013; 2015).

V11 and the antecedent potato events express two silencing cassettes. The first cassette down-regulates expression of the potato asparagine synthetase-1 gene (*AsnI*) and the potato polyphenol oxidase-5 gene (*Ppo5*). The second cassette lowers reducing sugars by down-regulating the potato phosphorylase-L gene (*PhL*) gene and the potato starch-associated gene (*RI*) by targeting the down-regulation of their promoters (Simplot, 2015). The suppression of *AsnI* is anticipated to result in potatoes with reduced free asparagine, and the suppression of *PhL* and *RI* is anticipated to result in potatoes with a lower content of reducing sugars. V11 potato and the antecedent potatoes were developed to benefit potato consumers, producers, and processors. The low acrylamide potential is intended to benefit consumers because of concerns about the health

effects of ingesting acrylamide (FDA, 2009; Simplot, 2013; 2015). Collectively, the silencing of these 3 genes should result in potato tubers with a reduced acrylamide potential. The suppression of *Ppo5* confers the non-browning phenotype resulting in tubers with reduced black spot bruising. Black spot bruise can lead to economic losses as high as 20 % (Partington *et al.*, 1999); the potato industry therefore has a vested interest in minimizing these losses. Bachem *et al.* (1994) demonstrated that black spot bruise can be reduced by silencing *Ppo* genes in potatoes, and Simplot has further developed this concept in the design of Simplot Innate™ potato (Simplot, 2013).

The purpose and need for developing potatoes with reduced black spot is reduced grower, consumer, and processor waste. Black spot is a post-harvest physiological phenomenon primarily resulting from the handling of potato tubers during harvest, transport, and processing, and refers to the black or grayish color that may form in the interior of damaged potatoes (USDA-APHIS, 2013). Similar to the antecedent potatoes, the benefits associated with reducing the severity of black spot in potatoes include improved quality (such as achieving the traditional golden brown colors required by most French fry or potato chip customers), which may result in greater economic benefits for growers and processors (Simplot, 2015). If V11 potato is to be grown commercially in the U.S., it would be subject to all U.S. Environmental Protection Agency (U.S. EPA) commercial planting registration requirements.

## **Coordinated Framework Review**

### ***Food and Drug Administration***

Similar to the antecedent potatoes, V11 potato is within the scope of the FDA policy statement concerning regulation of products that reduce acrylamide levels in food products. 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) for establishing 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.

V11 falls within the scope of the Food and Drug Administration’s (FDA) policy statement concerning regulation of food products derived from new plant varieties, including those developed by recombinant DNA techniques. A voluntary safety and nutritional assessment of V11 will be submitted to the FDA’s Center for Food Safety and Applied Nutrition (FDA CFSAN) (Simplot, 2015). 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.

Simplot has concluded through phenotypic and compositional analysis that antecedent potatoes and V11 potato and the foods and feeds obtained from these events are as safe as conventional

potato varieties, and with the exception that the genetically engineered varieties underwent transformation and contain a pSIM1278 insert, they are not materially different in composition or any other relevant parameter from other potato varieties now grown, marketed, and consumed in the U.S.

### ***Environmental Protection Agency***

As described in Subsection 2.4, Human Health, under FIFRA, all pesticides (including herbicides) sold or distributed in the U.S. must be registered by the EPA (US-EPA, 2011b). Registration decisions are based on scientific studies that assess the chemical's potential toxicity and environmental impact. To be registered, a pesticide must be able to be used without posing unreasonable risks to people or the environment. All pesticides registered prior to November 1, 1984 must also be reregistered to ensure that they meet the current, more stringent standards and should have a reregistration review every 15 years (US-EPA, 2011b). Before a pesticide can be used on a food or feed crop, the EPA must establish the tolerance value, which is the maximum amount of pesticide residue that can remain on the crop or in foods or feed processed from that crop (US-EPA, 2011b).

The EPA regulates plant-incorporated protectants (PIPs) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and certain biological control organisms under the Toxic Substances Control Act (TSCA). The EPA is responsible for regulating the sale, distribution and use of pesticides, including pesticides that are produced by an organism through techniques of modern biotechnology. Neither event V11 potato nor the antecedent potato events are engineered to express substances to protect the potatoes against plant pests, and are therefore not subject to EPA review.

### **Scope of the Environmental Analysis**

Based on its similarity to the antecedent organism in the 13-022-01p petition, APHIS has concluded that the Simplot extension request for a determination on the regulated status for V11 potato encompasses the same scope of environmental analysis as the antecedent potatoes. APHIS reviewed and analyzed the information submitted in the extension request (15-140-01p) by Simplot (Simplot, 2015) and has concluded that V11 potato is similar to the antecedent potatoes, and, therefore, based on its PPRA for these 10 GE potato events (USDA-APHIS, 2013), APHIS has concluded that V11 potato is unlikely to pose a plant pest risk (USDA-APHIS, 2015). Although a determination of nonregulated status under 7 CFR 340 of V11 potato would allow for new plantings of V11 potato anywhere in the U.S., APHIS primarily focused the environmental analysis on those geographic areas that currently support potato production. To determine areas of potato production, APHIS used data from the National Agricultural Statistics Service to determine where potato is produced in the U.S. Potato is primarily produced in the states of Idaho, Washington, Wisconsin, North Dakota, Oregon, Colorado, Minnesota, Maine, and California (USDA-APHIS, 2015).

### **Public Involvement**

APHIS is not aware of any substantive new information that would warrant alteration of the existing NEPA documentation for the antecedent potatoes including the proposed action or analysis of impacts in the EA since the completion of the public involvement process for the antecedent potatoes. APHIS has not received any additional information or comments from the public specifically directed at the antecedent potatoes, PPRA or NEPA documentation since a determination of non-regulated status was announced on November 10, 2014 (78 FR 25942–25943).

In preparing this NEPA decision/FONSI for V11 potato, APHIS carefully reviewed and took into consideration all public input that was received during the public involvement process that was completed for the antecedent potatoes. On May 3, 2013, APHIS published a notice in the Federal Register (78 FR 25942–25943, Docket no. APHIS-2012-0067) announcing the availability of the Simplot petition (13-022-01p), and the APHIS PPRA and draft EA for a 60-day public review and comment period. Comments were required to be received on or before July 2, 2013. All comments were carefully analyzed to identify new issues, alternatives, or information. Out of the 308 comments received, one included electronic attachments consisting of a consolidated document of many identical or nearly identical letters, for a total of 41,475 comments. No new issues, alternatives or substantive new information were identified in any of the comments received by APHIS. Issues raised during the comment period include concerns regarding potential impacts on conventional potato production, export markets, and plant fitness.

Comment documents may be viewed at:

<http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;dct=PS;D=APHIS-2012-0067>

## Major Issues Addressed in the FONSI

APHIS has concluded that the Simplot extension request for a determination of nonregulated status under 7 CFR 340 of V11 potato encompasses the same scope of environmental analysis as the antecedent potatoes. APHIS is not aware of any substantive new environmental or social issues associated with V11 potato that were not considered in the previous NEPA analysis completed for a determination on the regulated status of a petition request for the antecedent potatoes. Therefore, APHIS is using the same issues identified and analyzed in the existing NEPA documentation for the antecedent potatoes 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 Simplot for V11 potato.

The issues considered in the analysis of the antecedent potatoes, were developed based on APHIS' determination that certain genetically engineered organisms are no longer subject to the plant pest provisions of the PPA and 7 CFR part 340, and for this particular EA, the specific petition seeking a determination of nonregulated status for the antecedent potatoes. Issues discussed in the EA were developed by considering public concerns as well as issues raised in public comments submitted for other environmental assessments of genetically engineered organisms, concerns raised in lawsuits, as well as those issues that have been raised by various stakeholders. These issues, including those regarding the agricultural production of potato using various production methods, and the environmental food/feed safety of genetically engineered plants were addressed to analyze the potential environmental impacts of V11 potato.

The list of resource areas considered were developed by APHIS through experience in considering public concerns and issues raised in public comments submitted for other EAs of GE organisms. The following issues were identified as important to the scope of the analysis (40 CFR 1508.25). These same issues have been determined by APHIS to be relevant to APHIS' authority actions associated with Innate<sup>TM</sup> potato. These resource areas can be categorized as follows:

### Agricultural Production Considerations:

- Acreage and Areas of Potato Production
- Agronomic/Cropping Practices
- Potato Seed Production
- Organic Potato Production

### Environmental Considerations:

- Water Resources
- Soil
- Air Quality
- Climate Change
- Animals
- Plants
- Gene Flow

- Microorganisms
- Biological Diversity

Human Health Considerations:

- Public Health
- Worker Safety

Livestock Health Considerations:

- Livestock Health/Animal Feed

Socioeconomic Considerations:

- Domestic Economic Environment
- Organic Farming
- Trade Economic Environment

**Alternatives that were analyzed**

APHIS has concluded that the Simplot extension request for a determination of nonregulated status of V11 potato encompasses the same scope of environmental analysis and regulatory decision as the antecedent potatoes; that is, a determination of nonregulated status under 7 CFR part 340. APHIS reviewed and analyzed the information submitted in the extension request by Simplot (Simplot, 2015), and has concluded that V11 potato is similar to the antecedent potatoes, and therefore, based on its PPRA (USDA-APHIS, 2013) for the antecedent potatoes, APHIS has concluded that V11 potato is unlikely to pose a plant pest risk (USDA-APHIS, 2015). The comparison of characteristics of V11 potato to the antecedent potatoes, indicates that the phenotype and traits of both V11 and the antecedent potatoes are the same, as are the conclusions of the molecular, agronomic, phenotypic, and compositional assessments; and V11 potato does not exhibit any additional traits beyond what is expressed in the antecedent potatoes (Simplot, 2015). Therefore, the proposed action identified in the existing NEPA documentation completed for the antecedent potatoes is being used to evaluate APHIS' action associated with a determination of nonregulated status of V11 potato.

Based on the similarity to the antecedent potatoes, APHIS has concluded that all the alternatives identified in the EA for the antecedent potatoes to be relevant to APHIS' regulatory actions associated with V11 potato, 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 V11 potato that were not considered in the previous NEPA analysis for the antecedent potatoes. Therefore, APHIS is using the same alternatives, including the proposed action, identified and analyzed in the existing NEPA documentation completed for the antecedent potatoes to evaluate and determine if there are any potentially significant impacts to the human environment from a determination of nonregulated status of V11 potato.

### ***Alternatives described in existing Innate™ potato EA***

The EA analyzes the potential environmental consequences of a determination of nonregulated status of Innate™ potato. To respond favorably to a petition for nonregulated status, APHIS must determine that Innate™ potato is unlikely to pose a plant pest risk. Based on its PPRA (USDA-APHIS, 2013), APHIS has concluded that Innate™ potato is unlikely to pose a plant pest risk. Therefore, APHIS must determine that Innate™ potato is 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 Innate™ potato, APHIS has assessed the potential for environmental impacts for each alternative in the “Environmental Consequences” section of the EA.

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

Under the No Action Alternative, APHIS would deny the petition. Innate™ potato and progeny derived from Innate™ potato would continue to be regulated articles under the regulations at 7 CFR part 340. Permits or notifications acknowledged by APHIS would still be required for introductions of V11 potato 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 Innate™ potato.

This alternative is not the preferred alternative because APHIS has concluded through a PPRA that Innate™ potato is unlikely to pose a plant pest risk (USDA-APHIS, 2013) 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 Innate™ potato is No Longer a Regulated Article**

Under this alternative, Innate™ potato and progeny derived from it would no longer be regulated articles under the regulations at 7 CFR part 340. Innate™ potato is 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 Innate™ potato and progeny derived from these events. The Preferred Alternative, i.e., a determination of nonregulated status of Innate™ potato, is not expected to increase potato production, either by its availability alone or associated with other factors, or result in an increase in overall acreage of GE potato. Potential impacts would be similar to the No Action Alternative. 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 PPA. Because the agency has concluded that Innate™ potato is unlikely to pose a plant pest risk, a determination of nonregulated status of Innate™ potato 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 Innate™ potato. The agency evaluated these alternatives, in light of the agency's authority under the plant pest provisions of the PPA, and the regulations at 7 CFR part 340, with respect to environmental safety, efficacy, and practicality to identify which alternatives would be further considered for Innate™ potato. Based on this evaluation, APHIS rejected several alternatives. These alternatives are discussed briefly below along with the specific reasons for rejecting each.

### Prohibit any Innate™ potato from Being Released

APHIS considered prohibiting the release of Innate™ potato, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that Innate™ potato is unlikely to pose a plant health risk (USDA-APHIS, 2013).

In enacting the PPA, Congress found that

[D]ecisions affecting imports, exports, and interstate movement of products regulated under [the Plant Protection Act] shall be based on sound science... §402(57 FR 22984).

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

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

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

### Approve the petition in part

The regulations at 7 CFR 340.6(d) (51 FR 23302)(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 Innate™ potato is unlikely to pose a plant pest risk (USDA-APHIS, 2013) there is no regulatory basis under the plant pest provisions of the PPA for considering approval of the petition only in part.

## Isolation Distance between Innate™ potato and Non-GE Potato Production and Geographical Restrictions

Because APHIS has concluded that Innate™ potato is 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.

In response to public concerns of gene movement between GE and non-GE plants, APHIS considered requiring an isolation distance separating Innate™ potato from conventional or specialty potato production. APHIS also considered geographically restricting the production of Innate™ potato based on the location of production of non-GE potato 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 Innate™ potato, there are no geographic differences associated with any identifiable plant pest risks for Innate™ potato (USDA-APHIS, 2013). This alternative was rejected and not analyzed in detail because APHIS has concluded that Innate™ potato does 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. However, individuals might choose on their own to geographically isolate their non-GE potato production systems from Innate™ potato or to use isolation distances and other management practices to minimize gene movement between Innate™ potato and non-GE potato fields. Information to assist growers in making informed management decisions for Innate™ potato is available from the Association of Official Seed Certifying Agencies (AOSCA, 2010).

## Requirement of Testing for Innate™ potato

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 Innate™ potato does not pose a plant pest risk (USDA-APHIS, 2013) the imposition of any type of testing requirements is inconsistent with the plant pest provisions of the PPA, the regulations at 7 CFR part 340 and biotechnology regulatory policies embodied in the Coordinated Framework. Therefore, imposing such a requirement for Innate™ potato 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 potatoes to V11 potato, APHIS has concluded that the previous analysis of impacts completed for the antecedent potatoes to be relevant to APHIS’ regulatory actions associated with responding to the Simplot extension request for V11 potato. The potential impacts of V11 potato on agricultural production of potato, 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 the antecedent potatoes and therefore are being used in their entirety to evaluate APHIS’ action associated with a determination of nonregulated status of V11 potato. The EA for the antecedent potatoes 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 (USDA-APHIS, 2014).

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
<b>Meets Purpose and Need and Objectives</b>	<b>No</b>	<b>Yes</b>
Unlikely to pose a plant pest risk	Satisfied through use of regulated field trials	Satisfied—risk assessment (USDA-APHIS, 2013)
<b>Management Practices</b>		
Acreage and Areas of Potato Production	Total commercial potato production has increased while land area dedicated to potato has decreased. Based on potato production trends and projections, potatoes will continue to be a major crop in the U.S. for the foreseeable future.	Total acreage dedicated to potato is unlikely to change, but adoption of the Innate™ potato may reduce acreage dedicated to conventional potatoes.
Agronomic Practices	Agronomic practices will remain the same as used currently.	Unchanged from No Action Alternative
Pesticide Use	Pesticides are currently used to control insects, nematodes, fungi, and weeds.	Unchanged from No Action Alternative
Potato Seed Production	Potato seed is primarily supplied by seed potatoes.	Unchanged from No Action Alternative
Organic Potato Production	Organic potato growers use 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.	Unchanged from No Action Alternative
<b>Environment</b>		
Land Use	Current trends in the acreage and areas of production are likely to continue to be driven by market conditions (i.e., increased demand for US potato and potato products for	Unchanged from No Action Alternative

	animal feed, etc.) and federal policy.	
Water Resources	The primary cause of agricultural NPS pollution is increased sedimentation from soil erosion, which can introduce sediments, fertilizers, and pesticides to nearby lakes and streams. Agronomic practices such as conservation tillage, crop nutrient management, pest management, and conservation buffers help protect water quality from agricultural runoff.	Unchanged from No Action Alternative
Soil	Growers will adopt management practices to address their specific needs in producing potatoes. Erosion potential may continue to increase.	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 insecticides 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
<b>Animals and Plants</b>		
Animals	Potato fields 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.	Animals consuming Innate™ tubers may be exposed to increased levels of glutamine, but this is not expected to be detrimental.
Plants	Potatoes are a labor intensive, highly managed crop. Members of the plant community that adversely affect potato production may be characterized as weeds. Weed control is an important aspect of potato production. Potato growers use production practices to manage weeds in and around potato fields.	In the unlikely event of hybridization of the Innate™ potato with conventional varieties, resulting progeny may contain lowered polyphenol oxidase levels. However, this is not expected to be detrimental. Innate™ potato is no weedier than conventional potatoes.
Gene Movement	Since potato is primarily vegetatively propagated, gene flow between	The traits of Innate™ potato are not expected to increase weediness in potatoes.

	cultivars is low. Volunteer potatoes would continue to need to be controlled, although their survival is low.	
Soil Microorganisms	Abundance and diversity of soil microorganisms in and around potato fields is expected to remain as it is currently.	Unchanged from No Action Alternative
Biological Diversity	Not expected to have any effect on biological diversity.	Unchanged from No Action Alternative
<b>Human and Animal Health</b>		
Risk to Human Health	Glycoalkaloids and patatins would continue to pose a risk to human health. In the case of humans consuming high-temperature cooked potatoes, they would continue to be exposed to acrylamide.	Glycoalkaloid and patatin exposure would continue. For humans consuming high-temperature cooked potatoes, acrylamide levels would be reduced approximately 60-70%, which will benefit human health.
Risk to Animal Feed	Glycoalkaloids would continue to pose a risk to livestock if potato stems and foliage are fed to them, which is not likely.	Unchanged from No Action Alternative
<b>Socioeconomic</b>		
Domestic and Economic Environment	Most potato production is used for food. Market utilization would likely continue as it is currently.	Because of its potential human health benefits (lower acrylamide) and potential reduced wastage (low bruising), Innate™ potato may comprise a larger share of the domestic potato market, and may result in increased revenues.
Trade Economic Environment	U.S. potatoes and potato products will continue to play a role in global potato 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 Innate™ potato is anticipated to be similar to the No Action Alternative. However, import of each specific trait requires separate application and approval by the importing country. If the Innate™ traits are approved by importing countries, it may make up a larger percentage of potato import markets.
<b>Other Regulatory Approvals</b>	FDA completed consultations.	FDA approved the safety of Innate™ potato on March 20, 2015.
<b>Compliance with Other Laws</b>		
CWA, CAA, EOs	Fully compliant	Fully compliant

## Finding of No Significant Impact

Based on the analysis of impacts in the existing Innate™ potato EA (USDA-APHIS, 2014) and the similarity of new Innate™ V11 potato to the antecedent potatoes analyzed therein, a determination of nonregulated status of V11 potato 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 potato production systems, including surrounding environments and agricultural workers; human food and animal feed production systems; and foreign and domestic commodity markets.

Total acres of potatoes harvested in 2012, 2013 and 2014 were 1.13, 1.05 and 1.07 million acres, respectively (USDA-ERS, 2014; USDA-NASS, 2014a). Potatoes contribute approximately 15 % of farm sales receipts for vegetables, making potatoes the leading vegetable crop in the U.S. (USDA-ERS, 2012). The total value of U.S. potato production in 2012 was \$3.9 billion, the average yield was 409 centum weight (cwt)/acre (centum weight = 100 pounds) and the average price received was \$7.26/cwt (USDA-NASS, 2012). Potato acres harvested in the U.S. have declined over recent years, while total production has increased. Per-acre yields, which averaged 397 cwt/acre in 2011 and 401 cwt/acre in 2012 increased eight-fold since the early 1900s and doubled since the early 1960s (USDA-NASS, 2013).

Potatoes are grown throughout most of the continental United States. Six states (Idaho, Washington, Wisconsin, North Dakota, Oregon, and Colorado) account for approximately 73% of annual production (USDA-NASS, 2014b; 2014a). In recent years, land devoted to potato production has shifted from the East and Midwest to the Pacific Northwest. This shift has resulted from a number of factors, including improvements in the U.S. transportation system, the relative decline in consumption of fresh potatoes, advantages associated with processing potatoes in the Northwest such as lower taxes, lower power and labor costs, more favorable weather, and availability of arable land. The average American consumes about 115 lb of potato annually, of which about two-thirds is consumed as processed potato products (USDA-ERS, 2010).

After China, India, Russia, and the Ukraine, the U.S. is the fifth largest potato producing country (FAO, 2013; Zaheer and Akhtar, 2014), with annual production over the last three years of between 404-467 million centum weight (cwt), grown on 1.0-1.1M acres. In 2011, the United States produced approximately 5% of the total world supply of potato (NPC, 2012; Council, 2013). Major importers of U.S. potatoes are Canada, Mexico, Japan, South Korea, Malaysia and China (NPC, 2012; Council, 2013). U.S. exports of potatoes and potato products have grown 133% in value and 79% in volume during the last 10 marketing years (Board, 2013). Frozen potato products comprise 60% of the U.S. potato exports. During the 2012/ 2013 market year (September-August), U.S exports of potatoes and potato products totaled \$1.6 billion--up from \$1.4 billion in the previous market year (USDA-ERS, 2013). Exports to target markets were led by an increase in shipments to Mexico, South Korea, Malaysia, and Vietnam. During the 2012/ 2013 market year, Canada was the largest market for chips while Japan was the largest market for frozen potato products and dried, flour, and meal potato products (Board, 2012; USDA-ERS, 2013). Mexico provides the U.S. with the largest market for exporting potato flakes and granules and is the second largest market destination for frozen potatoes (Board, 2012; USDA-ERS, 2013).

A determination of nonregulated status of V11 potato is not expected to directly cause an increase in agricultural acreage devoted to potato production. The availability of V11 potato will not change cultivation areas for potato production in the U.S. and there are no anticipated changes to the availability other potato varieties on the market.

*Intensity* – Intensity is a measure of the degree or severity of an impact based upon the ten

factors. The following factors were used as a basis for this decision:

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

A determination of nonregulated status of V11 potato will have no significant environmental impact in relation to the availability of GE, conventional, organic or specialty potato varieties. Based on the discussions in Chapter 4 of the Innate™ potato EA (USDA-APHIS, 2014) and the similarity between V11 potato and Innate™ potato, an extension of nonregulated status to V11 potato is not expected to directly cause an increase in agricultural acreage devoted to potato production, or those potato acres devoted to GE potato cultivation. The availability of V11 potato will not change cultivation areas for potato production in the U.S. and there are no anticipated changes to the availability of GE and non-GE potato varieties on the market. Extending nonregulated status of V11 potato could add another GE potato variety to the conventional potato market and is not expected to change the market demands for GE potato or potato produced using organic methods or specialty systems.

Based on data provided by Simplot for V11 potato (Simplot, 2015), APHIS has concluded that the availability of V11 potato would not alter the agronomic practices, locations, and seed production and quality characteristics of conventional and GE potato seed production. A determination of nonregulated status of V11 potato will not require a change to seed production practices, nor current production practices.

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

A determination of nonregulated status of V11 potato would have no significant impacts on human or animal health. As discussed in Chapter 4 of the previously prepared Innate™ potato EA (USDA-APHIS, 2014) similar products were no longer subject to the plant pest provisions of the PPA and 7 CFR part 340 beginning in 1996 with the introduction of *Bt* products. In each case, FDA and EPA reviews and approvals determined that the products met the agency's review criteria for approval. The cultivation of these existing crop products would not change under either alternative. Both characteristics have been successfully cultivated in multiple crops in the ensuing years with no evidence of human health impacts.

Public health concerns associated with the use of GE potato, such as V11 potato, and GE potato products focus primarily on human and animal (livestock) consumption of GE food and feed commodities.

Non-GE potato 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 U.S. for human food or animal feed safety prior to release in the market. Under 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 V11 potato 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 (EFSA) and the Australia and New Zealand Food Standards Agency (ANZFS). Simplot provided the FDA with information on the identity, function, and characterization of the genes for V11 potato, including expression of the gene products, on July 10, 2015. The FDA is currently reviewing Simplot's submission.

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

There are no unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas that would be adversely impacted by a determination of nonregulated status of V11 potato. Similar to the antecedent potatoes, 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 V11 potato. The product will be deployed on agricultural land currently suitable for production of potato, will replace existing varieties, and is not expected to increase the acreage of potato production. This action would not convert land to nonagricultural use and therefore would have no adverse impact on prime farm land. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to V11 potato, including the use of EPA registered pesticides. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate potential impacts to the human environment. In the event of a determination of nonregulated status of V11 potato, 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 potato 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 of V11 potato are not highly controversial. Although there is some opposition to a determination of nonregulated status of V11 potato, 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 Innate™ potato EA (USDA-APHIS, 2014), a determination of nonregulated status is not expected to directly cause an increase in agricultural acreage devoted to potato production, or those acres devoted to GE potato cultivation. The availability of V11 potato will not change cultivation areas for potato production in the U.S., and there are no anticipated changes to the availability of potato varieties on the market. A determination of nonregulated status of V11 potato could add another potato variety to the potato market and is not expected to change the market demands for potatoes produced using organic methods. A determination of nonregulated status of V11 potato will not result in changes in the current practices of planting, tillage, fertilizer application/use, cultivation, pesticide application use/volunteer control. Management practices and seed standards for production of certified potato seed would not change. The effect of V11 potato on wildlife or biodiversity is not different than that of crops currently used in agriculture, or other potato produced in conventional agriculture in the U.S.

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 Innate™ potato EA (USDA-APHIS, 2014) and its similarity to V11 potato, the possible impacts on the human environment from a determination of nonregulated status of V11 potato 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 Innate™ potato EA (USDA-APHIS, 2014), a determination of nonregulated status of V11 potato is not expected to directly cause an increase in agricultural acreage devoted to potato, or those acres devoted to GE potato cultivation. A determination of nonregulated status of V11 potato will not result in changes in the current practices of planting, tillage, fertilizer application/use, and volunteer control. Management practices and seed standards for production of certified potato seed would not change. The effect of V11 potato on wildlife or biodiversity is no different than that from other crops currently used in agriculture, or other potato produced in conventional agriculture in the U.S. As described in Chapter 2 of the Innate™ potato EA (USDA-APHIS, 2014) well established management practices, production controls, and production practices (GE, conventional, and organic) are currently being used in potato production systems (commercial and seed production) in the U.S. Therefore, it is reasonable to assume that farmers, who produce conventional potato varieties, V11 potato, or produce potato using organic methods, will continue to use these reasonable, commonly accepted best management practices for their chosen systems and varieties during agricultural potato production. Based upon historic trends, conventional production practices that use GE varieties will likely continue to

dominate in terms of acreage with or without a determination of nonregulated status of V11 potato.

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 V11 potato 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. Under the authority of the plant pest provisions of the PPA and 7 CFR part 340, APHIS has issued regulations for the safe development and use of GE organisms. As required by 7 CFR 340.6, APHIS must respond to petitioners who request a determination of the regulated status of GE organisms, including GE plants such as V11 potato. When a request for an extension of nonregulated status is submitted, APHIS must make a determination if the GE organism is similar to the antecedent potatoes, which has previously been determined to be unlikely to pose a plant pest risk. If APHIS determines, based on its Plant Pest Risk Assessment of the antecedent organism, that the genetically engineered organism identified in the extension request is unlikely to pose a plant pest risk, the genetically engineered organism is no longer subject to the plant pest provisions of the PPA and 7 CFR part 340. As required by 7 CFR 340.6, APHIS must respond to petitioners who request a determination of the regulated status of GE organisms, including GE plants such as V11 potato. When a petition for nonregulated status is submitted, APHIS must make a determination if the GE organism is unlikely to pose a plant pest risk. If APHIS determines based on its PPRA that the genetically engineered organism is unlikely to pose a plant pest risk, the genetically engineered organism is no longer subject to the plant pest provisions of the PPA and 7 CFR part 340. APHIS regulations at 7 CFR part 340, which were promulgated pursuant to authority granted by the PPA, as amended (7 United States Code(U.S.C.) 7701-7772), regulate the introduction (importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is no longer subject to the plant pest provisions of the PPA or to the regulatory requirements of 7 CFR part 340 when APHIS determines that it is unlikely to pose a plant pest risk. A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation (7 CFR 340.2) and is also considered a plant pest. A GE organism is also regulated under Part 340 when APHIS has reason to believe that the GE organism may be a plant pest or APHIS does not have enough information to determine if the GE organism is unlikely to pose a plant pest risk. A person may petition the agency that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, is no longer regulated under the plant pest provisions of the PPA and the regulations at 7 CFR part 340. The petitioner is required to provide information under §340.6(c) (57 FR 22984) 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 person may also request that APHIS extend a determination of nonregulated status to other organisms under §340.6(e)(2). 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 regulatory requirements of 7 CFR part 340 or the plant pest provisions of the PPA when APHIS determines that it is unlikely to pose a plant pest risk.

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

Based on the similarity of the antecedent potatoes to V11 potato, no significant cumulative impacts were identified through this assessment. The Innate™ potato EA (USDA-APHIS, 2014) discussed cumulative impacts on potato management practices, human and animal health, and the environment and concluded that such impacts were not significant. A cumulative impacts analysis is included for each environmental issue analyzed in Chapter 4 of the Innate™ potato EA (USDA-APHIS, 2014). In the event APHIS reaches a determination of nonregulated status of V11 Potato, APHIS would no longer have regulatory authority over this potato. In the event of a determination of nonregulated status of V11 potato, APHIS has not identified any significant impact on the environment which may result from the incremental impact of a determination of nonregulated status of V11 potato 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 potatoes to V11 potato, a determination of nonregulated status of V11 potato 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 V11 potato 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 V11 potato. 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 V11 potato is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected under the National Historic Preservation Act (NHPA). 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. For example, for V11 potato, there is potential

for audible impacts on the use and enjoyment of a historic property when common agricultural practices, such as the operation of tractors and other mechanical equipment, are conducted close to such sites. A built-in mitigating factor for this issue is that virtually all of the methods involved would only have temporary impacts 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 impacts. Additionally, these cultivation practices are already being conducted throughout the potato production regions. The cultivation of V11 potato does not inherently change any of these agronomic practices so as to give rise to an impact under the NHPA.

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

Biotechnology Regulatory Services (BRS) regulates the introduction (importation, interstate movement, and release into the environment) of genetically engineered (GE) organisms that are or may be plant pests. BRS considers the effects on wildlife including ESA-listed species as well as migratory birds and their habitat prior to authorizing releases of regulated articles (organisms) into the environment and making determinations on petitions for non-regulated status.

As described in Chapter 6 of the Innate™ potato EA (USDA-APHIS, 2014), APHIS has analyzed the potential for effects from a determination of nonregulated status of the antecedent potatoes on federally listed threatened and endangered species (TES) and species proposed for listing, as well as designated critical habitat and habitat proposed for designation, as required under Section 7 of the Endangered Species Act. After reviewing possible effects of a determination of nonregulated status of V11 potato, APHIS has determined that a determination of nonregulated status of V11 potato would have no effect on Federally listed TES and species proposed for listing, or on designated critical habitat or habitat proposed for designation. As with the antecedent potatoes, APHIS has not identified any stressor that would affect the reproduction, numbers or distribution of any threatened or endangered species or affect their critical habitat.

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 V11 potato is unlikely to pose a plant pest risk, a determination of nonregulated status of V11 potato 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 the previously de-regulated 10 events (E12, E24, F10, F37, J3, J55, J78, G11, H37, and H50), as well as input from the public involvement process. Based on APHIS' conclusion that V11 potato encompasses the same scope of environmental analysis and regulatory decision as the antecedent potatoes, which previously received a determination of nonregulated status under 7 CFR part 340, I believe the issues identified and analyzed in the existing NEPA documentation for the antecedent potatoes are relevant to V11 potato, and have determined that the best regulatory action is to extend a determination of nonregulated status to V11 potato. This regulatory action meets APHIS' purpose and need to allow the safe development and use of genetically engineered organisms consistent with the plant pest provisions of the PPA and under 7 CFR 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 V11 potato) 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 2 is selected because (51 FR 23302) it allows APHIS to fulfill its statutory mission to protect America's agriculture and environment using science-based regulatory framework that allows for the safe development and use of genetically engineered organisms; and (2) it allows APHIS to fulfill its regulatory obligations. As APHIS has not identified any plant pest risks associated with V11 potato, the continued regulated status of V11 potato 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 V11 potato will not have any significant environmental impacts.

  
for Michael Firko, Ph.D.

1/13/2016

Date

APHIS Deputy Administrator  
Biotechnology Regulatory Services  
Animal and Plant Health Inspection Service  
U.S. Department of Agriculture

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