NATIONAL ENVIRONMENTAL POLICY ACT DECISION

AND

FINDING OF NO SIGNIFICANT IMPACT

J.R. Simplot Company

X17 and Y9 Potatoes with Late Blight Resistance, Low Acrylamide Potential, Lowered Reduced Sugars, and Reduced Black Spot (16-064-01p)

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.

J.R Simplot Company submitted a request on March 3, 2016, for extension of a determination of nonregulated status (16-064-01p) under 7 CFR 340 for two genetically engineered (GE) potatoes, Ranger Russet variety event SPS-00X17-5 (X17 potato) and Atlantic SPS-000Y9-7 (Y9 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 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 Simplot (16-064-01p) (Simplot, 2016) and has concluded that X17 and Y9 potatoes are similar to the antecedent event Simplot Innate^{TM} W8 Russet Burbank potato (herein after referred to as W8 potato) in the 14-093-01p petition, and therefore, that X17 and Y9 potatoes are 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 antecedent W8 potato in 2015 (80 FR 53101-53102, 2015); this FONSI for X17 and Y9 potatoes is based on

the EA prepared for the W8 potato. APHIS carefully examined the NEPA documentation completed for W8 potato, including comments received from the public involvement process and concluded that the Simplot extension request for a determination of nonregulated status for X17 and Y9 potatoes encompasses the same scope of environmental analysis and regulatory decision as W8 potato. This conclusion is based on:

- X17 and Y9 potatoes expresses the same phenotype and traits, as well as the conclusions of the molecular, agronomic, phenotypic, and compositional assessments as the antecedent potato.
- Similarly to the antecedent W8 potato, X17 and Y9 potatoes were also developed as retransformations of the previously deregulated events F10 (Ranger Russet), and J3 (Atlantic) (13-022-01p) potato varieties;
- X17 and Y9 potatoes were developed using the same DNA and *Agrobacterium-mediated* transformation method that was used for W8 potato (Russet Burbank) with pSIM1278 and retransformation with pSIM1678; introducing two traits (*Vlnv, Rpi-vnt1*) that promote late blight resistance and lowered reducing sugars
- X17 and Y9 potatoes do not exhibit any additional traits beyond what is expressed in the antecedent potato;
- the extension request for X17 and Y9 potatoes encompasses the same regulatory action as the antecedent W8 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 W8 potato is applicable to the extension request of X17 and Y9 potatoes;
- 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 W8 potato, including the proposed action or analysis of impacts in the EA; and

Based on the similarity of X17 and Y9 potatoes to the antecedent organism W8 potato, the existing NEPA documentation completed for W8 potato 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 pursuant to 7 CFR part 340 for X17 and Y9 potatoes.

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 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 should focus on the characteristics and risks of the biotechnology product, not the process by which it is created; and, (3) agencies should exercise oversight of biotechnology products only when there is evidence of "unreasonable" risk.

APHIS' authority to regulate GE organisms 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 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, 1992). 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. An experimental use permit (EUP) extension request (8917-EUP-2) was submitted by Simplot to EPA in July 2015; issued December 2015; and will expire in April 2017 (Simplot, 2016). Also, a registration for commercial planting and request for permanent tolerance exemption for the trait VNT1 (8917-R, 8917-E, and 8917-G) was submitted to EPA in November 2015, and is pending EPA decision (Simplot, 2016).

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.

Simplot submitted an extension request (16-064-01p) to APHIS seeking a determination that X17 and Y9 potatoes are unlikely to pose a plant pest risk and, therefore, should no longer be regulated articles pursuant to regulations at 7 CFR part 340. APHIS reviewed and analyzed the information submitted in the extension request by Simplot and has concluded that X17 and Y9 potatoes are similar to the antecedent organism W8 potato and therefore, based on the Plant Pest Risk Similarity Assessment (PPRSA)(USDA-APHIS, 2016), APHIS has concluded that X17 and Y9 potatoes are unlikely to pose a plant pest risk.

X17 and Y9 potatoes

Similar to the antecedent W8 potato, Simplot has developed X17 and Y9 potatoes as retransformations of previously deregulated potato events F10 (Ranger Russet) and J3 (Atlantic) (13-022-01p), respectively. The retransformation introduces late blight resistance and invertase down-regulation in addition to the quality traits of reduced black spot and lower reducing sugars, and the benefit of lower acrylamide potential (Simplot, 2016). The T-DNA inserts for X17 and Y9 potatoes are pSIM1278 and pSIM 1678. The pSIM1278 insert is maintained in X17 and Y9 potatoes, as well as in the previously deregulated Simplot potato events F10 and J3 potatoes (13-022-01p); containing a single copy of the pSIM1678 insert (Simplot, 2016). Similar to W8 potato, X17 and Y9 potatoes were generated by *agrobacterium*-

mediated transformation with pSIM1278 and retransformation with pSIM1678; demonstrating similarity for trait mechanism-of-action in the same crop (Simplot, 2016). Incorporation of these traits is most efficiently accomplished through the transformation of each potato variety of interest (introducing partial or full-length potato gene sequences); such as Ranger Russet and Atlantic, which are important for the processing and chipping industries (Simplot, 2016).

Similarly, the antecedent W8 and X17 and Y9 potatoes, all contain a DNA insert from plasmid pSIM1278 designed to silence four different potato genes: asparagine synthetase-1 (*Asn1*), polyphenol oxidase-5 (*Ppo5*), potato phosphorylase-L (*PhL*) and water-dikinase (*R1*) (Simplot, 2016). The suppression of *Asn*1 is anticipated to result in potatoes with reduced free asparagine contributing to low acrylamide potential, the suppression of *PhL* and *R1* is anticipated to result in potatoes with a lower content of reducing sugars, and *Ppo5* for reduced black spot. The T-DNA from pSIM1678 was designed to down-regulate the potato vacuolar invertase gene (*Vlnv*) through RNAi and express the *Rpi-vnt1* gene: *Vlnv* for lower reducing sugars contributing to low acrylamide potential and modified storage conditions, and *Rpi-vnt1* (resistance against *Phytophthora infestans* from *Solanum venturii*) for late blight resistance (Simplot, 2016). The VNT1 protein has a non-toxic mode of action against the target pest and signals the programmed death of pathogen-infected plant cells limiting spread of the disease (Simplot, 2016). The Genetic traits *Asn1, R1, PhL,* and *Pp05* were previously deregulated in the 13-022-01p, 15-140-01p, and 14-093-01p petitions (USDA-APHIS, 2014a; 2015a; 2015b; Simplot, 2016); whereas the *Rpi-vnt1*, and *vlnv* genes were both previously deregulated in the 14-093-01p petition (USDA-APHIS, 2015a; Simplot, 2016). The gene targets of these six silencing constructs have been well-studied in potato and/or other plant species (USDA-APHIS, 2014b; 2015c; 2015b).

The purpose and need for developing potatoes with late blight resistance, low acrylamide potential, lowered reduced sugars, and reduced black spot is to potentially lower costs associated with disease management, handling and processing, and storage. Decreased levels of both reducing sugars and asparagine contribute to lowering the amount of acrylamide formed in cooked potato products (Shepherd *et al.*, 2010). Reduced asparagine and sugar levels in X17 and Y9 potatoes resulted in approximately 70% reductions in the amount of acrylamide formed in fries and chips compared to control varieties (Simplot, 2016). Late blight is caused by the oomycete *P. infestans* and resulted in the Irish Potato Famine in the mid-1800s. Fungicides are used to prevent disease, however, over reliance can drive adaptation of the pathogen and lead to fungicide-resistant strains of *P. infestans* (Deahl et al., 1993; Daayf and Platt, 2003; Fry et al., 2015).

As disease pressure increases and frequent fungicide applications are needed, reliance of fungicides may become unsustainable. X17 and Y9 potatoes are currently targeted for the potato processing industry, producers, and potato consumers, and are expected to enhance quality by reducing the severity of black spot in potatoes; providing growers with another tool to use in conjunction with fungicide and crop rotation as part of an integrated pest management

strategy (Simplot, 2016). If X17 and Y9 potatoes are grown commercially in the United States, they would be subject to all U.S. EPA commercial planting registration requirements.

Field trials of X17 and Y9 potatoes have been conducted in the United States since 2012. X17 has been grown in eight states (Idaho, Washington, Pennsylvania, North Dakota, Michigan, Oregon, Wisconsin, and Nebraska) and Y9 has been grown in twelve states: (Idaho, Pennsylvania, Washington, North Dakota, Michigan, Maine, Oregon, Texas, New York, Nebraska, Wisconsin, and North Carolina). Data resulting from these field trials are described in the request for extension (Simplot, 2016).

Coordinated Framework Review

Food and Drug Administration

X17 and Y9 potatoes are within the scope of the 1992 FDA's policy statement concerning regulation of products derived from new plant varieties, including those developed through biotechnology (US-FDA, 1992),and its 2013 policy statement concerning regulation of products that reduce acrylamide levels in food products (US-FDA, 2013). 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" 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 (US-FDA, 2006). 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.

A voluntary safety and nutritional assessment of X17 and Y9 will be submitted to the FDA's Center for Food Safety and Applied Nutrition (CFSAN) for a review of details specific to compositional analyses as a component of the food and feed safety of X17 and Y9 potatoes (Simplot, 2016). 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 the antecedent W8 potato as well as X17 and Y9 potatoes and the foods and feeds obtained from these events are as safe as conventional potato varieties, and with the exception that the GE varieties underwent transformation and retransformation and contain pSIM 1278, and pSIM1678 inserts, they are not materially different in composition or any other relevant parameter from other potato varieties now grown, marketed, and consumed in the United States.

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 described in Subsection 2.4, Human Health, under FIFRA, all pesticides (including herbicides) sold or distributed in the United States must be registered by the EPA (US-EPA, 2016). 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, 2016). 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, 2016).

The EPA regulates plant-incorporated protectants (PIPs) under FIFRA and certain biological control organisms under 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.

Scope of the Environmental Analysis

Based on its similarity to the antecedent organism W8 potato in the 14-093-01p petition, APHIS has concluded that the Simplot extension request for a determination on the regulated status for X17 and Y9 potatoes encompasses the same scope of environmental analysis as the antecedent potato. APHIS reviewed and analyzed the information submitted in the extension request (16-064-01p) by Simplot (Simplot, 2016) and has concluded that X17 and Y9 potatoes are similar to the antecedent potato W8, and, therefore, based on its PPRA for W8 potato (USDA-APHIS, 2015c), APHIS has concluded that X17 and Y9 potatoes are unlikely to pose a plant pest risk (USDA-APHIS, 2015c). Although a determination of nonregulated status under 7 CFR 340 for X17 and Y9 potatoes would allow for new plantings of X17 and Y9 potatoes anywhere in the United States, 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 United States. In 2015, 59 percent of potato production was produced in the states of Idaho (30%), Washington (23%), Wisconsin (6%) (USDA-ERS, 2016b).

Public Involvement

APHIS is not aware of any substantive new information that would warrant alteration of the existing NEPA documentation for W8 potato including the proposed action or analysis of impacts in the EA since the completion of the public involvement process for W8 potato. APHIS has not received any new or additional information or comments from the public specifically directed at the antecedent W8 potato, PPRA or NEPA documentation since a determination of non-regulated status was announced on September 2, 2015 (80 FR 53101-53102, 2015).

On September 23, 2016 APHIS published a notice in the Federal Register (81 FR 65622-65623, Docket no. APHIS-2016-0057) announcing the availability of the draft Simplot X17 and Y9 potatoes' Extension Request for the Finding of No Significant Impact (FONSI) for a 30-day public review and comment period. To be considered, comments must have been received on or before October 24, 2016. All comments were carefully reviewed, and analyzed to identify any new issues, alternatives, or information. A total of 6 comments were received subsequent to the preliminary FONSI publication. Five public comments supported the determination of nonregulated status, and one public comment did not support the determination of nonregulated status. The public comment that opposed the determination of nonregulated status for X17 and Y9 potatoes, did not specify a specific issue of concern, and therefore was determined to be inadequate in supporting evidence for the commenter's claim.

There was no substantial information that was received that would warrant substantial changes to APHIS' analysis or determination. Comment documents may be viewed at: https://www.regulations.gov/document?D=APHIS-2016-0057-0001

As part of the public process for this request, APHIS will publish a notice in the Federal Register announcing its preliminary regulatory determination and the availability of the draft PPRSA, preliminary FONSI, and preliminary determination for a 30-day public review period. If no substantive information is 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 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 Simplot extension request for a determination of nonregulated status pursuant to 7 CFR part 340 of X17 and Y9 potatoes encompasses the same scope of environmental analysis as the antecedent potato. APHIS is not aware of any substantive new issues that may impact the human environment associated with X17 and Y9 potatoes that were not considered in the previous NEPA analysis completed for a determination on the regulated status of a petition request for the antecedent potato. The potential impacts of potatoes with

late blight resistance, low acrylamide potential, lowered sugars, and reduced black spot bruising on the agricultural production of potato, 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 W8 potato. Therefore, APHIS is using the same issues identified and analyzed in the existing NEPA documentation for W8 potato 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 X17 and Y9 potatoes.

The issues considered in the analysis of W8 potato, 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 W8 potato. 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 potato using various production methods, and the environmental food/feed safety of GE plants were analyzed to determine the potential environmental impacts of X17 and Y9 potatoes.

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 the antecedent event W8 potato. 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 Potatoes
- Domestic Commerce
- Organic Potato 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 Simplot extension request for a determination of nonregulated status of X17 and Y9 potatoes encompasses the same scope of environmental analysis and regulatory decision as the antecedent potato; 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 Simplot (Simplot, 2016), and has concluded that X17 and Y9 potatoes are similar to W8 potato, and therefore, based on its PPRA for W8 potato, APHIS has concluded that X17 and Y9 potatoes are unlikely to pose a plant pest risk (USDA-APHIS, 2015c). The comparison of characteristics of X17 and Y9 potatoes to the antecedent W8 potato, indicates that the phenotype and traits of X17 and Y9 and the antecedent W8 potato are the same, as are the conclusions of the molecular, agronomic, phenotypic, and compositional assessments; and X17 and Y9 potatoes do not exhibit any additional traits beyond what is expressed in the antecedent potato (Simplot, 2016). Therefore, the proposed action identified in the existing NEPA documentation completed for the antecedent W8 potato is being used to evaluate APHIS' action associated with a determination of nonregulated status of X17 and Y9 potatoes.

Based on the similarity to the antecedent W8 potato, APHIS has concluded that all the alternatives identified in the EA for W8 potato to be relevant to APHIS' regulatory actions associated with X17 and Y9 potatoes, 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 X17 and Y9 potatoes that were not considered in the previous NEPA analysis for W8 potato. Therefore, APHIS is using the same alternatives, including the proposed action, identified and analyzed in the existing NEPA documentation completed for the antecedent potato to evaluate and determine if there are any potentially significant impacts to the human environment from a determination of nonregulated status of X17 and Y9 potatoes.

Alternatives described in the existing EA for Simplot W8 potato

The EA analyzes the potential environmental consequences of a determination of nonregulated status of W8 potato. To respond favorably to a petition for nonregulated status, APHIS must determine that W8 potato is unlikely to pose a plant pest risk. Based on its PPRA (USDA-APHIS, 2015c). APHIS has concluded that W8 potato is unlikely to pose a plant pest risk. Therefore, APHIS must determine that W8 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 W8 potato, 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. W8 potato and progeny derived from W8 potato 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 W8 potatoes, 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 W8 potato.

This alternative is not the preferred alternative because APHIS has concluded through a PPRA that W8 potato is unlikely to pose a plant pest risk (USDA-APHIS, 2015c) 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 W8 potato is No Longer a Regulated Article

Under this alternative, W8 potato and progeny derived from it would no longer be regulated articles pursuant to the regulations at 7 CFR part 340. W8 potato is unlikely to pose a plant pest risk (USDA-APHIS, 2015c). Authorizations issued by APHIS would no longer be required for introductions of W8 potato and progeny derived from these events.

The Preferred Alternative, (i.e., a determination of nonregulated status of W8 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. Because the agency has concluded that W8 potato is unlikely to pose a plant pest risk, a determination of nonregulated status of W8 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 W8 potato. 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 W8 potato. 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 W8 potato

APHIS considered prohibiting the release of W8 potato, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that W8 potato is unlikely to pose a plant health risk (USDA-APHIS, 2015c).

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, 2015c) and the scientific data evaluated therein, APHIS concluded that W8 potato is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of Simplot potato event W8 potato.

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 the event W8 potato is unlikely to pose as a plant pest risk (USDA-APHIS, 2015c) 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 W8 potato event and Non-GE Potato Production and Geographical Restrictions

Because APHIS has concluded that the antecedent event W8 potato is unlikely to pose a plant pest risk (USDA-APHIS, 2015c), 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 W8 potato from conventional or specialty potato production. APHIS also considered geographically restricting the production of W8 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 W8 potato, there are no geographic differences associated with any identifiable plant pest risks for W8 potato (USDA-APHIS, 2015c). This alternative was rejected and not analyzed in detail because APHIS has concluded that W8 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 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 W8 potato or to use isolation distances and other management practices to minimize gene movement between potato fields. Information to assist growers in making informed management decisions for W8 potato is available from the Association of Official Seed Certifying Agencies (AOSCA, 2016).

4. Requirement of Testing for W8 potato

During the comment periods for other petitions for nonregulated status, some commenters requested that USDA require and provide testing for the presence of 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 W8 potato does not pose a plant pest risk (USDA-APHIS, 2015c), 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 W8 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 event W8 potato to X17 and Y9 potatoes (USDA-APHIS, 2016), APHIS has concluded that the previous analysis of impacts completed for W8 potato is relevant to APHIS' regulatory actions associated with responding to the Simplot extension request for X17 and Y9 potatoes. The potential impacts of X17 and Y9 potatoes 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 W8 potato and is therefore being used in its entirety to evaluate APHIS' action associated with a determination of nonregulated status of X17 and Y9 potatoes. The EA for W8 potato (USDA-APHIS, 2015a) contains a full analysis of the alternatives to which we refer the reader for specific details. The following table briefly summarizes the results for each of the issues fully analyzed in the Environmental Consequences section of the EA.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Meets Purpose and Need and Objectives	**No**	**Yes**
Unlikely to pose a plant pest risk	Satisfied through use of regulated field trials	Satisfied—risk assessment (USDA-APHIS, 2015c)
Management Practices		
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 United States for the foreseeable future.	Total acreage dedicated to potato is unlikely to change, but adoption of W8 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.
Environment		

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. Water usage for irrigation would be expected to continue to increase.	Unchanged from No Action Alternative.
Soil Quality	Agronomic practices such as crop type, tillage, and pest management can affect soil quality. Growers will adopt management practices to address their specific needs in producing 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 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.
Animals and Plants		
Animal Communities	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 W8 tubers may be exposed to increased levels of glutamine, but this is not expected to be detrimental.

Plant communities	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 Simplot W8 potato with conventional varieties, resulting progeny may contain lowered polyphenol oxidase levels. However, this is not expected to be detrimental. Simplot W8 potato is no weedier than conventional potatoes.
Gene Flow	Since potato is primarily vegetatively propagated, gene flow between cultivars is low. Volunteer potatoes would continue to need to be controlled, although their survival is low.	Simplot W8 potato traits are not expected to increase weediness in potatoes.
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	The biological diversity in potato fields is lower than in the surrounding habitats.	Unchanged from No Action Alternative
Human and Animal Health		
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 could 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.
Socioeconomic		
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, late blight resistance), Simplot W8 potato may comprise a larger share of the domestic potato market, and may result in increased revenues.
Trade Economic Environment	United States potatoes and potato products will continue to play a role in global potato production, and the United States will continue to be a supplier in the international market.	The foreign trade impacts associated with a determination of nonregulated status of Simplot W8 potatoes 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. If the Simplot W8 traits are approved by importing countries, it may make up a larger percentage of potato import markets.
Other Regulatory Approvals	FDA completed consultations, EPA tolerance exemptions and conditional pesticide registrations granted	FDA completed consultation on March 12, 2015 and concluded that Innate^{TM} potato varieties (which includes W8 potato), are safe for consumption (US-FDA, 2015b; 2015a; 2015c).

Other Countries	Countries importing potatoes would continue to do so.	Simplot would need to obtain regulatory approvals from any nations which plan to import Simplot W8 potato.
Compliance with Other Laws		
CWA, CAA, EOs	Fully compliant	Fully compliant

Finding of No Significant Impact

Based on the analysis of impacts in the Final EA for Simplot W8 potato (USDA-APHIS, 2015a) and the similarity of X17 and Y9 potatoes to W8 potato, a determination of nonregulated status pursuant to 7 CFR 340 of X17 and Y9 potatoes 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 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, 2013 and 2014, 2015 were 1.05, 1.07, and 1.06 million acres, respectively (USDA-NASS, 2015b; USDA-ERS, 2016b). Potatoes contribute approximately one third of farm sales receipts for vegetables, making potatoes the leading vegetable crop in the United States (USDA-ERS, 2016b). Compared to 2014, the total value of United States potato production in 2015 fell 2% to $3.8 billion, the average yield was 440 centum weight (cwt)/acre (centum weight = 100 pounds) and the average price received was $9.40/cwt (USDA-NASS, 2015a; USDA-ERS, 2016b). Potato acres harvested in the United States have declined over recent years, while total production has increased. Per acre yields which averaged 443 cwt/acre in 2014 increased eight-fold since the early 1900s and doubled since the early 1960s (USDA-ERS, 2016b).

Potatoes are grown throughout most of the continental United States. Three states account for 59% of annual production: Idaho (30%), Washington (23%), and Wisconsin (6%) (USDA-NASS, 2015b; USDA-ERS, 2016b). 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 United States 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 pounds (lbs) of potato annually, of which about two-thirds is consumed as processed potato products (USDA-ERS, 2013).

After China, India, Russia, and the Ukraine, the United States is the fifth largest potato producing country (FAOSTAT, 2014; Zaheer and Akhtar, 2014),with annual production over the last three years of between 197– 209 million tons (388-413 million centum weight (cwt)), grown on 1.1M acres (FAOSTAT, 2014) . In 2013, the United States produced approximately 5% of the total world supply of potato (NPC, 2015). Major importers of United States potatoes are Canada, Mexico, Japan, South Korea, Malaysia and China (NPC, 2015). For 2013/14 U.S exports of potato products are estimated at 450 thousand metric tons; a 30% increase from 2010. Exports of frozen potatoes from the top 3 suppliers, at over 3.0 million metric tons, are up nearly 35% since 2010 (USDA-FAS, 2014). Frozen potato products comprise 60% of the United States potato exports (Potatoes, 2016). During market year (MY) 2013/2014 (July 2013-June 2014), U.S exports of potatoes and potato products totaled $1.76 billion and 1.6 million metric tons (NPC, 2015). Mexico provides the United States with the largest market for exporting chips and prepared/preserved (canned) products, while the bulk of imports from Germany and the Netherlands are starches and other dehydrated products (USDA-ERS, 2016b). Canada is the leading importer of United States fresh table stock and seed potatoes. Since 2011, Canadian imports of fresh and seed potatoes averaged approximately $79 million, while Mexico's imports averaged $24 million. Exports to Canada are expected to remain about the same, while Mexico's imports averaged $24 million. Exports to Canada are expected to remain about the same, while Mexico has limited potential because of restrictive phytosanitary regulations regarding U.S fresh and seed potatoes (USDA-ERS, 2016a). In MY 2014/2015, Japanese imports of fresh potatoes from the US reached 22,741 metric tons, an increase of 15% over MY 2013/2014 (USDA-FAS, 2015).

A determination of nonregulated status of X17 and Y9 potatoes are not expected to directly cause an increase in agricultural acreage devoted to potato production. The availability of X17 and Y9 potatoes will not change cultivation areas for potato production in the United States and there are no anticipated changes to the availability of GE and non-GE 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 pursuant to 7 CFR part 340 for X17 and Y9 potatoes 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 EA for W8 potato (USDA-APHIS, 2015a) and the similarity to the antecedent event W8 potato (USDA-APHIS, 2016), a determination of nonregulated status of events X17 and Y9 potatoes are 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 X17 and Y9 potatoes will not change cultivation areas for potato in the United States and there are no anticipated changes to the

availability of GE and non-GE potato varieties on the market. A determination of nonregulated status of X17 and Y9 potatoes could add another GE potato variety to the conventional potato market but is not expected to change the market demands for GE potato or potatoes produced using organic methods or specialty systems.

Based on data provided by Simplot for X17 and Y9 potatoes (Simplot, 2016), APHIS has concluded that the availability of X17 and Y9 potatoes 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 X17 and Y9 potatoes 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 X17 and Y9 potatoes would have no significant impacts on human or animal health. As discussed in Chapter 4 of the previously prepared W8 potato EA (USDA-APHIS, 2015a) 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. These 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 X17 and Y9 potatoes, 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 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 X17 and Y9 potatoes 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. Simplot plans to submit a voluntary safety and nutritional assessment of X17 and Y9 potatoes to the FDA Center for Food Safety and Applied Nutrition (Simplot, 2016).

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 X17 and Y9 Potatoes. Similar to the antecedent W8 potato, 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 X17 and Y9 potatoes. 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 with X17 and Y9 potatoes, 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 X17 and Y9 potatoes, 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 pursuant to 7 CFR part 340 of X17 and Y9 potatoes are not highly controversial. Although there is some opposition to a determination of nonregulated status of X17 and Y9 potatoes, this action is not highly controversial in terms of size, nature or impact on the natural or physical environment. As discussed in Chapter 4 of

the EA for W8 potato (USDA-APHIS, 2015a) a determination of nonregulated status is not expected to directly cause an increase in agricultural acreage devoted to potato production. The availability of X17 and Y9 potatoes will not change cultivation areas for potato production in the United States and there are no anticipated changes to the availability of potato varieties on the market. A determination of nonregulated status of X17 and Y9 potatoes 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 X17 and Y9 potatoes 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 impact of X17 and Y9 potatoes on wildlife or biodiversity is not different than that of other potato 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 W8 potato EA (USDA-APHIS, 2015a) and its similarity to W8 potato, the possible impacts on the human environment from a determination of nonregulated status pursuant to 7 CFR part 340 of X17 and Y9 potatoes 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 W8 potato EA (USDA-APHIS, 2015a), a determination of nonregulated status of X17 and Y9 potatoes is not expected to directly cause an increase in agricultural acreage devoted to potato cultivation. A determination of nonregulated status of X17 and Y9 potatoes will not result in changes in the current practices of planting, tillage, fertilizer application/use, cultivation, and pesticide application. Management practices and seed standards for production of certified potato seed would not change. The impact of X17 and Y9 potatoes 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 United States. As described in Chapter 2 of the W8 potato EA (USDA-APHIS, 2015a) well established management practices, production controls, and production practices (conventional, and organic) are currently being used in potato production systems (commercial and seed production) in the United States. Therefore, it is reasonable to assume that farmers, who produce conventional potato varieties, X17 and Y9 potatoes, 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 X17 and Y9 potatoes.

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 X17 and Y9 potatoes 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 W8 potato to X17 and Y9 potatoes, no significant cumulative impacts were identified. The W8 potato EA (USDA-APHIS, 2015a) reviewed 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 W8 potato EA (USDA-APHIS, 2015a). In the event APHIS reaches a determination of nonregulated status of X17 and Y9 potatoes, APHIS would no longer have regulatory authority over these potatoes. In the event of a determination of nonregulated status of X17 and Y9 potatoes, APHIS has not identified any significant impact on the environment which may result from the incremental impact of a determination of nonregulated status of X17 and Y9 potatoes 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 W8 potato to X17 and Y9 potatoes, a determination of nonregulated status pursuant to 7 CFR part 340 of X17 and Y9 potatoes 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 X17 and Y9 potatoes 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 X17 and Y9 potatoes.

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 X17 and Y9 potatoes 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 potato production regions. The cultivation of X17 and Y9 potatoes 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 W8 potato EA (USDA-APHIS, 2015a). APHIS has analyzed the potential for effects from a determination of nonregulated status pursuant to 7 CFR part 340 of W8 potato 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 X17 and Y9 potatoes, APHIS has determined that a determination of nonregulated status of X17 and Y9 potatoes 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.

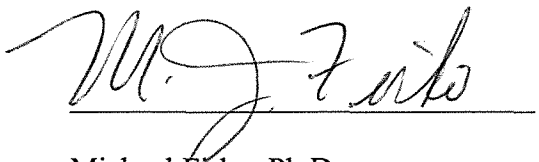
10. *Whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment.*

    The proposed action would be in compliance with all Federal, State, and local laws. Because the agency has concluded that X17 and Y9 potatoes are unlikely to pose a plant pest risk, a determination of nonregulated status of X17 and Y9 potatoes 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 W8 potato, including input from the public involvement process. Based on APHIS' conclusion that X17 and Y9 potatoes encompasses the same scope of environmental analysis and regulatory decision as W8 potato; 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 W8 potato are relevant to this regulatory action and best addressed by extending a determination of nonregulated status to X17 and Y9 potatoes. 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 X17 and Y9 potatoes) 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 X17 and Y9 potatoes, the continued regulated status of X17 and Y9 potatoes 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 X17 and Y9 potatoes will not have any significant environmental impacts.



10/28/2016

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Date

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