Final Extended Determination[1] of Nonregulated Status for JR Simplot Company X17 and Y9 Potato Varieties with Late Blight Resistance, Low Acrylamide Potential, Lowered Reducing Sugars, and Reduced Black Spot (Petition No. 16-064-01p)

In response to a request from JR Simplot Company (hereinafter referred to as JR Simplot) to extend a determination of nonregulated status to Ranger Russet SPS-ØØX17-5 (X17) and Atlantic SPS-ØØØY9-7 (Y9) potato events (hereinafter referred to as X17 and Y9 Potatoes) with late blight resistance, low acrylamide potential, lowered reducing sugars and reduced black spot (petition number 16-064-01p), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has determined, based on similarity to its antecedent organism that X17 and Y9 Potato varieties and progeny derived from them are unlikely to pose plant pest risks and are no longer to be considered regulated articles under APHIS' Biotechnology Regulations (Title 7 of Code of Federal Regulations (CFR), part 340). This extension request is based upon APHIS' determination of nonregulated status of its antecedent organism: JR Simplot's potato event, W8 Russet Burbank potatoes (hereinafter referred to as JR Simplot antecedent potato event), with late blight resistance, low acrylamide potential and reduced black spot and lower reducing sugars (Petition No.14-093-01p). JR Simplot antecedent potato event from petition number 14-093-01p was deregulated on September 2, 2015. APHIS approved permits or acknowledged notifications that were previously required for environmental release, interstate movement, or importation under those regulations will no longer be required for X17 and Y9 potatoes varieties and their progeny. Importation of X17 and Y9 potato seeds, other propagative material, and bulk or table stock, will still be subject to APHIS foreign quarantine notices at 7 CFR part 319 and the Federal Seed Act regulations at 7 CFR parts 201 and 361.

The same genetic constructs pSIM1278 and pSIM1678 were used to transform the JR Simplot antecedent potato event with late blight resistance low acrylamide potential, lowered reducing sugars and reduced black spot, was also used to transform and generate the X17 and Y9 potato events. APHIS evaluated the plant pest risk of X17 and Y9 potatoes by assessing its similarity to the deregulated JR Simplot antecedent potato event.

APHIS previously conducted a Plant Pest Risk Assessment on the antecedent organism and found them unlikely to pose risks as plant pests. Based on a the plant pest similarity assessment (see Appendix A) of X17 and Y9 potatoes to the antecedents, APHIS concludes that X17 and Y9 potatoes are unlikely to pose a plant pest risk and should no longer be regulated under 7 CFR part 340. From the similarity assessment, APHIS concludes the following with respect to X17 and Y9 potatoes and their progeny:

(1) No plant pest risk was identified from the transformation process, the insertion and/or expression of new genetic material, or from changes in metabolism in X17 and Y9 potatoes.

(2) Disease and pest incidence and/or damage are not expected to be increased or atypical

[1] This extended determination is not effective until officially signed and published.

for X17 and Y9 potatoes. No plant pest effects are expected on these or other agricultural products and no impacts are expected to APHIS pest control programs.

(3) Based on an evaluation of the gene products, and their similarity to the antecedent, X17 and Y9 potatoes are unlikely to adversely impact nontarget organisms beneficial to agriculture.

(4) X17 and Y9 potatoes are no more likely to become weedier or more difficult to control as a weed than the antecedents, which are not weedy.

(5) X17 and Y9 potatoes are not likely to increase the weed risk potential of other species with which they can interbreed in the U.S. or its territories. Gene flow, hybridization and/or introgression of inserted genes from X17 and Y9 potatoes to other sexually compatible relatives with which it can interbreed is not likely to occur.

(6) Significant changes to agricultural or cultivation practices (e.g. pesticide applications, tillage, irrigation, harvesting, etc.) from adoption of X17 and Y9 potatoes are not expected.

(7) Horizontal gene transfer of the new genetic material inserted into the GE plant to other organisms is highly unlikely, and is not expected to lead directly or indirectly to disease, damage, injury or harm to plants, including the creation of new or more virulent pests, pathogens, or parasitic plants.

In addition to our finding that X17 and Y9 potatoes are unlikely to pose a plant pest risk, APHIS prepared and reached a Finding of No Significant Impact (FONSI) for this action based on an Environmental Assessment completed for the antecedent W8 potatoes in 2015. X17 and Y9 potatoes will have no significant impacts, individually or collectively, on the quality of the human environment and will have no effect on federally listed threatened or endangered species, species proposed for listing, or their designated or proposed critical habitats (http://www.aphis.usda.gov/biotechnology/notreg.html).

Based on my review and consideration of all of the scientific and environmental data, analyses, information, and previous conclusions regarding the plant pest risk assessment for the antecedent organisms, the plant pest risk similarity assessment, and FONSI, and my knowledge and experience as APHIS' Deputy Administrator for Biotechnology Regulatory Services, I have determined and decided that this determination of nonregulated status of X17 and Y9 potatoes is the most scientifically sound and appropriate regulatory decision.

M. J. Firko

Michael J. Firko, Ph.D.
APHIS Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture

Date 10/28/2016

Appendix A

J.R. Simplot Company Request (16-064-01p) for Extension of Determination of Non-regulated Status of X17 Ranger Russet and Y9 Atlantic Potatoes with Late Blight Resistance, Low Acrylamide Potential, Lowered Reducing Sugars, and Reduced Black Spot

OECD Unique Identifiers: SPS-00X17-5 and SPS-000Y9-7

Final Plant Pest Risk Similarity Assessment

October 2016

Agency Contact
Cindy Eck
Biotechnology Regulatory Services 4700
River Road
USDA, APHIS
Riverdale, MD 20737
Fax: (301) 734-8669

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A. Introduction

The Animal and Plant Health Inspection Service (APHIS) of the United States Department Agriculture (USDA) has received an extension request (petition number 16-064-01p) from the J.R. Simplot Company (hereafter referred to as JR Simplot). In accordance with §340.6(e)(2), JR Simplot requests that APHIS extend the non- regulated status for JR Simplot antecedent potato event with late blight resistance, low acrylamide potential, lowered reducing sugars and reduced black spot potatoes to the genetically engineered (GE) X17 and Y9 potato events (late blight resistance, low acrylamide potential, lowered reducing sugars and reduced black spot potatoes) and any progeny derived from crosses of the X17 and Y9 events with conventional potatoes or with other GE potato varieties that have received a determination of nonregulated status, or are not considered regulated articles under regulations at 7 CFR Part 340. Earlier USDA announced its determination of non-regulated status for ten potato events on November 10, 2014 (petition number 13-022-01p), one potato event in September 2, 2015 (petition 14-093-01p), and one potato event in January 13, 2016 (15-140-01p). These events included:

- E12 and E24 - Russet Burbank varieties;
- F10 and F37- Ranger Russet varieties;
- J3, J55, and J78 - Atlantic varieties;
- G11, H37, and H50 - proprietary varieties and
- W8- Russet Burbank
- V11-Snowden variety

APHIS regulations in 7 CFR part 340 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 regulatory requirements of Part 340 when APHIS determines that it is unlikely to pose a plant pest risk. A GE organism is considered a regulated article under Part 340 if the donor organism, recipient organism, or vector, or vector agent used in engineering the organism belongs to any genera or taxa designated in 7 CFR 340.2 and meets the definition of plant pest, or is an unclassified organism and/or an organism whose classification is unknown, or any product which contains such an organism, or any other organism or product altered or produced through genetic engineering which the Administrator determines is a plant pest or has reason to believe is a plant pest. The X17 and Y9 events were produced by the *Agrobacterium tumefaciens* mediated transformation of potato internode sections (JR Simplot, 2015), and some of the introduced border sequences come from plant pest organisms listed in 7 CFR 340.2 (JR Simplot, 2015). Therefore, the X17 and Y9 events are considered a regulated article under APHIS regulations at 7 CFR part 340. Potential impacts in this Plant Pest Risk Similarity Assessment are those that pertain to plant pest risk associated with the X17 and Y9 events and its progeny and their use in the absence of confinement relative to the JR Simplot antecedent potato events. APHIS utilizes data and information submitted by the applicant, in addition to current literature, to determine if the X17 and Y9 events are any more likely than the JR Simplot antecedent potato event to pose a plant pest risk. APHIS specifies in 7 CFR 340.6(e) that an extension request for nonregulated status shall include information to establish the similarity of the antecedent organism to the regulated article in question.

APHIS may also consider information relevant to reviews conducted by other agencies that are part of the ‘Coordinated Framework for the Regulation of Biotechnology’ (51 FR 23302, 1986; 57 FR 22984, 1992). Under the Coordinated Framework, the oversight of biotechnology-derived plants rests with the USDA APHIS, the Food and Drug Administration (FDA), and the Office of Pesticide Programs of the U.S. Environmental Protection Agency (EPA). Depending on its characteristics, certain biotechnology-derived products are subjected to review by one or more of these agencies.

B. Development of the X17 and Y9 Potato Varieties

In producing the antecedents, JR Simplot used genetic engineering to introduce into the background of commercial potato cultivars four traits that are of interest to potato consumers, producers and processors: late blight resistance, reduced acrylamide potential, lowered reducing sugars and reduced black spot bruise (petition number 14-093-01p). X17 and Y9 events were produced by introducing the same genes and traits into the Ranger Russet variety and Atlantic variety. Multiple traits would be difficult to achieve through conventional breeding. Potato is tetraploid, highly heterozygous and sensitive to inbreeding depression. Each potato parent variety must be independently transformed to achieve the desired phenotype in that variety. The same genetic constructs pSIM1278 and pSIM1678 used to transform the JR Simplot antecedent potato events were used to transform and generate the X17 and Y9 events. The activity and function of expressed genes in X17 and Y9 are identical to those in W8 event. The intended purpose of the JR Simplot antecedent potato events and the X17 and Y9 events are to provide the potato processing industry with new potato lines with late blight resistance, low acrylamide potential, lowered reducing sugars and reduced black spot bruise. All these changes are intended to benefit potato consumers, producers, and processors. For example, California's Proposition 65 requires that food manufacturers warn consumers about the dangers of acrylamide in their products. The low acrylamide potential is intended to benefit consumers because of concerns about the health effects of ingesting acrylamide, and to benefit the industry relative to Proposition 65. The reduced black spot bruise is intended to benefit consumers by providing a higher quality product, to benefit producers by reducing culls at delivery, and to benefit processors by reducing pick-outs.

APHIS BRS completed a detailed plant pest risk assessment (PPRA) and environmental assessment (EA) for the JR Simplot antecedent potato events (i.e., the eleven events, one of which is the antecedents associated with this PPRSA) (http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml).

The EA fully addressed all resource areas of potential concern. In the antecedent petition 14-093-01p, APHIS concluded on the basis of the EA that the impacts would not be significant. The agency issued Findings of No Significant Impact (FONSI) and made determinations of non-regulated status for each event. As of September 2015, APHIS has deregulated eleven JR Simplot GE potato events.

C. Description of Inserted Genetic Material, Its Inheritance and Expression, Gene Products, and Changes to Plant Metabolism

To inform APHIS of the potential hazards resulting from the genetic modification and potential routes of exposure related to the inserted DNA and its expression products, APHIS assessed data and information presented in the extension request related to the similarity of the X17 and Y9 events to the JR Simplot antecedent potato event and : the transformation process; the source of the inserted genetic material and its function in both the donor organism and the GE crop event; and the integrity, stability and mode of inheritance of the inserted genetic material through sexual or asexual reproduction and the number of loci inserted.

APHIS also assessed data presented in the extension request on whether the genetic modification results in expression of new genes, proteins, or enzymes, suppression of existing genes and their products, or changes in plant metabolism or composition in the X17 and Y9 events. The assessment encompasses a consideration of the expressed double stranded RNA (dsRNA) and any observed or anticipated effects on plant metabolism including, e.g. any relevant changes in levels of metabolites, anti-nutrients, or nutrients in harvested potatoes derived from the X17 and Y9 events compared to the JR Simplot antecedent potato event or those in the conventional counterparts and other comparators.

Description of the genetic modification and inheritance of inserted DNA

Transformation of the X17 (Ranger Russet variety) and Y9 (Atlantic variety) events (*Solanum tuberosum* subsp. *tuberosum)* was accomplished through the *Agrobacterium tumefaciens* mediated transformation of potato internode segments from Ranger Russet and Atlantic variety as described in JR Simplot's extension request (JR Simplot, 2016, p. 19 & 26 and JR Simplot, 2014, p. 43).

The exact genetic constructs pSIM1278 and pSIM1678 (JR Simplot, 2016, p. 20), used to transform the JR Simplot antecedent potato event, were used to transform and generate the X17 and Y9 events. The T-DNA of pSIM1278 contains DNA sequence intended to down-regulate four genes through the mechanism of RNA interference (RNAi):

- The first cassette down-regulates expression of the potato asparagine synthetase-1 gene (*Asn1*) and the potato polyphenol oxidase-5 gene (*Ppo5*). This cassette is comprised of two 404-bp inverted repeat fragments of *Asn*1 and two 143-bp inverted repeat fragments of *Ppo5*. The *Asn1* and *Ppo5* fragments are arranged between the two convergent native potato promoters—the potato *Agp* promoter of the ADP glucose pyrophosphorylase gene (*Agp*) and the potato *Gbss* promoter of the granule-bound starch synthase gene (*Gbss*) that are primarily active in tubers. These promoters drive expression of the inverted repeats to generate double-stranded RNA targeting the native potato genes *Asn1* and *Ppo5* for down- regulation, also known as gene silencing.
- The second cassette lowers reducing sugars by down-regulating the potato phosphorylase-L (*PhL*) gene and the potato starch-associated (*R1*) gene by targeting the down-regulation of their promoters. This cassette is comprised of an inverted repeat fragment of the 508-bp promoter region *PhL* and a 531-bp inverted repeat fragment of *R1*. Similar to the first cassette, the *PhL* and *R1* inverted repeat fragments are transcribed by the potato *Agp* and *Gbss* promoters.

The T-DNA of pSIM1678 contains DNA sequence intended to express late blight resistance gene Rpi-vnt1 and down-regulates vacuolar invertase (VInv) gene through the mechanism of RNA interference (RNAi):

The pSIM1678 consists of the Rpi-vnt1 expression cassette and a silencing cassette for the plant vacuolar invertase gene VInv.

- The Rpi-vnt1 gene cassette consists of the Rpi-vnt1 gene coding sequence (2676 bps) region regulated by its native promoter and terminator sequences.
- The silencing cassette for the plant vacuolar invertase gene, VInv, consists of an inverted repeat of sequence from the potato VInv gene SENSE orientation (181bps) and Vlnv gene ANTI-SENSE orientation (504 bps) flanked by opposing plant promoters, pGbss and pAgp.

Expression of inserted DNA and changes in gene expression, new proteins or metabolism

As with the previously deregulated events, the only novel protein expressed in the X17 and Y9 events is the VNT1 protein for resistance to late blight. The JR Simplot antecedent potato event and the X17 and Y9 events contain no marker genes.

APHIS reviewed the information provided by JR Simplot in the extension request and determined the following:

- The X17 event contains a single, intact copy of the pSIM1278 T-DNA with a 2bp deletion of the left border and 6 bp addition not found in either genome or insert. It also contains a 55 bp deletion on right border region (JR Simplot, 2016).
- The X17 event contains a single, intact copy of the pSIM1678 T-DNA with a 7-bp deletion of the left border and 23 bp deletion on right border region (JR Simplot, 2016).
- The Y9 event contains a single, intact copy of the pSIM1278 T-DNA. and pSIM1678 insert contains a copy of the Rpi-vnt1 gene expression cassette and an intact copy of the VInv down-regulation cassette.
- The X17 and Y9 events do not contain any back bone sequence of extraneous DNA fragments from the transformation plasmid.
- The T-DNAs are stably inherited from generation to generation.
- Similar to the JR Simplot antecedent potato event, the X17 and Y9 events contain a stable, well-characterized inserts.
- There were no changes in gene expression, metabolism or additional proteins between the X17 and Y9 events and JR Simplot antecedent potato events.

D. Potential Plant Pest and Disease Impacts

APHIS assessed data and information presented in the extension request related to the similarity of the X17 and Y9 events to JR Simplot antecedent potato event to determine whether potential plant pest or disease impacts are likely to result from the transformation process, from DNA sequences from plant pests, or from any other expression products, new enzymes, proteins or changes in plant metabolism or composition in the X17 and Y9 events that are known or anticipated to cause disease symptoms, or to affect plant pests or diseases or plant defense responses. APHIS also assessed whether X17 and Y9 events are more likely to have significantly increased disease and pest susceptibility as compared to JR Simplot antecedent potato event. Impacts or changes in similarity to the JR Simplot antecedent potato event to the X17 and Y9 events were assessed to determine if they would (1) affect and/or result in significant introduction or spread of a damaging pest or disease to other plants; (2) result in the introduction, spread, and/or creation of a new disease; and/or (3) result in a significant exacerbation of a pest or disease for which APHIS has a control program.

Plant Protection and Quarantine (PPQ) is an APHIS program that safeguards agriculture and natural resources from the entry, establishment, and spread of animal and plant pests and noxious weeds into the United States; and supports trade and exports of U.S. agricultural products. PPQ responds to new introductions of plant pests to eradicate, suppress, or contain them through various programs in cooperation with state departments of agriculture and other government agencies. These may be an emergency or longer term domestic programs that target a specific pest. A variety of insect, plant disease, mollusk, nematode or weed programs exist (USDA-APHIS-BRS, 2015), however, none specifically target pests of the X17 and Y9 events.

Because the genetic makeup and transformation of the X17 and Y9 events are identical to previously deregulated JR Simplot antecedent potato event, no significant changes in composition are expected from the expression of genes in the X17 and Y9 events. Similarly, the X17 and Y9 events are not expected to differ from the antecedent in its ability to harbor or transmit plant pathogens or pests and cause indirect plant pest effects on other agricultural products.

E. Potential Impacts on Non-target Organisms Beneficial to Agriculture

APHIS has previously evaluated the potential impacts on non-target organisms beneficial to agriculture that could result from the deregulation of Simplot antecedent potato event. The JR Simplot antecedent potato event was determined by APHIS to be unlikely to have an adverse effect on non-target organisms in the environment. The genetic construct pSIM1278 and pSIM1678 used to transform the deregulated variety contain DNA sequences intended to down-regulate five genes through the mechanism of RNA interference (RNAi) and to express Rpi-vnt1.

- *Asn1* (asparagine synthetase) for reduced free asparagine contributing to low acrylamide potential
- *R1* (water dikinase) and *PhL* 9 (phosphorylase-L 9) for lower reducing sugars contributing to low acrylamide potential
- *PhL* (phosphoylase-L) for lower reducing sugars contributing to low acrylamide potential; and
- *Ppo5* (polyphenol oxidase-5) for reduced black spot
- VInv (vacuolar invertase gene), invertase converts sucrose into glucose and fructose.
- And expression of Rpi-vnt1 - VNT1 provides resistance against *P. infestans* and conferring resistance to late blight disease.

The same genetic constructs, pSIM1278 and pSIM1678, used to transform the previously deregulated JR Simplot antecedent potato event W8, was used to transform the X17 and Y9 events. Therefore, based on the high similarity of the X17 and Y9 events to the JR Simplot antecedent potato event, the compositional similarity of the X17 and Y9 events to its parent variety, the unlikely impacts of non-target effects due to RNAi, and on the finding that the JR Simplot antecedent potato event was unlikely to harm non-target organisms, APHIS concludes that it is unlikely that X17 and Y9 events will have an adverse effect on non-target organisms, including those beneficial to agriculture.

F. Potential for Enhanced Weediness of the X17 and Y9 Potato Varieties

The biology of potato is well studied and understood. As documented in the PPRA of the JR Simplot antecedent potato events W8, potatoes are not known to be weedy or persistent; they are incapable of survival outside of cultivation (Holm et al., 1979; Muenscher, 1980; Love, 1994; OECD, 1997).

In addition to considerations of the known biology of potato, APHIS analyzed information submitted in the petition on the antecedent organism on a suite of agronomic characteristics and plant-disease and plant-insect interactions. This agronomic data from the field showed that the antecedent was not different than its non-transgenic comparator. The assessments concluded that the antecedent was unlikely to become a weed. Based on the high similarity of the X17 and Y9 events to the JR Simplot antecedent potato event expressing similar proteins, and on the finding that the antecedent organism was unlikely to become a weed, APHIS concludes that it is unlikely that X17 and Y9 events will become a weed.

APHIS has previously assessed the potential of the JR Simplot antecedent potato event to become weeds. In addition, APHIS has also assessed the potential weediness of many other GE potato events representing a variety or traits. For both the antecedent and the other GE potato events, it was concluded that the new traits would not make the potato events any more likely to become a weed. Therefore, because of the similarity of the X17 and Y9 events to the JR Simplot antecedent potato event, APHIS has determined that the X17 and Y9 events are no more likely to be a weed.

G. Potential Impacts on the Weediness of Any Other Plants with which the X17 and Y9 events Potato Varieties Can Interbreed

APHIS evaluated the potential for gene introgression to occur from the JR Simplot antecedent potato event to sexually compatible wild relatives and considered whether such introgression would result in increased weediness. Those assessments found that among native *Solanum* spp. in the U.S., cultivated potato is potentially sexually- compatible only with the two tuber-bearing species, *S. jamesii* and *S. stoloniferum* (previously *S. fendleri* (Spooner et al., 2004)). Neither of these species is listed on the Federal or State weed lists (USDA-NRCS, 2013a). Gene flow, hybridization and/or introgression of the introduced genetic material from JR Simplot potatoes to the wild relatives, *S. stoloniferum* and *S. jamesii*, is unlikely to occur. In the case of *S. stoloniferum*, where there is a remote possibility of gene introgression, APHIS concluded that even if such introgression were to occur, this species is not considered a weed.

APHIS concluded that the gene silencing cassettes originating from the JR Simplot antecedent potato event was unlikely to impact the weediness of this wild species since the JR Simplot antecedent potato event does not exhibit characteristics that cause them to be any weedier than other cultivated potatoes. Therefore, the X17 and Y9 events are not expected to increase the weed risk potential of other species with which they can interbreed in the U.S. and its territories based on their similarity to the JR Simplot antecedent potato events.

H. Potential Changes to Agriculture or Cultivation Practices

APHIS assessed whether significant changes to agricultural or cultivation practices from the JR Simplot antecedent potato event is likely to impact plant diseases or pests or their management, including any APHIS control programs. This includes consideration of any changes in pesticide applications, tillage, irrigation, harvesting, etc. as they relate to plant pests and diseases.

APHIS did not identify any significant changes to agricultural or cultivation practices (e.g. pesticide applications, tillage, irrigation, harvesting, rotations, management of volunteers, etc.) from the JR Simplot antecedent potato event and concluded that no impact on plant diseases or pests or their management is likely to occur. Based on the similarity of the X17 and Y9 events to the JR Simplot antecedent potato event expressing the same proteins, APHIS concludes that it is unlikely that any significant changes to agriculture or cultivation practices would be associated with the X17 and Y9 events and therefore no impact on plant diseases or pests of their management is likely to occur.

I. Potential Impacts from Transfer of Genetic Information to Organisms with which the X17 and Y9 Potato Varieties Cannot Interbreed

APHIS has previously examined the potential for the JR Simplot antecedent potato event, expressing RNA interference (RNAi) of the *Asn1*, *R1*, *PhL* and *Ppo5* genes to be horizontally transferred without sexual reproduction to other organisms and whether such an event could lead directly or indirectly to disease, damage, injury or harm to plants, including the creation of new or more virulent pests, pathogens, or parasitic plants. The horizontal gene transfer (HGT) between unrelated organisms is one of the most intensively studied fields in the biosciences since 1940, and the issue gained extra attention with the release of transgenic plants into the environment (Dröge et al., 1998). Potential risks from stable HGT from genetically engineered organisms to another organism without reproduction or human intervention were recently reviewed (Keese, 2008). Mechanisms of HGT include conjugation, transformation and transduction, and other diverse mechanisms of DNA and RNA uptake and recombination and rearrangement, most notably through viruses and mobile genetic elements. APHIS has previously reviewed the potential for horizontal gene transfer from GE potato to bacteria, fungi, invertebrates, viruses, and parasitic plants (USDA, 2014).

APHIS previously concluded that HGT of the inserted genetic material from the JR Simplot antecedent potato event to other organisms is highly unlikely, and is not expected to lead directly or indirectly to disease, damage, injury or harm to plants, including the creation of new or more virulent pests, pathogens, or parasitic plants. Therefore, APHIS concludes that HGT from the X17 and Y9 events to other organisms is also highly unlikely.

J. Conclusion

APHIS has reviewed the information submitted in the extension request, supporting documents, and other relevant information to assess the similarity of plant pest risk of the X17 and Y9 events compared to the JR Simplot antecedent potato event. APHIS concludes that the X17 and Y9 events are **no more likely** to pose a plant pest risk than the previously deregulated JR Simplot antecedent potato events.

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J. R. Simplot (2016) Petition for Extension of Nonregulated Status for X17 Ranger Russet and Y9 Atlantic Potatoes with Late Blight Resistance, Low Acrylamide Potential, Lowered Reducing Sugars, and Reduced Black Spot. Submitted to USDA APHIS on March 3, 2016 (original submission) April 22, 2016 (revised submission), Petition Number 16-064-01p.

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L. Similarity Chart

Description		Extension Request SPS-00X17-5 and SPS-000Y9-7 Petition 16-064-01p	Antecedent W8 Petition 14-093-01p	Comments
Organism		**potato**	**potato**	
Phenotype		Low Acrylamide Potential Lowered Reducing Sugars Reduced Black Spot	Low Acrylamide Potential Lowered Reducing Sugars Reduced Black Spot Bruise	Same phenotypes
Genotype	***Asn1*** ***Ppo5***	**Construct pSIM1278** First cassette ADP glucose pyrophosphorylase promoter from *S. tuberosum* *Asn1* from *S. tuberosum* (RNAi) *Ppo5* gene from *S. verrucosum* (RNAi) 10-Kb spacer from *S. tuberosum* to create hairpin *Gbss* granule-bound starch synthase promoter from *S. tuberosum*	**Construct pSIM1278** First cassette ADP glucose pyrophosphorylase promoter from *S. tuberosum* *Asn1* from *S. tuberosum* (RNAi) *Ppo5* gene from *S. verrucosum* (RNAi) 10-Kb spacer from *S. tuberosum* to create hairpin *Gbss* granule-bound starch synthase promoter from *S. tuberosum*	Same genes, promoters, and spacers

Genotype		Extension Request SPS-00X17-5 and SPS-000Y9-7 Petition 16-064-01p	Antecedent W8 Petition 14-093-01p	Comments
	R1 ***PhL***	Second cassette ADP glucose pyrophosphorylase promoter from *S. tuberosum* fragment of the *R1* promoter sequence from *S. tuberosum* (RNAi) fragment of the *PhL* promoter from *S. tuberosum* (RNAi) Spacer-2, a 257 bp fragment from *S. tuberosum* to create hairpin	Second cassette ADP glucose pyrophosphorylase promoter from *S. tuberosum* fragment of the *R1* promoter sequence from *S. tuberosum* (RNAi) fragment of the *PhL* promoter from *S. tuberosum* (RNAi) Spacer-2, a 257 bp fragment from *S. tuberosum* to create hairpin	Same genes, promoters, and spacers.
	vnt1	**Construct pSIM1678** Rpi-vnt1 gene coding sequence (R- Over expression) from *S. venturii.*	**Construct pSIM1678** Rpi-vnt1 gene coding sequence (Over expression) from S. venturii.	Same genes, promoters, and spacers.
	Vlnv	**RNAi cassette** VInv gene fragment (**sense orientation – 498bp + 181**	**RNAi cassette** VInv gene fragment (**sense orientation – 498bp + 181**	Same genes, promoters, and spacers.

Genotype		) from *S. tuberosum* var. Ranger Russet. **Extension Request SPS-00X17-5 and SPS-000Y9-7 Petition 16-064-01p**	) from *S. tuberosum* var. Ranger Russet **Antecedent W8 Petition 14-093-01p**	**Comments**
		VInv gene fragment (**anti-sense orientation – 504bp**) from *S. tuberosum* var. Ranger Russet.	VInv gene fragment (**anti-sense orientation - 504 bp**) from *S. tuberosum* var. Ranger Russet.	Same genes, promoters, and spacers.
Transformation Method		*Agrobacterium tumefaciens*–mediated	*Agrobacterium tumefaciens*–mediated	Same
Insert and Copy Number		Single intact insertions	Single intact insertions	Same

Description	Extension Request SPS-00X17-5 and SPS-000Y9-7 Petition 16-064-01p	Antecedent W8 Petition 14-093-01p	Comments
Compositional analysis	Compositionally equivalent to conventional potato	Compositionally equivalent to conventional potato	Same
Backbone Absent	Yes	Yes	Same
Mechanism of Action	*Asn1*: reduces free asparagine *R1*: lowers reducing sugars *PhL*: lowers reducing sugars *Ppo5*: reduces enzymatic browning Rpi-vnt1: R-gene VNTI (over expression) Confers resistance to *P. infestans* and confers late blight resistance. VInv: vacuolar invertase (RNAi) down-regulation and lowers reducing sugars and prevents excess darkening during frying and contributes to low acrylamide potential.	*Asn1*: reduces free asparagine *R1*: lowers reducing sugars *PhL*: lowers reducing sugars *Ppo5*: reduces enzymatic browning Rpi-vnt1: R-gene VNTI (over expression) Confers resistance to *P. infestans* and confers late blight resistance. VInv: vacuolar invertase (RNAi) down-regulation and lowers reducing sugars and prevents excess darkening during frying and contributes to low acrylamide potential.	Same as Antecedent Same as Antecedent
Date of antecedent EA/ EIS	N/A	Deregulated on September 2, 2015	

Description	Extension Request SPS-00X17-5 and SPS-000Y9-7 Petition 16-064-01p	Antecedent W8 Petition 14-093-01p	Comments
Plant Pest Risk			
Disease and pest susceptibilities	Similar as antecedent	Unlikely to change disease and pest susceptibilities	
Impacts on beneficial non-targets	Similar as antecedent	Unlikely to impact beneficial non-target organisms	
Enhanced weediness	Similar as antecedent	Unlikely to enhance weediness	
Enhanced weediness of relatives	Similar as antecedent	Unlikely to enhance weediness of relatives	
Changes to agriculture or cultivation practices	Similar as antecedent	Unlikely to change agriculture or cultivation practices	
Horizontal Gene Transfer	Similar as antecedent	Unlikely to affect the probability of horizontal gene transfer	
Plant Pest Risk	Similar as antecedent	Unlikely to pose a plant pest risk	