Record of Categorical Exclusion Determination for an Extension to a Determination of Nonregulated Status for Z6 Potatoes with Late Blight Protection, Low Acrylamide Potential, Lowered Reducing Sugars, and Reduced Black Spot from J.R. Simplot

Brief History and Description of Proposed Action:

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) is proposing to extend a determination of nonregulated status to Z6 Potatoes with Late Blight Protection, Low Acrylamide Potential, Lowered Reducing Sugars, and Reduced Black Spot from J.R. Simplot.

APHIS regulations in 7 CFR part 340 regulate the introduction (importation, interstate movement, or release into the environment) of certain genetically engineered (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 Z6 potato event was produced by the *Agrobacterium*-mediated transformation of potato tissue and was shown to contain border sequences of the transfer DNA (T-DNA) from *Agrobacterium* (Simplot 2019). Therefore, the Z6 potato event meets the definition of a regulated article under APHIS regulations at 7 CFR part 340. APHIS specifies in 7 CFR 340.6(e) that a person may request that APHIS extend a determination of nonregulated status to other organisms, based on the similarity of that organism to an antecedent organism.

J.R. Simplot submitted an extension request (19-099-02p) to APHIS seeking a determination that Z6 potatoes are unlikely to pose a plant pest risk and, therefore, should no longer be a regulated article pursuant to regulations at 7 CFR part 340. APHIS reviewed and analyzed the information submitted in the extension request by J.R. Simplot and has concluded that Z6 potatoes are similar to the antecedent organism W8 potatoes and therefore, based on the Plant Pest Risk Similarity Assessment (PPRSA), APHIS has concluded that Z6 potatoes are unlikely to pose a plant pest risk (USDA-APHIS 2019).

Number and Title of Categorical Exclusion Applied:

The proposed action is within the class of actions which have been subject to categorical exclusion under APHIS's NEPA Implementing Procedures, in 7 CFR § 372.5(c), specifically (4) *Extending deregulations for genetically engineered organisms. Extension of nonregulated status under part 340 of this chapter to organisms similar to those already deregulated.*

Regulatory Requirements:

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 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. 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.

The proposed action is to extend a determination of nonregulated status under 7 CFR part 340 to Z6 potatoes from the similar antecedent organism W8 potatoes. J.R. Simplot has developed Z6 potatoes with the same genetic constructs used to generate the previously deregulated W8 potato (14-093-01p). The Z6 potatoes demonstrate late blight resistance and invertase down-regulation to the quality traits of reduced black spot and lower reducing sugars, and the benefit of lower acrylamide potential (Simplot 2019). Similar to the antecedent W8 potatoes, Z6 potatoes, contain a DNA insert from plasmid pSIM1278 designed to down regulate four different potato genes: asparagine synthetase-1 (*Asn1*), polyphenol oxidase-5 (*Ppo5*), potato phosphorylase-L (*PhL*) and water-dikinase (*R1*) (Simplot 2019). The suppression of *Asn1* results in potatoes with reduced free asparagine contributing to low acrylamide potential, the suppression of *PhL* and *R1* results 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 (resistance against *Phytophthora infestans* from *Solanum venturii*). *Vlnv* lowers reducing sugars contributing to low acrylamide potential and modified storage conditions, and *Rpi-vnt1* is for late blight resistance (Simplot 2019).

APHIS reviewed and analyzed the information submitted in the extension request by J.R. Simplot (Simplot 2019), and has concluded that Z6 potatoes are similar to W8 potatoes, and therefore, based on its PPRA for W8 potatoes, APHIS has concluded that Z6 potatoes are unlikely to pose a plant pest risk (USDA-APHIS 2019). The comparison of characteristics of Z6 potatoes to the antecedent W8 potatoes, indicates that the phenotype and traits of Z6 and the antecedent W8 potatoes are the same, as are the conclusions of the molecular, agronomic, phenotypic, and compositional assessments; and Z6 potatoes do not exhibit any additional traits beyond what is expressed in the antecedent potato (Simplot 2019). Field trials of Z6 potatoes have been conducted in the United States since 2016. Z6 potatoes have been grown in six states (Michigan, North Dakota, Pennsylvania, Idaho, Wisconsin, and Utah). Data resulting from these field trials are described in the request for extension (Simplot 2019).

Based on the prior EA and FONSI for W8 potato and similarity of W8 and Z6 potatoes, the proposed action will not affect the quality of the human environment, including the health of U.S. crops, because Z6 potatoes are similar to the deregulated antecedent organism W8 potato and so is presumed to interact with the environment in the same way as the antecedent. A determination of nonregulated status of Z6 potatoes is not expected to directly cause an increase in agricultural acreage devoted to potato production, or those potato acres devoted to GE potato

cultivation. The availability of Z6 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 Z6 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. APHIS has concluded that the availability of Z6 potatoes would not alter 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 Z6 potatoes on wildlife or biodiversity is not different than that of other potato varieties currently used in conventional agriculture in the United States.

The proposed action does not affect unique characteristics of a geographical area (e.g. waterfalls or bogs) because Z6 potatoes will be deployed on agricultural land currently suitable for production of potato, and therefore, is not expected to cause an increase in agricultural acreage devoted to potato production. The common agricultural practices that would be carried out under the proposed action are no different than those used for the antecedent W8 potatoes. The long history of potato production in the United States is a strong indicator that any potential effects on the quality for the human environment are not highly controversial, are not highly uncertain, or involve unique or unknown risks. The proposed action does not establish precedent or represent a decision in principle about a future consideration because APHIS handles each determination of nonregulated status on a case-by-case basis.

Based on the prior EA and FONSI for W8 potato and similarity of W8 and Z6 potatoes and no changes in the potential effects, APHIS has concluded that extending a determination of nonregulated status to Z6 potatoes would have no effect on species listed as threatened or endangered under the Endangered Species Act or on any species proposed for such listing, and would not affect designated critical habitat or habitat proposed for designation under the Act.

The incremental impact of this proposed action, when added to other past, present, and reasonably foreseeable future actions does not have the potential to impact the human environment because common agricultural practices that would be carried out under the proposed action are no different than those used for the antecedent W8 potatoes.

The proposed action has not been found to be inconsistent with any Federal, State, or local laws, other environmental review requirements, or administrative determinations. The proposed action will not occur on or near any districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places, and it will not cause the loss or destruction of scientific, cultural, or historical resources.

The exceptions for an action subject to a categorical exclusion identified in 7 CFR 372.5(d) do not apply to the proposed action because there is no use of a previously licensed or approved biologics, or new issues raised by genetically engineered species, organisms or novel modifications. There are no cumulative impacts with other related actions anticipated that might result in impacts on the human environment because APHIS evaluates each determination of nonregulated status on a case-by-case basis and examines information provided by applicants to assess whether the regulated article in question raises new issues meriting a separate review

under the petition process.

Additional mitigation measures incorporated into the action:

Each determination of nonregulated status is evaluated on a case-by-case basis and in accordance with standard requirements set out in 7 CFR part 340.

Determination:

I have determined that extending a determination of nonregulated status to Z6 potatoes will not result in an impact to the environment based upon my review of the available information. The proposed action meets the regulatory requirements set forth above for categorical exclusions, and further NEPA review is not required for this action.

BERNADETTE JUAREZ Digitally signed by BERNADETTE JUAREZ
Date: 2020.02.21 17:54:41 -05'00'

Bernadette Juarez
APHIS Deputy Administrator
Biotechnology Regulatory Services, APHIS, USDA

Date

Simplot. 2019. *Petition for Extension of Non-Regulated Status for Z6 Potatoes with Late Blight Protection, Low Acrylamide Potential, Lowered Reducing Sugars, and Reduced Black Spot*.

USDA-APHIS. 2019. *Plant Pest Risk Similarity Assessment Simplot Plant Sciences Request (19-099-02p) for the Extension of Non-Regulated Status for Z6 Potatoes with Late Blight Protection, Low Acrylamide Potential, Lowered Reducing Sugars, and Reduced Black Spot*.