Extended Determination of Nonregulated Status for J.R. Simplot Company Z6 Potatoes with Late Blight Protection, Low Acrylamide Potential, Lowered Reducing Sugars, and Reduced Black Spot (Extension Request No. 19-099-02p)

In response to a request from J.R. Simplot Company (hereinafter referred to as JR Simplot) to extend a determination of nonregulated status to Snowden SPS-ØØØZ6-5 (Z6) potatoes (hereinafter referred to as Z6 potatoes) with late blight tolerance, low acrylamide potential, lowered reducing sugars, and reduced black spot (Extension No. 19-099-02p), 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 Z6 potatoes and progeny derived from them are not likely to pose a plant pest risk and are no longer to be considered regulated articles under APHIS' Biotechnology Regulations at Title 7 of the Code of Federal Regulations, part 340 (7 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 W8 potatoes), with late blight resistance, low acrylamide potential, reduced black spot, and lower reducing sugars. W8 potatoes were deregulated on September 2, 2015 (Petition No. 14-093-01p). APHIS approved permits or acknowledged notifications that were previously required for environmental release, interstate movement, or importation will no longer be required for Z6 potatoes and their progeny. Importation of Z6 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, used to develop the antecedent W8 potatoes with late blight resistance, low acrylamide potential, lowered reducing sugars, and reduced black spot, were also used to generate Z6 potatoes. APHIS evaluated the plant pest risk of Z6 potatoes by assessing its similarity to the deregulated W8 potatoes.

APHIS previously conducted a Plant Pest Risk Assessment on the antecedent organism and concluded that it is unlikely to pose a plant pest risk. Based on the plant pest risk similarity assessment (see Appendix A) of Z6 potatoes to the antecedent, APHIS concludes that Z6 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 Z6 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 metabolism changes in Z6 potatoes.

(2) Disease and pest incidence and/or damage are not expected to be increased or atypical in Z6 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, Z6 potatoes are unlikely to adversely impact nontarget organisms beneficial to agriculture.

(4) Z6 potatoes are no more likely to become weedier or more difficult to control as a weed than the antecedent, which is not weedy.

(5) Z6 potatoes are not likely to increase the weed risk potential of other species with which they can interbreed in the United States or its territories. Gene flow,

hybridization and/or introgression of inserted genes from Z6 potatoes to other sexually compatible relatives with which they 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 Z6 potatoes are not expected.

(7) Horizontal gene transfer of the new genetic material inserted into Z6 potatoes 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 findings that Z6 potatoes are unlikely to pose a plant pest risk, APHIS prepared a Record of Categorical Exclusion Determination for this action based on an Environmental Assessment completed for the antecedent W8 potatoes in 2014. Z6 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.

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 organism, the plant pest risk similarity assessment, and record of categorical exclusion determination, 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 Z6 potatoes is the most scientifically sound and appropriate regulatory decision.

BERNADETTE JUAREZ Digitally signed by BERNADETTE JUAREZ
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August 28, 2020

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

Date