

Determination of Nonregulated Status for JR Simplot Company W8 Potatoes

In response to petition 14-093-01p from JR Simplot Company (hereinafter referred to as JR Simplot), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has determined that JR Simplot's W8 potatoes (hereinafter referred to as W8 potatoes) with late blight resistance, low acrylamide potential, reduced black spot and lower reducing sugars 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). Since APHIS has determined that W8 potatoes are unlikely to pose a plant pest risk, APHIS will approve the petition for nonregulated status of W8 potatoes. Therefore, APHIS approved permits or acknowledged notifications that were previously required for environmental release, interstate movement, or importation under these regulations will no longer be required for W8 potatoes and their progeny. Importation of W8 potato seeds, other propagative material, and bulk or table stock, will still be subject to APHIS foreign quarantine notices at 7 CFR part 319.

This Determination of nonregulated status for W8 potatoes is based on APHIS' analyses of field and laboratory data submitted by JR Simplot, references provided in the petition, peer-reviewed publications, and other relevant information as described in the Plant Pest Risk Assessment (PPRA) for W8 potatoes.

The PPRA conducted on W8 potatoes concluded that it is unlikely to pose a plant pest risk and should no longer be subject to the regulations at 7 CFR part 340 for the following reasons:

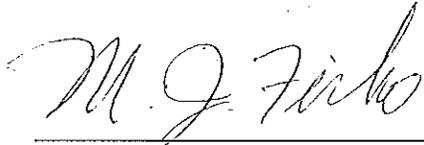
- (1) No plant pest risk was identified from the transformation process, the insertion and/or expression of new genetic material, or from changes in metabolism in W8 potatoes.
- (2) Disease and pest incidence and/or damage were not observed to be increased or atypical in W8 potatoes compared to the nontransgenic counterpart or other comparators in field trials conducted in growing regions representative of where W8 potatoes are expected to be grown. Observed agronomic traits also did not reveal any differences that would indirectly indicate that W8 potatoes are more susceptible to pests or diseases. Therefore 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, the compositional similarity of W8 potatoes to the parent variety, and the observed interactions of W8 potatoes with insects present in the field, exposure to and/or consumption of W8 potatoes are unlikely to adversely impact nontarget organisms beneficial to agriculture.
- (4) W8 potatoes are no more likely to become weedier or more difficult to control as a weed than conventional varieties of this crop based on the observed agronomic characteristics, the weediness potential of the crop and current management practices available to control W8 potatoes as a weed.
- (5) W8 potatoes are not likely to increase the weed risk potential of other species with which it can interbreed in the U.S. or its territories. Gene flow, hybridization and/or introgression of inserted genes from W8 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 W8 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.

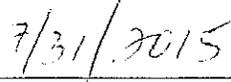
APHIS also concludes in its PPRA that new varieties derived from W8 potatoes are unlikely to exhibit new properties substantially different from the ones observed for W8 potatoes, or those observed in other potato varieties not considered regulated articles under 7 CFR part 340, that would pose a plant pest risk.

In addition to our finding that W8 potatoes are not likely to pose a plant pest risk, APHIS has completed an Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) for this action, and has concluded that a determination of nonregulated status for W8 potatoes and their progeny would have no significant impacts, individually or collectively, on the quality of the human environment and will have no effect on federally listed threatened and endangered species, species proposed for listing, or their designated or proposed critical habitats. APHIS also concludes with its Determination of nonregulated status, based upon its PPRA, that new varieties derived from W8 potatoes are unlikely to exhibit new properties substantially different from the ones observed for W8 potatoes, or those observed for other potato varieties not considered regulated articles under 7 CFR part 340, that would pose a plant pest risk.

Based on my full and complete review and consideration of all the scientific and environmental data, analyses and information, the input from the public involvement process, the conclusions of the PPRA, the EA and the FONSI, and my knowledge and experience as the APHIS Deputy Administrator for Biotechnology Regulatory Services, I have determined and decided that this Determination of nonregulated status for W8 potatoes is the most scientifically sound and appropriate regulatory decision.



Michael J. Firko, Ph.D.



Date

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