

## **Determination of Nonregulated Status Under 7 CFR Part 340 for JR Simplot Company F10, F37, E12, E24, J3, J55, J78, G11, H37, and H50 Potatoes**

In response to petition 13-022-01p 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 F10, F37, E12, E24, J3, J55, J78, G11, H37, and H50 potatoes (hereinafter referred to as F10, F37, E12, E24, J3, J55, J78, G11, H37, and H50 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's Biotechnology Regulations (Title 7 of the Code of Federal Regulations (CFR), part 340). Since APHIS has determined that F10, F37, E12, E24, J3, J55, J78, G11, H37, and H50 potatoes are unlikely to pose a plant pest risk, APHIS will approve the petition for nonregulated status of F10, F37, E12, E24, J3, J55, J78, G11, H37, and H50 potatoes. Therefore, APHIS-approved permits or acknowledged notifications that were previously required for environmental releases, interstate movement, or importation under these regulations will no longer be required for F10, F37, E12, E24, J3, J55, J78, G11, H37, and H50 potatoes and their progeny. Importation of F10, F37, E12, E24, J3, J55, J78, G11, H37, and H50 potato seeds and other propagative material will still be subject to APHIS foreign quarantine notices at 7 CFR part 319.

This Determination of nonregulated status under 7 CFR part 340 for F10, F37, E12, E24, J3, J55, J78, G11, H37, and H50 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 F10, F37, E12, E24, J3, J55, J78, G11, H37, and H50 potatoes.

The Plant Pest Risk Assessment (PPRA) conducted on F10, F37, E12, E24, J3, J55, J78, G11, H37, and H50 potatoes concluded that they are 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 the F10, F37, E12, E24, J3, J55, J78, G11, H37, and H50 potatoes.
- (2) Disease and pest incidence and/or damage were not observed to be significantly increased or atypical in the F10, F37, E12, E24, J3, J55, J78, G11, H37, and H50 potatoes compared to the nontransgenic counterpart or other comparators in field trials conducted in growing regions representative of where the F10, F37, E12, E24, J3, J55, J78, G11, H37, and H50 potatoes are expected to be grown and in laboratory studies. Observed agronomic traits also did not reveal any significant differences that would indirectly indicate that the F10, F37, E12, E24, J3, J55, J78, G11, H37, and H50 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 F10, F37, E12, E24, J3, J55, J78, G11, H37, and H50 potatoes to the parent varieties, and the observed interactions of F10, F37, E12, E24, J3, J55, J78, G11, H37, and H50 potatoes with insects,

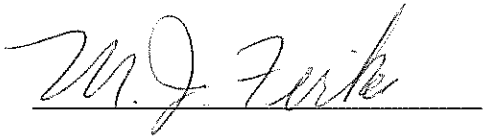
exposure to and/or consumption of the F10, F37, E12, E24, J3, J55, J78, G11, H37, and H50 potatoes is unlikely to adversely impact nontarget organisms beneficial to agriculture.

- (4) The F10, F37, E12, E24, J3, J55, J78, G11, H37, and H50 potatoes are no more likely to become weedier or more difficult to control as a weed than conventional varieties of this crop based on their observed agronomic characteristics, weediness potential of the crop and current management practices available to control the F10, F37, E12, E24, J3, J55, J78, G11, H37, and H50 potatoes as a weed.
- (5) The F10, F37, E12, E24, J3, J55, J78, G11, H37, and H50 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 the F10, F37, E12, E24, J3, J55, J78, G11, H37, and H50 potatoes to other sexually compatible relatives with which they can interbreed is not likely to occur. In the unlikely event of such introgression, these compatible relatives are not considered weedy or invasive. The new phenotype(s) conferred by genetic engineering are not likely to increase the weediness of these compatible relatives.
- (6) Significant changes to agricultural or cultivation practices (e.g. pesticide applications, tillage, irrigation, harvesting, etc.) from adoption of the F10, F37, E12, E24, J3, J55, J78, G11, H37, and H50 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 F10, F37, E12, E24, J3, J55, J78, G11, H37, and H50 potatoes are unlikely to exhibit new properties that are substantially different from the ones observed for F10, F37, E12, E24, J3, J55, J78, G11, H37, and H50 potatoes, or those observed in other potatoes varieties not considered regulated articles under 7 CFR part 340, that would pose a plant pest risk.

Prior to this Determination of nonregulated status, APHIS completed an Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) for this action, and concluded that a Determination of nonregulated status under 7 CFR part 340 for F10, F37, E12, E24, J3, J55, J78, G11, H37, and H50 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 under 7 CFR part 340, based upon its PPRA, and informed by the EA and FONSI, that new varieties derived from F10, F37, E12, E24, J3, J55, J78, G11, H37, and H50 potatoes are unlikely to exhibit new properties that are substantially different from the ones observed for F10, F37, E12, E24, J3, J55, J78, G11, H37, and H50 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, information, the input from the public involvement process, and the conclusions of the PPRA, the EA, and the FONSI, and my knowledge and experience as the Deputy Administrator of APHIS Biotechnology Regulatory Services, I have determined and decided that this Determination of non-regulated status for F10, F37, E12, E24, J3, J55, J78, G11, H37, and H50 potatoes is the most scientifically sound and appropriate regulatory decision.



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U.S. Department of Agriculture

Date:

10/17/2014