

Determination of Nonregulated Status for Westhoff Petunias containing the A1 gene of Maize (A1-DFR Petunias)

In response to petition 19-099-01p from Westhoff Vertriebsgesellschaft mbH (hereinafter referred to as Westhoff), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has determined that A1-DFR petunias, and any 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 A1-DFR petunias are unlikely to pose a plant pest risk, APHIS will approve the petition for a nonregulated status of A1-DFR petunias. Therefore, APHIS authorizations under these regulations will no longer be required for environmental release, interstate movement, or importation of A1-DFR petunias and their progeny. Importation of A1-DFR petunia seeds, or other propagative material will still be subject to APHIS foreign quarantine notices at 7 CFR part 319 and Federal Seed Act Regulations at 7 CFR parts 201 and 361.

This Determination of nonregulated status for A1-DFR petunias is based on analyses of field and laboratory data submitted by Westhoff, references provided in the petition, peer-reviewed publications, and other relevant information as described in the Plant Pest Risk Assessment (PPRA) conducted by APHIS for A1-DFR petunias.

The PPRA for A1-DFR petunias 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 or the insertion of new genetic material in A1-DFR petunias.

(2) No difference was observed for susceptibility to diseases and insect pests in A1-DFR petunias compared to the unmodified varieties. Observed agronomic or horticultural traits also did not reveal any differences that would indicate that A1-DFR petunias will become more susceptible to pests or diseases as the indirect result of genetic engineering. Therefore, no plant pest effects are expected from A1-DFR petunia varieties. They will not impact other agricultural products or APHIS pest control programs.

(3) Exposure to A1-DFR petunias is unlikely to have any adverse impacts on organisms beneficial to agriculture based on the analysis of phenotypic data, past observations, and pattern of the petunia production and usage.

(4) A1-DFR petunias are no more likely to become weeds than conventional petunia varieties based on their observed agronomic characteristics, the weediness potential of petunia, and current management practices available to control A1-DFR petunia as a weed.

(5) A1-DFR petunias 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 and/or introgression of inserted genes from A1-DFR petunias to other sexually compatible relatives with which they can interbreed is not likely to occur. A1-DFR petunias do not

confer or enhance the weedy characteristics of cultivated petunias.

(6) Significant changes to agricultural or cultivation practices (e.g. herbicide or pesticide applications, irrigation, etc.) from the adoption of A1-DFR petunias were not known in the past and are not expected to be identified in the future.

(7) Horizontal gene transfer of the new genetic material inserted into A1-DFR petunias 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' analyses and conclusions in the PPRA regarding the plant pest risk of A1-DFR petunias also apply to progeny such as any new varieties derived from A1-DFR petunias.

Prior to this Determination of nonregulated status, 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 A1-DFR petunias 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.

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 A1-DFR petunias and progeny is the most scientifically sound and appropriate regulatory decision.

Bernadette Juarez

Date

APHIS Deputy Administrator
Biotechnology Regulatory Services
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