

Preliminary Determination¹ of Nonregulated Status for Dow AgroSciences DAS-8191Ø-7 Cotton

In response to petition 13-262-01p from Dow AgroSciences LLC (hereafter referred to as DAS), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has determined that DAS glufosinate and 2,4-dichlorophenoxyacetic acid (2,4-D) herbicide-resistant DAS-8191Ø-7 cotton (hereinafter referred to as DAS-8191Ø-7 cotton) and progeny derived from it 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 DAS-8191Ø-7 cotton is unlikely to pose a plant pest risk, APHIS will approve the petition for nonregulated status of DAS-8191Ø-7 cotton. 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 DAS-8191Ø-7 cotton and its progeny. Importation of DAS-8191Ø-7 cotton seeds and 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 DAS-8191Ø-7 cotton is based on APHIS' analyses of field and laboratory data submitted by DAS, references provided in the petition, peer-reviewed publications, and other relevant information as described in the Plant Pest Risk Assessment (PPRA) for DAS-8191Ø-7 cotton.

The PPRA conducted on DAS-8191Ø-7 cotton 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 DAS-8191Ø-7 cotton.
- (2) Disease and pest incidence and/or damage were not observed to be significantly increased or atypical in DAS-8191Ø-7 cotton compared to the nontransgenic counterpart or other comparators in field trials conducted in growing regions representative of where DAS-8191Ø-7 cotton is expected to be grown. Observed agronomic traits also did not reveal any significant differences that would indirectly indicate that DAS-8191Ø-7 cotton is 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.

¹ Determination is not effective until officially signed and published.

- (3) Based on an evaluation of the gene products, the lack of amino acid sequence similarities with known toxins, mice acute toxicity studies and that the donor organisms are widely distributed in nature exposure to and/or consumption of DAS-8191Ø-7 cotton are unlikely to adversely impact nontarget organisms beneficial to agriculture.
- (4) DAS-8191Ø-7 cotton is no more likely to become weedier or more difficult to control as a weed than conventional varieties of cotton based on the observed agronomic characteristics of DAS-8191Ø-7 cotton, the weediness potential of cotton, and current management practices available to control cotton as a weed.
- (5) DAS-8191Ø-7 cotton is 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 DAS-8191Ø-7 cotton 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 DAS-8191Ø-7 cotton 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 DAS-8191Ø-7 cotton are unlikely to exhibit new properties substantially different from the ones observed for DAS-8191Ø-7 cotton, or those observed in other cotton 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 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 DAS-8191Ø-7 cotton and its 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 DAS-8191Ø-7 cotton are unlikely to exhibit new properties substantially different from the ones observed for DAS-8191Ø-7 cotton, or those observed for other cotton 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 DAS-8191Ø-7 cotton 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