

## **Preliminary Determination<sup>1</sup> of Nonregulated Status for Dow AgroSciences LLC 81419-2 Insect Resistant Soybean**

In response to petition 12-272-01p from Dow AgroSciences LLC (DAS), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has determined that event DAS-81419-2 soybean and progeny derived from it are unlikely to pose plant pest risks and are no longer to be considered regulated articles under APHIS' Biotechnology Regulations (Title 7 of Code of Federal Regulations (CFR), part 340). Since APHIS has determined that DAS-81419-2 soybean is unlikely to pose plant pest risks, APHIS will approve the petition for nonregulated status of DAS-81419-2 soybean. Therefore, APHIS approved permits or acknowledged notifications that were previously required for environmental release, importation, or interstate movement under those regulations will no longer be required for event DAS-81419-2 soybean and its progeny. Importation of DAS-81419-2 soybean seeds and other propagative material would still be subject to APHIS foreign quarantine notices at 7 CFR part 319 and the Federal Seed Act regulations at 7 CFR part 201.

This determination for DAS-81419-2 is based on APHIS' analysis of field, greenhouse and laboratory data submitted by Dow AgroSciences LLC, references provided in the petition, peer-reviewed publications, and other relevant information as described in the Plant Pest Risk Assessment (PPRA) for Dow AgroSciences LLC (DAS) event 81419-2 Insect Resistant Soybean.

The Plant Pest Risk Assessment conducted on DAS-81419-2 soybean concluded that it is unlikely to pose plant pest risks and should no longer be subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340 for the following reasons:

- (1) Disease and insect susceptibilities, agronomic performance, and compositional profiles of DAS-81419-2 soybean are similar to other soybean cultivars grown in the U.S., and are unlikely to alter disease and pest susceptibilities;
- (2) Based on an evaluation of the gene products and testing of representative non-target species, it has been concluded that of DAS-81419-2 soybean is unlikely to adversely affect nontarget organisms, including those considered beneficial;
- (3) Agronomic performance evaluations of DAS-81419-2 soybean revealed no characteristics that would cause it to be weedier than the non-genetically engineered parent soybean line or any other cultivated soybean;
- (4) Gene introgression from event DAS-81419-2 soybean into wild relatives in the United States and its territories is extremely unlikely and is not likely to increase the weediness potential of any resulting progeny nor adversely affect genetic diversity of related plants any more than would introgression from traditional soybean varieties;
- (5) DAS-81419-2 soybean are similar to those of its parent line and other soybean cultivars grown in the U.S, therefore, there will be no change in agricultural and cultural practices;
- (6) Horizontal gene transfer is unlikely to occur between DAS-81419-2 soybean and organisms with which it cannot interbreed.

In addition to our finding that event DAS-81419-2 is unlikely to pose a plant pest risk, APHIS has

---

<sup>1</sup> Determination is not effective until officially signed and posted.

completed an Environmental Assessment (EA) and preliminary Finding of No Significant Impact (FONSI) for this action and has determined that a determination of nonregulated status for DAS-81419-2 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 or endangered species, species proposed for listing, or their designated or proposed critical habitats (<http://www.aphis.usda.gov/brs/notreg.html>). APHIS also concludes, based upon its PPRA, that new varieties derived from DAS-81419-2 are unlikely to exhibit new plant pest properties that are substantially different from the ones observed for DAS-81419-2 soybean, or those observed for other soybean varieties not considered regulated articles under 7 CFR part 340.

Based on my full and complete review and consideration of all of the scientific and environmental data, analyses, information, public input, and conclusions of the PPRA, the EA, the preliminary FONSI, and my knowledge and experience as acting Deputy Administrator of APHIS Biotechnology Regulatory Services, I have determined and decided that this determination of nonregulated status of DAS-81419-2 soybean is the most scientifically sound and appropriate regulatory decision.

---

Michael J. Firko, Ph.D.

---

Date

Deputy Administrator, Acting  
Biotechnology Regulatory Services (BRS)  
Animal and Plant Health Inspection Service (APHIS)  
United States Department of Agriculture (USDA)