

Determination of Nonregulated Status for Dow AgroSciences' DAS-68416-4 Soybean

In response to petition 09-349-01p from Dow AgroSciences LLC (hereinafter referred to as DAS), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has determined that a genetically-engineered DAS soybean line with increased herbicide resistance to aryloxyalkanoate-based, including 2,4-D, pyridyl oxyacetate, glufosinate herbicides, hereinafter referred to as DAS-68416-4 soybean, 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's Biotechnology Regulations (Title 7 of the Code of Federal Regulations (CFR), part 340). Since APHIS has determined that DAS-68416-4 soybean is unlikely to pose a plant pest risk, APHIS will approve the petition for nonregulated status of DAS-68416-4 soybean. 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 DAS-68416-4 soybean and its progeny. Importation of DAS-68416-4 soybean 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 part 201 and 7 CFR part 361.

This Determination of nonregulated status for DAS-68416-4 soybean 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-68416-4 soybean.

The Plant Pest Risk Assessment (PPRA) conducted on DAS-68416-4 soybean 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 the DAS-68416-4 soybean.
- (2) Disease and pest incidence and/or damage were not observed to be significantly increased or atypical in the DAS-68416-4 soybean and derived hybrids compared to their nontransgenic control counterparts or other comparators in field trials conducted in growing regions representative of where the DAS-68416-4 soybean is expected to be grown. Observed agronomic traits also did not reveal any significant differences that would indirectly indicate that the DAS-68416-4 soybean is more susceptible to pests or diseases. Therefore no plant pest effects are expected on these or other agricultural products.
- (3) Based on an evaluation of the gene products (AAD-12 and PAT) and agronomic and compositional data, exposure to and/or consumption of the DAS-68416-4 soybean are unlikely to adversely impact nontarget organisms beneficial to agriculture.

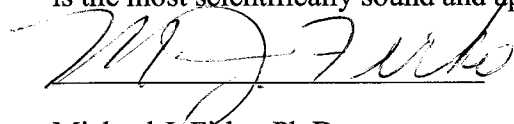
- (4) The DAS-68416-4 soybean is no more likely to become weedier or more difficult to control as a weed than conventional varieties of this crop based on its observed agronomic characteristics, the weediness potential of the crop and current management practices available to control the DAS-68416-4 soybean as a weed.
- (5) The DAS-68416-4 soybean 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 the DAS-68416-4 soybean to other sexually compatible relatives with which it can interbreed is not likely to occur.
- (6) Major changes in agricultural or cultivation practices associated with the adoption of DAS-68416-4 soybean are not expected with the exception of those associated with the use of the aryloxyalkanoate-based, including 2,4-D, pyridyl oxyacetate and glufosinate herbicides. These changes are not likely to increase plant diseases or pests or compromise their management.
- (7) Horizontal gene transfer of the new genetic material inserted into the DAS-68416-4 soybean 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, based on the PPRA, that new varieties derived from DAS 68416-4 soybean are unlikely to exhibit new properties that are substantially different from the ones observed for DAS 68416-4 soybean, or those observed in other soybean varieties not considered regulated articles, under 7 C.F.R. Part 340, that would pose a plant pest risk.

Prior to this Determination of nonregulated status, APHIS completed a Final Environmental Impact Statement (FEIS) which explored the potential environmental impacts that a Determination of nonregulated status for the DAS-68416-4 soybean and its progeny would have on the quality of the human environment. The FEIS concluded, among other things, that a determination of nonregulated status for DAS-68416-4 soybean (and its progeny) 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, and informed by the completion of the FEIS and the Record of Decision that was issued for the FEIS, that new varieties derived from DAS-68416-4 soybean are unlikely to exhibit new properties that are substantially different from the ones observed for DAS-68416-4 soybean, or those observed for other soybean 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, and the conclusions of the PPRA, the EIS and its Record of Decision, and my knowledge and experience as the Deputy Administrator of APHIS Biotechnology Regulatory Services, I have

determined and decided that this Determination of nonregulated status for DAS-68416-4 soybean is the most scientifically sound and appropriate regulatory decision.



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Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
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Date:

9/17/2014