

## **Preliminary Determination<sup>1</sup> of Nonregulated Status for Bayer CropScience GHB811 Cotton**

In response to petition 17-138-01p from Bayer CropScience LP (hereinafter referred to as Bayer), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has determined that Bayer glyphosate and HPPD-inhibitor Resistant GHB811 Cotton (hereinafter referred to as GHB811 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 GHB811 cotton is unlikely to pose a plant pest risk, APHIS will approve the petition for nonregulated status of GHB811 cotton. Therefore, APHIS authorizations under these regulations will no longer be required for environmental release, interstate movement, or importation of GHB811 cotton and its progeny. Importation of GHB811 cotton seeds, other propagative material, or grain for consumption 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 GHB811 cotton is based on analyses of field and laboratory data submitted by Bayer, 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 GHB811 cotton.

The PPRA for GHB811 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 GHB811 cotton.
- (2) Disease and pest incidence and/or damage were not observed to be increased or atypical in GHB811 cotton compared to the non-genetically engineered counterpart or other comparators in field trials conducted in growing regions representative of where GHB811 cotton would be expected to be grown commercially. Observed agronomic traits also did not reveal any differences that would indirectly indicate that GHB811 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.

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

- (3) Based on an evaluation of the gene products, plant composition, and agronomic characteristics, exposure to and/or consumption of GHB811 cotton is unlikely to adversely impact nontarget organisms beneficial to agriculture.
- (4) GHB811 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 GHB811 cotton, the weediness potential of cotton, and current management practices available to control cotton as a weed.
- (5) GHB811 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 GHB811 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 GHB811 cotton are not expected with the exception of the ability to apply herbicides containing HPPD inhibitors such as isoxaflutole on GHB811 cotton, and 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 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' analyses and conclusions in the PPRA regarding the plant pest risk of GHB811 cotton also apply to progeny such as any new varieties derived from GHB811 cotton.

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 GHB811 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.

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 GHB811 cotton and progeny is the most scientifically sound and appropriate regulatory decision.

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Michael J. Firko, Ph.D.

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Date

APHIS Deputy Administrator  
Biotechnology Regulatory Services  
Animal and Plant Health Inspection Service  
U.S. Department of Agriculture