

Determination of Nonregulated Status for BASF GMB151 Soybean

In response to petition 19-317-01p from BASF Corporation (hereafter referred to as BASF), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has determined that the new soybean (*Glycine max*) variety GMB151 developed using genetic engineering to be plant-parasitic nematode-protected and herbicide resistant (hereafter referred to as GMB151 soybean) and progeny derived from it are not likely to pose a greater plant pest risk than the unmodified soybean from which it was derived, and are no longer to be considered regulated under APHIS' Biotechnology Regulations at Title 7 of the Code of Federal Regulations, part 340 (7 CFR part 340)¹. Since APHIS has determined that GMB151 soybean is unlikely to pose a greater plant pest risk than the unmodified soybean from which it was derived, APHIS will approve the petition for nonregulated status of GMB151. Therefore, APHIS authorizations under these regulations will no longer be required for environmental release, interstate movement, or importation of GMB151 soybean and its progeny. Importation of GMB151 soybean 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 GMB151 soybean is based on APHIS' analyses of field and laboratory data submitted by BASF, references provided in the petition, peer-reviewed publications, and other relevant information as described in the Plant Pest Risk Assessment (PPRA) for GMB151 soybean.

The PPRA conducted on GMB151 soybean concluded that it is unlikely to pose greater plant pest risk than the unmodified soybean from which it was derived 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 and/or expression of new genetic material, or changes in metabolism in GMB151 soybean.

¹ The petition for nonregulated status described in the PPRA is being evaluated under the version of the regulations effective at the time that it was created. Animal and Plant Inspection Service (APHIS) issued a final rule published in the Federal Register on May 18, 2020 (85 FR 29790-29838. Docket No. APHIS-2018-0034) revising 7 CFR part 340; however, the final rule is being implemented in phases. The new Regulatory Status Review (RSR) process which replaces petition for determination of nonregulated status process, became effective on April 5, 2021 for corn, soybean, cotton, potato, tomato and alfalfa. The RSR process is effective for all crops as of October 1, 2021. However "until RSR is available for a particular crop, APHIS will continue to receive petitions for determination of nonregulated status for the crop in accordance with the (legacy) regulations at 7 CFR part 340.6" (85 FR 29815). This petition for a determination of nonregulated status is being evaluated in accordance with the regulations at 7 CFR 340.6 (2020) as it was received by APHIS on 11/13/2019.

- (2) Disease and pest incidence and/or damage were not observed to be significantly increased or atypical in GMB151 soybean compared to the unmodified counterpart or other comparators in field trials conducted in growing regions representative of where GMB151 is expected to be grown in the United States. Observed agronomic traits also did not reveal any significant differences that would indirectly indicate that GMB151 soybean 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.
- (3) Exposure to and/or consumption of the GMB151 soybean is unlikely to have any adverse impacts on organisms beneficial to agriculture based on the analysis of compositional, phenotypic, and agronomic data. This data was supplemented by field observations of the impacts of GMB151 soybean on the free-living soil nematode community.
- (4) The GMB151 soybean is no more likely to become a weed or become weedier than conventional soybean varieties based on its observed agronomic characteristics, the weediness potential of soybean, and current management practices available to control soybean as a weed. Volunteers and feral populations of the GMB151 soybean resistant to HPPD-4 inhibitor herbicides can be managed using a variety of currently available methods and herbicides.
- (5) The GMB151 soybean is not likely to increase the weed risk potential of other species with which it can interbreed in the United States or its territories. Gene flow, hybridization and/or introgression of inserted genes from the GMB151 soybean to other sexually compatible relatives with which it can interbreed is not likely to occur. Furthermore, there is no sexually compatible wild relative or weedy species of *Glycine* reported in natural environments in North America.
- (6) Significant changes to agricultural or cultivation practices (e.g., pesticide applications, tillage, irrigation, harvesting, etc.) from adoption of GMB151 soybean were not identified and thus are not likely to increase plant diseases or pests or compromise their management.
- (7) Horizontal gene transfer of the new genetic material inserted into GMB151 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' analyses and conclusions in the PPRA regarding the plant pest risk of GMB151 soybean also apply to progeny such as any new varieties derived from GMB151 soybean.

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 GMB151 soybean 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 GMB151 soybean and progeny is the most scientifically sound and appropriate regulatory decision.

Bernadette Juarez

Date

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