

Determination of Nonregulated Status for MON 87411 corn

In response to petition 13-290-01p from Monsanto company (hereinafter referred to as Monsanto), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has determined that Monsanto's corn rootworm resistant and glyphosate resistant corn (hereinafter referred to as MON 87411 corn) 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 MON 87411 corn is unlikely to pose a plant pest risk, APHIS will approve the petition for nonregulated status of MON 87411 corn. 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 MON 87411 corn and its progeny. Importation of MON 87411 corn seeds, other propagative material, and 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 MON 87411 corn is based on APHIS' analyses of field and laboratory data submitted by Monsanto, references provided in the petition, peer-reviewed publications, and other relevant information as described in the Plant Pest Risk Assessment (PPRA) for MON 87411 corn.

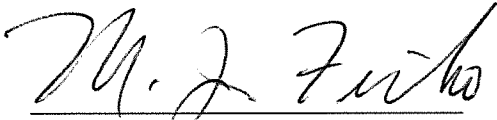
The PPRA conducted on MON 87411 corn concluded that it is unlikely to pose a plant pest risk and should no longer be subject to the regulations at 7 CFR part 340 for the following reasons:

- (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 MON 87411 corn.
- (2) Disease and pest incidence and/or damage were not observed to be increased or atypical in MON 87411 corn compared to the nontransgenic counterpart or other comparators in field trials conducted in growing regions representative of where MON 87411 corn is expected to be grown. Observed agronomic traits also did not reveal any differences that would indirectly indicate that Monsanto 87411 corn 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, bioassays involving the insecticidal double-stranded RNA to a range of insects varying in ecological function and to insects closely related taxonomically to corn rootworm, and on extensive literature and experience with genetically engineered plants expressing Cry proteins and EPSPS CP4 proteins, APHIS concludes that exposure to and/or consumption of MON 87411 corn are unlikely to adversely impact nontarget organisms beneficial to agriculture.
- (4) MON 87411 corn is no more likely to become weedier or more difficult to control as a weed than conventional varieties of corn based on the observed agronomic characteristics of MON 87411 corn, the weediness potential of corn, and current management practices available to control corn as a weed.
- (5) MON 87411 corn 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 MON 87411 corn to other sexually compatible relatives with which it can interbreed is not likely to occur. These compatible relatives are not considered weedy or invasive. The new phenotypes conferred by genetic engineering are not likely to increase the weediness of these compatible relatives or affect the current ability to control these relatives in situations where they are considered weedy or invasive.
- (6) Significant changes to agricultural or cultivation practices (e.g. pesticide applications, tillage, irrigation, harvesting, etc.) from adoption of MON 87411 corn 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' analyses and conclusions in the PPRA regarding the plant pest risk of MON 87411 corn also apply to progeny such as any new varieties derived from MON 87411 corn. 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 MON 87411 corn 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 MON 87411 corn and progeny is the most scientifically sound and appropriate regulatory decision.



Michael J. Firko, Ph.D.

10/23/2015
Date

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