

Determination of Nonregulated Status for Monsanto Event MON 87427 corn

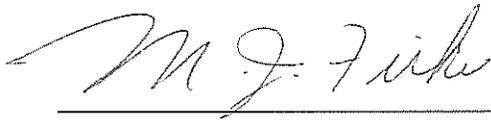
In response to petition 10-281-01p from Monsanto, The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has determined that Monsanto Event MON 87427 corn and progeny derived from it are not likely to pose a plant pest risk and are no longer to be considered regulated articles under APHIS's Biotechnology Regulations (Title 7 of the Code of Federal Regulations (CFR), part 340). Since APHIS has determined that Event MON 87427 corn is unlikely to pose a plant pest risk, APHIS will approve the petition for nonregulated status of Event MON 87427 corn. 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 Event MON 87427 corn and its progeny. Importation of Event MON 87427 corn 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.

This determination for Event MON 87427 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 Event MON 87427 corn.

The Plant Pest Risk Assessment conducted on Event MON 87427 corn concluded that it is unlikely to pose a plant pest risk and should no longer be subject to the plant pest provisions of the Plant Protection Act and 7CFR part 340 for the following reasons: (1) MON 87427 is not significantly different from its comparator or commercial varieties. There is no indication that MON 87427 possesses a selective advantage that would result in increased weediness. MON 87427, as other corns, lacks the ability to persist as a troublesome weed, and there would be no significant impact on current weed management practices for corn cultivation; (2) APHIS evaluated the potential for gene introgression to occur from MON 87427 to sexually compatible wild relatives (teosinte and to a lesser extent with *Tripsacum*) and considered outcrossing of MON 87427 not expected to be any different from other corn varieties. Therefore, USDA has determined that any adverse consequences of gene flow from MON 87427 to wild or weedy species in the U.S. are highly unlikely; (3) APHIS assessed whether horizontal gene transfer might occur between MON 87427 corn and inserted genes with other organisms. Also, the FDA has evaluated horizontal gene transfer following plant transformation with antibiotic resistance marker genes, and concluded that the likelihood of transfer of these genes from plant genomes to microorganisms in the gastrointestinal tract of humans or animals, or in the environment, is remote. Therefore, APHIS also concludes that horizontal gene transfer is unlikely to occur and thus poses no significant environmental or plant pest risk; (4) Corn is not a plant pest in the United States, and the introduced DNA in MON 87427 is unlikely to pose a plant pest risk. Based on the review of numerous field tests with MON 87427 provided by the petitioner, and the analysis of genetic modifications and their functions, APHIS concludes that there are no significant differences between MON 87427 corn and the non-transgenic counterparts relative to pest and disease susceptibility.

In addition to our finding that Event MON 87427 corn is unlikely to pose a plant pest risk, APHIS has completed an Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) for this action and has determined that a determination of nonregulated status of Event MON 87427 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 or endangered species, species proposed for listing, or their designated or proposed critical habitats (http://www.aphis.usda.gov/biotechnology/not_reg.html). APHIS also concludes, based upon its PPRA, that new varieties derived from Event MON 87427 corn are unlikely to exhibit new properties that are substantially different from the ones observed for Event MON 87427 corn, or those observed for other corn 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 of the scientific and environmental data, analyses, information, the input from the public involvement process, and conclusions of the PPRA, the EA, and the FONSI, and my knowledge and experience as the Deputy Administrator of APHIS Biotechnology Regulatory Services, I have determined and decided that this determination of non-regulated status for Event MON 87427 corn is the most scientifically sound and appropriate regulatory decision.



Michael J. Firko

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

Date: 9/25/2013