

Determination of Nonregulated Status for Monsanto Company MON 88701 Cotton

In response to petition 12-185-01p 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 dicamba and glufosinate herbicide-resistant MON 88701 cotton (hereinafter referred to as MON 88701 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 MON 88701 cotton is unlikely to pose a plant pest risk, APHIS will approve the petition for nonregulated status of MON 88701 cotton. 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 88701 cotton and its progeny. Importation of MON 88701 cotton 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 parts 201 and 361.

This Determination of nonregulated status for MON 88701 cotton 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 88701 cotton.

The PPRA conducted on MON 88701 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 MON 88701 cotton.
- (2) Disease and pest incidence and/or damage were not observed to be significantly increased or atypical in MON 88701 cotton compared to the nontransgenic counterpart or other comparators in field trials conducted in growing regions representative of where MON 88701 cotton is expected to be grown. Observed agronomic traits also did not reveal any significant differences that would indirectly indicate that MON 88701 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.