

## **Determination of Nonregulated Status for Monsanto MON 87701 soybeans**

In response to petition 09-082-01p from Monsanto Company, the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has determined that event MON 87701 soybean and progeny derived from it are unlikely to pose plant pest risks and are no longer to be considered regulated articles under APHIS' Biotechnology Regulations (Title 7 of Code of Federal Regulations (CFR), part 340). Since APHIS has determined that MON 87701 soybeans are unlikely to pose plant pest risks, APHIS will approve the petition for nonregulated status of MON 87701 soybeans. Therefore, APHIS approved permits or acknowledged notifications that were previously required for environmental release, importation, or interstate movement under those regulations will no longer be required for event MON 87701 soybeans and its progeny. Importation of MON 87701 soybeans seeds and other propagative material would still be subject to APHIS foreign quarantine notices at 7 CFR part 319 and the Federal Seed Act regulations at 7 CFR part 201.

This determination for MON 87701 is based on APHIS' analysis of field, greenhouse 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 87701.

The Plant Pest Risk Assessment conducted on MON 87701 concluded that it is unlikely to pose plant pest risks and should no longer be subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340 for the following reasons: (1) it exhibits no characteristics that would cause it to be weedier than the non-genetically engineered parent soybean line or any other cultivated soybeans; (2) gene introgression from event MON 87701 soybeans into wild relatives in the United States and its territories is extremely unlikely and is not likely to increase the weediness potential of any resulting progeny nor adversely affect genetic diversity of related plants any more than would introgression from traditional soybean varieties; (3) horizontal gene transfer is unlikely to occur between MON 87701 soybeans and organisms with which it cannot interbreed; (4) disease and insect susceptibilities are similar to other soybean cultivars grown in the U.S. ; (5) it does not pose a risk to non-target organisms, including beneficial organisms, and (6) compositional profiles of MON 87701 soybeans are similar to those of its parent line and other soybean cultivars grown in the U.S, therefore no direct or indirect plant pest effects on raw or processed plant commodities are expected.

In addition to our finding that event MON 87701 is unlikely to pose a plant pest risk, APHIS has completed a Final Environmental Assessment (EA) and FONSI for this action and has determined that a determination of nonregulated status for MON 87701 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/brs/not\\_reg.html](http://www.aphis.usda.gov/brs/not_reg.html)). APHIS also concludes in its PPRA that new varieties derived from MON 87701 are unlikely to exhibit new plant pest properties that are substantially different from the ones observed for MON 87701 soybeans, or those observed for other soybean varieties not considered regulated articles under 7 CFR part 340.

Based on my full and complete review and consideration of all of the scientific and environmental data, analyses, information, and conclusions of the PPRA, the Final EA, the agency's Response to Public Comments received in reference to the Draft EA, 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 nonregulated status of MON 87701 soybeans is the most scientifically sound and appropriate regulatory decision.

Michael C. Gregoire

9/22/2011

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

Date