

Determination of Nonregulated Status for MON 87460 Corn (*Zea mays* L.)

In response to petition 09-055-01p from Monsanto Company (hereafter referred to as Monsanto), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has determined that MON 87460 corn and progeny derived from it are unlikely to pose plant pest risks and is no longer to be considered regulated article under APHIS' Biotechnology Regulations (Title 7 of Code of Federal Regulations (CFR), part 340). Since APHIS has determined that MON 87460 corn is unlikely to pose plant pest risk, APHIS will approve the petition for nonregulated status of MON 87460 corn. Therefore, APHIS approved permits or acknowledged notifications that were previously required for environmental release, interstate movement, or importation under those regulations will no longer be required for MON 87460 corn and its progeny. Importation of MON 87460 corn 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 87460 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 87460 corn.

The Plant Pest Risk Assessment conducted on MON 87460 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 7 CFR part 340 for the following reasons: (1) agronomic performance and disease and insect susceptibility of MON 87460 corn is similar to that of its non-genetically engineered corn counterpart and/or other corn cultivars grown in the U.S.; (2) the disarmed *Agrobacterium* transformation vector used to introduce the genetic material into MON 87460 corn was eliminated and neither the transformation vector nor the introduced genetic material or gene products are known to cause or promote disease, damage or injury to plants; (3) gene introgression from MON 87460 corn into wild relatives in the United States and its territories is unlikely and is not likely to increase the weediness potential of any resulting progeny nor adversely affect the genetic diversity of related plants any more than would cultivation of traditional or other corn varieties; (4) they exhibit no characteristics that would cause them to be weedier or more difficult to control as weeds than non-genetically engineered corn or any other cultivated corn; (5) the gene products (cold shock protein B and neomycin phosphotransferase II protein) have no known toxicity and are unlikely to pose any risks to non-target or beneficial organisms (6) horizontal gene transfer is unlikely to occur between MON 87460 corn and organisms with which they cannot interbreed.

In addition to our finding that MON 87460 corn is unlikely to pose a plant pest risk, APHIS has completed a Final Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) for this action and has determined that a determination of nonregulated status for MON 87460 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 in its PPRA that new varieties derived from MON 87460 corn are unlikely to exhibit new plant pest properties that are substantially different from the ones observed for MON 87460 corn, or those observed for other corn 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 for MON 87460 corn is the most scientifically sound and appropriate regulatory decision.

Michael C. Gregoire

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

11/30/2011

Date