Determination of Nonregulated Status of MON 87769 Soybean (*Glycine max*)

In response to petition 09-183-01p 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 87769 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 87769 soybean is unlikely to a pose plant pest risk, APHIS will approve the petition for nonregulated status of MON 87769 soybean. 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 87769 soybean and its progeny. Importation of MON 87769 soybean 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 of nonregulated status of MON 87769 soybean 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 87769 soybean.

The Plant Pest Risk Assessment conducted on MON 87769 soybean 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 87769 soybean is similar to that of its non-genetically engineered soybean counterpart and/or other soybean cultivars grown in the U.S.; (2) the disarmed *Agrobacterium* transformation vector used to introduce the genetic material into MON 87769 soybean 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 87769 soybean 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 soybean varieties; (4) they exhibit no characteristics that would cause them to be weedier or more difficult to control as weeds than non-genetically engineered soybean or any other cultivated soybean; (5) the gene products (Δ6 desaturase and Δ15 desaturase proteins) 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 87769 soybean and organisms with which they cannot interbreed.

In addition to our finding that MON 87769 soybean 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 of MON 87769 soybean 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 87769 soybean are unlikely to exhibit new plant pest properties that are substantially different from the ones observed for MON 87769 soybean, 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 87769 soybean is the most scientifically sound and appropriate regulatory decision.

Michael C. Gregoire

5/15/2012

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

Date