Extended Determination of Nonregulated Status for MON 87751 Soy (*Glycine max*)

In response to a request to extend a determination of nonregulated status to lepidopteran resistant soy event MON 87751 (13-337-01p) 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 87751 soy 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). This extension request is based upon APHIS' determination of nonregulated status of Monsanto event MON 87701 (APHIS petition # 09-082-01p, effective October 12, 2011). Since APHIS has determined that MON 87751 soy is unlikely to pose a plant pest risk, APHIS will approve the request to extend the determination of nonregulated status to MON 87751 soy. 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 87751 soy and its progeny. Importation of MON 87751 soy 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 parts 201 and 361.

MON 87751 has been engineered to express two *Bacillus thuringiensis* proteins (Cry1A.105 and Cry2Ab2) that confer resistance to certain lepidopteran pests of soybeans. APHIS evaluated the plant pest risk of MON 87751 based upon its similarity to the previously deregulated antecedent soybean, MON 87701, which expresses the *Bt* protein Cry1Ac. Both MON87751 and MON87701 are resistant to the velvetbean caterpillar, soybean looper, soybean axil borer, and sunflower looper, but MON 87751 also includes resistance to fall armyworm.

APHIS has concluded that this difference in activity spectra is unlikely to affect the plant pest risk of MON 87751. APHIS has previously assessed the risks of the two proteins when expressed in corn (both Cry1A.105 and Cry2Ab2; APHIS Petition Number 06-298-01p) and cotton (Cry2Ab2; APHIS Petition Number 00-342-01p) and concluded that the organisms did not pose a plant pest risk. Furthermore, EPA has reviewed the safety of Cry1A.105 and Cry2Ab2 in corn and concluded that "adverse effects will not occur to nontarget organisms." This evidence together suggests that Cry1A.105 and Cry2Ab2 in MON 87751 are unlikely to pose a plant pest risk; nor is MON 87751 likely to pose a different plant pest risk than MON87701.

APHIS conducted a Plant Pest Risk Assessment on the antecedent organism, MON 87701 soy. Based on a comparative review of Monsanto's request to extend nonregulated status to MON 87751, APHIS concludes that MON 87751 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. Based upon the similarity of MON 87751 to MON 87701: (1) disease and insect susceptibility of MON 87751 should be similar to that of its non-genetically engineered cotton counterpart, the antecedent organism, and/or other cotton cultivars grown in the U.S.; (2) Like the antecedent organism, gene flow and

introgression from MON 87751 soy into wild relatives in the United States and its territories is unlikely to occur and genetic diversity of related plants is unlikely to be adversely affected any more so than might occur with cultivation of traditional or other cotton varieties; (3) MON 87751 soy will exhibit no characteristics that would cause it to be weedier or more difficult to control as a weed than non-genetically engineered cotton, the antecedent organism or any other cultivated cotton; (4) the plant and its gene products will not pose a risk to non-target organisms, including beneficial organisms; (5) horizontal gene transfer between MON 87751 soy and organisms with which it cannot interbreed is unlikely to occur.

In addition to our finding that MON 87751 soy is unlikely to pose a plant pest risk, APHIS has made a Finding of No Significant Impact (FONSI) for this action based on its similarity to MON 87701 soy and the Environmental Assessment completed for the petition submitted for that product (APHIS petition number 09-082-01p). The progeny of MON 87751 soy 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). Similar to APHIS' plant pest risk assessment conclusions regarding MON 87701 soy, APHIS concludes that new varieties derived from MON 87751 soy are unlikely to exhibit plant pest properties that are substantially different from the ones observed for other soy varieties not considered regulated articles under 7 CFR part 340.

Based on my review and consideration of all of the scientific and environmental data, analyses, information, and previous conclusions regarding the plant pest risk assessment for the antecedent organism MON 87701 soy the FONSI that was prepared based upon the previous NEPA review completed for MON 87701 soy, 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 87751 soy is the most scientifically sound and appropriate regulatory decision.

M. J. Firko

16 Oct 2014

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

Date