Determination of Nonregulated Status for Monsanto Company MON 87708 Soybean

In response to petition 10-188-01p 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 herbicide-resistant MON 87708 soybean (hereinafter referred to as MON 87708 soybean) 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 87708 soybean is unlikely to pose a plant pest risk, APHIS will approve the petition for nonregulated status of MON 87708 soybean. 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 87708 soybean and its progeny. Importation of MON 87708 soybean 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 87708 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 87708 soybean.

The PPRA conducted on MON 87708 soybean 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 87708 soybean.

(2) Disease and pest incidence and/or damage were not observed to be significantly increased or atypical in MON 87708 soybean compared to the nontransgenic counterpart or other comparators in field trials conducted in growing regions representative of where MON 87708 soybean is expected to be grown. Observed agronomic traits also did not reveal any significant differences that would indirectly indicate that MON 87708 soybean 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.

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(3) Based on an evaluation of the gene products, donor organisms, chemical composition, environmental interactions with beneficial arthropods, pollen characteristics and association with symbionts, exposure to and/or consumption of MON 87708 soybean are unlikely to adversely impact nontarget organisms beneficial to agriculture.

(4) MON 87708 soybean is no more likely to become weedier or more difficult to control as a weed than conventional varieties of this crop based on its observed agronomic characteristics, weediness potential of the crop and current management practices available to control MON 87708 soybean as a weed.

(5) MON 87708 soybean is not likely to increase the weed risk potential of other species with which it can interbreed in the U.S. or its territories. Gene flow, hybridization and/or introgression of inserted genes from MON 87708 soybean to other sexually compatible relatives with which it can interbreed is not likely to occur.

(6) Significant changes to agricultural or cultivation practices (e.g. pesticide applications, tillage, irrigation, harvesting, etc.) from adoption of MON 87708 soybean are expected, but are not likely to increase plant diseases or pests or compromise their management.

(7) Horizontal gene transfer of the new genetic material inserted into the GE plant to other organisms is highly unlikely, and is not expected to lead directly or indirectly to disease, damage, injury or harm to plants, including the creation of new or more virulent pests, pathogens, or parasitic plants.

APHIS also concludes in its PPRA that new varieties derived from MON 87708 soybean are unlikely to exhibit new properties substantially different from the ones observed for MON 87708 soybean, or those observed in other soybean varieties not considered regulated articles under 7 CFR part 340, that would pose a plant pest risk.

Prior to this Determination of nonregulated status, APHIS completed a Final Environmental Impact Statement (FEIS) which explored the potential environmental impacts that a determination of nonregulated status for MON 87708 soybean and its progeny would have on the quality of the human environment. The FEIS concluded, among other things, that a determination of nonregulated status for MON 87708 soybean and its progeny will have no effect on federally-listed threatened and endangered species, species proposed for listing, or their designated or proposed critical habitats. APHIS also concludes with its Determination of nonregulated status, based upon its PPRA, and informed by the completion of the FEIS and the Record of Decision that was issued for the FEIS, that new varieties derived from MON 87708 soybean are unlikely to exhibit new properties substantially different from the ones observed for MON 87708 soybean, or those observed for other soybean varieties not considered regulated articles under 7 CFR part 340, that would pose a plant pest risk.

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Based on my full and complete review and consideration of all of the scientific and environmental data, analyses and information, the input from the public involvement process, the conclusions of the PPRA, the FEIS and its Record of Decision, and my knowledge and experience as the APHIS Deputy Administrator for Biotechnology Regulatory Services, I have determined and decided that this Determination of nonregulated status for MON 87708 soybean is the most scientifically sound and appropriate regulatory decision.

M. J. Firko

14 January 2015

Michael J. Firko, Ph.D.

Date

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

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