Determination of Nonregulated Status for Monsanto MON-874Ø3 Maize

In response to petition 14-213-01p 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 Increased Ear Biomass MON-874Ø3 maize (hereinafter referred to as MON-874Ø3 maize) 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-874Ø3 maize is unlikely to pose a plant pest risk, APHIS will approve the petition for nonregulated status of MON-874Ø3 maize. Therefore, APHIS authorizations previously required for environmental release, interstate movement, or importation under these regulations will no longer be required for MON-874Ø3 maize and its progeny. Importation of MON-874Ø3 maize seeds, other propagative material, or grain for consumption 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-874Ø3 maize 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-874Ø3 maize.

The PPRA conducted on MON-874Ø3 maize 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-874Ø3 maize

(2) Disease and pest incidence and/or damage were not observed to be increased or atypical in MON-874Ø3 maize compared to the non-genetically engineered counterpart or other comparators in field trials conducted in growing regions representative of where MON-874Ø3 maize is expected to be grown. Data collected on observed agronomic traits also did not reveal any results that would indicate that MON-874Ø3 maize would be 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.

(3) Based on an evaluation of the gene products, the low expression level of the new expressed protein and its low potential for toxicity, the compositional similarity of MON-874Ø3 maize to parental lines and other comparators, and the observed phenotype and interactions of MON-874Ø3 with arthropods and other organisms, exposure to and/or consumption of MON-874Ø3 maize are unlikely to adversely impact nontarget organisms beneficial to agriculture.

(4) MON-874Ø3 maize is no more likely to become weedier or more difficult to control as a weed than conventional varieties of maize based on the observed agronomic characteristics of MON-874Ø3 maize, the weediness potential of maize and current management practices available to control maize as a weed.

(5) MON-874Ø3 maize 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-874Ø3 maize 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-874Ø3 maize are not expected.

(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' analyses and conclusions in the PPRA regarding the plant pest risk of MON-874Ø3 maize also apply to progeny such as any new varieties derived from MON-874Ø3 maize. Prior to this Determination of nonregulated status, APHIS has completed an Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) for this action, and has concluded that a determination of nonregulated status for MON-874Ø3 maize 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 and endangered species, species proposed for listing, or their designated or proposed critical habitats.

Based on my full and complete review and consideration of all the scientific and environmental data, analyses and information, the input from the public involvement process, the conclusions of the PPRA, the EA and the FONSI, 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-874Ø3 maize and progeny is the most scientifically sound and appropriate regulatory decision.

M. J. Firko

Michael J. Firko, Ph.D.

11/17/2015

Date

APHIS Deputy Administrator
Biotechnology Regulatory Services
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