

Final Extended Determination¹ of Nonregulated Status for Bayer CropScience LLP MS11 Canola for Male Sterile, Glufosinate Ammonium Tolerant (Petition No. 16-235-01p)

In response to a request from Bayer CropScience LLP (hereinafter referred to as Bayer) to extend a determination of nonregulated status to Canola Event MS11 (hereinafter referred to as MS11 canola) with male sterility and glufosinate tolerance (petition number 16-235-01p), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has determined, based on similarity to its antecedent organism, that MS11 canola 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 its antecedent organism: Bayer canola event MS8 Drakkar Canola (hereinafter referred to as Bayer antecedent canola), with male sterility and glufosinate tolerance (petition number 98-278-01p). Bayer antecedent canola event from petition number 98-278-01p was deregulated on March 22, 1999. When deregulated, APHIS approved permits and acknowledged notifications will no longer be required for environmental release, interstate movement, or importation of MS11 canola and its progeny. Importation of MS11 canola seeds and other propagative material will 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.

A similar gene cassette pTCO113 containing the same genetic events used to transform the Bayer antecedent canola event (gene cassette pTHW107) with male sterility and glufosinate tolerance, was used to transform and generate the MS11 canola event. APHIS evaluated the plant pest risk of MS11 canola by assessing its similarity to the deregulated Bayer antecedent canola event.

APHIS previously conducted a Plant Pest Risk Assessment on the antecedent organism and found it unlikely to pose a risk as a plant pest. Based on a the plant pest similarity assessment (see Appendix A) of MS11 canola to the antecedent, APHIS concludes that MS11 canola is unlikely to pose a plant pest risk and should no longer be regulated under 7 CFR part 340. From the similarity assessment, APHIS concludes the following with respect to MS11 canola and its progeny:

- (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 MS11 canola.
- (2) Disease and pest incidence and/or damage are not expected to be increased or atypical for MS11 canola. No plant pest effects are expected on these or other agricultural products and no impacts are expected to affect APHIS pest control programs.

¹ This extended determination is not effective until officially signed and published.

- (3) Based on an evaluation of the gene products, and their similarity to the antecedent, MS11 canola is unlikely to adversely impact nontarget organisms beneficial to agriculture.
- (4) MS11 canola is no more likely to become weedier or more difficult to control as a weed than the antecedent, which is not weedy.
- (5) MS11 canola is not likely to increase the weed risk potential of other species with which it can interbreed in the United States or its territories. Gene flow, hybridization and/or introgression of inserted genes from MS11 canola 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 MS11 canola is 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.

In addition to our finding that MS11 canola is unlikely to pose a plant pest risk, APHIS prepared and reached a Finding of No Significant Impact (FONSI) for this action based on an Environmental Assessment completed for the petition submitted for this product (APHIS petition number 16-235-01p). MS11 canola will 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/notreg.html>).

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 organisms, the plant pest risk similarity assessment, Environmental Assessment, and FONSI, and my knowledge and experience as APHIS' Deputy Administrator for Biotechnology Regulatory Services, I have determined and decided that this determination of nonregulated status of MS11 canola is the most scientifically sound and appropriate regulatory decision.

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

Date