

## **Preliminary<sup>1</sup> Determination of Nonregulated Status of MON 88302 Canola (*Brassica napus*)**

In response to petition 11-188-01p 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 88302 canola and progeny derived from it are unlikely to pose a plant pest risk and are no longer to be considered regulated articles under APHIS' Biotechnology Regulations in Title 7 of the Code of Federal Regulations, part 340 (7 CFR part 340). Since APHIS has determined that MON 88302 canola is unlikely to pose a plant pest risk, APHIS will approve the petition for nonregulated status of MON 88302 canola.

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 88302 canola and its progeny. Importation of MON 88302 canola 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 88302 canola is based on APHIS' assessment 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 88302 canola (including its progeny). Based on the above-mentioned assessment, APHIS concludes the following:

- a. Neither the introduced sequences nor the method of transformation has resulted in disease symptoms, pathogen infection, or expression of a pathogen in MON 88302.
- b. Composition of Mon 88302 seed is similar to that of the conventional control and/or within the natural variability of commercial reference varieties. Therefore, changes in gene expression, enzymes or metabolism from introduced genes in MON 88302 are unlikely to pose a plant pest risk.
- c. MON 88302 is unlikely to be more susceptible to the same plant pathogens and insect pests as conventional canola and it is unlikely to bring about any indirect plant pest effects on other agricultural products.
- d. MON 88302 is not expected to adversely impact wildlife or other organisms beneficial to agriculture any more than conventional canola varieties.
- e. Introduced genes in MON 88302 did not significantly alter any major characteristics of the plant that would facilitate the development of weedy characteristics in the crop or enhance its gene flow potential to wild or weedy relatives and consequently produce or alter characteristics associated with weediness. Furthermore, alternative herbicides are available to control glyphosate resistant canola and weedy relatives.
- f. The glyphosate resistance trait in MON 88302 and the anticipated changes in agricultural practices related to glyphosate resistance in MON 88302 are not expected to increase pests or diseases or impact their control in canola or other crops based on prior experience with previously deregulated glyphosate resistant canola.

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- g. Genes encoding variants of the EPSPS protein already exist among pathogens and symbionts in the environment, and horizontal transfer of the inserted glyphosate resistance gene from MON 88302 to other organisms with which it cannot interbreed is highly unlikely, and thus should not pose a plant pest risk.

In addition to our finding that MON 88302 canola is unlikely to pose a plant pest risk, APHIS has completed an Environmental Assessment (EA) and preliminary Finding of No Significant Impact (FONSI) for this action and has determined that a determination of nonregulated status of MON 88302 canola 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](http://www.aphis.usda.gov/biotechnology/not_reg.html)). APHIS also concludes, based upon its PPRA, that new varieties derived from MON 88302 canola are unlikely to exhibit new properties that are substantially different from the ones observed for MON 88302 canola, or those observed for other canola varieties not considered regulated articles under 7 CFR part 340, that would pose a plant pest risk.

Based on my full and complete review and consideration of all of the scientific and environmental data, analyses, information, the input from the public involvement process, and conclusions of the PPRA, the EA, and the preliminary 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 88302 canola is the most scientifically sound and appropriate regulatory decision.

Michael C. Gregoire

Date

Deputy Administrator

Biotechnology Regulatory Services

Animal and Plant Health Inspection Service

U.S. Department of Agriculture

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