

Preliminary ¹Determination of Nonregulated Status of 73496 Canola (*Brassica napus*)

In response to petition 11-063-01p from Pioneer Hi-Bred International, Inc. (hereafter referred to as Pioneer), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has determined that 73496 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 73496 canola is unlikely to pose a plant pest risk, APHIS will approve the petition for nonregulated status of 73496 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 73496 canola and its progeny. Importation of 73496 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 73496 canola is based on APHIS' assessment of field and laboratory data submitted by Pioneer, references provided in the petition, peer-reviewed publications, and other relevant information as described in the Plant Pest Risk Assessment (PPRA) for 73496 canola (including its progeny). Based on the above-mentioned assessment, APHIS concludes the following:

- a. The introduced synthetic *gat4621* gene encoding the glyphosate *N*-acetyltransferase enzyme GAT4621 in 73496 canola results in the detoxification of applied glyphosate herbicide; neither the introduced sequences nor the method of transformation has resulted in disease symptoms, pathogen infection, or expression of a pathogen in 73496 canola.
- b. Changes in gene expression, enzymes or metabolism in 73496 canola are unlikely to pose a plant pest risk; minor differences in the compositional constituents of 73496 canola seed compared to the control canola that could directly or indirectly impact plant pests or plant health were well within the range of commercial reference varieties, and did not raise any plant pest risks.
- c. The observed insect pests and diseases or resulting damage on 73496 canola compared to the control canola suggest that 73496 canola is unlikely to be more susceptible to pathogens and insect pests of conventional canola or to bring about indirect plant pest effects on other agricultural products.
- d. Based on the toxicity and safety assessment of the GAT4621 enzyme and minor changes in canola seed composition, 73496 canola is unlikely to adversely impact wildlife or other organisms beneficial to agriculture any more than conventional canola varieties.
- e. There were no meaningful observed differences in traits between 73496 canola and control canola that would (i) enhance weediness in canola, or (ii) enhance its gene flow potential to wild or weedy relatives and consequently increase weedy characteristics in wild or weedy relatives. Furthermore alternative herbicides are available to control glyphosate resistant canola and weedy relatives.

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- f. The glyphosate resistance trait and observed agronomic and pest response characteristics in 73496 canola are not expected to change agricultural or cultivation practices compared to those currently used in widely-cultivated glyphosate-resistant canola varieties, which experience has shown has not increased pests or diseases or impacted their control.
- g. Genes encoding variants of the GAT4621 protein already exist in a widespread, non-pathogenic soil bacterium in the environment, and horizontal transfer of the inserted glyphosate resistance gene from 73496 canola 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 73496 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 73496 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). APHIS also concludes, based upon its PPRA, that new varieties derived from 73496 canola are unlikely to exhibit new properties that are substantially different from the ones observed for 73496 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 73496 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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