Determination of Nonregulated status for Monsanto and Forage Genetics International Roundup Ready® Alfalfa Events J101 and J163

In response to petition (designated 04-110-01p) from Monsanto Company and Forage Genetics International (FGI), APHIS has determined that the petitioners genetically engineered alfalfa transformation Events J101 and J163 and progeny derived from them are unlikely to pose a plant pest risk and are no longer to be considered regulated articles under APHIS's biotechnology regulations at 7 CFR part 340. In fact, there is no evidence of plant pest risk associated with these two alfalfa events. Permits or acknowledged notifications that were previously required for environmental release, interstate movement, or importation under those regulations are no longer a requirement for alfalfa transformation Events J101 and J163 and its progeny. Importation of 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 part 201.

This determination is based on APHIS' analysis of field, greenhouse, and laboratory data, references provided in the petition, and other relevant information as described in the Plant Pest Risk Assessment for alfalfa Events J101 and J163, the Environmental Impact Statement prepared for this determination, and in APHIS's response to public comments (http://www.aphis.usda.gov/brs/not_reg.html) that indicate that alfalfa Events J101 and J163 are unlikely to pose a plant pest risk.

The Plant Pest Risk Assessment[1] (http://www.aphis.usda.gov/brs/not_reg.html) concluded that Monsanto and FGI alfalfa Events J101 and J163 are not likely to pose a plant pest risk and should be granted nonregulated status for the following reasons: (1) They exhibit no plant pathogenic properties – although a plant pathogen was used in their development, these plants are not infected by this organism nor do they contain genetic material from pathogens used as a donor organism that can cause plant disease. (2) They exhibit no characteristics that would cause them to be weedier than the non-transgenic parent alfalfa or other cultivated alfalfa and several control options besides glyphosate are available for control of feral or volunteer plants or for stand take-out. (3) Gene introgression from J101 and J163 to native, introduced, or naturalized species of *Medicago* in the United States is extremely unlikely and even if it were to occur, is not likely to increase the weediness potential of any resulting progeny any more than would introgression from other cultivated alfalfa. (4) Disease and insect susceptibility and compositional profiles (other than the intended CP4 EPSPS protein conferring glyphosate tolerance) of J101 and J163 are similar to those of the parent variety and other alfalfa cultivars grown in the United States, therefore pest and disease control methods are expected to be similar and no direct or indirect plant pest effect on raw or processed plant commodity is expected. (5) Field observations,

[1] APHIS prepared the revised Plant Pest Risk Assessment and EIS in response to ruling on February 13, 2007, by the United States District Court for the Northern District of California that vacated a previous determination of deregulated status of J101 and J163 alfalfa that was effective from June 14, 2005. On March 23, 2007, APHIS published a notice in the *FR* (72 *FR* 13735-13736 APHIS Docket No. 04-085-1) announcing the Court's decision that Monsanto and FGI GT alfalfa lines J101 and J163 were once again regulated articles under 7 CFR part 340.

compositional data including components related to nitrogen fixation and nodulation, and data on the safety of the engineered EPSPS protein all indicate that J101 and J163 should not have a greater potential than other cultivated alfalfa to damage or harm organisms beneficial to agriculture. (6) Horizontal gene transfer from these alfalfa Events to organisms with which they cannot interbreed is highly unlikely to occur, and is not expected to pose a plant pest risk.

APHIS also concludes that new varieties bred from glyphosate-tolerant alfalfa Events J101 and J163 are unlikely to exhibit new plant pest properties, i.e., properties substantially different from any observed for glyphosate-tolerant alfalfa Events J101 and J163, or those observed for other alfalfa varieties not considered regulated articles under 7 CFR part 340.

APHIS has completed an Environmental Impact Statement (EIS) (http://www.aphis.usda.gov/brs/not_reg.html) that assesses the possible impacts of a determination of non-regulated status for glyphosate-tolerant alfalfa Events J101 and J163 on the quality of the human environment consistent with APHIS obligations under the National Environmental Policy Act as amended, Council on Environmental Quality (CEQ) regulations for implementing NEPA, the USDA regulations implementing NEPA, and the APHIS National Environmental Policy Act (APHIS NEPA) of 1969 Implementing Procedures. The EIS also includes an analysis of the effects of to federally listed and proposed threatened and endangered species and their designated critical habitat and habitat proposed for designation consistent with our obligations under the Endangered Species Act (ESA) of 1973, as amended.

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1/28/11

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Date