

Determination of Nonregulated Status Under 7 CFR Part 340 for Monsanto Company and Forage Genetics International KK179 alfalfa

In response to petition 12-321-01p from Monsanto Company and Forage Genetics International (hereafter referred to as Monsanto and FGI), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has determined that Monsanto and FGI genetically engineered alfalfa Event KK179 (hereafter referred to as KK179 alfalfa) and progeny derived from it is not likely to pose a plant pest risk and is no longer to be considered a regulated article under APHIS's Biotechnology Regulations (Title 7 of the Code of Federal Regulations (CFR), part 340). Since APHIS has determined that KK179 alfalfa is unlikely to pose a plant pest risk, APHIS will approve the petition for nonregulated status of KK179 alfalfa. Therefore, APHIS approved permits or acknowledged notifications that were previously required for environmental releases, interstate movement, or importation under these regulations will no longer be required for KK179 alfalfa and its progeny. Importation of KK179 alfalfa 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 for KK179 alfalfa is based on APHIS' analyses of field and laboratory data submitted by Monsanto and FGI, references provided in the petition, peer-reviewed publications, and other relevant information as described in the Plant Pest Risk Assessment (PPRA) for KK179 alfalfa.

The PPRA conducted on KK179 alfalfa concluded that it is unlikely to pose a plant pest risk and should no longer be subject to 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 the GE alfalfa KK179.
- (2) Disease and pest incidence and/or damage were not observed to be significantly increased or atypical in the GE alfalfa KK179 compared to the nontransgenic counterpart or other comparators in field trials conducted in growing regions representative of where the GE alfalfa KK179 is expected to be grown. Observed agronomic traits also did not reveal any significant differences that would indirectly indicate that the GE alfalfa KK179 is 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, agronomic performance, and compositional profiles, exposure to and/or consumption of the GE alfalfa KK179 is unlikely to adversely impact nontarget organisms beneficial to agriculture.
- (4) The GE alfalfa KK179 is no more likely to become weedier or more difficult to control as a weed than conventional varieties of this crop based on its observed agronomic characteristics, weediness potential of the crop and current management practices available to control the GE alfalfa KK179 as a weed.

- (5) The GE alfalfa KK179 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 the GE alfalfa KK179 to other sexually compatible relatives with which it can interbreed is not likely to occur because there are no sexually compatible native relatives.
- (6) Significant changes to agricultural or cultivation practices (e.g. pesticide applications, tillage, irrigation, harvesting, etc.) from adoption of the GE alfalfa KK179 are not expected.
- (7) Horizontal gene transfer of the new genetic material inserted into the GE alfalfa KK179 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 KK179 alfalfa is not likely to pose a plant pest risk, 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 KK179 alfalfa 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. APHIS also concludes, based upon its PPRA, that new varieties derived from KK179 alfalfa are unlikely to exhibit new properties that are substantially different from the ones observed for KK179 alfalfa, or those observed for other alfalfa 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 the scientific and environmental data, analyses, information, the input from the public involvement process, and conclusions of the PPRA, the EA, and the FONSI, and my knowledge and experience as the Deputy Administrator of APHIS Biotechnology Regulatory Services, I have determined and decided that this determination of non-regulated status for KK179 alfalfa is the most scientifically sound and appropriate regulatory decision.



62 Michael J. Firko, Ph.D.

Deputy Administrator
Biotechnology Regulatory Services
Animal Plant Health Inspection Service
U.S. Department of Agriculture

Date: 9/4/2014