

Determination of nonregulated status for Bayer Event FG72 soybean

In response to petition 09-328-01p from Bayer CropScience (referred to as “Bayer” hereafter), The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has determined that Bayer Event FG72 soybean and progeny derived from it are not likely to pose a plant pest risk and are no longer to be considered regulated articles under APHIS’s Biotechnology Regulations (Title 7 of the Code of Federal Regulations (CFR), part 340). Since APHIS has determined that Event FG72 soybean is unlikely to pose a plant pest risk, APHIS will approve the petition for nonregulated status of Event FG72 soybean. 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 Event FG72 soybean and its progeny. Importation of Event FG72 soybean 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 Event FG72 soybean is based on APHIS’ analyses of field and laboratory data submitted by Bayer, references provided in the petition, peer-reviewed publications, and other relevant information as described in the Plant Pest Risk Assessment (PPRA) for Event FG72 soybean.

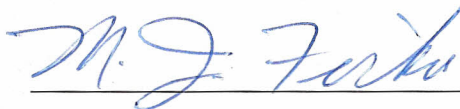
The Plant Pest Risk Assessment conducted on Event FG72 soybean concluded that it is unlikely to pose a plant pest risk and should no longer be subject to the plant pest provisions of the Plant Protection Act and 7CFR part 340 for the following reasons:

- (1) Disease and insect susceptibility, agronomic performance, and compositional profiles (except for the intended change-tolerance to glyphosate herbicide and isoxaflutole) of Event FG72 soybean are similar to those of its non-genetically engineered soybean counterparts and/or other soybean cultivars grown in the U.S., and are unlikely to alter disease and pest susceptibilities;
- (2) Agronomic performance evaluations of Event FG72 soybean revealed no characteristics that would cause it to be weedier or more difficult to control as a weed than non-genetically engineered soybean or any other cultivated soybean;
- (3) Gene introgression from Event FG72 soybean into wild relatives in the United States and its territories is extremely unlikely and is not likely to increase the weediness potential of any resulting progeny nor adversely affect the genetic diversity of related plants any more than would cultivation of traditional or other specialty soybean varieties;
- (4) Based on an evaluation of the gene products and testing of representative non-target species, it has been concluded that Event FG72 soybean is unlikely to adversely affect nontarget organisms, including those considered beneficial;

(5) Horizontal gene transfer is unlikely to occur between Event FG72 soybean and organisms with which they cannot interbreed;

In addition to our finding that Event FG72 soybean is not likely to pose a plant pest risk, APHIS has completed a Final Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) for this action and has determined that a determination of nonregulated status of Event FG72 soybean 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 Event FG72 soybean are unlikely to exhibit new properties that are substantially different from the ones observed for Event FG72 soybean, or those observed for other soybean 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, and conclusions of the PPRA, the Final EA, the agency's Response to Public Comments received in reference to the Draft EA, 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 Event FG72 soybean is the most scientifically sound and appropriate regulatory decision.



Michael Firko

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

Date: 13 August 2013