

Preliminary Determination¹ of Nonregulated Status for Syngenta and Bayer double herbicide-tolerant SYHT0H2 soybean

In response to petition 12-215-01p from Syngenta Seeds, Inc. and Bayer CropSciences AG (hereafter referred to as Syngenta and Bayer), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has determined that Syngenta and Bayer's double herbicide-tolerant soybean (hereafter referred to as SYHT0H2 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 SYHT0H2 soybean is unlikely to pose a plant pest risk, APHIS will approve the petition for nonregulated status of SYHT0H2 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 SYHT0H2 soybean and its progeny. Importation of SYHT0H2 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 SYHT0H2 soybean is based on APHIS' analyses of field and laboratory data submitted by Syngenta and Bayer, references provided in the petition, peer-reviewed publications, and other relevant information as described in the Plant Pest Risk Assessment (PPRA) for SYHT0H2 soybean.

The Plant Pest Risk Assessment conducted on SYHT0H2 soybean 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) Disease and insect susceptibility, agronomic performance, and other observed characteristics (except for the intended changes) of SYHT0H2 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) Based on an evaluation of the gene products and testing of representative non-target species, it has been concluded that SYHT0H2 soybean is unlikely to adversely affect nontarget organisms beneficial to agriculture;
- (3) Agronomic performance evaluations of SYHT0H2 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;
- (4) Gene introgression from SYHT0H2 soybean into wild relatives in the United States and its territories 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 soybean varieties;

¹ Determination is not effective until officially signed and published.

- (5) SYHT0H2 soybean cultivation is similar to those of its parent line and other soybean cultivars grown in the U.S., and therefore, there will be no change in agricultural and cultural practices;
- (6) Horizontal gene transfer is unlikely to occur between SYHT0H2 soybeans and organisms with which they cannot interbreed.

In addition to our finding that SYHT0H2 soybean 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 determined that a determination of 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 SYHT0H2 soybean are unlikely to exhibit new properties that are substantially different from the ones observed for SYHT0H2 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 the scientific and environmental data, analysis, 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 determine and decided that this determination of non-regulated status for SYHT0H2 soybean is the most scientifically sound and appropriate regulatory decision.

Michael J. Firko, Ph.D.

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

Date: