

Preliminary Determination¹ of Nonregulated Status for Genective Event VCO-Ø1981-5 Corn

In response to petition 11-342-01p from Genective SA (hereafter referred to as Genective), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has determined that Genective Event VCO-Ø1981-5 corn 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 VCO-Ø1981-5 corn is unlikely to pose a plant pest risk, APHIS will approve the petition for nonregulated status of Event VCO-Ø1981-5 corn. 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 VCO-Ø1981-5 corn and its progeny. Importation of Event VCO-Ø1981-5 corn 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 VCO-Ø1981-5 corn is based on APHIS' analyses of field and laboratory data submitted by Genective, references provided in the petition, peer-reviewed publications, and other relevant information as described in the Plant Pest Risk Assessment (PPRA) for Event VCO-Ø1981-5 corn.

The Plant Pest Risk Assessment conducted on Event VCO-Ø1981-5 corn 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) of Event VCO-Ø1981-5 corn are similar to those of its non-genetically engineered corn counterparts and/or other corn 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 VCO-Ø1981-5 corn is unlikely to adversely affect nontarget organisms, including those considered beneficial;
- (3) Agronomic performance evaluations of Event VCO-Ø1981-5 corn revealed no characteristics that would cause it to be weedier or more difficult to control as a weed than non-genetically engineered corn or any other cultivated corn;
- (4) Gene introgression from Event VCO-Ø1981-5 corn 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

¹ Determination is not effective until officially signed and posted.

diversity of related plants any more than would cultivation of traditional or other specialty corn varieties;

(5) Agriculture and cultivation practices using Event VCO-Ø1981-5 corn have almost no apparent potential changes compared with other corn varieties;

(6) Horizontal gene transfer is unlikely to occur between Event VCO-Ø1981-5 corn and organisms with which they cannot interbreed.

In addition to our finding that Event VCO-Ø1981-5 corn is not likely 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 Event VCO-Ø1981-5 corn 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 VCO-Ø1981-5 corn are unlikely to exhibit new properties that are substantially different from the ones observed for Event VCO-Ø1981-5 corn, or those observed for other corn 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 non-regulated status for Event VCO-Ø1981-5 corn is the most scientifically sound and appropriate regulatory decision.

Michael Gregoire

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

Date: