

Extended Determination of Nonregulated Status for HCEM485 corn (*Zea mays*)

In response to a request to extend a determination of nonregulated status to include glyphosate-resistant HCEM485 corn (APHIS #09-063-01p) from Stine Seed Farm, Inc. (hereafter referred to as Stine Seed) received on April 1, 2011, the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has determined that HCEM485 corn and progeny derived from it are unlikely to pose plant pest risks and are no longer to be considered regulated articles under APHIS' Biotechnology Regulations (Title 7 of Code of Federal Regulations (CFR), part 340). The requested extension was based on the similarity of HCEM485 corn to another glyphosate-resistant, Roundup Ready® corn line, GA21, from Monsanto Company and Dekalb Genetics Corp. (hereafter referred to as Monsanto and Dekalb) for which APHIS issued a determination of nonregulated status on November 18, 1997 (APHIS petition # 97-099-01p). Since APHIS has determined that HCEM485 corn is unlikely to pose a plant pest risk, APHIS will approve the request to extend the determination of nonregulated status to HCEM485 corn and its progeny. Therefore, APHIS-approved permits or acknowledged notifications that were previously required for environmental release, interstate movement, or importation under those regulations will no longer be required for HCEM485 corn and its progeny. Importation of HCEM485 corn seeds and other propagative material would still be subject to APHIS foreign quarantine notices at 7 CFR part 319 and the Federal Seed Act regulations at 7 CFR part 201.

Both GA21 corn and HCEM485 corn were developed using a direct DNA transfer method, i.e. without the use of plant pest vectors, to insert into the corn genome a gene expression cassette that only confers glyphosate resistance. Monsanto and Dekalb developed the glyphosate-resistant antecedent organism, transgenic GA21 corn by the insertion into the corn genome of a double-mutated form of the corn (*Zea mays* L.) 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) encoding gene containing optimized chloroplast transit sequences derived from *Z. mays* and *Helianthus annuus* (sunflower) ribulose-1,5-bisphosphate carboxylase genes under the control of regulatory sequences from both plant and bacterial sources (i.e. a 5' region of the rice (*Oryza sativa*) actin 1 gene containing the promoter and first intron and the 3' nontranslated terminator region from the nopaline synthase (*nos*) gene derived from the Ti plasmid of the plant pest, *Agrobacterium tumefaciens*). Similarly, the glyphosate tolerance in maize line HCEM485 is also based on expression of the same modified EPSPS enzyme derived from *Z. mays*, but with the notable difference that expression of the modified EPSPS enzyme is regulated by 5' promoter and 3' nontranslated terminator DNA sequences also derived from the *Z. mays* EPSPS-encoding gene rather than regulatory sequences derived from other species.

APHIS has conducted a Plant Pest Risk Assessment on glyphosate-resistant HCEM485 corn in comparison with nontransgenic counterpart control hybrids derived from the same inbred parents used to develop HCEM485 and with the antecedent organism, GA21 corn. Based on a comparative review of Stine Seed's request to extend nonregulated status to HCEM485 corn (09-063-01p), APHIS concludes that HCEM485 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 7 CFR part 340 for the following reasons: (1) disease and insect susceptibility of HCEM485 is similar to that of its non-genetically engineered corn counterpart, as it was with the antecedent organism; and furthermore, there are no sequences derived from plant pests and no changes in agricultural practices are expected related to diseases and pests; (2) Like the antecedent organism, gene flow and introgression from HCEM485 corn into wild relatives in the United States and its territories is unlikely to occur and genetic diversity of related plants is unlikely to be adversely affected any more so than might occur with cultivation of traditional or other corn varieties; (3) HCEM485 exhibits no characteristics that would cause it to be weedier or more difficult to control as a weed than non-genetically engineered corn, the antecedent organism or other previously deregulated glyphosate-resistant corn; (4) the similar composition of the transformed plant to other cultivated corn and the expressed product of the inserted gene (double-mutated *Z. mays* EPSPS) are common to the two events HCEM485 and GA21 corn and do not pose a risk to non-target organisms, including beneficial organisms; (5) horizontal gene transfer between HCEM485 corn and organisms with which it cannot interbreed is unlikely to occur. Similar to APHIS' conclusions regarding plant pest risk in the determination of nonregulated status regarding GA21 corn, APHIS concludes that new varieties derived from HCEM485 corn are unlikely to exhibit plant pest properties that are substantially different from the ones observed for other corn varieties not considered regulated articles under 7 CFR part 340.

Based on my review and consideration of all of the scientific and environmental data, analyses, information, and conclusions of the PPRA completed for HCEM485, the previous conclusions regarding plant pest risk for the antecedent organism (GA21 corn), the previous NEPA review completed for GA21 corn, and my knowledge and experience as the Deputy Administrator of APHIS Biotechnology Regulatory Services, I have determined and decided that this determination of nonregulated status of HCEM485 is the most scientifically sound and appropriate regulatory decision.

Michael C. Gregoire
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Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture

Date