

Determination of Nonregulated Status for DP-32138-1 Corn


In response to petition 08-338-01p from Pioneer Hi-Bred International, the Animal and Plant Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has determined that DP-32138-1 corn and progeny derived from it are unlikely to pose a plant pest risk and are no longer to be considered regulated articles under APHIS' Biotechnology Regulations (Title 7 of Code of Federal Regulations (CFR), part 340). Since APHIS has determined that DP-32138-1 corn is unlikely to pose a plant pest risk, APHIS will approve the petition for nonregulated status of DP-32138-1 corn. Therefore, APHIS approved permits or acknowledged notifications that were previously required for environmental release, interstate movement, or importation of DP-32138-1 corn and its progeny are no longer required. Importation of DP-32138-1 seeds and other propagative material will still be subject to APHIS foreign quarantine notices in 7 CFR part 319 and Federal Seed Act regulations in 7 CFR part 201.

This determination for DP-32138-1 is based on APHIS' analysis of field and laboratory data submitted by Pioneer, references provided in the petition, peer-reviewed publications, and other relevant information as described in the Plant Pest Risk Assessment (PPRA) for DP-32138-1 corn. The Final Environmental Assessment (EA), the Finding of No Significant Impact (FONSI), and the Response to Public Comments on the Draft Environmental Assessment (EA) indicate and confirm that DP-32138-1 corn is unlikely to pose a plant pest risk.

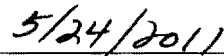
The Plant Pest Risk Assessment conducted on DP-32138-1 corn concluded that it is unlikely to pose a plant pest risk and no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340 for the following reasons: (1) the disarmed *Agrobacterium* plant transformation vector used to introduce the genetic material into DP-32138-1 corn was eliminated and neither the transformation vector nor the introduced genetic material can cause or promote disease, damage or injury to plants; (2) it exhibits no characteristics that would cause it to be weedier or more difficult to control as a weed than the non-genetically engineered corn hybrids evaluated or any other cultivated corn; (3) gene introgression from DP-32138-1 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 diversity of related plants any more than would cultivation of traditional or other specialty corn varieties; (4) agronomic performance, disease and insect susceptibility, and overall compositional profiles of DP-32138-1 corn are similar to those of its non-genetically engineered corn counterparts and/or other corn cultivars grown in the U.S., and therefore no direct or indirect plant pest effects on raw or processed plant commodities are expected; and (5) horizontal gene transfer is unlikely to occur between DP-32138-1 corn and organisms with which it cannot interbreed.

In addition to our finding that DP-32138-1 corn is unlikely to pose a plant pest risk, APHIS has completed a Final EA and FONSI for this action and has determined that a determination of nonregulated status of DP-32138-1 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/brs/not_reg.html). APHIS also concludes in its PPRA that new varieties derived from DP-32138-1 corn are unlikely to exhibit new plant pest properties that are substantially different from the ones observed for DP-32138-1 corn, or those observed for other corn varieties not considered regulated articles under 7 CFR part340.

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 nonregulated status of DP-32138-1 corn is the most scientifically sound and appropriate regulatory decision.



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



Date