

Determination of Nonregulated Status for Syngenta COT67B cotton

In response to petition 07-108-01p from Syngenta Biotechnology, Inc., the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has determined that event COT67B cotton 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). Since APHIS has determined that COT67B cotton is unlikely to pose plant pest risks, APHIS will approve the petition for nonregulated status of COT67B cotton. Therefore, APHIS approved permits or acknowledged notifications that were previously required for environmental release, importation, or interstate movement under those regulations will no longer be required for event COT67B cotton and its progeny. Importation of COT67B cotton 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.

This determination for COT67B is based on APHIS' analysis of field, greenhouse and laboratory data submitted by Syngenta, references provided in the petition, peer-reviewed publications, and other relevant information as described in the Plant Pest Risk Assessment (PPRA) for COT67B.

The Plant Pest Risk Assessment conducted on COT67B concluded that it is unlikely to pose plant pest risks 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) compositional profiles of COT67B cotton are similar to those of its parent line and other cotton cultivars grown in the U.S, therefore no direct or indirect plant pest effects on raw or processed plant commodities are expected; (2) it exhibits no characteristics that would cause it to be weedier than the non-genetically engineered parent cotton line or any other cultivated cotton; (3) gene introgression from event COT67B cotton 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 genetic diversity of related plants any more than would introgression from traditional cotton varieties; (4) horizontal gene transfer is unlikely to occur between COT67B cotton and organisms with which it cannot interbreed; (5) disease and insect susceptibilities are similar to other cotton cultivars grown in the U.S. ; and (6) it does not pose a risk to non-target organisms, including beneficial organisms.

In addition to our finding that event COT67B is unlikely to pose a plant pest risk, APHIS has completed a Final Environmental Assessment (EA) and FONSI for this action and has determined that a determination of nonregulated status for COT67B 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 COT67B are unlikely to exhibit new plant pest properties that are substantially different from the ones observed for COT67B cotton, or those observed for other cotton varieties not considered regulated articles under 7 CFR part 340.

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 COT67B cotton is the most scientifically sound and appropriate regulatory decision.

Michael C. Gregoire

8-23-11

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

Date