

Determination of Nonregulated Status for TwinLink™ cotton (*Gossypium hirsutum*)

In response to petition 08-340-01p from Bayer CropScience (hereafter referred to as Bayer), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has determined that TwinLink™ 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 TwinLink™ cotton is unlikely to pose a plant pest risk, APHIS will approve the petition for nonregulated status of TwinLink™ cotton. 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 TwinLink™ cotton and its progeny. Importation of TwinLink™ 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 TwinLink™ cotton is based on APHIS' analyses of field and laboratory data submitted by Bayer, references provided in the petition, peer-reviewed publications, and other relevant information as described in the Plant Pest Risk Assessment (PPRA) for TwinLink™ cotton.

The Plant Pest Risk Assessment conducted on TwinLink™ cotton 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 7 CFR part 340 for the following reasons: (1) disease and insect susceptibility of TwinLink™ cotton is similar to that of its non-genetically engineered cotton counterpart and/or other cotton cultivars grown in the US; (2) gene flow and introgression from TwinLink™ cotton 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 cotton varieties; (3) they exhibit no characteristics that would cause them to be weedier or more difficult to control as weeds than non-genetically engineered cotton or any other cultivated cotton; (4) the plant and its gene products (Cry1Ab, Cry2Ae and phosphinothricin-acetyl-transferase (PAT) protein) do not pose a risk to non-target organisms, including beneficial organisms; (5) horizontal gene transfer between TwinLink™ cotton and organisms with which it cannot interbreed is unlikely to occur.

In addition to our finding that TwinLink™ cotton is unlikely to pose a plant pest risk, APHIS has completed a Final Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) for this action and has determined that a determination of nonregulated status for TwinLink™ cotton 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 in its PPRA that new varieties derived from TwinLink™ cotton are unlikely to exhibit new plant pest properties that are substantially different from the ones observed for

TwinLink™ 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 for TwinLink™ cotton is the most scientifically sound and appropriate regulatory decision.

Michael C. Gregoire

9/23/2011

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

Date