

Extended Determination of Nonregulated Status for T303-3 cotton (*Gossypium hirsutum*)

In response to a request to extend a determination of nonregulated status to include insect-resistant, glufosinate ammonium tolerant cotton (12-033-01p) 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 T303-3 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). This extension request follows closely on APHIS' determination of nonregulated status of Bayer event T340-40 cotton which uses the trade name TwinLink™ (APHIS petition # 08-340-01p given nonregulated status October 12, 2011). Since APHIS has determined that T303-3 cotton is unlikely to pose a plant pest risk, APHIS will approve the request to extend the determination of nonregulated status to T303-3 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 T303-3 cotton and its progeny. Importation of T303-3 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.

Bayer developed the antecedent organism, transgenic TwinLink™ cotton, by hybridizing cotton event GHB119 (expressing the Cry2Ae protein from *Bacillus thuringiensis* and phosphinothricin-acetyl-transferase (PAT) protein from the *Streptomyces hygroscopicus*), with event T304-40 (expressing Cry1Ab from *B. thuringiensis* and PAT proteins). Bayer subsequently submitted a petition for nonregulated status (APHIS petition # 08-340-01p) for TwinLink™ cotton and APHIS made a determination of nonregulated status on October 12, 2011. The plasmid (designated pTDL004) used to produce event T303-3 cotton was very similar to the plasmid (pTDL008) used to produce T340-40 cotton and provided only one difference with respect to the inserted DNA. For event T303-3 cotton the promoter for the Cry protein was P35S2 derived from Cauliflower Mosaic Virus, whereas the antecedent utilized Ps7s7 from the Subterranean Clover Stunt Virus. All other regulatory sequences and expressed proteins are identical. A similar P35S3 promoter, also from Cauliflower Mosaic Virus, is used in both T303-3 and T340-40 cotton to drive expression of the PAT protein. In addition, P35S promoters are found in several petitions that have been given non-regulated status by APHIS (four corn [petition #'s 00-136-01p, 01-137-01p, 03-353-01p, 04-125-01p], one cotton [00-342-01p], one soybean [09-082-01p], and one plum [04-264-01p]), therefore USDA-APHIS is familiar with the functional role this promoter plays in a variety of crops. APHIS is also familiar with the PAT and Cry protein-expressing plants because these two components have been in a number of crops given nonregulated status, including cotton, corn and rice.

APHIS conducted a Plant Pest Risk Assessment on the antecedent organism, T340-40 cotton. Based on a comparative review of Bayer's request to extend nonregulated status to T303-3 insect-resistant, glufosinate ammonium tolerant cotton (12-033-01p), APHIS concludes that T303-3 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 T303-3 cotton is similar to that of its non-genetically engineered cotton counterpart, the antecedent organism, and/or other cotton cultivars grown in the U.S.; (2) Like the antecedent organism, gene flow and introgression from T303-3 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) T303-3 exhibits no characteristics that would cause it to be weedier or more difficult to control as a weed than non-genetically engineered cotton, the antecedent organism or any other cultivated cotton; (4) the plant and its gene products (Cry1Ab and PAT proteins) common to the two events do not pose a risk to non-target organisms, including beneficial organisms; (5) horizontal gene transfer between T303-3 cotton and organisms with which it cannot interbreed is unlikely to occur.

In addition to our finding that T303-3 cotton is unlikely to pose a plant pest risk, APHIS has made a Finding of No Significant Impact (FONSI) for this action based on its similarity to Bayer T340-40 cotton line (a component of TwinLink™ cotton) and the Environmental Assessment completed for the petition submitted for that product (APHIS #08-340-01p). Both T340-40 and T303-3 cotton express Cry1Ab and PAT proteins. The progeny of T303-3 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). Similar to APHIS' plant pest risk assessment conclusions regarding TwinLink™ cotton, APHIS concludes that new varieties derived from T303-3 cotton are unlikely to exhibit plant pest properties that are substantially different from the ones observed for other cotton 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 previous conclusions regarding the plant pest risk assessment for the antecedent organism (TwinLink™ cotton), the FONSI that was prepared based upon the previous NEPA review completed for TwinLink™ Cotton, 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 T303-3 cotton is the most scientifically sound and appropriate regulatory decision.

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

Date