Determination of Nonregulated Status for Texas A&M TAM66274 Cotton

In response to petition 17-292-01p from Texas A&M University (hereinafter referred to as Texas A&M), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has determined that Texas A&M ultra low gossypol cottonseed TAM66274 (hereinafter referred to as TAM66274 cotton) and progeny derived from it are not likely to pose a greater plant pest risk than the unmodified organism from which it was derived and are no longer to be considered regulated articles under APHIS' Biotechnology Regulations at Title 7 of the Code of Federal Regulations, part 340 (7 CFR part 340). Since APHIS has determined that TAM66274 cotton is unlikely to pose a greater plant pest risk than the unmodified organism from which it was derived, APHIS will approve the petition for nonregulated status of TAM66274 cotton. Therefore, APHIS authorizations under these regulations will no longer be required for environmental release, interstate movement, or importation of TAM66274 cotton and its progeny. Importation of TAM66274 cotton seeds, other propagative material, or grain for consumption will still be subject to APHIS foreign quarantine notices at 7 CFR part 319 and Federal Seed Act Regulations at 7 CFR parts 201 and 361.

This Determination of nonregulated status for TAM66274 cotton is based on APHIS' analyses of field and laboratory data submitted by Texas A&M, references provided in the petition, peer-reviewed publications, and other relevant information as described in the Plant Pest Risk Assessment (PPRA) for TAM66274 cotton.

The PPRA conducted on TAM66274 cotton concluded that it is unlikely to pose greater plant pest risk than the unmodified organism from which it was derived and should no longer be subject to the regulations at 7 CFR part 340 for the following reasons:

(1) No plant pest risk was identified from the transformation process, the insertion and/or expression of new genetic material, or from changes in metabolism in TAM66274 cotton.

(2) No increase in disease and pest incidence and/or damage was observed to be significant or atypical in TAM66274 cotton compared to the control variety or other comparators in field trials conducted in growing regions representative of where the TAM66274 cotton is expected to be grown commercially. Observed agronomic traits also did not reveal any differences that would indirectly indicate that TAM66274 cotton is more susceptible to pests or diseases. Therefore, no plant pest effects are expected on these or other agricultural products and no impacts are expected to APHIS pest control programs. Exposure to and/or consumption of the TAM66274 cotton are unlikely to have any adverse impacts on organisms beneficial to agriculture based on the analyses of compositional, phenotypic and agronomic data.

(3) TAM66274 cotton is no more likely to become a weed than conventional cotton varieties based on the observed agronomic characteristics of TAM66274 cotton, the weediness potential of cotton, and current management practices available to control cotton as a weed.

(4) TAM66274 cotton is not likely to increase the weed risk potential of other species with which it can interbreed in the U.S. or its territories. Gene flow, hybridization and/or introgression of inserted genes from TAM66274 cotton to other sexually compatible relatives with which it can interbreed is not likely to occur.

(5) Significant changes to agricultural or cultivation practices (e.g. pesticide and herbicide applications, tillage, irrigation, harvesting, etc.) from the adoption of TAM66274 cotton are not expected.

(6) Horizontal gene transfer of the new genetic material inserted into TAM66274 cotton to other organisms is highly unlikely, and is not expected to lead directly or indirectly to disease, damage, injury or harm to plants, including the creation of new or more virulent pests, pathogens, or parasitic plants.

APHIS' analyses and conclusions in the PPRA regarding the plant pest risk of TAM66274 cotton also apply to progeny such as any new varieties derived from TAM66274 cotton.

Prior to this Determination of nonregulated status, APHIS has completed an Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) for this action, and has concluded that a determination of nonregulated status for TAM66274 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 and endangered species, species proposed for listing, or their designated or proposed critical habitats.

Based on my full and complete review and consideration of all the scientific and environmental data, analyses and information, the input from the public involvement process, the conclusions of the PPRA, the EA and the FONSI, and my knowledge and experience as the APHIS Deputy Administrator for Biotechnology Regulatory Services, I have determined and decided that this Determination of nonregulated status for TAM66274 cotton and progeny is the most scientifically sound and appropriate regulatory decision.

M. J. Firko

Michael J. Firko, Ph.D.

10/16/2018

Date

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