

Animal Plant
Health Inspection
Service (APHIS)

Biotechnology
Regulatory
Services (BRS)

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Mr. David J. Chi
Bayer U.S. – Crop Science
700 Chesterfield Parkway West
Chesterfield, MO 63017

Dear Mr. Chi:

Thank you for your letter dated July 30, 2021 (21-211-01cr) requesting confirmation that your plant is exempt from regulation pursuant to 7 CFR § 340.1(c)(2). Your letter describes conventionally bred progeny of MON 15985 cotton (*Gossypium hirsutum*) containing only one of two possible DNA inserts for insect resistance.

The Plant Protection Act of 2000 (PPA) provides USDA with broad authority to protect U.S. agriculture, the environment, and the economy by, among other things, regulating the movement of plants and articles to prevent the introduction or dissemination of a plant pest within the United States. As such, USDA, through the Animal and Plant Health Inspection Service, regulates the “Movement of Organisms Modified or Produced through Genetic Engineering,” as described in 7 CFR part 340. These regulations do not apply to plants that contain a modification of a type listed in § 340.1(b) or § 340.1(c).

In your letter you describe breeding progeny of the deregulated cotton line MON 15985. MON 15985 contained a dual insert of Cry1Ac and Cry2Ab in such a way that the two inserts were not linked, meaning the two inserts assort independently and resulting progeny could contain either one or both inserts. The progeny with two inserts still contains introduced DNA sequences from both transformations; these are the same as the deregulated MON 15985. The progeny containing a single insert expressing Cry1Ac is the same as cotton line 531 deregulated under petition 94-308-01p. Cotton line MON 15947 is the subject of this letter and contains one insert expressing Cry2Ab. Either of these named lines could be expected to occur singly in the breeding progeny of MON 15985.

APHIS determinations of nonregulated status apply to the modified plant line(s) named in the petition and all progeny produced through conventional breeding. Based on our review of the representations made in your letter, USDA confirms the conventionally bred cotton with insect resistance conferred by only protein Cry2Ab is exempt from regulation pursuant to 7 CFR § 340.1(c)(2).

Although your cotton is not regulated under 7 CFR part 340, it may be subject to other USDA regulations or other regulatory authorities. For example, importation of your plant, or its seeds, may be subject to Plant Protection and Quarantine (PPQ) permit and/or quarantine requirements. For further information, you may contact the PPQ general number for such inquiries at (877) 770-5990. To inquire about the regulatory status of your plant with the Environmental Protection Agency, please contact Alan Reynolds at reynolds.alan@epa.gov or (703) 605-0515. To inquire about the regulatory status of your

plant with the Food and Drug Administration (FDA), please contact FDA at PlantBiotech@fda.hhs.gov.

Should you become aware at any time of any issues that may affect our confirmation of this exemption, please notify me immediately in writing of the nature of the issue.

Sincerely,



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

August 31, 2021
Date