



Biotechnology Regulatory Services  
Animal and Plant Health Inspection Service  
United States Department of Agriculture  
4700 River Road  
Riverdale, MD 20737

Attn: Bernadette Juarez  
APHIS Deputy Administrator  
Biotechnology Regulatory Services  
ConfirmationRequests@usda.gov

Subject: 7 CFR § 340.1(e) Request for Confirmation that Lepidopteran Resistant Cotton Plant MON 15947 is Exempt from Regulation Under § 340.1(c)(2).

Dear Bernadette Juarez,

I am writing on behalf of Bayer CropScience LP ("Bayer") to request confirmation from USDA-APHIS that the insect-protected line MON 15947 (OECD: MON-15947-5) cotton (*Gossypium hirsutum*) is exempt from regulation under § 340.1(c)(2) and within the scope of the previous determination of non-regulated status on MON 15985 granted in 2002.

The cotton plant trait mechanism of action (PTMOA) combination MON 15985-Cry1Ac/Cry2Ab, exhibiting toxicity to certain lepidopteran insects, was deregulated effective November 5, 2002 by USDA under petition No. 00-342-01p, where USDA-APHIS determined that "genetically engineered cotton event 15985 and progeny derived from it will no longer be considered regulated articles under APHIS regulations at 7 CFR Part 340".

The dual insert cotton plant MON 15985 contains one DNA insertion expressing the Cry2Ab protein, and another DNA insert present in the parental line 531, which expressed the Cry1Ac protein. Cotton line 531 expressing Cry1Ac was deregulated effective June 22, 1995 by USDA under petition No. 94-308-01p. Through conventional breeding (segregation and selection), a progeny line, identified as MON 15947, was generated that only expresses

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July 30, 2021

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the Cry2Ab protein. MON 15947 is stably inherited in subsequent breeding generations and the Cry2Ab protein expression profile in MON 15947 is comparable to that produced in MON 15985. Since this line is progeny from MON 15985 and not a new transformation event in cotton, MON 15947 has the same insert sequence (including identical *cry2Ab* coding sequence) and the same plant trait mechanism of action as that of the DNA insertion in MON 15985 expressing the Cry2Ab protein and thus should not be a regulated article under 7 CFR part 340 according to 7 CFR § 340.1(c)(2).

Furthermore, Bayer met with USDA-APHIS on August 29, 2019 and again on February 17, 2021 to consult on this matter. The points listed below were discussed during the two meetings and in follow-up email communications during the intervening period:

- The Cry2Ab2 protein in MON 15947 has a long history of safety use as a component of MON 15985 (since 2001).
- The Cotton MON 15947 event expressing Cry2Ab has been adequately assessed for plant pest risk and environmental safety (e.g., non-target organism studies, and other required data) under the evaluation of MON 15985 (USDA Petition No. 00-342-01p) that led to a determination of non-regulated status for MON 15985 and its progeny.
- We had met with USDA-APHIS, and even though MON 15947 is considered not to be a regulated article under 7 CFR part 340 because it is a segregant progeny of MON 15985, USDA-APHIS asked Bayer to submit a formal confirmation request under the provisions of the revised 7 CFR Part 340 (SECURE) rule in order to receive USDA-APHIS' determination in the form of formal confirmation response.
- MON 15947 was registered with EPA as a pesticide product pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq., FIFRA) under Section 3(c)(5) on September 1, 2005 (Reg. No. 524-556) and thus exempt from the requirement of permitting by USDA-APHIS under 7 CFR § 340.5(g).

Bayer is seeking confirmation from the agency that MON 15947 is not subject to regulation under 7 CFR Part 340 and that any progeny derived from crosses between MON 15947 and conventional cotton or other biotechnology-derived cotton that has been granted non-regulated status under 7 CFR Part 340, to



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

be not subject to regulation under 7 CFR Part 340. Therefore, to ensure transparency and alignment with the USDA we are seeking confirmation regarding the deregulated status of MON 15947 under 7 CFR § 340.1(c)(2) based on the event being progeny of an already deregulated event (MON 15985). We maintain that the previous deregulation decision for the MON 15985 event and the information submitted within that petition (No. 00-342-01p) should suffice to support the exemption of MON 15947.

Should you require any additional information regarding this confirmation request please feel free to contact James M. Nyangulu or myself.

Thank you for your attention to this matter.

Yours sincerely,

Bayer U.S. – Crop Science

DocuSigned by:  
  
 Signer Name: David Chi  
Signing Reason: I am the author of this document  
Signing Time: 30-Jul-2021 | 9:47:09 AM CDT  
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cc: ConfirmationRequests@usda.gov  
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Bayer Regulatory File