



United States Department of Agriculture

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Animal and
Plant Health
Inspection
Service

Biotechnology
Regulatory
Services

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Riverdale, MD
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August 26, 2014
Dr. Michael Braverman
IR-4 Project, Rutgers University
500 College Road East, Suite 201W
Princeton, New Jersey 08540

Re: Request for confirmation that TraitUp™- FB100 is not a regulated article

Dear Dr. Braverman

Thank you for your letter dated January 10th, 2013 requesting APHIS' confirmation that TraitUp™- FB100 is not a regulated article. This letter states that TraitUp™- FB100 is a plasmid [CBI] based product that is genetically engineered to control Fusarium crown rot on tomatoes.

APHIS regulates the introduction of certain genetically engineered organisms which are, or have the potential to be a plant pest. Regulations for genetically engineered organisms that have the potential to be plant pests, under the Plant Protection Act, are codified at 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pest or Which There Is Reason To Believe Are Plant Pests." Under the provisions of these regulations, a genetically engineered (GE) organism is deemed a regulated article if it has been genetically engineered from a donor organism, recipient organism, or vector or vector agent listed in §340.2 and the listed organism meets the definition of "plant pest" or is an unclassified organism and/or an organism whose classification is unknown, or if the Administrator determines that the GE organism is a plant pest or has reason to believe is a plant pest.

APHIS has evaluated the description of TraitUp™- FB100 product described in your January 10th, 2013 letter. As described, the TraitUp™- FB100 plasmid DNA based product is a [CBI] plasmid system that was created by cloning sequences from the following donors into a [CBI] plasmid: [

CBI]

APHIS has determined that although plant pest sequences were used in the genetic engineering of TraitUp™- FB100 plasmids, the plasmids themselves do not meet the definition of a plant pest or the definition of a regulated article as defined in 7 CFR 340.1 so long as they are not contained within a living organism in which they can replicate and produce a component that can control

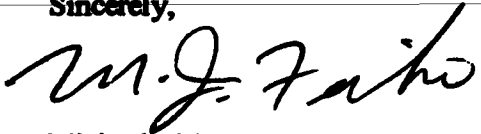
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Fusarium crown rot. Plasmids are not classified as living organisms, and in their isolated form (not contained within a living organism), plasmids do not cause damage or disease to plants. Therefore, APHIS does not consider the isolated genetically engineered DNA plasmids, TraitUp™-FB100, as described in your January 10th, 2013 letter to be regulated under 7 CFR part 340.

While the plasmids themselves are not a regulated article, APHIS has not yet made a determination regarding the regulatory status when the plasmids are in combination with the seed. Until that process is completed, any living organism or viable plant material (seeds, whole plants, or other viable plant parts) containing TraitUp™-FB100 would be regulated under 7 CFR part 340 and would be required to obtain a notification or permit for importation, interstate movement, or field release. Any unauthorized introduction of viable plant material containing TraitUp™-FB100 would be a violation of our regulations.

Please be advised that the TraitUp™-FB 100 plasmid system may still be subject to other regulatory authorities such as EPA and FDA.

Sincerely,



**Michael Firko
Deputy Administrator
Biotechnology Regulatory Services**