



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Biotechnology
Regulatory
Services

4700 River Road
Riverdale, MD
20737

Mr. Michael Weeks
U.S. Regulatory Manager
Bayer CropScience LP
2 T.W. Alexander Drive
Research Triangle Park, NC 27709

Re: Request for confirmation that Bayer Crop Sciences tobacco that has been modified for increased biomass production is not a regulated article

Dear Mr. Weeks:

Thank you for your letter dated December 14, 2015 inquiring whether or not your tobacco (*Nicotiana tabacum*) modified for increased biomass production is a regulated article under APHIS regulations found at 7 CFR part 340. Your letter describes your genetically engineered (GE) tobacco conferred with enhanced photosynthetic efficiency leading to an increased biomass production phenotype.

The Plant Protection Act (PPA) of 2000 gives USDA the authority to oversee the detection, control, eradication, suppression, prevention, or retardation of the spread of plant pests or noxious weeds to protect the agriculture, environment, and economy of the United States. The APHIS mission is to protect the health and value of American agriculture and natural resources.

APHIS regulates the importation, interstate movement and environmental release (field testing) of certain genetically engineered (GE) organisms that are, or have the potential to be, plant pests. Regulations for GE organisms that are or have the potential to be plant pests, under the PPA, are codified at 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason To Believe Are Plant Pests." Under the provisions of these regulations, a GE organism is deemed a regulated article if it has been genetically engineered using a donor organism, recipient organism, or vector or vector agent that is listed in §340.2 and meets the definition of a plant pest, or that 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 it is a plant pest.

In your letter of December 14, 2015, you describe that your GE tobacco with increased biomass production was created using the biolistic method of transformation and that the inserted genetic material was derived from the following donors: *Nicotiana tabacum*, *Rhodospirillum rubrum*, and *Shigella flexneri*.

Based on the information cited in your letter, APHIS has determined that tobacco itself is not a plant pest, no organisms used as sources of the genetic material to create the GE tobacco are plant pests, and the method used to genetically engineer the tobacco did not involve plant pests. Therefore, consistent with previous responses to similar letters of inquiry, APHIS does not consider your GE tobacco as described in your December 14, 2015 letter to be regulated under 7 CFR part 340. Additionally, cultivated tobacco is not listed as a Federal noxious weed under 7 CFR part 360, and APHIS has no reason to believe that the increased biomass phenotype of your GE tobacco would increase the weediness of tobacco.

Please be advised that the importation of GE tobacco seeds or plants, like all other tobacco, will be subject to APHIS Plant Protection and Quarantine (PPQ) permits or other requirements. For further information, should you plan to import these GE tobacco seeds or plants, you may contact Shailaja Rabindran at 301-851-2167 or contact PPQ general number for such inquiries at (877) 770-5990.

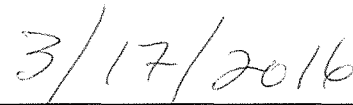
Please be advised that your GE tobacco lines may still be subject to other regulatory authorities such as FDA or EPA.

Furthermore, should you become aware at any time of any issues that may affect the Agency's conclusion regarding this inquiry; you must immediately notify the Agency in writing of the nature of the issue. We hope you appreciate our commitment to plant health and support for the responsible stewardship for the introduction of GE plants.

Sincerely,



Michael J. Firko, Ph.D.
APHIS Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture



Date