



United States
Department of
Agriculture

Animal and Plant
Health Inspection
Service
Plant Protection and
Quarantine

Biotechnology
Regulatory Services
4700 River Road
Unit 98
Riverdale, MD 20737

November 12, 2015
Lawrence E. Culleen
Arnold & Porter LLP
555 12th Street NW
Washington, D.C. 20004

Re: Confirming non-regulated status of tobacco varieties grown using novel breeding method

Dear Mr. Culleen:

Thank you for your letter dated April 28, 2015 inquiring whether the tobacco plants described in your letter would be regulated articles. Your letter describes an accelerated breeding method in which genetically engineered (GE) tobacco lines are used to facilitate the breeding of non-GE tobacco plants, as confirmed by phenotypic and molecular analyses.

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 GE organisms that are, or have the potential to be, plant pests. Regulations for GE 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 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 that 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 April 28, 2015 letter, you describe non-GE tobacco plants that will be selected from among the progeny of GE tobacco lines. The accelerated breeding method, as described in the reference cited (Lewis and Kernodle 2009¹), is based on the use of GE tobacco lines expressing the early flowering gene *FT*. Your letter

¹ Lewis SL, Kernodle SP (2009) A method for accelerated trait conversion in plant breeding. *Theoretical and Applied Genetics* 118:1499-1508.

further states that through traditional plant breeding methods (including crosses, backcrosses, and self-pollination techniques), supported by phenotypic and molecular data, the researcher selects non-GE plants from the final cross. These selected non-GE plants do not contain inserted genetic material.

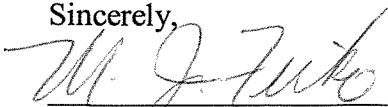
Based on the information cited in your letter, APHIS has determined that the initial GE tobacco lines were developed using plant pests and are likely to contain genetic material from plant pests. However, where phenotypic and molecular analyses demonstrate that the final tobacco plants do not contain any inserted genetic material, APHIS has no reason to believe that those non-GE tobacco plants would be plant pests. Therefore, consistent with previous responses to similar letters of inquiry, APHIS would not consider the final non-GE tobacco plants as described in your April 28, 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 genetic engineering of tobacco by this particular method resulting in a phenotype indistinguishable from plants of the same variety would increase the weediness of tobacco.

Please be advised that the importation of tobacco seeds or plants may be subject to APHIS Plant Protection and Quarantine (PPQ) permit and/or quarantine requirements depending on the country of origin. For further information, should you plan to import these 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 these tobacco plants may still be subject to other regulatory authorities such as those administered by FDA or EPA.

GE tobacco lines developed using this breeding method and retaining inserted genetic material would be considered regulated under 7 CFR part 340 and will require a notification or permit for importation, interstate movement, or environmental release. Furthermore, should you become aware at any time of any issues that may affect the Agency's response to this inquiry regarding this inquiry; you must immediately notify the Agency in writing of the nature of the issue. We hope you appreciate our commitment to protecting 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