USDA

United States Department of Agriculture

Animal and Plant Health Inspection Service

Biotechnology Regulatory Services

4700 River Road
Riverdale, MD
20737

November 12, 2015
Dr. R. Michael Raab
Agrivida, Inc.
200 Boston Avenue, #2975
Medford, MA 02155

Re: Confirmation of Regulatory Status

Dear Dr. Raab:

Thank you for your letter dated March 17, 2015 inquiring whether the maize variety described in your letter is a regulated article. This letter describes a maize variety expressing an altered [redacted] gene resulting in an increased starch 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.

As described in your letter of March 17, 2015, the final maize plant was created through introduction of a meganuclease transgene via [redacted] mediated transformation. The meganuclease created a deletion in the maize [redacted] that resulted in the increased starch phenotype. Traditional breeding methods allowed for selection of maize with only the altered [redacted] gene, as the meganuclease and the altered [redacted] gene were not physically connected in the genome. The final maize plant is described as a null segregant because the genetic material used to introduce the deletion (the meganuclease) is no longer present in the plant. No genetic material was inserted into the final maize plant genome.

Based on the information cited in your letter, APHIS has determined that the initial GE maize plant was developed using a plant pest and genetic material from plant pests. However, the final maize plants do not contain any introduced genetic material and APHIS has no reason to believe these non-GE maize plants are plant pests. Therefore, consistent with previous responses to similar letters of inquiry, APHIS does not consider the non-GE maize plants as described in your March 17, 2015 letter to be regulated under 7 CFR part 340. Additionally, maize is not listed as a Federal noxious weed under 7 CFR part 360, and APHIS has no reason to believe that the increased starch phenotype of your maize variety would increase the weediness of maize.

Please be advised that the importation of maize seeds or plants, like all other maize, will be subject to APHIS Plant Protection and Quarantine (PPQ) permit and/or quarantine requirements. For further information, should you plan to import these maize 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 non-GE maize variety may still be subject to other regulatory authorities such as FDA or EPA.

GE maize plants from this transformation that retain 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 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,

M. J. Firko

11/30/2015

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

Date