



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Biotechnology
Regulatory
Services

4700 River Road
Riverdale, MD
20737

Dr. Daria H. Schmidt
Director, Registration and Regulatory Affairs – North America
DuPont Pioneer
7100 NW 62nd Avenue
Johnston, IA 50131-1000

Re: Confirmation of Regulatory Status of Waxy Corn Developed by CRISPR-Cas
Technology

Dear Dr. Schmidt:

Thank you for your letter dated December 14, 2015 inquiring whether or not the corn product described in your letter is a regulated article. Your letter describes CRISPR-Cas waxy corn which has an altered starch composition.

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 December 14, 2015 letter, you describe your CRISPR-Cas waxy corn as a null segregant line that contains a targeted deletion of the waxy gene (*Wx1*). The genetic sequences that were used to introduce the deletion did not contain any plant pest sequences nor were the sequences introduced into the parent plant with a plant pest vector. Furthermore, any unintended insertion of genetic material used to introduce the deletion of the *Wx1* was segregated out through conventional breeding (null segregant).



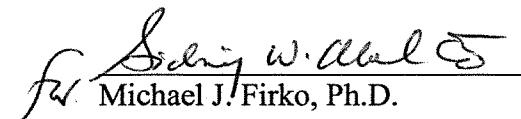
APHIS has reviewed the information in your letter and agrees that the CRISPR-Cas waxy corn you described is a null segregant line that contains a targeted deletion of the waxy gene (*Wx1*). APHIS also agrees that no plant pests or genetic material from plant pests were used in the development of CRISPR-Cas waxy corn. APHIS has no reason to believe that this CRISPR-Cas waxy corn is a plant pest. Therefore, consistent with previous responses to similar letters of inquiry, APHIS does not consider the CRISPR-Cas waxy corn as described in your December 14, 2015 letter to be regulated pursuant to 7 CFR part 340. Additionally, corn is not listed as a Federal noxious weed pursuant to 7 CFR part 360, and APHIS has no reason to believe that the genetic alteration of your CRISPR-Cas waxy corn would increase the weediness of corn.

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

Should you become aware at any time of any issues or additional information 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

4/18/2016
Date