



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection  
Service

Biotechnology  
Regulatory  
Services

4700 River Road  
Riverdale, MD  
20737

Mr. William Haun  
Calyxt, Inc.  
600 County Road D W.  
Suite 8  
New Brighton, MN 55112

Re: Confirmation that MLO\_KO Wheat is not a regulated article

Dear Mr. Haun:

Thank you for your letter dated August 25, 2015 inquiring whether or not the wheat product described in your letter is a regulated article. Your letter describes MLO\_KO wheat which has improved disease resistance to powdery mildew.

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 August 25, 2015 letter, you describe your wheat plant (MLO\_KO) as a null segregant. First, a parent plant was developed by using a TALEN to modify immature wheat embryos to generate a single gene (multi-allele) knockout and thereby



disabling the MLO protein. The TALEN and certain other genetic sequences used in the development of the wheat plants were derived from plant pests. The genetically engineered parent plant was self-pollinated and the final MLO\_KO wheat plant is described as a null segregant because the genetic material used to introduce the deletion (the TALEN) is no longer present in the plant. No genetic material was inserted into the final wheat plant genome. The final wheat products (wheat plants) do not contain inserted genetic material; they contain only the genetic material present in the original wheat plants.

Based on the information cited in your letter, APHIS has determined that this MLO\_KO wheat is a null segregant and does not contain any introduced genetic material. APHIS has no reason to believe that the plants of MLO\_KO wheat are plant pests. Therefore, consistent with previous responses to similar letters of inquiry, APHIS does not consider the MLO\_KO wheat as described in your August 25, 2015 letter to be regulated pursuant to 7 CFR part 340. Additionally, wheat 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 MLO\_KO wheat would increase the weediness of wheat.

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

GE wheat plants from this transformation that retain inserted genetic material would be considered regulated pursuant to 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,

A handwritten signature in black ink, appearing to read "M. J. Firko". The signature is written in a cursive style with a horizontal line underneath it.

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

A handwritten date in black ink, "2/14/2016", written in a cursive style. It is positioned above a horizontal line.

Date

