



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 PPO\_KO Potato is not a regulated article

Dear Mr. Haun:

Thank you for your letter dated March 16, 2016 inquiring whether or not the potato product described in your letter is a regulated article. Your letter describes PPO\_KO potato which has improved processing characteristics.

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 March 16, 2016 letter, you describe your potato plant (PPO\_KO) as a null segregant. First, a parent plant was developed by introducing a TALEN<sup>®</sup> reagent into potato protoplasts by polyethylene glycol mediated transformation followed by transient expression of the TALEN<sup>®</sup> reagent to achieve the PPO gene knockout and regeneration of protoplast cells into calli and then whole plants. Polymerase Chain Reaction techniques were used to screen regenerated potato plants to confirm that no DNA from the TALEN<sup>®</sup> reagent remained in plants selected for advancement. The TALEN<sup>®</sup> reagent and certain other genetic sequences used in the development of the potato plants were derived from plant pests but no genetic material was inserted into the final potato plant

genome. The final potato products (potato plants) contain only the genetic material present in the original potato plants and a small deletion in the original PPO gene.

Based on the information cited in your letter, APHIS has determined that this PPO\_KO potato does not contain any introduced genetic material. Therefore, consistent with previous responses to similar letters of inquiry, APHIS does not consider the PPO\_KO potato as described in your March 16, 2016 letter to be regulated pursuant to 7 CFR part 340. Additionally, potato 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 PPO\_KO potato would increase the weediness of potato.

Please be advised that the importation of PPO\_KO potato seeds, tubers or plants, like all other potato, will be subject to APHIS Plant Protection and Quarantine (PPQ), permit and/or quarantine requirements. For further information, should you plan to import these potato seeds, tubers 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 PPO\_KO potato variety, while not regulated by APHIS under 7 CFR part 340 may still be subject to other regulatory authorities such as FDA or EPA.

GE potato plants from this transformation that retain inserted genetic material would be considered regulated pursuant to 7 CFR part 340. 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