



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Biotechnology
Regulatory
Services

4700 River Road
Riverdale, MD
20737

Dr. Craig Richael
Ms. Tracy A Rood
J.R. Simplot Plant Sciences
5369 W. Irving Street
Boise, Idaho 83706

Re: Confirmation of the regulatory status of genome edited potato with reduced PPO and reduced glycoalkaloids

Dear Dr. Craig Richael and Tracy A. Rood:

Thank you for your letter dated June 16, 2020, inquiring whether the potato (*Solanum tuberosum* subsp. *tuberosum*) products described in your letter is a regulated article under 7 CFR part 340. Your letter describes two methods you intend to use to develop reduced PPO and reduced glycoalkaloid potatoes: The *Agrobacterium* (Agro) method and the Ribonucleoprotein (RNP) method.

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.

USDA regulates the importation, interstate movement and environmental release (field testing) of certain organisms developed using genetic engineering that are, or have the potential to be, plant pests under 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 regulations, an 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 organism is a plant pest or has reason to believe it is a plant pest.

In your letter, you describe two methods that you intend to use to develop your reduced PPO and reduced glycoalkaloid potatoes: The Agro method and the Ribonucleoprotein (RNP) method. Both methods enable the delivery of CRISPR/Cas9 elements into plant cells, causing double-stranded breaks that deactivate multiple alleles of each gene of interest resulting in reduced PPO and reduced glycoalkaloid potatoes. No external repair template will be provided. Confirmation of the absence of the binary vector (in the case of the Agro method) and presence of the desired genome edits will be done by molecular screening. Only plants confirmed to lack all elements of the binary vector and containing the desired targeted edits will be selected for commercial development.

Based on the representations you made in your letter, including your description of your intended confirmation methods, your genome edited potatoes with reduced PPO and

reduced glycoalkaloids are not themselves plant pests and no plant pest sequences will be integrated into the plant genome of potato. Consistent with previous responses to similar letters of inquiry, USDA does not consider your genome edited potatoes with reduced PPO and reduced glycoalkaloids to be regulated pursuant to 7 CFR part 340.

Although your genome edited potatoes are not regulated under 7 CFR part 340, other regulatory authorities may apply. For example, the importation of your potato seeds or plants will be subject to applicable Plant Protection and Quarantine (PPQ), permit and/or quarantine requirements. For further information, should you plan to import these potato seeds or plants, you may contact the PPQ general number for such inquiries at 877-770-5990. To inquire about the regulatory status of your product with the Environmental Protection Agency (EPA), please contact Alan Reynolds at 703-605-0515. To inquire about the regulatory status of your product with the Food and Drug Administration (FDA), please contact PlantBiotech@fda.hhs.gov.

Should you become aware at any time of any issues that may affect USDA's conclusion regarding this inquiry, you should immediately notify us in writing of the nature of the issue.

Sincerely,



Bernadette Juarez.
APHIS Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture

August 6, 2020
Date