



Animal Plant
Health Inspection
Service (APHIS)

Biotechnology
Regulatory
Services (BRS)

4700 River Road
Riverdale
MD 20737
T: 301.851.3877
F: 301.734.3135

Dr. Jack Peart
Tropic Bioscience UK LTD
Norwich Research Park Innovation Center, NR4 7GJ
United Kingdom

Dear Dr. Peart:

Thank you for your letter dated August 26, 2021 (21-141-01cr) requesting confirmation that your plant line is exempt from regulation pursuant to 7 CFR § 340.1(c). Your letter describes a potato (*Solanum tuberosum*) line that will be modified for altered tuber quality.

The Plant Protection Act of 2000 (PPA) provides USDA with broad authority to protect U.S. agriculture, the environment, and the economy by, among other things, regulating the movement of plants and articles to prevent the introduction or dissemination of a plant pest within the United States. As such, USDA, through the Animal and Plant Health Inspection Service, regulates the “Movement of Organisms Modified or Produced through Genetic Engineering,” as described in 7 CFR part 340. These regulations do not apply to plants that contain a modification of a type listed in § 340.1(b) or § 340.1(c).

In your letter, you state that the intended modification to your potato line is a result of CRISPR/Cas9 gene editing using the GEiGS® technology platform to make a directed modification of the *stu-MIR398a* gene by cellular repair of a targeted DNA break in the presence of an externally provided repair template. The modified *stu-MIR398a* gene will produce a miRNA that targets polyphenol oxidase-5 (*Ppo5*) transcripts resulting in the following plant-trait-mechanism of action (PTMOA) combination that has been determined by USDA not to be regulated under this part: potato (*Solanum tuberosum*) with altered tuber quality by tuber-specific RNAi mediated silencing of *Ppo5* (13-022-01p; 14-093-01p). Your letter describes how you will insert exogenous DNA into the plant’s genome to generate the genetic modification, and how you will eliminate it in the final modified plant. You also describe methods you plan to use to verify that you made the intended modification, that the gene silencing has the correct tissue specificity, that the potential secondary target (an unannotated *MIR398* family member) is not edited and the potato line is without evidence of additional modified traits, and that no unintended exogenous DNA remains in your plant.

Based on our review of the representations in your letter, USDA confirms the potato line modified for altered tuber quality through RNAi silencing of *Ppo5* via modification of the *stu-MIR398a* gene would meet the exemption described in § 340.1(c)(2) and would be exempt from regulation under 7 CFR part 340. Paramount to our confirmation is that the *Ppo5* silencing does not occur in the leaves and flowers of the plant and that altering the function of native *stu-MIR398a* does not result in any new traits other than the intended reduced browning. Plants with modifications that are exempt pursuant to

§ 340.1(c)(2) are unlikely to pose an increased plant pest risk compared to previous plants containing this PTMOA combination that USDA determined to not be regulated.

Although your modified potato line would not be regulated under 7 CFR part 340, it may be subject to other USDA regulations or other regulatory authorities. For example, importation of your plant or its tubers, may be subject to Plant Protection and Quarantine (PPQ) permit and/or quarantine requirements. For further information, you may contact the PPQ general number for such inquiries at (877) 770-5990. To inquire about the regulatory status of your plant with the Environmental Protection Agency, please contact Alan Reynolds at reynolds.alan@epa.gov or (703) 605-0515. To inquire about the regulatory status of your plant with the Food and Drug Administration (FDA), please contact FDA at PlantBiotech@fda.hhs.gov.

Should you become aware at any time of any issues that may affect our confirmation of this exemption, please notify me immediately 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

October 20, 2021
Date