

Animal Plant
Health Inspection
Service (APHIS)

Biotechnology
Regulatory
Services (BRS)

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Neal Carter, President
Okanagan Specialty Fruits Inc.
15304 Prairie Valley Road
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Dear Mr. Carter:

Thank you for your letter dated April 14, 2021 (21-105-01cr) requesting confirmation that the Nonbrowning Arctic[®] apple Event HCR835 (hereinafter referred to as the HCR835 apple) is exempt from regulation under 7 CFR § 340.1(c)(2). Your letter describes apple (*Malus x domestica*) genetically modified with a nonbrowning phenotype conferred by silencing expression of genes in the polyphenol oxidase (PPO) family.

The Plant Protection Act of 2000 (PPA) gives USDA the authority to oversee the detection, control, eradication, suppression, prevention, or retardation of the spread of plant pests to protect the agriculture, environment, and economy of the United States. The PPA provides USDA with broad authority to protect plants by regulating the movement of, among other items, plants and articles to prevent the introduction or dissemination of a plant pest within the United States. 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 genetic modification in the HCR835 apple is the result of *Agrobacterium*-mediated transformation of the apple cultivar Honeycrisp (HCR) with the binary vector VOSF containing an RNAi cassette for PPO suppression (PGAS2) and the *nptII* gene for use as a selectable marker. The PGAS2 cassette consists of partial coding sequences of four PPO genes from apple, as well as an intron for hairpin formation. This cassette is designed to reduce the expression of the entire PPO gene family, resulting in the nonbrowning phenotype in apple fruit. The *nptII* gene that encodes the enzyme neomycin phosphotransferase for kanamycin resistance is a commonly used selection marker for transformed plants. APHIS previously reviewed this plant-trait-mechanism of action (PTMOA) combination and determined it was not regulated under 7 CFR part 340: apple with altered fruit quality (reduced browning phenotype) via RNAi-induced silencing of the same four PPO genes (abbreviated PGAS as above) and a selectable marker (kanamycin resistance) using the *nptII* gene (petition 10-161-01p and extension request 16-004-01p). You provided data to indicate that the HCR835 apple has the modification and that no unintended exogenous DNA remains in the plant.

Based on the representations you made in your letter, the described modifications in the HCR835 apple meet the requirements for the exemption described in § 340.1(c)(2). APHIS notes that 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 the same PTMOA combination determined by APHIS not to be regulated under this part.

Although the HCR835 apple is not regulated under 7 CFR part 340, it may be subject to other USDA regulations or other regulatory authorities. For example, importation of the HCR835 apple 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

May 20, 2021
Date