

Animal Plant
Health Inspection
Service (APHIS)

Biotechnology
Regulatory
Services (BRS)

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Dr. Ofir Meir, Chief Technology Officer
Tropic Biosciences UK LTD
Norwich Research Park Innovation Centre, NR4 7GJ
United Kingdom

Dear Dr. Meir:

Thank you for your letter dated March 21, 2022 (21-356-01cr) requesting confirmation that your plant is exempt from regulation pursuant to 7 CFR § 340.1(b)(1). Your letter describes banana, *Musa acuminata*, modified for altered fruit 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 in your banana is a single change causing a frameshift in a single polyphenol oxidase allele, resulting from cellular repair of a targeted DNA break in the absence of an externally provided repair template. Your letter describes how you used transient expression of exogenous DNA to generate the genetic modification, and how you screened to ensure it did not integrate into the final modified plant. You also describe methods and data you used and additional methods you plan to use to verify that you made the intended modification, and no unintended exogenous DNA remains in the plant.

Based on our review of the representations in your letter, USDA confirms the banana modified for altered fruit quality would meet the exemption described in § 340.1(b)(1) and would be exempt from regulation under 7 CFR part 340. Plants with modifications that are exempt pursuant to § 340.1(b)(1) are achievable by conventional breeding and unlikely to pose an increased plant pest risk relative to their conventionally bred counterparts.

Although your banana 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, 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,

A handwritten signature in black ink, appearing to read 'BJ', with a stylized flourish extending to the right.

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

March 29, 2022

Date