

Animal Plant
Health Inspection
Service (APHIS)

Biotechnology
Regulatory
Services (BRS)

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Professor Ian T. Baldwin
Max Planck Institute for Chemical Ecology
Hans-Knöll-Straße 8
D-07745 Jena, Germany

Dear Professor Baldwin:

Thank you for your letter received on May 11, 2021 (21-025-01cr) requesting confirmation that your plant lines are exempt from regulation pursuant 7 CFR § 340.1(b)(1). Your letter describes *Nicotiana attenuata* plants modified for herbivore and fungal susceptibility.

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 modifications in your *N. attenuata* plant lines are mediated by CRISPR/Cas9 targeting of acyltransferase-like genes and a triterpene cyclase gene to make insertions, deletions, or substitutions resulting from cellular repair of a targeted DNA break in the absence of an externally provided repair template. Your letter describes how you inserted exogenous DNA into the plant’s genome to generate the modification, and how you eliminated it in the final modified plant lines. You also describe methods and provide data used to verify that the intended modification was made and that no unintended exogenous DNA remains in the plant lines.

Based on our review of the representations in your letter, the *N. attenuata* plant lines modified for herbivore and fungal susceptibility meet the exemption described in § 340.1(b)(1), and the regulations at 7 CFR part 340 do not apply to these plant lines. 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 *N. attenuata* plants are not regulated under 7 CFR part 340, they may be subject to other USDA regulations or other regulatory authorities. For example, importation of your plants or their seeds 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

June 10, 2021
Date