

Animal Plant
Health Inspection
Service (APHIS)

Biotechnology
Regulatory
Services (BRS)

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Dr. James Ligon
Agrivida, Inc.
78E Olympia Avenue
Woburn, MA 01801

Dear Dr. Ligon:

Thank you for your letter dated October 19, 2021 (21-271-01cr) requesting confirmation that your plant is exempt from regulation pursuant to 7 CFR § 340.1(c)(2). Your letter describes maize (*Zea mays*) modified for altered seed nutrient availability.

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 modification in your maize is the result of *Agrobacterium*-mediated transformation with plasmid pAG4916 containing *phy02opt* and the selectable marker *manA* leading to the following plant-trait-mechanism of action (PTMOA) combinations that USDA previously determined to not be regulated: corn with altered seed nutrient availability from seed-specific expression and endoplasmic reticulum (ER) localization of a thermostable phytase that catalyzes the hydrolysis of phytic acid and corn with marker gene phosphomannose isomerase (PMI) to utilize mannose 6-phosphate as a nutrient (carbon) source (petition 19-176-01p). You also describe methods and provide data used to verify that you made the intended modification and no unintended exogenous DNA remains in the plant.

Based on our review of the representations made in your letter, USDA confirms the corn with two altered traits from seed-specific expression of a thermostable phytase localized to the ER, stacked with a PMI marker gene, meets the exemption described in § 340.1(c)(2) and is exempt from regulation under 7 CFR part 340. 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 corn is not 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 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

November 23, 2021
Date