

Animal Plant
Health Inspection
Service (APHIS)

Biotechnology
Regulatory
Services (BRS)

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

Keith Cable, President
Dümmen NA, Inc
250 South High Sheet
Suite 650
Columbus, OH 43215

Dear Mr. Cable:

Thank you for your letter dated July 19, 2021 (21-161-01cr) requesting confirmation that your plants are exempt from regulation pursuant to 7 CFR § 340.1(c)(2). Your letter describes three petunia (*Petunia x hybrida*) varieties ((40257 (Potunia Plus Papaya), 40537 (Fortunia Red), and 40794 (Surprise Red)) modified for altered flower color.

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 represent, with supporting data, that your petunias descend from previously modified petunias containing both of the following plant-trait-mechanism of action (PTMOA) combinations: petunia with altered flower color via the maize *Al* gene encoding dihydroflavonol 4-reductase (DFR) and petunia with antibiotic resistance via neomycin phosphotransferase (NPTII). You also represent that petunia varieties with these same PTMOAs, descending from the same previously modified petunias, have been determined by USDA not to be regulated under 7 CFR part 340 (petition 19-099-01p).

Based on our review of the representations made in your letter, USDA confirms that the three petunia varieties modified to include the maize *Al-DFR* and *nptII* genes meet the exemption described in § 340.1(c)(2) and are 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 a PTMOA combination(s) that USDA has determined to not be regulated.

Although your petunias 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 plants 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 plants 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

August 25, 2021
Date