

Animal Plant  
Health Inspection  
Service (APHIS)

Biotechnology  
Regulatory  
Services (BRS)

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Ms. Lori A. Mann  
Ball Horticultural Company  
622 Town Road  
West Chicago, IL 60185-2698

Dear Ms. Mann:

Thank you for your letter dated April 11<sup>th</sup>, 2022 (22-007-01cr) requesting confirmation that your plant is exempt from regulation pursuant to 7 CFR § 340.1(c)(2). Your letter describes 19 petunia (*Petunia x hybrida*) varieties (CO5369, OR4842, OR4875, OR4877, gfOrg3132, OR4834, OR4878, OR5397, mfOrg3178, OR4822, OR5207, OR5396, mfOrg3180, RO5377, OR5398, PP5188, PET-2176-04, PET00292-07, PET00297-03) modified for altered flower color and antibiotic resistance.

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 19 petunia varieties contains both of the following plant-trait-mechanism of action (PTMOA) combinations that USDA previously reviewed and determined to not be regulated under 7 CFR part 340: petunia with altered flower color via the maize *Al* gene encoding dihydroflavonol 4-reductase (DFR) and petunia with antibiotic resistance via neomycin phosphotransferase (NPTII) (petition 19-099-01p). You describe methods, including a combination of PCR and directed DNA sequencing, used to verify the intended modification. You also explain that the impact of any remaining unintended exogenous DNA sequences would be the same as described in petition 19-099-01p.

Based on our review of the representations made in your letter, USDA confirms the 19 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 this PTMOA combination that USDA determined to not be regulated. Based on this confirmation, and per your request, we have removed four petunia varieties (CO5369, OR4842, OR4875, and OR4877) from the list of petunias requiring import authorization.

Although your petunia 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](mailto: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](mailto: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 27, 2022  
Date