



United States Department of Agriculture

Marketing and
Regulatory
Programs

Animal and
Plant Health
Inspection
Service

Washington,
DC 20250

Dr. Eric Ward
Norfolk Plant Science
524 N. Mangum St. Unit 11
Durham, NC 27701-2593

RSR number 21-166-01rsr

RE: Regulatory Status Review of tomato developed using genetic engineering to produce enhanced levels of endogenous anthocyanins in the fruit

Dear Dr. Ward:

Thank you for your letter dated August 4, 2021, requesting a Regulatory Status Review (RSR) for a tomato with altered fruit color developed using genetic engineering (modified tomato). In your letter, you described that the tomato was modified to produce increased levels of endogenous anthocyanins in fruit via tissue specific co-expression of the *Antirrhinum majus* Roseal and Delila transcription factors, and to contain a selectable marker that imparts antibiotic (kanamycin and neomycin) resistance using the neomycin phosphotransferase (NPTII) gene.

The Plant Protection Act of 2000 (7 U.S.C. §§ 7701 et seq.) provides USDA authority to oversee the detection, control, eradication, suppression, prevention, or retardation of the spread of plant pests to protect agriculture, environment, and the economy of the United States. USDA, through the Animal and Plant Health Inspection Service (APHIS), regulates the “Movement of Organisms Modified or Produced through Genetic Engineering” as described in 7 CFR part 340.

Consistent with 7 CFR 340.4, APHIS reviewed your modified tomato to determine whether it is subject to the regulations in 7 CFR part 340. Specifically, APHIS reviewed the modified tomato to determine whether there is a plausible pathway by which the tomato, or any sexually compatible relatives, would pose an increased plant pest risk relative to the plant pest risk posed by an appropriate tomato comparator. Based on information you provided, publicly available resources, and APHIS’ familiarity with tomato and knowledge of the trait, phenotype, and mechanism of action, APHIS considered the (1) biology of a comparator tomato and its sexually compatible relatives; (2) the trait and mechanism-of-action of the modification; and (3) the effect of the trait and mechanism-of-action on the (a) distribution, density, or development of the modified plant and its sexually compatible relatives, (b) production, creation, or enhancement of a plant pest or a reservoir for a plant pest, (c) harm to non-target organisms beneficial to agriculture, and (d) weedy impacts of the modified plant and its sexually compatible relatives. APHIS did not identify any plausible pathway by which your modified tomato, or any of its sexually compatible relatives, would pose an increased plant pest risk relative to a comparator tomato. APHIS has determined that your modified tomato is unlikely to pose an increased plant pest risk relative to its comparator. Once APHIS determines that a plant product is unlikely to pose an increased plant pest risk relative to its comparator, and, thus, is not a plant pest or a plant that requires regulation because it is capable of introducing or disseminating a plant pest, APHIS has no authority to regulate it under 7 CFR part 340. Accordingly, your tomato is not subject to the regulations under 7 CFR part 340.

Please be advised that APHIS’ decision applies to the tomato developed using genetic engineering exactly as described in your letter. If at any time you become aware of any information that may affect our review and determination of your modified tomato, including, for example, new information that shows the genetic changes are not exactly as described in your letter, you must contact APHIS at RSRrequests@usda.gov.

Please be advised that your plant product, while not regulated under 7 CFR part 340, may be subject to APHIS 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. Your plant product may also be subject to other regulatory authorities such as the U.S. Environmental Protection Agency (EPA) or the Food and Drug Administration (FDA). Please contact EPA and FDA to enquire about the regulatory status of your product.

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

September 6, 2022
Date