



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Biotechnology
Regulatory
Services

4700 River Road
Riverdale, MD
20737

Ren Tanimoto
GRA&GREEN Inc.
5-112, Higashiyamatori,
Chikusa-ku, Nagoya, 464-0807, Japan

Re: Confirmation of the regulatory status of gene-edited tomato with enhanced fruit quality

Dear Ren Tanimoto:

Thank you for your letter received June 10, 2025 (25-161-01air), inquiring whether the tomato (*Solanum lycopersicum* L. var. *lycopersicum*) product described in your letter is a regulated article under 7 CFR part 340. Your letter describes CRISPR-Cas editing, resulting in the desired enhanced fruit quality.

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 introduction of plants and articles to prevent the dissemination or establishment of a plant pest within the United States. As such, USDA, through the Animal and Plant Health Inspection Service, regulates the "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which are Plant Pests or Which There is Reason to Believe Are Plant Pests," as described in 7 CFR part 340. These regulations only apply to organisms that USDA deems regulated articles under § 340.1.

In your letter, you describe your use of CRISPR-Cas to induce a deletion in the target gene, which you have claimed as CBI. The gene editing elements were introduced into the plant using a method you have claimed as CBI. You used both polymerase chain reaction (PCR) and Southern blotting to confirm that no vector sequences, including plant pest sequences, were integrated into the genome of your tomato.

Based on the representations you made in your letter, including your description of the results of your confirmation methods, your tomato are not themselves plant pests and no plant pest sequences were integrated into the plant genome of tomato. Consistent with previous responses to similar letters of inquiry, USDA does not consider your tomato to be regulated pursuant to 7 CFR part 340.

Although your modified tomato 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 USDA's conclusion regarding this inquiry, you should immediately notify us 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

Date: June 27, 2025