



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Biotechnology
Regulatory
Services

5601 Sunnyside Ave
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Nian Wang
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Lake Alfred, FL 33850-2299

Re: Confirmation of the regulatory status of CRISPR-edited *Citrus sinensis* with improved disease resistance and quality in the presence of Huanglongbing (HLB)

Dear Nian Wang:

Thank you for your letter dated February 12, 2026 (26-028-01air), inquiring whether the sweet orange (*Citrus sinensis*) product described in your letter is a regulated article under 7 CFR part 340. Your letter describes genome edited sweet orange developed using CRISPR/Cas12a and a cytosine base editor, resulting in the desired resistance to Huanglongbing (HLB) disease.

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 sweet orange plants edited in a targeted gene claimed as confidential business information (CBI), resulting in improved resistance to HLB disease caused by *Candidatus Liberibacter asiaticus*. You used transient *Agrobacterium*-mediated transformation to introduce CRISPR/Cas12a components into sweet orange to generate mutations at the target gene via cellular repair of a targeted DNA break. You also state that the T-DNA construct you used contained a cytosine base editor (CBE) and associated guide RNA (gRNA) designed to edit the *acetolactate synthase (ALS)* gene, resulting in resistance to chlorsulfuron, which was used as a selectable marker. You used polymerase chain reaction analysis and whole genome sequencing to confirm the absence of plant pest sequences in the final plants.

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

Although your modified sweet orange is not regulated under 7 CFR part 340, it may be subject to other USDA regulations or other regulatory authorities. For example,

importation, interstate movement, and intrastate movement of your plant or its seeds may be subject to Plant Protection and Quarantine (PPQ) permit and/or quarantine requirements. For further information about movement of citrus, please see the APHIS website for Citrus Diseases: <https://www.aphis.usda.gov/plant-pests-diseases/citrus-diseases>. For further information, you may also 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,

Donna A. Lalli, Ph.D.
APHIS Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture