



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Biotechnology
Regulatory
Services

4700 River Road
Riverdale, MD
20737

LaSemilla. Co. Ltd
1447 Pyeongchang-ro, Pyeongchang,
Gangwon, 25354, Rep of Korea

Re: Confirmation of the regulatory status of genome-edited rice lines with drought tolerance

Dear Dr. Se-Jun Oh:

Thank you for your letter received January 5, 2026 (25-364-01air), inquiring whether the rice (*Oryza sativa* (L.)) product described in your letter is a regulated article under 7 CFR part 340. Your letter describes the use of CRISPR/Cas9 genome editing, resulting in the desired drought tolerance.

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 disarmed *Agrobacterium tumefaciens* to deliver a construct containing CRISPR/Cas9 reagents into rice plants to create a deletion in the targeted gene claimed as confidential business information (CBI). You state that you used conventional breeding techniques to remove the inserted construct DNA. You confirmed the absence of inserted DNA sequences, including plant pest sequences, using polymerase chain reaction (PCR) analysis with PCR primers that span the entire T-DNA region and the vector backbone.

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

Although your modified rice 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,

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