



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Biotechnology
Regulatory
Services

4700 River Road
Riverdale, MD
20737

Bing Yang, Ph.D.
University of Missouri
College of Agriculture, Food and Natural Resources; Division of Plant Sciences
340e Bond Life Science Center
Columbia, MO 65211-7145

Re: Confirmation of the regulatory status of genome edited rice with resistance to bacterial blight

Dear Dr. Yang:

Thank you for your letter dated May 22, 2020, inquiring whether the rice (*Oryza sativa*) product described in your letter is a regulated article under 7 CFR part 340. Your letter describes CRISPR-Cas genome editing of rice that disrupts the function of promoters for sugar transport genes critical for plant susceptibility to infection by *Xanthomonas oryzae* pv. *oryzae*, resulting in the desired resistance to bacterial blight.

The Plant Protection Act (PPA) of 2000 gives USDA the authority to oversee the detection, control, eradication, suppression, prevention, or retardation of the spread of plant pests or noxious weeds to protect the agriculture, environment, and economy of the United States.

USDA regulates the importation, interstate movement and environmental release (field testing) of certain organisms developed using genetic engineering that are, or have the potential to be, plant pests under 7 CFR part 340, "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." Under the regulations, an organism is deemed a regulated article if it has been genetically engineered using a donor organism, recipient organism, or vector or vector agent that is listed in § 340.2 and meets the definition of a plant pest; or that is an unclassified organism and/or an organism whose classification is unknown, or if the Administrator determines that the organism is a plant pest or has reason to believe it is a plant pest.

In your letter, you describe the use of disarmed *Agrobacterium tumefaciens* to introduce CRISPR-Cas gene editing reagents into rice cells to edit the promoters of three target genes. No DNA repair template was provided. Conventional breeding was used to generate and select progeny that contained the intended edits without the introduced exogenous DNA. The absence of DNA from the introduced construct was confirmed by PCR amplification using ten different primer pairs corresponding to different components of the CRISPR-Cas construct.

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

Although your genome edited rice line is not regulated under 7 CFR part 340, other regulatory authorities may apply. For example, the importation of your rice seeds or plants will be subject to applicable Plant Protection and Quarantine (PPQ), permit and/or quarantine requirements. For further information, should you plan to import these rice seeds or plants, you may contact the PPQ general number for such inquiries at 877-770-5990. To inquire about the regulatory status of your product with the Environmental Protection Agency (EPA), please contact Alan Reynolds at 703-605-0515. To inquire about the regulatory status of your product with the Food and Drug Administration (FDA), please contact 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,



Bernadette Juarez.
APHIS Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture

August 24, 2020
Date