United States Department of Agriculture

Animal and Plant Health Inspection Service

Biotechnology Regulatory Services

5601 Sunnyside Ave
Beltsville, MD 20705

Byung-Chun Yoo, Ph.D.
Director, Business Development
NAPIGEN, Inc.

Re: Inquiry of Regulatory Status of the Rice Plant Line, POET-100, with Cytoplasmic Male Sterility Developed by Mitochondrial Gene Editing

Dear Dr. Byung-Chun Yoo:

Thank you for your letter dated February 2, 2026 (26-033-01air), inquiring whether the rice (*Oryza sativa*) product described in your letter is a regulated article under 7 CFR part 340. Your letter describes mitochondrial gene editing resulting in rice lines that exhibit cytoplasmic male sterility.

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 the use of a two-step process to modify the mitochondrial genome of your rice lines. First, you describe using biolistic transformation to insert DNA sequences into the mitochondrial genome, resulting in cytoplasmic male sterility. Second, you describe the use of *Agrobacterium*-mediated transformation to insert a construct into the nuclear genome of your rice lines to make targeted edits to the mitochondrial genome. You state that the inserted construct will be subsequently segregated out by conventional breeding to remove all plant pest components. You will confirm the absence of plant pest sequence in the nuclear and mitochondrial genomes of your modified rice lines through next generation sequencing.

Based on the representations you made in your letter, your modified rice lines are not themselves plant pests and no plant pest sequences will remain integrated into the genome of rice. Consistent with previous responses to similar letters of inquiry, USDA does not consider your modified 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 rice 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 LALLI Digitally signed by DONNA LALLI
Date: 2026.03.19 10:39:09 -04'00'

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