



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Biotechnology
Regulatory
Services

4700 River Road
Riverdale, MD
20737

Sarah Forrester
Inari Agriculture, Inc.
One Kendall Square
Building 600/700, Suite 7-501
Cambridge, MA 02139

Re: Confirmation of the regulatory status of gene edited wheat lines with increased yield and modified plant architecture

Dear Sarah Forrester:

Thank you for your letter received November 13, 2025 (25-317-01air), inquiring whether the wheat (*Triticum aestivum* L.) product described in your letter is a regulated article under 7 CFR part 340. Your letter describes CRISPR-Cas gene editing, resulting in the desired increased yield and modified plant architecture.

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 CRISPR-Cas mediated gene editing technology for non-templated repair of targeted double stranded breaks to modify wheat genes claimed as confidential business information (CBI). You used and will use *Agrobacterium*-mediated transformation to introduce constructs into wheat to create edits in CBI target genes individually or in combination to obtain increased yield and modified plant architecture. You state that you will use conventional breeding to remove vector sequences and confirm the absence of vector sequences using quantitative-PCR assays that will cover every genetic element in your transformation vector.

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

Although your modified wheat 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