



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection  
Service

Biotechnology  
Regulatory  
Services

4700 River Road  
Riverdale, MD  
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Natalie Weber  
Inari Agriculture, Inc.  
One Kendall Square  
Building 600/700, Suite 7-501  
Cambridge, MA 02139

Re: Confirmation of the regulatory status of genome edited maize lines

Dear Ms. Weber:

Thank you for your letter dated June 16, 2020, inquiring whether the maize (*Zea mays* L.) products described in your letter are regulated articles under 7 CFR part 340. Your letter describes maize lines that will be generated by genome editing of one or more specifically identified genes using a proprietary CRISPR-Cas enzyme system, resulting in the desired phenotype (claimed as CBI).

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 a proprietary CRISPR-Cas genome editing system to edit one or more specifically identified target genes in maize. No DNA repair template will be provided. You state that the intended genetic changes will be confirmed by targeted sequencing methods. You also state that the genome edited maize lines will be selected from the segregating population, and that the absence of the exogenous vector DNA in the genome edited lines will be confirmed by polymerase chain reaction (PCR) analysis or by sequencing methods.

Based on the representations you made in your letter, including your description of the intended confirmation and selection methods, your genome edited maize lines are not themselves plant pests and no plant pest sequences were integrated into the plant genome

of maize. Consistent with previous responses to similar letters of inquiry, USDA does not consider your genome edited maize lines to be regulated pursuant to 7 CFR part 340.

Although your genome edited maize lines are not regulated under 7 CFR part 340, other regulatory authorities may apply. For example, the importation of your maize 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 maize 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](mailto: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 6, 2020  
Date