



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Biotechnology
Regulatory
Services

4700 River Road
Riverdale, MD
20737

Dan Jenkins
Regulatory Strategy and Quality Lead
Pairwise
807 East Main Street
Suite 4-100
Durham, NC 27701

Re: Confirmation of the regulatory status of genome edited *Brassica juncea* lines with improved flavor

Dear Mr. Jenkins:

Thank you for your letter dated June 16, 2020, inquiring whether the *Brassica juncea* (L.) product described in your letter is a regulated article under 7 CFR part 340. Your letter describes genome edited *B. juncea* plants with deletions in target genes claimed as confidential business information (CBI), resulting in leaves with improved flavor.

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 development of genome edited *B. juncea* lines with changes in target genes, all claimed as CBI. You describe that the targeted deletions were confirmed by polymerase chain reaction (PCR) analysis and next generation sequencing. You also describe that *B. juncea* plants with the intended deletions in target genes were selected, self-fertilized, and progeny plants were selected from the segregating population. You state that the absence of the exogenous plasmid construct DNA in the genome edited *B. juncea* lines was confirmed by PCR analysis.

Based on the representations you made in your letter, including your description of the results of your confirmation methods, your genome edited *B. juncea* lines are not

themselves plant pests. Consistent with previous responses to similar letters of inquiry, USDA does not consider your genome edited *B. juncea* lines to be regulated pursuant to 7 CFR part 340.

Although your genome edited *B. juncea* lines are not regulated under 7 CFR part 340, other regulatory authorities may apply. For example, the importation of your genome edited *B. juncea* 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 genome-edited *B. juncea* 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 12, 2020
Date