United States Department of Agriculture

Animal and Plant Health Inspection Service

Biotechnology Regulatory Services

4700 River Road
Riverdale, MD 20737

Dr. Karen Bohmert-Tatarev
Dr. Kristi Snell
Yield10 Bioscience
19 Presidential Way
Woburn, MA 01801

Re: Confirmation of the regulatory status of genome edited canola with altered oil content.

Dear Drs. Bohmert-Tatarev and Snell,

Thank you for your letter dated June 11, 2020, inquiring whether the canola (*Brassica napus*) products described in your letter is a regulated article under 7 CFR part 340. Your letter describes the use of CRISPR-Cas9 and multiple guide RNAs to deactivate multiple canola genes, resulting in the altered oil content phenotype.

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 *Agrobacterium* to transform canola with a construct containing CRISPR-Cas9 nuclease and multiple guide RNAs that resulted in the deactivation of multiple canola genes claimed as CBI. Your letter states that a selectable marker, claimed as CBI, was used to identify canola lines expressing the Cas9 nuclease, guide RNAs, and the selectable marker. Self-pollination of transformed plants was used to generate canola lines containing the targeted gene edits but not containing any of the DNA from the original construct. Polymerase Chain reaction (PCR) was used to verify that no plant pest sequences remained in the final genome edited canola lines.

Based on the representations you made in your letter, including your description of the results of your confirmation methods, your genome edited canola lines with altered oil content are not themselves plant pests and no plant pest sequences remain integrated into

the plant genome of canola. Consistent with previous responses to similar letters of inquiry, USDA does not consider your genome edited canola lines with altered oil content to be regulated pursuant to 7 CFR part 340.

Although your genome edited canola is not regulated under 7 CFR part 340, other regulatory authorities may apply. For example, the importation of your canola 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 canola 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,

August 12, 2020
Date

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