

Animal Plant
Health Inspection
Service (APHIS)

Biotechnology
Regulatory
Services (BRS)

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Drs. Karen Bohmert-Tatarev and Kristi Snell
Yield10 Bioscience
19 Presidential Way
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Dear Drs. Bohmert-Tatarev and Snell:

Thank you for your letter of February 26, 2021 (20-358-01cr) requesting confirmation that your plants are exempt from regulation under 7 CFR part 340. Your letter describes single genetic modifications to *Camelina sativa* plant lines, with a seed composition trait claimed as confidential business information (CBI). You requested confirmation that your plant lines with these modifications are exempt from regulation, pursuant to § 340.1(b)(1).

The Plant Protection Act of 2000 (PPA) gives USDA the authority to oversee the detection, control, eradication, suppression, prevention, or retardation of the spread of plant pests to protect the agriculture, environment, and economy of the United States. The PPA provides USDA with broad authority to protect plants by regulating the movement of, among other items, plants and articles to prevent the introduction or dissemination of a plant pest within the United States. USDA, through the Animal and Plant Health Inspection Service (APHIS), regulates the “Movement of Organisms Modified or Produced through Genetic Engineering,” as described in 7 CFR part 340. The regulations in 7 CFR part 340 do not apply to plants that contain a modification of a type listed in § 340.1(b) or § 340.1(c).

Your letter states that the genetic modification in each plant line is a single CRISPR/Cas9-mediated edit of one copy of a gene resulting from cellular repair of a targeted DNA break in the absence of an externally provided repair template. Your letter describes how you inserted exogenous DNA into the plant’s genome to generate the genetic modifications, and how you eliminated it in the final modified plant lines. You describe the methods and provide data to verify that only the intended modification was made in each line and no exogenous DNA remains in the plants.

Based on the representations made in your letter of February 26, 2021, the *C. sativa* plant lines with the modifications as described meet the eligibility criteria for exemption set forth in § 340.1(b)(1). USDA confirms that the genome-edited *C. sativa* lines described in your letter are exempted from regulation under 7 CFR part 340. USDA notes that plants with modifications that are exempt pursuant to § 340.1(b)(1) are unlikely to pose an increased plant pest risk as this type of modification is achievable by conventional breeding.

Although your plants are not regulated under 7 CFR part 340, they may be subject to other USDA regulations or other regulatory authorities. For example, importation of your *C. sativa* plants or their 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 plants 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 plants 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 our confirmation of this exemption, please notify me immediately 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

April 28, 2021

Date