



Animal Plant
Health Inspection
Service (APHIS)

Biotechnology
Regulatory
Services (BRS)

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Dr. Quan Zhang
Bioheuris Inc.
1100 Corporate Square Dr., Rm 236
St. Louis, MO 63132

Dear Dr. Quan Zhang:

Thank you for your letter dated March 25, 2021 (20-317-01cr) requesting confirmation that your plant is exempt from regulations under 7 CFR part 340. Your letter describes a planned genetic modification of *Glycine max* (soybean). You also provided the following description of the intended trait of the plant: herbicide resistance. Your letter indicates that the phenotype is resistance to herbicides that inhibit Acetolactate synthase (ALS). You requested confirmation that this modification is exempt from regulation, pursuant to § 340.1(b)(2).

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, 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).

In your letter you state that the planned genetic modification in your plant is a result of CRISPR/Cas9 gene editing technology to make a single base pair substitution in the ALS gene by cellular repair of a targeted DNA break in the presence of an externally provided repair template. You also describe the methods you plan to use to verify that the intended modification is made, and no unintended exogenous DNA remains in the plant.

Based on the representations made in your letter, the described modification in the soybean plant would meet the eligibility criteria for exemption set forth in § 340.1(b)(2). USDA confirms that the soybean genome-edited for herbicide resistance described in your March 25, 2021 letter would be exempt from 7 CFR part 340. USDA notes that plants with modifications that are exempt pursuant to § 340.1(b)(2) are unlikely to pose an increased plant pest risk as this type of modification already occurs as a result of conventional breeding.

Although your plant would not be 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.

USDA recommends implementation of best management practices (BMPs) to limit and delay the evolution of herbicide resistant weed populations in fields planted with herbicide resistant soybean. We have enclosed materials on this topic, including stewardship practices you and users of your product can take to delay or mitigate the emergence of herbicide resistant weeds. Please review these materials and provide guidance to users of your product.

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

May 03, 2021
Date

Enclosure

Norsworthy et al. (2012) Reducing the Risks of Herbicide Resistance: Best Management Practices and Recommendations. Weed Science 60(sp1):31-62. DOI: <https://doi.org/10.1614/WS-D-11-00155.1>

EPA (2017) PRN 2017-2: Guidance for Herbicide-Resistance Management, Labeling, Education, Training, and Stewardship
<https://www.epa.gov/pesticide-registration/prn-2017-2-guidance-herbicide-resistance-management-labeling-education>

PRN 2017-2 communicates EPA's approach to address herbicide-resistant weeds by providing guidance to herbicide users and registrants on useful strategies (including labeling, education, training, and stewardship) that, when implemented, will slow the development and spread of herbicide-resistant weeds and prolong the useful life of herbicides. Although the document is titled "Pesticide Registration Notice", we specifically refer you to the guidance on herbicide-resistance best management practices included in Sections 1, 3A, 3B, and 4, including the guidance on mitigating pollen flow to sexually compatible relatives and mitigating the selection of herbicide resistance in weeds.