



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Biotechnology
Regulatory
Services

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Chee Hark Harn, Ph. D.
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Seoul, South Korea 08501

Re: Confirmation of the regulatory status of genome edited soybean with high oleic acid content.

Dear Dr. Harn:

Thank you for your letter dated April 2, 2020, inquiring whether the high oleic acid soybean product described in your letter is a regulated article under 7 CFR part 340. Your letter describes the use of CRISPR-Cas9 to knockout genes resulting in the desired high oleic acid seed oil profile in soybean plants.

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 introduce CRISPR-Cas9 and sgRNA to generate a targeted knockout of genes in the soybean product. Your letter states that the soybean line was initially screened with PCR to determine that it contained the CRISPR-Cas9 expression cassette, the selectable marker cassette, and disruptions in genes claimed as confidential business information (CBI). Self-pollination of the soybean line resulted in the high oleic soybean product, in which both cassettes were removed and only the disruptions of the targeted genes remained. While certain genetic sequences used in the development of the genome edited soybean were derived from plant pests, your letter states that none of the inserted DNA remained in the final soybean product, as determined by whole genome sequencing.

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

themselves plant pests and no plant pest sequences are integrated into the soybean genome. Consistent with previous responses to similar letters of inquiry, USDA does not consider your high oleic acid soybean to be regulated pursuant to 7 CFR part 340.

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

July 21, 2020
Date