



**United States
Department of
Agriculture**

Animal and
Plant Health
Inspection
Service

Biotechnology
Regulatory
Services

4700 River Road
Riverdale, MD
20737

Fayaz Khazi, Ph.D.
The Traits Company
104 T.W. Alexander Drive, Bldg. 1,
Research Triangle Park, NC 27713

Re: Confirmation of the regulatory status of genome-edited soybean lines with improved yield

Dear Dr. Khazi:

Thank you for your letter dated July 29, 2025 (25-226-01air), inquiring whether the soybean (*Glycine max*) product described in your letter is a regulated article under 7 CFR part 340. Your letter describes the use of CRISPR/Cas genome editing, which will result in the described phenotype(s) to improve soybean yield.

The Plant Protection Act of 2000 (PPA) provides USDA with broad authority to protect U.S. agriculture, the environment, and the economy by, among other things, regulating the introduction of plants and articles to prevent the dissemination or establishment of a plant pest within the United States. As such, USDA, through the Animal and Plant Health Inspection Service, regulates the "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," as described in 7 CFR part 340. These regulations only apply to organisms that USDA deems regulated articles under § 340.1.

In your letter, you describe your use of CRISPR/Cas to induce indels in 600 targeted soybean gene sequences related to yield improvement but claimed as confidential business information (CBI). Your method will create gene edits via targeted DNA breaks in CBI genes using one or multiple guide RNAs, followed by natural cellular repair in the absence of an exogenous repair template. You state that foreign DNA, including plant pest DNA, will be absent in the final products, and that this will be confirmed by methods claimed as CBI.

Based on the representations you made in your letter, including your description of your confirmation methods, your soybean lines are not themselves plant pests and no plant pest sequences will remain integrated in the genome of soybean. Consistent with previous responses to similar letters of inquiry, USDA would not consider your modified soybean lines to be regulated pursuant to 7 CFR part 340.

Although your modified soybean 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 soybean 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.

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,

Donna A. Lalli, Ph.D.
APHIS Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture