



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Biotechnology
Regulatory
Services

4700 River Road
Riverdale, MD
20737

Celeste Varela, Ph.D.
BioHeuris Inc.
1100 Corporate Square Dr.,
St. Louis, MO 63132

Re: Confirmation of the regulatory status of gene edited sorghum lines with herbicide resistance

Dear Dr. Varela,

Thank you for your letter dated July 17, 2025 (25-189-01air), inquiring whether the sorghum (*Sorghum bicolor*) product described in your letter is a regulated article under 7 CFR part 340. Your letter describes the use of base editing technology to introduce precise gene edits at a site claimed as confidential business information (CBI), resulting in the desired herbicide resistance.

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 how you used the base editing CRISPR-Cas9 system to generate precise edits in a gene claimed as CBI to impart herbicide resistance. You used *Agrobacterium*-mediated transformation to introduce base editing reagents into sorghum embryos, and subsequently used conventional breeding methods, polymerase chain reaction, and Sanger sequencing to confirm the presence of edits and absence of transgenic vector sequences in modified sorghum plants.

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

Although your modified sorghum is not regulated under 7 CFR part 340, it may be subject to other USDA regulations or other regulatory authorities. For example, importation of your sorghum plants 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.

Finally, sorghum is sexually compatible with Johnsongrass (*Sorghum halepense*) and shattercane (*S. bicolor* subsp. *drummondii*); both are troublesome weeds of several crops. Herbicide resistance in Johnsongrass and shattercane reduces the number of herbicide management options available to control these weeds. 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 sorghum. We have enclosed materials on this topic, including stewardship practices you and users of your product can implement to minimize outcrossing to Johnsongrass and shattercane and 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 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

Date: July 23, 2025

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.