



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Biotechnology
Regulatory
Services

4700 River Road
Riverdale, MD
20737

Travis Bayer, PhD
Decibel Bio, Inc.
3100 San Pablo Avenue, Suite 120
Berkeley, CA 94702

Re: Confirmation of the regulatory status of epigenetically modified corn lines with improved yield

Dear Dr. Bayer:

Thank you for your letter received November 13, 2025 (25-317-04air), inquiring whether the corn (*Zea mays*) product described in your letter is a regulated article under 7 CFR part 340. Your letter describes epigenetic modification of corn, resulting in the desired improved 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 methods, claimed as CBI, to induce epigenetic changes in corn. You confirm that there are no mutations or insertions in your corn lines using long-read DNA sequencing.

Based on the representations you made in your letter your corn are not themselves plant pests, and you did not insert any DNA into the genome, thus no plant pest sequences were integrated into the plant genome of corn. Consistent with previous responses to similar letters of inquiry, USDA does not consider your corn lines to be regulated pursuant to 7 CFR part 340.

Although your modified corn 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 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.

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