



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection  
Service

Biotechnology  
Regulatory  
Services

4700 River Road  
Riverdale, MD  
20737

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

Re: Confirmation of the regulatory status of epigenetically modified lettuce lines with reduced expression of PAL1 and PAL2 genes

Dear Travis Bayer:

Thank you for your letter received February 26, 2025 (25-057-01air), inquiring whether the lettuce (*Lactuca sativa*) product described in your letter is a regulated article under 7 CFR part 340. Your letter describes epigenetic technology, resulting in a trait claimed as CBI.

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 lettuce. You confirm that there are no mutations or insertions in your lettuce lines using long read DNA sequencing.

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

Although your modified lettuce 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 lettuce 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](mailto: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](mailto: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,

A handwritten signature in black ink, appearing to read 'BJ', with a stylized flourish extending to the right.

Bernadette Juarez  
APHIS Deputy Administrator  
Biotechnology Regulatory Services  
Animal and Plant Health Inspection Service  
U.S. Department of Agriculture

Date: March 13, 2025