



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Biotechnology
Regulatory
Services

4700 River Road
Riverdale, MD
20737

The Wisconsin Crop Innovation Center
University of WI-Madison,
8520 University Green,
Middleton, WI 53562

Re: Confirmation of the regulatory status of *Cannabis sativa* plants gene edited to be resistant to powdery mildew

Dear Dr. Petersen:

Thank you for your letter received on December 9, 2025 (25-317-07air), inquiring whether the hemp (*Cannabis sativa*) product described in your letter is a regulated article under 7 CFR part 340. Your letter describes CRISPR/Cas9 technology resulting in the desired genome edited hemp Badger PMR product, resistant to powdery mildew disease.

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 hemp Badger (Type III variety) plants genome edited at one or more targeted sites claimed as confidential business information (CBI), resulting in resistance to powdery mildew disease. You used *Agrobacterium* mediated transformation to introduce CRISPR/Cas9 components into hemp to generate insertions, deletions and/or substitutions at targets claimed as CBI via non-homologous end joining. You used polymerase chain reaction analysis and sequencing to confirm your edits and conventional breeding and whole genome sequencing will be used to ensure the absence of any T-DNA sequences in the final plants.

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

Although your modified hemp 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 hemp 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

**United States
Department of
Agriculture**

Animal and
Plant Health
Inspection
Service

Biotechnology
Regulatory
Services

4700 River Road
Riverdale, MD
20737

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. Please be aware that cannabis lines with more than 0.3% dried weight of tetrahydrocannabinol are considered to be marijuana and regulated by Drug Enforcement Administration (DEA). Anyone planning to grow marijuana must be registered with the DEA ([DEA Diversion Control Division](#)) and be compliant with applicable state regulations.

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