United States Department of Agriculture

Animal and Plant Health Inspection Service

Biotechnology Regulatory Services

4700 River Road
Riverdale, MD 20737

Christina E. Huben
BioConsortia, Inc.
279 Cousteau Place, Suite 100
Davis, CA 95618

Re: Confirmation of the regulatory status of gene edited strains of *Paenibacillus polymyxa* modified for improved nitrogen fixation

Dear Christina Huben:

Thank you for your letter dated July 22, 2025 (25-182-01air), inquiring whether the gene edited strains of *Paenibacillus polymyxa* described in your letter are regulated under 7 CFR part 340. Your letter describes a gene editing method claimed as confidential business information (CBI), resulting in the desired ability for improved nitrogen fixation.

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 seven *Paenibacillus polymyxa* strains in which genes involved in nitrogen fixation have been edited to contain intraspecies modifications, including deletions and insertions. You used a natural homologous recombination-based CBI method to introduce the modifications. You used polymerase chain reaction, Sanger sequencing and whole genome sequencing to confirm the edits and ensure that no exogenous DNA is present in the strains. You further state that future strains of *P. polymyxa* with similar intraspecies modifications will be developed using the same methodology to improve nitrogen fixation.

Based on the representations you made in your letter, including your description of the confirmation methods, your seven *P. polymyxa* strains are not themselves plant pests and no plant pest sequences were integrated into the *P. polymyxa* genome. Consistent with previous responses to similar letters of inquiry, USDA does not consider your seven *P. polymyxa* strains to be regulated pursuant to 7 CFR part 340. Assuming that future modified *Paenibacillus polymyxa* strains with improved nitrogen fixation are developed using the same methodology described in your letter, and contain only intraspecies modifications, they would also not be regulated pursuant to 7 CFR part 340.

Although your modified *P. polymyxa* strains are not regulated under 7 CFR part 340, they may be subject to other USDA regulations or other regulatory authorities. For example,

importation of your *P. polymyxa* 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,



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

Date: July 25, 2025