



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Biotechnology
Regulatory
Services

4700 River Road
Riverdale, MD
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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 (25-182-02air), 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 edited *Paenibacillus polymyxa* strains in which genes involved in nitrogen fixation contain different combinations of modifications, including coding and non-coding sequences derived from another CBI *Paenibacillus* species. 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 unintended DNA sequences remain in the strains. You further state that future strains of *P. polymyxa* with similar modifications will be developed using coding and non-coding sequences from *Paenibacillus durus*, *Paenibacillus odorifer*, *Paenibacillus typhae*, *Paenibacillus graminis*, *Paenibacillus borealis*, and *Paenibacillus donghaensis*. You will use the same CBI methodology to develop and confirm the future strains.

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 introduced 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 *P. polymyxa* strains with improved nitrogen fixation are developed and confirmed using the same methodology described in your letter, and contain only sequences from *Paenibacillus durus*, *Paenibacillus odorifer*, *Paenibacillus typhae*,

Paenibacillus graminis, *Paenibacillus borealis*, and *Paenibacillus donghaensis*, 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,

Donna A. Lalli, Ph.D.
APHIS Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture

Date: August 14, 2025

DONNA LALLI

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