

Davis, January 6, 2025

Bernadette Juarez
APHIS Deputy Administrator
Biotechnology Regulatory Services
4700 River Rd, Unit 98
Riverdale, MD 20737

Re: Request for confirmation of regulatory status – Am I Regulated – *Paenibacillus odorifer* strain BEC180

Dear Ms. Juarez,

BioConsortia, Inc. hereby requests that USDA/APHIS/BRS confirms the regulatory status for the transport, field testing and commercialization of BioConsortia's gene edited diazotrophic *Paenibacillus odorifer* strain BEC180. This request is based on BioConsortia's assertion that:

- The parent strain is not a plant pest
- The gene edits are specifically to improve nitrogen fixation activities
- []
- The strain as edited is not a plant pest.

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Background

BioConsortia is a private US corporation formed in 2014 for the purpose of discovering and developing microbial solutions for increased plant growth and health, pest control and plant yield enhancement. Utilizing its proprietary Advanced Microbial Selection™ (AMS) methods (US Patent 9,777,267), microbes are selected by plants in iterative rounds of plant cultivation in randomly collected soil samples. AMS selected microbes are the basis for our research and development activities because the microbes in these experiments interact closely with the plants, have evolved along with the plants, and do not exhibit any harmful effects on the plants. BioConsortia has developed several of these plant-associated microbes as fungicides, nematicides, insecticides, biostimulants and nitrogen fixing agents.

It is no secret that one of the greatest contributors to yield in modern agriculture practice is the implementation of effective fertilizer programs. It is reported that by 2010, average US corn yields were nearly 160 bushels per acre, which is more than a six-fold increase in yield in a period of 70 years, much of this credited to the availability of low cost fertilizers created by converting Nitrogen (N) in the air and Hydrogen in water into ammonia, a form of nitrogen readily taken up by plants, using Haber-Bosch process. Nitrogen fertilizer is, in fact, a critical enabler of modern food systems which endeavor to feed the nearly 9 billion people on Earth.

However, synthesis and application of N fertilizers is not without environmental impact. The production process is energy intensive, requiring about 0.65 tons of natural gas to make 1 ton of

ammonia. Much of this N fertilizer is applied on our best agricultural land in an environment where N may be lost by nitrate leaching, some of which may reach the marine environment and cause eutrophication of our waterways. Ammonia volatilization from fertilizers and animal manures may also cause eutrophication and soil acidification. Finally, some N may be lost as nitrous oxide by denitrification and nitrification; and nitrous oxide is a strong greenhouse gas.

Since 2018, BioConsortia has developed and grown its gene editing expertise and capabilities, concentrating its efforts on gram positive spore-forming diazotrophs, trickier to edit, but with greater commercial applicability due to their robust nature. Focusing primarily on *Paenibacillus* and like genera of microbes, BioConsortia successfully edited several potential N-fixing leads.

BioConsortia purposefully selected and advanced its research and development using *Paenibacillus* because of their fit for commercial use due to their long shelf life and applicability as seed treatments, spore forming capabilities, general safety profile, and abundance in the environment.

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1. Developer (Responsible Party) name and contact information, including email address.

Christina E. Huben
Senior Vice President Operations & Administration
chuben@bioconsortia.com

2. Taxonomic description of organism (genus, species, and subspecies, if relevant).

BEC180 is a gene-edited variant of a naturally occurring *Paenibacillus odorifer* strain BEC109. The BEC109 strain was discovered and isolated for [] The taxonomical species identification of BEC109 is based on whole genome sequence analyses.

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3. Description of intended phenotype(s).

BEC180 is a gene-edited variant of BEC109 with improved nitrogen fixation capacities. [

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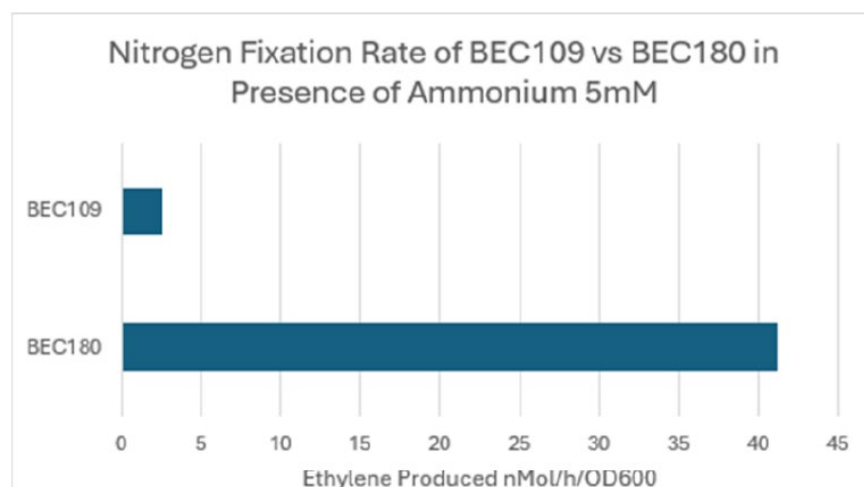


Figure 1: Nitrogenase activity measured by Acetylene Reduction Assay

4. Description of intended activity (movement or release).

The intended activities for BEC180 are both movement and release.

5. Description of intended genetic change in final product (e.g., insertion, deletion, substitution, other).

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6. Description of vector or vector agent used to induce genetic change in the organism (e.g., biolistic delivery, disarmed *Agrobacterium*, nuclease).

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7. Name of construct(s)

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8. Description of construct, including the following information for all elements, in order in which they occur in construct:[

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Table 1:

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9. Description of scientific methodology that you used or intend to use to confirm that the intended genetic changes were achieved.

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Due to the above understanding of *Paenibacillus* species and the targeted manner in which our gene edits have been developed, we cannot identify any risk associated with any potential non-target effects.

Thank you for your consideration and we of course remain available for any questions you may have in this regard.

Sincerely,

Christina E. Huben

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