



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Biotechnology
Regulatory
Services

4700 River Road
Riverdale, MD
20737

Dr. Natalie Hubbard
Pivot Bio, Inc.
2929 Seventh St., Suite 120
Berkeley, CA 94710

Re: Confirmation of the Regulatory Status of Modified Diazotrophic Bacteria

Dear Dr. Hubbard,

Thank you for your letter dated October 4, 2019, inquiring whether the diazotrophic bacteria you intend to engineer for delivery of nitrogen to non-leguminous crops, as described in your letter, are regulated articles under 7 CFR part 340. Your letter describes how you will develop diazotrophic bacteria with enhanced ability to fix and secrete nitrogen.

The Plant Protection Act (PPA) of 2000 gives USDA the authority to oversee the detection, control, eradication, suppression, prevention, or retardation of the spread of plant pests or noxious weeds to protect the agriculture, environment, and economy of the United States.

USDA regulates the importation, interstate movement and environmental release (field testing) of certain organisms developed using genetic engineering that are, or have the potential to be, plant pests under 7 CFR part 340, "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." Under the regulations, an organism is deemed a regulated article if it has been genetically engineered using a donor organism, recipient organism, or vector or vector agent that is listed in § 340.2 and meets the definition of a plant pest; or that is an unclassified organism and/or an organism whose classification is unknown, or if the Administrator determines that the organism is a plant pest or has reason to believe it is a plant pest.

In your letter, you describe how your company is using genome editing techniques to enhance the ability of diazotrophic bacteria to fix and secrete nitrogen for delivery to non-leguminous crops. You state that the diazotrophic bacteria being modified are not plant pests, as confirmed by a review of 7 CFR part 330, and that the modified bacteria will not contain any inserted material from outside the species or from a donor organism, vector or vector agent that is considered to be a plant pest. You further state that none of the genetic changes will increase the plant pest potential of the diazotrophic bacteria.

Assuming that the diazotrophic bacteria do not meet the definition of plant pest in part 330, and based on the representations made in your letter, USDA has concluded that the modified diazotrophic bacteria described are not themselves plant pests and do not contain plant pest sequences integrated into their genome. Therefore, consistent with previous

responses to similar letters of inquiry, USDA does not consider the diazotropic bacteria, if developed as as described in your letter, to be regulated pursuant to 7 CFR part 340.

Although your diazotropic bacteria products are not regulated under 7 CFR part 340, other regulatory authorities may apply. For example, the importation of your diazotropic bacteria will be subject to applicable Plant Protection and Quarantine (PPQ), permit and/or quarantine requirements. For further information, should you plan to import these diazotropic bacteria, you may contact the PPQ general number for such inquiries at 877-770-5990. To inquire about the regulatory status of your product with the Environmental Protection Agency (EPA), please contact Alan Reynolds at 703-605-0515. To inquire about the regulatory status of your product with the Food and Drug Administration (FDA), please contact 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 'Bernadette Juarez', with a stylized, flowing script.

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

June 23, 2020
Date