USDA

CBI Deleted Copy

United States Department of Agriculture

Animal and Plant Health Inspection Service

Biotechnology Regulatory Services

4700 River Road
Riverdale, MD 20737

Breeanne Schillianskey
Ginkgo Bioworks Inc.
27 Drydock Avenue, 8th Floor
Boston, MA 02201 USA

Re: Confirmation of the regulatory status of microbes modified for improved nitrogen fixation

Dear Breeanne Schillianskey:

Thank you for your letter, received July 17, 2025 (25-175-01air), inquiring whether the modified microbes described in your letter are regulated articles under 7 CFR part 340. Your letter describes genetic modifications intended to improve 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 methods claimed as confidential business information (CBI) to introduce targeted genetic modifications into your recipient species claimed as CBI to create multiple strains with improved nitrogen fixation. In your letter, you state that the modifications will involve both coding and non-coding elements originating from multiple donor species. Your final strains will be confirmed using whole genome sequencing.

Based on the representations you made in your letter, your CBI recipient species and the donor species for the coding elements in your strains that are listed in the attachment below are not themselves plant pests. In addition, because your recipient species are not themselves plant pests, the insertion of well-characterized non-coding elements from the donor species in your letter will not result in the creation of strains that meet the definition of a regulated article. Consistent with previous responses to similar letters of inquiry, USDA does not consider your modified microbe strains that contain the non-coding elements described in your inquiry or coding elements from the donor organisms listed below to be regulated pursuant to 7 CFR part 340.

Although your modified bacteria 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 microorganisms 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 organisms 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 organisms 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 LALLI

Digitally signed by DONNA LALLI
Date: 2025.09.10 13:46:57 -04'00'

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

List of species not considered plant pests by APHIS-BRS

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