United States Department of Agriculture

Animal and Plant Health Inspection Service

Biotechnology Regulatory Services

4700 River Road
Riverdale, MD 20737

Patrick Mellor
Living Carbon PBC
1458 San Bruno Ave
Building A Unit 1
San Francisco, CA 94110

Re: Confirmation of the regulatory status of hybrid poplar engineered for altered photosynthesis.

Dear Patrick Mellor:

Thank you for your letter dated April 10, 2020, inquiring whether the poplar (*Populus tremula* x *Populus alba*) product described in your letter is a regulated article under 7 CFR part 340. Your letter describes a poplar line transformed with non-plant pest DNA using a biolistic method, resulting in the desired altered photosynthesis phenotype.

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 your poplar product as genetically engineered using biolistic-mediated transfer of an expression construct. This construct is assembled from genetic elements of non-plant pest donor organisms and confers an altered photosynthesis phenotype.

Based on the representations you made in your letter, your poplar product is not itself a plant pest, no plant pest vector was used to develop the poplar, and no plant pest sequences were integrated into its genome. Consistent with previous responses to similar letters of inquiry, USDA does not consider your poplar product with a hyperaccumulation phenotype to be regulated pursuant to 7 CFR part 340.

Although your poplar product is not regulated under 7 CFR part 340, other regulatory authorities may apply. For example, the importation of your poplar seeds or plants will be subject to applicable Plant Protection and Quarantine (PPQ), permit and/or quarantine requirements. For further information, should you plan to import these poplar seeds or plants, 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,

July 2, 2020
Date

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