



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection  
Service

Biotechnology  
Regulatory  
Services

4700 River Road  
Riverdale, MD  
20737

PII [REDACTED]

TAXA Biotechnologies, Inc  
65 3rd Street, Suite 250  
San Francisco, CA 94107

Re: Confirmation of regulatory status of transgenic fragrant moss.

Dear PII [REDACTED]

Thank you for your letter dated February 14, 2017, inquiring whether the *Physcomitrella patens* product described in your letter is a regulated article under 7 CFR part 340. Your letter describes PEG-mediated transformation of the moss, resulting in the desired fragrance production.

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. The APHIS mission is to protect the health and value of American agriculture and natural resources.

APHIS regulates the importation, interstate movement and environmental release (field testing) of certain genetically engineered (GE) organisms that are, or have the potential to be, plant pests. Regulations for GE organisms that are or have the potential to be plant pests, under the PPA, are codified at 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 provisions of these regulations, a GE 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 GE organism is a plant pest or has reason to believe it is a plant pest.

In your February 14, 2017 letter, you describe your fragrant moss. *P. patens* will be transformed via protoplast PEG methods. The transformed construct will consist of three genetic components, a promoter, a protein coding region, and a terminator. The donor organisms of the promoters that your letter indicates would be used are *Zea mays*, *Arabidopsis thaliana*, and *Oryza sativa japonica*. The donor organisms of the protein coding regions that your letter indicates would be used are *Pogostemon cablin*, *Citrus limon*, *C. jambhiri*, *Alstroemeria peruviana*, *Coriandrum sativum*, *Ocimum basilicum*, *Matricaria recutita*, *Cucumis melo*, *Lotus corniculatus*, and *Chamaecyparis obtusa*. The donor organism of the terminators that your letter indicates would be used is *Arabidopsis thaliana*. The transgenic constructs may also contain a fluorescent marker derived from *Aequorea victoria*. In other cases, selection of transgenic events will be performed using transient plasmid markers

conferring resistance to hygromycin or geneticin, and the removal of the plasmid markers will be confirmed by demonstrating sensitivity to the appropriate compound and by PCR.

Based on the information you provided in your letter, APHIS has determined that the donor organisms and recipient organism listed as promoters, protein coding regions, and terminators are all classified organisms, and that the donor organisms and recipient organism are not from taxa designated in 7 CFR § 340.2 and do not meet the definition of a plant pest. The transformation method described in your letter does not involve a vector or vector agent that belongs to the taxa designated in 7 CFR § 340.2 and that meets the definition of a plant pest. Therefore, consistent with previous responses to similar letters of inquiry, APHIS does not consider *Physcomitrella patens* genetically engineered to produce fragrance using the donor organisms described in your February 14, 2017 letter to be regulated pursuant to 7 CFR part 340. Additionally, *P. patens* is not listed as a Federal noxious weed pursuant to 7 CFR part 360, and APHIS has no reason to believe that the fragrance phenotype in your moss would increase the weediness of *P. patens*.

Please be advised that the importation of *P. patens* spores or plants, like all other plants, will be subject to APHIS Plant Protection and Quarantine (PPQ), permit and/or quarantine requirements. For further information, should you plan to import these spores or plants, you may contact PPQ at (877) 770-5990.

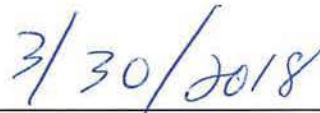
Please be advised that your fragrant *P. patens*, while not regulated by APHIS under 7 CFR part 340, may still be subject to other regulatory authorities such as FDA or EPA.

Should you become aware at any time of any issues that may affect the Agency's conclusion regarding this inquiry, you must immediately notify the Agency in writing of the nature of the issue. We hope that you appreciate our commitment to plant health and support for the responsible stewardship for the introduction of GE plants.

Sincerely,



Michael J. Firko, Ph.D.  
APHIS Deputy Administrator  
Biotechnology Regulatory Services  
Animal and Plant Health Inspection Service  
U.S. Department of Agriculture



Date