



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Biotechnology
Regulatory
Services

4700 River Road
Riverdale, MD
20737

Mr. Antony Evans
Glowing Plant, Inc.
665 3rd Street, Suite 250
San Francisco, CA 94107

Re: Request for APHIS confirmation of the regulatory status of transgenic
bioluminescent plants

Dear Mr. Evans:

Thank you for your letter dated October 5, 2015 inquiring whether your transgenic bioluminescent plants are regulated articles. Your letter describes *Nicotiana tabacum* plants that have been genetically engineered to emit a dim glow upon the addition of a proprietary formula. APHIS notes that your original inquiry claimed Confidential Business Information (CBI); however, you subsequently withdrew your CBI claims.

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.

APHIS has evaluated the description of the transgenic auto-luminescent plants described in your October 5, 2015 letter. As described, transgenic bioluminescent plants of *N. tabacum* were created using the biolistic method of transformation and genetic material from the following donors: *Arabidopsis thaliana*, *Malus x domestica*, *Photinus pyralis*, and *Aequorea Victoria*.

APHIS has determined that *N. tabacum* is not a plant pest, no organisms used as sources of the genetic material to create the transgenic plants are plant pests, and the method used to genetically engineer the plants did not involve plant pests. No plant pests, unclassified organisms, or organisms whose classification is unknown were used to genetically engineer the *N. tabacum*. In addition, APHIS has no reason to believe that *N. tabacum* is

a plant pest. Therefore, consistent with previous responses to similar letters of inquiry, APHIS does not consider the GE *N. tabacum* as described in your October 5, 2015 letter to be regulated under 7 CFR part 340.

APHIS is also authorized to protect American agriculture from damage caused by noxious weeds. APHIS has determined that *N. tabacum* is not currently listed as a Federal Noxious Weed or listed in any state as a noxious weed. APHIS also has no reason to believe that introduction of the bioluminescent trait will increase the weediness or invasiveness of *N. tabacum*.

Please be advised that the importation of GE auto-luminescent *N. tabacum*, like all other *N. tabacum*, will be subject to APHIS Plant Protection and Quarantine (PPQ), permit and/or quarantine requirements. For further information, should you plan to import these transgenic plants, you may contact Shailaja Rabindran at 301-851-2167 or contact PPQ general number for such inquiries at (877) 770-5990.

Please be advised that your GE *N. tabacum* may still be subject to other APHIS regulations or other regulatory authorities such as FDA or EPA.

Furthermore, 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 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