

United States Department of Agriculture

Animal and Plant Health Inspection Service

Biotechnology Regulatory Services

4700 River Road Riverdale, MD 20737 December 23, 2014

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

Re: Request for confirmation of the regulatory status of transgenic bioluminescent *Arabidopsis thaliana*.

Dear Mr. Evans:

Thank you for your letter dated October 1, 2014 regarding the transgenic *Arabidopsis thaliana* plant your company is in the process of developing. The letter indicated the genus and species of the plant that you are transforming (*Arabidopsis thaliana*), the method of transformation (biolistics/gene gun), and the purpose of the transformation; along with the genes and donors of the construct components being inserted. APHIS' response that follows evaluated your request for this plant species only and the transformation, genes and donors used to produce this specific plant line, therefore, this response is not considered relevant to other plant species, transformation, donors, or genetic material.

APHIS regulates the introduction of certain genetically engineered (GE) organisms which are, or have the potential to be plant pests. Regulations for GE organisms that have the potential to be plant pests, under the Plant Protection Act, 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 from a donor organism, recipient organism, or vector or vector agent listed in §340.2 and the listed organism meets the definition of "plant pest" or 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 is a plant pest.

APHIS has evaluated the description of the specific plant described in your October 1st, 2014 letter along with the specific method of transformation, the genetic material (promoters, terminators, and genes) used, and the donors of these components, all as listed in Table 1 of your October 1, 2014 request. APHIS has determined that the plant itself (as described in the letter) is not a plant pest nor is it currently listed as a Federal Noxious Weed or listed in any state as a noxious weed as of the date of this letter, no organisms used as sources of the genetic material to create the plant are plant pests, and the method used to genetically engineer the plant did not involve plant pests.

No plant pests, unclassified organisms, or organisms whose classification is unknown are being used to genetically engineer this plant. In addition, APHIS has no reason to believe



that this plant is a plant pest. Therefore APHIS does not consider the GE plant as described in your October 1, 2014 letter to be regulated under 7 CFR part 340.

Please be advised that if you intend to use genetic material, donor sources or transformation methods that are not listed in your letter of October 1, 2014, you are advised to seek our review before importing, moving interstate, or releasing into the environment. Also, be advised that the use of this plant and any transgenic lines derived via transformation may still be subject to other APHIS regulations or other regulatory authorities such as EPA.

Sincerely,

M.J. Finko

Michael Firko, PhD Deputy Administrator Biotechnology Regulatory Services