USDA

United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Biotechnology
Regulatory
Services

4700 River Road
Riverdale, MD
20737

April 02, 2012

Dr. Dennis Gray
Professor
University of Florida
Institute of Food and Agricultural Sciences
Mid-Florida Research and Education Center
Apopka, FL 32703

Re: APHIS confirmation of the regulatory status of grapevine with genes and regulatory elements from grapevine

Dear Dr. Gray:

Thank you for your letter dated February 8, 2012 regarding the regulatory status of a grapevine variety you are developing that is genetically engineered using an approach you describe as ingenic or cisgenic.

APHIS regulates the environmental release of certain genetically engineered organisms which are, or have the potential to be, plant pests. Regulations for genetically engineered 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." Pursuant to the provisions of these regulations, a genetically engineered (GE) organism is deemed a regulated article if it has been genetically engineered from a donor organism, recipient organism, vector or vector agent listed in §340.2 and the listed organism meets the definition of a "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 grapevines that you have under development. As described, the grapevines are being developed through protoplast engulfment of vector DNA or biolistics and include genetic material (promoters, terminators, and genes) from grapevine.

APHIS has determined that grapevine itself is not a plant pest, no organisms used as sources of the genetic material being used to create these particular plants are plant pests, and the methods being used to genetically engineer these grapevines do not involve plant pests. No plant pests, unclassified organisms, or organisms whose classification is unknown are being used to genetically engineer this variety of GE grapevine. In addition, APHIS has no reason to believe this genetically engineered grapevine is a plant pest. Therefore, APHIS does not consider this genetically engineered grapevine as described in your February 8, 2012 letter to be regulated under 7 CFR part 340.

APHIS

Please be advised that the use of these grapevines lines may still be subject to other applicable regulatory authorities such as EPA and FDA.
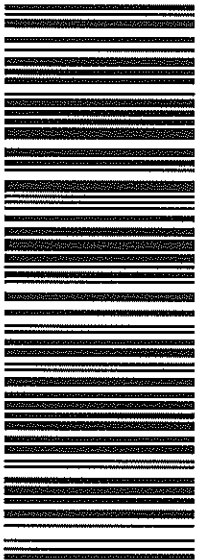
Sincerely,

Michael C. Gregoire
Deputy Administrator
Biotechnology Regulatory Services

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