



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection  
Service

Biotechnology  
Regulatory  
Services

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Riverdale, MD  
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Dr. Richard Hamilton  
President and Chief Executive Officer  
Ceres Inc.  
1535 Rancho Conejo Blvd.  
Thousand Oaks, CA 91320

Re: Request for APHIS confirmation that TRSOG101B Transgenic Sugarcane is not a regulated article

Dear Dr. Hamilton:

Thank you for your letter dated January 28, 2015 inquiring whether or not the TRSOG101B transgenic sugarcane (*Saccharum officinarum*) line described in your letter is a regulated article under APHIS regulations found at 7 CFR part 340. Your letter describes that TRSOG101B transgenic sugarcane is conferred with altered plant architecture to achieve enhanced sugar yield.

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 letter of January 28, 2015, you describe that your TRSOG101B transgenic sugarcane line was created using the biolistic method of transformation and that the inserted genetic material was derived from the following donors: *Arabidopsis thaliana*, *Sorghum bicolor*, and *E. coli* K-12.

Based on the information cited in your letter, APHIS has determined that sugarcane itself is not a plant pest, no organisms used as sources of the genetic material to create TRSOG101B transgenic sugarcane line are plant pests, and the method used to genetically engineer TRSOG101B transgenic sugarcane line did not involve plant pests. Therefore, consistent with previous responses to similar letters of inquiry, APHIS does not consider the TRSOG101B transgenic sugarcane line as described in your January 28, 2015 letter to be regulated under 7 CFR part 340.

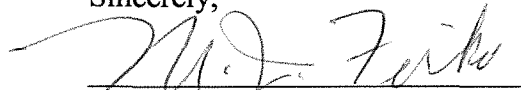
Regarding weediness, APHIS has concluded that cultivated sugarcane is not known to be a weedy species impacting agriculture. In addition, APHIS' has no reason to believe that TRSOG101B sugarcane engineered for enhanced plant architecture and sugar yield would increase the weediness of cultivated non-GE sugarcane if gene flow were to occur. However, please note that *S. spontaneum*, a close relative of sugarcane, is listed as a Federal noxious weed and is present in Florida, Hawaii and Puerto Rico. And, although APHIS has no reason to believe cultivation of this GE sugarcane would increase the weediness of *S. spontaneum*, because of the presence of *S. spontaneum* in Florida, Hawaii or Puerto Rico, if you intend to plant your GE sugarcane, we suggest that you contact the appropriate state plant health authorities prior to planting.

Please be advised that the importation of GE sugarcane seeds or plants, like all other sugarcane, will be subject to APHIS Plant Protection and Quarantine (PPQ) permit and/or quarantine requirements. For further information, should you plan to import these sugarcane seeds or 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 sugarcane line may still be subject to 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

6/3/2016  
Date