



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Biotechnology
Regulatory
Services

4700 River Road
Riverdale, MD
20737

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

Re: Request for APHIS confirmation that TRSOG103B, TRSOG102W, and TRSOG108W Transgenic Sugarcane are not regulated articles

Dear Dr. Hamilton:

Thank you for your letter dated August 20, 2015 inquiring whether or not the TRSOG103B, TRSOG102W, and TRSOG108W transgenic sugarcane (*Saccharum officinarum*) lines described in your letter are regulated articles under APHIS regulations found at 7 CFR part 340. Your letter describes that the TRSOG103B, TRSOG102W, and TRSOG108W transgenic sugarcane lines are conferred with increased plant 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 August 20, 2015, you describe that your TRSOG103B, TRSOG102W, and TRSOG108W transgenic sugarcane lines were created using the biolistic method of transformation and that the inserted genetic material was derived from the following donors: *Arabidopsis thaliana*, *Sorghum bicolor*, *Panicum virgatum*, 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 the

TRSOG103B, TRSOG102W, and TRSOG108W transgenic sugarcane lines are plant pests, and the method used to genetically engineer the TRSOG103B, TRSOG102W, and TRSOG108W transgenic sugarcane lines did not involve plant pests. Therefore, consistent with previous responses to similar letters of inquiry, APHIS does not consider the TRSOG103B, TRSOG102W, and TRSOG108W transgenic sugarcane lines as described in your August 20, 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 TRSOG103B, TRSOG102W, and TRSOG108W transgenic sugarcane lines engineered for increased plant 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 GE 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.

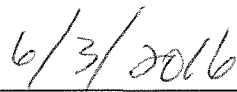
Please be advised that your GE sugarcane lines may still be subject to other regulatory authorities such as FDA or EPA.

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



Date