

United States Department of Agriculture

Animal and Plant Health Inspection Service

Biotechnology Regulatory Services

4700 River Road Riverdale, MD 20737 Mr. Richard Hamilton Ceres Inc. 1535 Rancho Conejo Blvd. Thousand Oaks, CA 91320

Re: Request for confirmation that TRSBG101S Transgenic Sorghum is not a regulated article

Dear Mr. Hamilton:

Thank you for your letter dated July 17, 2015 requesting APHIS' confirmation that TRSBG101S Transgenic Sorghum is not a regulated article under 7 CFR part 340. Your letter states that TRSBG101S sorghum has increased starch content, giving the plants a higher energy content as a feedstock for the forage sorghum industry.

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 TRSBG101S Transgenic Sorghum in your July 17, 2015 letter. As described, TRSBG101S Transgenic Sorghum (*Sorghum biocolor*, Moench ssp. *bicolor*) was created using the biolistic method of transformation and the genetic material from the following donors: *Arabidopsis thaliana, Sorghum bicolor*, and *Escherichia coli* K-12.

APHIS has determined that sorghum itself is not a plant pest, no organisms used as sources of the genetic material to create TRSBG101S Transgenic Sorghum are plant pests, and the method used to genetically engineer TRSBG101S Transgenic Sorghum did not involve plant pests. No plant pests, unclassified organisms, or organisms whose classification is unknown are being used to genetically engineer the variety of this plant.

Therefore, consistent with previous responses to similar letters of inquiry, APHIS does not consider TRSBG101S Transgenic Sorghum as described in your July 17, 2015 letter to be regulated under 7 CFR part 340.

Regarding weediness, APHIS has concluded that cultivated sorghum is not known to be a weedy species impacting agriculture. In addition, APHIS has reviewed the open literature related to increasing starch accumulation in leaves and stems of plants. Based on this literature, APHIS has no reason to believe that the increased starch content phenotype of your GE sorghum lines would increase the fitness or weediness of non-GE sorghum were gene flow to occur. Please note that two sexually compatible weedy species, shattercane (*Sorghum bicolor* nothosubsp. *Drummondii* – same species different subspecies) and Johnsongrass (*Sorghum halepense* – same genus different species) are present in the United States. APHIS has no reason to believe cultivation of this GE sorghum would increase the fitness or weediness of shattercane or Johnsongrass were gene flow to occur.

Please be advised that the importation of TRSBG101S Transgenic Sorghum, like all other sorghum, will be subject to APHIS Plant Protection and Quarantine (PPQ), permit and/or quarantine requirements. For further information, should you plan to import TRSBG101S Transgenic Sorghum, 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 TRSBG101S Transgenic Sorghum may still be subject to other regulatory authorities such as FDA or EPA.

Should you become aware at any time of any issues or additional information 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

18 July 2016

Date