

United States Department of Agriculture

Animal and Plant Health Inspection Service

Biotechnology Regulatory Services

4700 River Road Riverdale, MD 20737 August 6, 2014

Mr. Richard Hamilton

Ceres Inc.

1535 Rancho Conejo Blvd. Thousand Oaks, CA 91320

Re: Request for confirmation that TRSBG101B Sorghum is not a regulated article

Dear Mr. Hamilton:

Thank you for your letter dated February 22, 2013 requesting APHIS' confirmation that TRSBG101B sorghum is not a regulated article under 7 CFR part 340. Your letter states that TRSBG101B sorghum has enhanced stem biomass yield, increased juice volume and total sugars.

APHIS regulates the environmental release of certain genetically engineered organisms which are, or have the potential to be a plant pest. 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 Pest or Which There Is Reason To Believe Are Plant Pests." Under 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, 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 TRSBG101B sorghum in your February 22, 2013 letter. As described, the TRSBG101B sorghum, *Sorghum bicolor*, Moench ssp. Bicolor (sweet sorghum) was created using the biolistic method of transformation and the genetic material from the following donors: *Arabidopsis thaliana*, *Sorghum bicolor*, and *E. 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 TRSBG101B sorghum are plant pests, and the method used to genetically engineer TRSBG101B 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. In addition, APHIS has no reason to believe that the plant is a plant pest. Therefore APHIS does not consider this genetically engineered plant as described in your February 22, 2013 letter to be regulated under 7 CFR part 340.

APHIS is also authorized to protect American agriculture from damage caused by noxious weeds. Within APHIS, the Plant Pest and Quarantine (PPQ) program implements this authority through use of various regulations including 7 CFR part 360 "Noxious Weed Regulations". APHIS has been considering regulating TRSBG101B and other modified sorghum under 7 CFR part 360, but will discuss that topic in a separate communication.

Michael J. Firko, Ph.D.

Deputy Administrator

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