

United States Department of Agriculture

Animal and Plant Health Inspection Service

Biotechnology Regulatory Services

4700 River Road Riverdale, MD 20737 April 24, 2012

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

Re: APHIS confirmation of the regulatory status of TRG101B Transgenic Switchgrass

Dear Mr. Hamilton:

Thank you for your letter dated January 20, 2012 regarding the transgenic switchgrass (TRG101B) your company has recently developed. The letter stated this switchgrass produces greater biomass and contains more fermentable sugars than conventional switchgrass varieties, thereby offering a higher yield potential.

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." 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 TRG101B Switchgrass in your January 20, 2012 letter. As described, the TRG101B Switchgrass was created using the biolistic method of transformation and include genetic material (promoters, terminators, and genes) from *Sorghum bicolor*, *Arabidopsis thaliana* and *E. coli* K-12.

APHIS has determined that switchgrass itself is not a plant pest, no organisms used as sources of the genetic material to create TRG101B Switchgrass are plant pests, and the method used to genetically engineer TRG101B Switchgrass did 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 switchgrass. In addition, APHIS has no reason to believe TRG101B Switchgrass is a plant pest. Therefore APHIS does not consider this genetically engineered TRG101B Switchgrass as described in your January 20, 2012 letter to be regulated under 7 CFR part 340.



Please be advised that the use of TRG101B Switchgrass lines may still be subject to other applicable regulatory authorities such as EPA and FDA.

Sincerely,

Michael C. Siegere

Michael C. Gregoire Deputy Administrator Biotechnology Regulatory Services

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