United States Department of Agriculture

Animal and Plant Health Inspection Service

Biotechnology Regulatory Services

4700 River Road
Riverdale, MD
20737

January 2, 2013

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 TRG101W switchgrass

Dear Mr. Hamilton:

Thank you for your letter dated July 23, 2012 regarding the genetically engineered (GE) switchgrass that your company has recently developed. The letter stated that TRG101W switchgrass has enhanced water use efficiency relative to conventional switchgrass varieties.

APHIS regulates the environmental release of certain GE organisms which are, or have the potential to be plant pests. Regulations for GE 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 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 TRG101W switchgrass in your July 23, 2012 letter. As described, the TRG101W switchgrass was created using the biolistic method of transformation and includes genetic material (promoters, terminators, and genes) from *Oryza sativa, Hordeum vulgare, 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 TRG101W switchgrass are plant pests, and the method used to genetically engineer TRG101W switchgrass did not involve plant pests.

No plant pests, unclassified organisms, or organisms whose classification is unknown were used to genetically engineer TRG101W switchgrass. In addition, APHIS has no reason to believe TRG101W switchgrass is a plant pest. Therefore APHIS does not consider TRG101W switchgrass as described in your July 23, 2012 letter to be regulated under 7 CFR part 340.

Re: APHIS confirmation of the regulatory status of TRG101W switchgrass

Please be advised that the use of TRG101W switchgrass lines may still be subject to other applicable regulatory authorities such as EPA and FDA.

Sincerely,

Michael C. Gregoire

Michael C. Gregoire
Deputy Administrator
Biotechnology Regulatory Services

United States Department of Agriculture

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

Re: APHIS confirmation of the regulatory status of TRG108E switchgrass

Dear Mr. Hamilton:

Thank you for your letter dated July 23, 2012 regarding the genetically engineered (GE) switchgrass that your company has recently developed. The letter stated that TRG108E switchgrass produces biomass that is more easily converted to simple fermentable sugars than conventional switchgrass varieties.

APHIS regulates the environmental release of certain GE organisms which are, or have the potential to be plant pests. Regulations for GE 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 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 TRG108E switchgrass in your July 23, 2012 letter. As described, the TRG108E switchgrass was created using the biolistic method of transformation and includes genetic material (promoters, terminators, and genes) from *Sorghum bicolor, Panicum virgatum, 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 TRG108E switchgrass are plant pests, and the method used to genetically engineer TRG108E switchgrass did not involve plant pests.

No plant pests, unclassified organisms, or organisms whose classification is unknown were used to genetically engineer TRG108E switchgrass. In addition, APHIS has no reason to believe TRG108E switchgrass is a plant pest. Therefore APHIS does not consider TRG108E switchgrass as described in your July 23, 2012 letter to be regulated under 7 CFR part 340.

Re: APHIS confirmation of the regulatory status of TRG108E switchgrass

Please be advised that the use of TRG108E switchgrass lines may still be subject to other applicable regulatory authorities such as EPA and FDA.

Sincerely,

Michael C. Gregoire

Michael C. Gregoire
Deputy Administrator
Biotechnology Regulatory Services

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

Re: APHIS confirmation of the regulatory status of TRG106E switchgrass

Dear Mr. Hamilton:

Thank you for your letter dated July 23, 2012 regarding the genetically engineered (GE) switchgrass that your company has recently developed. The letter stated that TRG106E switchgrass produces biomass that is more easily converted to simple fermentable sugars than conventional switchgrass varieties.

APHIS regulates the environmental release of certain GE organisms which are, or have the potential to be plant pests. Regulations for GE 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 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 TRG106E switchgrass in your July 23, 2012 letter. As described, the TRG106E switchgrass was created using the biolistic method of transformation and includes genetic material (promoters, terminators, and genes) from *Oryza sativa, Panicum virgatum, 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 TRG106E switchgrass are plant pests, and the method used to genetically engineer TRG106E switchgrass did not involve plant pests.

No plant pests, unclassified organisms, or organisms whose classification is unknown were used to genetically engineer TRG106E switchgrass. In addition, APHIS has no reason to believe TRG106E switchgrass is a plant pest. Therefore APHIS does not consider TRG106E switchgrass as described in your July 23, 2012 letter to be regulated under 7 CFR part 340.

Re: APHIS confirmation of the regulatory status of TRG106E switchgrass

Please be advised that the use of TRG106E switchgrass lines may still be subject to other applicable regulatory authorities such as EPA and FDA.

Sincerely,

Michael C. Gregoire

Michael C. Gregoire
Deputy Administrator
Biotechnology Regulatory Services

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Mr. Richard Hamilton
President and Chief Executive Officer
Ceres, Inc.
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Re: APHIS confirmation of the regulatory status of TRG107E switchgrass

Dear Mr. Hamilton:

Thank you for your letter dated July 23, 2012 regarding the genetically engineered (GE) switchgrass that your company has recently developed. The letter stated that TRG107E switchgrass produces biomass that is more easily converted to simple fermentable sugars than conventional switchgrass varieties.

APHIS regulates the environmental release of certain GE organisms which are, or have the potential to be plant pests. Regulations for GE 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 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 TRG107E switchgrass in your July 23, 2012 letter. As described, the TRG107E switchgrass was created using the biolistic method of transformation and includes genetic material (promoters, terminators, and genes) from *Oryza sativa, Panicum virgatum, 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 TRG107E switchgrass are plant pests, and the method used to genetically engineer TRG107E switchgrass did not involve plant pests.

No plant pests, unclassified organisms, or organisms whose classification is unknown were used to genetically engineer TRG107E switchgrass. In addition, APHIS has no reason to believe TRG107E switchgrass is a plant pest. Therefore APHIS does not consider TRG107E switchgrass as described in your July 23, 2012 letter to be regulated under 7 CFR part 340.

Re: APHIS confirmation of the regulatory status of TRG107E switchgrass

Please be advised that the use of TRG107E switchgrass lines may still be subject to other applicable regulatory authorities such as EPA and FDA.

Sincerely,

Michael C. Gregoire

Michael C. Gregoire
Deputy Administrator
Biotechnology Regulatory Services