



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection  
Service

Biotechnology  
Regulatory  
Services

4700 River Road  
Riverdale, MD  
20737

Dr. Richard Hamilton  
Ceres Inc.  
1535 Rancho Conejo Blvd.  
Thousand Oaks, CA 91320

Re: Confirmation that Biolistically-Derived GE Maize is not a regulated article

Dear Dr. Hamilton:

Thank you for your letter dated August 30, 2013 inquiring whether or not the genetically engineered (GE) maize described in your letter is a regulated article. Your letter described that your biolistically-derived GE maize, *Zea mays*, will contain genes inserted to confer improved digestibility, insecticidal properties, improved palatability, drought tolerance, increased seed yield and/or dwarfing.

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, pursuant to 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 August 30, 2013 letter, you describe a series of specific GE Maize varieties to be created using the biolistic method of transformation with genetic material from the following donors: *Arabidopsis thaliana*, *Sorghum bicolor*, *Oryza sativa*, *Zea mays*, *Bacillus thuringiensis*, *Panicum virgatum*, *Populus trichocarpa*, *Escherichia coli*, and multiple synthetic cloning sites.

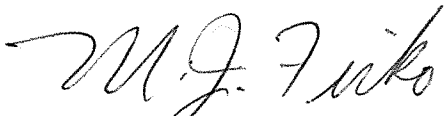
Based on the information cited in your letter, APHIS has determined that *Zea mays* itself is not a plant pest, no organisms that will be used as sources of genetic material to create the specific biologically-derived GE maize varieties are plant pests, and the method to be used to genetically engineer the specific GE maize varieties does not involve plant pests. No plant pests, unclassified organisms, or organisms whose classification is unknown are being used to genetically engineer the GE maize varieties described in your letter. Therefore, consistent with previous responses to similar letters of inquiry, APHIS does not consider the specific GE maize varieties described in your August 30, 2013 letter to be regulated under 7 CFR part 340. This determination only applies to the specific GE Maize varieties described in your letters. Additionally, maize is not listed as a Federal noxious weed under 7 CFR part 360, and APHIS has no reason to believe that the intended phenotypes of your GE maize varieties would increase the weediness of maize.

Please be advised that the importation of maize seeds, grain or plants, like all other maize, will be subject to APHIS Plant Protection and Quarantine (PPQ), permit and/or quarantine requirements. For further information, should you plan to import these maize seeds, grain 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 maize varieties may still be subject to other regulatory authorities such as FDA or EPA. Specifically, any GE maize variety expressing insecticidal properties would come under the regulatory jurisdiction of the U.S. 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