

United States Department of Agriculture

Animal and Plant Health Inspection Service

Biotechnology Regulatory Services

4700 River Road Riverdale, MD 20737 May 18, 2015

Mr. Matthew Crisp President and Chief Executive Officer Benson Hill Biosystems Post Office Box 13487 Research Triangle Park, NC 27709

Re: APHIS confirmation that BHB Hi-yield Maize is not a regulated article

Dear Mr. Crisp:

Thank you for your letter dated January 13, 2015 inquiring whether or not the genetically engineered maize (*Zea mays*) product described in your letter is a regulated article. The letter states that the BHB Hi-yield Maize product is designed to have higher photosynthetic efficiency and/or capacity, thereby offering a higher yield potential.

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 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 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 January 13, 2015 letter, you describe a maize plant (BHB Hi-yield Maize) developed using biolistic transformation to insert genetic materials derived from specific plants, bacteria and algae, that are themselves not plants pests.

Based on the information cited in your letter, APHIS has determined that the BHB Hi-Yield maize plant described in your letter is not a plant pest, no organisms that are used as sources of the genetic material to create the plant are plant pests, and the transformation of the plant using biolistics does not involve plant pests. No plant pests, unclassified organisms, or organisms whose classification is unknown are being used to



genetically engineer this plant. In addition, APHIS has no reason to believe that this plant, as described in your letter, would be a plant pest. Therefore, consistent with previous responses to similar letters of inquiry, APHIS would not consider the BHB Hi-Yield maize product as described in your January 13, 2015 letter to be regulated under 7 CFR part 340. Additionally, maize is not listed as a Federal noxious weed under 7 CFR part 360, and APHIS has no reason to believe that the genetic engineering of your GE maize would increase the weediness of maize.

Please be advised that the importation of maize seeds or plants, like all other maize, will be subject to APHIS Plant Protection and Quarantine (PPQ) phytosanitary certificate, permit and/or quarantine requirements. For further information, should you plan to import these corn seeds 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 the GE maize may still be subject to other regulatory authorities such as FDA or 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 Firko, Ph.D. Deputy Administrator Biotechnology Regulatory Services