USDA
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Animal and
Plant Health
Inspection
Service

Biotechnology
Regulatory
Services

4700 River Road
Unit 147
Riverdale, MD
20737

Dr. Wayne Parrott
111 Riverbend Road
Athens, GA 30602-1680

Re: APHIS confirmation of the regulatory status of soybean engineered for altered flavonoid profiles

Dear Dr. Parrott:

Thank you for your inquiry dated June 1, 2013, regarding the regulatory status of the soybean, *Glycine max* cv. Jack. The letter stated: "this soybean does not contain any DNA of a pest/pathogen origin, nor is their behavior altered in any way that would convert them into a plant pest or increase their weediness."

APHIS regulations for genetically engineered (GE) organisms 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 at §340.1, 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 it is a plant pest.

APHIS has evaluated the description of the GE soybean in your June 1, 2013, letter. No plant pests, unclassified organisms, or organisms whose classification is unknown are being used in the genetic engineering of this variety of GE soybean. APHIS has no reason to believe this variety of GE soybean is a plant pest. Therefore, APHIS does not consider this GE soybean described in your letter to be regulated under 7 CFR part 340. Soybean is not listed as a Federal noxious weed according to 7 CFR part 360, and APHIS has no reason to believe that the genetic engineering of this soybean would increase the weediness of soybean. Please be advised that the importation of the GE soybean may be subject to APHIS Plant Protection and Quarantine (PPQ) permit and/ or quarantine requirements. To find out if this GE soybean is subject to APHIS PPQ permit and/ or quarantine requirements, contact PPQ at (877) 770-5990.

Please be advised that genetically engineered plants may still be subject to other applicable regulatory authorities such as EPA and FDA. APHIS is committed to protecting plant health and encourages responsible stewardship of the introduction of GE plants.

Sincerely,

Michael Firko
Acting Deputy Administrator
Biotechnology Regulatory Services

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