

United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection  
Service

Biotechnology  
Regulatory  
Services

4700 River Road  
Riverdale, MD  
20737

May 5, 2015  
Dr. Luc Mathis  
Cellestis Plant Sciences  
600 County Road D West, Suite 8  
New Brighton, MN 55112

Re: Confirmation that FAD2KO soybean is not a regulated article

Dear Dr. Mathis:

Thank you for your letter dated November 17, 2014 inquiring whether or not the soybean product described in your letter is a regulated article. This letter describes that the FAD2KO Soybean product has improved consumer safety and processing attributes attributable to a two gene knock-out achieved through transient expression of a Transcription Activator-Like Effector Nuclease (TALEN).

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 is a plant pest.

In your November 17, 2014 letter, you describe a soybean plant (FAD2KO) developed by using a TALEN to modify soybean cotyledons. The TALEN and the other genetic sequences important to the development of the soybean were derived from plant pests. According to your letter, the individual plant cells were genetically engineered to generate nucleotide deletions in two genes and thereby disrupt the function of specific proteins. However, all of the genetic material used to create the deletion was removed



*Safeguarding American Agriculture*  
APHIS is an agency of USDA's Marketing and Regulatory Program

An Equal Opportunity Provider and Employer

from the final soybean plant. Additionally, no genetic material was inserted into the final soybean plant genome.

Based on the information cited in your letter, APHIS has determined this FAD2KO soybean variety was developed using [REDACTED] and genetic material from plant pests. However, the final soybean plant does not contain any introduced genetic material and APHIS has no reason to believe that the plants of this soybean variety are plant pests. Therefore, consistent with previous responses to similar letters of inquiry, APHIS does not consider the FAD2KO soybean product as described in your November 17, 2014 letter to be regulated under 7 CFR part 340. Additionally, soybean 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 soybean would increase the weediness of soybean.

Please be advised that the importation of soybean seeds or plants, like all other soybean, 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 soybean 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 soybean may still be subject to other regulatory authorities such as FDA or EPA.

GE soybean plants from this transformation that retain inserted genetic material may be considered regulated under 7 CFR part 340 and may require a notification or permit for importation, interstate movement, or environmental release. 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,

A handwritten signature in black ink, appearing to read "M. J. Firko". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Michael Firko, Ph.D.  
APHIS Deputy Administrator  
Biotechnology Regulatory Services