



United States
Department of
Agriculture

Animal and Plant
Health Inspection
Service

Biotechnology
Regulatory
Services

4700 River Road
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Re: Inquiry regarding APHIS position on null-segregant TALEN-mutagenized rice lines as non-regulated articles

Dear Dr. Bing:

Thank you for your letter dated February 17, 2014 inquiring whether or not the rice lines described in your letter are regulated articles under 7 CFR part 340. Your letter describes that the genetically engineered (GE) rice varieties have increased disease resistance attributable to deletions in the promoters of two rice genes 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 that 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 February 17, 2014 letter, you describe five rice lines developed by using a TALEN to modify rice calli. The TALEN and certain other genetic sequences important to the development of the GE rice were derived from plant pests. In addition, according to the reference cited in your letter (Ting et al, 2012), the TALEN and the other genetic sequences were transferred into rice using *Agrobacterium*-mediated transformation. According to your letter, the individual plant cells were genetically engineered to generate nucleotide deletions in the promoters of two genes and thereby disrupt the function of specific proteins. However, all of the genetic material used to create the deletions was removed by segregation from the final rice plants. Additionally, no genetic material remains or was inserted into the final rice plant genomes.


Based on the information cited in your letter, APHIS has determined that the five rice lines were developed using plant pests and genetic material from plant pests. However, the final rice plants do not contain any inserted genetic material and APHIS has no reason to believe that the plants of these rice lines are plant pests. Therefore, consistent with previous responses to similar letters of inquiry, APHIS does not consider the five rice lines as described in your February 17, 2014 letter to be regulated under 7 CFR part 340. Additionally, cultivated rice 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 rice would increase the weediness of rice.

Please be advised that the importation of rice plants (*Oryza sativa*) is prohibited from all sources. The importation of rice seeds is also prohibited from all sources, and is restricted from Mexico. A PPQ 588 permit is required for importation of rice plants and rice seeds from all countries including Mexico, as specified in the regulations at 7 CFR part 319.55 and & CFR 319.37. For further information, should you plan to import these rice seeds or plants, you may contact Shailaja Rabindran at 301-851-2167 or contact the PPQ general number for such inquiries at (877) 770-5990.

Please be advised that the GE rice may still be subject to other regulatory authorities such as FDA or EPA.

GE rice plants from this transformation that retain inserted genetic material would be considered regulated under 7 CFR part 340 and would 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 "Michael Firko", followed by the date "5/22/2015".

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