



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection  
Service

Biotechnology  
Regulatory  
Services

4700 River Road  
Riverdale, MD  
20737

Harry J. Klee  
University of Florida, Horticulture Sciences  
P.O. Box 1169  
Gainesville, FL 32611

Re: Request for Regulatory Status of a Genome Edited Tomato Variety

Dear Harry J. Klee,

Thank you for your letter dated February 21, 2018, inquiring whether the tomato (*Solanum lycopersicum*) product described in your letter is a regulated article under 7 CFR part 340. Your letter describes the use of the CRISPR/Cas9 system to create deletions in the *J2* gene. The deletion results in a change whereby the tomato fruit comes cleanly off the vine without the stem attached to the fruit when picked.

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.

USDA 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, under 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 February 21, 2018 letter, you describe your GE tomatoes as having a deletion in the *J2* gene created using a CRISPR/Cas9 system. You state that the plasmid system containing the Cas9 gene and guide RNAs was delivered to your tomato variety via *Agrobacterium tumefaciens*. Plant pest sequences from *A. tumefaciens*, Cauliflower Mosaic Virus (CaMV35S) and Tobacco Mosaic Virus (TMV) were used in the plasmid as regulatory elements. You stated that two independent *J2* deletion tomato lines were selected, events 17854 and 18001, and back-crossed (selfed) to the non-GE parent. The two plant events with the *J2* deletion were then subjected to PCR analysis after backcrossing using four sets of PCR primers to determine that the T-DNA insert was not present.

Based on the information you provided in your letter, USDA has determined that the *J2* tomato lines were developed using a plant pest and genetic material from plant pests. However, the final tomato plants do not contain any introduced genetic material and

USDA has no reason to believe that these tomatoes are plant pests. Therefore, consistent with previous responses to similar letters of inquiry, USDA does not consider the J2 deletion tomato lines as described in your February 21, 2018 letter to be regulated pursuant to 7 CFR part 340. Additionally, tomato is not listed as a Federal noxious weed pursuant to 7 CFR part 360, and USDA has no reason to believe that the J2 deletion phenotype in the progeny of your tomato events 17854 and 18001 would increase the weediness of tomato.

Please be advised that the importation of tomato seeds or plants, like all other tomatoes, will be subject to Plant Protection and Quarantine (PPQ), permit and/or quarantine requirements. For further information, should you plan to import these tomato seeds or plants, you may contact the PPQ general number for such inquiries at (877) 770-5990.

Please be advised that your genome-edited tomato lines, while not regulated by USDA under 7 CFR part 340 may still be subject to other regulatory authorities such as FDA or EPA.

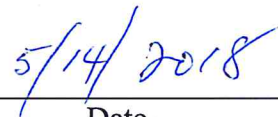
Should you become aware at any time of any information or issues that may affect the Agency's conclusion regarding this inquiry, you must immediately notify the Agency in writing of the nature of the information or issue. We hope that you appreciate our commitment to plant health and support for the responsible stewardship for the introduction of GE plants.

Sincerely,



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Michael J. Firko, Ph.D.  
APHIS Deputy Administrator  
Biotechnology Regulatory Services  
Animal and Plant Health Inspection Service  
U.S. Department of Agriculture



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Date