USDA

United States Department of Agriculture

Animal and Plant Health Inspection Service

Biotechnology Regulatory Services

4700 River Road
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Dr. Ewen Mullins
Senior Research Officer
Teagasc, The Agriculture and Food Development Authority
Department of Crop Science,
Oak Park, Carlow
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Re: Confirmation of the regulatory status for Ensifer Mediated Transformation (EMT)

Dear Dr. Mullins:

Thank you for your letter dated October 7, 2015, in which you requested that Biotechnology Regulatory Services confirm your understanding that plants modified via Ensifer Mediated Transformation (EMT) for the purposes of transgenesis/cisgenesis/genome editing (e.g. ZFN, TALEN, CRISPR/Cas) would not meet the definition of a regulated article under our current biotechnology regulation found at 7 CFR part 340. As we understand your request, there are two aspects: (1) does APHIS consider the bacterium *Ensifer adhaerens* strain OV14 to be a plant pest?; and (2) if *E. adhaerens* strain OV14 is used as the vector agent in the genetic engineering of plants, would all resulting plants not meet the definition of "regulated article"?

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 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 letter of October 7, 2015, you provided a summary of information to facilitate an understanding of the organism involved, *E. adhaerens* strain OV14 in the family Rhizobiaceae. We are able to confirm that this family is listed as one of the taxa in §340.2, where the Agency lists plant pests subject to our regulations. However, APHIS does not consider all genera within this family to be plant pests. The most notable genera of the Rhizobiaceae which are not plant pests include the many species of the genera *Rhizobium*, *Sinorhizobium*, etc., which are beneficial symbionts of plants. Based upon the available information, we have no reason to believe that *E. adhaerans* strain OV14 is a plant pest as defined in our regulations, and we can confirm your conclusion that *E. adhaerens* strain OV14 is not a plant pest subject to APHIS' regulations at 7 CFR part 340.

In response to the second part of your letter, as we understand it, we cannot conclude that all plants which are transformed via EMT would necessarily fall outside the scope of the definition of regulated article in our regulation at 7 CFR part 340 or not be subject to our review under APHIS' noxious weed authority at 7 CFR part 360. If EMT were used to introduce donor sequences derived from plant pests, the resulting GE plant would likely meet the definition of a regulated article under 7 CFR part 340. In addition, depending on the plant species and the resulting phenotype, plants engineered using EMT may need to be evaluated for potential weediness. Therefore, plants engineered using EMT would need to be evaluated on a case-by-case basis. If you have such a specific GE plant, we would welcome an inquiry with the necessary details to complete a full analysis.

Please be advised that the importation of plants transformed using EMT, like all other plants, will be subject to APHIS Plant Protection and Quarantine (PPQ) permit and/or quarantine requirements. For further information, should you plan to import GE plants produced using EMT, you may contact Shailaja Rabindran at 301-851-2167 or contact PPQ general number for such inquiries at +1 (877) 770-5990.

Please be advised that GE plants transformed using EMT may still be subject to other Federal regulatory authorities such as the Food and Drug Administration (FDA) or the Environmental Protection Agency (EPA).

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,

for Sidney W. Abel

5/31/2016

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

Date