USDA

United States Department of Agriculture

Animal and Plant Health Inspection Service

Biotechnology Regulatory Services

4700 River Road
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Drs. John Sedbrook and Michaela McGinn
Illinois State University
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Campus Box 4120
Normal, IL 61790-4120

Re: Confirmation of the regulatory status of *Thlaspi arvense* L. (pennycress) mutant plant lines.

Dear Dr. Sedbrook and Dr. McGinn,

Thank you for your letter dated March 9th, 2018, inquiring whether the *T. arvense* product described in your letter is a regulated article under 7 CFR part 340. Your letter describes null-segregant *T. arvense* mutant lines developed through CRISPR/Cas9-mediated genome editing to confer a seed oil phenotype claimed as Confidential Business Information (CBI).

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 March 9th, 2018 letter, you describe the production process of your null-segregant *T. arvense* mutant lines, the intended phenotype, and supporting evidence of these claims. These null-segregant *T. arvense* mutant lines were developed through a combination of CRISPR/Cas9 technology (causing the mutation) and traditional breeding techniques (segregating out the introduced genetic material). The absence of a DNA donor template during the CRISPR/Cas9-mediated genome editing process allowed the plant's own processes to direct the DNA repair which, according to your letter, resulted in mutations at the targeted loci made by the plant's own naturally-occurring DNA repair mechanism. As a result of this production process, these null-segregant *T. arvense* mutant lines possess an altered seed oil phenotype. A follow up letter was sent by

USDA on April 9th, 2018 regarding clarification on the null-segregant claims made in the original March 9th, 2018 letter. A response to the USDA follow up letter dated March 9th, 2018 was received on May 20th. 2018.

Based on the information you provided in your letter, USDA has determined that your null-segregant *T. arvense* mutant lines are not themselves a plant pest. Additionally, USDA has determined that these null-segregant *T. arvense* mutant lines are unlikely to contain any introduced genetic material. Therefore, consistent with previous responses to similar letters of inquiry, USDA does not consider your null-segregant *T. arvense* mutant lines as described in your March 9th, 2018 letter to be regulated pursuant to 7 CFR part 340.

USDA is also authorized to protect American agriculture from damage caused by noxious weeds. If USDA determines that a plant poses a noxious weed risk, USDA would consider regulating the plant under the noxious weed regulation, 7 CFR part 360. USDA has the option to regulate plants under 7 CFR part 360 regardless of whether or not they meet the definition of a regulated article under 7 CFR part 340. USDA has determined that *T. arvense* is not listed as a Federal noxious weed pursuant to 7 CFR part 360 or listed in any State as a noxious weed. However, USDA has concluded after reviewing the relevant literature and a review of a weed risk assessment that was completed by USDA's Center for Plant Health Sciences and Technology (CPHST) in December 2015 (https://www.aphis.usda.gov/plant_health/plant_pest_info/weeds/downloads/wra/Thlaspi-arvense.pdf) that *T. arvense* is an agricultural weed. The introduced trait may plausibly alter some aspects of stress tolerance in *T. arvense*. However, a similar GE seed oil trait in a related taxon has not led to significant changes in traits associated with weediness, including germination, dormancy, persistence, and stress tolerance. Therefore, it appears that the modified seed oil phenotype is unlikely to change the weediness of *T. arvense,* if the trait has a similar phenotypic effect as observed with the similar trait in a related taxon.

USDA is committed to helping ensure that GE and non-GE agricultural sectors can continue to thrive and be successful. Although the GE *T. arvense* is in the early stages of development, the USDA recognizes that if this GE plant were to be commercially released as a GE variety, farmers in the vicinity may have concerns related to *T. arvense* occurring in their fields and having to control it as a weed. Similar to the Department's experience with other GE crop varieties, USDA encourages Illinois State University to discuss these concerns with various stakeholders during these early stages of research and development of this GE *T. arvense* and to consider developing stewardship measures to minimize *T. arvense* from becoming a problematic weed in the environment.

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

Please be advised that your null-segregant *T. arvense* mutant lines, while not regulated by APHIS 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 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 that you appreciate our commitment to plant health and support for the responsible stewardship for the introduction of GE plants.

Sincerely,

M. J. Firko

8/6/2018

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

Date