Dear Dr. Carlos Perez:

Thank you for your letter dated July 29, 2022 (22-151-01cr) requesting confirmation that your plant is exempt from regulation pursuant to 7 CFR § 340.1(b)(2). Your letter describes alfalfa (Medicago sativa L.) to be modified for resistance to acetolactate synthase (ALS) inhibitor herbicides.

The Plant Protection Act of 2000 (PPA) provides USDA with broad authority to protect U.S. agriculture, the environment, and the economy by, among other things, regulating the movement of plants and articles to prevent the introduction or dissemination of a plant pest within the United States. As such, USDA, through the Animal and Plant Health Inspection Service, regulates the “Movement of Organisms Modified or Produced through Genetic Engineering,” as described in 7 CFR part 340. These regulations do not apply to plants that contain a modification of a type listed in § 340.1(b) or § 340.1(c).

In your letter you state that the intended modification in your alfalfa is a one base pair substitution in one allele of als1 resulting from a Cas9-fused cytidine deaminase enzyme targeted to the DNA. Your letter describes how you plan to insert exogenous DNA into the plant’s genome to generate the genetic modification, and how you plan to eliminate it in the final modified plant. You also describe the methods you plan to use to verify that you made the intended modification and no unintended exogenous DNA remains in the plant.

Based on our review of the representations in your letter, USDA confirms the alfalfa modified for resistance to ALS herbicides would meet the exemption described in § 340.1(b)(2) and would be exempt from regulation under 7 CFR part 340. Plants with modifications that are exempt pursuant to § 340.1(b)(2) are achievable by conventional breeding and unlikely to pose an increased plant pest risk relative to their conventionally bred counterparts.

Although your modified alfalfa is not regulated under 7 CFR part 340, it may be subject to other USDA regulations or other regulatory authorities. For example, importation of your plant or its seeds may be subject to Plant Protection and Quarantine (PPQ) permit and/or quarantine requirements. For further information, you may contact the PPQ general number for such inquiries at (877) 770-5990. To inquire about the regulatory status of your plant with the Environmental Protection Agency, please contact Alan Reynolds at reynolds.alan@epa.gov or (703) 605-0515. To inquire about the regulatory status of your plant with the Food and Drug Administration (FDA), please contact FDA at PlantBiotech@fda.hhs.gov.
USDA recommends implementation of best management practices (BMPs) to limit and delay the evolution of herbicide resistant weed populations in fields planted with herbicide resistant alfalfa. We have enclosed materials on this topic, including stewardship practices you and users of your product can take to delay or mitigate the emergence of herbicide resistant weeds. Please review these materials and provide guidance to users of your product.

Should you become aware at any time of any issues that may affect our confirmation of this exemption, please notify me immediately in writing of the nature of the issue.

Sincerely,

Bernadette Juarez.
APHIS Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture

August 18, 2022
Date
Enclosure

DOI: https://doi.org/10.1614/WS-D-11-00155.1

PRN 2017-2 communicates EPA’s approach to address herbicide-resistant weeds by providing guidance to herbicide users and registrants on useful strategies (including labeling, education, training, and stewardship) that, when implemented, will slow the development and spread of herbicide-resistant weeds and prolong the useful life of herbicides. Although the document is titled “Pesticide Registration Notice”, we specifically refer you to the guidance on herbicide-resistance best management practices included in Sections 1, 3A, 3B, and 4, including the guidance on mitigating pollen flow to sexually compatible relatives and mitigating the selection of herbicide resistance in weeds.