United States Department of Agriculture

Marketing and Regulatory Programs

Animal Plant Health Inspection Service

Biotechnology Regulatory Services

4700 River Road
Riverdale
MD 20737

Randall Shultz, Ph.D., Vice President of Research
InnerPlant, Inc.
202 Cousteau Place, Suite 150
Davis, CA 95618

RSR number 22-276-01rsr

RE: Regulatory Status Review of soybean developed using genetic engineering for expression of a fluorescent protein and an antibiotic marker gene

Dear Dr. Shultz:

Thank you for your letter dated December 6, 2022, requesting a Regulatory Status Review (RSR) for soybean developed using genetic engineering (modified soybean). In your letter, you described that the soybean was modified to express a fluorescent protein and to contain a marker gene imparting antibiotic resistance.

The Plant Protection Act of 2000 (7 U.S.C. §§ 7701 et seq.) provides USDA authority to oversee the detection, control, eradication, suppression, prevention, or retardation of the spread of plant pests to protect agriculture, environment, and the economy of the United States. USDA, through the Animal and Plant Health Inspection Service (APHIS), regulates the "Movement of Organisms Modified or Produced through Genetic Engineering" as described in 7 CFR part 340.

Consistent with 7 CFR 340.4, APHIS reviewed your modified soybean to determine whether it is subject to the regulations in 7 CFR part 340. Specifically, APHIS reviewed the modified soybean to determine whether there is a plausible pathway by which the soybean would pose an increased plant pest risk relative to the plant pest risk posed by an appropriate soybean comparator. Based on information you provided, publicly available resources, and APHIS' familiarity with soybean and knowledge of the trait, phenotype, and mechanism of action, APHIS considered the (1) biology of nonmodified soybean and its sexually compatible relatives; (2) the trait and mechanism-of-action of the modification; and (3) the effect of the trait and mechanism-of-action on the (a) distribution, density, or development of the plant and its sexually compatible relatives, (b) production, creation, or enhancement of a plant pest or a reservoir for a plant pest, (c) harm to non-target organisms beneficial to agriculture, and (d) weedy impacts of the plant. APHIS did not identify any plausible pathway by which your modified soybean would pose an increased plant pest risk relative to comparator soybean plants. APHIS has determined your soybean is unlikely to pose an increased plant pest risk relative to its comparators. Once APHIS determines that a plant product is unlikely to pose an increased plant pest risk relative to its comparator, and, thus, is not a plant pest or a plant that requires regulation because it is capable of introducing or disseminating a plant pest, APHIS has no authority to regulate it under 7 CFR part 340. Accordingly, your soybean is not subject to the regulations under 7 CFR part 340. APHIS' determination that this modified plant is not subject to the regulations extends to any progeny of the modified plant that is derived from crosses with other non-modified plants or other modified plants that are also not subject to the regulations in 7 CFR part 340.

Please be advised that APHIS' decision applies to the soybean developed using genetic engineering exactly as described in your letter. If at any time you become aware of any information that may affect our review of your modified soybean, including, for example, new information that shows the trait, phenotype, or mechanism of action is different than described in your letter, you must contact APHIS for further review of the plant at RSRrequests@usda.gov.

Please be advised that your plant product, while not regulated under 7 CFR part 340, may be subject to APHIS 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. Your plant product may also be subject to other regulatory authorities such as the U.S. Environmental Protection Agency (EPA) or the Food and Drug Administration (FDA). Please contact EPA and FDA to enquire about the regulatory status of your product.

Sincerely,

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Bernadette Juarez DATE: 6/23/2023
APHIS Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture