United States Department of Agriculture

Marketing and Regulatory Programs

Animal Plant Health Inspection Service

Biotechnology Regulatory Services

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MD 20737

Mr. Taizo Chinju
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JAPAN

RSR number 21-277-01rsr

RE: Regulatory Status Review of Chrysanthemum morifolium developed using genetic engineering for altered flower color and a marker gene

Dear Mr. Chinju:

Thank you for your letter dated November 10, 2021, requesting a Regulatory Status Review (RSR) for *Chrysanthemum morifolium* developed using genetic engineering (modified *C. morifolium*). In your letter, you described that the *C. morifolium* was modified to impart an altered flower color via the enhanced expression of *F3'5'H* and *UDPG* transgenes with the *CMF3Hp* promotor and to contain a selectable marker that confers antibiotic (kanamycin and neomycin) resistance using the neomycin phosphotransferase (*NPTII*) gene.

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 *C. morifolium* to determine whether it is subject to the regulations in 7 CFR part 340. Specifically, APHIS reviewed the modified *C. morifolium* to determine whether there is a plausible pathway by which the *C. morifolium* would pose an increased plant pest risk relative to the plant pest risk posed by an appropriate *C. morifolium* comparator. Based on information you provided, publicly available resources, and APHIS' familiarity with *C. morifolium* and knowledge of the trait, phenotype, and mechanism of action, APHIS considered the (1) biology of nonmodified *C. morifolium* 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 *C. morifolium* would pose an increased plant pest risk relative to comparator *C. morifolium* plants. APHIS has determined your *C. morifolium* is unlikely to pose an increased plant pest risk relative to its comparator. 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 *C. morifolium* is not subject to the regulations under 7 CFR part 340.

Please be advised that APHIS' decision applies to the *C. morifolium* 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 *C. morifolium*, 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,

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

Date: December 14, 2022