E 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2025-0005]

Ishihara Sangyo Kaisha, Limited: Availability of a Petition for a Determination of Nonregulated Status, Draft Plant Pest Risk Assessment, and Draft Environmental Assessment for ISK-311NR-4 Phalaenopsis (moth orchid)

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has received a petition from Ishihara Sangyo Kaisha, Limited seeking a determination of nonregulated status for ISK-311NR-4 Phalaenopsis (moth orchid) which has been developed using genetic engineering to produce a blue-purple flower color. We are making the petition, draft plant pest risk assessment, and draft environmental assessment available for public review and comment.

DATES: We will consider all comments that we receive on or before [**INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to www.regulations.gov. Enter APHIS-2025-0005 in the Search field. Select the Documents tab, then select the Comment button in the list of documents.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2025-0005, Regulatory Analysis and Development, PPD, APHIS, Station 2C-10.16, Unit 25, 4700 River Road Unit 25, Riverdale, MD 20737-1238.

The petition, draft plant pest risk assessment, draft environmental assessment, and any comments we receive on this docket may be viewed at www.regulations.gov, or in our reading

room, which is located in 1620 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

The petition, draft plant pest risk assessment, and draft environmental assessment are also available on the APHIS website at: https://www.aphis.usda.gov/biotechnology/legacy-petition-process/petitions. Search for APHIS petition 25-062-01p.

FOR FURTHER INFORMATION CONTACT: Mr. Alan Pearson, Biotechnology Regulatory Services, APHIS, USDA, 4700 River Road Unit 78, Riverdale, MD 20737-1236; (301) 851-3944; email: alan.pearson@usda.gov.

SUPPLEMENTARY INFORMATION: Under the authority of the plant pest provisions of the Plant Protection Act (7 U.S.C. 7701 *et seq*.), the regulations in 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," regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such organisms and products are considered "regulated articles."

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. Paragraphs (b) and (c) of § 340.6 describe the form that a petition for a determination of nonregulated status must take and the information that must be included in the petition.

APHIS has received a petition (APHIS Petition Number 25-062-01p) from Ishihara Sangyo Kaisha, Limited seeking a determination of nonregulated status for ISK-311NR-4 Phalaenopsis (moth orchid) which has been developed using genetic engineering to produce

blue-purple flower color. The petition states that the information provided indicates that ISK-311NR-4 Phalaenopsis is unlikely to pose a plant pest risk and therefore should not be regulated under APHIS' regulations in 7 CFR part 340.

As part of our decision-making process regarding the organism's regulatory status, APHIS prepared a draft plant pest risk assessment (PPRA) to assess the plant pest risk of the organism, and a draft environmental assessment (EA) to evaluate potential impacts on the human environment that may result if the petition request is approved.

APHIS' draft PPRA compared the pest risk posed by the ISK-311NR-4 Phalaenopsis with that of the unmodified variety from which it was derived. The draft PPRA concluded that ISK-311NR-4 Phalaenopsis is unlikely to pose an increased plant pest risk compared to the unmodified moth orchid.

The draft EA evaluated potential impacts that may result from the commercial production of ISK-311NR-4 Phalaenopsis, to include potential impacts on conventional moth orchid production; the acreage and area required for U.S. moth orchid production; agronomic practices and inputs; the physical environment; biological resources; human health and worker safety; and animal health and welfare. APHIS applied USDA' regulation at 7 CFR part 1b, and APHIS' National Environmental Policy Act (NEPA) implementing regulations (7 CFR part 372), when preparing this draft EA.

Paragraph (d) of § 340.6 provides that APHIS will publish a notice in the *Federal Register* providing 60 days for public comment on petitions for a determination of nonregulated status. In accordance with § 340.6(d), we are publishing this notice to inform the public that APHIS will accept written comments regarding the petition, draft PPRA, and draft EA from interested or affected persons for a period of 60 days from the date of this notice. The petition, draft PPRA, and draft EA are available for public review and comment, and copies are available as indicated under ADDRESSES and from the individual listed under the FOR FURTHER INFORMATION CONTACT section of this notice. We are particularly interested in receiving

comments regarding biological or ecological issues, and we encourage the submission of scientific data, studies, or research to support your comments.

After the comment period closes, APHIS will review and evaluate any information received during the comment period and any other relevant information. After reviewing and evaluating the comments and other information, APHIS will prepare a final PPRA and EA. Based on the final EA, APHIS will prepare a NEPA decision document (either a Finding of No Significant Impact (FONSI) or a notice of intent to prepare an environmental impact statement). If a FONSI is reached, APHIS will furnish a response to the petitioner, either approving or denying the petition. APHIS will also publish a notice in the Federal Register announcing the regulatory status of the modified plant and the availability of APHIS' final EA, PPRA, FONSI, and our regulatory determination

(Authority: 7 U.S.C. 7701-7772 and 7781-7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3)

Done in Washington, DC, this 28th day of May 2025.

Michael Watson,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2025-10138 Filed: 6/3/2025 8:45 am; Publication Date: 6/4/2025]