



## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

[Docket No. APHIS-2025-0005]

### **Ishihara Sangyo Kaisha, Limited: Determination of Nonregulated Status of ISK-311NR-4 Phalaenopsis (Moth Orchid) Genetically Engineered to Produce a Blue-Purple Flower Color**

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Notice.

**SUMMARY:** We are advising the public of our determination that ISK-311NR-4 phalaenopsis (moth orchid), which was developed using genetic engineering to produce a blue-purple flower color, is no longer considered regulated. Our determination is based on our evaluation of information and data Ishihara Sangyo Kaisha, Limited submitted in its petition for a determination of nonregulated status, available scientific data, the plant pest risk assessment, and public comments received in response to a previous notice announcing the availability of the petition for nonregulated status and a draft plant pest risk assessment. This notice announces the availability of our written determination and supporting documents.

**DATES:** This change in regulatory status is recognized as of September 2, 2025.

**ADDRESSES:** You may read the petition, our determination referenced in this notice, and supporting documents by any of the following methods:

- Federal eRulemaking Portal: Go to [www.regulations.gov](http://www.regulations.gov). Enter APHIS-2025-0005 in the Search field.
- Our reading room, 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.

**FOR FURTHER INFORMATION CONTACT:** Mr. Joseph Tangredi, Biotechnology Regulatory Services, APHIS, USDA, 5601 Sunnyside Avenue, AP100-3-WS-1100, Beltsville, MD 20705; (301) 851-4061; email: joseph.tangredi@usda.gov.

**SUPPLEMENTARY INFORMATION:**

Under the authority of the plant pest provisions of the Plant Protection Act (7 U.S.C. 7701-7772, 7781-7786) and 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," APHIS regulates, 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.

APHIS received a petition (APHIS Petition Number 25-062-01p) from Ishihara Sangyo Kaisha, Limited (ISK) 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 provides information in support of petitioners' position that ISK-311NR-4 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.

APHIS also prepared and published a draft environmental assessment (EA). However, on July 9, 2025, APHIS issued a Program Update titled "APHIS Announces Update to Practices

for Reviewing Petitions Seeking a Determination of Nonregulated Status for Organisms Altered or Produced Through Genetic Engineering,” available at <https://www.aphis.usda.gov/news/program-update/aphis-announces-update-practices-reviewing-petitions-seeking-determination>. In this Program Update, APHIS announced that it will no longer prepare a National Environmental Policy Act analysis to accompany its review of petitions seeking a determination nonregulated status. Therefore, consistent with this July 9, 2025 Program Update, APHIS terminated work on the EA.

APHIS published the petition and draft PPRA in the *Federal Register* [90 FR 23666-23667, APHIS-2025-0005] and accepted public comments from June 4, 2025, through August 4, 2025. APHIS received three comments; one comment was specific to the PPRA, one comment was specific to the EA, and one comment arguably addressed both the PPRA and the EA.

#### Determination

Based on APHIS’ evaluation in the final PPRA of information and data submitted by ISK in its petition, available scientific data, and public comments received in response to the petition and PPRA, APHIS has determined that ISK-311NR-4 is unlikely to pose a greater plant pest risk than the unmodified comparator and therefore is no longer subject to our regulation governing the introduction of certain organisms developed using genetic engineering.

Copies of the signed determination, final PPRA, and response to comments, as well as the previously published petition and supporting documents, are available as indicated in the **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT** sections of this notice.

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 2<sup>nd</sup> day of September 2025 .

**Michael Watson** \_

*Administrator, Animal and Plant Health Inspection Service.*

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