Animal and Plant Health Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

Ishihara Sangyo Kaisha, LTD. Petition for Determination of Nonregulated Status for Moth Orchid (*Phalaenopsis* spp. Hybrid) Containing the Flavonoid 3’5’-Hydroxylase Gene of Asiatic Dayflower (*Commelina communis*) Event ISK311NR-4

OECD Unique Identifier: ISK-311NR-4

Draft Environmental Assessment

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ACRONYMS AND ABBREVIATIONS

APHIS	Animal and Plant Health Inspection Service
CAA	Clean Air Act
CFR	Code of Federal Regulations (U.S.)
CWA	Clean Water Act
EA	Environmental Assessment
EFSA	European Food Safety Agency
EO	Executive Order
EPA	U.S. Environmental Protection Agency
ESA	Endangered Species Act
FDA	U.S. Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FONSI	Finding of No Significant Impact
FQPA	Food Quality Protection Act
GE	Genetically engineered
GHG	Greenhouse gas
N_2O	Nitrous oxide
NAAQS	National Ambient Air Quality Standards
NASS	National Agricultural Statistics Service
NEPA	National Environmental Policy Act of 1969 and subsequent amendments
NHPA	National Historic Preservation Act
NO_2	Nitrogen dioxide
NOx	Nitrogen oxides
OECD	Organization for Economic Cooperation and Development
OSHA	Occupational Safety and Health Administration
Pb	Lead
PM	Particulate matter
PPA	Plant Protection Act
PPRA	Plant pest risk assessment
SO_2	Sulfur dioxide
T&E	Threatened & Endangered
TSCA	Toxic Substances Control Act
U.S.	United States and its territories and possessions
USDA	U.S. Department of Agriculture
USC	U.S. Code
USFWS	U.S. Fish & Wildlife Service
WPS	Worker protection standards
WTO	World Trade Organization

1 PURPOSE AND NEED

1.1 Ishihara Sangyo Kaisha, LTD. Petition for Nonregulated Status

In March 2025, Ishihara Sangyo Kaisha, LTD. (ISK) submitted a petition (ISK 2025) to the U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) requesting a determination of nonregulated status for genetically engineered (GE) moth orchid (*Phalaenopsis* spp. hybrid) (referred to as 311NR Phalaenopsis; OECD Unique Identifier ISK-311NR-4), and any progeny derived from them, under Title 7 of the Code of Federal Regulations part 340 (7 CFR 340). APHIS assigned number 25-062-01p to the petition. APHIS administers 7 CFR part 340 under the authority of the plant pest provisions of the Plant Protection Act (PPA) of 2000 (7 U.S.C. 7701 *et seq.*). A GE organism is no longer subject to the requirements of 7 CFR part 340 if APHIS determines that it is unlikely to pose a plant pest risk. 311NR Phalaenopsis has been genetically engineered to express the flavonoid 3’ 5’-hydroxylase enzyme from *Commelina communis* allowing the plants to produce delphinidin-based anthocyanins resulting in violet-blue colored flowers. 311NR moth orchids are currently regulated by APHIS.

As part of the evaluation of ISK’s petition APHIS has developed this Environmental Assessment (EA) in compliance with the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*), which requires that Federal agencies consider the potential effects on the human environment that may derive from proposed actions.

1.2 Purpose of 311NR moth orchids

Flower color is one of the most important characteristics in the commercial success of products in the floriculture industry. Flower color is determined by the production of pigments, principally anthocyanins, terpenoids, and betalains. Anthocyanins are a class of flavonoids which play a role in flower color and contribute to flower color in the orange/red and violet/blue spectrum (Katsumoto et al. 2007; Tanaka et al. 2008; Liang et al. 2020). Terpenoids are fat soluble compounds synthesized in chloroplasts and are yellow to orange to red in color (Tanaka et al. 2008). Betalains are yellow to red, water-soluble compounds derived from tyrosine. Among these, the flavonoids contribute most to the range and type of pigments (colors) in plants.

There are three groups of glycosylated anthocyanins responsible for producing flower colors: delphinidin, cyanidin, and pelargonidin (Tanaka et al. 2008). Delphinidins and their derivatives generally produce blue flower color, cyanidins and their derivatives produce red or pink flower color, and pelargonidins and their derivatives produce orange or brick red flower color (Tanaka et al. 2008).

Moth orchids are among the most popular orchids in flower markets because of their long-lived and spectacular flowers (Liang et al. 2020). They are typically white, yellow, and red purple (Liang et al. 2020). Violet blue flowers rarely occur. It is anticipated that a violet blue and blue moth orchid would be a highly desired horticultural trait. Hence the developer sought to use genetic engineering to introduce a single gene, *F3’5’H*, that would produce delphinidin from the naturally occurring flavonoids in the plant to create moth orchids with a novel color (ISK 2025). These plants would be produced in greenhouses in the United States for horticultural and ornamental use. The gene was derived from Asiatic dayflower which naturally produces blue flowers.

311NR Phalaenopsis were also genetically engineered to express the selectable marker gene for the enzyme hygromycin B phosphotransferase (*hpt*) (ISK 2025). HPT confers resistance to the antibiotic hygromycin B (Gritz and Davies 1983). Transformed plants can grow in the presence of hygromycin B, while the growth of nonmodified cells is inhibited. This allows the selection of moth orchid plants that have the linked *F3'5'H* gene.

1.3 The Coordinated Framework and Regulation of Biotechnology Products

Since 1986, the U.S. government has regulated GE organisms pursuant to a regulatory framework known as the Coordinated Framework for the Regulation of Biotechnology (referred to as the Coordinated Framework). The Coordinated Framework, established by the White House Office of Science and Technology Policy (OSTP), describes the regulatory roles and authorities for the three major agencies involved in regulating GE organisms: the USDA APHIS, the U.S. Environmental Protection Agency (EPA), and the U.S. Food and Drug Administration (FDA) (51 FR 23302; 57 FR 6753). In 2017, the Biotechnology Working Group (established by a Memorandum issued by the Executive Office of the President (EOP) in 2015, with representatives from the EOP, EPA, FDA, and USDA) released a 2017 update to the Coordinated Framework (Biotechnology WG 2017) and earlier descriptions can be found in the original 1986 policy statement (51 FR 23302) and a 1992 update (57 FR 6753).

1.3.1 **USDA-APHIS**

APHIS regulations at 7 CFR part 340, which were promulgated pursuant to the Plant Protection Act (PPA), as amended (7 U.S.C. 7701 *et seq.*), govern the introduction (importation, interstate movement, and environmental release) of organisms developed using genetic engineering that may pose a plant pest risk. APHIS also regulates an organism it has reason to believe may be a plant pest or APHIS does not have sufficient information to determine if the organism is unlikely to pose a plant pest risk. An organism developed using genetic engineering is no longer subject to the plant pest provisions of the PPA or to the regulatory requirements of 7 CFR part 340 when APHIS determines that the organism is unlikely to pose a greater plant pest risk than the unmodified organism from which it was derived.

1.3.2 **Environmental Protection Agency**

The EPA is responsible for regulating the sale, distribution, and use of pesticides, including pesticides that are produced by GE organisms, termed plant incorporated protectants. The EPA regulates pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq*.) and certain GE microorganisms under the Toxic Substances Control Act (TSCA) (15 U.S.C. 53 *et seq*.). Before a pesticide may legally be used in the United States, the EPA must evaluate the pesticide to ensure that it will not cause unreasonable adverse effects on the environment and a reasonable certainty of no harm to humans when used in accordance with label instructions. Pesticides that complete this evaluation are issued a "registration" that permits their sale and use according to requirements set by the EPA. The EPA must also approve the language used on the pesticide label in accordance with 40 CFR part 158. Once registered, a pesticide may not legally be used unless the use is consistent with the approved directions for use on the pesticide's label. The overall intent of the label is to provide clear directions for effective product performance while minimizing risks to human health and the environment. Under FIFRA the EPA has a standard of reviewing pesticide registrations every 15 years (US-EPA 2011). The Food Quality Protection Act (FQPA) of 1996 amended FIFRA, and set a standard to reassess, over a 10-year period, all pesticide tolerances that were in place when the FQPA was signed, make a safety finding when setting tolerances that the pesticide can be used with “a reasonable certainty of no harm,” take into consideration aggregate and cumulative effects/risks in assessing human health, and emphasize risks to special sub-populations such as infants and children (US-EPA 2015).

The EPA also sets tolerances (maximum limits) for pesticide residues that may remain on or in food and animal feed or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. 301 *et seq.*). In establishing a pesticide tolerance, the EPA conducts dietary risk assessments to ensure that all tolerances established for each pesticide and food product reach a safety determination based on a finding of reasonable certainty of no harm. The FDA enforces pesticide tolerances set by the EPA to ensure the safety of the nation's food supply.

311NR Phalaenopsis do not contain a GE pesticide and there is no change to pesticide use, therefore, the EPA has no oversight role over 311NR Phalaenopsis.

1.3.3 **Food and Drug Administration**

The FDA regulates GE organisms under the authority of the FFDCA (21 U.S.C. 301 *et seq.*). The FDA published its policy statement concerning the regulation of products derived from new plant varieties, including those derived from genetic engineering, in the *Federal Register* on May 29, 1992 (57 FR 22984). Under this policy, the FDA implements a voluntary consultation process to ensure that human food and animal feed safety issues or other regulatory issues, such as labeling, are resolved before commercial distribution of GE food. This voluntary consultation process provides a way for developers to receive assistance from the FDA in complying with their obligations under federal food safety laws prior to marketing.

In June 2006, the FDA published recommendations in “Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use” (US-FDA 2006) for establishing voluntary food safety evaluations for new non-pesticidal proteins produced by new plant varieties intended to be used as food, including plants developed using genetic engineering. Early food safety evaluations help make sure that potential food safety issues related to a new protein in a new plant variety are addressed early in development. These evaluations are not intended as a replacement for a biotechnology consultation with the FDA, but the information may be used later in the biotechnology consultation.

Because 311NR Phalaenopsis is not intended for human and animal consumption and *Phalaenopsis* generally are not consumed as food or feed, the FDA does not have regulatory authority over 311NR Phalaenopsis.

1.4 Purpose and Need for APHIS Action

APHIS regulations at 7 CFR part 340 govern the introduction (importation, interstate movement, and environmental release) of GE organisms that may pose a plant pest risk. The regulations provide that any person may submit a petition to APHIS requesting that a plant developed using genetic engineering should not be regulated, because it is unlikely to present a plant pest risk.[1] If, after conducting a Plant Pest Risk Assessment (PPRA), APHIS determines that a plant developed using genetic engineering is unlikely to pose a greater plant pest risk than the non-GE plant from which it was derived (its comparator), the GE plant is no longer subject to the requirements of 7 CFR part 340 and the plant pest provisions of the PPA.

Consistent with NEPA (42 U.S.C. 4321 *et seq.*) and the USDA (7 CFR part 1b at 48 FR 11403, Mar. 18, 1983 as amended at 60 FR 66481, Dec. 22, 1995) and APHIS (7 CFR part 372 at 60 FR 6002, Feb. 1, 1995, as amended at 83 FR 24009, May 24, 2018) NEPA implementing procedures (7 CFR part 372), APHIS has prepared this EA to consider the potential effects of a determination of nonregulated status for 311NR Phalaenopsis on the human environment.

1.5 Public Involvement

APHIS seeks public comments on petitions it receives that request a decision of nonregulated status for organisms developed using genetic engineering. APHIS does this through a notice published in the *Federal Register*. When the Agency decides to prepare an EA as part of its decision-making process for a petition, it also seeks public comment on the EA. Details on APHIS policy and procedures for public participation in the petition review and NEPA process are available on the APHIS website.[2]

1.5.1 Public Involvement for Petition 25-062-01p

Through a Notice in the *Federal Register*, APHIS is making ISK's petition, the draft PPRA, and the draft EA available for a 60-day public review and comment period. APHIS will consider new information on potential environmental and interrelated economic effects that contribute to or alter the analyses presented in the draft EA.

APHIS developed the list of resource areas considered in this EA through experience in considering issues raised by the public, with specific attention to the issues raised in public comments submitted for petitions, EAs, and Environmental Impact Statements (EISs) of other organisms developed using genetic engineering. The resource areas considered also address

[1] Petitioners are required to describe known and potential differences from the unmodified organism that would substantiate that the regulated organism is unlikely to pose a greater plant pest risk than the unmodified organism from which it was derived.

[2] USDA-APHIS, Enhancements to Public Input, available at: https://www.aphis.usda.gov/news/program-update/resuming-federal-register-publications-petitions-nonregulated-status

issues raised in previous and unrelated lawsuits, and issues that various stakeholders have raised for prior petitions. The resource areas considered in this EA are categorized as follows:

Commercial Production

Commercial Growing Practices and Use

Pest and Pathogen Management

Physical Environment

Soils

Water Resources

Air Quality

Biological Environment

Soil Biota

Animal Communities

Plant Communities

Weediness and Gene Flow

Biological Communities

Human Health Considerations

Consumer Health

Worker Safety

Socioeconomic Considerations

Domestic Economic Environment

International Trade

In addition, potential effects on threatened and endangered (T&E) species are considered, as well as adherence of the regulatory status decision to Executive Orders, and environmental laws and regulations to which the action may be subject.

2 ALTERNATIVES

Two alternatives are evaluated in this EA: (1) No Action, denial of the petition, which would result in the continued regulation of 311NR Phalaenopsis and (2) the Preferred Alternative, approval of the petition, which would be a determination of nonregulated status for 311NR Phalaenopsis.

2.1 No Action Alternative: Deny the Petition and Continuation as Regulated

Under the No Action Alternative, APHIS would deny the petition. 311NR Phalaenopsis and its progeny would remain regulated under 7 CFR part 340. Permits issued or notifications acknowledged by APHIS would be required for the introduction of 311NR Phalaenopsis. APHIS might choose this alternative if 311NR Phalaenopsis posed a greater plant pest risk or was determined likely to pose a greater plant pest risk than its comparator.

This Alternative is not the Preferred Alternative because APHIS concluded that 311NR Phalaenopsis is unlikely to pose a greater plant pest risk than its comparator (USDA-APHIS-BRS 2025). Choosing this alternative would not satisfy the purpose and need of making a determination of plant pest risk status and responding to the petition for nonregulated status.

2.2 Preferred Alternative: Approval of the Petition for Nonregulated Status

Under this alternative, 311NR Phalaenopsis and progeny derived from this event would no longer be regulated under the regulations at 7 CFR part 340. APHIS would no longer require authorizations for introductions of 311NR Phalaenopsis and progeny derived from this event. This Alternative best meets the purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the Agency's authority under the plant pest provisions of the PPA. Because the agency has concluded that 311NR Phalaenopsis are unlikely to pose a greater plant pest risk than its comparator (USDA-APHIS-BRS 2025), a determination of nonregulated status of 311NR Phalaenopsis is a response that is consistent with the plant pest provisions of the PPA, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework.

2.3 Alternatives Considered but Dismissed from Detailed Analysis

APHIS has evaluated several additional alternatives for consideration in previous EAs and EISs for petitions for nonregulated status. For example, APHIS has considered alternatives that would entail approving a petition request in part, mandatory isolation or geographic restriction of plants developed using genetic engineering and those that were not, and requirements for testing for the presence of plant material from plants developed using genetic engineering in conventional plants.

Based on the draft PPRA for 311NR Phalaenopsis (USDA-APHIS-BRS 2025), experience regulating organisms developed using genetic engineering, and broad general experience with plant varieties, APHIS determined that 311NR Phalaenopsis are unlikely to pose a greater plant pest risk than its comparator. Thus, the imposition of testing, release/planting, and/or isolation requirements on 311NR Phalaenopsis would be inconsistent with the Agency's statutory authority under the plant pest provisions of the PPA, implementing regulations at 7 CFR part 340, and federal regulatory policies embodied in the Coordinated Framework.

2.4 Comparison of the Alternatives

Table 2-1 presents a summary of the potential effects associated with selection of either of the alternatives evaluated in this EA. Detailed analysis of the affected environment and environmental consequences is discussed in Chapter 3.

Table 2-1. Summary of Potential Effects for the Alternatives Considered

Analysis	No Action Alternative: Continue to Regulate 311NR Phalaenopsis	Preferred Alternative: Determination of Nonregulated Status for 311NR Phalaenopsis
Meets Purpose and Need	No	Yes
Horticultural Production and Use		
Commercial Growing Practices and Use	*Phalaenopsis* are primarily grown under controlled conditions inside greenhouses for the retail market. They are widely available throughout the United States as a potted plant primarily for indoor use or as cut flowers. Many *Phalaenopsis* are imported into the United States as potted plants or cut flowers from other countries. After importation of potted plants, plants are grown to flowering before entering the retail market. Potted *Phalaenopsis* production has been increasing.	311NR Phalaenopsis will provide an additional color variety. The developer does not expect that launch of 311NR Phalaenopsis, after a determination of nonregulated status, will have significant effects on market trends so no increase in overall production is anticipated. It is possible that 311NR Phalaenopsis may have subtle changes in stress tolerance, but these are not expected to result in changes to commercial growing methods.
Pest and Pathogen Management	Standard pest management practices, including treatment and disposal of plants, are used to manage pests and diseases of Phalaenopsis plants during production. These practices would remain unchanged.	311NR Phalaenopsis will not require any different pest and pathogen managements practices compared to nonmodified Phalaenopsis plants. Therefore, no effects are expected.
Physical Environment		
Soils	*Phalaenopsis* does not grow in soil and therefore does not have an effect. It is an epiphyte that	The potential effects of 311NR Phalaenopsis production on soil

Table 2-1. Summary of Potential Effects for the Alternatives Considered		
Analysis	**No Action Alternative: Continue to Regulate 311NR Phalaenopsis**	**Preferred Alternative: Determination of Nonregulated Status for 311NR Phalaenopsis**
	can be grown on the bark of trees outdoors. Potted plants are grown principally on pine bark or sphagnum moss.	quality are not expected to differ from the No Action Alternative.
Water Resources	*Phalaenopsis* represent a small U.S. crop which consume little water resources.	311NR Phalaenopsis may have slightly increased drought tolerance compared to existing varieties, but this is not expected to change the effects on water resources compared to commercial production of nonmodified *Phalaenopsis*.
Air Quality	*Phalaenopsis* represent a small U.S. crop which are primarily grown indoors and have little effect on air quality.	311NR Phalaenopsis are not expected to change the effects on air quality compared to nonmodified *Phalaenopsis*
Biological Resources		
Soil Biota	*Phalaenopsis* are primarily grown indoors or on the sides of trees and have negligible effects on soil biota.	311NR Phalaenopsis are not expected to change the effects on soil biota compared to nonmodified *Phalaenopsis*.
Animal Communities	Very few animal species interact with *Phalaenopsis* that are grown indoors. Outdoor-grown plants may be visited by animal and invertebrate species that use *Phalaenopsis* for food or feed on the insects feeding on *Phalaenopsis*.	311NR Phalaenopsis, which would accumulate delphinidin relative to the comparator, present negligible risk to wildlife.
Plant Communities	Because *Phalaenopsis* cultivation typically occurs in greenhouses or indoors, there is little interaction between *Phalaenopsis* and plant communities. Plants that are grown outdoors may be contained within pots but some may also be grown on trees.	Potential effects to plant communities are not anticipated to be different compared to the No Action Alternative
Weediness and Gene Flow	*Phalaenopsis* lacks weedy properties. Although introduced	311NR Phalaenopsis is not expected to have changes in

Table 2-1. Summary of Potential Effects for the Alternatives Considered		
Analysis	**No Action Alternative: Continue to Regulate 311NR Phalaenopsis**	**Preferred Alternative: Determination of Nonregulated Status for 311NR Phalaenopsis**
	throughout the US, *Phalaenopsis* has not naturalized. Production is indoors, and there is very limited cultivation outdoors in small private or public gardens. In addition, specialized conditions are needed for crossing and germination of seeds. Therefore, the likelihood of geneflow to other *Phalaenopsis* plants is very low. *Phalaenopsis* is not expected to have any gene flow to other types of orchids such as U.S. native orchids.	gene flow or weediness relative to other existing *Phalaenopsis* varieties. 311NR Phalaenopsis would still be expected to be limited to cultivation and the likelihood of gene flow is very low. In the unlikely event of gene flow to other cultivated *Phalaenopsis* plants, the progeny are also not expected to have increased weediness.
Biological Communities	*Phalaenopsis* production in greenhouses is primarily to produce potted plants that will be used as house plants or for cut flowers. Greenhouse production reduces effects on biological communities.	Trends in volume of greenhouse production are not expected to change due to 311NR Phalaenopsis. 311NR Phalaenopsis would not be expected to affect biological communities any differently than conventional *Phalaenopsis*.
Human and Animal Health		
Human Health	*Phalaenopsis* are not used for food or feed and have negligible effects on human health.	Potential effects to human health are not anticipated to be different from those under the No Action Alternative.
Socioeconomics		
Domestic Economic Environment	US producers produce about 35 million pots of *Phalaenopsis* per year worth about $300 million. Most of this production is centered in California, Florida, Hawaii, and New York.	A determination of nonregulated status for 311NR Phalaenopsis is not expected to significantly affect domestic Phalaenopsis markets. 311NR Phalaenopsis would provide novel colored flowers. This additional color variety is not expected to result in a significant increase in *Phalaenopsis* demand or production in the United States.

Table 2-1. Summary of Potential Effects for the Alternatives Considered		
Analysis	**No Action Alternative: Continue to Regulate 311NR Phalaenopsis**	**Preferred Alternative: Determination of Nonregulated Status for 311NR Phalaenopsis**
International Trade	International *Phalaenopsis* production is over $800 million with Taiwan and Netherlands being the major producers. Taiwan, having authorization to ship potted orchids, is the major exporter to the United States. Exported plants are primarily shipped in the preflowering stage and grown in U.S. facilities to flowering.	A determination of nonregulated status for 311NR Phalaenopsis is not expected to alter international trade. The developer may locate tissue culture production and pre-flowering plants overseas similar to current *Phalaenopsis* production. It is also possible that the developer would locate tissue culture facilities in the United States. In the latter case, there is a possibility that imports of preflowering *Phalaenopsis* would decrease. -
Coordinated Framework		
U.S. Regulatory Agencies	EPA has regulatory oversight of pesticides used on *Phalaenopsis*. FDA has no role in the regulation of *Phalaenopsis*.	Neither EPA nor FDA have regulatory oversight over 311NR Phalaenopsis. Determination of nonregulated status for 311NR Phalaenopsis is not expected to alter pesticide use.
Regulatory and Policy Compliance		
ESA, CWA, CAA, SDWA, NHPA, EOs	Fully compliant	Fully compliant

3 AFFECTED ENVIRONMENT AND ENVIRONMENTAL CONSEQUENCES

This chapter provides an overview of the current (baseline) conditions of those aspects of the human environment potentially affected by a determination of nonregulated status of 311NR Phalaenopsis, and the scientific and analytical comparison of the potential environmental consequences that could derive from the alternatives considered in this EA, i.e. denying the petition or issuing a determination of nonregulated status. For the purposes of this EA, those aspects of the human environment considered include production practices used for *Phalaenopsis*, the physical environment, biological resources, public health, and socioeconomic issues. The geographic extent of the affected environment corresponds to those parts of the United States in which producers and consumers can grow 311NR Phalaenopsis.

Each section of this chapter discusses the baseline (current conditions) for one of the considered aspects listed above and then addresses the environmental consequences for that aspect associated with the alternatives. The evaluation of effects includes the potential direct and indirect effects and their significance. An *effect* would be any change, beneficial or adverse, from existing (baseline) conditions for the affected environment as described. For purposes of this analysis, a *direct effect* is that which would derive from APHIS' decision to no longer regulate 311NR Phalaenopsis without being mediated by another entity or result from any intermediate steps or processes. An *indirect effect* is that which would occur later in time or at another place, and those that involve the actions or decisions of other individuals, or natural processes. Indirect effects may include economic growth effects (e.g., changes in commodity markets), changes in the pattern of land use, and effects on air and water quality as a result of horticultural production. Compliance of APHIS's decision on the petition with federal, state, and local requirements (National Environmental Policy Act of 1969 as amended (42 U.S.C. **§** 4321 et seq.)) is discussed in Chapter 5.

3.1 *Phalaenopsis* Uses and Production Practices

Phalaenopsis are tropical and subtropical perennial plants found throughout tropical Asia and the larger islands of the Pacific Ocean. They reach their westernmost limit in Sri Lanka and South India and their easternmost limit in Papua New Guinea and Australia. In the north they occur in southern China, Taiwan, and the Philippines (Christenson 2001). In their natural habitats, most *Phalaenopsis* orchid species are epiphytic plants, meaning that they grow on tree trunks and limbs (Christenson 2001; Wang et al. 2005). Their roots are exposed to air movement and absorb moisture from humid air as well as from rains and dews (Wang et al. 2005). *Phalaenopsis* dominate the orchid market because of their long-lasting flowers, wide range of flower colors, ease of care and ease to schedule into flower (Runkle et al. 2005).

There are 80 *Phalaenopsis* species within the genus and nine natural hybrids (POWO 2024). *Phalaenopsis* have a high hybridization capacity and as a result, they are bred extensively: the Royal Horticultural Society lists over 40,000 *Phalaenopsis* hybrids in its registry (Royal Horticultural Society 2025). *Phalaenopsis* seeds lack endosperm to nourish the germinating embryo. The germinated orchid embryo produces a structure unique to orchids known as the protocorm (Yeung and Yeung 2024). One end of the embryo develops into a shoot and the other forms root like structures known as rhizoids that serve as sites for interaction with mycorrhizae which absorb water and nutrients to nourish the embryo. In the wild, *Phalaenopsis* requires a mycorrhizal symbiont for successful germination (Arditti 1967). Symbiotic germination is not very efficient. An alternative much more efficient technique has been developed known as asymbiotic germination under conditions free of microorganisms including those symbionts that assist in germination. Instead, the seeds are grown aseptically in a culture medium containing sucrose that effectively substitutes for the symbiont. It is widely used to germinate seedlings from hybrid crosses that are subsequently grown into adult plants (Cardoso et al. 2020).

Polyploid cultivars with superior horticultural traits (particularly larger flowers) are the mainstream (Yuan et al. 2021a). Most hybrids are contributed by many species (up to 15) through generations of introgression by cross hybridization (Yuan et al. 2021a). 311NR Phalaenopsis is derived from the cultivar Wedding Promenade PP3387, and is comprised primarily of the following 7 species: 50% *Phalaenopsis equestris, 18% P. amabilis, 13% P. schilleriana, 10% P. rimestadiana; 5% P. Aphrodite, 3% P. sanderiana, and 0.5% P. stuartiana (Orchid Roots 2025).* Wedding promenade is a fertile hypertriploid (2n=3x + 3=60) (Rungruchkanont and Promchot 2017; Lee et al. 2020). *Phalaenopsis* represent 80% of orchid sales in the United States (Runkle et al. 2005). They are now the most valuable potted plant in the United States ahead of poinsettias. They are most commonly sold as house plants or for other ornamental purposes. They dominate the orchid market because of their long lasting flowers, wide range of flower colors, diverse architecture, size and number of inflorescences, ease of care, and ease to schedule into flower (Runkle et al. 2005; Iiyama et al. 2024). Natural colors include white, yellow, and red purple where flowers in the red-purple series range from red-purple, purple, purple-violet, violet, and violet blue (Liang et al. 2020). However violet-blue flowers are rarely available commercially because of the difficulty in breeding blue-color flowers (Liang et al. 2020). Currently, grocery and big box stores throughout the United States sell most *Phalaenopsis* as potted plants aimed at the mass market consumer. Some florist shops sell *Phalaenopsis* as cut flowers in bouquets, arrangements or corsages.

APHIS defines a built environment to mean all human-created areas where people live and work on a day-to-day basis (e.g., homes, buildings, streets, open spaces, and infrastructure). The built environment represents an important sector of the affected environment for this EA and an important consideration in this NEPA analysis. Due to the growth conditions *Phalaenopsis* requires (warm temperatures and high humidity), *Phalaenopsis* is principally relegated to indoor spaces as interior decoration in residences, hotels, offices, corporate spaces, and at gatherings such as weddings and festivals (ECON Market Research 2025). In Hawaii, parts of California, Florida, and Puerto Rico, there is limited use of *Phalaenopsis* in outdoor gardens (USDA-NASS 2019).

3.1.1 **Commercial Growing Practices and Use**

Being native to tropical regions, *Phalaenopsis* is damaged by air temperatures below 50°F. Therefore, *Phalaenopsis* is grown for retail markets inside laboratories and greenhouses designed and equipped to maintain optimum growing conditions. Production practices involve tissue culture, transplanting, pruning, lighting, temperature regulation, irrigation, humidity control, application of fertilizers and plant growth regulators, optimizing growing substrate, and pest and disease control.

A factor contributing to the successful cultivation and commercialization of orchids is the development of efficient clonal propagation systems using techniques such as micropropagation or protocorm like bodies (PLB) (Iiyama et al. 2024). In the first case, orchids are propagated from a growing point, or meristem (Runkle et al. 2005). These plants are called “mericlones.” The cloning process reduces variability from plant to plant, so populations have similar growth and flowering characteristics (Runkle et al. 2005). PLB are structures that resemble protocorms but are developed from any tissue other than the embryo and are induced to form during tissue culture (Cardoso et al. 2020). One advantage to the induction, proliferation, and regeneration of PLB is the increased rate of seedling propagation. PLB are commonly used in mutation breeding where tissue is mutagenized by chemicals or radiation or somaclonal variants naturally arise during tissue culture. These techniques have resulted in plants with useful traits that have been further bred into hybrids (Cardoso et al. 2020). Clonal propagation systems have resulted in the production of millions of clonal plantlets annually (Iiyama et al. 2024).

Phalaenopsis orchids are propagated in laboratories by tissue culture, and are usually grown in flasks for 10 to 12 months under low light (maximum of 50 to 100 footcandles, or 10 to 20 µmol•m-2•s-1)(Runkle et al. 2005). When young plants reach a leaf span of about 2 inches (5 cm), they are taken out of the flasks and transplanted into flats or small pots containing a fine bark or sphagnum-based media (Runkle et al. 2005). Once plants are removed from their flasks, they are grown for 20 to 25 weeks at 80°F to 90°F (27°C to 32°C), until they are ready for transplanting into a typically 5 inch (1 liter) pot (Runkle et al. 2005). Vegetative growth is promoted by high temperature (80°F to 90°F), and thus most plants are grown until maturity in greenhouses mimicking tropical and subtropical environments (Runkle et al. 2005). After transplanting to a larger container, plants may need another 20 to 25 weeks before being capable of spiking (the emergence of the flower stalk) (Runkle et al. 2005). Subsequent growth continues at these high temperatures to inhibit flowering and promote rapid leaf development (Runkle et al. 2005). Plants must be large enough, or mature, before they are capable of flowering. Although differences exist among cultivars, most cultivars won’t flower uniformly until the leaf span of a greenhouse population averages at least 10 inches (25 cm) wide (Runkle et al. 2005). *Phalaenopsis* is induced to flower when exposed to temperatures lower than 79°F (typically 77°F day/68°F night) for a period of 4-6 weeks (Lopez et al. 2005). Plants are finished by growing at 63-79°F for another 8-15 weeks. They are then sleeved and shipped to distribution centers for sale to consumers.

<u>No Action Alternative: Commercial Growing Practices and Use</u>

APHIS' continued regulation of 311NR Phalaenopsis would preclude commercial distribution of this variety. The present trend of a modest 3.7-4.6% compound annual growth rate (CAGR) in *Phalaenopsis* production would be expected to continue. Consumers would not have violet blue *Phalaenopsis* for purchase but other colors including white, yellow, and red purple would remain available to them. A segment of the floriculture industry dyes white *Phalaenopsis* flowers to non-natural and typically vibrant colors including blue by injecting dye into stems (Schier 2023). Consumers could purchase blue dyed *Phalaenopsis* that would remain blue for the life of the flower but subsequent flowers produced the following season would appear white (Schier 2023). Commercial growing practices of *Phalaenopsis* would be expected to continue unchanged.

<u>Preferred Alternative: Commercial Growing Practices and Use</u>

A determination of nonregulated status for 311NR Phalaenopsis is not expected to change the acreage, methods, and areas used for *Phalaenopsis* production. According to APHIS' draft PPRA, the insertion of CcF3'5'H may increase the overall anthocyanin content of 311NR Phalaenopsis; if so, this could result in a slight increase in plant resistance to disease and herbivory and tolerance to water limitation compared to the comparator (USDA-APHIS-BRS 2025). In addition, the developer observed that 311NR Phalaenopsis may be more sensitive to heat than the nonmodified comparator (ISK 2025). It is unknown to what extent these physiological differences (if they occur) would result in changes to specific cultivation parameters, but this would not change the general methods used for *Phalaenopsis* production. Furthermore, cultivation of non-GE *Phalaenopsis* varieties includes a range of temperatures with extreme heat already considered suboptimal (Lopez and Runkle 2005; Lopez et al. 2007). Moreover, no changes are expected to 311NR Phalaenopsis that would alter where or how it can be grown compared to non-GE *Phalaenopsis* varieties.

311NR Phalaenopsis will provide additional color varieties of *Phalaenopsis* and is expected to compete with other color varieties that are currently in production and offered for sale in the United States as a potted plant or cut flower. Commercial production of *Phalaenopsis* will continue to be dictated by the domestic and import floral market demands and choices made by consumers and growers.

3.1.2 **Pest and Pathogen Management**

Phalaenopsis are susceptible to a variety of diseases and insects. *Erwinia* (bacterial soft rot) and *Pseudomonas* (brown rot) are more prevalent during moist and warm conditions (Lopez et al. 2005). Optimizing the timing of watering can be used to avoid these diseases (Lopez et al. 2005). Fungal diseases caused by *Fusarium*, *Rhizoctonia*, *Pythium*, and *Phytophthora* can also be problematic (Lopez et al. 2005). When conditions are cool and humid, botrytis petal blight can develop quickly as small brown spots on flower buds and flowers. Insect pests of *Phalaenopsis* include mealy bugs, spider mites, scales, thrips, slugs, and snails primarily in greenhouses (Lopez et al. 2007).

Insects maybe treated with Malathion, Orthene, summer oil, safer soap, or imidacloprid; mites with Talstar®, Avid®, or Kelthane®; and fungi with Physan, copper compounds, Subdue®, Banrot®, Cleary's 3336®, Medallion®, Pageant® (Bottom 2017).

Viral diseases can also pose a problem for *Phalaenopsis* production (Chang 2017). Some viruses reported in *Phalaenopsis* in the United States include *Cymbidium mosaic virus* (CymMV), *Odontoglossum ringspot virus* (ORSV), *Orchid fleck virus* (OFV), *Capsicum chlorosis virus* (CaCV), and *Impatiens necrotic spot virus* (INSV) (Chang 2017). Disposing of virus-infected plants can be an effective mode of control (Christenson 2001).However, the impact of viruses on the economics of large-scale production has prompted research on detection methods to avoid via tissue culture (Chang 2017).

Weeds in greenhouses are problematic for a number of reasons. They can serve as a host for insect pests or disease organisms, they may maintain moist conditions that are favorable to fungal diseases, and they can directly compete with plants for light, water, and nutrients. Weeds also reduce the aesthetic value of plants (Pundt 2018; University of California 2019). Management typically occurs to remove any weeds that are in the vicinity of the greenhouse with small cultivators, hand weeding, broad spectrum pre-plant and/or residual herbicides, and solarization (Pundt 2018; University of California 2019). Physical barriers such as mulches and ground cloth are also used to prevent weed growth (Pundt 2018; University of California 2019).

<u>No Action Alternative: Pest and Pathogen Management</u>

Under the No Action Alternative, 311NR Phalaenopsis would continue to be regulated by APHIS and current management practices of pests and pathogens in *Phalaenopsis* production would be expected to continue unchanged.

<u>Preferred Alternative: Pest and Pathogen Management</u>

A determination of nonregulated status for 311NR Phalaenopsis is not expected to change the acreage, methods, and areas used for *Phalaenopsis* production. According to APHIS' draft PPRA, 311NR Phalaenopsis may have slightly increased resistance to pests and diseases (USDA-APHIS-BRS, 2025). However, if this occurs it would be slight and would not be expected to change the general practices for management of pests and diseases compared to current practices for *Phalaenopsis* varieties (USDA-APHIS-BRS 2025).

3.2 Physical Environment

The physical aspects of the affected environment include the soil, water, and air resources associated with the production and use of *Phalaenopsis*.

Commercial floriculture production is a high-intensity and high-input form of agriculture that is often concentrated in one area, and may involve intensive use of resources, such as land, water, and inputs such as fertilizers, soil media, irrigation, and pesticides (Dennis et al. 2010; Wainwright et al. 2014). *Phalaenopsis* is principally propagated vegetatively in tissue culture in laboratories outside the United States and mature non-flowering plants are imported into nurseries in the U.S. where flowering is induced and potted plants are sold in groceries and big box stores. The intensive and non-sustainable use of resources can negatively affect the environment. Because of the relatively high per-unit value of *Phalaenopsis* plants, extensive inputs may be economically justified in their production. *Phalaenopsis* production is timed to be available all year round.

3.2.1 **Soils**

Phalaenopsis does not grow in the soil. For this section we discuss the media associated with the production and use of *Phalaenopsis*. Primarily these are materials used for the production of plants for commercial sale in the form of potted plants and intermediate plant stages used for production as well as sterile tissue culture substrates used for micropropagation.

The traditional substrate for orchid growth is sphagnum moss, moss plants harvested alive from the surface of bogs and dried. Sphagnum moss is distinct from peat moss which consists of moss plants harvested from under the surface of peat bogs consisting entirely of dead plants (Bulla 2023). It has been estimated that 55% of orchids are planted in sphagnum moss and 45% in pine bark (Yuan et al. 2021b). Sphagnum moss holds more water than pine bark so plants need less watering (Yuan et al. 2021b). However, renewable sphagnum moss is not sustainable as demand exceeds production (Bulla 2023), peat production areas represent only 0.5% of Earth’s land surface (Gaudig et al. 2018), sustainable sphagnum farm production has yet to be realized (Pouliot et al. 2015; Gaudig et al. 2018), and costs are steadily increasing. In contrast, pine bark is a plentiful waste product from the lumber industry. In 2020, global pine bark production was estimated to be between 200-400 million cubic meters (Sessa et al. 2022). Global production of *Phalaenopsis* has been estimated to be 300 million plants per year. If each were to be planted in a 5” (1 l pot) filled with pine bark, 300,000 cubic meters of park bark would be needed, or just 0.1% of the annual production.

<u>No Action Alternative: Soil Quality</u>

Under the No Action Alternative, 311NR Phalanaeopsis would continue to be regulated by APHIS and current acreage and area used for *Phalaenopsis* production would be expected to continue unchanged. Current availability and usage of *Phalaenopsis* as well as growing practices and inputs used for commercial and production of *Phalaenopsis* in the built environment would not change from those currently used. *Phalaenopsis* is grown on sphagnum moss and/or pine bark. As demand for sphagnum moss outstrips supply resulting in increased costs, the current trend is to increase bark use at the expense of sphagnum moss.

<u>Preferred Alternative: Soil Quality</u>

The potential effects on soil quality from production of 311NR Phalaenopsis are not expected to differ from the No Action Alternative. 311NR Phalaenopsis do not require different growing practices or inputs from other *Phalaenopsis* varieties (ISK 2025). Consequently, cultivation of

311NR Phalaenopsis, would present the same potential effects to soil quality as *Phalaenopsis* varieties not developed using genetic engineering.

3.2.2 **Water Resources**

Water resources in the affected environment include all those that could possibly be affected by *Phalaenopsis* production and cultivation. That would include effects on water quantity or water quality related to sources or receiving waters along the life cycle of the *Phalaenopsis* product, from commercial production of seeds or plants to consumer use. Such sources and receiving water could include surface or groundwater sources or municipally supplied or otherwise delivered water or wastewater service.

Many states now require a water discharge permit to control irrigation runoff, as well as regulation of groundwater withdrawals (Fulcher et al. 2016). Laws and regulations limit nursery water consumption in California, Florida, North Carolina, Texas, and Oregon and are expected to become more stringent (Fulcher et al. 2016). California and Florida greenhouses accounted for 60% of the orchid sales in the United States (see **Figure 3-2**). Permits regulate the level of discharge that flows into surface waters and groundwater use/access (Fulcher et al. 2016; Texas A&M 2019). Although permits differ somewhat from state-to-state, there are some common features:

- Usually 3-5 years in duration
- Must retain all irrigation runoff
- Must retain all or part of storm runoff (usually first 2")
- Must dispose of irrigation runoff
- No pesticides discharged
- Nitrate and Ammonia discharge < 2ppm
- Discharge pH between 6 and 9
- Acceptable level of suspended solids.

Many operations are required to capture storm water runoff from production areas. Homeowners as well may choose to capture or "harvest" rainwater for landscape and garden use (Waterfall 2006). Reuse or recycling of runoff is becoming a more common production practice. Water-recycling technology has been adopted by some nursery producers to improve crop water productivity and to enhance water supply security (Cao et al. 2017). Careful monitoring of salts, chemicals, nutrients, and pH are critical in managing water resources. Treating recycled runoff is also an important part of this process (Texas A&M 2019).

Due to the potential effects of agriculture/horticulture on water resources, various national and regional efforts are underway to reduce non-point source contaminants in runoff, and runoff itself, such as the EPA's Mississippi River/Gulf of Mexico Hypoxia Task Force (US-EPA 2017) and USDA-NRCS National Water Quality Initiative (USDA-NRCS 2019a). The EPA provides specific advice for reducing pollution from yards (US-EPA 2019).

The U.S. nursery and greenhouse industry, including the sector involved in *Phalaenopsis* production, is concerned with the challenges of reduced water availability, increased costs for water use, and the need to mitigate water pollution from horticultural production. Growers rely on fertilizers and pesticides (Wang et al. 2005; Bottom 2017). The potential contamination of surface and groundwater from runoff containing inputs from production can be a challenge for nursery/greenhouse operators. For example, excess nitrates and phosphates from fertilizer are potential environmental hazards if they enter groundwater or surface water through leaching or runoff (Cox 2018).

Phalaenopsis produced in greenhouses, for the potted plant market, are grown in containers with a limited amount of substrate, from which water and nutrients are rapidly depleted (Rouphael et al. 2008). As a result, irrigation and fertilization is required more frequently for potted plants than for plants grown in the field (Rouphael et al. 2008). Some operators minimize water and nutrient losses by efficient drip irrigation systems and/or using recirculating systems that monitor nutrient levels and inject fertilizer only as needed (Cox 2018). *Phalaenopsis* being a slow growing succulent plant with low light requirements has relatively low water and nutrient needs compared to other potted and nursery grown plants (Wang et al. 2005).

Phalaenopsis benefit from fertilization. It is recommended that a complete fertilizer containing 150-200 ppm nitrogen be included in each watering (Wang et al. 2005). Plants are very sensitive to salt accumulation and it is recommended that the salinity be kept at an electrical conductivity under 1.5 dS/m (Wang et al. 2005). Many growers use reverse osmosis water to reduce background salts to keep the electrical conductivity within range.

Growing media pH alters the chemical availability of nutrients for root uptake by plants. Several nutrients are affected by growing media pH, including phosphorus and many micronutrients, especially iron, manganese, copper, zinc, and boron (which decrease in solubility at high pH), and molybdenum (which increases in solubility at high pH) (Fisher and Argo 2007). *Phalaenopsis* grow best at a slightly acid pH range of 5.5-6.5 because of increased availability of micronutrients at this lower pH range.

<u>No Action Alternative: Water Resources</u>

Ornamental flower production can affect water quality through the use of pesticides, fertilizers, growth regulators, and soil management practices, and the runoff of these inputs from nurseries/greenhouses, and urban landscapes into adjacent water bodies. Leaching of agronomic inputs into groundwater is also a concern. Irrigation can strain groundwater resources.

Under the No Action Alternative, 311NR Phalaenopsis would continue to be regulated by APHIS and current acreage and growing practices for *Phalaenopsis* production would be expected to continue unchanged. The potential effects of *Phalaenopsis* production on water resources in the United States, and national and local programs to reduce non-point source contaminants in agricultural runoff, and runoff itself, would continue under current trends. Existing water use and water quality conditions would be expected to be unchanged.

Preferred Alternative: Water Resources

According to APHIS' draft PPRA, it is possible that 311NR Phalaenopsis may be slightly more tolerant to drought compared to the comparator (USDA-APHIS-BRS 2025). However, this difference (if it occurs) would be very minor, and is not likely to significantly affect water use during greenhouse production, which would be for the purpose of optimal growth not growth under drought conditions. Moreover, because the general practices and inputs utilized for production of 311NR Phalaenopsis are expected to be the same as those commonly used for other *Phalaenopsis* varieties, the sources of potential effects on water resources would not be expected to differ. In addition, a determination of nonregulated status for 311NR Phalaenopsis is not expected to change the acreage, methods, timing, and areas used for *Phalaenopsis* production. Consequently, APHIS does not expect there to be any substantive changes in pesticides or other pest control measures, or volumes of water or fertilizers used, which can present potential effects on water quality.

3.2.3 **Air Quality**

The Clean Air Act (CAA) requires the maintenance of National Ambient Air Quality Standards (NAAQS). The NAAQS, developed by the EPA to protect public health, establishes limits for six criteria pollutants: ozone, nitrogen dioxide, carbon monoxide, sulfur dioxide, lead, and Particulate Matter (US-EPA 2020a). The CAA requires states to achieve and maintain the NAAQS within their borders. Each state may adopt requirements stricter than those of the national standard and each is required by the EPA to develop a State Implementation Plan that contains strategies to achieve and maintain the national standard of air quality within the state. Areas that violate air quality standards are designated as non-attainment areas for the relevant pollutants, whereas areas that comply with air quality standards are designated as attainment areas (US-EPA 2020b). Certain horticultural activities can affect air quality by releasing particulates, gases, and other chemicals into the air. Emissions released from horticultural production (e.g., use of fertilizers and pesticides, energy production) include carbon dioxide, nitrogen oxides (NOx), reactive organic gases, particulate matter, and sulfur dioxide (FAO 2013). Nitrous oxide (N_2O) may also be released following the use of nitrogen fertilizer (FAO 2013).

While the EPA establishes NAAQS, the standards do not set emission control requirements for any particular industry, including horticulture. The USDA and the EPA provide guidance for regional, state, and local regulatory agencies, and farmers, on how to best manage agricultural emissions sources and limit NAAQS pollutant emissions (USDA-EPA 2012). These measures allow stakeholders flexibility in choosing which measures are best suited for their specific situations/conditions and desired purposes. The USDA Environmental Quality Incentives Program Air Quality Initiative provides financial and technical assistance to help farmers and ranchers limit air pollution. The EPA has developed USDA-approved measures to help manage air emissions from cropping systems to help satisfy state implementation plan requirements. The EPA recommends that in areas where agricultural activities have been identified as a contributor to a violation of NAAQS, USDA-approved conservation systems and activities may be implemented to limit emissions.

No Action Alternative: Air Quality

Under the No Action Alternative, 311NR Phalaenopsis would continue to be regulated by APHIS and current effects to air quality associated with *Phalaenopsis* production practices would be expected to continue unchanged. The EPA and USDA efforts to reduce emissions, along with state and local efforts would likewise continue (US-EPA 2025).

Preferred Alternative: Air Quality

A determination of nonregulated status for 311NR Phalaenopsis would have no effect on emission sources associated with *Phalaenopsis* cultivation. Because agronomic practices and inputs would remain unchanged, as well as acreage utilized for *Phalaenopsis* production, no changes to emission sources (i.e., fossil fuel burning equipment) or quantities are expected and efforts to reduce emissions will remain unchanged.

3.3 Biological Environment

The biological aspects of the affected environment include the soil biota, animals, plants, and biological communities that would be affected by *Phalaenopsis* production.

3.3.1 **Soil Biota**

Phalaenopsis are grown primarily indoors as ornamental plants. They do not grow well outside a temperature range of 50-95ºF which greatly restricts their outdoor growth in the US. In those areas of zone 11-13 (HI, PR, and limited parts of southern CA, AZ, FL, and TX), *Phalaenopsis* can be grown as an epiphyte attached to trees. Hence these plants do not interact with the typical soil biota. In their native range, orchid mycorrhizae are a type of fungus that play an essential role in the life cycle of orchids. They promote seed germination, provide sugars for young seedling development, and assist with absorption of water and nutrients. The association often occurs at the protocorm stage of orchid development where the mycorrhizae penetrate and associate with the developing rhizoid (Yeung and Yeung 2024).

No Action Alternative: Soil Biota

Phalaenopsis are propagated in tissue culture and then grown in containers using soilless media within greenhouses which limit effects to soil biota. Under the No Action Alternative, 311NR *Phalaenopsis* would continue to be regulated by APHIS, and would have negligible effects on soil biota.

Preferred Alternative: Soil Biota

A determination of nonregulated status of 311NR Phalaenopsis is not expected to result in any new effects to soil biota. 311NR Phalaenopsis are not expected to change the practices and inputs used in *Phalaenopsis* production due to the inserted *F3'5'H* gene that confers the change in petal color in 311NR Phalaenopsis (ISK 2025). The 311NR Phalaenopsis express both the *F3'5'H* gene which allows for production of delphinidin, and the *hpt* gene which confers resistance to hygromycin B and is used for genetic selection. Although both genes occur naturally in the environment and would not be expected to present any new risk to soil biota, *Phalaenopsis* is seldom grown outdoors in the US. When they are, they are grown in pots or attached to trees, and accordingly have negligible exposure to soil biota.

3.3.2 Animal Communities

Animals and animal communities in the affected environment include all those that are present where *Phalaenopsis* is grown. The types of animals that feed on or use *Phalaenopsis* include invertebrates and mammals.

Invertebrates that use *Phalaenopsis* include both beneficial pollinator species such as bees (Pramanik et al. 2020; Ackerman et al. 2023), as well as pest species. Scent, rewards such as nectar, and visual cues, including flower color, shape, and size all likely play a role in attracting the pollinators, although few *Phalaenopsis* species have been directly studied to determine the most important cues for each species (Christenson 2001; Ackerman et al. 2023). Invertebrate pests that forage on *Phalaenopsis* include mealy bugs, spider mites, scales, thrips, slugs, and snails (Lopez et al. 2005) (see Section 3.1.2 Pest and Pathogen Management). Deer, mice, and rats will consume orchids if they have access.

<u>No Action Alternative: Animal Communities</u>

As discussed in Section 3.3.2 a variety of animal and insect species feed on *Phalaenopsis*. Mammals and birds may use *Phalaenopsis* for food or may feed on the insects feeding on *Phalaenopsis*. Invertebrates can feed on *Phalaenopsis* plants or pollen or prey upon other insects feeding on *Phalaenopsis*. Under the No Action Alternative, 311NR Phalaenopsis would continue to be regulated by APHIS and current effects to animal communities associated with *Phalaenopsis* production would be expected to continue unchanged. When used consistently with the EPA-registered uses and labels, pesticide applications used during *Phalaenopsis* production present an acceptable level of risk to non-target animals.

<u>Preferred Alternative: Animal Communities</u>

Under the Preferred Alternative, potential effects to animal communities are not anticipated to be different compared to the No Action Alternative as no changes in production practices associated with 311NR Phalaenopsis are expected and *F3'5'H* or *hpt* and their respective metabolites are not known to be toxic to animals through direct exposure at naturally occurring concentrations (EFSA 2004; European Food Safety Authority 2009; Husain et al. 2022).

Delphinidin occurs widely in nature in flowers and fruits and we were unable to find evidence of any harmful effects of blue flowers or fruits, or delphinidin specifically, on invertebrate species.

F3'5'H and associated delphinidin and *hpt* introduced into 311NR Phalaenopsis present negligible risk to wildlife, including the primary *Phalaenopsis* pollinators (bees), both from the standpoint of negligible toxicity and exposure given the indoor production of orchids.

3.3.3 **Plant Communities**

As *Phalaenopsis* only grows under cultivation in the United States (USDA-NRCS 2025) and it is primarily grown in greenhouses and residences, the plant communities associated with *Phalaenopsis* production are limited. Broadleaf and grass weeds in the greenhouse can compete with *Phalaenopsis*; they also serve as a primary reservoir of aphids, whiteflies, thrips, mites, and slugs and can be a primary inoculum source for several important greenhouse plant diseases (Pundt 2018). Weed management is encouraged as a way to reduce insect pressure. Common greenhouse weeds include chickweed, oxalis, bittercress, dandelion, ground ivy, creeping wood sorrel, prostrate spurge, and grasses (Pundt 2018). It is recommended to not only keep greenhouses free of weeds, but to also maintain a 10 to 20-foot weed-free barrier around the greenhouse (Pundt 2018).

No Action Alternative: Plant Communities

As discussed in Section 3.3.3, *Phalaenopsis* is primarily grown in greenhouses away from plant communities. In those circumstances there may be unwanted vegetation in and around greenhouses used for *Phalaenopsis* cultivation that are further limited by weed control practices. To a small extent, *Phalaenopsis* grown outside may be attached to trees causing no harm to the tree. Under the No Action Alternative, 311NR Phalaenopsis would continue to be regulated by APHIS and potential effects to plant communities associated with *Phalaenopsis* production would be expected to continue unchanged. When used consistently with the EPA-registered uses and labels, pesticide applications used during *Phalaenopsis* production present an acceptable level of risk to non-target plants.

Preferred Alternative: Plant Communities

Under the Preferred Alternative, potential effects to plant communities are not anticipated to be different compared to the No Action Alternative. 311NR Phalaenopsis are not expected to change the practices and inputs used in *Phalaenopsis* production due to the inserted *F3'5'H* gene that confers the blue-colored petals to 311NR Phalaenopsis (ISK 2025).

3.3.4 **Weediness and Gene Flow**

Phalaenopsis is not weedy. Although widely introduced into the United States as a potted plant it has not established here. It is slow growing and has specialized requirements for tropical temperature, high humidity, epiphytic growth, orchid mycorrhizae for germination, and is intolerant of flooding, high light, arid climates, and chilling.

Gene flow can occur between organisms of the same species, or among closely related species or genera that are sexually compatible. Gene flow is a biological process that facilitates the production of hybrid plants, introgression of novel alleles, and evolution of new plant genotypes. A hybrid is the offspring of two genetically dissimilar but sexually compatible species, generally within the same genus, although hybrids between different genera are possible. Hybrids can then in turn cross with original parental type individuals. Through this process, called introgression, over several generations novel alleles (genes) can be transferred (flow) from one species to another. These processes can occur by intentional plant breeding programs or without human actions among certain plant populations.

Gene flow in seed plants can occur via pollination and production of seeds. *Phalaenopsis* are not known to form natural hybrids with any other genus of orchid, therefore geneflow to other types of orchids, including native orchids, is not expected to occur. While *Phalaenopsis* is capable of interspecific crosses, because most plants are grown in greenhouses, plants do not naturalize in the United States, most *Phalaenopsis* in the United States are hybrids with variable fertility, and seed germination requires mycorrhizal association or specialized laboratory conditions, unintended gene flow to other *Phalaenopsis* plants is highly unlikely. For those that are grown outdoors, there are few opportunities for pollination due to the likely low number of compatible *Phalaenopsis* spp. plants flowering within the same timeframe and vicinity.

<u>No Action Alternative: Weediness and Gene Flow</u>

Under the No Action Alternative, 311NR Phalaenopsis would continue to be regulated by APHIS. As described in Section 3.3.4, gene flow is a biological process that facilitates the production of hybrid plants, introgression of novel alleles, and evolution of new plant genotypes. In the case of *Phalaenopsis*, hybridization in the United States is entirely man-made given the rarity of these orchids in the natural environment, the specialized requirements for mycorrhizae for seed germination, the slow growth of the plants, and the lack of suitable environmental conditions within most of the United States. These attributes also mean that *Phalaenopsis* is not weedy and according to USDA Plants Database, there are no naturalized populations of *Phalaenopsis* in the United States (USDA-NRCS 2025).

<u>Preferred Alternative: Weediness and Gene Flow</u>

311NR Phalaenopsis are not expected to have increased rates of gene flow and weediness from the addition of *F3’5’H or hpt*. As described previously, *Phalaenopsis* orchids have not naturalized in the United States and are limited by multiple ecological factors. According to APHIS’ draft PPRA, it is possible that 311NR Phalaenopsis may have a slight increase in plant resistance to disease and herbivory and tolerance to water limitation compared to the comparator (see section 3.1.1) (USDA-APHIS-BRS 2025). However, these potential changes would be slight and 311NR Phalaenopsis’ ability to escape cultivation would still be limited. The developer observed that 311NR Phalaenopsis may be more sensitive to heat than the nonmodified comparator (ISK 2025); if so, this would potentially further limit 311NR Phalaenopsis. Moreover, the changes to 311NR Phalaenopsis are not expected to affect where it can be grown or increase its weediness compared to its comparator or existing *Phalaenopsis* varieties.

The changes to 311NR Phalaenopsis are also not expected to affect the potential for cross pollination, as flower color already varies among *Phalaenopsis* varieties (Liang et al. 2020), 311NR Phalaenopsis are expected to rarely be grown outside, and there is no expectation that fertility or pollinator visitation of 311NR Phalaenopsis would be different. As with the No Action Alternative, they will still require human intervention for hybridization so unintended gene flow is expected to be minimal. Furthermore, even in the unlikely event of crossing between 311NR Phalaenopsis and another *Phalaenopsis* plant cultivated outdoors, no weediness issues are anticipated from the introduced trait.

3.3.5 **Biological Communities**

A variety of living organisms can occupy a given area forming complex, integrated ecological systems in which they occur (Wilson 1988). Ecologists employ several indices to measure these communities; these generally include the number of different species present, the turnover of species across time and space, as well as the physical structure of an ecosystem and food web structure. Within the context of biological communities, organisms are organized at many different levels, ranging from whole ecosystems to microscopic biota, as well as the genomes that define genera and species. Increased numbers of organisms tends to correspond to greater ecosystem resilience and stability (Ives and Carpenter 2007).

Reductions in the complexity of a biological community can result from land use changes that lead to habitat loss and habitat fragmentation, which can derive from suburban/urban development including the building of greenhouses, introduction of non-native or invasive species, and expansion of agricultural lands (USDA-FSA 2010).

As an ornamental plant primarily used as a potted plant for indoor use or cut flower, *Phalaenopsis* is primarily grown in monoculture in the built environment. In this context, there would be limited opportunity to supply food for pollinators, habitat for various insect species, or to interact with natural ecosystems.

<u>No Action Alternative: Biological Communities</u>

In greenhouse production systems used to grow *Phalaenopsis*, growers intensively manage plant and animal communities through chemical and cultural controls to protect the crop from damage and limit the biological communities as a result.

Under the No Action Alternative, 311NR Phalaenopsis would continue to be regulated and conventional orchids would continue to be grown in monoculture greenhouse environments.

Preferred Alternative: Biological Communities

311NR Phalaenopsis would not be expected to change growing practices. Other than the availability of an additional color there are no differences between 311NR *Phalaenopsis* and conventional *Phalaenopsis* varieties. Based on this information, APHIS has determined that approval of a petition for nonregulated status of 311NR Phalaenopsis will have the same effect on biological communities as the No Action Alternative.

3.4 Human Health

3.4.1 **Consumer Health**

Human health considerations associated with plants developed using genetic engineering (principally crops) are those related to (1) the safety and nutritional value of plants developed using genetic engineering and their products to consumers, and (2) the potential health effects of pesticides that may be used in association with plants developed using genetic engineering. As for food safety, consumer health concerns can be related to the potential toxicity or allergenicity of the introduced genes/proteins, the potential for altered levels of existing allergens in plants, or the expression of new antigenic proteins. Consumers may also be concerned about the potential consumption of pesticides on/in foods derived from plants developed using genetic engineering. Occupational exposure to pesticides can also be a concern.

Certain ornamental flowers are edible such as borage blossoms, calendula, zucchini blossoms, hibiscus petals, lavender, nasturtium, pansies, rose, sage flowers, and violets. *Phalaenopsis* are generally not eaten and considered to have low toxicity though it has been reported that ingestion can result in mild symptoms of nausea, vomiting, diarrhea, and oral irritation (Joes 2024) while others claim it is safe to eat the leaves and flowers (Colbert 2023).

As discussed in Section 1.3, the EPA has oversight of pesticides and protection of human and environmental health from potential pesticide hazards. Any pesticides used in the production or rearing of *Phalaenopsis* are subject to EPA review, registration, and label use requirements. States may also regulate certain pesticide practices deployed in *Phalaenopsis* production.

3.4.2 **Worker Safety**

Horticultural service workers are at risk of injury from a variety of potential hazards, including exposure to chemicals, machinery, lifting, and construction. Horticultural hazards are addressed in specific Occupational Safety and Health Administration (OSHA) standards for General Industry (29 CFR part 1910).

The EPA established the Worker Protection Standard (WPS) (40 CFR part 170) in 1992 to reduce the risk of pesticide poisonings and injuries among pesticide handlers and applicators. The WPS applies to horticultural workers and contains requirements for pesticide safety training, notification of pesticide applications, use of personal protective equipment, restricted entry intervals following pesticide application, decontamination supplies, and emergency medical assistance.

In November 2015, the EPA issued revisions to the WPS regulations intended to enhance the protections provided to agricultural workers, pesticide handlers, and other persons by strengthening elements of the existing WPS such as training, pesticide safety and hazard communication information, use of personal protective equipment, and the provision of supplies for routine washing and emergency decontamination (80 FR 211, November 2, 2015, p. 67496).

In September 2016, the EPA in conjunction with the Pesticide Educational Resources Collaborative made available a guide to help users of agricultural pesticides comply with the requirements of the 2015 revised federal WPS. Agricultural workers and handlers, owners/managers of agricultural establishments, commercial (for-hire) pesticide handling establishments, and crop production consultants are advised to employ this guidance. The updated 2016 WPS How to Comply Manual supersedes the 2005 version.[3]

All pesticides must be used in strict accordance with their label instructions. All pesticides labeled for use in the United States must be evaluated for safety and registered by the EPA. Worker safety precautions and use restrictions are clearly noted on pesticide registration labels. Growers are required to use pesticides consistent with the application instructions provided on the EPA-approved pesticide labels. These restrictions provide instructions as to the appropriate levels of personal protection required for agricultural workers to use pesticides. These may include instructions on personal protective equipment, specific handling requirements, and field reentry procedures. These label restrictions carry the weight of law and are enforced by the EPA and the states (FIFRA 7 U.S.C. 136j (a)(2)(G) Unlawful Acts); therefore, it is expected that pesticide use would be consistent with the EPA-approved labels.

<u>No Action Alternative: Consumer Health and Worker Safety</u>

Under the No Action Alternative, 311NR Phalaenopsis would continue to be regulated by APHIS. Current availability and usage of *Phalaenopsis* is expected to remain the same under the No Action Alternative. As noted in Section 3.4.1 – Consumer Health, *Phalaenopsis* plants are not a food and not consumed by humans or used for animal feed. Exposure to pesticides used on *Phalaenopsis* would continue under the No Action Alternative. Management practices for *Phalaenopsis* production, and the associated human health effects, are expected to continue under the No Action Alternative. Worker safety is taken into consideration by the EPA in the pesticide registration and registration review processes. When use is consistent with the label, pesticides present minimal risks to workers.

<u>Preferred Alternative: Consumer Health and Worker Safety</u>

[3] https://www.epa.gov/pesticide-worker-safety/pesticide-worker-protection-standard-how-comply-manual

Under the Preferred Alternative, potential effects to human health are not anticipated to be different from those under the No Action Alternative. *Phalaenopsis* is not consumed by humans and is not used as animal feed.

The potential human health effects associated with pesticide use for the production of 311NR *Phalaenopsis* under the Preferred Alternative would be the same as under the No Action Alternative as production practices will not change. The EPA WPS will continue to provide the same level of protection as is currently available under the No Action Alternative. Accordingly, effects to worker health under the Preferred Alternative are expected to be the same as the No Action Alternative.

3.5 Socioeconomics

3.5.1 **Domestic Economic Environment**

The 2021 USDA National Agricultural Statistics Service (USDA-NASS) data, for the floriculture industry as a whole, indicated a $4.8 billion market value for floriculture crops and potted flowering plants were valued at $850 million (USDA-NASS 2021). Among potted plants, orchids are the top produced in the United States, surpassing poinsettias since 2009 (Yuan et al. 2021b). Prior to the 1990s, orchid nurseries were very common, typically very small, and catered to hobbyists by offering a wide range of orchid species and hybrids (Yuan et al. 2021b). In the 1990s a mass *Phalaenopsis* market began using bare root plants imported from Taiwan in late summer and selling them the following spring 6-7 months later (Yuan et al. 2021b). Advances in production technology in the late 1990s resulted in *Phalaenopsis* being available for sale in the United States year round (Yuan et al. 2021b) and by 2018, growers shipped close to 35 million pots at a wholesale value of $300 million (USDA-NASS 2019) (see **Figure 3-1** and **Figure 3-2**). Production dipped in 2020 to $276 million (USDA-NASS 2021), presumably as a result of COVID, but has been forecasted to continue growth at a compound annual growth rate (CAGR) of 3.67% - 4.6% over 10 years (AllTheResearch 2021; Business Research Insights 2025). Global production of *Phalaenopsis* has reached 300 million plants per year (Iiyama et al. 2024).

The USDA-NASS tracks floriculture statistics in 17 floriculture producing states that have at least $10,000 in annual gross sales: Alaska, California, Colorado, Connecticut, Florida, Illinois, Michigan, New Jersey, New York, North Carolina, Ohio, Oregon, Pennsylvania, Texas, Virginia, Washington, and Wisconsin (USDA-NASS 2021) .[4] Floriculture products and operations with

[4] The Commercial Floriculture Survey is a census of all known growers with an operation that produced and sold $10,000 or more of product in the 17 Program States. However, detailed crop information is collected from only operations with $100,000 or more in sales. The data in this report for annual bedding and garden plants, potted herbaceous perennials, potted flowering plants for indoor and patio use, foliage plants for indoor or patio use, cut flowers, cut cultivated greens, and propagative floriculture materials are summarized only from growers with $100,000 or more in annual sales. The data summarized in tables showing grower numbers, hired workers, and growing area represent all growers having whole gross sales of $10,000 or more during the calendar year.

$100,000 or more in annual sales in the 17 states account for 99% of the total dollar value of floriculture crops but comprise only 44% of all producers (USDA-NASS 2021).

For *Phalaenopsis*, USDA-NASS only tracks the end product of production, i.e. the potted plants intended as house plants or cut flowers for floral arrangements. As noted in section 3.1.1, there are many steps in *Phalaenopsis* production and depending on how specialized the grower is, they may only produce and sell an intermediate product. The intermediate products include the breeding to produce mericlones or PLB clones, the mass propagation of clones of value in laboratories, the tissue culture propagation of the clones in laboratories to produce plantlets with 2” leaves, the greenhouse production of plants to reach the flowering stage, and the final product where flowering is induced and the plants are grown to the flowering stage. U.S. producers primarily produce the latter using imported nonflowering seedlings that are induced to flower in the U.S. greenhouse.

In 2005, USDA approved the importation of *Phalaenopsis* orchids from Taiwan in their original growing pots (Yuan et al. 2021b). Potted plants are typically shipped by sea and immediately placed on greenhouse benches upon arrival and induced to flower (Yuan et al. 2021b). Approximately 20 million pots are imported each year from Taiwan (Yuan et al. 2021b). In 2010, 176 U.S. growers produced 21.1 million potted orchids, generating $170.8 million (Onofrey 2011). In 2020, potted orchids totaled about 34.3 million produced by 126 growers at a value of $276 million (see **Table 3-1**) (USDA-NASS 2021). In 2019, California and Florida each accounted for 45 and 30%, respectively, of the total national value, followed by Ohio (11%), West Virginia (4%), Hawaii (3.9%), Virginia (3.2%), Pennsylvania (1.6%), and Colorado (0.6%) (Yuan et al. 2021b) (see **Figure 3-2**). Whereas most of the states produce potted *Phalaenopsis*, Hawaii predominantly produces other types of orchids especially *Dendrobium* (Yuan et al. 2021b).

Orchids for cut flowers have been diminishing over the years. Only California and New Jersey produce enough cut flower orchids to be listed by USDA-NASS: in 2020 California produced about $6.9 million dollars and New Jersey $155,000 dollars in sales while all other states combined produced $138,000 (see **Table 3-2**). There were only 19 producers for cut orchids in 2018 in the USA (USDA-NASS 2021).

Ornamentals produced using biotechnology

Several cut flower varieties developed using genetic engineering are currently produced: 19 varieties of carnation (*Dianthus caryophyllus*), 1 rose (*Rosa* × *hybrida*), and 1 baby’s breath (*Gypsophila* spp.) (USDA 2016). Most distributors, flower auctions, brokers, wholesalers, floral designers, and consumers are not aware that these varieties are developed using genetic engineering (Anderson and Walker 2013).

Biotech carnation (*Dianthus caryophyllus*) products were first marketed in Australia in 1997 and are now authorized for import in the European Union, Japan, Canada, Malaysia, Singapore, and the United States (Chandler and Sanchez 2012; Suntory 2015; OGTR 2018). Carnations developed using genetic engineering are currently produced in Colombia and Ecuador, and then exported as cut flowers to approving countries. More than 4 million of these carnations are sold world-wide each year (OGTR 2018). A blue rose developed using genetic engineering is commercially available in Japan and North America (ISAAA 2014). APHIS reviewed and deregulated this rose variety in 2011. A chrysanthemum developed using genetic engineering, also modified for production of blue flowers, has been developed, although not yet available in commercial markets (Noda et al. 2017). APHIS also reviewed and deregulated an orange petunia developed using genetic engineering in 2021. In 2023, APHIS reviewed and determined that a glow in the dark petunia developed using genetic engineering was not subject to regulation.

Consumer preference for an orchid created with biotechnology is uncertain (Anderson and Walker 2013). Violet blue carnations, and roses with the *F3'5'H* gene have been successfully commercialized (Anderson and Walker 2013). There is no requirement, in the United States, for labeling a flower as developed using genetic engineering (USDA-AMS 2018) (other countries have different requirements) so it is difficult to know if consumers would react differently if they were aware the plants were made using biotechnology. Recently, a purple tomato made using biotechnology was marketed to consumers and a company survey found that 80% of consumers are interested to eat, purchase, and grow the purple tomato (Norfolk Healthy Produce 2024). These observations suggest that the flower will be accepted by certain consumers. Unlike the No Action Alternative where 311NR Phalaenopsis is not marketable, there will be markets for these *Phalaenopsis* under the Preferred Alternative.

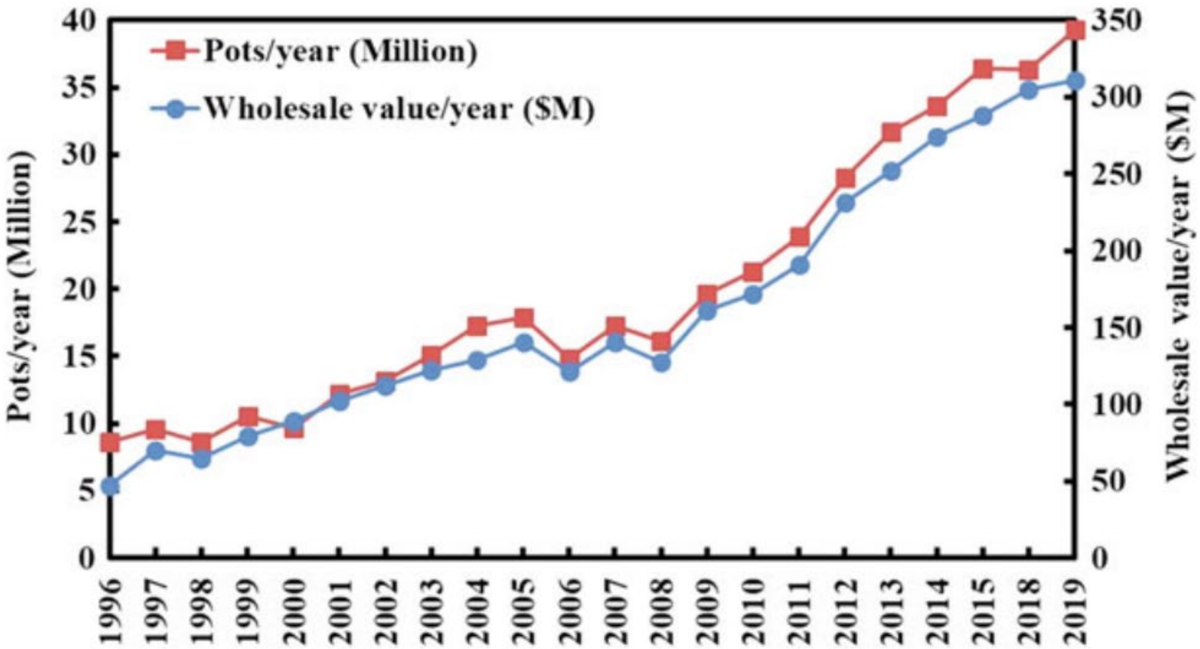

Figure 3-1. The production volume and wholesale value of potted orchids in the United States, including the state of Hawaii, 1996-2019 (Yuan et al. 2021b).
USDA approved the importation of Phalaenopsis orchids from Taiwan in their original growing pots (with sphagnum moss) in 2005 (arrow). After a three-year lag, production has grown steadily since.

Figure 3-2. The major orchid producing areas in the United States (Yuan et al. 2021b).

Table 3-1. Orchids sold in pots in the United States in 2019 and 2020 (USDA-NASS 2021).

Flowering Plants for Indoor or Patio Use Sold in Pots, Orchids – States and Total: 2019 and 2020

[Operations with $100,000+ sales]

State	Producers		Quantity sold: Less than 5 inches		Quantity sold: 5 inches or larger		Quantity sold: Total all sizes	
	2019	2020	2019	2020	2019	2020	2019	2020
	(number)	(number)	(1,000 pots)	(1,000 pots)	(1,000 pots)	(1,000 pots)	(1,000 pots)	(1,000 pots)
Alaska	-	-	-	-	-	-	-	-
California	35	27	13,167	12,026	3,807	3,325	16,974	15,351
Colorado	6	4	(D)	(D)	(D)	(D)	88	154
Connecticut	7	2	(D)	(D)	(D)	-	(D)	(D)
Florida	56	46	3,537	3,109	7,419	7,425	10,956	10,534
Illinois	3	2	(D)	(D)	(D)	(D)	(D)	(D)
Michigan	3	4	-	(D)	(D)	(D)	(D)	(D)
New Jersey	9	6	(D)	(D)	(D)	(D)	(D)	(D)
New York	9	7	(D)	(D)	(D)	(D)	539	465
North Carolina	5	6	(D)	(D)	(D)	(D)	(D)	145
Ohio	2	3	-	(D)	(D)	(D)	(D)	(D)
Oregon	1	-	(D)	-	-	-	(D)	-
Pennsylvania	-	2	-	(D)	-	-	-	(D)
Texas	1	5	(D)	(D)	(D)	(D)	(D)	(D)
Virginia	6	6	(D)	17	(D)	94	(D)	111
Washington	3	3	(D)	(D)	(D)	(D)	(D)	(D)
Wisconsin	6	3	(D)	(D)	(D)	(D)	(D)	(D)
Other States [1]	-	-	2,340	2,259	7,407	6,072	9,120	7,567
Total	152	126	19,044	17,411	18,633	16,916	37,677	34,327

State	Percentage of quantity sold at wholesale		Wholesale price: Less than 5 inches		Wholesale price: 5 inches or larger		Wholesale price: Total		Value of all sales at wholesale [2]	
	2019	2020	2019	2020	2019	2020	2019	2020	2019	2020
	(percent)	(percent)	(dollars per pot)	(dollars per pot)	(dollars per pot)	(dollars per pot)	(dollars per pot)	(dollars per pot)	(1,000 dollars)	(1,000 dollars)
Alaska	-	-	-	-	-	-	-	-	-	-
California	99	98	7.29	6.72	10.72	11.92	8.06	7.85	136,782	120,491
Colorado	(D)	(D)	(D)	(D)	(D)	(D)	17.09	11.48	1,504	1,768
Connecticut	(D)	(D)	(D)	(D)	(D)	-	(D)	(D)	(D)	(D)
Florida	98	98	6.36	6.26	9.27	8.85	8.33	8.09	91,280	85,188
Illinois	(D)	(D)	(D)	(D)	(D)	(D)	(D)	(D)	(D)	(D)
Michigan	(D)	(D)	-	(D)	(D)	(D)	(D)	(D)	(D)	(D)
New Jersey	(D)	(D)	(D)	(D)	(D)	(D)	(D)	(D)	(D)	(D)
New York	(D)	(D)	(D)	(D)	(D)	(D)	9.10	9.70	4,906	4,509
North Carolina	(D)	(D)	(D)	(D)	(D)	(D)	(D)	10.46	(D)	1,517
Ohio	(D)	(D)	-	(D)	(D)	(D)	(D)	(D)	(D)	(D)
Oregon	(D)	-	(D)	-	-	-	(D)	-	(D)	-
Pennsylvania	-	(D)	-	(D)	-	-	-	(D)	-	(D)
Texas	(D)	(D)	(D)	(D)	(D)	(D)	(D)	(D)	(D)	(D)
Virginia	(D)	88	(D)	8.76	(D)	13.94	(D)	13.14	(D)	1,459
Washington	(D)	(D)	(D)	(D)	(D)	(D)	(D)	(D)	(D)	(D)
Wisconsin	(D)	(D)	(D)	(D)	(D)	(D)	(D)	(D)	(D)	(D)
Other States [1]	98	98	5.40	5.93	7.86	9.15	7.06	8.08	64,417	61,150
Total	98	98	6.88	6.54	9.01	9.59	7.93	8.04	298,889	276,082

- Represents zero.
(D) Withheld to avoid disclosing data for individual operations.
[1] Includes data withheld above.
[2] Equivalent wholesale value of all sales.

Table 3-2. U.S. Production of orchids for cut flowers during 2019 and 2020 (USDA-NASS 2021).

Cut Flowers by Type – States and Total: 2019 and 2020 (continued)
[Operations with $100,000+ sales]

Plant and State	Producers		Quantity sold		Percentage of quantity sold at wholesale		Wholesale price		Value of all sales at wholesale [1]	
	2019	2020	2019	2020	2019	2020	2019	2020	2019	2020
	(number)	(number)	(1,000 blooms)	(1,000 blooms)	(percent)	(percent)	(cents per bloom)	(cents per bloom)	(1,000 dollars)	(1,000 dollars)
Orchids, all										
Alaska	-	-	-	-	-	-	-	-	-	-
California	11	8	2,941	3,236	100	100	172.7	213.8	5,079	6,919
Colorado	-	-	-	-	-	-	-	-	-	-
Connecticut	-	-	-	-	-	-	-	-	-	-
Florida	1	2	(D)	(D)	(D)	(D)	(D)	(D)	(D)	(D)
Illinois	2	1	(D)	(D)	(D)	(D)	(D)	(D)	(D)	(D)
Michigan	-	-	-	-	-	-	-	-	-	-
New Jersey	3	4	(D)	34	(D)	91	(D)	455.9	(D)	155
New York	2	2	(D)	(D)	(D)	(D)	(D)	(D)	(D)	(D)
North Carolina	3	1	(D)	(D)	(D)	(D)	(D)	(D)	(D)	(D)
Ohio	1	1	(D)	(D)	(D)	(D)	(D)	(D)	(D)	(D)
Oregon	-	-	-	-	-	-	-	-	-	-
Pennsylvania	-	-	-	-	-	-	-	-	-	-
Texas	-	-	-	-	-	-	-	-	-	-
Virginia	-	-	-	-	-	-	-	-	-	-
Washington	-	-	-	-	-	-	-	-	-	-
Wisconsin	-	-	-	-	-	-	-	-	-	-
Other States [2]	-	-	106	28	85	100	431.1	492.9	457	138
Total	23	19	3,047	3,298	99	100	181.7	218.7	5,536	7,212

See footnote(s) at end of table. --continued

No Action Alternative: Domestic Economic Environment

Under the No Action Alternative, 311NR Phalaenopsis would continue to be regulated by APHIS. Non-GE *Phalaenopsis* production and use is expected to continue much as it is currently. If the *F3'5'H* gene were to be found in other orchids under the No Action Alternative, there could be socioeconomic effects associated with removing the orchids from the marketplace. This situation happened with GE petunias (COGEM 2017) and was costly to the industry.

Preferred Alternative: Domestic Economic Environment

A determination of nonregulated status for 311NR Phalaenopsis is not expected to have a large effect on the *Phalaenopsis* market. 311NR Phalaenopsis would provide novel-colored flowers, which is likely desired but may not stimulate sales. For example, in a survey of 2,200 orchid purchasing customers, respondents indicated that flower color wouldn't matter for the purchase of their next orchid but matching the pot color to home décor was important (Onofrey 2011). Due to the novel flower color, 311NR Phalaenopsis may take market share from other orchid varieties, as well as other ornamental plants.

3.5.2 **International Trade**

Goods imported into a given country must meet that country's established sanitary and phytosanitary requirements. For example, plants and plant products exported to the European Union (EU) must comply with EU legislation on plant health. Likewise, seeds and plant propagating material, to include ornamental plants, must comply with specific marketing requirements to ensure plant health and quality.

Cut orchids were valued at $214 million dollars and represent 2.5% of all cut flower imports in 2019 (Yuan et al. 2021b). Japan is the largest importer of cut orchids ($62.4 million) followed by the United States at $22.9 million (Yuan et al. 2021b). Other major cut orchid importers in order of value are Italy China Vietnam, United Kingdom, France, Germany, Singapore, and Australia (Yuan et al. 2021b). The major exporters to Japan are Taiwan and Thailand. The major exporters to the United States are Thailand with a 57% share of U.S. imports of cut orchids valued at $17.1 million and the Netherlands with a 29.5% share of imports (Yuan et al. 2021b). The Netherlands and Taiwan are noted for export of cut *Phalaenopsis*; Thailand, another major exporter of cut orchids, principally exports dendrobium orchid (Yuan et al. 2021b).

For whole plants, U.S. operations typically avoid the high cost of tissue culture production by importing preflowering potted plants from Taiwan and forcing them to bloom in the United States. The United States is the major importer of Taiwan potted *Phalaenopsis* importing 38% of Taiwan's *Phalaenopsis* production estimated at $146 million in 2018 (Yuan et al. 2021b). Japan also imports significant amounts of potted *Phalaenopsis* from Taiwan and the demand for *Phalaenopsis* is increasing where *Phalaenopsis* represents 84% of the orchids imported from Taiwan (Yuan et al. 2021b). The Netherlands produces even more *Phalaenopsis* than Taiwan; in

2018 their production was valued at €410 million (Yuan et al. 2021b). Most countries do not have the phytosanitary approvals to send potted orchids into the United States. However, that is now changing as *Phalaenopsis* in the original growing container were approved for importation from China in 2016, South Korea in 2017, and Costa Rica in 2023 (pending operational approval), and a decision for import from Germany and Netherlands is pending. Therefore, Taiwan *Phalaenopsis* exports to the United States can expect more competition from other countries moving forward.

No Action Alternative: Trade Economic Environment

As discussed in section 3.5.1, most U.S. *Phalaenopsis* growers import non-flowering plants that are induced to flower in the U.S. Currently Taiwan is the major exporter but other countries are in the process of getting the phytosanitary approvals to ship potted seedlings into the United States. The United States is a net importer of cut orchids, importing over $20 million of cut orchids and producing about $7 million. Under the No Action Alternative, 311NR Phalaenopsis would remain regulated and would not be imported for cultivation in the United States. 311NR Phalaenopsis cut flowers could be imported; APHIS has previously granted exemptions for the import of GE cut chrysanthemums and carnations.

Preferred Alternative: Trade Economic Environment

311NR Phalaenopsis would be subject to the same international regulatory requirements, discussed above, as currently traded flower varieties. In general, developers have various legal, quality control, and marketing motivations to implement rigorous stewardship measures to ensure identity preservation, and compliance with international agreements and standards. By necessity, all international regulatory and industry standards and requirements must be met for marketing of 311NR Phalaenopsis. In correspondence with the developer, ISK has indicated that breeding will only be carried out at ISK's dedicated facilities. The company has indicated that all pots containing 311NR Phalaenopsis will be labeled as genetically modified and contained during production. These measures are expected to ensure identity preservation of 311NR Phalaenopsis and to minimize commingling. International movement of *Phalaenopsis* is not expected to be different under the Preferred Alternative.

International socioeconomic effects under the Preferred Alternative are not expected to be different than under the No Action Alternative.

4 THREATENED AND ENDANGERED SPECIES

The Endangered Species Act (ESA) of 1973, as amended, is a far-reaching wildlife conservation law. The purpose of the ESA is to prevent extinctions of fish, wildlife, and plant species by conserving endangered and threatened species and the ecosystems upon which they depend. To implement the ESA, the U.S. Fish and Wildlife Service (USFWS) works in cooperation with the National Marine Fisheries Service (NMFS), together “the Services,” as well as other Federal, State, and local agencies, Tribes, non-governmental organizations, and private citizens.

Before a plant or animal species can receive protection under the ESA, it must be added to the federal list of threatened and endangered wildlife and plants. Threatened and endangered (T&E) species are those plants and animals at risk of becoming extinct throughout all or part of their geographic range (endangered species) or species likely to become endangered in the foreseeable future throughout all or a significant portion of their ranges (threatened species).

The Services add a species to the list when they determine the species to be endangered or threatened because of any of the following factors:

- The present or threatened destruction, modification, or curtailment of its habitat or range;
- Overutilization for commercial, recreational, scientific, or educational purposes;
- Disease or predation;
- The inadequacy of existing regulatory mechanisms; or
- The natural or manmade factors affecting its survival.

Once a species is added to the list, protective measures apply to the species and its habitat. These measures include protection from adverse effects of federal activities.

4.1 Requirements for Federal Agencies

Section 7(a)(2) of the ESA requires that federal agencies, in consultation with the USFWS and/or the NMFS, ensure that any action they authorize, fund, or carry out is “not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat.” It is the responsibility of the federal agency taking the action to assess the effects of their action and to consult with the USFWS and NMFS if it is determined that the action “may affect” listed species or designated critical habitat (a process known as a Section 7 Consultation).

To facilitate the development of its ESA consultation requirements, APHIS met with the USFWS from 1999 to 2003 to discuss factors relevant to APHIS’ regulatory authority and effects analysis for petitions that request determination of nonregulated status of GE crop lines. By working with USFWS, APHIS developed a process for conducting an effects determination consistent with the Plant Protection Act (PPA) of 2000 (Title IV of Public Law 106-224). APHIS uses this process to help fulfill its obligations under Section 7 of the ESA for biotechnology regulatory actions.

As part of developing its EA, APHIS analyzed the potential effects of 311NR Phalaenopsis on the environment, including any potential effects to T&E species and/or critical habitat. As part of this process, APHIS thoroughly reviews GE product information and data related to the GE organism to inform the ESA effects analysis and, if necessary, the biological assessment. For each transgenic plant that APHIS receives a petition to no longer regulate, APHIS considers the following:

- A review of the biology, taxonomy, and weediness potential of the crop plant and its sexually compatible relatives;
- Characterization of each transgene with respect to its structure and function and the nature of the organism from which it was obtained;
- A determination of where the new transgene and its products (if any) are produced in the plant and their quantity;
- A review of the agronomic performance of the plant including disease and pest susceptibilities, weediness potential, and agronomic and environmental effect;
- Determination of the concentrations of known plant toxicants (if any are known in the plant);
- Analysis to determine if the transgenic plant is sexually compatible with any T&E species of plants or a host of any T&E species; and
- Any other information that may inform the potential for an organism to pose a plant pest risk.

As described below, in following this review process, APHIS has evaluated the potential effects that a determination of nonregulated status for 311NR Phalaenopsis may have, if any, on federally-listed T&E species and species proposed for listing, as well as designated critical habitat and habitat proposed for designation.

4.2 Potential Effects of 311NR *Phalaenopsis* on T&E Species and Critical Habitat

As described in further detail elsewhere in this EA, in the petition (ISK 2025), and in the draft PPRA (USDA-APHIS-BRS 2025), ISK engineered 311NR Phalaenopsis to synthesize delphinidin and exhibit novel flower color possibilities, as well as to express a commonly used selectable marker (*hpt*). APHIS considered the potential for 311NR Phalaenopsis to extend the range of production, alter production practices, and also the potential to extend production or consumer use into additional areas. As discussed in 3.1 – *Phalaenopsis* Uses and Production Practices, production of 311NR *Phalaenopsis* is not expected to differ from conventional *Phalaenopsis* in methods, acreage, or geographic range. ISK reported that horticultural characteristics and cultivation practices required for 311NR Phalaenopsis are essentially indistinguishable from practices used to grow other *Phalaenopsis* varieties. 311NR Phalaenopsis is not expected to differ from non-GE *Phalaenopsis* in growth habit, temperature, moisture, or nutritional requirements, or other physical conditions that would affect growth and survival (ISK 2025; USDA-APHIS-BRS 2025). Production and consumer use of 311NR Phalaenopsis would only differ from conventional *Phalaenopsis* as a function of consumer preferences and market responses. Although 311NR Phalaenopsis may replace certain other varieties of *Phalaenopsis* that are currently grown, APHIS does not expect the introduction of 311NR Phalaenopsis to result in an incremental increase in *Phalaenopsis* production beyond the current trends in industry growth.

The issues discussed herein focus on the potential environmental consequences that a determination of nonregulated status for *Phalaenopsis* would have on T&E species in the areas where *Phalaenopsis* are currently grown. Commercial production occurs entirely in greenhouses; small-scale cultivation occurs in consumer residences and public spaces such botanical gardens. There could be some residences or locations in tropical areas such as HI, PR, or southern FL where 311NR Phalaenopsis could be grown outside year-round. Based upon the scope of the EA and production areas identified in the Affected Environment (Chapter 3) of this EA, APHIS reviewed the USFWS list of T&E species (both listed and proposed for listing) for tropical areas in the United States (USFWS 2025). *Phalaenopsis* is not weedy nor does it occur outside of cultivation in the United States so it would not be expected to affect any critical habitat or plant species. Threatened and endangered species of potential pollinators in the tropics include the endangered, yellow-faced bees in the genus *Hylaeus* (family Colletidae), such as *Hylaeus anthracinus*, *H. assimulans*, *H. facilis*, *H. hilaris*, *H. kuakea*, *H. longiceps*, and *H. mana* (USFWS 2025). Other taxa, such as birds and other types of insects, are not expected to visit 311NR Phalaenopsis flowers based on the morphology of its flower being similar to *Phalaenopsis* flowers known to be visited by bees. No other types of pollinator has been documented to visit *Phalaenopsis* plants (Ackerman et al. 2023). However, the *F3’5’H* gene and its metabolites are widely prevalent in nature and we are unaware of reports of toxicity to bees. Similarly, the *hpt* gene has been reported to be safe for environmental use (EFSA 2004) so T&E pollinator species should not be affected. Given the absence of *Phalaenopsis* in the environment and the lack of toxicity of the GE traits and metabolites, APHIS concluded that there would be no effects on T&E species and critical habitat.

4.3 Summary of Potential Effects of 311NR Phalaenopsis on T&E Species

After reviewing the possible effects of a determination of nonregulated status of 311NR Phalaenopsis, APHIS has not identified any stressor that could affect the reproduction, numbers, or distribution of a listed T&E species or species proposed for listing. As a result, a detailed exposure analysis for individual species is not necessary. APHIS also considered the potential effect of a determination of nonregulated status of 311NR Phalaenopsis on designated critical habitat or habitat proposed for designation and could identify no differences from effects that would occur from the production of other available *Phalaenopsis* varieties. As described above, 311NR Phalaenopsis is not considered a competitive plant species. 311NR Phalaenopsis is not sexually compatible with, nor does it serve as a host species for any listed species or species proposed for listing under the ESA. Consumption of 311NR Phalaenopsis by any listed species or species proposed for listing will not result in a toxic or allergic reaction. APHIS expects no adverse effects to any listed plant or animal species or critical habitat. Based on these factors, APHIS has concluded that a determination of nonregulated status of 311NR Phalaenopsis, and the corresponding environmental release of this 311NR Phalaenopsis, will have no effect on listed species or species proposed for listing, and would not affect designated habitat or habitat proposed for designation. Because of this “no-effect” determination, consultation under Section 7(a)(2) of the ESA or the concurrences of the USFWS or NMFS are not required.

5 CONSIDERATION OF EXECUTIVE ORDERS, STANDARDS AND TREATIES RELATING TO ENVIRONMENTAL EFFECTS

5.1 Executive Orders Related to Domestic Issues

The following executive orders (EO) require consideration of the potential effects of federal actions to various segments of the population.

- **EO 13045 – Protection of Children from Environmental Health Risks and Safety Risks**

  Children may suffer disproportionately from environmental health and safety risks due to their developmental stage, higher metabolic rates, and behavior patterns, as compared to adults. This EO requires each federal agency to identify, assess, and address the potential environmental health and safety risks that may disproportionately affect children.

The No Action and Preferred Alternatives were analyzed with respect to EO 13045. Neither alternative evaluated in this EA is expected to have disproportionate adverse effects on children. As reviewed in Chapter 3 and 4, it is highly improbable the trait genes and gene products in 311NR *Phalaenopsis* present any risks to human health, nor to animal health and welfare. 311NR *Phalaenopsis* would be produced and marketed as are all other *Phalaenopsis* varieties, using the same growing practices and inputs.

- **EO 13175 – Consultation and Coordination with Indian Tribal Governments**

  Executive departments and agencies are charged with engaging in consultation and collaboration with tribal governments; strengthening the government-to-government relationship between the United States and Indian tribes; and reducing the imposition of unfunded mandates upon Indian tribes. This EO emphasizes and pledges that federal agencies will communicate and collaborate with tribal officials when proposed federal actions have potential tribal implications.

Tribal entities are recognized as independent governments and agricultural activities on tribal lands would only be conducted if approved by the tribe. Tribes would have control over any potential conflict with cultural resources on tribal properties. Approval nor denial of the petition is not expected to have any effect on Indian tribal self-governance or sovereignty, tribal treaties, or other rights.

APHIS will offer to consult and collaborate with tribal officials to ensure that they are well-informed and represented in policy and program decisions that may impact their agricultural interests, in accordance with EO 13175. A determination of nonregulated status for 311NR *Phalaenopsis* will not adversely impact cultural resources on tribal properties.

- **EO 13751 – Safeguarding the Nation from the Impacts of Invasive Species**

  Invasive species are a significant issue in the United States, causing both adverse economic and environmental impacts. This EO directs federal agencies to take action to prevent the introduction of invasive species, to provide for their control, and to minimize the economic, ecological, and human health impacts that invasive species cause.

Phalaenopsis is not listed in the United States as a noxious weed species by the Federal government (USDA-NRCS 2019b), nor is it listed as an invasive species by major invasive plant data bases. Based on observations and data submitted by the applicant and reviewed by APHIS, 311NR *Phalaenopsis* are similar in fitness characteristics to other *Phalaenopsis* varieties currently grown and is not expected to become more weedy or invasive than conventional *Phalaenopsis*. As part of its draft PPRA, APHIS evaluated the potential weediness and invasiveness of 311NR *Phalaenopsis* and concluded that it is unlikely that 311NR Phalaenopsis will become weedy or invasive in areas where it is grown (USDA-APHIS-BRS 2025).

- **EO 13186 – Responsibilities of Federal Agencies to Protect Migratory Birds**

  Federal agencies taking actions that have, or are likely to have, a measurable negative effect on migratory bird populations are directed to develop and implement, within two years, a Memorandum of Understanding (MOU) with the Fish and Wildlife Service that shall promote the conservation of migratory bird populations.

A small number of *Phalaenopsis* are grown outdoors and migratory birds could visit those *Phalaenopsis* to feed on insects on *Phalaenopsis* plants, which would provide a source of nutrition to migratory birds. As reviewed in Chapter 3, it is highly unlikely the trait genes and their products present any risks to the health of migratory birds. Delphinidin occurs naturally in several food plants, on which birds may forage (blueberries, for example) and the *hpt* gene and associated HPT enzyme are not considered toxic to wildlife (EFSA 2004; European Food Safety Authority 2009; Husain et al. 2022). Because migratory birds that forage on 311NR *Phalaenopsis* are unlikely to be adversely affected by ingesting associated insects, APHIS has concluded that a determination of nonregulated status for 311NR *Phalaenopsis* would not have a negative impact on migratory bird populations.

5.2 Executive Orders Relative to International Issues

- **EO 12114 - Environmental Effects Abroad of Major Federal Actions**

  This Order requires federal officials to take into consideration any potential environmental effects that may occur outside the United States, its territories, and possessions, that may result from actions being taken.

The United States is a member of the World Trade Organization (WTO), which facilitates harmonizing the global rules of trade between nations. The Agreement on the Application of Sanitary and Phytosanitary Measures (the "SPS Agreement"), entered into force with the establishment of the WTO on January 1, 1995, sets out the basic rules for food safety and animal and plant health standards. The SPS agreement recognizes three international organizations/frameworks that have established standards and guidelines related to SPS measures (WTO 2019), these are; the Codex Alimentarius Commission (Codex), the World Organization for Animal Health (OIE), and the International Plant Protection Convention (IPPC).

Any international trade of 311NR *Phalaenopsis* following a determination of nonregulated status would be subject to national phytosanitary requirements and be in accordance with international SPS standards, inclusive of the IPPC (plant pests and disease).

Any cultivation of 311NR *Phalaenopsis* outside of the United States, its territories, or possessions would utilize the same (or similar) growing practices and inputs as those utilized in the United States. Consequently, the sources and degree of environmental impacts that derive from *Phalaenopsis* production abroad would be no different than those described for the United States, as discussed in this EA. APHIS does not expect a significant environmental impact outside the United States in the event of a determination of nonregulated status of 311NR *Phalaenopsis*.

5.3 Federal Laws and Regulations

The laws most relevant to APHIS determinations of regulatory status are the National Environmental Policy Act of 1969 (NEPA), the Clean Water Act of 1972 (CWA), the Safe Drinking Water Act of 1974 (SDWA), the Clean Air Act of 1970 (CAA), the Endangered Species Act of 1973 (ESA), and the National Historic Preservation Act of 1966 (NHPA). Compliance with the requirements of the ESA has been addressed in Chapter 6. Compliance with the requirements of NEPA, CWA, SDWA, CAA, and NHPA, are specifically addressed in the following subsections.

5.3.1 National Environmental Policy Act (NEPA)

NEPA (42 United States Code (U.S.C) 4321, *et seq*.) is designed to ensure transparency and communication of the possible environmental effects of federal actions prior to implementation. The Act and implementing regulations require federal agencies to document, in advance and in detail, the potential effects of their actions on the human environment, so as to ensure that there is a full understanding of the possible environmental outcomes of federal actions by both the decision-makers and the public. This EA documents the potential environmental outcomes of the alternatives considered, approval or denial of ISK's petition, and is consistent with the requirements of NEPA.

5.3.2 Clean Air Act (CAA), Clean Water Act (CWA), and Safe Drinking Water Act (SDWA)

The CAA, CWA, and SDWA authorize the EPA to regulate air and water quality in the United States. Because 311NR *Phalaenopsis* are agronomically/horticulturally equivalent to currently cultivated *Phalaenopsis* varieties, with the exception of the new color, the potential sources of impacts on water resources and air quality are the same under both the No Action and Preferred Alternatives. Production of 311NR *Phalaenopsis* would entail the use of pesticides and fertilizers, which will contribute to potential effects on air quality, and potentially water quality. The sources and degree of potential effects would be no different than that which occurs with current *Phalaenopsis* production. APHIS assumes use of all pesticides on 311NR Phalaenopsis will be compliant with the EPA registration and label requirements. As discussed in Chapters 3 and 4, the change in color in 311 R *Phalaenopsis* presents no known risks to water or air quality. Considering these factors, a determination of nonregulated status for 311NR

Phalaenopsis would not lead to circumstances that resulted in non-compliance with the requirements of the CWA, CAA, and SDWA.

5.3.3 **National Historic Preservation Act (NHPA)**

The NHPA of 1966 and its implementing regulations (36 CFR part 800) requires federal agencies to: 1) determine whether activities they propose constitute "undertakings" that have the potential to cause effects on historic properties and 2) if so, to evaluate the effects of such undertakings on such historic resources and consult with the Advisory Council on Historic Preservation (i.e., State Historic Preservation Office, Tribal Historic Preservation Officers), as appropriate.

A determination of nonregulated status for 311NR *Phalaenopsis* is not a decision that would directly or indirectly result in alteration of the character or use of historic properties protected under the NHPA, nor would it result in any loss or destruction of cultural or historical resources.

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