NATIONAL ENVIRONMENTAL POLICY ACT

FINDING OF NO SIGNIFICANT IMPACT

Regarding Deregulating a Petition (19-099-01p) Under 7 CFR part 340 from: Westhoff Vertriebsgesellschaft mbH

A1-DFR petunias

United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) has developed this Finding of No Significant Impact (hereafter referred to as FONSI) to comply with the requirements of the National Environmental Policy Act (NEPA) of 1969, as amended, the Council of Environmental Quality's (CEQ) NEPA implementing regulations, and APHIS NEPA implementing procedures (7 CFR part 372). This FONSI sets forth APHIS' NEPA decision with respect to potential impacts to the human environment that could derive from a determination of nonregulated status for A1-DFR petunias.

Westhoff Vertriebsgesellschaft mbH (Westhoff), submitted a petition (19-099-01p) to the USDA APHIS, requesting that petunias developed using genetic engineering referred to as A1-DFR petunias, and any petunia lines derived from crosses of A1-DFR petunias and conventional petunias, or nonregulated petunias developed using genetic engineering, no longer be considered regulated under Title 7 of the Code of Federal Regulations part 340 (7 CFR part 340). An organism developed using genetic engineering 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. A1-DFR petunias are currently regulated by APHIS.

A1-DFR petunias (23 events that contain one or more copies of the *A1* DFR gene), have been genetically engineered to express the dihydroflavonol 4-reductase (DFR) enzyme from maize (A1-DFR) allowing the plants to produce the plant pigment pelargonidin, which is a type of anthocyanin pigment, in their flower petals. A1-DFR petunias are intended to provide additional color varieties.

As part of evaluation of Westhoff's petition, APHIS conducted an Environmental Assessment (EA) to inform APHIS' decision regarding the regulatory status of A1-DFR petunias. The EA evaluates the potential impacts of APHIS' regulatory decision on the quality of the human environment.[1] The EA did not identify any significant impacts that would derive from either an approval or a denial of the petition. Therefore, the Agency has prepared this FONSI, pursuant to 40 CFR part 1508.13, which provides a summary of the EA, and the reasons why APHIS'

[1] Under NEPA regulations, the "human environment" includes "the natural and physical environment and the relationship of people with that environment" (40 CFR § 1508.14).

decision to issue a determination of nonregulated status for A1-DFR petunias will not have a significant impact on the human environment.

The Coordinated Framework and APHIS Regulatory Authority

In 1986, the United States government issued a comprehensive regulatory policy for the regulation of products of biotechnology known as the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) (51 FR 23302, 57 FR 22984). Since 1986, the Environmental Protection Agency (EPA), Food and Drug Administration (FDA), and USDA have regulated organisms developed using genetic engineering consistent with the principles of this framework. On January 4, 2017, the USDA, EPA, and FDA released a 2017 update to the Coordinated Framework (USDA-APHIS 2018), and an accompanying National Strategy for Modernizing the Regulatory System for Biotechnology Products (ETIPCC 2017). The authorities and regulatory roles for USDA–APHIS, the EPA, and FDA are briefly summarized below.

USDA-APHIS

Protecting animal and plant health is among APHIS' primary strategic goals. APHIS provides leadership in ensuring the health and care of plants and animals. The agency's strategic goals help improve agricultural productivity and competitiveness, and contributes to the national economy and the public health. The USDA asserts that all methods of agricultural production (conventional, organic, or the use of plant varieties developed using genetic engineering) can provide benefits to the environment, consumers, and farm income.

APHIS regulates organisms developed using genetic engineering to ensure that they do not pose a plant pest risk pursuant to the Plant Protection Act (PPA) of 2000, as amended (7 USC §§ 7701 et seq.) and APHIS implementing regulations at 7 CFR part 340. APHIS regulations at 7 CFR part 340 govern the importation, interstate movement, and environmental release of organisms developed using genetic engineering that may pose a plant pest risk. An organism developed using genetic engineering is no longer subject to the PPA or to the requirements of 7 CFR part 340 when APHIS determines that an organism developed using genetic engineering is unlikely to pose a plant pest risk.

FDA

The FDA regulates organisms developed using genetic engineering under the authority of the Federal Food, Drug, and Cosmetic Act (FFDCA). The FDA is responsible for ensuring the safety and proper labeling of all plant-derived foods and feeds, including those that are genetically engineered. The FDA policy statement concerning oversight of products derived from new plant varieties, including those developed using genetic engineering, was published in the *Federal Register* on May 29, 1992 (57 FR 22984). Pursuant to this policy, the FDA uses what is termed a voluntary consultation process to ensure that human food and animal feed safety issues and other regulatory issues are resolved prior to commercial distribution of products of genetic engineering. To help developers of food and feed derived from crops developed using genetic engineering comply with their obligations pursuant under Federal food safety laws, the FDA encourages them to participate in a voluntary consultation process.

EPA

The EPA is responsible for regulating the sale, distribution, and use of pesticides, including pesticides that are produced by an organism through techniques of modern biotechnology pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The EPA sets tolerance limits for residues of pesticides on and in food and animal feed, or establishes an exemption from the requirement for a tolerance, pursuant to FFDCA. In addition, the EPA regulates certain biological control organisms pursuant to the Toxic Substances Control Act (TSCA).

APHIS' Response to Petitions for Nonregulated Status

APHIS regulations at 7 CFR part 340 govern the movement (e.g., transport, environmental release) of organisms developed using genetic engineering that may pose a plant pest risk. An organism developed using genetic engineering is no longer subject to the requirements of 7 CFR part 340 or the plant pest provisions of the PPA if APHIS determines through conduct of a Plant Pest Risk Assessment (PPRA) that it is unlikely to pose a plant pest risk.

Public Involvement

On July 25, 2019, APHIS announced in the *Federal Register* that it was making Westhoff's petition available for public review and comment to help identify potential environmental and interrelated economic impacts that APHIS should consider in evaluation of the petition.[2] APHIS accepted written comments on the petition for a period of 60 days, until midnight September 23, 2019. At the end of the comment period APHIS had received a total of nine comments – seven were in support of the Westhoff petition and two were opposed to deregulation. APHIS evaluated the comments and integrated the concerns raised into the EA. All comments received on the petition are available for public review at www.regulations.gov, Docket ID: APHIS-2019-0037.

On September 28, 2020, APHIS announced in the Federal Register it was making available the preliminary PPRA, draft EA, and preliminary finding of no significant impact (FONSI) for a 30-day public review and comment period. At the end of the comment period APHIS had received 4 public comments. Three were in support of Westhoff's petition for a determination of nonregulated status for A1-DFR petunias and one was out of scope. No new information was presented to APHIS in the comments that contributed to or altered the analyses presented in the draft EA, thus, none of the comments was deemed substantive in the sense that they warranted a formal response from APHIS. Comments received on the draft EA are available for public review at www.regulations.gov, Docket ID: APHIS-2019-0037.

Environmental Assessment and Scope of Analysis

An EA was prepared consistent with CEQ regulations (40 CFR parts 1500-1508) and USDA-APHIS NEPA implementing procedures (7 CFR part 372). APHIS developed a list of topics for consideration in the EA based on issues identified in public comments submitted on the petition and draft EA for A1-DFR petunias, other EAs and EISs evaluating petitions for nonregulated

[2] Federal Register, Vol. 84, No. 143, July 25, 2019, p. 35849 – Westhoff Vertriebsgesellschaft mbH; Availability of Petition for Determination of Nonregulated Status of Petunias Genetically Engineered for Flower Color [Docket No. APHIS-2019-0037, www.regulations.gov].

status, and the scientific literature on floriculture, plant biotechnology, and the environmental sciences. The following topics were identified as relevant to the scope of analysis (40 CFR §1508.25):

Commercial Production

Petunia Production
Pest and Pathogen Management

Physical Environment

Soils
Water Resources
Air Quality

Biological Environment

Soil Biota
Animal and Plant Communities
Gene Flow and Weediness
Biodiversity

Human Health Considerations

Public Health and Worker Safety

Socioeconomic Considerations

Domestic Economic Environment
International Trade

In addition to evaluation of potential direct and indirect impacts, potential cumulative impacts relative to these topics were also considered. Additionally, potential impacts on threatened and endangered species, as well as adherence of the regulatory decision to executive orders, and environmental laws and regulations to which the regulatory status decision may be subject were analyzed.

Alternatives Evaluated in the EA

The EA considered two alternatives in responding to Westhoff's petition, to either deny or approve the request for nonregulated status, and analyzed the potential environmental, human health, and socioeconomic impacts that may result from the two alternatives.

No Action: Deny the Petition and Continuation as Regulated

One of the alternatives that must be considered by APHIS is a "No Action Alternative," pursuant to CEQ regulations at 40 CFR § 1502.14. Under the No Action Alternative, APHIS would deny the petition. A1-DFR petunias and progeny derived from A1-DFR petunias would continue to be regulated under 7 CFR part 340. Because APHIS concluded in its PPRA that A1-DFR petunias are unlikely to pose a plant pest risk (USDA-APHIS 2020) this is not APHIS' preferred alternative. Choosing this alternative would not be an appropriate response to the petition for nonregulated status, nor satisfactorily meet the purpose and need for making a regulatory status decision pursuant to the requirements of 7 CFR part 340.

Preferred Alternative: Determination of Nonregulated Status for A1-DFR Petunias

Under this alternative, A1-DFR petunias and progeny derived from this event would no longer be regulated under the regulations at 7 CFR part 340 because it was determined that, based on the scientific evidence before the Agency, A1-DFR petunias are unlikely to pose a plant pest risk (USDA-APHIS 2020). APHIS would no longer require authorizations for introductions of A1-DFR petunias and progeny derived from this event. This alternative best satisfies the purpose and need to respond appropriately to the petition for nonregulated status pursuant to the requirements of 7 CFR § 340.6, the Agency's statutory authority under the PPA, and the biotechnology regulatory policies described for the Coordinated Framework.

Alternatives Considered but Dismissed from Detailed Analysis in the EA

APHIS evaluated several alternatives for consideration in the EA in light of the Agency's statutory authority under the PPA and APHIS implementing regulations at 7 CFR part 340, but dismissed these alternatives from detailed analysis in the EA. The alternatives considered are described in the EA along with the reasons for dismissal from detailed analysis.

Environmental Consequences of APHIS' Selected Action

The EA provides analyses of the alternatives APHIS considered, to which the reader is referred for specific details. The following table briefly summarizes the potential environmental impacts of the alternatives evaluated in the EA.

Summary of Potential Impacts for the Alternatives Considered		
Analysis	**No Action Alternative: Continue to Regulate A1-DFR Petunias**	**Preferred Alternative: Determination of Nonregulated Status for A1-DFR Petunias**
Meets Purpose and Need	No	Yes
Horticultural Production		
Acreage and Areas of Petunia Production	Petunias are primarily grown for the retail market inside greenhouses. Michigan, Ohio, New York, and Pennsylvania are the leading producers of petunia. Petunias have consistently ranked among the five most commonly sold bedding plants and are grown throughout the United States in home gardens and commercial and public landscapes. Current trends in petunia production and use are not anticipated to change.	A1-DFR petunias will provide an additional color variety of petunia and is expected to compete with other color varieties that are currently in production and offered for sale. A determination of nonregulated status for A1-DFR petunias is not expected to change the acreage or areas used for petunia seed and bedding plant production.

Summary of Potential Impacts for the Alternatives Considered		
Analysis	**No Action Alternative: Continue to Regulate A1-DFR Petunias**	**Preferred Alternative: Determination of Nonregulated Status for A1-DFR Petunias**
Horticultural Practices and Inputs	Horticultural practices and inputs used in petunia production would remain unchanged.	The change in color in A1-DFR petunias does not cause changes in growth habit, temperature tolerances, nutritional requirements, or other factors that would alter horticultural practices used in petunia production.
Physical Environment		
Soils	Growing practices and inputs used for commercial production of petunia that may impact soil resources would not change from those currently used.	The potential impacts of A1-DFR petunias production on soil quality are not expected to differ from the No Action Alternative.
Water Resources	Existing water use and water quality conditions would be expected to be unchanged.	Because A1-DFR petunias are similar to non-GE cultivated petunia, approval of the petition and subsequent commercial production of A1-DFR petunias would present the same potential risks to water resources as conventional cultivated petunia varieties.
Air Quality	Current impacts to air quality associated with petunia production practices would be expected to continue unchanged.	Sources of potential impacts on air quality are the same as those under the No Action Alternative.
Biological Resources		
Soil Biota	Current impacts to soil biota associated with petunia production practices would be expected to continue unchanged.	A1-DFR petunias are not expected to change the practices and inputs used in petunia production that could cause new impacts to soil biota.
Animal Communities	A variety of animal and insect species feed on or use petunia. Mammals and birds may use petunias for food or feed on the insects feeding on petunias. Invertebrates can feed on petunia plants or prey upon other insects as well as using petunia for pollen and nectar sources.	A1-DFR petunias would not require any change to petunia production practices. DFR and associated pelargonidin and NPTII introduced into A1-DFR petunias present negligible risk to wildlife. Potential impacts to animal communities are not anticipated to be different compared to the No Action Alternative
Plant Communities	Because petunia cultivation typically occurs in greenhouses and then plants are transplanted on the	Potential impacts to plant communities are not anticipated to be

Summary of Potential Impacts for the Alternatives Considered		
Analysis	**No Action Alternative: Continue to Regulate A1-DFR Petunias**	**Preferred Alternative: Determination of Nonregulated Status for A1-DFR Petunias**
	grounds of homes, business, and common areas such as parks for ornamental purposes, the plant communities associated with petunia production and use are limited. Potential impacts to plant communities associated with petunia production and use would be expected to continue unchanged. The impacts to plant communities from petunias in commercial or residential areas is not expected to change.	different compared to the No Action Alternative
Gene Flow and Weediness	Petunia lacks weedy properties. Petunia does not cross with other genera and hybrids of closely related species are rare in nature. No plants among the Petunia genera are on the Federal noxious weed list nor are they listed as invasive by any state. Petunia does not spread vegetatively, and roots will not form on discarded parts of a plant under outdoor conditions (Westhoff 2019).	A1-DFR petunias have been modified for a change in flower color only. The change in color in A1-DFR petunias does not cause changes in seed set, pollen availability, growth habit, temperature tolerances, nutritional requirements, or other factors that would alter where it can be grown or the potential for cross pollinating compared to currently available petunia varieties.
Biodiversity	Petunia production in greenhouses is primarily to raise young plants that will be transplanted outdoors in the built environment. Greenhouse production reduces any impacts on biodiversity. As an ornamental plant grown in beds, pots, and hanging baskets, petunia largely relates to biodiversity within the built environment by serving as a food source for pollinators.	A1-DFR petunias would not be expected to change growing practices, and therefore would not likely impact biodiversity any differently than conventional petunia.
Human and Animal Health		
Human Health	Petunias are not a food and not consumed by humans or used for animal feed. Management practices for petunia production, and the associated human health impacts, are expected to continue unchanged.	Potential impacts to human health are not anticipated to be different from those under the No Action Alternative. The EPA WPS will continue to provide the same level of protection as is currently available

Summary of Potential Impacts for the Alternatives Considered		
Analysis	**No Action Alternative: Continue to Regulate A1-DFR Petunias**	**Preferred Alternative: Determination of Nonregulated Status for A1-DFR Petunias**
Socioeconomics		
Domestic Economic Environment	Petunia production and use are expected to continue much as it is currently.	A determination of nonregulated status for A1-DFR petunias is not expected to adversely impact domestic petunia markets. A1-DFR petunias would provide novel colored flowers. This additional color variety is not expected to result in a significant increase in petunia demand or production in the United States.
International Trade	There would be no impacts on trade under the No Action Alternative.	A1-DFR petunias would be subject to the same international regulatory requirements as currently traded flower varieties, growers looking to export A1-DFR petunias or seeds would need to comply with these regulatory requirements. U.S. imports of A1-DFR petunias would no longer require authorization under 7 CFR part 340, otherwise U.S. petunia imports and exports would be unaffected by a determination of nonregulated status to A1-DFR petunias.
Coordinated Framework		
U.S. Regulatory Agencies	Because A1-DFR petunias do not contain a pesticide developed using genetic engineering and there is no change to pesticide use and A1-DFR petunias are not intended for human and animal consumption, neither EPA nor FDA have regulatory oversight.	Because A1-DFR petunias do not contain a pesticide developed using genetic engineering and there is no change to pesticide use and A1-DFR petunias are not intended for human and animal consumption, neither EPA nor FDA have regulatory oversight.
Regulatory and Policy Compliance		
ESA, CWA, CAA, SDWA, NHPA, EOs	Fully compliant	Fully compliant

Finding of No Significant Impact

The analysis in the EA indicates that there will not be a significant impact, individually or cumulatively, on the quality of the human environment as a result of this proposed action. I agree

with this conclusion and therefore find that an EIS need not be prepared. This NEPA finding is based on the following context and intensity factors (40 CFR part 1508.27).

Context

The term "context" means identification of the locations and resources that could potentially be affected by the Agency's action. The EA identified the areas in which petunia is grown and may be cultivated in the United States, and those aspects of the human environment potentially affected by the Agency's regulatory decision. This action has the potential to affect petunia production systems; environments adjacent to and associated with A1-DFR petunias production systems; and domestic and foreign horticultural markets. The areas affected by a determination of nonregulated status of A1-DFR petunias are those areas of the United States in which producers and consumers can grow A1-DFR petunias. In the United States, petunia is commercially produced in many states. Michigan, Ohio, New York, and Pennsylvania are the leading states in terms of number of producers. In 2018, there were 1,056 producers of nursery flats in the United States, 984 of hanging baskets, and 872 of pots (USDA-NASS 2019a). If all petunias produced were eventually planted in outdoor flower gardens in the United States, the planted area would be fairly small, about 419 million sq. ft. (~10,000 acres), a small area compared to the total covered area for commercial floriculture crop production of 859 million sq. ft. (USDA-NASS 2019a) and a small fraction of the 319 million acres planted in principle crops in the United States (USDA-NASS 2019b). 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).

During 2015 and 2016, bright orange-colored petunias were observed in flower boxes decorating the Helsinki railway station (Servick 2017). The cultivar at the Helsinki railways station was Bonnie Orange. Tests showed that this variety was developed using genetic engineering (Haselmair-Gosch et al. 2018). Additionally, these tests suggested the petunia was the same as that developed by Meyer (Meyer et al. 1987). Distributors apparently imported or bred the flowers without realizing the plants were varieties developed using genetic engineering. On May 2, 2017, the Germany-based horticultural firm Selecta Klemm informed APHIS that it had moved an orange petunia developed using genetic engineering into the United States (Malakoff 2017). This led to testing of numerous petunia varieties, which confirmed this particular variety and several others were developed using genetic engineering and met APHIS' regulatory definition of regulated under 7 CFR part 340. On May 16, 2017, APHIS announced to the public and industry that several varieties of petunias had been imported into the United States and distributed interstate without proper APHIS authorization (Malakoff 2017). The USDA asked the industry supply chain to voluntarily stop sale of the unauthorized varieties. APHIS worked with breeders and growers represented by the American Seed Trade Association (ASTA) and AmericanHort to ensure that all the unauthorized petunia varieties were withdrawn from distribution and destroyed. The petunia industry has voluntarily removed the unauthorized petunias from commerce.

A1-DFR petunias will provide additional color varieties of petunia and is expected to compete with other color varieties that are currently in production and offered for sale in the United States. Commercial production of petunia will continue to be dictated by the domestic and import floral market demands and choices made by consumers, not only for petunias, but for other flowers that serve similar ornamental purposes as potted plants, hanging baskets, and in

flower beds. A determination of nonregulated status for A1-DFR petunias is not expected to change the acreage, methods, and areas used for petunia seed and bedding plant production.

Intensity

Within the context discussed above, intensity means the degree or severity of potential impacts. As recommended by CEQ (40 CFR part 1508.27), the following were considered in evaluating intensity and making this NEPA determination.

1. *Impacts that may be both beneficial and adverse.*

   A determination of nonregulated status for A1-DFR petunias will have no significant environmental impact on the availability of petunia varieties. As considered and analyzed in Chapter 4 of the EA, a determination of nonregulated status for A1-DFR petunias is not expected to change the acreage, methods, and areas used for petunia seed and bedding plant production. The availability of A1-DFR petunias will not alter the areas of commercial petunia production in the United States, and there are no anticipated changes in the availability of petunia varieties on the market. A determination of nonregulated status for A1-DFR petunias will provide additional color varieties of petunia and is expected to compete with other color varieties that are currently in production and offered for sale in the United States.

2. *The degree to which the proposed action affects public health or safety.*

   Petunia is not consumed by humans and is not used as animal feed; therefore, FDA's voluntary consultation is not necessary. The potential human health impacts associated with pesticide use for the production of A1-DFR petunias would be the same as those used for conventional petunia varieties as production practices will not change. The EPA WPS will continue to provide the same level of protection as is currently available.

3. *Unique characteristics of the geographic area such as proximity to historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas.*

   The EA concluded it is unlikely that historic or cultural resources, park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas would be significantly impacted by a determination of nonregulated status for A1-DFR petunias. There are no species in the *Petunia* genus that are native to the United States, although there are several introduced (naturalized) species that derived from *Petunia* plants/seed brought to the United States during the early 1900s. Introduced petunias can be found along roadsides, edges of fields, areas along railroads, cracks along urban sidewalks and roadside curbs, edges of garden beds, vacant lots, and waste ground (Hilty 2017). Hybrids of closely related Petunia species are rare in nature with varying degrees of fertility (Jędrzejuk et al. 2017). Therefore, invasion of park lands, wetlands, wild and scenic areas, or ecologically critical areas by A1-DFR petunias or feral hybrids is considered unlikely. APHIS conducted a PPRA and concluded that it is unlikely that A1-DFR petunias will become weedy or invasive, and that it is similarly unlikely that gene introgression from A1-DFR petunias into wild *Petunia* species will increase the weediness of any A1-DFR petunias hybrids (USDA-APHIS 2020). Consequently, a determination of nonregulated status for A1-DFR petunias is not expected to have

significant impacts on historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas.

4. *The degree to which the effects on the quality of the human environment are likely to be highly controversial.*

   Approval of Westhoff's petition for nonregulated status for A1-DFR petunias is not an action considered highly controversial in nature. The EA concluded that the agronomic practices and inputs that would be used for production of A1-DFR petunias are no different than those utilized for production of current petunia varieties. Thus, the potential sources of impacts, and the nature of potential impacts on physical and biological resources that could derive from production of A1-DFR petunias are no different than that of currently cultivated petunia varieties. The change in color in A1-DFR petunias does not cause changes in growth habit, temperature tolerances, nutritional requirements, or other factors that would alter where or how it can be grown compared to non-biotech petunia varieties; they present no risk to plants, animals, and other taxa. There are no novel or unique impacts on the human environment, nor any considered controversial, that would derive from approval of the petition.

5. *The degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks.*

   The potential impacts of petunia production on the human environment are well understood and thoroughly evaluated in the EA. A1-DFR petunias will provide additional color varieties of petunia and is expected to compete with other color varieties that are currently in production and offered for sale in the United States. Commercial production of petunia will continue to be dictated by the domestic and import floral market demands and choices made by consumers, not only for petunias, but for other flowers that serve similar ornamental purposes as potted plants, hanging baskets, and in flower beds. Over a million orange petunias (presumed to be petunia varieties developed using genetic engineering) have been sold over the last 15 years (COGEM 2017); APHIS is unaware of any reports of naturalized populations of petunias developed using genetic engineering, or adversely impacted naturalized populations. APHIS is unaware of any reports of petunia populations developed using genetic engineering adversely impacting the built environment. Therefore, the impacts are not highly uncertain, and do not involve unique or unknown risks.

6. *The degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration.*

   Approval of Westhoff's petition would not establish a precedent for future actions that would result in significant impacts on the human environment, nor would it represent a decision in principle about a future decision. Approval of the petition is based upon an independent determination of whether A1-DFR petunias are unlikely to pose a plant pest risk (USDA-APHIS 2020) pursuant to 7 CFR part 340, and an environmental analysis consistent with NEPA and CEQ implementing regulations. APHIS has reviewed and approved petitions for nonregulated status since 1992. All petitions submitted were reviewed independent of the other, and determinations of regulatory status issued in part based on plant pest risk assessments and relevant NEPA analyses specific for the

organism developed using genetic engineering subject of the petition. Each petition that APHIS receives is specific for a particular organism-trait combination and undergoes an independent review to determine if the regulated organism may pose a plant pest risk. The requirements for petitions for nonregulated status, applicable to both APHIS and the petitioner, are described in 7 CFR part 340. These requirements have been reviewed above under the sections summarizing APHIS' regulatory authority, and APHIS' requirements to respond to petitions for nonregulated status.

7. *Whether the action is related to other actions with individually insignificant but cumulatively significant impacts.*

   The EA discusses potential cumulative impacts on horticultural practices and inputs; human and animal health; physical and biological resources; as well as on socioeconomic issues. Impacts from the cultivation of A1-DFR petunias would not be considered cumulatively significant and no different from that which occurs with currently cultivated petunia varieties.

8. *The degree to which the action may adversely affect districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places or may cause loss or destruction of significant scientific, cultural, or historic resources.*

   The EA concluded that approval of the petition is not an action that would directly or indirectly alter the character or use of properties protected under the National Historic Preservation Act. It would have no impact on districts, sites, highways, structures, or objects listed in, or eligible for listing in, the National Register of Historic Places, nor cause any loss or destruction of significant scientific, cultural, or historic resources.

9. *The degree to which the action may adversely affect the endangered or threatened species or its habitat that has been determined to be critical under the Endangered Species Act of 1973.*

   APHIS analyzed the potential effects of A1-DFR petunias on threatened and endangered species and critical habitat in Chapter 6 of the EA. APHIS concluded that approval of the petition for nonregulated status for A1-DFR petunias, and any subsequent commercial production of these petunia events, 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 Act or the concurrences of the U.S. Fish and Wildlife Service and National Marine Fisheries Services are not required.

10. *Whether the action threatens a violation of federal, state, or local law or requirements imposed for the protection of the environment.*

    The EA evaluated the federal, state, and local laws and regulations, executive orders, and policy related to Westhoff's petition. The EA concluded that approval of the petition would not lead to circumstances that resulted in non-compliance with federal, state, or local laws and regulations providing protections for environmental and human health.

NEPA Finding and Rationale

I have carefully reviewed the EA prepared for this NEPA finding and the input from the public involvement process. In light of the FONSI, APHIS will implement Alternative 2 as described in the EA (Determination of nonregulated status for A1-DFR petunias). This alternative meets APHIS' purpose and need to allow the safe development and use of organisms developed using genetic engineering, and is consistent with the plant pest provisions of the PPA.

As stated in CEQ regulations, "the agency's preferred alternative is the alternative which the agency believes would fulfill its statutory mission and responsibilities, giving consideration to economic, environmental, technical and other factors." The Preferred Alternative has been selected for implementation taking into consideration a number of environmental, economic, and social factors. Based upon our evaluation and analysis, the Preferred Alternative is selected because (1) it allows APHIS to fulfill its statutory mission to protect the health and value of American agriculture and natural resources using a science-based regulatory framework that allows for the safe development and use of organisms developed using genetic engineering; and (2) it allows APHIS to fulfill its regulatory obligations. As a result of the analyses conducted in the EA and summarized in this FONSI, I have concluded that granting nonregulated status to Westhoff's A1-DFR petunias will have no significant impacts on the human environment as a result of making a determination of nonregulated status.

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Bernadette Juarez
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Date

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