NATIONAL ENVIRONMENTAL POLICY ACT DECISION
AND
FINDING OF NO SIGNIFICANT IMPACT

INTERNATIONAL FLOWER DEVELOPMENTS PTY. LTD.
IFD-524Ø1-4 and IFD-529Ø1-9 *Rosa* x *hybrida* (ROSE)

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 decision document to comply with the requirements of the National Environmental Policy Act (NEPA) of 1969, as amended, the Council of Environmental Quality's (CEQ) regulations implementing NEPA, and the USDA APHIS' NEPA implementing regulations and procedures. This NEPA decision document, a Finding of No Significant Impact (FONSI), sets forth APHIS' NEPA decision and its rationale. Comments from the public involvement process were evaluated and considered in developing this NEPA decision.

In accordance with APHIS procedures implementing NEPA (7 CFR part 372), APHIS has prepared an Environmental Assessment (EA) to evaluate and determine if there are any potentially significant impacts to the human environment from a determination on the regulated status of a petition request (APHIS number 08-315-01p) by International Flower Developments Pty. Ltd. (IFD) (Victoria, Australia) for their IFD-524Ø1-4 and IFD-529Ø1-9 hybrid tea roses (*Rosa x hybrida*). This EA has been prepared in order to specifically evaluate the effects on the quality of the human environment[1] that may result from a determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 hybrid tea roses. The EA assesses alternatives to a determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 hybrid tea roses and analyzes the potential environmental and social effects that result from the proposed action and the alternatives.

Regulatory Authority

"Protecting American agriculture" is the basic charge of APHIS. APHIS provides leadership in ensuring the health and care of plants and animals. The agency improves agricultural productivity and competitiveness, and contributes to the national economy and the public health. USDA asserts that all methods of agricultural production (conventional, organic, or the use of genetically engineered varieties) can provide benefits to the environment, consumers, and farm income.

Since 1986, the United States government has regulated genetically engineered (GE) organisms pursuant to a regulatory framework known as the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) (51 FR 23302, 57 FR 22984). The Coordinated Framework, published by the Office of Science and Technology Policy, describes the comprehensive federal regulatory policy for ensuring the safety of biotechnology research and

[1] Under NEPA regulations, the "human environment" includes "the natural and physical environment and the relationship of people with that environment" (40 CFR §508.14).

products and explains how federal agencies will use existing Federal statutes in a manner to ensure public health and environmental safety while maintaining regulatory flexibility to avoid impeding the growth of the biotechnology industry. The Coordinated Framework is based on several important guiding principles: (1) agencies should define those transgenic organisms subject to review to the extent permitted by their respective statutory authorities; (2) agencies are required to focus on the characteristics and risks of the biotechnology product, not the process by which it is created; (3) agencies are mandated to exercise oversight of GE organisms only when there is evidence of "unreasonable" risk.

The Coordinated Framework explains the regulatory roles and authorities for the three major agencies involved in regulating GE organisms: USDA's APHIS, the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA).

APHIS is responsible for regulating GE organisms and plants under the plant pest authorities in the Plant Protection Act of 2000, as amended (7 USC § 7701 *et seq.*) to ensure that they do not pose a plant pest risk to the environment.

The FDA regulates GE organisms under the authority of the Federal Food, Drug, and Cosmetic Act. The FDA is responsible for ensuring the safety and proper labeling of all plant-derived foods and feeds, including those that are genetically engineered. To help developers of food and feed derived from GE crops comply with their obligations under Federal food safety laws, FDA encourages them to participate in a voluntary consultation process. All food and feed derived from GE crops currently on the market in the United States have successfully completed this consultation process. The FDA policy statement concerning regulation of products derived from new plant varieties, including those genetically engineered, was published in the Federal Register on May 29, 1992 (57 FR 22984-23005). Under this policy, FDA uses what is termed a consultation process to ensure that human food and animal feed safety issues or other regulatory issues (e.g., labeling) are resolved prior to commercial distribution of bioengineered food.

The EPA regulates plant-incorporated protectants under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and certain biological control organisms under the Toxic Substances Control Act (TSCA). 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.

Regulated Organisms

The APHIS Biotechnology Regulatory Service's (BRS) mission is to protect America's agriculture and environment using a dynamic and science-based regulatory framework that allows for the safe development and use of GE organisms. APHIS regulations at 7 Code of Federal Regulations (CFR) part 340, which were promulgated pursuant to authority granted by the Plant Protection Act, as amended (7 United States Code (U.S.C.) 7701–7772), regulate the introduction (importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is no longer subject to the plant pest provisions of the Plant Protection Act or to the regulatory requirements of 7 CFR part 340 when APHIS determines that it is unlikely to pose a plant pest risk. A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent used in engineering the

organism belongs to one of the taxa listed in the regulation (7 CFR 340.2) and is also considered a plant pest. A GE organism is also regulated under Part 340 when APHIS has reason to believe that the GE organism may be a plant pest or APHIS does not have information to determine if the GE organism is unlikely to pose a plant pest risk.

A person may petition the agency that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, is no longer regulated under the plant pest provisions of the Plant Protection Act or the regulations at 7 CFR 340. The petitioner is required to provide information under § 340.6(c)(4) related to plant pest risk that the agency may use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act when APHIS determines that it is unlikely to pose a plant pest risk.

APHIS' Response to Petition for Nonregulated Status

Under the authority of the plant pest provisions of the Plant Protection Act and 7 CFR part 340, APHIS has issued regulations for the safe development and use of genetically engineered organisms. As required by 7 CFR 340.6, APHIS must respond to petitioners that request a determination of the regulated status of genetically engineered organisms, including genetically engineered plants such as IFD-524Ø1-4 and IFD-529Ø1-9 roses with novel colored flowers. When a petition for nonregulated status is submitted, APHIS must make a determination if the genetically engineered organism is unlikely to pose a plant pest risk. If APHIS determines based on its Plant Pest Risk Assessment (PPRA) that the genetically engineered organism is unlikely to pose a plant pest risk, the genetically engineered organism is no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340.

International Flower Developments Pty. Ltd. (IFD) (Victoria, Australia) has submitted a petition to APHIS seeking a determination that their IFD-524Ø1-4 and IFD-529Ø1-9 hybrid tea roses (*Rosa x hybrida*) are unlikely to pose a plant pest risk and, therefore, should no longer be a regulated article under regulations at 7 CFR Part 340.

IFD-524Ø1-4 and IFD-529Ø1-9 hybrid tea roses (*Rosa x hybrida*)

According to IFD, both IFD-524Ø1-4 and IFD-529Ø1-9 are engineered to produce a novel flower color in the same shades of color as that developed for their GE carnation of which the cut flowers have been traded in the USA for several years, with no reports of adverse effects (IFD 2010). Both of these rose lines include added genes for flavonoid 3'-5' hydroxylase (from a black pansy, *Viola tricolor*) and anthocyanin 5-acyltransferase (from torenia, *Torenia hybrida*). These rose lines also contain the neomycin phosphotransferase gene (from the bacterium *Escherichia coli*) which was used for selection in the laboratory. Both of these rose lines have been approved for commercial use in Japan, including unregulated environmental release (IFD 2010). One line, IFD-524Ø1-4, has also been approved for commercial use/environmental release in Australia (IFD 2010) (costs of the regulatory request for the other rose line and the small size of the Australian market led the company to only request approval for one line there). Addition of the Viola and Torenia genes alter the anthocyanin biosynthesis pathways and shunt some of these biochemicals toward production of the delphinidin-based anthocyanins, resulting in production of blue pigments in these rose lines. Production of these blue pigments alters the

flower color of these rose lines as noted in the Petition comparing Figure 14 (p. 39) with Figures 15 and 16 (pp. 40) (IFD 2010). IFD intends to allow trials, propagation and commercial production of approximately 3-6 million cut flowers of these two varieties in the U.S., most likely in California (Chandler 2010a), as well as possibly import cut flowers into the U. S., (IFD 2010). Production of these two varieties in nurseries for producing plants for planting into gardens is a possibility, but this option is not in the present IFD plans (Chandler 2010b).

Coordinated Framework Review

IFD-524Ø1-4 and IFD-529Ø1-9 roses are not designed for human and animal consumption nor do they contain any GE pesticides. FDA has a voluntary consultation process to ensure that human food and animal feed safety issues or other regulatory issues (e.g., labeling) are resolved prior to commercial distribution of biotechnology-derived food. Because IFD-524Ø1-4 and IFD-529Ø1-9 are not intended for human and animal consumption and hybrid tea roses generally are not consumed as food or feed or used as a source of fragrances, FDA's voluntary consultation is not necessary. Because IFD-524Ø1-4 and IFD-529Ø1-9 do not contain any GE pesticides or the genetic machinery necessary to produce them, or tolerance to herbicides, EPA consultation is not required.

Scope of the Environmental Analysis

The analysis of environmental consequences addresses the potential impact to the human environment of a determination of nonregulated status of IFD's IFD-524Ø1-4 and IFD-529Ø1-9 roses.

Public Involvement

On April 13, 2011, APHIS published a notice in the Federal Register (76 FR 20623-20624, Docket No. APHIS-2010-0040) announcing the availability of the IFD petition, and the APHIS PPRA and draft EA for a 60-day public review and comment period. Comments were required to be received on or before June 13, 2011. All comments were carefully analyzed to identify new issues, alternatives, or information. A total of 2 comments were received during the comment period with one expressing support of the EA's preferred alternative and the other expressing opposition to a determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 roses. No new issues, alternatives or substantive new information were identified in any of the comments received by APHIS. Responses to the comments are attached to this FONSI.

Major Issues Addressed in the EA

The issues considered in the EA were developed based on APHIS' determination that certain genetically engineered organisms are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340, and for this particular EA, the specific petition seeking a determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 roses. Issues discussed in the EA were developed by considering comments and information received from the public in response to publication of the draft EA, the petition for a determination of nonregulated status, and supporting materials submitted by IFD; as well as issues raised in public comments submitted for other environmental assessments of genetically engineered organisms, concerns raised in lawsuits, as well as those issues that have been raised by various stakeholders. These issues, including those regarding the agricultural production of roses using various production

methods, and the environmental and food/feed safety of genetically engineered plants were addressed to analyze the potential environmental impacts of IFD-524Ø1-4 and IFD-529Ø1-9 roses.

The EA describes the alternatives considered and evaluated using the identified issues. The following issues were identified as important to the scope of the analysis (40 CFR 1508.25):

Management Considerations:
- Size and Areas of Rose Production
- Growing Practices
- Organic Gardening and Production

Environmental Considerations
- Water Use
- Soil
- Air Quality
- Climate Change
- Animals
- Plants
- Biological Diversity
- Gene Movement

Public Health Considerations
- Human Health
- Worker Safety

Socioeconomic Considerations
- Domestic Economic Environment
- Trade Economic Environment
- Social Environment

Alternatives that were fully analyzed
The EA analyzes the potential environmental consequences of a determination of nonregulated status of IFD's IFD-524Ø1-4 and IFD-529Ø1-9 roses. To respond favorably to a petition for nonregulated status, APHIS must determine that IFD's IFD-524Ø1-4 and IFD-529Ø1-9 roses are unlikely to pose a plant pest risk. Based on its Plant Pest Risk Assessment (USDA-APHIS 2010) APHIS has concluded that both of IFD's IFD-524Ø1-4 and IFD-529Ø1-9 roses are unlikely to pose a plant pest risk. Therefore APHIS must determine that IFD-524Ø1-4 and IFD-529Ø1-9 roses are no longer subject to 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. Two alternatives were evaluated in the EA: (1) no action and (2) determination of nonregulated status of IFD's IFD-524Ø1-4 and IFD-529Ø1-9 roses. APHIS has assessed the potential for environmental impacts for each alternative in the "Environmental Consequences" section of the EA.

<u>No Action:</u> Continuation as a Regulated Article

Under the No Action Alternative, APHIS would deny the petition. IFD-524Ø1-4 and IFD-529Ø1-9 roses and progeny derived from them would continue to be regulated articles under the regulations at 7 CFR part 340. Permits issued or notifications acknowledged by APHIS would still be required for introductions of IFD-524Ø1-4 and IFD-529Ø1-9 roses and measures to ensure physical and reproductive confinement would continue to be implemented. APHIS might choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from the unconfined cultivation of IFD-524Ø1-4 and IFD-529Ø1-9 roses.

This alternative is not the preferred alternative because APHIS has concluded through a Plant Pest Risk Assessment (USDA-APHIS 2010) that IFD-524Ø1-4 and IFD-529Ø1-9 roses are unlikely to pose a plant pest risk. 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.

Preferred Alternative: Determination that IFD-524Ø1-4 and IFD-529Ø1-9 Roses are No Longer a Regulated Articles

Under this alternative, IFD-524Ø1-4 and IFD-529Ø1-9 roses and progeny derived from them would no longer be regulated articles under the regulations at 7 CFR part 340. IFD-524Ø1-4 and IFD-529Ø1-9 roses are unlikely to pose a plant pest risk (USDA-APHIS 2010). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of IFD-524Ø1-4 and IFD-529Ø1-9 roses and progeny derived from this event. This alternative best meets the agency's 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 Plant Protection Act. Because the agency has concluded that IFD-524Ø1-4 and IFD-529Ø1-9 roses are unlikely to pose a plant pest risk, a determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 roses 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.

Under this alternative, growers may have future access to IFD-524Ø1-4 and IFD-529Ø1-9 roses and progeny derived from this event if the developer decides to commercialize IFD-524Ø1-4 and IFD-529Ø1-9 roses.

Alternatives Considered but Rejected from Further Consideration

APHIS assembled a list of alternatives that might be considered for IFD-524Ø1-4 and IFD-529Ø1-9 roses. The agency evaluated these alternatives, in light of the agency's authority under the plant pest provisions of the Plant Protection Act, and the regulations at 7 CFR part 340, with respect to environmental safety, efficacy, and practicality to identify which alternatives would be further considered for IFD-524Ø1-4 and IFD-529Ø1-9 roses. Based on this evaluation, APHIS rejected several alternatives. These alternatives are discussed briefly below along with the specific reasons for rejecting each.

Prohibit any IFD-524Ø1-4 and IFD-529Ø1-9 Roses from Being Released

In response to public comments that stated a preference that no GE organisms enter the marketplace, APHIS considered prohibiting the release of IFD-524Ø1-4 and IFD-529Ø1-9 roses, including denying any permits associated with the field testing. APHIS determined that this

alternative is not appropriate given that APHIS has concluded that IFD-524Ø1-4 and IFD-529Ø1-9 roses are unlikely to pose a plant pest risk (USDA-APHIS 2010).

In enacting the Plant Protection Act, Congress found that:

> [D]ecisions affecting imports, exports, and interstate movement of products regulated under [the Plant Protection Act] shall be based on sound science... § 402(4).

On March 11, 2011, in a Memorandum for the Heads of Executive Departments and Agencies, the White House Emerging Technologies Interagency Policy Coordination Committee developed broad principles, consistent with Executive Order 13563, to guide the development and implementation of policies for oversight of emerging technologies (such as genetic engineering) at the agency level. In accordance with this memorandum, agencies should adhere to Executive Order 13563 and, consistent with that Executive Order, the following principle, among others, to the extent permitted by law, when regulating emerging technologies:

> "[D]ecisions should be based on the best reasonably obtainable scientific, technical, economic, and other information, within the boundaries of the authorities and mandates of each agency"

Based on our Plant Pest Risk Assessment (USDA-APHIS 2010) and the scientific data evaluated therein, APHIS has concluded that both of IFD's IFD-524Ø1-4 and IFD-529Ø1-9 roses are unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of IFD-524Ø1-4 and IFD-529Ø1-9 roses.

Approve the petition in part

The regulations at 7 CFR 340.6(d)(3)(i) state that APHIS may "approve the petition in whole or in part." For example, a determination of nonregulated status in part may be appropriate if there is a plant pest risk associated with some, but not all lines described in a petition. Because APHIS has concluded that both of IFD's IFD-524Ø1-4 and IFD-529Ø1-9 roses are unlikely to pose a plant pest risk, there is no regulatory basis under the plant pest provisions of the Plant Protection Act for considering approval of the petition only in part.

Isolation Distance between IFD-524Ø1-4 and IFD-529Ø1-9 Roses and Non-GE Roses and Geographical Restrictions

In response to public concerns of gene movement between GE and non-GE plants, APHIS considered requiring an isolation distance separating IFD-524Ø1-4 and IFD-529Ø1-9 roses from non-GE rose production. However, because APHIS has concluded that IFD-524Ø1-4 and IFD-529Ø1-9 roses are unlikely to pose a plant pest risk (USDA-APHIS 2010), an alternative based on requiring isolation distances would be inconsistent with the statutory authority under the plant pest provisions of the Plant Protection Act and regulations in 7 CFR part 340.

APHIS also considered geographically restricting the production of IFD-524Ø1-4 and IFD-529Ø1-9 roses based on the location of production of non-GE roses in organic production systems in response to public concerns regarding possible gene movement between GE and non-GE plants. However, as presented in APHIS' plant pest risk assessment for IFD-524Ø1-4 and

IFD-529Ø1-9 roses, there are no geographic differences associated with any identifiable plant pest risks for IFD-524Ø1-4 and IFD-529Ø1-9 roses (USDA-APHIS 2010). This alternative was rejected and not analyzed in detail because APHIS has concluded that IFD-524Ø1-4 and IFD-529Ø1-9 roses do not pose a plant pest risk, and will not exhibit a greater plant pest risk in any geographically restricted area. Therefore, such an alternative would not be consistent with APHIS' statutory authority under the plant pest provisions of the Plant Protection Act and regulations in Part 340 and the biotechnology regulatory policies embodied in the Coordinated Framework.

Based on the foregoing, the imposition of isolation distances or geographic restrictions would not meet APHIS' 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 Plant Protection Act. Nevertheless, APHIS is not expecting significant effects. However, individuals might choose on their own to geographically isolate their non-GE rose productions systems from IFD-524Ø1-4 and IFD-529Ø1-9 roses or to use isolation distances and other management practices to minimize gene movement between rose fields.

Requirement of Testing For IFD-524Ø1-4 and IFD-529Ø1-9 Roses

During the comment periods for other petitions for nonregulated status, some commenters requested USDA to require and provide testing to identify GE products in non-GE production systems. APHIS notes there are no nationally-established regulations involving testing, criteria, or limits of GE material in non-GE systems. Such a requirement would be extremely difficult to implement and maintain. Additionally, because IFD-524Ø1-4 and IFD-529Ø1-9 roses do not pose a plant pest risk (USDA-APHIS 2010), the imposition of any type of testing requirements is inconsistent with the plant pest provisions of the Plant Protection Act, the regulations at 7 CFR part 340 and the biotechnology regulatory policies embodied in the Coordinated Framework. Therefore, imposing such a requirement for IFD-524Ø1-4 and IFD-529Ø1-9 roses would not meet APHIS' purpose and need to respond appropriately to the petition in accordance with its regulatory authorities.

Environmental Consequences of APHIS' Selected Action

The EA contains a full analysis of the alternatives to which we refer the reader for specific details. The following table briefly summarizes the results for each of the issues fully analyzed in the Environmental Consequences section of the EA.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Non-regulated Status
Meets Purpose and Need and Objectives	**No**	**Yes**
Unlikely to pose a plant pest risk	Satisfied through use of regulated field trials	Satisfied—risk assessment (USDA-APHIS 2010)
Management Practices		
Size and Areas of Rose Production	Unchanged	Unchanged

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Non-regulated Status
Growing practices	Unchanged	Unchanged
Pesticide use	Unchanged	Unchanged
Organic Gardening and Production of Roses	Unchanged	Unchanged
Environment		
Water use	Unchanged	Unchanged
Soil	Unchanged	Unchanged
Air Quality	Unchanged	Unchanged
Climate Change	Unchanged	Unchanged
Animals	Unchanged	Unchanged
Plants	Unchanged	Unchanged
Biological Diversity	Unchanged	Unchanged
Gene Movement	Unchanged	Unchanged
Human and Animal Health		
Public Health: Risk to Human Health	Unchanged	Unchanged
Public Health: Risk to Worker Safety	Unchanged	Unchanged
Socioeconomic		
Domestic Economic Environment	Unchanged	Unchanged
Trade Economic Environment	Unchanged	Unchanged
Other Regulatory Approvals		
U. S.	Unchanged	Unchanged
Compliance with Other Laws		
CWW, CAA. EOs	Unchanged	Unchanged

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 determination is based on the following context and intensity factors (40 CFR 1508.27):

Context – The term "context" recognizes potentially affected resources, as well as the location and setting in which the environmental impact would occur. As described in the EA, this action has potential to affect the production of roses, including surrounding environments and

agricultural workers; public health; and foreign and domestic floriculture markets. IFD intends to allow trials, propagation and commercial production of approximately 3-6 million cut flowers of these two varieties in the U.S., most likely in California (Chandler 2010a), as well as possibly import cut flowers into the U. S., (IFD 2010). Field nursery production of IFD-524Ø1-4 and IFD-529Ø1-9 is not anticipated at the present time (Chandler 2010a). If field production of IFD-524Ø1-4 and IFD-529Ø1-9 does occur in the future, they will be two of over 100 varieties of roses available to the floral industry (Society of American Florists 2010) that could be produced on the 1100-1200 acres and 20-25 million plants of nursery rose production. A determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 is not expected to alter the production level of roses as the new GE trait (IFD-524Ø1-4 and IFD-529Ø1-9) changes only the color of the rose flower and does not change the growth habits compared to conventional varieties (USDA-APHIS 2010). Although IFD-524Ø1-4 and IFD-529Ø1-9 will have a new and unique color among roses, they will provide an additional variety to the approximately 120 varieties of roses currently available to the U.S. floral market (Society of American Florists 2010). This additional variety is not expected to have a measurable increase on production levels or land acreage used for rose production in the U.S. since it will be competing for the same market share as the roses that are in current production. Commercial production levels of roses will continue to be dictated by the domestic and import floral markets.

Intensity – Intensity is a measure of the degree or severity of an impact based upon the ten factors. The following factors were used as a basis for this decision:

1. *Impacts that may be both beneficial and adverse.*
   A determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 will have no significant impact in relation to the availability of rose varieties or production practices. As discussed in Chapter 4 of the EA, a determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 is not expected to alter the production level of cut flowers of roses or container and bare root stock as the new GE trait (IFD-524Ø1-4 and IFD-529Ø1-9) changes only the color of the rose flower and does not change the growth habit, growth rate or resistance to diseases or insects (IFD 2010; USDA-APHIS 2010). A determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 will not change the growing practices or pesticides used in the production of cut roses, container roses or garden roses in the U.S. Although IFD-524Ø1-4 and IFD-529Ø1-9 will have a new and unique color among roses, they will provide an additional variety to the approximately 120 varieties of roses currently available to the U.S. floral market (Society of American Florists 2010). This additional variety is not expected to have a measurable increase on production levels or land acreage used for rose production in the U.S. since it will be competing for the same market share as the roses that are in current production. The petitioner has noted that their goal for the new varieties is an annual U.S. production of 3-6 million cut flowers once the new varieties become established in the marketplace (Chandler 2010a). This number of flowers represents 7 to 10% of the 2009 U.S. cut rose production and 0.16 to 0.33% of total U.S. usage of cut roses. Since 2000, U.S. production of cut roses has fallen from 186 million flowers to 42 million in 2009, the proposed production of 6 million cut flowers of IFD-524Ø1-4 and IFD-529Ø1-9 will most likely only slow the rate of annual decrease in U.S. production for a short time. Production levels of roses will continue to be dictated by the domestic and import

floral markets. Both domestic and import varieties of roses will continue to be available to consumers.

2. *The degree to which the proposed action affects public health or safety.*
A determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 will have no significant impact on human or animal health. As discussed in Chapters 2 and 4 of the EA, hybrid tea roses are not generally consumed as food or used as a source of perfume and no adverse effects of consuming IFD-524Ø1-4 and IFD-529Ø1-9 have been identified. The genes introduced into these rose lines result directly in production of the F3'5'H and 5AT proteins and indirectly in production of delphinidin, a blue pigment. Delphinidin and delphinidin derivatives are contained in many common foods in relatively large amounts (USDA-ARS 2007; IFD 2010). Anyone consuming these foods, therefore, consumes delphinidin as well as the F3'5'H and 5AT proteins required for its production. The 5AT protein is also found in foods containing other related anthocyanin pigments. Fresh blueberries contain approximately 40-50 times the amount of delphinidin than found in these rose lines (USDA-ARS 2007). Anthocyanins have a very low toxicity (IPCS INCHEM 2010). APHIS has reviewed this information and has determined that in the unlikely event these GE hybrid tea roses are consumed as food, there would be no adverse effects to humans by eating flowers or hips of IFD-524Ø1-4 and IFD-529Ø1-9 roses.

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.*
There are no unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas that would be adversely impacted by a determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9. The common agricultural practices that would be carried out under the proposed action will not cause major ground disturbance, do not cause any physical destruction or damage to property, do not cause any alterations of property, wildlife habitat, or landscapes, and do not involve the sale, lease, or transfer of ownership of any property. This action is limited to a determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9. This additional variety is not expected to have a measurable increase on production levels or land acreage used for rose production in the U.S. since it will be competing for the same market share as the roses that are in current production. Commercial production levels of roses will continue to be dictated by the domestic and import floral markets. This action would not convert land use to nonagricultural use and therefore would have no adverse impact on prime farm land. The transgenes in IFD-524Ø1-4 and IFD-529Ø1-9 change only the flower color and have no effect on growth habit, growth rate, or resistance to diseases or insects (IFD 2010; USDA-APHIS 2010). A determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 will not change the growing practices or pesticides used in the production of cut roses, container roses or garden roses in the U.S. Growing practices associated with IFD-524Ø1-4 and IFD-529Ø1-9 roses would be the same as conventional rose production. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate potential impacts to the human environment. In the event of a determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9, the action is not likely to affect historic or cultural resources,

park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas that may be in close proximity to rose production sites.

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

The effects on the quality of the human environment from a determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 are not highly controversial. Although there is some opposition to a determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9, this action is not highly controversial in terms of size, nature or effect on the natural or physical environment. As discussed in Chapter 4 of the EA, a determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 is not expected to alter the production level of cut flowers of roses or container and bare root stock. Although IFD-524Ø1-4 and IFD-529Ø1-9 will have a new and unique color among roses, they will provide an additional variety to the approximately 120 varieties of roses currently available to the U.S. floral market (Society of American Florists 2010). This additional variety is not expected to have a measurable increase on production levels or land acreage used for rose production in the U.S. since it will be competing for the same market share as the roses that are in current production. Commercial production levels of roses will continue to be dictated by the domestic and import floral markets. The petitioner has noted that their goal for the new varieties is an annual U.S. production of 3-6 million cut flowers once the new varieties become established in the marketplace (Chandler 2010a). This number of flowers is 7 to 10% of the 2009 U.S. cut rose production and 0.16 to 0.33% of total U.S. usage of cut roses. The transgenes in IFD-524Ø1-4 and IFD-529Ø1-9 change only the flower color and have no effect on growth habit, growth rate, or resistance to diseases or insects (IFD 2010; USDA-APHIS 2010). A determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 will not change the growing practices or pesticides used in the production of cut roses, container roses or garden roses in the U.S. Growing practices associated with IFD-524Ø1-4 and IFD-529Ø1-9 roses would be the same as conventional rose production. The effect of IFD-524Ø1-4 and IFD-529Ø1-9 on wildlife, plants or biodiversity is no different than that of conventionally grown roses in the U.S. During the public comment period, APHIS received one comment letter opposing a determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9. APHIS has addressed these concerns in the response to public comments document attached to this FONSI based on scientific evidence found in peer-reviewed, scholarly, and scientific journals.

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

Based on the analysis documented in the EA the possible effects on the human environment are well understood. The effects of the proposed activities are not highly uncertain and do not involve unique or unknown risks on the natural or physical environment. According to IFD, both IFD-524Ø1-4 and IFD-529Ø1-9 are engineered to produce a novel flower color in the same shades of color as that developed for their GE carnation of which the cut flowers have been traded in the USA for several years, with no reports of adverse effects (IFD 2010). As discussed in Chapter 4 of the EA, a determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 is not expected to have a measurable increase on production levels or land acreage used for rose production in the U.S. since it will be competing for the same market share as the roses

that are in current production. The transgenes in IFD-524Ø1-4 and IFD-529Ø1-9 change only the flower color and have no effect on growth habit, growth rate, or resistance to diseases or insects (IFD 2010; USDA-APHIS 2010). A determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 will not change the growing practices or pesticides used in the production of cut roses, container roses or garden roses in the U.S. Growing practices associated with IFD-524Ø1-4 and IFD-529Ø1-9 roses would be the same as conventional rose production. Furthermore, because these rose varieties do not produce pollen or seed with transgenes, have poor seed set, have poor seed germination, and have poor vegetative propagation characteristics, gene movement would not likely occur. The new proteins NPT II, F3'5'H, 5AT, and the anthocyanin delphinidin added to the soil by IFD-524Ø1-4 and IFD-529Ø1-9 are already present in some widely grown genetically engineered crops and are naturally present in many foods and flowers that are widely grown with no effects. Since varying soils and soil microbes have been exposed to these same or similar proteins and the resulting anthocyanin delphinidin, no impacts are expected. The genes introduced into these rose lines result directly in production of the F3'5'H and 5AT proteins and indirectly in production of delphinidin, a blue pigment. Delphinidin and delphinidin derivatives are contained in many common foods in relatively large amounts (USDA-ARS 2007; IFD 2010). The effect of IFD-524Ø1-4 and IFD-529Ø1-9 on wildlife, plants or biodiversity is no different than that of conventionally grown roses in the U.S.

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.*
A determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 would not establish a precedent for future actions with significant effects or represent a decision in principle about a future decision. Similar to past regulatory requests reviewed and approved by APHIS, a determination of nonregulated status will be based upon an independent determination on whether an organism is unlikely to pose a plant pest risk pursuant to the regulatory requirements of 7 CFR part 340. Each petition that APHIS receives is specific to a particular GE organism and undergoes this independent review to determine if the regulated article poses a plant pest risk. Under the authority of the plant pest provisions of the Plant Protection Act and 7 CFR Part 340, APHIS has issued regulations for the safe development and use of GE organisms. As required by 7 CFR 340.6, APHIS must respond to petitioners who request a determination of the regulated status of GE organisms, including GE plants such as IFD-524Ø1-4 and IFD-529Ø1-9. When a petition for nonregulated status is submitted, APHIS must make a determination if the GE organism is unlikely to pose a plant pest risk. If APHIS determines based on its Plant Pest Risk Assessment that the genetically engineered organism is unlikely to pose a plant pest risk, the genetically engineered organism is no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340. APHIS regulations at 7 CFR part 340, which were promulgated pursuant to authority granted by the Plant Protection Act, as amended (7 United States Code (U.S.C.) 7701–7772), regulate the introduction (importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is no longer subject to the plant pest provisions of the Plant Protection Act or to the regulatory requirements of 7 CFR part 340 when APHIS determines that it is unlikely to pose a plant pest risk. A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector

agent used in engineering the organism belongs to one of the taxa listed in the regulation (7 CFR 340.2) and is also considered a plant pest. A GE organism is also regulated under Part 340 when APHIS has reason to believe that the GE organism may be a plant pest or APHIS does not have information to determine if the GE organism is unlikely to pose a plant pest risk. A person may petition the agency that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, is no longer regulated under the plant pest provisions of the Plant Protection Act or the regulations at 7 CFR 340. The petitioner is required to provide information under § 340.6(c)(4) related to plant pest risk that the agency may use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act when APHIS determines that it is unlikely to pose a plant pest risk.

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

No significant cumulative effects were identified through this assessment. The EA discussed cumulative effects on rose management practices, physical and biological environments, human and animal health, and the socioeconomic environment and concluded that such impacts were not significant. A cumulative effects analysis is included for each environmental issue analyzed in Chapter 4 of the EA. In the event of a determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9, these varieties may be stacked (combined) by traditional breeding techniques with conventional varieties or other nonregulated GE rose varieties, if and when additional GE varieties become available. There is no guarantee that IFD-524Ø1-4 and IFD-529Ø1-9 will be stacked with any particular non-GE or GE rose varieties that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340, as company plans and market demands play a significant role in those business decisions. Thus, predicting all potential combinations of stacked varieties that could be created using both non-GE and GE rose varieties that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340 is hypothetical and purely speculative.

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 historical resources.*

A determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 will not adversely impact cultural resources on tribal properties. Any farming activities that may be taken by farmers on tribal lands are only conducted at the tribe's request; thus, the tribes have control over any potential conflict with cultural resources on tribal properties. A determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 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 would they likely cause any loss or destruction of significant scientific, cultural, or historical resources. This action is limited to a determination of non-regulated status of IFD-524Ø1-4 and IFD-529Ø1-9. A determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 will not change the growing practices or pesticides used in the production of cut roses, container roses or garden roses in the U.S. Growing practices associated with IFD-524Ø1-4 and IFD-529Ø1-9 roses would be the same as conventional rose production. Applicant's adherence to EPA label use restrictions for all pesticides will mitigate potential impacts

to the human environment. A determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected under the NHPA. In general, common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or audible elements to areas in which they are used that could result in effects on the character or use of historic properties. For example, there is potential for audible effects on the use and enjoyment of a historic property when common agricultural practices, such as the operation of tractors and other mechanical equipment, are conducted close to such sites. A built-in mitigating factor for this issue is that virtually all of the methods involved would only have temporary effects on the audible nature of a site and can be ended at any time to restore the audible qualities of such sites to their original condition with no further adverse effects. Additionally, these cultivation practices are already being conducted throughout the rose production regions. The cultivation of IFD-524Ø1-4 and IFD-529Ø1-9 does not inherently change any of these agronomic practices so as to give rise to an impact under the NHPA.

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

As described in Chapter 4 of the EA, APHIS has analyzed the potential for effects from cultivation of IFD-524Ø1-4 and IFD-529Ø1-9 and their progeny on federally listed threatened and endangered species (TES) and species proposed for listing, as well as designated critical habitat and habitat proposed for designation, as required under Section 7 of the Endangered Species Act. After reviewing possible effects of a determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9, APHIS has reached a conclusion that the release of IFD-524Ø1-4 and IFD-529Ø1-9 roses, following a determination of nonregulated status, would have no effect on federally listed threatened or endangered species or species proposed for listing, nor would it affect designated critical habitat or habitat proposed for designation.

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

The proposed action would be in compliance with all federal, state, and local laws. Because the agency has concluded that IFD-524Ø1-4 and IFD-529Ø1-9 are unlikely to pose a plant pest risk, a determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 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. IFD-524Ø1-4 and IFD-529Ø1-9 roses are not designed for human and animal consumption nor do they contain any GE pesticides. Because IFD-524Ø1-4 and IFD-529Ø1-9 are not intended for human and animal consumption and hybrid tea roses generally are not consumed as food or feed or used as a source of fragrances, FDA's voluntary consultation is not necessary. Because IFD-524Ø1-4 and IFD-529Ø1-9 do not contain any GE pesticides or the genetic machinery necessary to produce them, or tolerance to herbicides, EPA consultation is not required. There are no other Federal, state, or local permits that are needed prior to the implementation of this action.

NEPA Decision and Rationale

I have carefully reviewed the EA prepared for this NEPA determination and the input from the public involvement process. I believe that the issues identified in the EA are best addressed by selecting Alternative 2 (Determination that IFD-524Ø1-4 and IFD-529Ø1-9 roses are No Longer Regulated Articles). This alternative meets APHIS' purpose and need to allow the safe development and use of genetically engineered organisms consistent with the plant pest provisions of the Plant Protection Act.

As stated in the 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 based on consideration of a number of environmental, regulatory, and social factors. Based upon our evaluation and analysis, Alternative 2 is selected because (1) it allows APHIS to fulfill its statutory mission to protect America's agriculture and environment using a science-based regulatory framework that allows for the safe development and use of genetically engineered organisms; and (2) it allows APHIS to fulfill its regulatory obligations. As APHIS has not identified any plant pest risks associated with IFD-524Ø1-4 and IFD-529Ø1-9 roses, the continued regulated status of IFD-524Ø1-4 and IFD-529Ø1-9 roses would be inconsistent with the plant pest provisions of the PPA, the regulations codified at 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework. For the reasons stated above, I have determined that a determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 roses will not have any significant environmental effects.

Michael C. Gregoire

8/24/2011

Michael C. Gregoire
Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Services
U.S. Department of Agriculture

Date:

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Attachment
Finding of No Significant Impact
Response to Comments
Petition 08-315-01p

APHIS received a comment that touched on a number of points that the submitter felt was relevant to APHIS' determination decision on the regulated status of IFD-524Ø1-4 and IFD-529Ø1-9. Those points are addressed here, as are two questions the commenter presented.

1. Comment: Complex questions relating to release of genetically engineered woody plants in the environment remain unresolved and baseline biological information is lacking. Genetically engineered roses should be released with "great caution."

Response: APHIS agrees that there is much information that is not known about the biology of huge numbers of woody species and their various complex interactions in both managed landscapes as well as natural ecosystems. The petition at hand, however, is specific in that it is for a hybrid rose with just two added genes from pansy (flavonoid 3', 5'-hydroxylase) and torenia (anthocyanin 5-acyltransferase), resulting in the production and accumulation of blue delphinidin-based pigments in the flowers. The commenter suggests no explanation or plausible hypothesis as to how addition of these two genes, with the resulting pigment production, constitutes a hazard or any possible plant pest risk. As risk is defined as a function of a hazard and exposure to that hazard (Wilkinson, et al. 2003), APHIS did not identify any hazard associated with production of these pigments in these roses, and therefore did not identify any plant pest risk associated with any type of environmental release (USDA-APHIS 2010).

2. Comment: There is a history of introduced roses (e.g., *Rosa multiflora*) becoming invasive in the U.S. and gene flow among a variety of Rosa species has been documented. The commenter further objects to APHIS' use of the term "wild rose" and believes that this use suggests nativity or benign presence.

Response: APHIS also recognizes that *Rosa multiflora* is an introduced species in the U.S. and is considered a weed or noxious weed by a number of states and weed references (http://plants.usda.gov/java/profile?symbol=ROMU, accessed June 17, 2011). Of the over 100 species or interspecific hybrids of Rosa noted on the USDA Plants database (http://plants.usda.gov/java/, accessed June 17, 2011), however, only 3 are considered to have significant weedy or invasive characteristics (IFD 2010, page 13). Other than these few species, the vast majority of other Rosa species (both introduced and native) are not noted as being invasive or otherwise weedy (see Table 1, page 14 in IFD 2010 which contains a sampling of many of these species). The Florigene roses which are the subject of the petition, however, are considered hybrid tea roses and are not noted in any reference that APHIS could locate as being a weed or invasive. These and other cultivated roses have a history of safe use in the U.S. And as pointed out above, the commenter does not propose a plausible hypothesis on how the insertion of these two genes would cause this rose to become invasive.

Depending upon the context in the EA, APHIS' use of the term "wild" when referring to roses could refer to either native or introduced species which have escaped cultivation and are found

growing in the "wild", or to any number of native roses which are often noted as having diploid genomes. In either case, APHIS disagrees that the term necessarily suggests nativity or a benign presence.

3. Comment: The documents overlook the persistence of rose bushes in unmanaged landscapes and may have the potential to become invasive.

Response: While the commenter notes that rose bushes persist in diverse unmanaged landscapes, no note is made of what species or hybrids these might be. As noted in the EA and in published literature, hybrid tea roses living in unmaintained locations are usually not long-lived (see p. 17 in EA; Shaw 1983) and populations of hybrid tea roses have never been reported in the wild (IFD 2010, p. 4; USDA-NRCS 2010). Grafting of hybrid tea roses onto suitable/vigorous rootstocks (including Rosa multiflora) is extremely common as is sprouting of those rootstocks from axillary buds (http://www.heirloomroses.com/care/rootstock/, accessed June 17, 2011). The commenter has provided no supporting evidence or citations indicating that hybrid tea roses have become invasive in the U.S.

4. Comment: These roses present no significant benefits to society.

Response: While the commenter may believe that these roses provide no benefit to society, those involved in their development as well as those who have already purchased these varieties in other countries would likely disagree. It is also reasonable to assume that anyone in the business of growing and selling roses in the U.S. (a multi-million dollar industry) (see pp 21-22 in EA) would also disagree. Regardless, APHIS does not make this value judgment and does not base its decisions under 7 CFR part 340 regulations on "benefits to society," but rather whether the new GE organism poses a risk as a plant pest under the plant pest provisions of the Plant Protection Act.

5. Comment: How stable is this rose chimera?

Response: The petition provides no information on the genetic stability of these rose varieties. Lacking such specific information, APHIS assumes that they are as genetically stable as any other L1-type chimeras. The developer and growers recognize the value of maintaining the chimeric nature of these roses for their unique flower color and can be expected to select for this trait at every opportunity. Some authors have noted that periclinal chimeras can be quite stable (Szymkowiak and Sussex, 1996; Jackson, 2008). Regardless of the genetic stability of these roses, and as noted previously, APHIS identified no hazard associated with production of these pigments in these roses, and therefore did not identify any plant pest risk associated with any type of environmental release (USDA-APHIS 2010).

6. Comment: Do these rose plants generate GE seed and progeny?

Response: While this point may be of interest to the commenter, APHIS did not find this point critical to its review of the petition in order to make a plant pest determination and therefore did not specifically request this information from the applicant. As the applicant pointed out, hybrid tea roses generally show poor reproduction (low fruit set, poor seed germination, few seeds per

hip) and those being grown for commercial production almost never produce hips or seed. Regardless of whether GE seed are produced or not, however, APHIS did not identify any hazard associated with production of these pigments in these roses, and therefore did not identify any plant pest risk associated with any type of environmental release (USDA-APHIS 2010).

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