# Assessment of Plant Pest Risk for International Flower Developments Pty. Ltd. IFD-524Ø1-4 and IFD-529Ø1-9 *Rosa* x *hybrida* (rose) varieties

International Flower Developments Pty. Ltd. (IFD) (Victoria, Australia) has petitioned the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture for a determination that IFD-524Ø1-4 and IFD-529Ø1-9 roses (*Rosa* x *hybrida*) are unlikely to pose a plant pest risk and, therefore, should no longer be regulated articles under APHIS' regulations at 7 CFR part 340. APHIS administers 7 CFR part 340 under the authority of the plant pest provisions of the Plant Protection Act of 2000[1]. This plant pest risk assessment was conducted to determine whether IFD-524Ø1-4 and IFD-529Ø1-9 are unlikely to pose a plant pest risk.

## History of Development of IFD-524Ø1-4 and IFD-529Ø1-9 *Rosa* x *hybrida* varieties

Working with a rose grower in the U.S., Florigene and IFD have been researching and developing two lines of genetically engineered roses since 2004. 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, including environmental release, in Japan (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 (IFD 2010).

## Description of added genes

Florigene's IFD-524Ø1-4 and IFD-529Ø1-9 roses (*Rosa* x *hybrida*) were produced using disarmed *Agrobacterium tumefaciens* (IFD 2010) and contain 3 transgene fragments (IFD 2010) from plasmid pSPB130 (IFD 2010):

(1) A nopaline synthase promoter/ neomycin phosphotransferase gene/ nopaline synthase terminator (NOS/NPT II/ NOS) fragment:

- The NOS promoter is from *Agrobacterium tumefaciens* and drives production of the *npt II* gene.

---

[1] Section 403 (14) of the Plant Protection Act (7USC Sec 7702(14)) defines plant pest as:
"Plant Pest - The term "plant pest" means any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: (A) A protozoan. (B) A nonhuman animal. (C) A parasitic plant. (D) A bacterium. (E) A fungus. (F) A virus or viroid. (G) An infectious agent or other pathogen. (H) Any article similar to or allied with any of the articles specified in the preceding subparagraphs."

- The *npt II* gene (from *Escherichia coli*) results in production of neomycin phosphotransferase and confers tolerance to the antibiotic kanamycin. Kanamycin is used to select for transgenic tissues under laboratory conditions.
- The NOS terminator is from *Agrobacterium tumefaciens*.

(2) A cauliflower mosaic virus 35S promoter/ flavonoid 3’, 5’- hydroxylase gene/ nopaline synthase fragment (CaMV35S/ F3’5’H/ NOS) fragment:

- The enhanced 35S promoter from cauliflower mosaic virus results in production of flavonoid 3’, 5’- hydroxylase.
- The flavonoid 3’, 5’-hydroxylase gene from *Viola tricolor* results in production of this biochemical.
- The NOS terminator is from *Agrobacterium tumefaciens*.

(3) A cauliflower mosaic virus 35S promoter/ anthocyanin 5-acyltransferase/ nopaline synthase fragment (CaMV35S/ 5AT/ NOS) fragment:

- The enhanced 35S promoter from cauliflower mosaic virus drives production of anthocyanin 5-acyltransferase.
- The anthocyanin 5-acyltransferase gene from *Torenia hybrida* results in production of this biochemical.
- The NOS terminator is from *Agrobacterium tumefaciens*.

Production of F3’5’H and 5AT enzymes shunts production of anthocyanins in these rose lines away from the cyanidin based anthocyanins (pink) and toward production of delphinidin based anthocyanins (blue) (IFD 2010).

Southern blots were used to analyze gene insertion from plasmid pSPB130 into the rose genome and to examine the integrity and expression of the inserted DNA. APHIS evaluated Florigene’s Southern blot data and came to several conclusions regarding insertion of the various genes into these 2 rose lines. Based on gel quantitation analysis of DNA, there are between 1 and 4 copies of each of the genes (*npt II*, *F3’5’H*, and *5AT*) in both IFD-524Ø1-4 and IFD-529Ø1-9. Additionally, the Southern blots show the presence of multiple DNA bands (IFD 2010) indicating that it is also likely that some gene rearrangements have occurred. The DNA banding patterns does indicate that these genes were inserted differently in each of the two rose lines.

Florigene also provided Northern analyses documenting production of RNA from the inserted genes (IFD 2010). Each gene was expressed in the transgenic plants and there was no expression noted in the control non-transformed rose line.

Further, Florigene presented data on production of delphinidin and cyanidin in the petals of these roses. Both transgenic lines showed accumulation of delphinidin (a blue anthocyanin) and much decreased production of cyanidin (a red anthocyanin) (IFD 2010). The control non-transformed rose did not produce delphinidin but did produce cyanidin.

## *Plant Pest Risk Assessment*

APHIS has prepared a Plant Pest Risk Assessment in response to a petition (APHIS No. 08-315-01p) from International Flower Developments Pty Ltd. APHIS regulation 7 CFR 340.6(c) (4) stipulates the information needed to be considered in a petition for nonregulated status. APHIS uses information submitted by the applicant related to plant pest risk characteristics, disease and pest susceptibilities, expression of the gene product, new enzymes, or changes to plant metabolism, weediness of the regulated article, any impacts on the weediness of any other plant with which it can interbreed, and the transfer of genetic information to organisms with which it cannot interbreed for IFD-524Ø1-4 and IFD-529Ø1-9 roses. Issues related to agricultural or cultivation practices and the effects of the regulated article on non-target organisms will be considered in the Environmental Assessment for these rose lines.

Based on information on the biology of rose (http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1, accessed 1/26/10), data presented in the Petition and scientific data relevant to a discussion of plant pest risk, APHIS has concluded the following regarding IFD-524Ø1-4 and IFD-529Ø1-9 roses:

### Potential impacts of altered disease and pest susceptibilities

USDA-APHIS assessed whether IFD-524Ø1-4 and IFD-529Ø1-9 roses are likely to have significantly altered disease and pest susceptibilities. The assessment encompasses a consideration of introduced traits and interactions with pests and diseases.

Hybrid tea roses (*Rosa* x *hybrida*) are not considered plant pests in the United States. None of the gene sequences derived from the plant pests (*Agrobacterium* and cauliflower mosaic virus) that were incorporated into these rose lines result in the production of infectious agents or disease symptoms in plants, and so they are unlikely to pose a plant pest risk. The description of the genetic modifications, including genetic elements, expression of the gene products and their functions in these roses has been summarized above.

Cultivated hybrid tea roses are susceptible to numerous insect pests and diseases. Florigene has noted some of the major ones (IFD 2010). A variety of insecticides, miticides and other pesticides are commonly used on roses (http://urbanext.illinois.edu/roses/disease.cfm, accessed 1/25/10; http://www.ipm.ucdavis.edu/PMG/PESTNOTES/pn7466.html, accessed 1/25/10).

Florigene has contracted for growing these rose lines in greenhouses in California for over 4 years. The grower (Jackson and Perkins Wholesale, Inc.) has noted that these rose lines grow normally in all respects (IFD 2010). They further make note of the major pests of roses in California: two spotted spider mites, powdery mildew and downy mildew. They also indicate that all of these pests are controlled using common treatments and conventional protocols (IFD 2010). These rose lines have also been grown extensively in

Columbia under typical rose cultivation conditions there. The grower there indicates that both the transgenic and non-transgenic parental lines are susceptible to mildew but that there was no difference between the transgenic and non-transgenic plants (IFD 2010).

Finally, this information submitted by Florigene indicates that there are no significant differences in terms of pest or disease susceptibilities between these rose lines and their non-transgenic counterparts.

### Potential impacts from new gene products, changes to plant metabolism or composition

As a point of reference, Figure 4 in the Petition (p. 22) presents the basic biochemical pathways for production of anthocyanins in plants.

New proteins produced in both IFD-524Ø1-4 and IFD-529Ø1-9 include the following:

1. Neomycin phosphotransferase (NPT II)
2. Flavonoid 3’, 5’-hydroxylase (F3’5’H)
3. Anthocyanin 5- acyltransferase (5AT)

NPT II is a common protein found in a number of genetically engineered plants that have been widely planted across the U.S. and in other parts of the world. In every case, no issues related to health or environmental safety have been noted (APHIS petitions 04-317-01p, 04-264-01p, 01-137-01p, 01-206-02p, 01-206-01p, 95-352-01p, 96-051-01p, 95-045-01p, 94-308-01p) (USDA-APHIS 2011). NPT II confers tolerance to the antibiotic kanamycin and is used in a laboratory setting to select tissues transformed with the genes of interest.

Flavonoid 3’, 5’-hydroxylase (F3’5’H) is an enzyme that is widely found in nature in plants producing anthocyanins, most often blue colors. This enzyme can be found in grapes (Bogs 2006), petunia (Toguri 1993), eggplant (*Solanum melongena*) (Chapple 1998), gentian, torenia, campanula and many other plants (Tanaka 2006). F3’5’H is in the cytochrome P450 family of enzymes (designated in the CYP75A subfamily) (Nelson 2009, http://drnelson.utmem.edu/CytochromeP450.html, accessed 1/26/10). Plant species lacking flavonoid 3’-5’-hydroxylase, such as non-engineered roses, do not make the blue delphinidin-based anthocyanins (Deng 2001).

Anthocyanin 5-acyltransferase (5AT) is also an enzyme that is widely found in nature in plants producing anthocyanins. In the anthocyanin biosynthesis pathways, this enzyme, as well as related anthocyanin acyltransferases, act to alter the biochemical structure of anthocyanin glucosides (AGS) (such as pelargonidin GS, cyanidin GS, and delphinidin GS) and make the resulting pigment (anthocyanin) more chemically stable in the plant cell (Nakayama et al 2003).

As described above, compositional assessment data supplied in the Petition regarding production of DNA, RNA and delphinidin supports the conclusion that IFD-524Ø1-4 and

IFD-529Ø1-9 roses contain introduced *f3'5'h* and *5at* genes from Florigene plasmid pSPB130 (IFD 2010).

Florigene also provided an assessment of delphinidins found in common foods and common flowers (IFD 2010). As noted in the tables, many foods, which are consumed widely, and ornamental flowers, which are grown widely, contain measurable quantities of delphinidin. None of the foods or ornamental plants noted are known to pose unique environmental risks because of the presence of delphinidin, its precursor biochemicals or catalytic enzymes (i.e., F3'5'H or 5AT) in the anthocyanin pathways. Specific data on toxicity and potential environmental effects of F3'5'H and 5AT is sparse but information on the chemistry of delphinidins and other anthocyanins is noted (Beheshti 2008; Vilanova 2009; Yu 2006). None of the documents identified or noted raise environmental concerns related to new gene products, changes in plant metabolism or plant composition.

Based on all the noted considerations, APHIS concludes that IFD-524Ø1-4 and IFD-529Ø1-9 roses pose no more of a plant pest risk from new gene products, changes to plant metabolism or composition than conventional hybrid tea roses.

### Potential impacts from outcrossing of IFD-524Ø1-4 and IFD-529Ø1-9 roses to wild relatives

Florigene has described the biology of roses, including hybrid tea roses, in its Petition (IFD 2010). They note that the first hybrid tea roses were produced in France in 1867 and that since then, hundreds of new cultivars of hybrid tea roses have been introduced. They also note that cultivated rose is the most widely produced cut flower crop in the world and that over 60 million rose plants are planted each year just to meet demand for cut flower production. The Australian Office of Gene Technology Regulator (OGTR) has also produced an extensive document on the biology of *Rosa* x *hybrida* (http://www.health.gov.au/internet/ogtr/publishing.nsf/Content/rose-3/$FILE/biologyrose09.pdf, accessed 1/25/10) and completed a risk assessment of one of these rose lines (IFD-524Ø1-4) in 2009 (http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir090-4/$FILE/dir090rarmp.doc, accessed 1/25/10). They describe the taxonomy of roses, rose species, centers of diversity and domestication, development and commercialization of modern rose cultivars, cultivation practices, breeding work (including use of "sports" as well as irradiation induced mutations), plant morphology, plant development and reproduction, biochemistry, biotic and abiotic interactions, disease and insect pests and weediness. Most of the information in those documents is directly relevant to this application and plant pest risk assessment and is incorporated here by reference.

Florigene's description and analysis of IFD-524Ø1-4 and IFD-529Ø1-9 roses indicates that they are both L1 periclinal chimeras[2]. The significance of this is that the *f3'5'h* and *5at* genes introduced are only found and expressed in the epidermal tissues and cannot be

[2] An L-I periclinal chimera is a type of plant chimera in which the L-I cell layer has a different genetic make-up than the L-II and L-III cell layers. The L-I cell layer gives rise to epidermal tissues of a plant while the L-II and L-III layers give rise to reproductive tissues, vascular tissues and other internal plant tissues.

passed on to progeny through cross pollination (i.e., outcrossing). Florigene demonstrated this in the various pollination and *in situ* hybridization experiments they conducted during development of these lines (IFD 2010). Florigene analyzed over 100 seeds of hybrid pollinations with grandiflora and floribunda roses and found none that contained the IFD-524Ø1-4 and IFD-529Ø1-9 transgenes. They also analyzed 19 seeds from pollinations with wild rose (*Rosa multiflora*) and found none that contained the introduced genes. They also conducted specific RNA hybridization experiments using petal tissues of control and transgenic lines and identified stained cells only in the epidermis of the transgenic rose lines (IFD 2010).

In assessing the risk of gene introgression from IFD-524Ø1-4 and IFD-529Ø1-9 roses into its sexually compatible relatives, APHIS considers two primary issues: 1) the potential for gene flow and introgression and, 2) the potential impact of introgression.

Given the demonstrated L-I chimeric nature of these rose lines, the potential for gene flow and introgression into sexually compatible relatives of rose is essentially zero. Since gene flow cannot occur, any potential impact of introgression, therefore, is also zero.

### Potential impacts based on the relative weediness of IFD-524Ø1-4 and IFD-529Ø1-9 rose.

APHIS assessed whether Florigene IFD-524Ø1-4 and IFD-529Ø1-9 roses are any more likely to become weeds than the non-transgenic recipient rose line, or other rose currently cultivated. The assessment encompasses a thorough consideration of the basic biology of rose and an evaluation of unique characteristics of these rose lines.

The biology and cultivation practices of hybrid tea rose have been well described (http://www.health.gov.au/internet/ogtr/publishing.nsf/Content/rose-3/$FILE/biologyrose09.pdf) and Florigene has also provided information on *Rosa x hybrida* cultivation, taxonomy, pollination, weediness and potential modes of gene flow (IFD 2010). Cultivated hybrid tea roses are all complex hybrids (IFD 2010) derived from breeding work done over centuries from more than 5 different rose species and numerous rounds of selection and cross hybridization at each step. Cut flower rose varieties are the most widely cultivated cut flower crop worldwide with sales of over 6 billion stems per year (IFD 2010). Florigene has noted that USDA lists over 100 species of *Rosa* in its Plants database (http://plants.usda.gov/). Only 3 of these *Rosa* species are common weeds in the U.S. (*Rosa arkansana, Rosa multiflora, and Rosa rugosa*) (http://plants.usda.gov/java/noxiousDriver#state) and *Rosa arkansana* is native to the U.S. None of the *Rosa* species are listed as Federal noxious weeds.

In the U.S., *Rosa* x *hybrida* is not listed as a weed in several major weed references (Crockett 1977; Holm et al. 1979; Muenscher 1980) nor is it listed as a noxious weed species by the U.S. Federal Government (http://www.aphis.usda.gov/plant_health/permits/organism/federal_noxious_weeds.shtml, accessed 12/22/09). As noted by Florigene, these roses also do not readily propagate by vegetative means (IFD 2010). Because of the L-I chimeric nature of these rose lines, they also will not disperse the genes for *f3'5'h* and *5at* by pollen. As is typical of hybrid tea roses grown for cut flowers, the likelihood of moving genes around by seed is very small as these roses are cut and harvested long before hips or seeds would mature. Compared to the non-transgenic progenitor roses, these attributes are no different.

Weediness for the purposes of this part of the plant pest risk assessment is an attribute, which causes a crop to act as a weed due to the addition of genes, in comparison to the non-transgenic comparator. If the fitness of these rose lines improves in natural or agricultural ecosystems due to the inserted DNA, the potential for weediness could increase. The following analysis of the inserted DNA is intended to document that IFD-524Ø1-4 and IFD-529Ø1-9 roses have a negligible likelihood of increased weediness. As described previously, these rose lines differ only in the expression of the F3'5'H and 5AT enzymes which ultimately result in production of blue delphinidin-based anthocyanins.

Florigene collected data on numerous phenotypical features of these rose lines. Data collected related to plant height, flower stem length, flower height, flower diameter, petal length and width, number of pistils, number of stamens, and others (IFD 2010). While some of these characteristics showed statistical differences between the non-transgenic and transgenic lines, none of these characteristics stand out as ones that would provide a fitness advantage to these lines in an unmanaged situation. Florigene also collected data on pollen viability, pollen grain germination, and pollen diameter (IFD 2010). None of the data on pollen characteristics showed any statistical significance between the non-transgenic and transgenic lines.

None of the characteristics that APHIS considers in its assessment of weediness point to the potential for these rose lines to become more weedy or invasive than the non-transgenic comparator lines. APHIS concludes that introduction of these rose lines do no result in increased plant pest risk related to weediness.

## Potential Impacts on Target and Non-target Organisms, Including Beneficial Organisms

Based on the data provided by the applicant and existing literature, APHIS evaluated the potential for deleterious effects or significant impacts of these rose lines on non-target or beneficial organisms.

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. Florigene notes that delphinidin and delphinidin derivatives are contained in many common foods in relatively large amounts (IFD 2010). Anyone or anything 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 (IFD 2010). As noted by Florigene, the amount of delphinidin found in these rose lines is approximately 100 times less than that found in fresh blueberries (IFD 2010). Florigene also notes that, as a group, anthocyanins have a very low toxicity (IFD 2010; http://www.inchem.org/, accessed 1/25/10).

In addition to this lack of toxicity associated with these rose lines, Florigene notes that these roses will be grown in a limited number of locations under highly controlled conditions by experienced rose growers (IFD 2010). As such, exposure to organisms outside these conditions will be extremely limited.

This data submitted by the applicant indicates that the interactions between these rose lines and other roses, including the control lines, are similar. Considering all this, APHIS concludes that Florigene rose lines IFD-524Ø1-4 and IFD-529Ø1-9 are unlikely to pose safety risks to non-target or beneficial organisms.

### Potential impacts from transferring genetic information from IFD-524Ø1-4 and IFD-529Ø1-9 rose to organisms with which it cannot interbreed.

APHIS examined the potential for the new genetic material inserted into these rose lines to be horizontally transferred to other organisms without sexual reproduction and whether such an event could lead directly or indirectly to disease, damage, injury or harm to plants, including the creation of more virulent pathogens. First, many genomes (or parts thereof) have been sequenced from bacteria that are closely associated with plants including *Agrobacterium* and *Rhizobium* (Kaneko et al. 2000; Wood et al. 2001; Kaneko et al. 2002). There is no evidence that these organisms contain genes derived from plants. Second, in cases where review of sequence data implied that horizontal gene transfer occurred, these events are believed to occur on an evolutionary time scale on the order of millions of years (Koonin et al. 2001; Brown 2003). Third, transgene DNA promoters and coding sequences are optimized for plant expression, not prokaryotic bacterial expression. Thus even if horizontal gene transfer occurred, proteins corresponding to the transgenes are not likely to be produced. Fourth, the FDA has evaluated horizontal gene transfer from the use of antibiotic resistance marker genes, and concluded that the likelihood of transfer of antibiotic resistance genes from plant genomes to microorganisms in the gastrointestinal tract of humans or animals, or in the environment, is remote (Council for Biotechnology Information, 2001; http://vm.cfsan.fda.gov/~dms/opa-armg.html, accessed 1/26/10). Finally, a recent review of issues related to horizontal gene transfer concluded that this type of gene transfer is unlikely to occur and poses negligible risks to human health or the environment (Keese 2008). Therefore APHIS concludes that horizontal gene transfer is unlikely to occur and thus poses no significant environmental or plant pest risk.

### Conclusion

APHIS has reviewed and conducted a plant pest risk assessment on Florigene's IFD-524Ø1-4 and IFD-529Ø1-9 roses. Due to the lack of plant pest risk from the inserted genetic material, the lack of weediness characteristics of these rose lines, the lack of atypical responses to disease or plant pests, the lack of deleterious effects on non-targets or beneficial organisms in the agro-ecosystem, and the lack of horizontal gene transfer, APHIS concludes that IFD-524Ø1-4 and IFD-529Ø1-9 roses are unlikely to pose a plant pest risk.

## Reference:


Bogs, J., A. Ebadi, D. McDavid, and S.P. Robinson. 2006. Identification of the Flavonoid Hydroxylases from Grapevine and Their Regulation during Fruit Development. Plant Phys. 140: 279-291.

Beheshiti, E.H. 2008. Characterization of antioxidant activities from fruits rich in delphinidin or malvidin anthocyanins. M.S. Thesis in Food Science, The University of British Columbia.

Brown, J. R. 2003. Ancient horizontal gene transfer. Genetics. 4:121-132.

Chapple, C. 1998. Molecular-genetic Analysis of Plant Cytochrome P450-dependent Monooxygenases. Annu. Rev. Plant Physiol. Plant Mol. Biol. 49: 311-343.

Council for Biotechnology Information. 2001. The Use of Antibiotic Resistance Markers to Develop Biotech Crops. (http://www.foodsafety.ksu.edu/articles/12/ant_res_mark_council4biotech.pdf, accessed 1/26/10).

Crockett, L. (1977) Wildly Successful Plants: North American Weeds. University of Hawaii Press, Honolulu, Hawaii. 609 pp.

Deng, C and T.M. Davis. 2001. Molecular identification of the yellow fruit color (*c*) locus in diploid strawberry: a candidate gene approach. Theor. Appl. Genet. 103: 316-322.

Gebhard, F., Smalla, K. 1998 Transformation of *Acinetobacter* sp. strain BD413 by transgenic sugar beet DNA. Apl. Environ. Microbiol. 64, 1550-1554.

Holm, L., Pancho, J. V., Herbarger, J. P., and Plucknett, D. L. (1979) A Geographical Atlas of World Weeds. John Wiley and Sons, New York. 391 pp.

IFD (2010). Petition for the determination of nonregulated status for Rosa x hybrida (rose) IFD-524Ø1-4 and IFD-529Ø1-9 varieties. Submitted by K. Terdich, Registration Manager. International Flower Developments Pty. Ltd (See Table http://www.aphis.usda.gov/biotechnology/not_reg.html).

Johnson, R., Narvaez, J., AN, G., Ryan, C.A. (1989) Expression of proteinase inhibitors I and II in transgenic tobacco plants: Effects on natural defense against *Manduca sexta* larvae. Proc. Natl. Acad. Sci. USA 86:9871-75

Kaneko, T., Y. Nakamura, S. Sato, E. Asamizu, T. Kato, and S. Sasamoto. 2000. Complete genome structure of the nitrogen-fixing xymbiotic bacterium *Mesorhizobium loti*. DNA Research. 7:331-338.

Kaneko, T., Y. Nakamura, S. Sato, K. Minamisawa, T. Uchiumi, S. Sasamoto, A. Watanabe, K. Idesawa, M. Iriguchi, K. Kawashima, M. Kohara, M. Matsumoto, S. Shimpo, H. Tsuruoka, T. Wada, M. Yamada, and S. Tabata. 2002. Complete genomic sequence of nitrogen-fixing symbiotic bacterium *Bradyrhizobium japonicum.* USDA 110. DNA Research.

Keese, P. 2008. Risks from GMOs due to Horizontal Gene Transfer. Environ. Biosafety Res. 7: 123-149.

Koonin, E. V., K. S. Makarova, and L. Aravind. 2001. Horizontal gene transfer in prokaryotes: quantification and classification. Annual Review of Microbiology. 55:709-742.

Muenscher, W. C. (1980) Weeds. Second Edition. Cornell University Press, New York and London. 586 pp.

Nakayama, T., H. Suzuki, and T. Nishino. 2003. Anthocyanin acyltransferases: specificities, mechanism, phylogenetics, and applications. J. Molec. Catalysis B: Enzymatic. 23: 117-132.

Nelson, D.R. 2009. The Cytochrome P450 Homepage. Human Genomics 4: 59-65. (http://drnelson.utmem.edu/CytochromeP450.html)

Tanaka, Y. 2006. Flower colour and cytochromes P450. Phytochem Rev. 5: 283-291.

Toguri, T., M. Azuma, and T. Ohtani. 1993. The cloning and characterization of a cDNA encoding a cytochrome P450 from the flowers of *Petunia hybrida.* Plant Sci. 94: 119-126.

USDA-APHIS. 2006. Federal Noxious Weed List as of January 26, 2010. http://www.aphis.usda.gov/plant_health/plant_pest_info/weeds/index.shtml.

USDA-APHIS (2011). "Petitions for Nonregulated Status Granted or Pending by APHIS." Retrieved June, 2011, from http://www.aphis.usda.gov/biotechnology/not_reg.html.

USDA, NRCS. 2010. The PLANTS Database (http://plants.usda.gov, January 25, 2010). National Plant Data Center, Baton Rouge, LA 70874-4490 USA.

Vilanova, M., M. Santalla, and A. Masa. 2009. Environmental and genetic variation of phenolic compounds in grapes (*Vitis vinifera*) from northwest Spain. J. Agric. Sci. 147: 683-697.

Wood, D. W., J. C. Setubal, R. Kaul, D. E. Monks, J. P. Kitajima, V. K. Okura, Y. Zhou, L. Chen, G. E. Wood, N. F. Almeida Jr., L. Woo, Y. Chen, I. T. Paulsen, J. A. Eisen, P. D. Karp, D. Bovee Sr., P. Chapman, J. Clendenning, G. Deatherage, W. Gillet, C. Grant, T. Kutyavin, R. Levy, M.-J. Li, E. McClelland, A. Palmieri, C. Raymond, G. Rouse, C. Saenphimmachak, Z. Wu, P. Romero, D. Gordon, S. Zhang, H. Yoo, Y. Tao, P. Biddle, M. Jung, W. Krespan, M. Perry, B. Gordon-Kamm, L. Liao, S. Kim, C. Hendrick, Z.-Y. Zhao, M. Dolan, f. Chumley, S. V. Tingey, J.-F. Tomb, M. P. Gordon, M. V. Olson, and E. W. Nester. 2001. The genome of the natural genetic engineer *Agrobacterium tumefaciens* C58. Science. 294: 2317-2323.

Yu, O., M. Matsuno, and S. Subranmanian. 2006. Flavonoid Compounds in Flowers: Genetics and Biochemistry. In: Floriculture, Ornamental and Plant Biotechnology, Volume I. Global Science Books, UK. pp. 282-292.

# International Flower Developments Pty. Ltd. Petition (08-315-01p) for Determination of Nonregulated Status of Events IFD-524Ø1-4 and IFD-529Ø1-9 Rosa x hybrida (rose)

## OECD Unique Identifiers: IFD-524Ø1-4 and IFD-529Ø1-9

## Final Environmental Assessment

**July 2011**

**Agency Contact**
**Cindy Eck**
**Biotechnology Regulatory Services**
**USDA, APHIS**
**Riverdale, MD 20737Phone: (301) 734-0667**
**Fax: (301) 734-8669**
Cynthia.A.Eck@aphis.usda.gov

# Table of Contents

# I. Purpose & Need

**Regulatory Authority**

"Protecting American agriculture" is the basic charge of the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (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 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 Animal and Plant Health Inspection Service (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.

**Petition for Determination of Nonregulated Status (08-315-01p): International Flower Developments Pty. Ltd. (IFD) IFD-524Ø1-4 and IFD-529Ø1-9 Roses (Rosa x hybrida)**

International Flower Developments Pty. Ltd. (IFD) (Victoria, Australia) submitted a petition (08-315-01p) to APHIS seeking a determination of non-regulated status of their IFD-524Ø1-4 and IFD-529Ø1-9 hybrid tea roses (*Rosa* x *hybrida*) (IFD 2010). 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). IFD-524Ø1-4 and IFD-529Ø1-9 roses are currently regulated under 7 CFR part 340. Interstate movements and field trials of IFD-524Ø1-4 and IFD-529Ø1-9 have been conducted under permits issued or notifications acknowledged by APHIS.

**Purpose of Product**

International Flower Developments Pty. Ltd. (IFD) is a company jointly owned by Florigene Pty. Ltd. (Australia) and Suntory Limited (Japan). Florigene Pty. Ltd. is a fully owned subsidiary of Suntory Limited (Florigene 2010). IFD has developed two lines of GE hybrid tea roses to produce a novel flower color. 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).

**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.

APHIS has prepared this environmental assessment (EA) to consider the potential environmental effects of an agency determination of nonregulated status consistent with NEPA regulations (40 CFR parts 1500-1508, 7 CFR part 1b, and 7 CFR part 372) and the USDA and APHIS NEPA implementing regulations and procedures. 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 the IFD-524Ø1-4 and IFD-529Ø1-9 roses.

## 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.

## Public Involvement

APHIS routinely seeks public comment on draft environmental assessments prepared in response to petitions seeking a determination of nonregulated status of GE organisms. APHIS does this through a notice published in the Federal Register. The issues discussed in this EA were developed by considering public concerns as well as issues raised in public comments submitted for other environmental assessments of GE 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 GE plants were addressed to analyze the potential environmental impacts of IFD-524Ø1-4 and IFD-529Ø1-9 roses.

This EA, the petition submitted by IFD (IFD 2010), and APHIS' Plant Pest Risk Assessment, (USDA-APHIS 2010) will be available for public comment for a period of 60 days (7 CFR § 340.6(d)(2)). Comments received by the end of the 60-day period will be analyzed and used to inform APHIS' determination decision of the regulated status of IFD-524Ø1-4 and IFD-529Ø1-9 and to assist APHIS in determining whether an Environmental Impact Statement is required prior to the determination decision of the regulated status of these rose lines.

## Issues Considered

As stated above, the issues considered in this 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.

---

[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)

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

# II. Affected Environment

**Production of Roses**

Roses (*Rosa* sp.) are cultivated as perennial ornamental plants in private gardens, parks, public facilities and botanical gardens, as potted plants in homes and on patios, and in contained facilities, such as greenhouses, to produce cut flowers to be used in bouquets (IFD 2010). Many species of *Rosa* have been modified through selection and hybridization to give rise to thousands of varieties (Phillips and Rix 1988; Gudin 2003; Zlesak 2007; OGTR 2009). The flowers of cut-flower rose varieties with their many petals are now quite different to a flower from wild rose species that generally have only five petals (Beales 1985). The *Rosa* genus belongs to the Rosaceae family (Klastersky 1968) which contains many important fruit trees, such as apple, pear, plum, peach and cherry, and berry plants, such as strawberry and blackberry (Hickey and King 1981). There are over 200 *Rosa* species (Hickey and King 1981; Phillips and Rix 1988) and all are native of temperate regions or tropical mountains of the northern hemisphere including North America, Europe, Asia and the Middle East. The greatest diversity of species is found in Western China (Hickey and King 1981; Phillips and Rix 1988). The USDA website lists 105 Rosa species for North America (USDA-NRCS 2010a) with this list summarized indicating its status as to whether it is “native” or “introduced” in the petition (IFD 2010).

The modern rose varieties are considered to be the hybrid teas, floribundas, grandifloras and miniatures, which are combinations of 7-10 major wild species (Gudin 2003; Marriott 2003; Zlesak 2007). Both IFD-524Ø1-4 and IFD-529Ø1-9 are lines of hybrid tea roses (IFD 2010). The rose species most commonly used for cut flowers is the hybrid tea rose (IFD 2010). The hybrid tea rose and other cultivated roses are complex hybrids. Hybrid tea rose contains genes from five major species [see Figure 1 of the petition (IFD 2010)]: *R. damascena, R. moschata, R. chinensis, R. gigantea* and *R. gallica* as described in Hurst (1941), Mastalerz and Langhans (1969), Marriot (2003), and Phillips and Rix (1988).

*Size and Areas of Rose Production*

The production of roses as field grown, container grown and cut flowers is part of the world-wide floriculture industry. The number of producers in the U.S. floricultural industry for 2008 at 7,189 is down 3 percent with the revised 2007 count of 7,387. The number of producers with sales of $100,000 or more dropped 5 percent to 2,967 for 2008 from 3,136 in 2007 (USDA-NASS 2009). Total covered area (covered areas are all areas, such as greenhouses and shade houses, other than open ground) for floriculture crop production was 729 million square feet (16,736 acres), 5 percent less than the revised 2007 figure. Greenhouse space for 2008, at 414 million square feet (9504 acres), is down 2 percent from 2007. This accounts for 57 percent of the total covered area. Shade and temporary cover is down 8 percent, to 314 million square feet (7208 acres). Open ground totaled 33,150 acres, 5 percent less than the revised 2007 total (USDA-NASS 2009). Floriculture crop producers may have any combination of growing facilities from greenhouses to open ground and may grow any number of floriculture crops from bedding plants, foliage plants to perennial flowers to cut flowers. The statistics in *Floriculture Crops* (USDA-ERS 2007) are collected from annual surveys of all known growers of floriculture crops in selected major producer states. Starting in 2005, 15 States are surveyed—California, Florida, Hawaii, Illinois, Maryland, Michigan, New Jersey, New York, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, Texas, and Washington (USDA-ERS 2007; USDA-NASS 2009).

Cut flowers are a subset of the floriculture industry. In 2008, the number of producers of cut flowers dropped 4 percent to 365 from 2007 with 382 (USDA-NASS 2009).

Cut flower of roses, which includes hybrid tea, floribunda and miniature roses, is a subset of cut flowers. In 2009 cut roses for the U.S. had 33 producers selling 42.0 million stems (USDA-NASS 2010). California, the top producing state of cut roses had 29 producers (88% of producers) selling 40.9 million stems (97% of stems) (USDA-NASS 2010). An estimated 15-18 billion stems of roses (includes hybrid tea, floribunda and miniature) were sold worldwide in 2003 in greenhouses totaling about 21,000 acres (Blom and Tsujita 2003), which implies that approximately 800,000 rose stems are harvested per acre of greenhouse.

Cut flowers of hybrid tea roses are a subset of cut flowers of roses. Although no USDA published data are available to describe the area of greenhouse space devoted specifically to production of cut flowers of hybrid tea roses, an estimated 55-70 acres of greenhouse space are devoted to cut flowers of hybrid tea roses based on the following information:

- An estimated 3 million square feet (69 acres) of greenhouse space in California is devoted to cut flowers of hybrid tea roses in 2009 with approximately 90% of all cut roses being hybrid tea roses (Zary 2010).
- Using an average of 160 cut flowers per square meter (Olij Rozen Int 2010; Chandler 2010c) , approximately 90% of all cut roses being hybrid tea roses (Zary 2010), and the 42.0 million rose stems sold in 2009 (USDA-NASS 2010) equates to 2.8 million square feet (65 acres).
- Using the estimate of 15-18 billion stems of roses sold worldwide in 2003 in greenhouses totaling about 21,000 acres (Blom and Tsujita 2003), these statistics imply that approximately 800,000 rose stems (probably an overestimate for hybrid teas since the hybrid teas have larger but fewer flowers per square foot (Olij Rozen Int 2010)) are harvested per acre of greenhouse, which in turn imply that the 2009 U.S. production of 42.0 million stems took place in 53 acres of greenhouse space.

The hybrid tea rose is one of the most widely produced cut flower crops in the world with over six billion stems sold annually in recent years (IFD 2010). Globally, 60-80 million new rose plants are planted annually just to meet the demand for cut flower production (IFD 2010) and over 200 million roses planted worldwide in 1991 (Zlesak 2007).

Production levels of roses are also categorized within two groups in addition to cut flower: Potted Flowering Plants that are also noted as Florist Roses for use indoors or on the patio and Nursery Crops-Deciduous Shrubs that are sold bare rooted and sold in containers for planting outdoors as landscaping and in gardens (USDA-ERS 2007).

In 2008 8,409,000 pots of Florist Roses were grown in the U.S. mostly in 7 states: North Carolina-769,000 pots; Florida-524,000 pots; Hawaii-28,000 pots; Michigan-30,000 pots; Ohio-26,000 pots; New York-18,000 pots; and Pennsylvania-3,000 pots (USDA-NASS 2009).

The number of acres specifically devoted to bare root/container rose production is not available in USDA statistics. This rose plant production information is grouped in and reported with other Deciduous Shrubs (USDA-ERS 2007). Deciduous Shrubs is one of 12 subgroups of Nursery Crops that contains roses and many species of deciduous shrubs that are used in the landscape (Cox and Klett 2007; Skarphol 2007; Sheridan Lawn and Landscaping L.L.C. 2010) and more than 100 varieties of roses available to florists (Society of American Florists 2010). By 2003 most of the rose plants were being produced in Arizona and California with some production in Texas (Karlik, Becker et al. 2003).

The U.S. production of bare root or container hybrid tea roses is estimated at 1100-1200 acres and approximately 20-25 million hybrid tea rose plants are sold to gardeners in the U.S. based on the following information:

- About 1800 acres of rose production takes place in or close to Kern County, California, which is approximately 50% of the U.S. production, with about one third of these acres devoted to hybrid tea roses (Karlik 2010).

- The rose production acres in California are approximately 55% of the total U.S. production. Over 50 million rose plants are produced annually by more than 9 major companies in the Kern County area (Wasco 2010).
- In the 1990's the rose growing industry from the Tyler, Texas area consisted of fewer than 50 growers producing 8-10 million rose bushes annually, which was 16-20% of the U.S. rose crop (Harris 2010), which is about 50 million rose plants for the U.S.
- 100 acres of rose production in Texas producing 1 million plants annually. Hybrid tea roses are about 60% of this production (Pemberton 2010).
- 600-700 acres of rose production in Arizona producing about 10 million plants annually with approximately 60% hybrid tea roses (Pemberton 2010).

*Growing Practices*

Growing practices of roses can be subdivided into four categories: cut flowers, potted plants for inside use (florist roses), bare root/container for use outdoors, and gardens. The first three categories are commercial production and the last category is the growing practices used by the final consumer.

For cut flowers of roses, all the production in the U.S. is in greenhouses under highly controlled conditions. Large volumes and premium prices occur shortly before special holidays, especially Valentine's Day and Mother's Day and also Thanksgiving, Christmas, and Easter (Goodrich 1969; Blom and Tsujita 2003). All production practices are developed and chosen to hit these key marketing dates. Production practices include variety choice, propagation, pruning, bud pinching, dormancy control, artificial lighting, temperature regulation, irrigation, nutrition, carbon dioxide supplement, humidity control, growing substrate, grafting of rootstock, shoot bending, pest control, harvesting practices, and postharvest practices (Blom and Tsujita 2003).

Variety choice affects flower color, size and shape, leaves, stem strength and length, thorns (prickles), vase life, transportation tolerance, fragrance, disease tolerance, insect tolerance, number of flowers, winter growth, cycling rate, performance on own roots, and plant vigor (Morey 1969; Chaanin 2003; Gudin 2003). Flower color, shape and size are consumer preferences affected by time of year, holiday, occasion and age of recipient with price premiums for quality and uniqueness, such as a truly unique color of blue (Chaanin 2003). Good fragrance will demand better prices, but fragrance and vase life are negatively correlated resulting in most roses having less or very little fragrance (Chaanin 2003). Stems with higher strength and longer length with large flowers demand higher prices. Small flowers (sweetheart roses) have lower prices, and harvesting costs may be 80% of all costs, so these roses are generally not grown in areas with high labor costs (Chaanin 2003). Stems with fewer or no thorns are easier to harvest and handle with lower costs (Chaanin 2003). Damages from diseases and insects result in lower quality flowers and lower prices. Increased disease and insect tolerance may result in fewer applications of fewer pesticides resulting in lower costs. APHIS phytosanitary regulations generally prohibit any insect or disease activity on imports of cut flowers so additional pesticides and more frequent applications are made to prevent any pest presence or damage (Blom and Tsujita 2003; Chaanin 2003). Although relatively low air transportation cost for cut flowers has made it possible for under developed countries, such as Columbia, Ecuador, and Kenya, to become important producers of cut flowers, these flowers must be able to tolerate normal shipping and storage stresses of higher levels of ethylene and cold temperatures (Blom and Tsujita 2003; Chaanin 2003). General vigor affects growth rate and rate of cycling between major bloom production dates. This general vigor affects greenhouse operation inputs such as heating to maintain temperatures, artificial lighting, shoot bending procedures to maximize flower production, and levels and timing of fertilizer applications and carbon dioxide supplementation (Blom and Tsujita 2003; Chaanin 2003).

With changes in greenhouse operations to improve growing efficiencies and lowering costs, computer controls of temperature, lighting, humidity control, watering, fertilizer applications, and carbon dioxide supplementation and changes in growing substrates have become common place in the last 20 years. Changing these operations has changed the need for grafting of rootstock to using the plants own root system which eliminates time and effort in placing new varieties into the growing systems (Blom and Tsujita 2003; Chaanin 2003).

Pot roses (florist roses, miniature roses) have become more popular in the last 30 years since the introduction of new varieties and development of an economical system of year around pot production using cutting propagation and supplemental light to produce plants in small pots for the mass market (Pemberton, Kelly et al. 2003). Hybrid tea roses are large plants that do not grow and survive well in small pots (Chandler 2010c). Although hybrid tea roses may be used in crosses to other *Rosa* species in the development of pot roses (De Vries 2003; Gudin 2003), no hybrid tea roses are grown in small pots (De Vries 2003) for sale and therefore this subject will not be covered in more detail in this analysis.

Hybrid tea roses can be grown in the field and when ready to market, soil removed from the roots and sold with bare roots or transplanted into containers before sale to the end consumer who will then plant them into gardens around homes or into parks, etc. Because of APHIS phytosanitary regulations (7 CFR parts 319.37-8 and 319.5) involved with importation of potted containers of plants, very few potted roses are imported into the U.S. or exported out of the U.S. Most of the field production of roses, some of which are hybrid tea roses, are grown in California and Arizona (Karlik, Becker et al. 2003). Outdoor rose production requires a long growing season, well drained soils, and sufficient water. Sandy soils are preferred since the soil can be easily removed at harvest. From planting to harvest requires about two years for plants on root stock. Cultural practices include soil preparation, which generally involves soil fumigation, growth of the root stock started from seeds or cuttings, budding of scions, and providing water and fertilizers (Karlik, Becker et al. 2003). Weeds are removed by tractor cultivation or hand-hoeing. Irrigation water is supplied through overhead sprinklers, furrows, or drip tubing. Soil fumigation is generally required to control nematodes, wilt fungus and *Agrobacterium tumefaciens.* Pesticide applications may be necessary during the growing season, but pesticides can be minimized by using Integrated Pest Management procedures (Karlik and Tjosvold 2003).

Growing practices for roses in gardens varies considerably based on the area of the country, soils, climate and the individual caretaker. Since hybrid tea roses are susceptible to various diseases and insects, pesticides are frequently required to meet a gardener’s expectations for their roses. Extension horticulturalists frequently recommend that the average home gardener grow easier to maintain shrub roses, which need fewer pesticide applications, less pruning, and have a wider range of favorable soil types over the hybrid tea rose (Mason 1998; Pollock 2002; Eisel and Meyer 2009; Zuzek, Richards et al. 2010).

*Organic Gardening and Production of Roses*

Organic production as defined in this document includes any production system that falls under the USDA National Organic Program (NOP) definition of organic farming and is a certified organic production system. The National Organic Program is administered by USDA's Agricultural Marketing Service (AMS). Organic farming operations as described by the National Organic Program requires organic production operations to have distinct, defined boundaries and buffer zones to prevent unintended contact with excluded methods from adjoining land that is not under organic management. Organic production operations must also develop and maintain an organic production system plan approved by their accredited certifying agent. This plan enables the production operation to achieve and document compliance with the National Organic Standards, including the prohibition on the use of excluded methods. Excluded methods include a variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes. In organic systems, the use of synthetic pesticides, fertilizers, and genetically engineered crops is strictly limited.

In accordance with the USDA Organic Standard, an accredited organic certifying agent conducts an annual review of the operation's organic system plan and makes on-site inspections of the operation and its records. Organic growers must maintain records to show that production and handling procedures comply with USDA organic standards. Practices growers may use to exclude genetically engineered products include planting only organic seed, planting earlier or later than neighboring farmers who may be using GE crops so that the crops will flower at different times, and employing adequate isolation distances between the organic fields and the fields of neighbors to minimize the chance that pollen will be carried between the fields. Although the National Organic Standards prohibit the use of excluded methods, they do not require testing of inputs or products for the presence of excluded methods. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of the National Organic Standards (USDA-AMS 2010). The unintentional presence of the products of excluded methods will not affect the status of an organic product or operation when the operation has not used excluded methods and has taken reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan. Organic certification of a production or handling operation is a process claim, not a product claim.

For those individuals that may wish to have roses in their gardens and to grow these roses "organically" for their own pleasure and not for sale, they may not follow NOP standards, but instead prefer not using synthetic pesticide, synthetic fertilizers, or other "non-organic growing techniques" (Garden Web 2010; Ibiblio 2010). Growing roses "organically", using this much broader definition of "organic", is generally no different than growing any type of plant with "organic techniques" and involves more than just not using chemicals. Healthy plants are generally better able to withstand pest attacks so providing the plant with more optimum growing conditions is necessary. Gardeners are very particular about what type of rose they wish to grow.

It can be difficult to give up the idea of long stem tea roses in favor of shrubby rugosas, but choosing the right rose for a specific area is rule number one (Stroom, Fetzer et al. 2008; Iannotti 2010; Shoultz, Shoultz et al. 2010). For those individuals desiring a rose garden but not willing to deal with the difficulties of pest control and other management problems associated with hybrid tea roses, various cultivars and rose species are recommended (Krischik, Bevacqua et al. 2010; Zuzek, Richards et al. 2010).

"Organic" roses appear to be available (East and Walzel 2006; Market Wire 2010; Organic Bouquet Inc. 2010; Whole Blossoms 2010), however information as to whether these roses meet USDA Certified Organic standards and on the total market size for roses that are "organic" or non- GE is not available. USDA certified organic rose oil is available from the species *Rosa damascene* from Bulgaria (Alteya Organics 2010). *Rosa damascene* does not cross with hybrid tea roses without human intervention (Beales 1985).

## Physical Environment

### *Water Resources*

Roses require between 500 to 1000 grams of water per gram of plant dry weight with requirements changing daily and seasonally depending on atmospheric conditions of level of sunlight, relative humidity, air temperature and air movement (White 1969). Roses can be injured by too little water as well as too much water with both conditions resulting in wilting and yellowing leaves (White 1969). For cut rose production in greenhouses, irrigation has changed considerably in the last 20 years. Early greenhouse production used plants growing in soil beds with above ground sprinkler irrigation with subsoil drainage to take away excess water (Blom and Tsujita 2003). Starting in the 1980's, soil was replaced by rock wool, peat or coco coir. Water and nutrients are supplied by microirrigation systems supplying 1-2 liters per hour per plant using computer controls based on incoming radiation, plant growth, air temperature and time. The advantages are more precise delivery based on crop needs, water management, sterilizing and adjusting pH of recycled water, recycling of excess nutrients and growing in troughs at a convenient working height (Blom and Tsujita 2003).

For outdoor field production, roses require a long growing season, well drained soils (preferably sandy texture which aids in removing soil from the roots at harvest time) and sufficient water (Karlik, Becker et al. 2003). Roses can be grown wherever rainfall is sufficient, but planned irrigation helps assure steady growth and is required in arid climates and in areas with long dry periods. Water delivery using furrows, overhead sprinklers and underground or above ground drip tubing are all acceptable for rose production (Karlik, Becker et al. 2003).

### *Soil*

In cut rose production, greenhouses are used and in the last 20 years, the soil beds in the greenhouses have been replaced with soilless media (Blom and Tsujita 2003). For outdoor field production, rose plant production is primarily concentrated in California and Arizona in areas with coarse textured soils which are favored at harvest by allowing easier removal of the soil from the roots (Karlik, Becker et al. 2003). Sanitation and good soil preparation are key elements in successful rose production (Karlik, Becker et al. 2003). Nematodes and wilt fungus infesting soil are problems associated with rose production that have been controlled by pre-plant soil fumigation such as methyl bromide (Karlik, Becker et al. 2003). Methyl bromide has been used for the elimination of these soil pests for the last 40 years (Karlik, Becker et al. 2003). In addition, methyl bromide has been successful in controlling other plant diseases and weeds in rose fields (Karlik, Becker et al. 2003). With the identification of methyl bromide potentially contributing to stratospheric ozone depletion, its elimination for use was targeted for 2005 in developed nations (US-EPA 2010a). Potential replacements for methyl bromide have not been able to provide the same or similar control of various soil borne pests resulting in a likely increase in pesticide load per acre (Karlik, Becker et al. 2003). Further regulatory restrictions on soil fumigants can be expected resulting in changes in current cultural practices in rose production (Karlik, Becker et al. 2003). However, as of 2010 through 2012, methyl bromide is and can be used in Kern County, California under a Critical Use Exemption with the EPA for control of nematodes (US-EPA 2010a; US-EPA 2010b). The California nematode certification program (CDFA 2001; CDFA 2009) requires an approved treatment for nematodes for shipping any plant materials out of the county of origin. Methyl bromide is the only effective control for the nematodes available under the California nematode certification program (Hanson 2010).

Disturbance and exposure of the top soil surface layer by certain cultural practices used in rose production, such as fumigation, pesticide applications and tillage, may leave crop soils prone to degradation (Hoeft, Nafziger et al. 2000). Two environmental impacts of soil degradation are the decline in water quality and the contribution to the greenhouse effect (Lal and Bruce 1999). A decline in soil quality and soil resilience[2] enhances the greenhouse effect through emissions of radiatively-active gases[3] ($CO_2$, $N_2O$) and depletion of the soil carbon pool (Lal 2003; US-EPA 2010). In turn, a decrease in carbon aggregation and sequestration in the soil leads to increase runoff and soil erosion.

Bacteria typically represent the most abundant microbes in the soil followed by fungi (Hoeft, Nafziger et al. 2000). These microbial groups play an important and particular role in the ecology of the soil, including nutrient cycling and the availability of these nutrients for plant growth. In addition, certain microbial organisms may contribute to the protection of the root system against soil pathogens (OECD 2003).

*Air Quality*

The production of cut roses in enclosed greenhouses generally results in the depletion of carbon dioxide levels below the normal ambient levels of approximately 0.038% by volume during the daytime with high levels of sunlight due to high levels of carbon dioxide assimilation during photosynthesis. Raising the carbon dioxide level to 0.08-0.10% during the daytime is beneficial for rose production by increasing dry matter accumulation resulting in quicker growth cycles of flower production (Blom and Tsujita 2003). Raising carbon dioxide levels is accomplished by burning natural gas or propane or using liquid carbon dioxide (Blom and Tsujita 2003).

---

[2] Soil resilience is the ability of a soil to restore itself.

[3] Radiatively-active gases are gases that absorb incoming solar radiation or outgoing infrared in turn, affecting the temperature of the atmosphere.

Many agricultural activities affect air quality including smoke from agricultural burning, tillage, traffic and harvest emissions, pesticide drift from spraying, and nitrous oxide emissions from the use of nitrogen fertilizer (Hoeft, Nafziger et al. 2000; Aneja, Schlesinger et al. 2009). These agricultural activities individually have potentially adverse environmental impacts on air quality. Tillage contributes to the release of greenhouse gases (GHG) because of the loss of $CO_2$ to the atmosphere, and the exposure and oxidation of soil organic matter (Baker, Southard et al. 2005). Emissions released from agricultural equipment (e.g., irrigation pumps and tractors) include carbon monoxide, nitrogen oxides, reactive organic gases, particulate matter, and sulfur oxides (US-EPA 2010). Nitrous oxide may also be released following the use of nitrogen fertilizer (US-EPA 2010). Aerial application of pesticides may cause impacts from drift and diffusion. Pesticides may volatilize after application to soil or plant surfaces and move following wind erosion (Vogel, Majewski et al. 2008). Agriculture, including land-use changes for farming, is responsible for an estimated 6 % of all human-induced GHG emissions in the U.S., and $N_2O$ emissions from agricultural soil management are a large part of this, 68 % of all U.S. $N_2O$ emissions (US-EPA 2010).

*Climate Change*

Climate change is possibly interrelated with agriculture in several relevant ways. Production of agricultural commodities is one of the many human activities that could contribute greenhouse gases to the air (Iserman 1993; Hoeft, Nafziger et al. 2000; Aneja, Schlesinger et al. 2009). First, this may occur through the combustion of fossil fuels to run farm equipment, the use of fertilizers, or the decomposition of agricultural waste products including crop residues and animal wastes. Second, the classes of crops planted are relevant to climate change, whether trees, grasses or field crops (Cole, Duxbury et al. 1997; Freibauer, Rounsevell et al. 2004). The location and the soil types in which they are planted also affect production of greenhouse gases (Flessa, Wild et al. 1998; Kamp, Steindl et al. 2001). Third, climate change itself may force changes to agricultural practices by extending the ranges of weeds and pests of agriculture (IPCC 2007). The influences that GE agricultural organisms may have on global climate change are unclear. Many of the indirect effects of these organisms will be determined by the traits engineered into organisms and the management strategies used in the production of these organisms. APHIS will continue to monitor developments that may lead to possible changes in the conventional production system likely to result from GE products brought to APHIS for approval. Some of the crops submitted by developers may clearly promote changes that may have impacts on greenhouse gases or the climate.

Climate changing greenhouse gas production will not be significant unless large amounts of crop plantings produce changes in measureable concentrations. The contribution of agriculture to climate change is largely dependent on the production practices employed to grow various commodities, the region in which the commodities are grown, and the individual choices made by growers. A recent IPCC forecast (IPCC 2007) for aggregate North American impacts on agriculture from climate change actually projects yield increases of 5-20% for this century. The IPCC report notes, however, that certain regions of the U.S. will be more heavily impacted because water resources may be substantially reduced. While agricultural impacts on existing crops may be significant, North American production is expected to adapt with improved cultivars and responsive farm management (IPCC 2007).

## Animal and Plant Communities

### *Animals*

Deer, rabbits, gophers and voles are known to eat roses and can damage roses and other garden plants (Bauer 2010). A wide range of invertebrate organisms also feed on roses. Beneficial insects, such as numerous species of bees, flies, beetles and wasps, feed on rose pollen (Shorthouse 2003; IFD 2010). Common predators of rose feeding insects include larvae of syrphids; lacewings; ladybird beetles that feed on aphids; and vespid wasps and damsel bugs that feed on caterpillars (Shorthouse 2003). Rose feeding insects that are considered pests include thrips, aphids, spider mites (not considered insects), green capsid bug, spittlebug, rose leafhopper, whiteflies, scales, chafers (particularly Japanese beetles), wood-boring beetles, weevils, rose midge, larvae of moths and sawflies, leafcutter bees, and cynipid gall wasps. For most rose fanciers and for rose production facilities, much effort is expended in trying to eradicate these feeding insects and other animals from their roses (Shorthouse 2003; Stroom, Fetzer et al. 2008).

### *Plants*

Most modern roses and the gardens, greenhouses and production fields in which they grow, are biologically simplified and much effort is expended to not share them with other plants and animals in which there is no interest (Shorthouse 2003). In order to maximize total production, all other plants are considered weeds within the greenhouses and production fields of container rose plants and these weeds are eliminated using herbicides, mechanical tillage, or hoeing (Karlik, Becker et al. 2003). Hybrid tea roses living in the wild or unmaintained gardens are usually not long lived plants without care of spraying and pruning (Shaw 1983). If these poorly maintained hybrid tea roses do happen to produce seeds, because of the very low seed set and poor germination, hybrid tea rose seedlings are not found among mature plants in gardens (OGTR 2009). Populations of hybrid tea roses have never been reported in the wild (IFD 2010; USDA-NRCS 2010a).

### *Biological Diversity*

Most modern roses and the gardens, greenhouses and production fields in which they grow, are biologically simplified and much effort is expended to not share them with other plants and animals in which there is no interest (Shorthouse 2003). Biological diversity is minimized in order to maximize total production or to maximize the performance of individual plants within the garden (Karlik, Becker et al. 2003). Integrated Pest Management procedures are helpful in maximizing biological diversity while controlling harmful pest damage below economic thresholds. For cut rose production and potted rose production, very little damage is permissible in order to meet consumer acceptability standards (Karlik and Tjosvold 2003).

*Gene Movement*

Gene movement in plants can occur by three basic methods: pollen, seeds and vegetative propagation. All three methods are possible in the genus *Rosa*. Wild *Rosa* species are insect pollinated with the pollen too large and heavy to be dispersed by wind (OGTR 2008; IFD 2010). Numerous insects capable of pollinating flowers have been observed visiting flowers of Rosa species including Syrphid flies, Apis mellifera (honey bees), Bombus spp. (bumble bees), Eristalis tenax (Hoverflies or droneflies), and other bees and flies (Knuth 1908; Kevan, Elslkowitcu et al. 1990; Fussell and Corbet 1992; Jesse, Moloney et al. 2006). Rosa species such as R. multiflora and R. rubiginosa can produce seeds that remain viable for 10-20 years and can spread vegetatively (MDC 2010; USDA-NRCS 2010b).

Hybrid tea roses can produce viable pollen and seed, but have great difficulty propagating vegetatively and only under optimum conditions (IFD 2010). Hybrid tea roses have a low level of fertility that produce low levels of pollen and produce very low levels of seed that have irregular and poor germination. Special procedures are often required for germination such as after ripening techniques, acid and other chemical treatments, removal of seed coats, cold treatment, and embryo culture on nutrient media especially for seeds from interspecific crosses (Semeniuk 1969; Gudin 2003). This level of infertility has been associated with the many different species crosses and levels of ploidy in the genetic background of hybrid tea roses. Hybrid tea roses can only be hybridized with other hybrid tea roses and other *Rosa* species with great difficulty (Gudin 2001; OGTR 2009). Hybrid tea roses are generally tetraploids or occasionally sterile triploids. Since most wild species of *Rosa* are diploids, interspecific crosses generally result in sterile triploids with no fertile pollen or germinating seeds without using special laboratory procedures (OGTR 2009).

In the production of cut roses that generally occurs in greenhouses, very little cross pollination among plants takes place and no seed is produced because:

- Screening all openings in the greenhouse to the outdoors discourages the presence of insects that are helpful in cross pollination as well as those that may cause injury to the plant by insect feeding and disease damage to the roses;
- Regular use of insecticides within the greenhouse to minimize insect related problems of feeding damage and transmission of diseases also affects pollinating insects;
- Harvesting or destroying all flower buds before flowers open and weeks before the formation of mature seeds eliminates all possibilities of seed formation (OGTR 2009; IFD 2010).

After the harvest of cut roses and the distribution to the final consumer, roses may be kept for up to a few weeks inside without contact with pollinating insects and destroyed before any seed can form and mature (OGTR 2009; IFD 2010). There is a possibility that viable buds on the long stem roses could be used for grafting onto garden roses (Hulse 2001), but this procedure to be successful takes considerable effort by a highly trained and experienced horticulturist (OGTR 2009).

Most hybrid tea roses growing outdoors are found in gardens and parks, and these plants are generally maintained to some degree for their ornamental value of the flowers. Generally the older flowers are removed (deadheading) to promote the development of new flowers. Deadheading prevents the possibility of mature seeds developing (OGTR 2009). Hybrid tea roses living in the wild or unmaintained gardens are usually not long lived plants without care of spraying and pruning (Shaw 1983). If these poorly maintained hybrid tea roses do happen to produce seeds, because of the very low seed set and poor germination, hybrid tea rose seedlings are not found among mature plants in gardens (OGTR 2009). Populations of hybrid tea roses have never been reported in the wild (IFD 2010; USDA-NRCS 2010a).

In plants such as roses that can develop sports (individuals that have originated from mutations in the vegetative parts of the plant) or can be grafted (joining parts of two individual plants to form one plant), periclinal chimeras can form with one of the three cell layers having a distinct genetic background differing from the other two layers. Both IFD-524Ø1-4 and IFD-529Ø1-9 are L1 periclinal chimeras (IFD 2010). A L1 periclinal chimera is a type of plant chimera in which the L1 cell layer has a different genetic make-up than the L2 and L3 cell layers. The L1 cell layer gives rise to epidermal tissues of a plant while the L2 and L3 layers give rise to reproductive tissues, vascular tissues and other internal plant tissues. Flower petals are epidermal tissue and therefore a L1 periclinal chimera in rose could have a flower color different from individual plants arising from the L2 cell line. For example, bud grafting a L1 periclinal chimera red flower hybrid tea rose to a non-chimera white flower hybrid tea rose will give rise to a L1 periclinal chimera red flower hybrid tea rose. However, pollen from a L1 periclinal chimera plant contains no genes that are unique to the L1 cell line since the pollen originates from the L2 cell line. Periclinal chimeras can often be vegetatively propagated indefinitely (Howell 1998).

**Public Health**

Public health concerns about GE hybrid tea roses, like IFD-524Ø1-4 and IFD-529Ø1-9, focus primarily on human and animal consumption as well as the effect of contact with the plant parts or products, such as perfume in the case of roses. Non-GE rose varieties as well as any other plant variety developed for conventional use, for use in organic production systems, or for use in the production of cosmetics, do not require routine evaluation by any regulatory agency in the U.S. for food or feed safety or for safety of the cosmetic prior to release in the market.

Under the Federal Food, Drug, and Cosmetic Act (FFDCA), it is the responsibility of food, feed, and cosmetic manufacturers to ensure that the products they market are safe and properly labeled. Food, feed and cosmetics derived from IFD-524Ø1-4 and IFD-529Ø1-9 must be in compliance with all applicable legal and regulatory requirements. GE organisms for food, feed or cosmetics may undergo a voluntary consultation process with the FDA prior to release onto the market. Although a voluntary process, applicants who wish to commercialize a GE variety that will be included in the food or cosmetic supply invariably complete a consultation with the FDA. In a consultation, a developer who intends to commercialize a bioengineered food or cosmetic meets with the agency to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food or cosmetic and then submits to FDA a summary of its scientific and regulatory assessment of the food or cosmetic; FDA evaluates the submission and responds to the developer by letter (US-FDA 2010).

All rose flowers are considered to be edible with the precaution that roses from florists, nurseries, and garden centers may have been treated with pesticides not labeled for food crops (Lauderdale and Evans 1999; Gegner 2004; Newman and O'Connor 2009; What's Cooking America 2010). Rose hips are also considered edible although some may not be palatable (Giese 1995; Reiffenstein 2004; Practically Edible 2010).

Hybrid tea roses are not the traditional sources for food and perfumes utilizing *Rosa* species. Rose oil, used in perfumes and food flavorings, is generally obtained from *R. damascena* and *R. centifolia* (OGTR 2009). Rose hips, used in foods, are generally obtained from *R. canina*, *R. moschata*, and *R. rubiginosa* (Cutler 2003; OGTR 2009).

*Worker Safety*

During production of cut flowers of roses and roses in nurseries, worker may be exposed to EPA registered pesticides during application of these chemicals to the soil and to the plants, as well as being exposed to safety hazards associated with farm equipment.

**Socioeconomic**

The production of roses as field grown, container grown and cut flowers is part of the world-wide floriculture industry with the U.S. cut flower industry facing strong competition especially for roses, mums, and carnations from imports, largely from Columbia and Ecuador (USDA-ERS 2007). The total floriculture crop value at wholesale for the U.S. is estimated at $4.22 billion for 2008, compared with $4.32 billion for 2007. California continues to be the leading state with floriculture crops valued at $1.02 billion, but is down 2 percent from the 2007 value. Florida, the next largest producer, is down 5 percent from the prior year to $922 million in wholesale value. These two states account for 46 percent of U.S. wholesale value. For 2008, the top 5 States are California, Florida, Michigan, Texas, and North Carolina, which account for $2.80 billion, or 66 percent, of U.S. sales (USDA-NASS 2009).

The number of producers for 2008 at 7,189 is down 3 percent with the revised 2007 count of 7,387. The number of producers with sales of $100,000 or more dropped 5 percent to 2,967 for 2008 from 3,136 in 2007 (USDA-NASS 2009). The total wholesale value of floriculture crops grown by operations with $100,000 or more of sales is $4.04 billion for 2008, down 2 percent from the revised 2007 total. These largest operations account for 96 percent of the total value of floriculture crops, but comprise only 41 percent of all producers. California contributed 25 percent of the total wholesale value. Florida ranks second with 22 percent; while Michigan, Texas, and North Carolina round out the top 5 States accounting for 9 percent, 6 percent, and 5 percent of the total, respectively. The average peak number of hired workers employed on operations in 2008 is 17.0, down 1 percent from a revised 17.2 in 2007. A total of 5,313 operations hired workers during 2008, compared with 5,460 a year earlier. Overall, 74 percent of operations used some hired labor during 2008, the same as in 2007 (USDA-NASS 2009). In 2008 the 1704 producers with sales of $100,000-499,999 hired an average of 9.4 peak workers, and the 1263 producers with sales equal to or exceeding $500,000 hired an average of 52.4 peak workers (USDA-NASS 2009). Floriculture crop producers may have any combination of growing facilities from greenhouses to open ground and may grow any number of floriculture crops from bedding plants, foliage plants to perennial flowers to cut flowers. The statistics in *Floriculture Crops* are collected from annual surveys of all known growers of floriculture crops in selected major producer states. Starting in 2005, 15 States are surveyed—California, Florida, Hawaii, Illinois, Maryland, Michigan, New Jersey, New York, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, Texas, and Washington (USDA-ERS 2007; USDA-NASS 2009).

Cut flowers are a subset of the floriculture industry. The wholesale value of domestically produced cut flowers is $403 million for 2008, 5 percent less than 2007. California's value is $314 million, accounting for 78 percent of the total cut flower value. The next three states with the largest wholesale value of cut flowers are New Jersey with $13.3 million, Hawaii with $13.2 million and Oregon with $11.4 million. In 2008, the number of producers of cut flowers dropped 4 percent to 365 from 2007 with 382 (USDA-NASS 2009).

Cut flower of roses is a subset of cut flowers. In 2008 cut roses for the U.S. had 39 producers selling 59.6 million stems at a wholesale value of $0.395 per stem for a total wholesale value of $23.5 million. California, the top producing state of cut roses had 33 producers (85% of producers) selling 55.0 million stems (92% of stems) at an average of $0.379 per stem for a total wholesale value of $20.8 million (89% of sales dollars) (USDA-NASS 2009). Using the 2007 floriculture industry average of $48,000 of sales per worker (includes all hired individuals except those individuals employed only for the retail operations, landscapers, and unpaid family members) (USDA-ERS 2007), the U.S. total cut rose industry with sales of $23.5 million appears to employ approximately 490 people during the peak work period of one or more days (USDA-ERS 2007). The major trends in cut flowers of roses are:

1. Total use of cut roses has risen from 1.1 billion stems with a value of $265 million in 1992 to 1.8 billion stems with a value of $332 million in 2006 (USDA-ERS 2007).
2. Imports of cut roses has increased each year since 1992 with the imports share of total usage of 34.1% in 1992 increasing to 97.7% in 2009. In 2000 969 million stems worth $213 million were imported increasing to 1.4 billion stems worth $301 million in 2006. Columbia and Ecuador are the two major sources of imported cut roses followed in order by Mexico, Guatemala, Costa Rico, Netherlands, Kenya, and Canada. In 2006 imports of cut roses totaled 959 million stems worth $206 million from Columbia, 421 million stems worth $83 million from Equador,14 million stems worth $4.1 million from Mexico, 15 million stems worth $3.6 million from Guatemala, 17 million stems worth $1.9 million from Costa Rica, 3 million stems worth $1.2 million from Netherlands, 8 million stems worth $0.7 million from Kenya, and 0.4 million stems worth $0.2 million from Canada (USDA-ERS 2007).
3. U.S. production of cut roses has decreased every year since 1992 from 534 million stems and $175 million in 1992 decreasing to 83 million stems and $31 million in 2006 (USDA-ERS 2007).
4. California's proportion of the total U.S. production of cut roses has been increasing. Based on sales, in 2000 California produced 60.7% of the U.S. production increasing to 88.5% in 2008. Based on quantity of stems sold, in 2000 California produced 69.4% of

the U.S. production increasing to 92.2% in 2008 (USDA-ERS 2007; USDA-NASS 2009).

5. California's production of cut roses has been decreasing every year since 2000 from 129 million stems and $42 million in 2000 decreasing to 55 million stems and $21 million in 2008 (USDA-ERS 2007; USDA-NASS 2009).

The U.S. imported $766 million of cut flowers, $301 million of this total was cut roses as noted above, and exported a total of $24.1 million of cut flowers with no specific information available on exports of cut roses (USDA-ERS 2007).

Production levels of roses are also categorized within two groups in addition to cut flower: Potted Flowering Plants that are noted as Florist Roses for use indoors or on the patio and Nursery Crops-Deciduous Shrubs that are sold bare rooted and sold in containers for planting outdoors as landscaping and in gardens. In 2006 the Potted Flowering Plants category was valued at $620 million, and the Nursery Crops category was valued at $4.6 billion (USDA-ERS 2007).

In 2008 8,409,000 pots of Florist Roses valued at $25,851,000 were grown in the U.S. mostly in 7 states: North Carolina-769,000 pots valued at $2,118,000; Florida-524,000 pots valued at $2,256,000; Hawaii-28,000 pots valued at $209,000; Michigan-30,000 pots valued at $197,000; Ohio-26,000 pots valued at $110,000; New York-18,000 pots valued at $167,000; and Pennsylvania-3,000 pots valued at $11,000 (USDA-NASS 2009).

Recent information on the specific value of rose plants in containers or as bare-root plants or on the number of workers involved with rose production nurseries is not available for the U.S. This rose plant production information is grouped in and reported with other Deciduous Shrubs (USDA-ERS 2007). Deciduous Shrubs is a subgroup of Nursery Crops that contains roses and many species of deciduous shrubs that are used in the landscape (Cox and Klett 2007; Skarphol 2007; Sheridan Lawn and Landscaping L.L.C. 2010). In 2006, the value of the Deciduous Shrub group was $648 million (USDA-ERS 2007).

# III. Alternatives

This document 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 will be evaluated in this 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.

### A. No Action: 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.

### B. Preferred Alternative: Determination that IFD-524Ø1-4 and IFD-529Ø1-9 roses are no longer 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.

### C. 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.

## D. Comparison of Alternatives

Table 1, below, briefly summarizes the results for each of the issues raised in the Environmental Consequences (Section IV) by each of the alternatives described in the Alternatives section

(Section III).

Table 1. Issues of potential impacts and consequences of alternatives

| 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 |
| 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** | | |

| Attribute/Measure | Alternative A: No Action | Alternative B: Determination of Non-regulated Status |
|---|---|---|
| CWW, CAA. EOs | Unchanged | Unchanged |

# IV. Environmental Consequences

This analysis of potential environmental consequences addresses the potential impact to the human environment from the alternatives analyzed in this EA, namely taking no action and a determination by the agency that IFD-524Ø1-4 and IFD-529Ø1-9 roses do not pose a plant pest risk.

Potential environmental impacts from the No Action Alternative and the Preferred Alternative for IFD-524Ø1-4 and IFD-529Ø1-9 roses are described in detail throughout this section. A cumulative effects analysis is also included for each environmental issue. Certain aspects of this product and its cultivation would be no different between the alternatives; those are described below.

### Production of Rose

Roses are cultivated as perennial ornamental plants in gardens and parks, and in greenhouses to produce cut flowers to be used in bouquets (IFD 2010). The rose species most commonly used for cut flowers is the hybrid tea rose (IFD 2010).

*Size and Areas of Rose Production*

The production of container grown roses and cut flowers of roses is part of the world-wide floriculture industry with the U.S. cut flower of roses industry in 2009 consisted of 33 major producers selling 42.0 million stems produced in an estimated 55-70 acres of greenhouse space with California, the top producing state having 88% of producers selling 97% of the stems (USDA-NASS 2010). Imports of cut flowers of roses has increased each year since 1992 with the imports share of total usage of 34.1% in 1992 (USDA-ERS 2007) increasing to 97.7% in 2009 with Columbia and Ecuador as the two major sources of imported cut flowers of roses (USDA-ERS 2007). In 2009 1.78 billion cut rose stems were imported (USDA-AMS 2010b). Based on the most recent 2009 U.S. production (USDA-NASS 2010) and the most recent 2009 imports (USDA-AMS 2010b), the total U.S. cut rose flower market is approximately 1.82 billion stems with only a little over 2% produced in the U.S.

U.S. nursery production of 20-25 million hybrid tea rose plants is estimated to take place on approximately 1100-1200 acres in California, Arizona and Texas (Karlik 2010, Wasco 2010, Pemberton 2010).

<u>No Action: Size and Areas of Rose Production</u>

Maintaining the regulated status of IFD-524Ø1-4 and IFD-529Ø1-9 under the No Action Alternative will not impact production levels or locations of roses in the US, including the number of acres and producers devoted to rose production. Plantings of IFD-524Ø1-4 and IFD-529Ø1-9 would be restricted to areas that are approved for regulated releases by APHIS. Commercial production levels of roses will continue to be dictated by the domestic and import floral markets.

Preferred Alternative: Size and Areas of Rose 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 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. Production of cut roses of these varieties in Columbia remains a possibility (IFD 2010), but too many commercial uncertainties exists presently to determine the relative level of production of these varieties outside the United States (Chandler 2010a). 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. 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 under the Preferred Alternative 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. Impacts would be similar to the no action alternative.

Cumulative Effects: Size and Areas of Rose Production

The production of cut flowers of roses has been steadily decreasing over at least the last 15 years (USDA-ERS 2007). A determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 under the Preferred Alternative 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 habits compared to conventional varieties (USDA-APHIS 2010). 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.

*Growing Practices*

Growing practices of hybrid tea roses can be subdivided into four categories: cut flowers, potted plants for inside use (Florist Roses), bare root/container for use outdoors, and gardens. The first three categories are commercial production and the last category is the growing practices used by the final consumer.

Roses are susceptible to various insects and diseases and would likely survive the diseases and pests without treatment with fungicides and insecticides but the pest injuries may be unattractive to varying degrees (Phillips and Rix 1988; Flint and Karlik 2008; Eisel and Meyer 2009; Stack 2010; Zuzek, Richards et al. 2010). In the growing of cut fresh roses, the product must meet consumer expectations and therefore pesticides are used more frequently to prevent damage (Parrella 2000; IFD 2010). For cut roses that are exported or imported into the U.S., the product must meet APHIS phytosanitary requirements for disease and pest insects, so pesticides are frequently used to aid in the prevention of disease and pest problems in international trade (IFD 2010). Growers of roses make choices to use certain varieties, use of rootstocks, irrigation practices, pesticides, fertilizer use and other growing practices to contain costs, increase production, ease maintenance requirements, and to meet market demand (Mastalerz and Langhans 1969; IFD 2010).

<u>No Action: Growing Practices</u>

Under the No Action Alternative, rose production growing practices will remain as it is practiced today. Growers make choices to use certain rose varieties, pesticides based on insect and disease pressures, cost of various inputs, and ease and flexibility of the production system. Growers will ultimately base their choice of these inputs on individual needs.

<u>Preferred Alternative: Growing Practices</u>

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. Impacts would be similar to the no action alternative.

<u>Cumulative Effects: Growing Practices</u>

A determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 will not have any cumulative effect on growing practices or on the pesticides used in the production of roses in the U.S. Growing practices used in rose production will be unchanged and remain available for use.

*Organic Gardening and Production of Roses*

“Organic” production (information is not available as to whether this production meets USDA Certified Organic standards) of cut roses appears to be conducted at a very low level with recent notices of availability of organic cut hybrid tea rose flowers. “Organic” gardening of hybrid tea roses by individual private gardeners may also be attempted with success under limited and special environmental circumstances. Recommendations for facilitating “organic” growing of roses in the garden often include planting easier to grow shrub roses instead of hybrid tea roses.

No Action: Organic Gardening and Production of Roses

Under the No Action Alternative, “organic” growing practices of cut rose production will remain as it is practiced today. Growers make choices to use certain varieties, approved organic pesticides based on insect and disease pressures, cost of various inputs, ease and flexibility of the system. Growers will ultimately base their choice of these inputs on individual wants and needs. Any effects due to organic growing practices of cut roses or plants in gardens will remain the same under the No Action Alternative.

Preferred Alternative: Organic Gardening and Production of Roses

Since IFD-524Ø1-4 and IFD-529Ø1-9 are genetically engineered, they would not meet USDA Certified Organic standards and therefore could not be used in the production of roses for this market or non-GE preferred markets if these markets exist. The transgenes in IFD-524Ø1-4 and IFD-529Ø1-9 change only the flower color versus other rose varieties, but have no effect on growth habit, growth rate or resistance to diseases or insects (IFD 2010; USDA-APHIS 2010). Therefore, a determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 will have no effect on the conventional or organic growing practices or pesticides used in the production of cut roses, container roses or garden roses in the U.S., compared to the No Action Alternative.

Cumulative Effects: Organic Gardening and Production of Roses

A determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 will not have any cumulative effect on growing practices or on the pesticides used in the “organic” production of cut roses or “organic” practices of caring for organic roses in gardens in the U.S. Growing practices used in “organic” rose production will be unchanged and remain available for use.

**Physical Environment**

*Water Use*

Irrigation is used in the growing of cut roses in greenhouses, and in the field production of roses in areas of limited rainfall. Supplemental irrigation is used in growing roses outdoors, whether in gardens or in field production of containers roses during dry periods with little or no rainfall.

No Action: Water Use

Under the No Action Alternative, plantings of IFD-524Ø1-4 and IFD-529Ø1-9 would be restricted to areas that are approved for regulated releases by APHIS. Irrigation practices associated with rose production would be applied by growers and gardeners to meet the water requirements needs of rose plants.

Preferred Alternative: Water Use

IFD-524Ø1-4 and IFD-529Ø1-9 plants have no unique growth characteristics that would change water use requirements and do not result in any changes to cultivation practices that are currently used for growing roses. A determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 will not change irrigation practices or water use patterns used in commercial production of cut flowers of roses, pot roses or field production of container roses, or used by gardeners. Irrigation practices associated with IFD-524Ø1-4 and IFD-529Ø1-9 roses would be the same as conventional rose production. Impacts would be similar to the no action alternative.

Cumulative Effect: Water Use

No cumulative effects have been identified for this issue. A determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 will not change the current irrigation practices or water use patterns used in commercial rose production or roses gardens.

*Soil*

Bacteria typically represent the most abundant microbes in the soil followed by fungi (Hoeft, Nafziger et al. 2000). These microbial groups play an important and particular role in the ecology of the soil, including nutrient cycling and the availability of these nutrients for plant growth. In addition, certain microbial organisms may contribute to the protection of the root system against soil pathogens (OECD 2003).

Agricultural practices associated with field production of roses such as cultivation causes disturbance and exposure of the top surface layer of soils and may allow some soils to be prone to degradation by weathering elements (i.e. rain, wind, snow, ice). For most of the production of cut roses in greenhouses in the U.S., roses are grown in soilless growth media.

No Action: Soil

Under the No Action Alternative, plantings of IFD-524Ø1-4 and IFD-529Ø1-9 would be restricted to areas that are approved for regulated releases by APHIS. Cultivation practices associated with rose production would be used by growers and gardeners to meet the needs of rose plants.

Preferred Alternative: Soil

Under the Preferred Alternative, IFD-524Ø1-4 and IFD-529Ø1-9 rose plants used in commercial container/bare root production and in gardens could have possible impacts on soils by the presence of the three new proteins: Neomycin phosphotransferase (NPT II), Flavonoid 3', 5’-hydroxylase (F3’5’H), Anthocyanin 5- acyltransferase (5AT), as well as the new anthocyanin-delphinidin.

- NPT II is a common protein found in a number of genetically engineered plants that have been widely planted across the U.S. and in other parts of the world. In every case, no issues related to health or environmental safety have been noted (APHIS petitions 04-337-01p, 04-264-01p, 01-137-01p, 01-206-02p, 01-206-01p, 95-352-01p, 96-051-01p, 95-045-01p, and 94-308-01p). NPT II confers tolerance to the antibiotic kanamycin and is used in a laboratory setting to select tissues transformed with the genes of interest (USDA-APHIS 2010).
- Flavonoid 3’, 5’-hydroxylase (F3’5’H) is an enzyme that is widely found in nature in plants producing anthocyanins, most often blue colors. This enzyme can be found in grapes (Bogs, Ebadi et al. 2006), petunia (Toguri, Azuma et al. 1993), eggplant (*Solanum melongena*) (Chapple 1998), gentian, torenia, campanula and many other plants (Tanaka 2006). F3’5’H is in the cytochrome P450 family of enzymes (designated in the CYP75A subfamily) (Nelson 2009). Plant species lacking flavonoid 3’-5’-hydroxylase, such as non-engineered roses, do not make the blue delphinidin-based anthocyanins (Deng and Davis 2001).
- Anthocyanin 5-acyltransferase (5AT) is also an enzyme that is widely found in nature in plants producing anthocyanins. In the anthocyanin biosynthesis pathways, this enzyme, as well as related anthocyanin acyltransferases, act to alter the biochemical structure of anthocyanin glucosides (AGS) (such as pelargonidin GS, cyanidin GS, and delphinidin GS) and make the resulting pigment (anthocyanin) more chemically stable in the plant cell (Nakayama, Suzuki et al. 2003).
- Delphinidins are found in common foods and common flowers listed in Tables 17 and 18 of the petition (USDA-ARS 2007; IFD 2010). As noted in the tables, many foods, which are grown and consumed widely, and ornamental flowers, which are grown widely, contain measurable quantities of delphinidin. None of the foods or ornamental plants noted are known to pose unique environmental risks because of the presence of delphinidin, its precursor biochemicals or catalytic enzymes (i.e., F3’5’H or 5AT) in the anthocyanin pathways. Specific data on toxicity and potential environmental effects of F3’5’H and 5AT is sparse but information on the chemistry of delphinidins and other anthocyanins is noted (Yu, Matsuno et al. 2006; Beheshiti 2008; Vilanova, Santalla et al. 2009). None of the documents identified or noted raise environmental concerns related to new gene products, changes in plant metabolism or plant composition.

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.

A determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 will not change the growing practices used in the production of cut roses, container roses or garden roses in the U.S. Cultivation practices associated with IFD-524Ø1-4 and IFD-529Ø1-9 roses would be the same as conventional rose production during soil preparation, planting, growing and harvest in container production fields as well as in gardens resulting in impacts similar to the no action alternative.

Cumulative Effects: Soil

No cumulative effects have been identified for this issue. A determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 will not change the current cultivation practices used in commercial rose production or roses gardens and no impacts have been identified with the new proteins and the anthocyanin delphinidin. Soil associated with agricultural practices will continue to be prone to degradation by weathering elements.

*Air Quality*

Many agricultural activities affect air quality including smoke from agricultural burning, tillage, traffic and harvest emissions, pesticide drift from spraying, and nitrous oxide emissions from the use of nitrogen fertilizer (Hoeft, Nafziger et al. 2000; Aneja, Schlesinger et al. 2009).

No Action: Air Quality

Under the No Action Alternative, plantings of IFD-524Ø1-4 and IFD-529Ø1-9 would be restricted to areas that are approved for regulated releases by APHIS. Agricultural practices associated with rose production would be used by growers and gardeners. Production of container/bare root roses and rose gardens generally requires tillage and pesticide applications both of which are generally regarded as affecting air quality. Production of cut roses generally requires application of pesticides and in some cases the addition of carbon dioxide to supplement the low levels of the enclosed greenhouses during sunny days. Air quality would be affected by agricultural practices such as tillage, pesticide application, use of agricultural equipment, and the supplementation of carbon dioxide in greenhouses.

Preferred Alternative: Air Quality

IFD-524Ø1-4 and IFD-529Ø1-9 plants have no unique growth characteristics that would change agricultural practices that are currently used for growing roses. A determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 will not change the agricultural practices used in commercial rose production or by rose gardeners. Agricultural practices associated with IFD-524Ø1-4 and IFD-529Ø1-9 roses would be the same as conventional rose production. Impacts on air quality would be similar to the no action alternative.

Cumulative Effects: Air Quality

No cumulative effects have been identified for this issue. A determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 will not change the current agricultural practices used in commercial rose production or roses gardens. Air quality issues associated with agricultural practices will continue to occur.

*Climate Change*

Production of agricultural commodities is one of the many human activities that could possibly contribute greenhouse gases (GHG) that affect climate. $CO_2$, $NO_2$, and $CH_4$ may be produced through the combustion of fossil fuels to run farm equipment, the use of fertilizers, or the decomposition of agricultural waste products including crop residues.

<u>No Action: Climate Change</u>

Under the No Action Alternative, plantings of IFD-524Ø1-4 and IFD-529Ø1-9 would be restricted to areas that are approved for regulated releases by APHIS. Agricultural practices associated with rose production would be used by growers and gardeners. Potential impacts on climate change associated agricultural practices such as tillage, pesticide application, use of agricultural equipment, and the supplementation of carbon dioxide in greenhouses used in rose production activities would occur with no expected measurable effect on overall climate change.

<u>Preferred Alternative: Climate Change</u>

IFD-524Ø1-4 and IFD-529Ø1-9 plants have no unique growth characteristics that would change agricultural practices that are currently used for growing roses. A determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 will not change the agricultural practices used in commercial rose production or by rose gardeners. Agricultural practices associated with IFD-524Ø1-4 and IFD-529Ø1-9 roses would be the same as conventional rose production. Impacts on climate change would be similar to the no action alternative.

<u>Cumulative Effects Climate Change</u>

No cumulative effects have been identified for this issue. A determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 will not change the current agricultural practices used in commercial rose production or roses gardens. Climate change issues associated with agricultural practices will continue to occur.

**Animal and Plant Communities**

*Animals*

Roses growing outdoors, whether in container/bare root production fields or in gardens, are host to many animal species including mammals, birds, and invertebrates. The cumulative effects analysis for this issue is found below at “Cumulative Effects: Plants, Animals, Biodiversity.”

<u>No Action: Animals</u>

Under the No Action Alternative, plantings of IFD-524Ø1-4 and IFD-529Ø1-9 would be restricted to areas that are approved for regulated releases by APHIS. Animals would be exposed to rose plants and agricultural practices associated with rose production. Potential impacts to individual animal species would depend upon the field location, time of the year and grower preference to use specific agricultural practices to include or exclude a specific animal species. Impacts would be limited in scope to specific areas where roses are being grown. Animal exposure to IFD-524Ø1-4 and IFD-529Ø1-9 plants would be limited to regulated confined field trials.

APHIS' plant pest risk assessment evaluated the potential for deleterious effects of IFD-524Ø1-4 and IFD-529Ø1-9 rose plants on animals (USDA-APHIS 2010). Based on data and information provided in the petition (IFD 2010) and existing literature , APHIS concluded that IFD-524Ø1-4 and IFD-529Ø1-9 rose plants are unlikely to pose safety risks to non-target or beneficial organisms (USDA-APHIS 2010).

<u>Preferred Alternative: Animals</u>

Agricultural practices associated with rose production would be used by growers and gardeners. The agricultural practices used to produce IFD-524Ø1-4 and IFD-529Ø1-9 will be the same as those used to produce conventionally grown roses and would have similar impacts to animals as the no action alternative.

As indicated in the petition, unlike non-genetically engineered roses, lines IFD-524Ø1-4 and IFD-529Ø1-9 accumulate delphinidin and delphinidin-derivatives, and neither are known to be toxic compounds. References such as the Merck Index do not provide toxicity data, and delphinidin is found in many raw foods such as fruits and berries, as well as in a number of widely grown ornamental plants (IFD 2010). The proteins encoded by the inserted genes are common non-toxic proteins and the transgenic lines have no increased allergenicity potential when compared to any non-GM rose (IFD 2010).

APHIS' plant pest risk assessment evaluated the potential for deleterious effects of IFD-524Ø1-4 and IFD-529Ø1-9 rose plants on animals (USDA-APHIS 2010). Based on APHIS' evaluation of data and information provided in the petition (IFD 2010) and existing literature, APHIS concluded that IFD-524Ø1-4 and IFD-529Ø1-9 rose plants are unlikely to pose safety risks to non-target or beneficial organisms (USDA-APHIS 2010). Impacts would be similar to the No Action Alternative.

*Plants*

When growing hybrid tea roses, generally the only other plants that are allowed to grow within the garden, greenhouse or container production fields are those selected by the caretaker of these growing areas. Much effort is expended to not share them with other plants and animals in which there is no interest (Shorthouse 2003). Hybrid tea roses living in the wild or unmaintained gardens are usually not long lived plants without care of spraying and pruning (Shaw 1983).

<u>No Action: Plants</u>

Under the No Action Alternative, plantings of IFD-524Ø1-4 and IFD-529Ø1-9 would be restricted to areas that are approved for regulated releases by APHIS. Plants would be exposed to agricultural practices associated with rose production. Potential impacts to individual plant species would depend upon the field location, time of the year and grower preference to use specific agricultural practices to include or exclude a specific plant species. Impacts would be limited in scope to specific areas where roses are being grown. APHIS' plant pest risk assessment evaluated the potential for deleterious effects of IFD-524Ø1-4 and IFD-529Ø1-9 rose plants on plants (USDA-APHIS 2010). Based on APHIS' evaluation of information and data provided in the petition (IFD 2010) and existing literature, APHIS concluded that IFD-524Ø1-4 and IFD-529Ø1-9 are unlikely to pose a plant pest risk (USDA APHIS 2010).

<u>Preferred Alternative: Plants</u>

Agricultural practices associated with rose production would be used by growers and gardeners. The agricultural practices used to produce IFD-524Ø1-4 and IFD-529Ø1-9 will be the same as those used to produce conventionally grown roses and would have similar impacts to plants as the no action alternative. IFD-524Ø1-4 and IFD-529Ø1-9 have not been genetically engineered to be tolerant to any herbicides, therefore no change in herbicide use or patterns are expected. Similar to the no action alternative, weeds within rose production fields and gardens of IFD-524Ø1-4 and IFD-529Ø1-9 will be managed using mechanical, cultural, and chemical control methods. IFD-524Ø1-4 and IFD-529Ø1-9 do not exhibit characteristics associated with weedy growth and will not compete with plants found outside of agricultural production or gardens (USDA-APHIS 2010).

*Biological Diversity*

Most modern roses and the gardens, greenhouses and production fields in which they grow, are biologically simplified and much effort is expended to not share them with other plants and animals in which there is no interest (Shorthouse 2003). Biological diversity is minimized in order to maximize total production or to maximize the performance of individual plants within the garden (Karlik, Becker et al. 2003).

<u>No Action: Biological Diversity</u>

Under the No Action Alternative, plantings of IFD-524Ø1-4 and IFD-529Ø1-9 would be restricted to areas that are approved for regulated releases by APHIS. APHIS' plant pest risk assessment evaluated the potential for deleterious effects of IFD-524Ø1-4 and IFD-529Ø1-9 rose plants on animals and plants (USDA-APHIS 2010). Based on APHIS' evaluation of information and data provided in the petition (IFD 2010) and existing literature, APHIS concluded that IFD-524Ø1-4 and IFD-529Ø1-9 rose plants are unlikely to pose safety risks to non-target or beneficial organisms (USDA-APHIS 2010). Animal and plant species that typically inhabit rose production fields and greenhouse and gardens will be affected by agricultural practices used in commercial rose production and rose gardening, which includes the use of mechanical, cultural, and chemical control methods. Potential impacts would be dependent upon the field location, time of the year and grower preference to use specific agricultural practices to include or exclude specific animal and plant species. Impacts would be limited in scope to specific areas where roses are being grown.

Preferred Alternative: Biological Diversity

Agricultural practices associated with rose production would be used by growers and gardeners. The agricultural practices used to produce IFD-524Ø1-4 and IFD-529Ø1-9 will be the same as those used to produce conventionally grown roses and would have similar impacts to biological diversity as the no action alternative. APHIS' plant pest risk assessment evaluated the potential for deleterious effects of IFD-524Ø1-4 and IFD-529Ø1-9 rose plants on animals and plants (USDA-APHIS 2010). Based on APHIS' evaluation of information and data provided in the petition (IFD 2010) and existing literature, APHIS concluded that IFD-524Ø1-4 and IFD-529Ø1-9 rose plants are unlikely to pose safety risks to non-target or beneficial organisms (USDA-APHIS 2010). Impacts would be similar to the No Action Alternative.

Cumulative Effects: Animals, Plants, Biodiversity

APHIS has determined that there are no impacts from past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action to create cumulative impacts or reduce the long-term productivity or sustainability of any of the resources associated with the ecosystem in which IFD-524Ø1-4 and IFD-529Ø1-9 are planted. IFD-524Ø1-4 and IFD-529Ø1-9 have not been genetically engineered to produce a toxin or pesticide, and have not been genetically engineered to be tolerant to an herbicide. IFD-524Ø1-4 and IFD-529Ø1-9 are unlikely to affect the animal or plant communities found in rose production or rose gardens because of the lack of toxicity, and because there will be no change to cultural practices used in the growing of IFD-524Ø1-4 and IFD-529Ø1-9.

*Gene Movement*

An environmental impact to consider as a result of planting of this hybrid tea rose variety is the potential for gene flow (the transfer of genetic information between different individuals or populations). Gene movement in plants can occur by three basic methods: pollen, seeds and vegetative propagation. Hybrid tea roses have great difficulty hybridizing with plants from other *Rosa* species. Hybrid tea roses even have great difficulty hybridizing with other hybrid tea roses to produce viable seeds since no new volunteer seedlings have ever been noted in gardens (Gudin 2001; OGTR 2009). For cut rose production and use of cut roses, development of mature seed essentially never happens because of growing and handling procedures (OGTR 2009). Vegetative propagation of hybrid tea roses only happens under optimal conditions (OGTR 2009). In addition, both IFD-524Ø1-4 and IFD-529Ø1-9 are L1 periclinal chimeras that produce pollen and seeds with no transgenes.

No Action: Gene Movement

Under the No Action Alternative, plantings of IFD-524Ø1-4 and IFD-529Ø1-9 would be restricted to areas that are approved for regulated releases by APHIS. Under regulated release, growers would be required to maintain confinement of IFD-524Ø1-4 and IFD-529Ø1-9 plantings. The characteristics of L1 periclinal chimera hybrid tea roses of pollen and seed production with no transgenes, poor seed set, poor seed germination and poor vegetative propagation are considered to be very helpful in maintaining confinement conditions (Gudin 2001; OGTR 2009).

Preferred Alternative: Gene Movement

Under the preferred alternative, IFD-524Ø1-4 and IFD-529Ø1-9 would be additional hybrid tea rose varieties with a unique flower color that may be available to the commercial rose industry and to the gardening community. 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. Impacts would be similar to the no action alternative.

Cumulative Effect: Gene Movement

No cumulative effects have been identified for this issue. No gene movement is expected to occur with this GE hybrid rose variety.

## Public Heath

*Human Health*

Under FFDCA, it is the responsibility of food, feed, and cosmetic manufacturers to ensure that the products they market are safe and properly labeled. Food, feed and cosmetics derived from IFD-524Ø1-4 and IFD-529Ø1-9 roses must be in compliance with all applicable legal and regulatory requirements. GE organisms for food, feed and cosmetics may undergo a voluntary consultation process with the FDA prior to release onto the market. All rose flowers are considered to be edible with the precaution that roses from florists, nurseries, and garden centers may have been treated with pesticides not labeled for food crops (Lauderdale and Evans 1999; Gegner 2004; Newman and O'Connor 2009; What's Cooking America 2010). Rose hips are also considered edible although some may not be palatable (Giese 1995; Reiffenstein 2004; Practically Edible 2010).

Hybrid tea roses are not the traditional sources for food and perfumes utilizing *Rosa* species. Rose oil, used in perfumes and food flavorings, is generally obtained from *R. damascena* and *R. centifolia* (OGTR 2009). Rose hips, used in foods, are generally obtained from *R. canina*, *R. moschata*, and *R. rubiginosa* (Cutler 2003; OGTR 2009).

No Action: Human Health

Under the No Action Alternative, plantings of IFD-524Ø1-4 and IFD-529Ø1-9 would be restricted to areas that are approved for regulated releases by APHIS. Under APHIS permits or notifications, confinement measures and permit conditions would limit the use and accessibility of these GE hybrid rose species. Any food, feed and cosmetics derived from IFD-524Ø1-4 and IFD-529Ø1-9 roses would be in compliance with all applicable legal and regulatory requirements.

Preferred Alternative: Human Health

Since hybrid tea roses are generally not consumed as food or used as a source of perfume (Cutler 2003; OGTR 2009), IFD did not undergo the voluntary consultation process with the FDA. In addition, the primary marketing of IFD-524Ø1-4 and IFD-529Ø1-9 is intended to be as cut long stem roses (IFD 2010). Despite the fact that hybrid tea roses are not generally consumed as food, the possibility still exist that these flowers may be consumed by people.

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.

Cumulative Effects: Human Health

No cumulative effects have been identified for this issue. 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.

*Worker Safety*

No Action: Worker Safety

During production of roses, workers may be exposed to EPA registered pesticides during application of these chemicals, as well as being exposed to safety hazards associated with farm equipment. Adherence to EPA label use restrictions limits potential exposure of chemicals to pesticide applicators.

Preferred Alternative: Worker Safety

Worker safety issues related to the use of EPA registered pesticides and farm equipment during production of IFD-524Ø1-4 and IFD-529Ø1-9 would remain the same as the No Action Alternative. As discussed under the issue of "Growing Practices", IFD-524Ø1-4 and IFD-529Ø1-9 do not change the growing practices, or use of chemicals such as pesticides, associated with growing roses. IFD-524Ø1-4 and IFD-529Ø1-9 have not been genetically engineered to be tolerant to any herbicides, therefore no change in herbicide use or patterns are expected. Impacts would be similar to the No Action Alternative.

Cumulative Effects: Worker Safety

No cumulative effects have been identified for this issue. Growing practices used in rose production will be unchanged. Worker safety issues related to the use of pesticides and farm equipment during production of IFD-524Ø1-4 and IFD-529Ø1-9 will continue and remain unchanged.

## Socioeconomic Issues

*Domestic Economic Environment at Risk*

The production of container grown roses and cut flowers of roses is part of the world-wide floriculture industry with the U.S. cut flower of roses industry in 2009 consisted of 33 major producers selling a total wholesale value of $17.7 million with California, the top producing state having 88% of producers and 96% of the sales (USDA-NASS 2010). Imports of cut flowers of roses has increased each year since 1992 with the imports share of total usage of 34.1% in 1992 increasing to 97.7% in 2009 (USDA-NASS 2010) with Colombia and Ecuador as the two major sources of imported cut flowers of roses (USDA-ERS 2007). The hybrid tea rose is the most widely produced cut flower crop in the world with over six billion stems sold annually in recent years. Globally, 60-80 million new rose plants are planted annually just to meet the demand for cut flower production (IFD 2010).

No Action: Domestic Economic Environment

Under the No Action Alternative, plantings of IFD-524Ø1-4 and IFD-529Ø1-9 would be restricted to areas that are approved for regulated releases by APHIS. Maintaining the regulated status of IFD-524Ø1-4 and IFD-529Ø1-9 under the No Action Alternative will not impact production levels of roses in the US. Commercial production levels of roses will continue to be dictated by the domestic and import floral markets.

Preferred Alternative: Domestic Economic Environment

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. 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. 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 under the Preferred Alternative 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 rose production levels 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. Impacts would be similar to the no action alternative.

Cumulative Effects: Domestic Economic Environment

The production of cut flowers of roses has been steadily decreasing over at least the last 15 years (USDA-ERS 2007). A determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 under the Preferred Alternative 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 habits compared to conventional varieties (USDA-APHIS 2010). 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.

*Trade Economic Environment at Risk*

The production of container grown roses and cut flowers of roses is part of the world-wide floriculture industry. Imports of cut flowers of roses has increased each year since 1992 with the imports share of total usage of 34.1% in 1992 increasing to 97.7% in 2009 (USDA-NASS 2010) with Colombia and Ecuador as the two major sources of imported cut flowers of roses (USDA-ERS 2007). The hybrid tea rose is the most widely produced cut flower crop in the world with over six billion stems sold annually in recent years. Globally, 60-80 million new rose plants are planted annually just to meet the demand for cut flower production (IFD 2010).

No Action: Trade Economic Environment

Maintaining the regulated status of IFD-524Ø1-4 and IFD-529Ø1-9 under the No Action Alternative will not impact levels of roses imported into the US. Commercial production levels of roses will continue to be dictated by the domestic and import floral markets.

Preferred Alternative: Trade Economic Environment

A determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 under the Preferred Alternative 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 roses imported into the U.S. since it will be competing for the same market share as the roses that are in current production. Production of cut roses of these new GE varieties in Colombia remains a possibility (IFD 2010), but too many commercial uncertainties exists presently to determine the relative level of production of these varieties outside the United States (Chandler 2010a). Commercial production levels of roses will continue to be dictated by the domestic and import floral markets. Impacts would be similar to the no action alternative.

Cumulative Effects: Trade Economic Environment

The production of cut flowers of roses has been steadily decreasing over at least the last 15 years (USDA-ERS 2007). A determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 under the Preferred Alternative is not expected to alter the production level of cut flowers 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). 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.

**Other Cumulative Effects**

The potential cumulative effects regarding specific issues have been analyzed and addressed above. No further potential cumulative effects have been identified. APHIS' regulations at 7 CFR Part 340 do not provide for Agency oversight of GE varieties that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340, nor over stacked varieties combining GE varieties that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340 unless it can be positively shown that such stacked varieties were to pose a likely plant pest risk. To date, none of the GE plants that are no longer subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340 and used for commercial purposes have been subsequently found to pose a plant pest risk.

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.

**Threatened and Endangered Species**

APHIS has obtained a list of federally listed threatened and endangered species (TES) and species proposed for listing, as well as designated critical habitat and habitat proposed for designation from the United States Fish and Wildlife Service (USFWS) and has analyzed the potential for effects from cultivation of IFD-524Ø1-4 and IFD-529Ø1-9 hybrid tea roses 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. Direct effects are analyzed by considering the response that TES could have if exposed to IFD-524Ø1-4 and IFD-529Ø1-9 roses. Indirect effects are those that could result from the use of IFD-524Ø1-4 and IFD-529Ø1-9 in rose production, would occur later in time, but are still reasonably certain to occur. Consideration is given for the potential of IFD-524Ø1-4 and IFD-529Ø1-9 to change the baseline habitat of TES including critical habitat. If the analysis determines that a determination of non-regulated status of IFD-524Ø1-4 and IFD-529Ø1-9 may affect listed species or critical habitat, consultation with the United States Fish and Wildlife Service (USFWS) or the National Marine Fisheries Service (NMFS) is required.

IFD-524Ø1-4 and IFD-529Ø1-9 were developed solely to have a new and unique flower color that would be primarily commercialized as cut rose flowers (many of which may be imported) and possibly as a garden rose (IFD 2010). The carefully controlled expression of two genes allows for the generation of a unique blue color not found in the *Rosa* genus. IFD-524Ø1-4 and IFD-529Ø1-9 contain a DNA insert with three genes- the neomycin phosphotransferase (NPT II) gene conferring tolerance to the antibiotic kanamycin; and two genes coding for two enzymes, flavonoid 3', 5'-hydroxylase (F3'5'H) and anthocyanin 5-acyltransferase (5AT), for the production of the anthocyanin delphinidin which is responsible for the blue pigment in a wide variety of edible fruits and garden flowers (USDA-ARS 2007; IFD 2010).

IFD-524Ø1-4 and IFD-529Ø1-9 are not genetically engineered to produce a toxin or pesticide, and are not genetically engineered to be tolerant to an herbicide. NPT II confers tolerance to the antibiotic kanamycin and is used in a laboratory setting to select tissues transformed with the genes of interest (USDA-APHIS 2010). NPT II is a common protein found in a number of genetically engineered plants that have been widely planted across the U.S. [APHIS petitions 04-337-01p (papaya), 04-264-01p (plum), 01-137-01p (corn), 01-206-02p (rapeseed), 01-206-01p (rapeseed), 95-352-01p (squash), 96-051-01p (papaya), 95-045-01p (cotton), 94-308-01p (cotton)]. In every case, no issues related to health or environmental safety has been noted.

Approximately 1.5 billion cut rose stems are used in the U.S. annually with over 97% of these stems being imported (USDA-ERS 2007). Of the total U.S. production of cut roses, over 90% (55 million stems) are produced in California greenhouses (USDA-ERS 2007). Most of these cut roses are assumed to be hybrid tea roses. Small pot roses, Florist roses, or Miniatures are intended for indoors or patios. These small roses are not hybrid tea roses. IFD-524Ø1-4 and IFD-529Ø1-9 could possibly be used in gardens, in which case bare root/container production could take place. Most container rose production (55 million plants) takes place in California and Arizona with some production in Texas (Karlik, Becker et al. 2003). The same cultural practices for conventional rose production would be used for IFD-524Ø1-4 and IFD-529Ø1-9 production- including the same fertilizers, herbicides, fungicides, insecticides, irrigation, crop rotations, and tillage. There is no hazard associated with growing IFD-524Ø1-4 and IFD-

529Ø1-9 hybrid tea rose plants that would be different from growing conventional hybrid tea rose plants.

All rose hips and flowers are edible (Lauderdale and Evans 1999; Gegner 2004; Newman and O'Connor 2009; What's Cooking America 2010); however, hybrid tea roses are generally not used for food, feed or cosmetics although some *Rosa* species are preferred sources for rose hips and other *Rosa* species are preferred for use in the perfume industry (Cutler 2003; OGTR 2009). A wide range of insects, deer, rodents and possibly birds feed on rose plants and a range of insects feed on rose pollen (Bauer 2010). To identify the direct effects on listed animal species that could result from feeding on roses, APHIS reviewed the data available to evaluate the potential for deleterious effects or significant impacts of these rose lines on threatened and endangered species. 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 or anything 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).

IFD-524Ø1-4 and IFD-529Ø1-9 plants are L1 periclinal chimeras which indicate that only the epidermal layers of these rose plants contain the transgenes and the resulting proteins and delphinidin. For the flower, the petals are the only L1 tissue with the reproductive tissues (pollen, anthers, hips and seeds) being L2 and L3 tissues. The L2 and L3 tissues of IFD-524Ø1-4 and IFD-529Ø1-9 do not contain the transgenes or any of the resulting proteins or delphinidin. Insects feeding on IFD-524Ø1-4 and IFD-529Ø1-9 pollen would be feeding on non-transgenic or conventional pollen and therefore would not be exposed to any new transgenic proteins. Any animal feeding on IFD-524Ø1-4 and IFD-529Ø1-9 hips would be feeding on non-transgenic or conventional hips and therefore would not be exposed to any new transgenic proteins. Since the composition of IFD-524Ø1-4 and IFD-529Ø1-9 plants is similar to other hybrid tea rose plants, it is unlikely that IFD-524Ø1-4 and IFD-529Ø1-9 would affect listed animal species, regardless of exposure. The composition and nutritional quality of IFD-524Ø1-4 and IFD-529Ø1-9 are not biologically different than conventional roses, and therefore would not be expected to affect TES differently.

No *Rosa* species is a listed plant species and hybrid tea roses itself is not sexually compatible with any listed species therefore there is no potential for a direct effect of IFD-524Ø1-4 and IFD-529Ø1-9 on TES plants. Indirect effects of IFD-524Ø1-4 and IFD-529Ø1-9 on listed plant species were also evaluated. Hybrid tea roses are tetraploids plants while wild *Rosa* species are diploids. Any progeny from cross fertilization of hybrid tea roses and wild *Rosa* species would result in sterile triploid plants. No populations of hybrid tea roses have ever been noted in natural areas (IFD 2010; USDA-NRCS 2010a). As stated above, IFD-524Ø1-4 and IFD-529Ø1-9 will have no effect on animals, including animals such as insects, bats or birds that may be pollinators of TES plants. Because hybrid tea roses cannot naturalize and would not affect pollinators, there are no expected indirect effects of IFD-524Ø1-4 and IFD-529Ø1-9 on TES plants.

Cultivation of IFD-524Ø1-4 and IFD-529Ø1-9 is not expected to differ from practices normally used for growing conventional roses. The potential environmental impacts on TES from this product are those associated with typical rose production in areas where roses are typically produced, and therefore would not affect the baseline habitat or critical habitat of any listed species.

After reviewing possible effects of a determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9, APHIS has not identified any stressor that could affect the reproduction, numbers, or distribution of a listed TES or species proposed for listing. As a result, a detailed exposure analysis for individual species is not necessary. APHIS has considered the effect of IFD-524Ø1-4 and IFD-529Ø1-9 production on designated critical habitat or habitat proposed for designation and could identify no difference from effects that would occur from the production of other hybrid tea rose varieties. Therefore, 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. Consequently, consultation with the USFWS or NMFS is not required for this action.

**Consideration of Executive Orders, Standards and Treaties relating to environmental impacts**

***Executive Order (EO) 12898 (US-NARA 2010), "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,"*** requires Federal agencies to conduct their programs, policies, and activities that substantially affect human health or the environment in a manner so as not to exclude persons and populations from participation in or benefiting from such programs. It also enforces existing statutes to prevent minority or low-income communities from being subjected to disproportionately high and adverse human health or environmental effects. ***EO 13045 (US-NARA 2010), "Protection of Children from Environmental Health Risks and Safety Risks,"*** acknowledges that children may suffer disproportionately from environmental health and safety risks because of their developmental stage, greater metabolic activity levels, and behavior patterns, as compared to adults. The EO (to the extent permitted by law and consistent with the agency's mission) required each Federal agency to identify, assess, and address environmental health risks and safety risks that may disproportionately affect children.

Each alternative was analyzed with respect to EO 12898 and 13045. Based on the information submitted by the applicant and assessed by APHIS, IFD-524Ø1-4 and IFD-529Ø1-9 are not significantly different than conventional roses. Therefore, IFD-524Ø1-4 and IFD-529Ø1-9 are not expected to have a disproportionate adverse effect on minorities, low-income populations, or children.

***EO 13112 (US-NARA 2010), "Invasive Species"***, states that Federal agencies take action to prevent the introduction of invasive species, to provide for their control, and to minimize the economic, ecological, and human health impacts that invasive species cause. Based on historical experience with roses and the data submitted by the applicant and assessed by APHIS, IFD-524Ø1-4 and IFD-529Ø1-9 plants are very similar in fitness characteristics to other hybrid tea rose varieties currently grown and are not expected to become weedy or invasive (USDA-APHIS 2010).

***EO 13186 (US-NARA 2010), "Responsibilities of Federal Agencies to Protect Migratory Birds"***, states that Federal agencies taking actions that have, or are likely to have, a measurable negative effect on migratory bird populations are directed to develop and implement, within 2 years, a Memorandum of Understanding (MOU) with the Fish and Wildlife Service that shall promote the conservation of migratory bird populations. Data submitted by the applicant has shown no differences of IFD-524Ø1-4 and IFD-529Ø1-9 compared to conventional hybrid tea roses, apart from the presence of the proteins and delphinidin, all of which are present in widely used foods, feeds or flowers. Based on APHIS' assessment of IFD-524Ø1-4 and IFD-529Ø1-9 it is unlikely that a determination of nonregulated status of these hybrid tea rose varieties will have a negative effect on migratory bird populations.

*International Implications*

***EO 12114 (US-NARA 2010), "Environmental Effects Abroad of Major Federal Actions"***, requires Federal officials to take into consideration any potential environmental effects outside the U.S., its territories, and possessions that result from actions being taken. APHIS has given this careful consideration and does not expect a significant environmental impact outside the U.S. in the event of a determination of nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9. It should be noted that all the considerable, existing national and international regulatory authorities and phytosanitary regimes that currently apply to introductions of new rose cultivars internationally, apply equally to those covered by an APHIS determination of nonregulated status under 7 CFR part 340. Any international trade of IFD-524Ø1-4 and IFD-529Ø1-9 subsequent to a determination of nonregulated status of the product would be fully subject to national phytosanitary requirements and be in accordance with phytosanitary standards developed under the ***International Plant Protection Convention*** (IPPC 2010). Both IFD-524Ø1-4 and IFD-529Ø1-9 have been approved for commercial use in Japan (IFD 2010), and IFD-524Ø1-4 has been approved for commercial use in Australia (IFD 2010).

The purpose of the IPPC "is to secure a common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control" (IPPC 2010); the protection it affords extends to natural flora and plant products and includes both direct and indirect damage by pests, including weeds. The IPPC set a standard for the reciprocal acceptance of phytosanitary certification among the nations that have signed or acceded to the Convention (172 countries as of March 2010). In April 2004, a standard for pest risk analysis (PRA) of living modified organisms (LMOs) was adopted at a meeting of the governing body of the IPPC as a supplement to an existing standard, International Standard for Phytosanitary Measure No. 11 (ISPM-11, Pest Risk Analysis for Quarantine Pests). The standard acknowledges that all LMOs will not present a pest risk and that a determination needs to be made early in the PRA for importation as to whether the LMO poses a potential pest risk resulting from the genetic modification. APHIS pest risk assessment procedures for genetically engineered organisms are consistent with the guidance developed under the IPPC. In addition, issues that may relate to commercialization and transboundary movement of particular agricultural commodities produced through biotechnology are being addressed in other international forums and through national regulations.

***The Cartagena Protocol on Biosafety*** is a treaty under the United Nations Convention on Biological Diversity (CBD) that established a framework for the safe transboundary movement, with respect to the environment and biodiversity, of LMOs, which includes those modified through biotechnology. The Protocol came into force on September 11, 2003, and 157 countries are Parties to it as of March, 2010 (CBD 2010). Although the U.S. is not a party to the CBD, and thus not a party to the Cartagena Protocol on Biosafety, U.S. exporters will still need to comply with domestic regulations that importing countries that are Parties to the Protocol have put in place to comply with their obligations. The first intentional transboundary movement of LMOs intended for environmental release (field trials or commercial planting) will require consent from the importing country under an advanced informed agreement (AIA) provision, which includes a requirement for a risk assessment consistent with Annex III of the Protocol, and the required documentation.

LMOs imported for food, feed, or processing (FFP) are exempt from the AIA procedure, and are covered under Article 11 and Annex II of the Protocol. Under Article 11 Parties must post decisions to the Biosafety Clearinghouse database on domestic use of LMOs for FFP that may be subject to transboundary movement. To facilitate compliance with obligations to this protocol, the U.S. Government has developed a website that provides the status of all regulatory reviews completed for different uses of bioengineered products (NBII 2010). These data will be available to the Biosafety Clearinghouse. APHIS continues to work toward harmonization of biosafety and biotechnology consensus documents, guidelines, and regulations, including within the North American Plant Protection Organization (NAPPO), which includes Mexico, Canada, and the U.S., and within the Organization for Economic Cooperation and Development. NAPPO has completed three modules of a standard entitled, *Importation and Release into the Environment of Transgenic Plants in NAPPO Member Countries* (NAPPO 2009).

APHIS also participates in the ***North American Biotechnology Initiative (NABI)***, a forum for information exchange and cooperation on agricultural biotechnology issues for the U.S., Mexico and Canada. In addition, bilateral discussions on biotechnology regulatory issues are held regularly with other countries including: Argentina, Brazil, Japan, China, and Korea.

*Compliance with Clean Water Act and Clean Air Act*

This Environmental Assessment evaluated the changes in rose production due to the unrestricted use of IFD-524Ø1-4 and IFD-529Ø1-9 roses. IFD-524Ø1-4 and IFD-529Ø1-9 will not lead to the increased production of roses in the U.S. There is no expected change in water use due to the production of IFD-524Ø1-4 and IFD-529Ø1-9 compared to current rose growing practices, nor is it expected that air quality will change because of production of IFD-524Ø1-4 and IFD-529Ø1-9.

*Impacts on Unique Characteristics of Geographic 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.

*National Historic Preservation Act (NHPA) of 1966 as Amended*

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

A determination of nonregulated status 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.

# V. References


Alteya Organics (2010). "100% Pure Therapeutic Grade USDA Organic Rose Oil." Retrieved June 4, 2010, from http://www.alteyaorganics.com/roseoil.html.

Aneja, V. P., W. H. Schlesinger, et al. (2009). "Effects of Agriculture upon the Air Quality and Climate: Research, Policy, and Regulations." Environ. Sci. Technol. **43**: 4234–4240.

Baker, J., R. Southard, et al. (2005). "Agriculture dust production in standard and conservation tillage system in the San Joaquin Valley." J. Environ. Qual. **34**: 1260-1269.

Bauer, B. (2010). "Mammal Troublemakers In The Roses ". Retrieved May 17, 2010, from http://www.rose-roses.com/problems/mammals.html.

Beales, P. (1985). Classic roses. London, William Collins and Sons.

Beheshiti, E. H. (2008). Characterization of antioxidant activities from fruits rich in delphinidin or malvidin anthocyanins. M.S. Thesis in Food Science, The University of British Columbia.

Blom, T. J. and M. J. Tsujita (2003). PRODUCTION AND MARKETING | Cut Rose Production. Encyclopedia of Rose Science. V. R. Andrew. Oxford, Elsevier**:** 594-600.

Bogs, J., A. Ebadi, et al. (2006). "Identification of the Flavonoid Hydroxylases from Grapevine and Their Regulation during Fruit Development." Plant Physiology **140**: 279-291.

CBD (2010). "The Cartegena Protocol on Biosafety." Retrieved March 30, 2010, from http://www.cbd.int/biosafety/.

CDFA (2001). "Sampling Procedures and Techniques for Detection of Nematodes by Laboratory Examination." Retrieved June 1, 2010, from http://www.cdfa.ca.gov/phpps/PE/Nursery/pdfs/nipm_7_1.pdf.

CDFA (2009). "Approved Treatment and Handling Procedures to Ensure Against Nematode Pest Infestation of Nursery Stock." Retrieved June 1, 2010, from http://www.cdfa.ca.gov/phpps/PE/Nursery/pdfs/NIPM_7.pdf

Chaanin, A. (2003). BREEDING | Selection Strategies for Cut Roses. Encyclopedia of Rose Science. V. R. Andrew. Oxford, Elsevier**:** 33-41.

Chandler, S. (2010a). Personal communication with V. Meier June 3, 2010. Marysville, OH.

Chandler, S. (2010b). Personal communication with V. Meier May 16, 2010. Marysville, OH

Chandler, S. (2010c). Personal communication with V. Meier June 2, 2010. Marysville, OH

Chapple, C. (1998). "Molecular-genetic Analysis of Plant Cytochrome P450-dependent Monooxygenases." Annu. Rev. Plant Physiol. Plant Mol. Biol. **49**: 311-343.

Cole, C. V., J. Duxbury, et al. (1997). "Global estimates of potential mitigation of greenhouse gas emissions by agriculture." Nutrient Cycling in Agroecosystems **49**: 221–228.

Cox, R. A. and J. E. Klett (2007). "Deciduous Shrubs." Retrieved May 12, 2010, from http://www.ext.colostate.edu/pubs/garden/07415.html.

Cutler, R. R. (2003). SECONDARY METABOLITES | Culinary Uses and Nutritional Value. Encyclopedia of Rose Science. V. R. Andrew. Oxford, Elsevier**:** 707-716.

De Vries, D. P. (2003). BREEDING | Selection Strategies for Pot Roses. Encyclopedia of Rose Science. V. R. Andrew. Oxford, Elsevier**:** 41-48.

Deng, C. and T. M. Davis (2001). "Molecular identification of the yellow fruit color (c) locus in diploid strawberry: a candidate gene approach." Theor. Appl. Genet. **103**: 316-322.

East, R. and S. Walzel (2006). "Greening the Rose." Retrieved May 3, 2010, from http://www.forumforthefuture.org/greenfutures/articles/602472.

Eisel, M. C. and M. H. Meyer (2009). "Culture of Garden Roses ". Retrieved May 2, 2010, from http://www.extension.umn.edu/distribution/horticulture/DG1105.html.

Flessa, H., U. Wild, et al. (1998). "Nitrous oxide and methane fluxes from organic soils under agriculture." European Journal of Soil Science **49**: 327–335.

Flint, M. L. and J. F. Karlik (2008). "Roses: Insect and Mite Pests and Beneficials." Retrieved May 10, 2010, from http://www.ipm.ucdavis.edu/PMG/PESTNOTES/pn7466.html.

Florigene (2010). "Florigene News." Retrieved May 3, 2010, from http://florigene.com/news/news.php.

Freibauer, A., M. D. A. Rounsevell, et al. (2004). "Carbon sequestration in the agricultural soils of Europe." Geoderma **122**: 1-23.

Fussell, M. and S. A. Corbet (1992). "Flower usage by bumble-bees: A basis for forage management." Journal of Applied Ecology **29**: 451-465.

Garden Web (2010). "What is the correct definition of Organic Gardening?". Retrieved June 4, 2010, from http://faq.gardenweb.com/faq/lists/organic/2002083353003940.html.

Gegner, L. (2004). "Edible Flowers." Retrieved May 12, 2010, from http://attra.ncat.org/attra-pub/PDF/edibleflowers.pdf.

Giese, P. (1995). "Wild Roses: Hips, Haws, Vitamin C." Retrieved May 12, 2010, from http://www.kstrom.net/isk/food/wildrose.html.

Goodrich, D. C. (1969). Prices and Costs. Roses: A Manual on the Culutre, Management, Diseases, Insects, Economics and Breeding of Greenhouse Roses. J. W. Mastalerz and W. L. Robert, Pennsylvania Flower Growers, New York and State Flower Growers Association, Inc.

Gudin, S. (2001). "Rose breeding technologies. In: Proceedings of the third international symposium on rose research and cultivation. (Zieslin, N. and Agbaria, H. eds.)." Acta Horticulturae **547**: 23-26.

Gudin, S. (2003). BREEDING | Overview. Encyclopedia of Rose Science. V. R. Andrew. Oxford, Elsevier**:** 25-30.

Hanson, B. (2010). Personal communication with V. Meier June 3, 2010. Marysville, OH.

Harris, R. (2010). "The Handbook of Texas Online: Rose Industry." Retrieved May 5, 2010, from http://www.tshaonline.org/handbook/online/articles/RR/drr1.html

Hickey, M. and C. King (1981). 100 families of flowering plants. New York, Cambridge University Press.

Hoeft, R. G., E. D. Nafziger, et al. (2000). Modern Corn and Soybean Production. Champaign, IL, MCSP Publications.

Howell, S. (1998). Molecular genetics of plant development, Cambridge University Press.

Hulse, M. (2001). "The Rose Rustler's Toolkit." Retrieved May 12, 2010, from http://www.rdrop.com/~paul/hulse.html.

Iannotti, M. (2010). "Organic Rose Gardening: Can Temperamental Roses Be Grown Organically?". Retrieved May 3, 2010, from http://gardening.about.com/od/rose1/a/OrganicRose.htm.

Ibiblio (2010). "Overview of Organic Gardening." Retrieved June 4, 2010, from http://www.ibiblio.org/rge/course/overview.htm.

IFD (2010). Petition for the determination of nonregulated status for Rosa x hybrida (rose) IFD-524Ø1-4 and IFD-529Ø1-9 varieties. Submitted by K. Terdich, Registration Manager. International Flower Developments Pty. Ltd (See Table http://www.aphis.usda.gov/biotechnology/not_reg.html).

IPCC (2007). 14.4.4.4. Agriculture, forestry and fisheries IPPC Fourth Assessment Report Climate Change 2007: Contribution of Working Group II to the Fourth Assessment Report of the Intergovernmental Panel on Climate Change, 2007. M. L. Parry, O. F. Canziani, J. P. Palutikof, P. J. van der Linden and C. E. Hanson. Cambridge United Kingdom and New York, NY, USA Intergovernmental Panel on Climate Change.

IPCS INCHEM (2010). "Anthocyanins." Retrieved May 12, 2010, from http://www.inchem.org/documents/jecfa/jecmono/v17je05.htm.

IPPC (2010). "Official web site for the International Plant Protection Convention: International Phytosanitary Portal ". Retrieved March 30, 2010, from https://www.ippc.int/IPP/En/default.jsp.

Iserman, K. (1993). "Agriculture's share in the emission of trace gases affecting the climate and some cause-oriented proposals for sufficiently reducing this share." Environmental Pollution **83**: 95-111.

Jesse, L., K. Moloney, et al. (2006). "Insect pollinators of the invasive plant Rosa multiflora (Rosaceae) in Iowa, USA." Weed biology and management **6**: 235-240.

Kamp, T., H. Steindl, et al. (2001). "Monitoring trace gas fluxes (N2O, CH4) from different soils under the same climatic conditions and the same agricultural management." Phyton - Annales Rei Botanicae **41**: 119-130.

Karlik, J. F. (2010). Personal communication with V. Meier June 1, 2010. Marysville, OH

Karlik, J. F., J. O. Becker, et al. (2003). PRODUCTION AND MARKETING | Field Rose Production. Encyclopedia of Rose Science. V. R. Andrew. Oxford, Elsevier**:** 580-587.

Karlik, J. F. and S. A. Tjosvold (2003). INTEGRATED PEST MANAGEMENT. Encyclopedia of Rose Science. V. R. Andrew. Oxford, Elsevier**:** 466-473.

Kevan, P. G., D. Elslkowitcu, et al. (1990). "Cryptic dioecy and insect pollination in Rosa setigera Michx. (Rosaceae), a rare plant of Carolinian Canada." Biol. J. Linn. Soc. **40**: 229-243.

Klastersky, I. (1968). Rosa L. Flora Europaea, Vol 2. T. G. Tutin, V. H. Heywood, N. A. Burgeset al. Cambridge, Cambridge University Press.

Knuth, K. (1908). Handbook of flower pollination. Oxford, Clarendon Press.

Krischik, V., K. Bevacqua, et al. (2010). "Selecting Hardy Roses for Northern Climates." Retrieved May 3, 2010, from http://www.extension.umn.edu/distribution/horticulture/DG6750.html.

Lal, R. (2003). "Soil erosion and the global carbon budget." Environment International **29**: 437-450.

Lal, R. and J. P. Bruce (1999). "The potential of world cropland soils to sequester C and mitigate the greenhouse effect." Environmental Science & Policy **2**: 177-185.

Lauderdale, C. and E. Evans (1999). "Edible Flowers ". Retrieved May 12, 2010, from http://www.ces.ncsu.edu/depts/hort/hil/hil-8513.html.

Market Wire (2010). "World's First Organic Roses Debut At Whole Foods Markets." Retrieved May 3, 2010, from http://findarticles.com/p/articles/mi_pwwi/is_20050229/ai_mark03049534/?tag=content.

Marriott, M. (2003). HISTORY OF ROSES IN CULTIVATION | Modern (Post-1800). Encyclopedia of Rose Science. V. R. Andrew. Oxford, Elsevier**:** 402-409.

Mason, S. (1998). "Outstanding New Shrub Roses ". Retrieved May 3, 2010, from http://web.extension.illinois.edu/champaign/homeowners/980328.html.

Mastalerz, J. W. and R. W. Langhans (1969). Roses, Penn. Flower growers and NY State Flower Growers Association Inc.

MDC (2010). "Vegetation Management Guideline: Multiflora Rose." Retrieved May 3, 2010, from http://mdc.mo.gov/nathis/exotic/vegman/seventee.htm.

Morey, D. (1969). Selection Criteria for Breeding. Roses: A Manual on the Culture, Management, Diseases, Insects, Economics and Breeding of Greenhouse Roses. J. W. Mastalerz and W. L. Robert, Pennsylvania Flower Growers and New York State Flower Growers Association, Inc.

Nakayama, T., H. Suzuki, et al. (2003). "Anthocyanin acyltransferases: specificities, mechanism, phylogenetics and applications." Journal of Molecular Catalysis B: Enzymatic **23**: 117-132.

NAPPO (2009). "NAPPO approved standards." Retrieved April 22, 2010, from http://www.nappo.org/Standards/Std-e.html.

NBII (2010). "United States Regulatory Agencies Unified Biotechnology Website." Retrieved March 30, 2010, from http://usbiotechreg.nbii.gov/.

Nelson, D. R. (2009). "The Cytochrome P450 Homepage." Retrieved January 26, 2010, from http://drnelson.uthsc.edu/CytochromeP450.html.

Newman, S. E. and A. S. O'Connor (2009). "Edible Flowers." Retrieved May 12, 2010, from http://www.ext.colostate.edu/pubs/garden/07237.html.

OECD (2003). "Consensus Document on the Biology of Zea Mays Subsp. Mays (Maize).". from http://www.olis.oecd.org/olis/2003doc.nsf/LinkTo/NT0000426E/$FILE/JT00147699.PDF.

OGTR (2008). Risk assessment and risk management plan. Application for license for dealings involving an intentional release into the environment. DIR084/2008. Limited and controlled release of torenia genetically modified for enhanced phosphate uptake. Canberra, Office of the Gene Technology Regulator, Autralian Government.

OGTR (2009). The Biology of Hybrid Tea Rose (Rose x hybrida). Canberra, Office of the Gene Technology Regulator, Autralian Government.

Olij Rozen Int (2010). "Assortment." Retrieved June 2, 2010, from http://www.olijrozen.nl/eng/assortment.php.

Organic Bouquet Inc. (2010). "Organic Bouquet." Retrieved May 3, 2010, from http://www.organicbouquet.com.

Parrella, M. P. (2000). Demonstration and Implementation of Reduced-Risk Pesticides in Fresh Cut Roses. Davis, University of California.

Pemberton, H. B. (2010). Personal communication with V. Meier June 8, 2010. Marysville, OH

Pemberton, H. B., J. W. Kelly, et al. (2003). PRODUCTION AND MARKETING | Pot Rose Production. Encyclopedia of Rose Science. V. R. Andrew. Oxford, Elsevier**:** 587-593.

Phillips, R. and M. Rix (1988). Roses, Pan Books.

Pollock, C. (2002). "Shrub Rose Versatility Appealing to Flower-Lovers ". Retrieved May 3, 2010, from http://www.ag.ohio-state.edu/~news/story.php?id=1942.

Practically Edible (2010). "Rose Hip." Retrieved May 12, 2010, from http://www.practicallyedible.com/edible.nsf/pages/rosehips.

Reiffenstein, K. (2004). "Edible Roses." Retrieved May 12, 2010, from http://www.suite101.com/article.cfm/container_gardening/111783.

Semeniuk, P. (1969). Specialized Breeding Techniques. Roses: A Manual on the Culture, Management, Diseases, Insects, Economics and Breeding of Greenhouse Roses. J. W. Mastalerz and W. L. Robert, Pennsylvania Flower Growers and New York State Flower Growers Association, Inc.

Shaw, J. (1983). Gardening with Species Roses. Arnoldia, Arnold Arboretum of Harvard University. **43**.

Sheridan Lawn and Landscaping L.L.C. (2010). "Deciduous Shrubs Zone." Retrieved May 12, 2010, from http://www.buyshrubszone.com/deciduous_shrubs.htm.

Shorthouse, J. D. (2003). INSECTS AND OTHER ANIMALS | Overview of Insects. Encyclopedia of Rose Science. V. R. Andrew. Oxford, Elsevier**:** 415-425.

Shoultz, B., J. Shoultz, et al. (2010). "Good Earth R.O.S.E Care." Retrieved May 3, 2010, from http://www.organicrosecare.org/index.php.

Skarphol, B. (2007). "Recommended Small and Medium-Sized Deciduous Shrubs for the Washington, D.C. Area." Retrieved May 12, 2010, from http://www.fairfaxcounty.gov/parks/gsgp/infosheets/decshrub.pdf.

Society of American Florists (2010). "Rose Flowers." Retrieved May 21, 2010, from http://aboutflowers.com/flower-a-plant-information-and-photos/flowers/rose.html.

Stack, G. (2010). "Our Rose Garden: Disease and Insect Pests." Retrieved May 10, 2010, from http://urbanext.illinois.edu/roses/disease.cfm.

Stroom, K., J. Fetzer, et al. (2008). "Insect Pests of Roses." Retrieved May 3, 2010, from http://www.extension.umn.edu/distribution/horticulture/DG6953.html.

Tanaka, Y. (2006). "Flower colour and cytochromes P450." Phytochem Rev **5**: 283-291.

Toguri, T., M. Azuma, et al. (1993). "The cloning and characterization of a cDNA encoding a cytochrome P450 from the flowers of Petunia hybrida." Plant Science **94**: 119-126.

US-EPA (2010). "Draft 2010 Inventory of Greenhouse Gas Emissions and Sinks Executive Summary." Retrieved March 30, 2010, from http://www.epa.gov/climatechange/emissions/.

US-EPA (2010a). "The Phaseout of Methyl Bromide." Retrieved June 1, 2010, from http://www.epa.gov/ozone/mbr/.

US-EPA (2010b). "Nursery Stock — Fruit, Nut, and Rose." Retrieved June 1, 2010, from http://www.epa.gov/ozone/mbr/CUN2012/2012_USNurseryStock.pdf.

US-FDA (2010). "The FDA List of Completed Consultations on Bioengineered Foods." Retrieved January 4, 2010, from http://www.fda.gov/Food/Biotechnology/Submissions/default.htm.

US-NARA (2010). "Executive Orders disposition tables index." Retrieved March 11, 2010, from http://www.archives.gov/federal-register/executive-orders/disposition.html.

USDA-AMS (2010). "National Organic Program." Retrieved April 22, 2010, from http://www.ams.usda.gov/AMSv1.0/nop

USDA-AMS (2010b). "Available Domestic Shipments and Imports of Ornamental Crops." Retrieved June 9, 2010, from http://www.ams.usda.gov/mnreports/wa_fv281.txt.

USDA-APHIS (2010). Plant Pest Risk Assessment for International Flower Developments Pty. Ltd. IFD-524Ø1-4 and IFD-529Ø1-9 Rosa x hybrida (rose) varieties.

USDA-ARS (2007). USDA Database for the Flavonoid Content of Selected Foods. Beltsville, Nutrient Data Laboratory Food Composition Laboratory Beltsville Human Nutrition Research Center Agricultural Research Service U.S. Department of Agriculture.

USDA-ERS (2007). "Floriculture and Nursery Crops Yearbook." Retrieved May 3, 2010, from http://www.ers.usda.gov/Publications/Flo/2007/09Sep/FLO2007.pdf.

USDA-NASS (2009). "Floriculture Crops 2008 Summary." Retrieved May 2, 2010, from http://usda.mannlib.cornell.edu/usda/current/FlorCrop/FlorCrop-04-23-2009.pdf.

USDA-NASS (2010). "Floriculture Crops 2009 Summary." Retrieved June 7, 2010, from http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1072.

USDA-NRCS (2010a). "Plants Profile Rose L." Retrieved April 30, 2010, from http://plants.usda.gov/java/profile?symbol=ROSA5.

USDA-NRCS (2010b). "Plants Profile: Roa multiflora Thunb.". Retrieved May 3, 2010, from http://www.plants.usda.gov/java/profile?symbol=ROMU.

Vilanova, M., M. Santalla, et al. (2009). "Environmental and genetic variation of phenolic compounds in grapes (Vitis vinifera) from northwest Spain." J. Agric. Sci. **147**: 683-697.

Vogel, J. R., M. S. Majewski, et al. (2008). "Pesticides in rain in four agricultural watersheds in the United States." J Environ. Qual. **37**: 1101-1115.

Wasco, C. o. (2010). "Festival of Roses." Retrieved June 2, 2010, from http://wascoca.virtualtownhall.net/Public_Documents/WascoCA_Chamber/festival.

What's Cooking America (2010). "Edible Flowers: How to Choose Edible Flowers." Retrieved May 12, 2010, from http://whatscookingamerica.net/EdibleFlowers/EdibleFlowersMain.htm.

White, J. W. (1969). Water Requirements and Irrigation Practices. Roses: A Manual on the Culture, Management, Diseases, Insects, Economics and Breeding of Greenhouse Roses. J. W. Mastalerz and W. L. Robert, Pennsylvania Flower Growers and New York State Flower Growers Association, Inc.

Whole Blossoms (2010). "Organic Bulk Flowers Forever Young Red Rose." Retrieved May 3, 2010, from http://www.wholeblossoms.com/producto.php?ids=10&id=121&idt=221.

Yu, O., M. Matsuno, et al. (2006). Flavonoid Compounds in Flowers: Genetics and Biochemistry. In: Floriculture, Ornamental and Plant Biotechnology Volume I. UK, Global Science Books.

Zary, K. (2010). Personal communication with V. Meier June 3, 2010. Marysville, OH

Zlesak, D. C. (2007). Rose Rosa x hybrida. Flower Breeding and Genetics Issues, Challenges and Opportunities for the 21st Century. N. O. Anderson. The Netherlands, Springer.

Zuzek, K., M. Richards, et al. (2010). "Roses for the North." Retrieved May 3, 2010, from http://www.extension.umn.edu/distribution/horticulture/components/6594-01.html.

## Determination of Nonregulated Status for IFD-524Ø1-4 and IFD-529Ø1-9 Rose Varieties

In response to petition 08-315-01p from International Flower Developments Pty, Ltd (hereafter referred to as IFD), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has determined that IFD-524Ø1-4 and IFD-529Ø1-9 roses and progeny derived from them are unlikely to pose plant pest risks and are no longer to be considered regulated articles under APHIS' Biotechnology Regulations (Title 7 of Code of Federal Regulations (CFR), part 340). Since APHIS has determined that IFD-524Ø1-4 and IFD-529Ø1-9 roses are unlikely to pose plant pest risks, APHIS will approve the petition for nonregulated status of IFD-524Ø1-4 and IFD-529Ø1-9 roses. Therefore, APHIS approved permits or acknowledged notifications that were previously required for environmental release, interstate movement, or importation of IFD-524Ø1-4 and IFD-529Ø1-9 roses and their progeny are no longer required. Importation of IFD-524Ø1-4 and IFD-529Ø1-9 rose propagative material will still be subject to APHIS foreign quarantine notices in 7 CFR part 319 and Federal Seed Act regulations in 7 CFR part 201.

This determination for IFD-524Ø1-4 and IFD-529Ø1-9 roses is based on APHIS' analyses of field and laboratory data submitted by IFD, references provided in the petition, peer-reviewed publications, and other relevant information as described in the Plant Pest Risk Assessment (PPRA) for IFD-524Ø1-4 and IFD-529Ø1-9 roses.

The Plant Pest Risk Assessment conducted on IFD-524Ø1-4 and IFD-529Ø1-9 roses concluded that they are unlikely to pose plant pest risks and should no longer be subject to the plant pest provisions of the Plant Protection Act and 7 CFR part 340 for the following reasons: (1) agronomic performance and disease and insect susceptibility of IFD-524Ø1-4 and IFD-529Ø1-9 roses are similar to those of their non-genetically engineered rose counterparts and/or other rose cultivars grown in the U.S.; (2) the disarmed *Agrobacterium* transformation vector used to introduce the genetic material into IFD-524Ø1-4 and IFD-529Ø1-9 roses was eliminated and neither the transformation vector nor the introduced genetic material or gene products are known to cause or promote disease, damage or injury to plants; (3) gene introgression from IFD-524Ø1-4 and IFD-529Ø1-9 roses into wild relatives in the United States and its territories is unlikely and is not likely to increase the weediness potential of any resulting progeny nor adversely affect the genetic diversity of related plants any more than would cultivation of traditional or other rose varieties; (4) they exhibit no characteristics that would cause them to be weedier or more difficult to control as weeds than non-genetically engineered roses or any other cultivated rose; (5) the gene products (delphinidin and delphinidin derivatives) have very low toxicity and are unlikely to pose any risks to non-target or beneficial organisms (6) horizontal gene transfer is unlikely to occur between IFD-524Ø1-4 and IFD-529Ø1-9 roses and organisms with which they cannot interbreed.

In addition to our finding that IFD-524Ø1-4 and IFD-529Ø1-9 roses are unlikely to pose plant pest risks, APHIS has completed a Final EA and FONSI for this action and has determined that a determination of nonregulated status for IFD-524Ø1-4 and IFD-529Ø1-9 roses and their progeny would have no significant impacts, individually or collectively, on the quality of the human environment and will have no effect on federally listed threatened or endangered species, species proposed for listing, or their designated or proposed critical habitats (http://www.aphis.usda.gov/brs/not_reg.html ). APHIS also concludes in its PPRA that new varieties derived from IFD-524Ø1-4 and IFD-529Ø1-9 roses are unlikely to exhibit new plant pest properties that are substantially different from the ones observed for IFD-524Ø1-4 and IFD-529Ø1-9 roses, or those observed for other rose varieties not considered regulated articles under 7 CFR part 340.

Based on my full and complete review and consideration of all of the scientific and environmental data, analyses, information, and conclusions of the PPRA, the Final EA, the agency's Response to Public Comments received in reference to the Draft EA, the FONSI, and my knowledge and experience as the Deputy Administrator of APHIS Biotechnology Regulatory Services, I have determined and decided that this determination of nonregulated status for IFD-524Ø1-4 and IFD-529Ø1-9 roses is the most scientifically sound and appropriate regulatory decision.

Michael C. Gregoire 8/26/2011

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