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

Date