



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Biotechnology
Regulatory
Services

4700 River Road
Riverdale, MD
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Mr. Nobuyuki Fukui
Director, Member of the Board
Suntory Global Innovation Center Limited
Suntory World Research Center
8-1-1 Seikadai, Seika-cho, Soraku-gum
Kyoto 619-0284, Japan

Request for confirmation of the regulatory status for genetically engineered roses for altered flower color for import into the United States as cut flowers only

Dear Mr. Fukui:

Thank you for your letter dated November 5, 2015, in which you requested that Biotechnology Regulatory Services (BRS) confirm your understanding that genetically engineered (GE) roses altered for flower color for import into the United States only as cut flowers, not whole plants, would not meet the definition of regulated articles under our current biotechnology regulation found at 7 CFR part 340. You also indicated in your letter that in September, 2008, Florigene Pty. Ltd., a fully owned subsidiary of Suntory Ltd., received a letter from us indicating that import of GE cut roses, not whole plants, expressing a modified flower color was not subject to our regulations under 7 CFR part 340. As we understand your request, you are requesting a similar confirmation for GE roses altered for blue color flowers to be imported into the United States as cut flowers for commercial sale and not for propagation.

The Plant Protection Act (PPA) of 2000 gives the Secretary of the Department of Agriculture (USDA) the authority to oversee the detection, control, eradication, suppression, prevention, or retardation of the spread of plant pests or noxious weeds in order to protect the agriculture, environment, and economy of the United States. The USDA's Animal and Plant Health Inspection Service (APHIS) is the agency charged with implementing the provisions of the PPA and regulations promulgated under this Act.

Under the APHIS regulations found at 7 CFR Part 340, APHIS regulates the importation, interstate movement and environmental release (field testing) of certain genetically engineered (GE) organisms, which this regulation refers to as "regulated articles." The regulation defines a regulated article as "any organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in sub-section 340.2 and meets the definition of plant pest, or is an unclassified organism and/or an organism whose classification is unknown, or any product which contains such an organism, or any other organism or product altered or produced through genetic engineering which the Administrator, determines is a plant pest or has reason to believe is a plant pest. Excluded

are recipient microorganisms which are not plant pests and which have resulted from the addition of genetic material from a donor organism where the material is well characterized and contains only non-coding regulatory regions.”

In your letter of November 5, 2015, you describe roses that have been genetically engineered by inserting plant genes from other flowers that result in altered flower color, specifically, blue. The method of transformation, promoters and terminators are all sourced from plant pests. However, as you noted in previous reviews by APHIS, certain types of cut flowers pose little risk to plant health. Consistent with those interpretation, we have evaluated the information described in your letter. Based on that information and the public literature, APHIS considers cut roses as being incapable of self-propagation, incapable of forming seeds, spreading vegetatively, and because gene flow from pollen produced from these roses during transit is not reasonably foreseeable, no permits would be required from APHIS under 7 CFR part 340 for importation or interstate movement of these cut flowers.

If you plan to develop these same GE roses in the United States at some future time, please be aware that because they have been transformed using known plant pests, *Agrobacterium tumefaciens* and cauliflower mosaic virus, they would be considered regulated articles under APHIS’ current regulations at 7 CFR part 340 for importation, interstate movement or release into the environment (field testing).

Finally, APHIS has confirmed that commercial roses are not known to be a weed in the United States and they have not been known to escape cultivation or plantings in gardens and parks throughout the United States. An invasive species, multi-floral rose, *Rosa multiflora*, is widely distributed in the northeast and north central United States. If outcrossing was to occur, there is no reason to believe that altered color trait would increase its invasiveness or extend its current range. Therefore, APHIS has no weediness concerns for this GE rose.

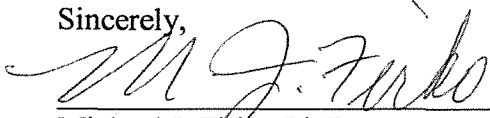
Please be advised that the importation of these GE cut flowers will be subject to APHIS Plant Protection and Quarantine (PPQ) permit and/or quarantine requirements. For further information you may contact Shailaja Rabindran at 301-851-2167 or contact PPQ general number for such inquiries at +1 (877) 770-5990.

Please be advised that GE rose cut flowers may still be subject to other Federal regulatory authorities such as the Food and Drug Administration (FDA) or the Environmental Protection Agency (EPA).

Should you become aware at any time of any issues that may affect the Agency's conclusion regarding this inquiry; you must immediately notify the Agency in writing of

the nature of the issue. We hope you appreciate our commitment to plant health and support for the responsible stewardship for the introduction of GE plants.

Sincerely,

A handwritten signature in cursive script, appearing to read "M. J. Firko".

Michael J. Firko, Ph.D.

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

5/20/2016
Date

