

Determination of Nonregulated Status for Okanagan Specialty Fruits' GD743 and GS784 Apples

In response to petition 10-161-01p from Okanagan Specialty Fruits (hereafter referred to as OSF), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has determined that OSF's GD743 and GS784 apples and progeny derived from them are not likely to pose a plant pest risk and are no longer to be considered regulated articles under APHIS's Biotechnology Regulations (Title 7 of the Code of Federal Regulations (CFR), part 340). Since APHIS has determined that GD743 and GS784 apples are unlikely to pose a plant pest risk, APHIS will approve the petition for nonregulated status of GD743 and GS784 apples. Therefore, APHIS approved permits or acknowledged notifications that were previously required for environmental releases, interstate movement, or importation under these regulations will no longer be required for GD743 and GS784 apples and their progeny. Importation of GD743 and GS784 apple fruit and propagative material will still be subject to APHIS foreign quarantine notices listed under 7 CFR part 319.

This determination for GD743 and GS784 apples is based on APHIS' analyses of field and laboratory data submitted by OSF, references provided in the petition, peer-reviewed publications, and other relevant information as described in the Plant Pest Risk Assessment (PPRA) for GD743 and GS784 apples.

The Plant Pest Risk Assessment conducted on GD743 and GS784 apples concluded that they are unlikely to pose a plant pest risk and should no longer be subject to regulations at 7 CFR part 340 for the following reasons:

- (1) Disease and insect susceptibility, agronomic performance, and other observed characteristics (except for the intended changes) of GD743 and GS784 apples are similar to those of its non-genetically engineered apple counterparts and/or other apple cultivars grown in the U.S., and are unlikely to alter disease and pest susceptibilities;
- (2) Based on an evaluation of the gene products and consideration of representative non-target species, it has been concluded that GD743 and GS784 apples are unlikely to adversely affect nontarget organisms beneficial to agriculture;
- (3) Agronomic performance evaluations of GD743 and GS784 apples revealed no characteristics that would cause them to be weedier or more difficult to control as a weed than non-genetically engineered apples or any other cultivated apples;
- (4) Gene introgression from GD743 and GS784 apples into wild relatives in the United States and its territories 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 apple varieties;
- (5) GD743 and GS784 apples are similar to their respective parent lines and other apple cultivars grown in the U.S., and therefore, there will be no change in agricultural and cultivation practices;

(6) Horizontal gene transfer is unlikely to occur between GD743 and GS784 apples and organisms with which they cannot interbreed.

In addition to our finding that GD743 and GS784 apples are not likely to pose a plant pest risk, APHIS has completed an Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) for this action, and has determined that a determination of nonregulated status for GD734 and GS784 apples 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 and endangered species, species proposed for listing, or their designated or proposed critical habitats. APHIS also concludes, based upon its PPRA, that new varieties derived from GD743 and GS784 apples are unlikely to exhibit new properties that are substantially different from the ones observed for GD743 and GS784 apples, or those observed for other apple varieties not considered regulated articles under 7 CFR part 340, that would pose a plant pest risk.

Based on my full and complete review and consideration of all the scientific and environmental data, analyses, information, the input from the public involvement process, and conclusions of the PPRA, the EA, and 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 non-regulated status for GD743 and GS784 apples is the most scientifically sound and appropriate regulatory decision.

Janet L. Beechall

for Michael J. Firko, Ph.D.

Deputy Administrator
Biotechnology Regulatory Services
Animal Plant Health Inspection Service
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