USDA

United States Department of Agriculture

Animal and Plant Health Inspection Service

Biotechnology Regulatory Services

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Dr. Henk Schouten
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The Netherlands

Re: APHIS regulation of cisgenic scab resistant apple cultivar Gala and disease resistant cisgenic plants

Dear Dr. Schouten:

This letter is in response to your inquiry of February 23, 2012 requesting APHIS' confirmation on the regulatory status of cisgenic scab resistant apple cultivar Gala, and of disease resistant cisgenic plants in general.

APHIS regulations for genetically engineered organisms are codified at 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason To Believe Are Plant Pests." Under the provisions of these regulations at § 340.1, a genetically engineered (GE) organism is deemed a *regulated article* if it has been genetically engineered from a donor organism, recipient organism, or vector or vector agent listed in § 340.2, and the listed organism meets the definition of plant pest or is an unclassified organism and/or an organism whose classification is unknown, or if the Administrator determines that the GE organism is a plant pest or has reason to believe it is a plant pest.

Cisgenic scab resistant apple cultivar Gala

Further information you provided on March 7, 2012 indicates that *Agrobacterium tumefaciens* was used to transform the apples described in your February 2012 inquiry.

Based on this information, APHIS has determined a plant pest (*A. tumefaciens*) was used as a vector agent. Because a plant pest vector was used for transformation, your GE scab resistant apple is a regulated article as defined in 7 CFR part 340. Therefore, importation, interstate movement, or environmental release permits from APHIS would be required for introductions of your GE scab resistant apples in the United States.

Disease resistant cisgenic plants

The March 2012 correspondence also provided APHIS the following definition of cisgenesis:

> "Cisgenesis is the genetic modification of a recipient plant with a natural gene from a crossable—sexually compatible—plant. Such a gene includes its introns and is flanked by its native promoter and terminator in the normal sense orientation. Cisgenic plants can harbour one or more cisgenes, but they do not contain any transgenes."

As stated above, APHIS reviews the vector used during transformation, in addition to the genetic material inserted into a plant genome, when considering the regulatory status of a GE plant. Genetically-engineered disease resistant cisgenic plants, as defined above, may be regulated by APHIS under 7 CFR part 340 if a plant pest vector was used during transformation. Therefore, APHIS' confirmation of regulatory status of such GE plants will be made on a case-by-case basis.

Please be advised that genetically-engineered disease resistant cisgenic plants may be subject to other applicable regulatory authorities such as EPA and FDA.

Sincerely,

Michael C. Gregoire

Michael C. Gregoire
Deputy Administrator
Biotechnology Regulatory Services