



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

4700 River Road
Riverdale, MD
20737

October 27, 2011

Ralph Scorza, Ph.D. and Ann Callahan, Ph.D.
Appalachian Fruit Research Station
2217 Wiltshire Road
Kearneysville, West Virginia 25430

Re: APHIS confirmation on regulatory status of null segregant (NS) lines derived from genetically engineered (GE) plants in the 'FasTrack' plum breeding program.

Dear Drs. Scorza and Callahan:

Thank you for your letter dated January 18, 2011 to Dr. John Turner at APHIS BRS. Your letter informed APHIS about the NS lines derived from GE parent trees used in the 'FasTrack' plum breeding program.

As described in your letter, the 'FasTrack' breeding program for perennial fruit trees accelerates breeding in plum trees and ultimately results in the field use of null segregant (NS) plum cultivars. As described in your letter, the absence of any transgenes or parts of transgenes is verified for NS trees through phenotypic and molecular analyses.

APHIS regulates the environmental release of certain genetically engineered organisms which are, or have the potential to be plant pests. Regulations for genetically engineered organisms that have the potential to be plant pests, under the Plant Protection Act, 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, 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 is a plant pest.

APHIS has evaluated the description of the NS lines and the 'FasTrack' breeding program as described in your January 18, 2011 letter. As described, the NS trees are indistinguishable from plants developed in a non-GE based breeding program, and never contained inserted, transgenic material. When confirmed via phenotypic and molecular analyses, the NS lines from the 'FasTrack' do not contain inserted genetic material and do not contain sequences from a plant pest.

As described, APHIS does not consider the NS lines created via the 'FasTrack' breeding program to be regulated articles. However, please be aware that accidental release of plant from the 'FasTrack' breeding program that does contain inserted GE material may be a violation of our regulations. We encourage ARS to continue to use both phenotypic



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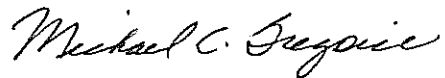
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Drs. Ralph Scorza and Ann Callahan
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and molecular analyses to confirm the end product of the 'FasTrack' breeding program are NS lines and do not contain inserted GE material from the GE parents.

Please be advised that the use of NS lines may still be subject to other applicable regulatory authorities such as EPA and FDA.

Sincerely,

A handwritten signature in cursive script that reads "Michael C. Gregoire".

Michael C. Gregoire
Deputy Administrator
Biotechnology Regulatory Services