USDA

United States Department of Agriculture

Animal and Plant Health Inspection Service

Biotechnology Regulatory Services

4700 River Road
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October 27, 2011

Dr. Ramsey S. Lewis
North Carolina State University
Associate Professor of Crop Science
Crop Science Department
4310 Williams Hall
Campus Box 7620
Raleigh, NC 27695

Re: APHIS confirmation of the regulatory status of null segregant (NS) lines derived from genetically engineered (GE) plants in an accelerated tobacco breeding program

Dear Dr. Lewis:

Thank you for your letter dated January 22, 2011 to APHIS. Your letter informed APHIS about the null segregant (NS) lines derived from genetically-engineered (GE) tobacco plants using an accelerated tobacco breeding method.

As described in your letter, this breeding method can significantly shorten the time required for tobacco cultivar development, and ultimately results in improved varieties of tobacco that do not contain any inserted genetic material; the resulting tobacco plants are null segregants (NS). As described in your letter, the absence of any transgenes or parts of transgenes is verified for NS tobacco plants 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 breeding approach described in your January 22, 2011 letter. As described, the NS tobacco plants 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 this novel breeding approach 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 this novel breeding approach to be regulated articles. However, please be aware that accidental release of tobacco plants that do contain inserted GE material may be a violation of our regulations. We encourage North Carolina State University to continue to use both phenotypic and molecular analyses to confirm the end products of this novel breeding approach 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,

Michael C. Gregoire

Michael C. Gregoire
Deputy Administrator
Biotechnology Regulatory Services