USDA

United States Department of Agriculture

Animal and Plant Health Inspection Service

Biotechnology Regulatory Services

4700 River Road
Riverdale, MD
20737

June 06, 2012

Sally Mackenzie, PhD
Ralph and Alice Raikes Professor of Plant Science
N305 Beadle Center
University of Nebraska
Lincoln, NE 68588-0660

Re: APHIS confirmation of the regulatory status of null segregant (NS) plants derived from genetically engineered (GE) plants in your breeding program.

Dear Dr. Mackenzie:

Thank you for your letter of inquiry dated December 20, 2011. Your letter inquired about the regulatory status of null segregant (NS) plant lines derived from genetically engineered (GE) parent plants in your breeding program. The NS lines will ultimately be used as parents for commercial variety development.

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." Pursuant to the provisions of these regulations, a 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 your breeding method and the resulting NS plant lines as described in your December 20, 2011 letter. As described, the NS plants will not contain any inserted, transgenic material and will not contain sequences from a plant pest.

As described, APHIS does not consider the NS lines created via your breeding method to be regulated articles. However, please be aware that, as described in your letter, the GE parent plants are regulated articles because a plant pest vector was used to introduce DNA that contains plant pest sequences. Therefore, the GE parent plants require a notification or permit for interstate movement or field release. Any unauthorized release of these GE plants could be a violation of our regulations. We encourage you to use molecular analyses to confirm the end products of your breeding program are NS lines and do not contain inserted GE material from the GE parents.

Please be advised that the use of these same 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