USDA

United States Department of Agriculture

Animal and Plant Health Inspection Service

Biotechnology Regulatory Services

4700 River Road
Riverdale, MD
20737

October 27, 2011

Dr. PII
New Zealand Institute for Plant and Food Research Ltd
PII

Re: APHIS confirmation of the regulatory status of CBI offspring derived from genetically engineered (GE) plants using the centromere-mediated chromosome elimination (CCE) technique.

Dear Dr. PII :

Thank you for your inquiry on January 27, 2011 to Michael Gregoire at APHIS BRS.

As described in your letter, centromere-mediated chromosome elimination (CCE) is a novel breeding method used to accelerate CBI breeding. In CCE, the genetically-engineered (GE) parent is engineered in such a way that the heritability of the chromosomes of the GE parent is eliminated, and the resulting improved CBI varieties do not contain any GE material.

APHIS regulates 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 CCE CBI breeding system described in your inquiry of January 27, 2011. As described, the resulting CBI offspring will not contain inserted GE material. Furthermore, routine phenotypic and molecular analyses can confirm that the CBI offspring developed by using the CCE technique do not contain inserted genetic material.

As described in your January 27, 2011 letter, APHIS does not consider the CBI progeny created via CCE to be regulated articles. However, please be aware that accidental release of plants that do contain inserted GE material may be a violation of our regulations. We encourage Plant and Food Research to continue to use both phenotypic

and molecular analyses to confirm the end products of CCE do not contain inserted GE material from the GE parent.

Please be advised that progeny of CCE may still be subject to other applicable regulatory authorities in the United States, such as EPA and FDA.

Sincerely,

Michael C. Gregoire

Michael C. Gregoire
Deputy Administrator
Biotechnology Regulatory Services