United States Department of Agriculture

Animal and Plant Health Inspection Service

Biotechnology Regulatory Services

4700 River Road
Riverdale, MD
20737

March 21, 2013

Dr. Alexander Krichevsky
BioGlow LLC
1005 N. Warson Rd, Suite 214
St Louis, MO 63132

Re: APHIS confirmation of the regulatory status of genetically engineered plants developed by BioGlow

Dear Dr. Krichevsky:

Thank you for your letter dated October 23, 2012 regarding the genetically-engineered (GE) plants your company is developing. The letter indicated the genus and species of the two plants that you are transforming, the method of transformation, and the purpose of the transformation; along with the genes and donors of the construct components being inserted.

APHIS regulates the environmental release of certain GE organisms which are, or have the potential to be plant pests. Regulations for GE 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 GE organism is deemed a regulated article if it has been genetically engineered from a donor organism, recipient organism, or vector or vector agent that belongs to any genera or taxa designated in §340.2 and 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 plants described in your October 23, 2012 letter along with the method of transformation, the genetic material (promoters, terminators, genes, and other elements) used, and the donors of these components.

APHIS has determined the plants, as described in the letter, are not plant pests, no organisms used as sources of the genetic material to create the plants are plant pests, and the method used to genetically engineer the plants did not involve plant pests.

No plant pests, unclassified organisms, or organisms whose classification is unknown are being used to genetically engineer these plants. In addition, APHIS has no reason to believe these plants are plant pests. Therefore APHIS does not consider these GE plants as described in your October 23, 2012 letter to be regulated under 7 CFR part 340.

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Please be advised that the use of these plants and any lines derived via transformation 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

cc: Dr. Sue MacIntosh, MacIntosh and Associates, Inc.