USDA

United States Department of Agriculture

Animal and Plant Health Inspection Service

Biotechnology Regulatory Services

4700 River Road
Riverdale, MD
20737

September 20, 2012

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

Re: APHIS confirmation of the regulatory status of the transgenic plant about which you inquired

Dear Dr. Krichevsky:

Thank you for your letter dated June 15th, 2012 regarding the transgenic plant your company is in the process of developing. The letter indicated the genus and species of the plant 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 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 plant described in your June 15th, 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 that the plant itself (as described in the letter) is not a plant pest, no organisms used as sources of the genetic material to create the plant are plant pests, and the method used to genetically engineer the plant did not involve plant pests

No plant pests, unclassified organisms, or organisms whose classification is unknown are being used to genetically engineer the variety of this plant. In addition, APHIS has no reason to believe that the plant is a plant pest. Therefore APHIS does not consider this genetically engineered plant as described in your June 15, 2012 letter to be regulated under 7 CFR part 340.

Please be advised that the use of this plant and any transgenic lines derived via transformation may still be subject to other applicable regulatory authorities such as EPA and FDA.

Sincerely,

Michael Gregoire
Deputy Administrator
Biotechnology Regulatory Services

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