

Dr. Michael Gregoire
Biotechnology Regulatory Services
USDA-APHIS
4700 River Road, Unit 98
Riverdale, MD 20737

Date: June 15th, 2012

Re: Confirmation of Regulatory Status

Dear Dr. Gregoire,

We kindly request to maintain information provided in this letter confidential, particularly bracketed [] sections. CBI justification can be provided upon request. Non-confidential copy of the letter is provided.

In this letter we inquire regarding certain genetically engineered [] plants currently under development by BioGlow LLC. Our company has developed technology allowing plants [

[] is not a plant pest, genetic elements used in the proposed transgenics are all sourced from fully classified organisms and the transformation process does not introduce any plant pest components, we hereby respectfully submit that there is no basis to assume that proposed transgenic [] is or will become a plant pest within the meaning of the Plant Protection Act (PPA)¹. BioGlow further maintains that under current regulations, transgenic [] is not a regulated article within the meaning of 7 CFR 340.1, because it does not satisfy any of the regulatory criteria that would subject it to the USDA's Animal Plant Health and Inspection Service's (APHIS) oversight.

We, therefore, respectfully request APHIS to confirm that the proposed [] modified with genetic elements as described in Table 1 below is not a regulated article within the scope of current regulations.

I. [] plants
[

[] DNA transfer does not involve *Agrobacterium* transformation or any other plant pest regulated under the Plant Protection Act. []

Genetic elements employed in the transformation are listed in Table 1, each element is described and its sources and functions identified.

¹ Plant Protection Act; 7 U.S.C. 7701 et seq. (recently revised: 2000)

Table 1. Description of genetic elements in commercial constructs [
]

GENETIC ELEMENT	SOURCE	FUNCTION

II. [] plants
[]

[] are not federal noxious weeds (7 CFR 361). They are available in a wide range of colors and sizes and are hardy plants that tolerates low humidity and moisture. Most home gardens are planted with []

III. **APHIS' interpretation of its 7 CFR 340 regulation dictates a finding that transgenic [] is not a regulated article**

- a. APHIS has been clear that not all transgenic plants are subject to regulatory oversight

APHIS defines a 'regulated article' as (Part 340.1):

*'Any organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belong to any genera or taxa designated in Part 340.2 and meets the definition of plant pest, or is an unclassified organism and/or an organism whose classification is unknown, or any product which contains such an organism, or any other organism or product altered or produced through genetic engineering which the Administrator, determines is a plant pest or has reason to believe is a plant pest. Excluded are recipient microorganisms which are not plant pests and which have resulted from the addition of genetic material from a donor organism where the material is well characterized and contains only non-coding regulatory regions.'*²

Consistent with the PPA's definition of a plant pest, APHIS further defines:

*'Plant pest. Any living stage (including active and dormant forms) of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof; viruses; or any organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants.'*³

² Well-characterized and contains only non-coding regulatory regions (e.g. operators, promoters, origins of replication, terminators, and ribosome binding regions). The genetic material added to a microorganism in which the following can be documented about such genetic material: (a) The exact nucleotide base sequence of the regulatory region and any inserted flanking nucleotides; (b) The regulatory region and any inserted flanking nucleotides do not code for protein or peptide; and (c) The regulatory region solely controls the activity of other sequences that code for protein or peptide molecules or act as recognition sites for the initiation of nucleic acid or protein synthesis. (7 CFR 340.1)

³ 7 CFR 340.1

APHIS further states that its regulations are consistent with the Coordinated Framework, because they apply *'only (to) genetically engineered organisms or products which are plant pests or for which there is a reason to believe are plant pests, and not to...an organism or product merely because of the process by which it was produced.'* And that concern arises only *'when an organism or product is altered or produced by genetic engineering and one or more of its constituents (donor, vector/vector agent or recipient) comes from a family or genus of organisms known to contain plant pests.... This is because... there is a risk that certain undesirable traits may be transferred to the new organism and may survive when the organism is released into the environment.'*⁴

This APHIS policy has been reiterated on several occasions, first with introduction of the notification and permit process for the confined release of transgenic organisms⁵, and again during the proposed revision of the regulations⁶. Furthermore, it has been ascertained that not all transgenic plants are to be regulated and, those that are, belong to the limited group of plant pests defined in the regulations.

- b. Transgenic [] does not fall within the regulatory definition of a regulated article.

Under APHIS regulations, a transgenic organism is considered a 'regulated article' if a) the donor organism, recipient organism, or vector agent(s) belongs to a genera or taxa designated in 7 CFR 340.2 AND b) the organism meets the definition of a plant pest. The language of the regulation requires that both criteria must be met to satisfy the definition of a regulated article.

For the product described above, neither the donor organisms, the recipient organism, nor the vectors BioGlow LLC will utilize to transform [] belong to any taxa identified in Part 340.2. All the genetic elements described in Table 1 are not sourced from any plant pest and the recipient organism, [], is also not a plant pest. Thus, the regulation dictates that transgenic [] generated using the genetic elements described in Table 1 is not a 'regulated article'.

Another definition of a 'regulated article' includes transgenic organisms that are unclassified or whose classification is unknown. The genetic donor element sources and [] itself are well classified and do not relate to the types of organisms that could raise concerns, such as pathogens, predators or parasites, or weeds or commercially available pollinators such as honeybees, bumble bees and alkali bees⁷.

⁴ Office of Science and Technology Policy's Coordinated Framework for Regulation of Biotechnology, June 26, 1986 (51 FR 23302).

⁵ 57 Fed Ref 53036 (Feb 1991)

⁶ 73 Red Reg 60008, 60010 (Oct 8, 2008)

⁷ 66 Fed Reg 51340 (Oct 9, 2001)

IV. Finding that transgenic [] is not a regulated article is consistent with previous precedents of APHIS determinations.

APHIS has previously made a number of determinations that transgenic plants, analogous to Bioglow's proposed genetically modified [], are not 'regulated articles'. One such example is a determination made to [], regarding genetically engineered [] and other modifications. Several additional examples are posted and available on USDA website.⁸

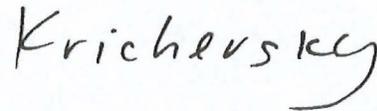
V. Conclusions

In summary, [] is not itself a plant pest and there are no plant pest elements involved in the genetic transformation, and further all sources for the genetic elements to be used have been fully classified. Therefore, we respectfully ascertain that there is no basis to assume that Bioglow's transgenic [] is or will become a plant pest within the meaning of the Plant Protection Act.

We thank the agency in advance for a prompt confirmation of this regulatory status. If APHIS have any questions or need further clarification, please contact Dr. Alexander Krichevsky at the address indicated below.

Sincerely,

Alexander Krichevsky, Ph.D, MBA.



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⁸ http://www.aphis.usda.gov/biotechnology/reg_loi.shtml