

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

Date: October 23rd, 2012

Re: Confirmation of Regulatory Status of Product Line Expansion

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 CBI-deleted copy is accompanying this letter.

Bioglow LLC is a biotechnology company developing novel ornamental plants. [

]. In present inquiry, we would like to request confirmation regarding regulatory status of additional plant varieties and additional genes aimed to expand Bioglow's product line.

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We, therefore, respectfully request APHIS to confirm that the proposed [] plants [] are not regulated articles within the scope of current regulations.

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

I. Recipient [] plants

[

] Those are popular ornamental plants used in many botanical and private gardens and known for their fragrant flowers and pleasant appearance, and these plants are not federal noxious weeds (7 CFR 361).

II. []

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III. []

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IV. APHIS' interpretation of its 7 CFR 340 regulation dictates a finding that [] plants are not regulated articles

- 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 (Part 340.1):

'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.'

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

This APHIS policy has been reiterated on several occasions, first with introduction of the notification and permit process for the confined release of transgenic organisms,⁴ and again during the proposed revision of the regulations.⁵ 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. Bioglow's [] plants do 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.

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VI. Conclusions

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⁴ 57 Fed Ref 53036 (Feb 1991)

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

⁶ 66 Fed Reg 51340 (Oct 9, 2001)

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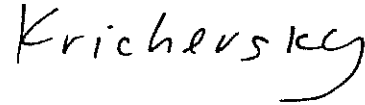
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BIOGLOW™

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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*Cc: Sue MacIntosh, MacIntosh & Associates, Inc.
Regulatory agent on behalf of BioGlow, LLC.*