

**EDITION OF LETTER WITH CONFIDENTIAL BUSINESS INFORMATION REDACTED**

Michael Gregoire  
Deputy Administrator  
Biotechnology Regulatory Services  
4700 River Rd, Unit 98  
Riverdale, MD 20737

Dear Deputy Administrator Gregoire,

This letter contains confidential business information. An edition of this letter with the confidential business information redacted follows.

I would like to request a determination concerning the production of dwarf plants and their regulation. Two scientific papers were published concerning the development of dwarf *Kalanchoe* plants (species *Kalanchoe blossfeldiana* or *Kalanchoe* hybrid, Crassulaceae).

The citations are:

Transformation of *Kalanchoe blossfeldiana* with rol-genes is useful in molecular breeding towards compact growth.

Authors: Brian Christensen, Sridevy Sriskandarajah, Margrethe Serek, and Renate Müller  
Plant Cell Reports (2008) 27:1485-1495

Inheritance of rol-genes from *Agrobacterium rhizogenes* through two generations in *Kalanchoë*

Authors: Henrik Lütken, Sabá Victoria Wallström, Erik Bjørn Jensen, Brian Christensen, and Renate Müller

Euphytica (2012) 188:397-407

These two papers describe research in which *Kalanchoe* plants were regenerated after exposure to an isolate of *Agrobacterium rhizogenes* (syn. *Rhizobium rhizogenes*) that was collected from nature (isolate ATCC 15834).

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The dwarf plants showed the integration of DNA from *Agrobacterium rhizogenes* isolate ATCC 15834. The ATCC 15834 isolate of *Agrobacterium rhizogenes* is collected from nature and does not include a synthetic construct created by humans; it is a naturally occurring isolate.

Would plants produced in this way be subject to regulation in the jurisdiction of the U.S. under applicable biotechnology statutes?

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