



Animal and
Plant Health
Inspection
Service

Biotechnology
Regulatory
Services

4700 River Road
Unit 98
Riverdale, MD
20737

June 24, 2014

[REDACTED]
[REDACTED]
[REDACTED]

Re: APHIS Confirmation of the Regulatory Status of Regenerated Dwarf
Kalanchoe Plants

Dear Dr. [REDACTED]:

Thank you for your inquiry dated March 25, 2013, regarding the regulatory status of certain dwarf *Kalanchoe* plants. The letter stated that these dwarf *Kalanchoe* plants were regenerated after exposure to an isolate of *Agrobacterium rhizogenes* collected from nature.

APHIS regulates the environmental release of certain genetically engineered (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 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 dwarf *Kalanchoe* plants in your February 25, 2013, email and attached documentation. As described in the research provided, these dwarf *Kalanchoe* plants were created by a natural transformation process using wild type *Agrobacterium rhizogenes*. The resulting, dwarf *Kalanchoe* plants have the root loci (*rol*) genes from *Agrobacterium rhizogenes* integrated in to their genome.

APHIS has determined that although the development of these dwarf *Kalanchoe* plants involved a plant pest component (*A. rhizogenes*), the *Kalanchoe plants* are not regulated articles under 7 CFR part 340 because they were not modified with recombinant DNA techniques, and therefore, they were not altered or produced through genetic engineering as defined in the regulations. Therefore, APHIS does not consider these dwarf *Kalanchoe* plants as described in your February 25, 2013, correspondence to be regulated under 7 CFR part 340.

Please be advised that the use of the dwarf *Kalanchoe* plants may still be subject to other applicable regulatory authorities such as EPA and FDA.

Sincerely,

A handwritten signature in black ink, appearing to read "M. J. Firko". The signature is fluid and cursive, with a long horizontal stroke at the beginning.

Michael J. Firko, Ph.D.
Deputy Administrator
Biotechnology Regulatory Services (BRS)
Animal and Plant Health Inspection Service (APHIS)
United States Department of Agriculture (USDA)