

United States Department of Agriculture

Animal and Plant Health Inspection Service

Biotechnology Regulatory Services

4700 River Road Riverdale, MD 20737 December 16, 2011

J. Scott Thenell 1181 Keaveny Ct. Walnut Creek, CA 94597

Re: APHIS response on the regulatory status of importing genetically engineered cut Baby's Breath into the United States.

Dear Mr. Thenell:

Thank you for your letter dated February 21, 2011 to Levis Handley at APHIS BRS. Your letter informed APHIS about Baby's Breath (*Gypsophila paniculata*) genetically engineered for altered flower color.

As described in your letter, the plants have been genetically engineered by inserting a plant gene that results in altered flower colors, ranging from dark purple and red to light pink. These flowers will be imported as cut flowers, in closed containers, and will not be imported as flowers for reproduction, seeds, or seedlings.

APHIS has previously stated that certain types of cut flowers pose little risk:

"The commercial distribution of cut flowers is one ... movement situation that APHIS has considered in light of the regulations, especially in cases where the flowers are grown in other countries then imported only as cut flowers. APHIS considers these circumstances to pose little, if any risk, and therefore would not require permits for these activities." (2008, FR 73 60015)

Consistent with that interpretation, we have evaluated the information described in your letter and in a supporting document supplied by Danziger on the biology and ecology of Baby's Breath. These documents outline the remote potential for outcrossing with wild *Gypsophila* present in the United States, the remote potential for asexual reproduction, and the remote potential for seed formation and dissemination from these cut flowers. APHIS confirms that the cut Baby's Breath described in your documentation does not require an importation or interstate movement permit under 7 CFR part 340. Even though these cut flowers originate from a genetically engineered organism, they do not have the ability to propagate once they have been harvested.

Our confirmation that these genetically engineered cut Baby's Breath do not require a movement permit depends on the above evaluation of the ability of the flowers to escape and reproduce in the environment. If any information comes to light to indicate that the information or data are not correct or no longer correct, it may change our evaluation and the regulatory status of these plants. Additionally, the planting of the described genetically engineered Baby's Breath outside a contained facility may require a permit from APHIS.



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Please be advised that the importation of cut Baby's Breath is still be subject to other applicable APHIS Plant Protection and Quarantine phytosanitary and importation requirements, and may be subject to other applicable authorities such as EPA and FDA.

Sincerely,

Michael C. Gregorie
Michael C. Gregorie

Deputy Administrator

Biotechnology Regulatory Services