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

Dear Dr. Gregoire:

I am a Professor of Developmental Biology ant the University of Florida. I established the UF Grape Biotechnology Laboratory, which I currently direct, over 25 years ago. One of our goals is to produce improved grapevines via genetic modification. We are pursuing genetic modification by an “ingenic” or “cisgenic” approach.

I am writing to inquire about your agency policies concerning a specific ingenic plant I am developing. I’ll try to make this brief by describing just two examples. In most regards, ingenic plants do not appear different from those produced by breeding or protoplast fusion, neither of which is regulated. The plants described differ by the method of gene insertion: either protoplast engulfment of vector DNA or biolistic (gene gun) mediated gene insertion.

Here is a description of the purely ingenic plants that I have in development: Both plants constitute a grapevine expressing a grapevine-derived anthocyanin regulatory gene (VvMybA1). The regulatory gene is driven by a grapevine-derived 2S albumin promoter with its terminator such that only embryos, seeds and berries express anthocyanin. All of these genes and elements are from grapevine.

The genetic elements are placed into grape cells either via 1) protoplast infusion, or 2) particle bombardment. The plants will have only one copy of the 2S Alb/VvMybA1 complex. There will be no other markers, accessory genes or regulatory elements used. These do not constitute plant pest sequences. The product will be a red-berried Thompson Seedless grapevine.

Since the described plants contain only grapevine genes & regulatory elements, it does not appear that they fit within USDA guidelines for regulation. Could you comment as to whether they will need to be submitted for deregulation and/or give me some guidance as to how such a grapevine might be processed by your agency?

Sincerely,

Dennis Gray

Dennis J. Gray
Professor, Developmental Biologist