

**CONFIDENTIAL**

DEC 19 1988

Dr. Rod Townsend  
Pioneer Hi-Bred International, Inc.  
Department of Biotechnology Research  
7300 NW 62nd Avenue Box 38  
Johnston, Iowa 50131-0038

Dear Dr. Townsend:

This is in response to your letter of December 1, 1988, requesting a determination as to whether transgenic maize and tobacco cells that have been engineered to contain hybrid constructs altering a plant biosynthetic pathway constitute regulated articles under 7 CFR Part 340 and require movement permits for interstate shipment. The transgenic materials that you describe carry a microbial gene derived from a nonplant pest source and regulatory sequences from plant pests (cauliflower mosaic virus, tobacco mosaic virus, and Agrobacterium tumefaciens). The materials are to be shipped interstate to another laboratory in one of three forms: as either detached leaves, freeze-dried ground leaf tissue, or crude leaf extract.

After a thorough review of your letter of inquiry, we have concluded that two of the transgenic materials you list (dried tissue and leaf extracts) will not be regulated articles, but detached leaves from transgenic plants will be regulated articles and will require movement permits.

There are two issues relevant to this judgment. The first is that of the genetically engineered plants themselves. Under the provisions of the regulations in 7 CFR Part 340 entitled "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," there are several requirements in order for an organism to be classified as a regulated article. An organism is deemed a regulated article if it was altered or produced using genetic engineering (i.e., recombinant DNA technology) and if it was produced using a donor or recipient organism, or vector or vector agent which is, or which there is reason to believe is, a plant pest. Whole tobacco or maize plants (or their seeds) that have been transformed with constructs produced by genetic engineering and carry genetic material from the plant pests tobacco mosaic virus, cauliflower mosaic virus, and Agrobacterium tumefaciens are, accordingly, regulated articles. The second issue concerns the definition of "organism" as it applies to the particular materials that you wish to transport interstate. An organism is defined as "any active, infective, or dormant stage or life form of an entity characterized as living." This definition does not apply to dried tissue or subcellular extracts of tissue from regulated articles, and

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such materials are therefore exempt. However, because leaf cells from both organisms can be regenerated into viable plants, leaves as such must be classified as "active forms," and hence as organisms which are regulated articles.

You may choose to transport only exempt plant materials and accordingly apply for no movement permits. However, you might find it advantageous to obtain courtesy permits for these materials. Such permits expedite inspection and classification of transported materials and provide dated legal records of any new products you produce.

The principal reviewer of your submission was Dr. Michael Schechtman, Staff Biotechnologist. If you have any questions about our review, please call him at Area Code (301) 436-8761.

Sincerely,

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Arnold Foudin, Ph.D.  
Acting Deputy Director  
Biotechnology Permit Unit  
Biotechnology, Biologics, and  
Environmental Protection

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