



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

PP

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

MAY 11 1998

MEMORANDUM

**SUBJECT:** Consideration of Section 3(c)(5) Unconditional Registration for Plant Genetic Systems' (America) *Bt* Corn Plant-pesticide: *Bacillus thuringiensis* subspecies *tolworthi* Protein and the Genetic Material Necessary for Its Production in Corn (EPA File Symbol 70218-R)

-DECISION MEMORANDUM-

**FROM:** Janet L. Andersen, Ph.D., Director  
Biopesticides and Pollution Prevention Division

**TO:** Marcia E. Mulkey, Director  
Office of Pesticide Programs

I. ISSUE

Should the Agency conditionally register Plant Genetic Systems' *Bt* corn product for one year for use of this plant-pesticide for corn intended for seed increase, animal feed, and industrial use (ethanol production) pursuant to FIFRA §3(c)(5)?

II. RATIONALE FOR RECOMMENDATION

BPPD believes that a section 3(c)(5) registration that is limited in scope and duration is appropriate in this situation. This registration will be limited as to the duration of the registration, the acreage of corn plants grown, and subsequent harvesting and processing of the resulting crop. BPPD in recommending a finding of no unreasonable adverse effects, is relying in part upon the limitations set in the limited registration. In addition, the registration stipulates that the company acquiring the registration is liable for the actions of their customers in terms of meeting the terms and limitations of the registrations. Data requirements for granting this limited plant propagation registration under section 3(c)(5) of the Federal Insecticide, Fungicide, and

Rodenticide Act (FIFRA) have been met. The data have been reviewed and BPPD foresees no unreasonable adverse effects from the use of this product if it is used pursuant to the following limitations.

1. This registration will automatically expire on midnight May 30, 1999. After this registration has expired, no field corn seed that contain the pesticide product may be sold or planted. However, harvesting of such corn planted prior to May 30, 1999 is permissible subject to the terms of this registration. Plant Genetic Systems (America) is liable for the actions of its customers in regard to meeting the terms and limitations of this registration
2. This registration is for field corn to be used only in animal feed, industrial non-food uses such as ethanol production, and seed increase. In addition, any corn grown within 660 feet of Cry9C corn must also be limited to use in animal feed and industrial non-food uses such as ethanol production. The acreage of corn planted may not exceed 109,000 acres for the animal feed and industrial uses and 11,000 acres for seed increase.
3. Plant Genetic Systems must require that growers follow the USDA NC-205 guidelines for refuge for all Cry9C corn. These guidelines reflect the current knowledge base among USDA, academic, industry, and EPA scientists. Specifically, a 25% unsprayed or 40% sprayed non-Bt corn structured refuge in close proximity to the Bt crop is required. The refuge must be established within 1500-2000 feet of the Bt crop. Any insecticide treatment cannot include sprayable *Bt* products.
4. Plant Genetic Systems must provide specific information through their technical bulletins, brochures, product labels, and educational presentations so that growers have the necessary tools to successfully implement an IRM plan. A World Wide Web site on the internet would be a practical way to provide specific resistance management information. Included in this IRM information should be instructions on the appropriate use of the Bt plant-pesticides in a resistance management program, compatibility with existing Integrated Pest Management (IPM) programs, refuge deployment and management (including IPM options), monitoring, reporting of unusual pest damage, and any local and regional IRM considerations. The success of any IRM program will ultimately depend on growers who have the knowledge and tools to understand the problem of resistance and the steps that can be taken to combat it.
5. Plant Genetic Systems must maintain a (confidential) database to track sales by units and location of Cry9C corn on a state and county-by-county basis. This material should be submitted annually (by January 31 of the year following each growing season) to the Agency on a Confidential Business Information (CBI) basis. As part of this report, Plant Genetic Systems must provide an estimate of the acreage for Cry9C corn within each state.

### III. RECOMMENDATION

The Biopesticides and Pollution Prevention Division recommends that the Plant Genetic Systems Bt product containing the new active ingredient *Bacillus thuringiensis* subspecies *tolworthi* protein and the genetic material necessary for its production in corn be REGISTERED under FIFRA section 3(c)(5), with appropriate limitations, for the purpose of seed increase, feed use, and commercial non-food use such as ethanol production.

CONCUR: Marcia J. Mulheys

NONCONCUR: \_\_\_\_\_

DATE: 5/11/98