



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg. Number:

69575-2

Date of Issuance:

MAR 25 1997

NOTICE OF PESTICIDE:
 x Registration
 Reregistration

Term of Issuance: Conditional

Name of Pesticide Product:

DEKALBt

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

DEKALB Genetics Corporation
3100 Sycamore Road
DeKalb, Illinois 60178

~~Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.~~

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

The registration application referred to above, submitted in connection with registration under § 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you do the following terms and conditions.

1. Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Submit production information for this product for the fiscal year in which this product is conditionally registered, in accordance with FIFRA § 29. The fiscal year begins October 1 and ends September 30. Production information will be submitted to the Agency no later than November 15, following the end of the preceding fiscal year.
3. This registration will automatically expire on midnight April 1, 2001. EPA will reevaluate the effectiveness of Dekalb's resistance management plan before April 1, 2001 on whether to convert the registration to a non-expiring registration.
4. This registration is for field corn only.

Signature of Approving Official:

Janet Z. Anderson see pages 2-6

Date:

MAR 25 1997

5. Dekalb will:

- a. Unless demonstrated to EPA's satisfaction that alternative resistance management practices are equally or more effective than a structured refugia, develop and submit to EPA a draft plan for "structured" refugia by 8/9/98 and a final plan by 1/31/99;
- b. Discuss the development and implementation of the plan and alternative resistance management practices with EPA throughout development and implementation; and
- c. Implement the "structured" refugia plan or an EPA approved alternative resistance management plan no later than April 1, 2001.

6. Dekalb will monitor for the development of resistance using baseline susceptibility data and/or a discriminating concentration assay when such an assay is available. Dekalb will proceed with efforts to develop a discriminating concentration assay. Dekalb will ensure that monitoring studies are conducted annually to determine the susceptibility of ECB and corn earworm (CEW) populations to the CryIA(c) protein. This resistance monitoring program will be developed to measure increased tolerance to *Bt* corn above the various regional baseline ranges. Annual reports of resistance monitoring will be submitted to the Agency by January 31 each year and include units sold per state of the Dekalb European corn borer protected corn. Lepidoptera pest resistance, for CEW, will be monitored in areas where ECB resistance is being investigated.

Populations of ECB and CEW will be collected from representative distribution areas of the registrant's *Bt* corn hybrids and monitored/screened for resistance, with particular focus on those areas of highest distribution in each State. The variability of ECB populations and their sensitivity to CryIA(c) was not demonstrated in Dekalb's submission although it is referred to in passing. In the first annual report, Dekalb must indicate where this variability is found and if it has changed with deployment of DBT418. The results of monitoring studies will be communicated to the Agency on an annual basis, by January 31 of the year following the population collections for a given growing season.

In addition, Dekalb will instruct its customers (growers and seed distributors) to contact Dekalb (e.g., via a toll-free customer service number) if incidents of unexpected levels of ECB & CEW damage occur. Dekalb will investigate and identify the cause for this damage by local field sampling of plant tissue from its hybrids and sampling of ECB & CEW populations, followed by appropriate *in vitro* and *in planta* assays. Upon Dekalb's confirmation by immunoassay that the plants contain CryIA(c) protein, bioassays will be conducted to determine whether the collected ECB population exhibits a resistant phenotype.

Until such time that a discriminating concentration assay is established and validated by Dekalb, Dekalb will utilize the following to define a confirmed instance of ECB & CEW resistance:

Progeny from the sampled ECB or CEW population will exhibit both of the following characteristics in bioassays initiated with neonates:

- a. An LC50 in a standard CryIA(c) diet bioassay that exceeds the upper limit of the 95% confidence interval of the mean historical LC50 for susceptible ECB or CEW populations, as established by the ongoing baseline monitoring program.
- b.
 1. For ECB, > 30% survival and > 25% leaf area damaged in a 5-day bioassay using CryIA(b)-positive leaf tissue under controlled laboratory conditions.
 2. For CEW, upon validation of the assay, a specified % survival and % leaf area damaged in a 5-day bioassay using CryIA(c)-positive leaf tissue under controlled laboratory conditions. Per your 3/12/97 letter, "... Dekalb will validate whether or not the leaf bioassay is useful for detecting corn earworm resistance to DEKALB's Bt corn during the first year of registration.

Based upon continued experience and research, this working definition of confirmed resistance may warrant further refinement. In the event that Dekalb finds it appropriate to alter the criteria specified in the working definition, Dekalb must obtain Agency approval in establishing a more suitable definition.

7. Dekalb will report all instances of confirmed ECB & CEW resistance, as defined above, to the Agency within 30 days. Upon identification of a confirmed instance of ECB resistance Dekalb will take the following immediate mitigation measures:

- a. Notify customers and extension agents in the affected area,
- b. Recommend to customers and extension agents in the affected area the use of alternative control measures to reduce or control the local ECB population, and
- c. Recommend to customers and extension agents in the affected area that crop residues be incorporated into the soil following harvest, to minimize the possibility of overwintering of ECB.

Within 90 days of a confirmed instance of ECB and/or CEW resistance, as defined above, Dekalb will: (1) notify the Agency of the immediate mitigation measures that were implemented, and (2) submit to the Agency a proposed long-term resistance management action plan for the affected area, (3) work closely with the Agency in assuring that an appropriate long-term resistance management action plan for the affected area is implemented, and (4) implement an action plan that is approved by EPA and that consists of some or all the following elements, as warranted:

- a. Informing customers and extension agents in the affected area of ECB and/or CEW resistance,
- b. Increasing monitoring in the affected area, and ensuring that local ECB populations are sampled on an annual basis,
- c. Recommending alternative measures to reduce or control ECB or CEW populations in the affected area,

- d. Implementing a structured refuge strategy in the affected area based on the latest research results. The implementation of such a strategy will be coordinated by the Agency with other registrants.
- e. If the above elements are not effective in mitigating resistance, Dekalb will voluntarily cease sale of all of Dekalb's CryIA(c) corn in the county experiencing loss of product efficacy and the bordering counties until an effective local management plan approved by EPA has been implemented. During the voluntary suspension period, Dekalb may sell and distribute in these counties only by obtaining EPA approval to study resistance management in those counties. The implementation of such a strategy will be coordinated by the Agency with other registrants.

If EPA agrees that an effective resistance management plan has been implemented which mitigates resistance, Dekalb can resume sales in the affected county(ies).

8. Dekalb will maintain a (confidential) database to track its sales (units and location) of its Bt corn on a county-by-county basis, to the extent that such data are available. Dekalb will provide annually, on a CBI basis, sales data for each state indicating the number of units of its Bt corn hybrids that it sells. This information will be provided by January 31 of the year following each growing season.

9. Dekalb will provide grower education. Dekalb will agree to include an active partnership with such parties as: university extension entomologists and agronomists, consultants, and corn grower groups. Dekalb will implement a grower education program directed at increasing grower awareness of resistance management, in order to promote responsible product use. As specific resistance management recommendations are developed (e.g., as a result of ongoing research or experience) these will be incorporated, as appropriate, into the various grower communication and educational media. Dekalb will inform the Agency as it develops, implements, and refines its communication strategies. In addition to grower communication vehicles, Dekalb will also develop a Grower Guide, to be distributed to all customers, that will include current information regarding resistance management and integrated pest management.

10. Dekalb will confer with the EPA as Dekalb develops various aspects of its resistance management research program. Dekalb agrees, as a condition of this registration, to submit annually progress reports including results and conclusions from research (including literature) as they become available in the following areas as a basis for developing a long-term resistance management strategy which include:

- a. ECB pest biology and behavior including adult movement and mating patterns, larval movement, survival on silks, kernels, and stalks, and overwintering survival and fecundity on non-corn hosts.
- b. The feasibility of "structured" refuge options for ECB including both "block" refugia, "50-50 early/late season patchwork"; research needs to be done in both northern and southern areas on ECB.

- c. Development of a discriminating concentration (diagnostic concentration) assay for field resistance (field screening) for ECB and CEW. Specific sampling locations will be established in each state to determine if increases in *Bt* toxin tolerance may be detected before crop failures develop. Increased tolerance levels need to be identified before field failure occurs. In monitoring for tunneling damage, the number of trivial tunnels may be less indicative of resistance development than the total extent of tunneling damage (e.g. length of tunnels). The extent of tunneling damage should be monitored as well as the number of tunnels.
- d. Effects of corn producing the CryIA(c) delta endotoxin on pests other than ECB, including but not limited to the corn earworm, the stalk borer complex, and the fall armyworm. Dekalb should provide information to support their claim of CEW control from foliar feeding.
- e. The biology of ECB resistance including receptor-mediated resistance and its potential effect on population fitness, as well as the effects on insect susceptibility to other Cry proteins. Possible high dose control exists for the first generation ECB on whorl stage, but not for later generation(s) on more mature corn plants. More data are needed on toxin expression in various parts of the plant at different stages of the plant in regard to ECB and CEW. As part of this data, Dekalb must provide information in silk expression levels and on any reduced CEW reproduction offered by DBT418 from field data. Data will also be required of other secondary pests of corn (i.e. stalk borer complex, fall armyworm, and S.W. corn borer) if EPA determines that research in Section 10.d. above so warrants.

11. Dekalb must not sell or distribute, under this registration, any corn that contains the plant-pesticide product covered by this document in all counties of the following states unless specific prohibited counties are listed:

- Alabama
- Arkansas
- Florida
- Georgia
- Louisiana
- Mississippi
- Missouri: Butler, Dunkin, Mississippi, New Madrid, Pemiscot, Scott, Stoddard Counties.
- Oklahoma: Bryan, Caddo, Canadian, Garvin, Grady Counties.
- North Carolina
- South Carolina
- Tennessee: Carroll, Chester, Crockett, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Henderson, Lake, Lauderdale, Lawrence, Lincoln, McNairy, Madison, Obion, Rutherford, Shelby, Tipton Counties.
- Texas
- Virginia: Greensville, Isle of Wright, Northampton, Southampton, Sussex, Suffolk Counties.

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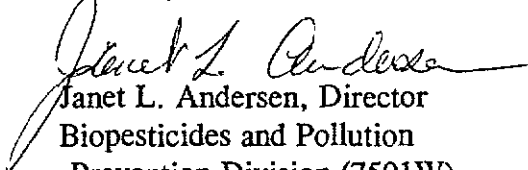
Dekalb will develop a resistance management program that is acceptable to EPA that includes the research specified in Section 10.a. through e. above.

This registration is registered under FIFRA § 3(c)(7)(C) because of the outstanding resistance management data .

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,


Janet L. Andersen, Director
Biopesticides and Pollution
Prevention Division (7501W)

DEKALBt

***Bacillus thuringiensis* subsp. *kurstaki* CryIA(c) delta endotoxin and the genetic material necessary for its production in corn.**

Pure form of the Plant Pesticide, *Bacillus thuringiensis* subsp. *kurstaki* CryIA(c) delta endotoxin insect control protein as expressed by the *cryIA(c)* gene in corn cells

Active Ingredient

Bacillus thuringiensis CryIA(c) delta-endotoxin and the genetic material necessary for its production in corn.....0.00005 to 0.00019 %*

Inert Ingredient

Phosphinothricin acetyltransferase protein and the genetic material necessary for its production in corn..... 0.009 to 0.115 %*

* Percentage of total protein on a dry weight basis.

Keep Out of Reach of Children

CAUTION

EPA REGISTRATION NUMBER 69575-2

EPA ESTABLISHMENT NUMBER 69575-CT-1

DEKALB Genetics Corporation
3100 Sycamore Road
DeKalb, Illinois 60178

**ACCEPTED
with COMMENTS
In EPA Letter Dated
MAR 25 1997**

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

69575-2

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Use restrictions: Corn seed containing this plant pesticide is for use as field corn only. Corn seed containing this plant pesticide may not be sold or used in the following states or counties under this registration:

ALABAMA All Counties	ARKANSAS All Counties	FLORIDA All Counties	GEORGIA All Counties	LOUISIANA All Counties
MISSISSIPPI All Counties	NORTH CAROLINA All Counties	SOUTH CAROLINA All Counties	TEXAS All Counties	
MISSOURI Counties of: Butler Dunklin Mississippi New Madrid Pemiscot Scott Stoddard	OKLAHOMA Counties of: Bryan Caddo Canadian Garvin Grady	TENNESSEE Counties of: Carroll Chester Crockett Fayette Franklin Gibson Hardeman Hardin Haywood Henderson	Lake Lauderdale Lawrence Lincoln McNairy Madison Obion Rutherford Shelby Tipton	VIRGINIA Counties of: Greensville Isle of Wight Northampton Southampton Sussex Suffolk

Corn has been transformed to express the CryIA(c) form of the *Bacillus thuringiensis* subsp. *kurstaki* (*B.t.k.*) delta endotoxin for the control or suppression of the following lepidopteran corn insect pest:

- European corn borer
- Ostrinia nubilalis*

Corn hybrids that contain DEKALB's *B.t.* corn plant pesticide must be accompanied by a Grower Guide which contains the following:

1. The *B.t.* delta-endotoxin protein expressed in this corn controls or suppresses the listed lepidopteran corn insect pest.
2. Routine applications of insecticides to control these insects are usually unnecessary when corn containing the *B.t.* delta-endotoxin protein is planted.
3. Instruction for growers to read the Grower Guide prior to planting; for information on planting, production and insect resistance management.