US EPA ARCHIVE DOCUMENT

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EEB Out :

To: Phillip Hutton
Product Manager 18
Registration Division (H7505C)

From: Anthony F. Maciorowski, Chief
Ecological Effects Branch/EFED (H7507C)

Attached, please find the EEB review of...

Reg./File # : 066736-EUP-R
Chemical Name : *Bacillus thuringiensis* S-endotoxin
Type Product : Transgenic corn
Product Name :
Company Name : Ciba Seeds
Purpose : Review data for EUP and comment on adequacy.

Action Code: 720 Date Due: 4/18/93
Reviewer: David Bays

EEB Guideline/MRID Summary Table: The review in this package contains an evaluation of the following:

GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT
71-1(A)			72-2(A)			72-7(A)		
71-1(B)			72-2(B)			72-7(B)		
71-2(A)			72-3(A)			122-1(A)		
71-2(B)			72-3(B)			122-1(B)		
71-3			72-3(C)			122-2		
71-4(A)			72-3(D)			123-1(A)		
71-4(B)			72-3(E)			123-1(B)		
71-5(A)			72-3(F)			123-2		
71-5(B)			72-4(A)			124-1		
72-1(A)			72-4(B)			124-2		
72-1(B)			72-5			141-1		
72-1(C)			72-6			141-2		
72-1(D)						141-5		

Y=Acceptable (Study satisfied Guideline)/Concur
P=Partial (Study partially fulfilled Guideline but additional information is needed
S=Supplemental (Study provided useful information but Guideline was not satisfied)
N=Unacceptable (Study was rejected)/Nonconcur

EEB REVIEW

Pesticide Name: Genetically Engineered Corn Plants containing a gene which expresses *Bacillus thuringiensis* var. *kurstaki* delta-endotoxin, Cry1A(b).

100.0.0 Submission Purpose and Label Information

100.1.0 Submission Purpose and Pesticide Use

Ciba Geigy Corporation, Ciba Seeds, has requested a two year EUP for transgenic corn plants containing *B. thuringiensis* var *kurstaki* (Btk) delta endotoxin. The product is a genetically engineered corn plant which has a gene for the Btk delta-endotoxin inserted into its genome. The plants will be evaluated for control of European Corn Borer on potato.

100.1.1 Proposed EUP Program

100.1.2 Objectives

The objectives of the EUP program are to test Btk delta-endotoxin expressed in corn plants as a control agent for European Corn Borer (ECB) in larger acerages. Most of the test plots will contain plants that will express the Btk protein and the enzyme phosphinothricin acetyltransferase as a selectable marker protein. One of the plant lines will also produce a B-glucuronidase enzyme as a scorable marker.

In the first year, 33 acres will be planted with transgenic corn plants in six states and in the second year, 104 acres will be planted in nine states. The objectives during the first year will be to evaluate gene efficacy, do resistance management and insect susceptibility experiments, continue with breeding activities and seed increases. In the second year, these experiments and activities will be continued along with yield evaluations and insect populations dynamics studies.

100.1.3 Date, Duration

The duration of the proposed EUP permit is for two years which includes the 1993 (through March 1994) and 1994 (April 1994 through March 1995) growing seasons.

100.1.4 Amount Shipped, Geographical Distribution

PROPOSED FIRST YEAR EUP PROGRAM (93-94)

State	County	Experiments	Maximum[1] Transgenic Acreage	Maximum[1] Transgenic Plants	Maximum Cry1A(b) Protein
Florida	Palm Beach	Breeding	5.2	140 000	6.0
		Seed increase	4.0	100,000	4.3
Hawaii	Maui	Breeding	7.8	210,000	9.0
		Seed increase	12.0	300,000	12.9
Illinois	McClean	Gene efficacy	0.6	14,000	0.6
		Breeding	1.3	35,000	1.5
	Shelby	Gene efficacy	0.3	7,000	0.3
Iowa	Linn	Gene efficacy	0.3	7,000	0.3
	Madison	Gene efficacy	0.3	7,000	0.3
Nebraska	Seward	Gene efficacy	0.3	7,000	0.3
North Carolina	Durham	Insect susceptibility	0.1	1,200	0.1
	Johnson	Resistance mgmt.	0.3	3,000	0.1
Total			32.5	831,000	35.7

PROPOSED SECOND YEAR EUP PROGRAM (94-95)

State	County	Experiments	Maximum[1] Transgenic Acreage	Maximum[1] Transgenic Plants	Maximum Cry1A(b) Protein
Florida	Palm Beach	Breeding	5.2	140,000	6.0
		Seed increase	4.0	100,000	4.3
Hawaii	Maui	Breeding	7.8	210,000	9.0
		Seed increase	24.0	600,000	25.8
Illinois	McDonough	Gene efficacy	0.3	7,000	0.3
		Yield	0.3	7,000	0.3
	McClean	Gene efficacy	0.3	7,000	0.3
		Breeding	1.3	35,000	1.5
		Seed increase	12.0	300,000	12.9
		Yield	0.3	7,000	0.3
		Pop'n dynamics	2.0	50,000	2.1
	Shelby	Gene efficacy	0.3	7,000	0.3
		Yield	0.3	7,000	0.3
	Champaign	Pop'n dynamics	2.0	50,000	2.1
		Gene efficacy	0.3	7,000	0.3

	Ogle	Gene efficacy	0.3	7,000	0.3
		Yield	0.3	7,000	0.3
	Lee	Seed increase	12.0	300,000	12.9
	Sangamon	Seed increase	12.0	300,000	12.9
Indiana	Wells	Gene efficacy	0.3	7,000	0.3
		Yield	0.3	7,000	0.3
	Tippecanoe	Gene efficacy	0.3	7,000	0.3
		Pop'n dynamics	2.0	50,000	2.1
	Madison	Gene efficacy	0.3	7,000	0.3
Iowa	Linn	Gene efficacy	0.3	7,000	0.3
		Yield	0.3	7,000	0.3
	Madison	Gene efficacy	0.3	7,000	0.3
		Yield	0.3	7,000	0.3
	Kossuth	Gene efficacy	0.3	7,000	0.3
		Yield	0.3	7,000	0.3
	Boone	Pop'n dynamics	2.0	50,000	0.3
		Gene efficacy	0.3	7,000	0.3
Minnesota	Steele	Gene efficacy	0.3	7,000	0.3
		Yield	0.3	7,000	0.3
	Waseca	Gene efficacy	0.3	7,000	0.3
		Pop'n dynamics	2.0	50,000	2.1
Nebraska	Seward	Gene efficacy	0.3	7,000	0.3
		Yield	0.3	7,000	0.3
	Lancaster	Gene efficacy	0.3	7,000	0.3
		Pop'n dynamics	2.0	50,000	2.1
North Carolina	Durham	Insect susceptibility	0.1	1,200	0.1
	Johnson	Resistance mgmt.	1.0	25,000	1.1
		Pop'n dynamics	2.0	50,000	2.1
Wisconsin	Columbia	Gene efficacy	0.3	7,000	0.3
		Yield	0.3	7,000	0.3
	Dane	Gene efficacy	0.3	7,000	0.3
		Pop'n dynamics	2.0	50,000	2.1
Total			104.1	2,614,200	112.0

[1]Reflects cumulative acreage/plants for total plantings at each location.

100.2.0 Formulation Information

INSECT RESISTANT CORN SEED

ACTIVE INGREDIENT:
Bacillus thuringiensis delta-endotoxin as produced in corn by a cry1A(b) gene and its controlling sequences as found on plasmid vector pCIB11.....00.01%
Inert Ingredients.....99.99%
Total.....100.00%

100.3.0 Application Methods, Directions, Rates

Recommended Rates and Timing

The Btk insecticidal protein is contained within the corn plants and will be applied when the corn seed is planted in the field.

Application rate:

Crops	Pests	plants/acre
Potato	European corn borer	25,000

100.4.0 Target Organisms

European corn borer, corn earworm, southwestern corn borer and fall armyworm.

100.5.0 Precautionary Labeling

FOR EXPERIMENTAL USE ONLY

KEEP OUT OF REACH OF CHILDREN

Pesticide and container storage and disposal directions are adequate.

101.0.0 Hazard Assessment

101.1.0 Discussion

Data on the effect of this product on nontarget organisms will not be required for the first year experiments, since the experimental plots will be contained or severely limited (less than 1.0% outcrossing) and there should not be any significant exposure to nontarget organisms. However, EFGWB will need to make an exposure assessment before EEB can make a risk assessment for nontarget organisms.

101.2.0 Likelihood of Adverse Effects on Nontarget Organisms

This EUP is for a limited duration and acreage. EFGWB estimates that minimal movement of the Btk gene will occur during the field tests planned for the first year. This should lead to a very low exposure to nontarget organisms.

As a result of the above considerations, no significant environmental impact is expected from the limited acreage EUP in the first year. However additional information on the second year experiments will have to be submitted to EFGWB for them to make an assessment on exposure before EEB can make a risk assessment.

For unlimited Section 3 registration the ecological effects data requirements will have to be reevaluated according to the regulations currently being developed by the Agency for Transgenic Plant Pesticides.

101.3.0 Endangered Species Considerations

Since, the field tests will be located in counties of 9 states which do not have any known populations of endangered lepidopteran species, no risk to endangered insect species is expected as a result of the proposed field test. Based on the low exposure from the limited acreage and duration of the EUP, EEB feels that there will not be a "may affect" situation for endangered mammals, birds, invertebrates, plants and aquatic species.

101.4.0 Adequacy of Toxicity Data

Not Applicable

101.5.0 Adequacy of Labeling

Labeling is adequate

103.0.0 Conclusions

EEB has reviewed the proposed EUP application for transgenic corn which contains a delta-endotoxin gene from *Bacillus thuringiensis* var. *kurstaki*. The Btk will be used to primarily control the European corn borer. Approximately 32.5 acres of transgenic corn will be planted in plots scattered throughout 6 States in the first year and approximately 104.1 acres in 9 states during the second year. Based upon the available data EEB concludes that the proposed limited uses and limited exposure to nontargets in the first year experiment (EFGWB has determined these experiments will be contained or limited to one percent or less outcrossing) will provide a minimal risk to nontarget organisms or endangered species.

However, not enough information was provided by the registrant for EFGWB to make recommendations concerning exposure to nontargets for the second year experiment. Therefore, EEB is not able to make a risk assessment concerning nontarget effects on the second year experiment at this time. Once sufficient information has been submitted to EFGWB for them to make an assessment on exposure, then EEB will be able to make a risk assessment on the effects to nontargets.

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