

067979-00001-030399

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Systems Integration Group, Inc.

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Dr. Demetra Vlachos
Senior Manager, Regulatory Affairs
Novartis Seeds, Inc. - Field Crops - NAFTA
P.O. Box 12257
Research Triangle Park, NC 27709-2257

Dear Dr. Vlachos:

Subject: Application to Amend the Terms and Conditions of the Subject Registration
Regarding Item 11 Concerning the Planting of Bt11/YieldGard Corn in Cotton
Growing Areas and Refuges in Cotton Growing Areas; Your Submissions Dated
2/17/98 and 2/23/98
EPA Registration No. 67979-1

The amendment referred to above, submitted in connection with registration under
FIFRA section 3(c)(7)(A), is acceptable provided that:

- 1) You submit and/or cite all data required for registration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
- 2) The term and condition restricting commercial sale listed in item 11 of our 10/29/98 letter approving limited use in the South is modified to read as follows:

Novartis Seeds must require growers who intend to plant field corn seed containing the plant-pesticide in any state or county specified below to sign an agreement specifying that they will plant a minimum 50% refuge of non-Bt corn. The combined sale of this plant-pesticide in any state or county specified below must not exceed the amounts required to plant 150,000 acres per annum. Novartis will encourage growers to plant their refuge acres within ¼ mile of their Bt11/YieldGard™ corn acres, where feasible, but must require placement of the refuge no more than ½ mile from their Bt11/YieldGard™ corn acres. Novartis will further instruct growers not to use B.t. based foliar insecticides in the refuge.

Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Bryan, Caddo, Canadian, Garvin, and Grady), Tennessee (only the counties of Carroll, Chester, Crockett, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Henderson, Lake, Lauderdale, Lawrence, Lincoln, McNairy, Madison, Obion, Rutherford, Shelby, and Tipton), Texas

CONCURRENCES

SYMBOL	(except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltrie,						
SURNAME							
DATE							

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

2/54

Roberts, and Sherman), Virginia (only the counties of Greensville, Isle of Wight, Northampton, Southampton, Sussex, Suffolk) and Missouri (only the counties of Butler, Dunklin, Mississippi, New Madrid, Pemiscot, Scott, Stoddard).

Per item 8 of the 1/24/97 letter approving use in the South, Novartis will report all sales of this product by Novartis or its distributors annually to EPA no later than January 31st of the following year. For the 150,000 acres in the South, sales must be reported in counties as well as states.

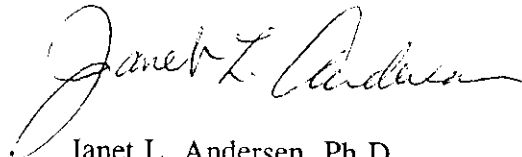
3) This amendment to item 11 of the terms and conditions of this registration will expire on January 1, 2000.

Your release of Bt corn into commerce under a modified term and condition 11 constitutes acceptance of these conditions. We agree that this amendment will not apply retroactively to deliveries of Novartis Seeds' Bt11/YieldGard™ hybrid seed already received by growers prior to the implementation date (within 10 business days of the date of this letter) of this amendment. We also agree that in such cases, sales and distribution of Novartis Seeds' Bt11/YieldGard™ seed in the affected states and counties will occur under the terms of your 10/29/98 amendment approval.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e).

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

Sincerely,



Janet L. Andersen, Ph.D.
 Director
 Biopesticides and Pollution
 Prevention Division (7511C)

Enclosure

CONCURRENCES							
SYMBOL				2			
SURNAME							
DATE							

INSECT RESISTANT CORN

Bt Protein Plant Pesticide Active Ingredient for the Control of European Corn Borer in Corn

(Pure form of the plant pesticide,
Bacillus thuringiensis subsp. *kurstaki* delta-endotoxin protein,
as expressed in corn cells)

Active Ingredient:

Bacillus thuringiensis CryIA(b) delta-endotoxin
and the genetic material (as contained in plasmid
vector pZO1502) necessary for its production
in corn 0.0002 - 0.0006%
by seed weight

Inert Ingredient:

Substance produced by a marker gene and its
controlling sequences in corn < 0.0000001%
by seed weight

Keep Out of the Reach of Children

CAUTION

Keep out of lakes, ponds or streams. Do not contaminate water
by cleaning of equipment or disposal of wastes.

EPA Reg. No. 67979-1
EPA Est. No. 67979-IA-2

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67979-1

Novartis Seeds, Inc. - Field Crops - NAFTA
3054 Cornwallis Road
P. O. Box 12257
Research Triangle Park, NC, USA 27709-2257

Directions for Use:

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

Novartis must require growers who intend to plant field corn seed containing the plant-pesticide in any state or county specified below to sign an agreement specifying that they will plant a minimum 50% refuge of non-Bt corn. The combined sale of this plant-pesticide in any state or county specified below must not exceed the amounts required to plant 150,000 acres per annum. Novartis will encourage growers to plant their refuge acres within ¼ mile of their YieldGard™ corn acres, where feasible, but must require that growers plant the refuge no more than ½ mile from their YieldGard corn acres. Novartis will further instruct growers not to use B.t.-based foliar insecticides in the refuge.

- Alabama: all counties
- Arkansas: all counties
- Florida: all counties
- Georgia: all counties
- Louisiana: all counties
- Mississippi: all counties
- Missouri: only the counties of Butler, Dunklin, Mississippi, New Madrid, Pemiscot, Scott and Stoddard
- North Carolina: all counties
- Oklahoma: only the counties of Bryan, Caddo, Canadian, Garvin and Grady
- South Carolina: all counties
- Tennessee: only the counties of Carroll, Chester, Crockett, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Henderson, Lake, Lauderdale, Lawrence, Lincoln, McNairy, Madison, Obion, Rutherford, Shelby and Tipton
- Texas: all except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman
- Virginia: only the counties of Greensville, Isle of Wight, Northampton, Southampton, Sussex and Suffolk

Novartis Seeds will report all sales of this product by Novartis Seeds or its distributors annually to the EPA no later than January 31 of the following year.

Corn has been genetically modified to produce a *Bacillus thuringiensis* CryIA(b) delta-endotoxin protein for control of:

European corn borer (*Ostrinia nubilalis*)

In addition, some control or suppression of the following corn pests can be provided:

- Southwestern corn borer (*Diatraea grandiosella*)
- Southern cornstalk borer (*Diatraea crambidoides*)
- Corn earworm (*Helicoverpa zea*)
- Fall armyworm (*Spodoptera frugiperda*)

All corn seed that contains the plant pesticide that is sold or distributed by Novartis Seeds or its distributors must be accompanied by informational material indicating the registration number (67979-1) and the active ingredient [*Bacillus thuringiensis* CryIA(b) delta-endotoxin and the genetic material (as contained in plasmid vector pZO1502) necessary for its production in corn], and stipulating that growers read the Grower Guide prior to planting the seed.

A Grower Guide must be distributed to all customers using seed containing the plant pesticide that will include instructions and recommendations regarding product use, insect resistance management, and integrated pest management.