

PM 92

524-489

2/6/98

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEB 6 1998

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Dr. Keith Reding  
Regulatory Affairs Manager  
700 Chesterfield Parkway North  
St. Louis, MO 63198

Dear Dr. Reding:

Subject: Label Amendment Applications to Modify the Terms and Conditions of the Subject Registrations to 1) Allow Unlimited Use of Yieldgard/MON810 Bt Corn in Ten Counties of the Texas Panhandle and to 2) Prohibit the Use of Bt Cotton in the Same Ten Counties EPA Registration Nos ~~524-489~~ & 524-478

The amendment for Yieldgard, EPA Reg. No. 524-489, referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable and the term and condition restricting commercial sale listed as item 12 in the notice of registration is modified to read as follows:

Monsanto will ensure that in the combined states of 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 (with the exception of the counties of Dallam, Sherman, Hansford, Ochiltree, Lipscomb, Hartey, Moore, Hutchinson, Roberts and Carson), 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) that the combined sale of this plant-pesticide in all the above states will not exceed the amounts required to plant 100,000 acres per anum. Further, Monsanto will ensure that for the states and counties listed above that the amount sold will result in no more than 5% of the corn planted in any county with more than 1000 acres of cotton. Per item 9 of the notice of registration Monsanto will report all sales of this product by Monsanto or its distributors annually to EPA no later than January 31st of the following year.

A stamped copy of the label and a copy of our recent resistance management review are enclosed for your records. Submit five (5) copies of the final printed labeling.

The amendment for EPA Reg. No. 524-478, Bollgard, referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is

SYMBOL	acceptable subject to the following comments and the term and condition restricting commercial					
SURNAME	Mando	Nelson	Hutton			
DATE	2/4/98	2/4/98	2/4/98			

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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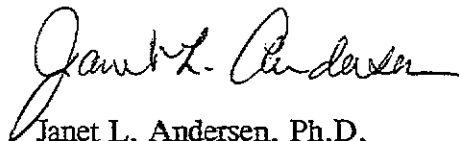
sale is modified to read:

In Florida do not plant south of Tampa, (Florida Route 60). Not for commercial sale or use in Hawaii. Test plots or breeding nurseries established in Hawaii must be surrounded by either 12 border rows of non-transgenic cotton if the plot size is less than 10 acres or 24 border rows if the plot is over 10 acres, and must not be planted within 1/4 mile of *Gossypium tomentosum*. Not for commercial planting in the following counties in the Texas panhandle, which historically are not cotton-producing counties: Dallam, Sherman, Hansford, Ochiltree, Lipscomb, Hartley, Moore, Hutchinson, Roberts, and Carson.

- 1) Modify the ingredient statement on the product label by changing "*Bacillus thuringiensis* subsp. *kurstaki* delta endotoxin as produced by the CryIA(c) gene and its controlling sequences in cotton" to read "*Bacillus thuringiensis* subsp. *kurstaki* CryIA(c) delta endotoxin and the genetic material necessary for its production in cotton".
- 2) Modify the label by adding the EPA establishment number(s) to the label.
- 3) Modify the label by adding the KEEP OUT OF REACH OF CHILDREN statement and immediately below it the signal word CAUTION on the front panel of the label after the ingredient statement.
- 4) This amendment restricting the sale of Bt cotton in ten counties of the Texas Pan Handle must be implemented during the 1998 growing season.

Your release of Bt cotton into commerce with the amended grower guide constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e).

Sincerely,



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

Enclosures

CONCURRENCES							
SYMBOL			2				
SURNAME							
DATE							

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# YieldGard™

## ***Bacillus thuringiensis* CryIA(b) delta-endotoxin and the genetic material necessary for its production in corn**

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

**Active Ingredient:**

*Bacillus thuringiensis* CryIA(b) delta endotoxin and the genetic material necessary for its production in corn . . . . . 0.023 - 0.029%\*

\*Percentage of total protein on a dry weight basis.

Keep Out of Reach of Children

CAUTION

EPA REGISTRATION NUMBER 524-489

EPA ESTABLISHMENT NUMBER 524-MO-002

Monsanto Company  
700 Chesterfield Parkway North  
St. Louis, Missouri 63198

**ACCEPTED  
with COMMENTS  
In EPA Letter Dated  
FEB 6 1998  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.  
524-489**

**Directions for Use:**

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

Monsanto will ensure that in the combined states of Alabama, Arkansas, Florida, Georgia, Louisiana, North Carolina, Mississippi, South Carolina, Virginia (only the counties of Greenville, Isle of Wight, Northhampton, Southhampton, Sussex, and Suffolk), Missouri (only the counties of Butler, Dunklin, Mississippi, New Madrid, Pemiscot, Scott, and Stoddard), 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) and Texas (with exception of the counties of Dallam, Sherman, Hansford, Ochiltree, Lipscomb, Hartley, Moore, Hutchinson, Roberts and Carson) that the combined sale of this plant pesticide will not exceed the amounts required to plant 100,000 acres per anum. Further, Monsanto will ensure that for the states and counties listed above that the amount sold will result in no more than 5% of the corn planted in any county with more than 1,000 acres of cotton. Monsanto will report all sales of this product by Monsanto or its distributors annually to the EPA no later than January 31st of the following year.

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

- |                            |                              |
|----------------------------|------------------------------|
| European corn borer        | <i>Ostrinia nubilalis</i>    |
| Southwestern corn borer    | <i>Diatraea grandiosella</i> |
| — Southern cornstalk borer | <i>Diatraea crambidoides</i> |
| Corn earworm               | <i>Helicoverpa zea</i>       |
| Fall armyworm              | <i>Spodoptera frugiperda</i> |
| Stalk borer                | <i>Paratropis nebris</i>     |

Sales of corn hybrids that contain Monsanto's *B.t.* corn plant pesticide must be accompanied by a Grower Guide which instructs growers to read the Grower Guide prior to planting for information on planting, production and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the *B.t.* delta-endotoxin protein are planted.

