

PM 92

524-478

2/6/98

page 1 of 4

FEB 6 1998

3-5 / 554367  
18

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 annum. 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 acceptable subject to the following comments and the term and condition restricting commercial

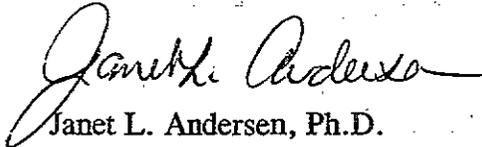
sale is modified to read:

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

3 9 4

# PLANT PESTICIDE ACTIVE INGREDIENT

## *Bacillus thuringiensis* subsp. *kurstaki* Insect Control Protein

Pure form of the Plant Pesticide, *Bacillus thuringiensis* subsp. *kurstaki* control protein as expressed in cotton cells.

Active Ingredient:

*Bacillus thuringiensis* subsp. *kurstaki* delta endotoxin protein as produced by the CryIA(c) gene and its controlling sequences in cotton . . . . . 0.001 - 0.006%\*

Inert:

Substances produced by marker genes and their controlling sequences in cotton . . . . . 0.001 - 0.003%

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

EPA REGISTRATION NUMBER 524-478

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. 524-478

Directions for Use:

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

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, or 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.

Cotton has been transformed to express the *Bacillus thuringiensis* subsp. *kurstaki* (*B.t.k.*) delta endotoxin protein for the control of the following lepidopteran cotton insect pests:

- |                 |                                 |        |        |
|-----------------|---------------------------------|--------|--------|
| Cotton bollworm | <i>Helicoverpa zea</i>          | )))))) | )))))) |
| Tobacco budworm | <i>Heliothis virescens</i>      | )))))) | )))))) |
| Pink bollworm   | <i>Pectinophora gossypiella</i> | )))))) | )))))) |

Transformed cotton must be accompanied by the Grower Guide which contains the following:

1. The *B.t.k.* delta endotoxin protein expressed in this cotton controls the listed lepidopteran cotton insect pests.
2. Routine applications of insecticides to control these insects are usually unnecessary when cotton containing the *B.t.k.* delta endotoxin protein are planted.
3. Instruction for growers to read the product grower guide prior to planting; for information on planting, production and insect resistance management.

