524-576 09-18-2009

UN) STATES ENVIRONMENTAL PROTECT AGENCY

1/9

Dr. Russell P. Schneider
Senior Director, Regulatory Affairs and Policy
Monsanto Company
1300 I Street, NW, Suite 450 East
Washington, DC 20005

SEP 1 8 2009

Re: Monsanto Company; MON 89034 x MON 88017
EPA Registration No. 524-576
Minor Label ("Fast Track") Amendment
Submission dated 07/23/2009
Decision #418440

Dear Dr. Schneider:

The Agency has reviewed your request to amend the subject product registration, which included the following changes to the product label:

1) Addition of more detailed language regarding the planting of structured refuge (i.e., second paragraph found under "Refuge Requirements for MON 89034 x MON 88017 Field Corn" of the current label).
2) Replacement of "seed" with "product" in the following sentence: "It is a violation of Federal law to use this product in any manner inconsistent with this labeling."
3) Modification of "Inert Ingredient:" to "Other Ingredient:" in accordance with PR Notice 97-6.
4) Correction of minor typographical errors.

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

1) 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.

CONCURRENCES								
SYMBOL ▶	7511P	7511P	7511P					
SURNAME ▶	KAUSCH	Reynolds	Rull					
DATE ▶	09/15/2009	9/16/09	9/18/09					

☆ U.S. Government Printing Office: 2005 206-899 (mac)

If the above condition is not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment constitutes acceptance of this condition. If you have any questions, contact Jeannine Kausch at 703-347-8920 or by email at kausch.jeannine@epa.gov.

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

Sincerely,

Sheryl K. Reilly, Ph.D., Chief
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

Enclosure (1):
-Accepted Label

Plant-Incorporated Protectant Label

MON 89034 x MON 88017

Lepidopteran-and Rootworm-Protected Corn
(OECD Unique Identifier: MON-89Ø34-3 × MON 88Ø17-3)

Active Ingredients:

Bacillus thuringiensis Cry1A.105 protein and the genetic material necessary for its production (vector PV-ZMIR245) in event MON 89034 corn.....0.0010-0.0024%*

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary for its production (vector PV-ZMIR245) in event MON 89034 corn.....0.0030-0.0057%*

Bacillus thuringiensis Cry3Bb1 protein and the genetic material necessary for its production (vector PV-ZMIR39) in event MON 88017 corn.....0.0037-0.0070%*

Other Ingredient:

CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and genetic material necessary (vector PV-ZMIR39) for its production in corn event MON 88017.....0.0038-0.0069%*

*Percentage (wt/wt) on a dry weight basis whole plant (forage)

KEEP OUT OF REACH OF CHILDREN

Caution

NET CONTENTS_____

EPA Registration No. 524-576

EPA Establishment No. 524-MO-002

Monsanto Company
800 North Lindbergh Blvd.
St Louis, MO 63167

ACCEPTED

SEP 18 2009

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 524-576

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with this labeling. Information regarding commercial production must be included in the Technology Use Guide.

MON 89034 x MON 88017 protects corn crops from leaf, stalk, and ear damage caused by corn borers and root damage caused by corn rootworm larvae.

This plant-incorporated protectant (PIP) may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

1) Refuge Requirements for MON 89034 x MON 88017 Field Corn

In order to minimize the risk of corn borers and corn rootworms developing resistance to MON 89034 x MON 88017 corn, an insect resistance management plan must be implemented which includes planting of a structured refuge. Growers who fail to comply with the IRM requirements risk losing access to Monsanto corn PIP products. These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year. Furthermore, these refuge requirements do not apply to commercial hybrid sweet corn.

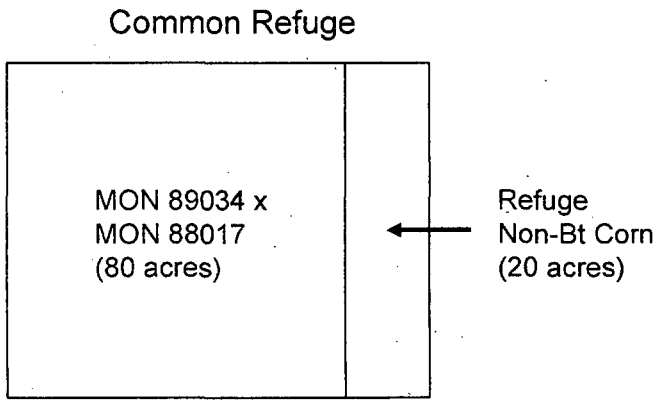
The refuge and MON 89034 x MON 88017 corn should be sown on the same day, or with the shortest window possible between planting dates to ensure that corn root development is similar among varieties. If the refuge is planted on rotated ground, then the MON 89034 x MON 88017 corn must also be planted on rotated ground. If the combined refuge is planted on continuous corn, then MON 89034 x MON 88017 may be planted on either continuous or rotated land (option encouraged where WCRW rotation resistant biotype may be present). Refuge options are based on the planting of MON 89034 x MON 88017 in cotton or non-cotton growing regions and the insect pressure present in those locations. If insecticides are applied to the refuge for control of CRW adults, the same treatment must also be applied in the same timeframe to MON 89034 x MON 88017.

a) Corn-Belt/Non-Cotton Growing Area Refuge Requirements

For MON 89034 x MON 88017 field corn grown outside cotton-growing areas (e.g., the Corn Belt), two options for deployment of the refuge are available to growers.

The first option is planting a **common refuge** for both corn borers and corn rootworms. The common refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn borers or corn rootworms. The refuge area must represent at least

20% of the grower's corn acres (i.e., sum of MON 89034 x MON 88017 acres and refuge acres; refuge area must contain 20 acres of corn for every 80 acres of MON 89034 x MON 88017 corn planted). It must be planted as block within or adjacent (e.g., across the road) to the MON 89034 x MON 88017 field, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The common refuge can be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-Bt foliar insecticide for the control of late season pests if pest pressure reaches an economic threshold for damage; however, if rootworm adults are present at the time of foliar applications then the MON 89034 x MON 88017 field (acres) must be treated in a similar manner. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). A schematic illustration of one common refuge deployment option is shown below:

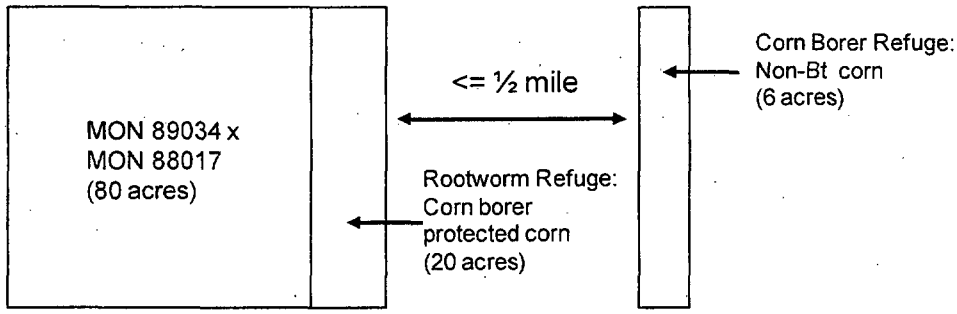


The second option is planting **separate refuge** areas (e.g., two refuge areas, a double refuge, or paired refuge areas) for corn borers and corn rootworms. Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The corn borer refuge must be planted with corn that is not a lepidopteran-protected Bt hybrid, must represent at least 5% of the grower's corn acres, and must be planted within ½ mile of the MON 89034 x MON 88017 field. The corn borer refuge can be treated with a soil-applied or seed-applied insecticide for corn rootworm larval control, or a non-Bt foliar applied insecticide for corn borer control if pest pressure reaches an economic threshold for damage. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

The corn rootworm refuge must be planted with corn that is not a corn rootworm-protected Bt hybrid, but can be planted with Bt hybrids that control corn borers. The corn rootworm refuge must represent at least 20% of the grower's corn acres (i.e., corn rootworm refuge must contain 20 acres of corn for every 80 acres of MON 89034 x MON 88017 corn planted) and must be planted as a block within or adjacent to the MON 89034 x MON

88017 field, strips around the field, perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The corn rootworm refuge can be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-Bt foliar insecticide for control of late season pests; however, if corn rootworm adults are present at the time of foliar applications then the MON 89034 x MON 88017 field must be treated in a similar manner. A schematic illustration of one separate refuge option with the corn rootworm refuge planted as a block within the field and the corn borer refuge planted within a ½ mile of the MON 89034 x MON 88017 field is shown below:

Separate Refuge



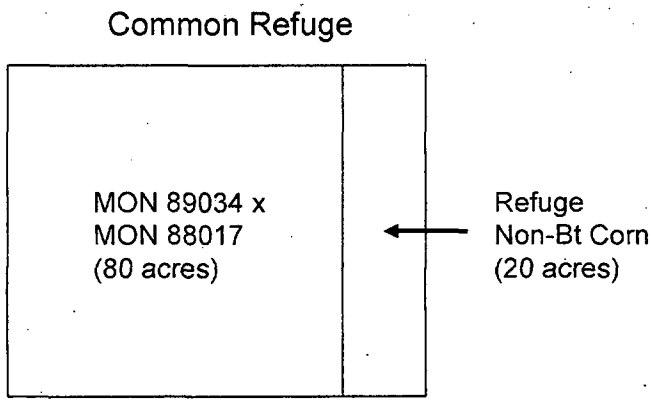
b) Cotton-Growing Area Refuge Requirements

Cotton-growing areas include the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, Stoddard).

For MON 89034 x MON 88017 field corn grown in cotton growing areas of the U.S. the common refuge and separate refuge options (e.g., two-refuge options, double-refuge options, paired-refuge options) are also available as specified below.

The first option is planting a **common refuge** for both corn borers and corn rootworms. The common refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn borers or corn rootworms. The refuge area must represent at least 20% of the grower's corn acres (i.e., sum of MON 89034 x MON 88017 acres and refuge acres; refuge area must contain 20 acres of corn for every 80 acres of MON 89034 x MON 88017 corn planted). It must be planted as block within or adjacent (e.g., across the road)

to the MON 89034 x MON 88017 field, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The common refuge can be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-Bt foliar insecticide for the control of late season pests if pest pressure reaches an economic threshold for damage; however, if rootworm adults are present at the time of foliar applications then the MON 89034 x MON 88017 field (acres) must be treated in a similar manner. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). A schematic illustration of one common refuge deployment option is shown below:

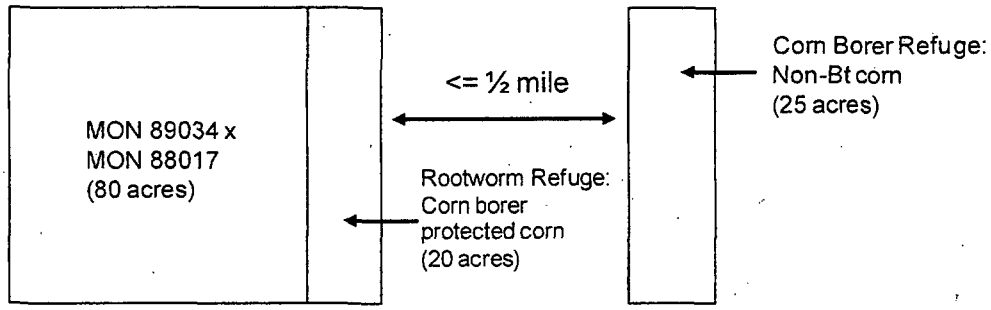


The second option is planting **separate refuge** areas (e.g., two refuge areas, a double refuge, or paired refuge areas) for corn borers and corn rootworms. Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The corn borer refuge must be planted with corn that is not a lepidopteran-protected Bt hybrid, must represent at least 20% of the grower's corn acres, and must be planted within ½ mile of the MON 89034 x MON 88017 field. The corn borer refuge can be treated with a soil-applied or seed-applied insecticide for corn rootworm larval control, or a non-Bt foliar applied insecticide for corn borer control if pest pressure reaches an economic threshold for damage. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

The corn rootworm refuge must be planted with corn that is not a corn rootworm-protected Bt hybrid, but can be planted with Bt hybrids that control corn borers. The corn rootworm refuge must represent at least 20% of the grower's corn acres (i.e., corn rootworm refuge must contain 20 acres of corn for every 80 acres of MON 89034 x MON 88017 corn planted) and must be planted as a block within or adjacent to the MON 89034 x MON 88017 field, perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The corn rootworm

refuge can be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-Bt foliar insecticide for control of late season pests; however, if corn rootworm adults are present at the time of foliar applications then the MON 89034 x MON 88017 field must be treated in a similar manner. A schematic illustration of one separate refuge option with the corn rootworm refuge planted as a block within the field and the corn borer refuge planted within a ½ mile of the MON 89034 x MON 88017 field is shown below:

Separate Refuge



2) Post-Harvest Requirements for MON 89034 x MON 88017 Sweet Corn

For MON 89034 x MON 88017 sweet corn, growers are required to destroy any MON 89034 x MON 88017 sweet corn stalks that remain in the field following harvest via rotary mowing, discing, or plow-down within one (1) month of harvest.

Corn Insects Controlled

European corn borer	*Ostrinia nubilalis*
Southwestern corn borer	*Diatraea grandiosella*
Southern cornstalk borer	*Diatraea crambidoides*
Corn earworm	*Helicoverpa zea*
Fall armyworm	*Spodoptera frugiperda*
Corn stalk borer	*Papaipema nebris*
Sugarcane borer	*Diatraea saccharalis*
Western corn rootworm	*Diabrotica virgifera virgifera*
Northern corn rootworm	*Diabrotica barberi*
Mexican corn rootworm	*Diabrotica virgifera zeae*

Sales of corn hybrids that contain Monsanto's Bt corn plant incorporated protectants must be accompanied by a Grower Guide which includes 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 Bt proteins is planted.

MON 89034 x MON 88017 is a product of Monsanto's research program offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5023179, 5110732, 5164316, 5196525, 5322938, 5352605, 5359142, 5378619, 5424412, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6962705, 7064249, 7227056, and 7250501.