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GOVERNOR

STATE OF MAINE
DEPARTMENT OF AGRICULTURE, FOOD AND RURAL RESOURCES
BOARD OF PESTICIDES CONTROL
28 STATE HOUSE STATION
AUGUSTA, MAINE 04333-0028

SETH H. BRADSTREET III
COMMISSIONER

HENRY JENNINGS
DIRECTOR

TO: Board Members
FROM: Lebelle Hicks PhD DABT
RE: Monsanto request to register two more Bt corn products

March 18, 2008

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On February 26, 2008, the Board received a request from Monsanto to register five Bt modified corn varieties providing protection from European Corn Borer (ECB) and/or Rootworm (RW). Information on these products is summarized in Table 1.

Table 1. Monsanto Bt Corn Products

#	Name	EPA#	Pest	Protein	Genetic Event	ME-08 Reg
1	YieldGard Plus	524-545	ECB	Cry1Ab	Bt 11	Yes
			RW	Cry3Bb1	MON 863	
2	Yieldgard Corn Borer	524-489	ECB	Cry1Ab	Bt 11	Yes
3	Yieldgard Rootworm	524-528	RW	Cry3Bb1	MON 863	Yes
4	Yieldgard VT Rootworm	524-551	RW	Cry3Bb1	MON 88017	Pending
5	Yieldgard VT Triple	524-552	RW	Cry3Bb1	MON 88017	Pending
			ECB	Cry1Ab1	Bt 11	

The genetic event resulting in ECB protection found in numbers 1, 2 and 5 (Table 1), is Bt 11. The genetic event resulting in the Yieldgard RW products, numbers 1 and 3 (Table 1), is MON 863. The VT products, numbers 4 and 5 (Table 1) were created with a different genetic modification event, MON 88017. As seen in Table 1, the staff reregistered Yieldgard Plus and registered Yieldgard Corn Borer and Rootworm products, numbers 1, 2 and 3, because the events in the latter two products were the same as those in Yieldgard Plus.

The label review indicated that the refuge requirements for the VT products are equivalent to the currently registered Bt corn varieties.

EPA summarized the comparison of the Cry3Bb1 proteins from the genetic events MON 863 and MON 88017 in their 2004 Biopesticides Registration Action Document (BRAD) (EPA 2004). Their conclusions are:

- The proteins are similar in immuno-reactivity, amino acid status (differing by one amino acid), molecular weight and glycosylation status.

- The protein expression, functional activity, and field activity were equivalent.

- The mammalian database generated for the MON 863 Cry3Bb1 was bridged to the MON 88017 protein. This included *in vitro* digestion, similarities to known protein toxins and allergens and acute toxicity of single doses at high level. With regard to both proteins, EPA concluded that there "is a reasonable certainty that no harm will result form aggregate exposure to the US population including infants and children to the Cry3Bb1 proteins and the genetic material necessary for its production."

- Cry3Bb1 is exempt for tolerance (CFR 180.1214).

Conclusion

Given EPA's conclusions and a similar exposure pattern, the mammalian health risks from exposure to the Cry3Bb1 from event MON 88017 are comparable to risks from the currently registered Bt corn varieties. In addition, the required refuge is equivalent to the currently registered products.

MON 88017

Rootworm-Protected Corn Seed
(OECD Unique Identifier: MON-88Ø17-3)

This product is effective in controlling damage caused by corn rootworm larval feeding on corn roots.

Active Ingredient:

Bacillus thuringiensis Cry3Bb1 protein and the genetic material necessary for its production (Vector ZMIR39) in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3).....0.0075 - 0.013%

Other Ingredients:

Substance produced by a marker gene and the genetic material necessary for its production (Vector ZMIR39) in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3).....0.0042 - 0.0069%

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

CAUTION

KEEP OUT OF REACH OF CHILDREN

NET CONTENTS_____

EPA Registration No. 524-[redacted] 551

EPA Establishment No. 524-MO-002

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

ACCEPTED
with COMMENTS
In EPA Letter Dated
12-13-05
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 524-551

DIRECTIONS FOR USE

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

The following information regarding commercial production must be included in the MON 88017 corn Technology Use Guide (IRM Guide).

INSECT RESISTANCE MANAGEMENT

Growers of MON 88017 must adhere to the following refuge requirements. Growers must plant a structured refuge of at least 20% non-corn rootworm protected corn.

Refuge planting options include: adjacent blocks, perimeter strips or in-field strips. If blocks are implemented they must be adjacent (e.g., across the road) to the MON 88017 field. If perimeter strips are implemented, the strips must be at least 4, and preferably 6 consecutive rows wide. If strips within a MON 88017 field are implemented, the strips must be at least 4, and preferably 6 consecutive rows wide.

The refuge and MON 88017 acres should be managed under comparable agronomic regimes. If the refuge is planted in a field that is in a crop rotation system, then MON 88017 must also be planted in a field that is in a crop rotation system. If the refuge is planted on continuous corn, then the MON 88017 field may be planted on either continuous or in a field that is in a crop rotation system.

Growers have the option of applying conventional insecticides to the corn refuge for control of corn rootworm larvae and other soil pests. The corn refuge can be treated with a non-*B.t.* insecticide to control late season pests such as corn borer or corn rootworm adults. However, if growers opt to treat the refuge while adult corn rootworm are present, then the MON 88017 acres must be treated in a like manner.

These refuge requirements will not apply to operations engaged in the propagation of inbred seed corn.

CORN INSECTS CONTROLLED OR SUPPRESSED

This field corn has been transformed using biotechnology to produce the *B.t.* protein, Cry3Bb1, for control or suppression of the following coleopteran insects:

Western corn rootworm (*Diabrotica virgifera virgifera*)
Northern corn rootworm (*Diabrotica barberi*)
Mexican corn rootworm (*Diabrotica virgifera zeae*)

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: 4,940,835, 5,164,316, 5,188,642, 5,196,525, 5,322,938, 5,359,142, 5,633,435, 5,641,876, 5,717,084, 5,728,925, 5,804,425, and 6,501,009.

MON 88017 x MON 810

Rootworm- and Corn Borer-Protected Corn Seed
(OECD Unique Identifier: MON-88Ø17-3 x MON-ØØ81Ø-6)

This product is effective in controlling corn leaf, stalk and ear damage caused by corn borers and root feeding damage caused by corn rootworm larvae.

Active Ingredient:

Bacillus thuringiensis Cry3Bb1 protein and the genetic material necessary for its production (Vector ZMIR39) in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)	0.0071 - 0.015%
Bacillus thuringiensis Cry1Ab delta-endotoxin and the genetic material necessary for its production in corn	0.0011 - 0.0017%

Other Ingredients:

Substance produced by a marker gene and the genetic material necessary for its production (Vector ZMIR39) in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)	0.0038 - 0.007%

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

CAUTION

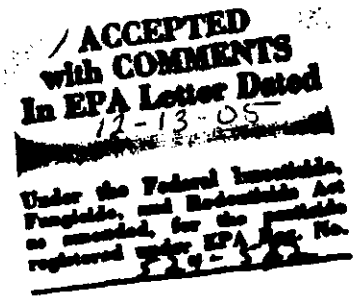
KEEP OUT OF REACH OF CHILDREN

NET CONTENTS_____

EPA Registration No. 524-552

EPA Establishment No. 524-MO-002

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



DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with this labeling. The following information regarding commercial production must be included in the MON 88017 x MON 810 Technology Use Guide (IRM Guide).

MON 88017 x MON 810 protects corn crops from leaf, stalk, and ear damage caused by corn borers and root damage caused by corn rootworm larvae. In order to minimize the risk of these pests developing resistance to MON 88017 x MON 810 corn, an insect resistance management plan must be implemented which includes planting of a structured refuge.

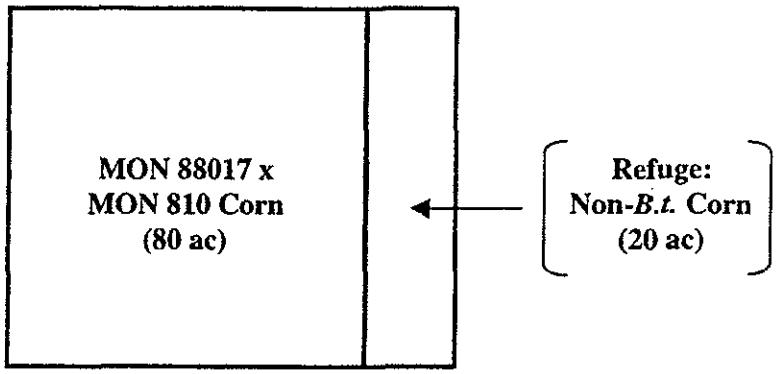
INSECT RESISTANCE MANAGEMENT

Corn Belt / Noncotton Growing Region Refuge Requirements

For MON 88017 x MON 810 corn grown in noncotton growing regions of the United States, 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 *Bacillus thuringiensis* (*B.t.*) 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 88017 x MON 810 acres and refuge acres; refuge area must contain 20 acres of corn for every 80 acres of MON 88017 x MON 810 corn planted). It can be planted as a block within or adjacent (e.g., across the road) to the MON 88017 x MON 810 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, and preferably 6 consecutive rows wide. The common refuge can be treated with an insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-*B.t.* foliar insecticide for 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 88017 x MON 810 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, etc.). A schematic of one common refuge deployment option is shown below:

Common Refuge

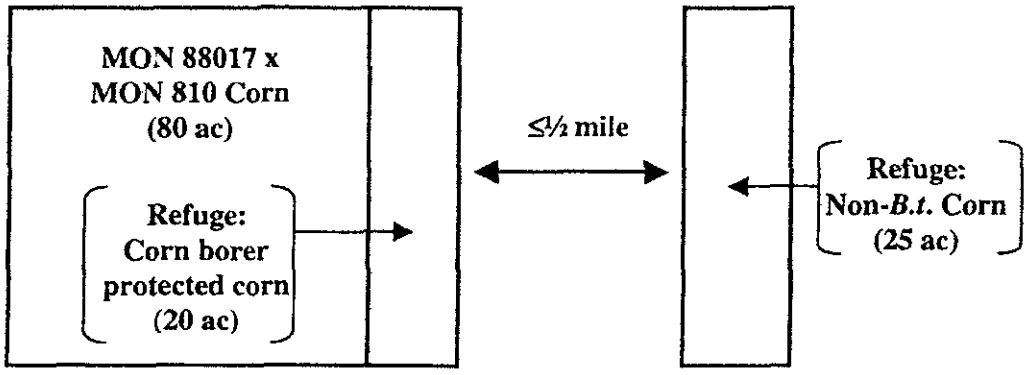


The second option is planting separate refuge areas (e.g., two refuge areas, a double refuge, paired refuge areas) for corn borers and corn rootworms. The corn borer refuge must be planted with corn that is not a lepidoteran-protected *B.t.* hybrid, must represent at least 20% of the grower's corn acres, and must be planted within ½ mile of the MON 88017 x MON 810 field. The corn borer refuge can be treated with an insecticide for corn rootworm larval control, or a non-*B.t.* foliar-applied insecticide for corn borer control if pest pressure reaches an economic threshold for damage.

The corn rootworm refuge must be planted with corn that is not a corn rootworm-protected *B.t.* hybrid, but can be planted with *B.t.* 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 88017 x MON 810 corn planted) and can be planted as a block within or adjacent to the MON 88017 x MON 810 field, strips around the field, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4, and preferably 6 consecutive rows wide. The corn rootworm refuge can be treated with an insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-*B.t.* foliar insecticide for control of late season pests; however, if corn rootworm adults are present at the time of foliar applications then the MON 88017 x MON 810 field must be treated in a similar manner. A schematic 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 88017 x MON 810 field is shown below:

12/15

Separate-Refuge Option
Two-Refuge Option, Double-Refuge Option, Paired-Refuge Option

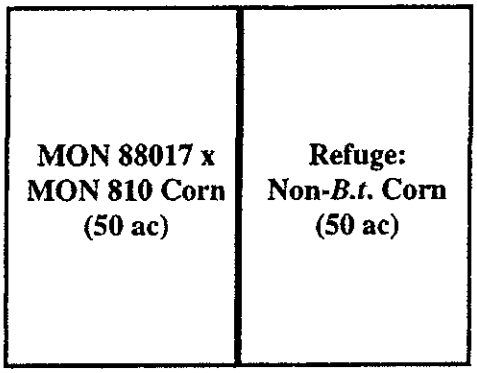


Corn/Cotton Growing Area (Cotton Growing Area) Refuge Requirements

For MON 88017 x MON 810 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, however, the refuge area is larger. Cotton growing areas include the following states: Alabama, Arkansas, Florida, Georgia, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and 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, and Sussex), and Missouri (only the counties of Dunkin, New Madrid, Pemiscot, Scott, and Stoddard).

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 *B.t.* technologies for the control of corn rootworms or corn borers. The refuge area must represent at least 50% of the grower's corn acres (i.e., refuge must contain 50 acres of non-*B.t.* corn for every 50 acres of MON 88017 x MON 810 corn planted). It can be planted as a block within or adjacent to the MON 88017 x MON 810 field, strips around the field, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4, and preferably 6 consecutive rows wide. The common refuge can be treated with an insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-*B.t.* foliar insecticide for 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 88017 x MON 810 field must be treated in a similar manner. A schematic of one common refuge deployment option is shown below:

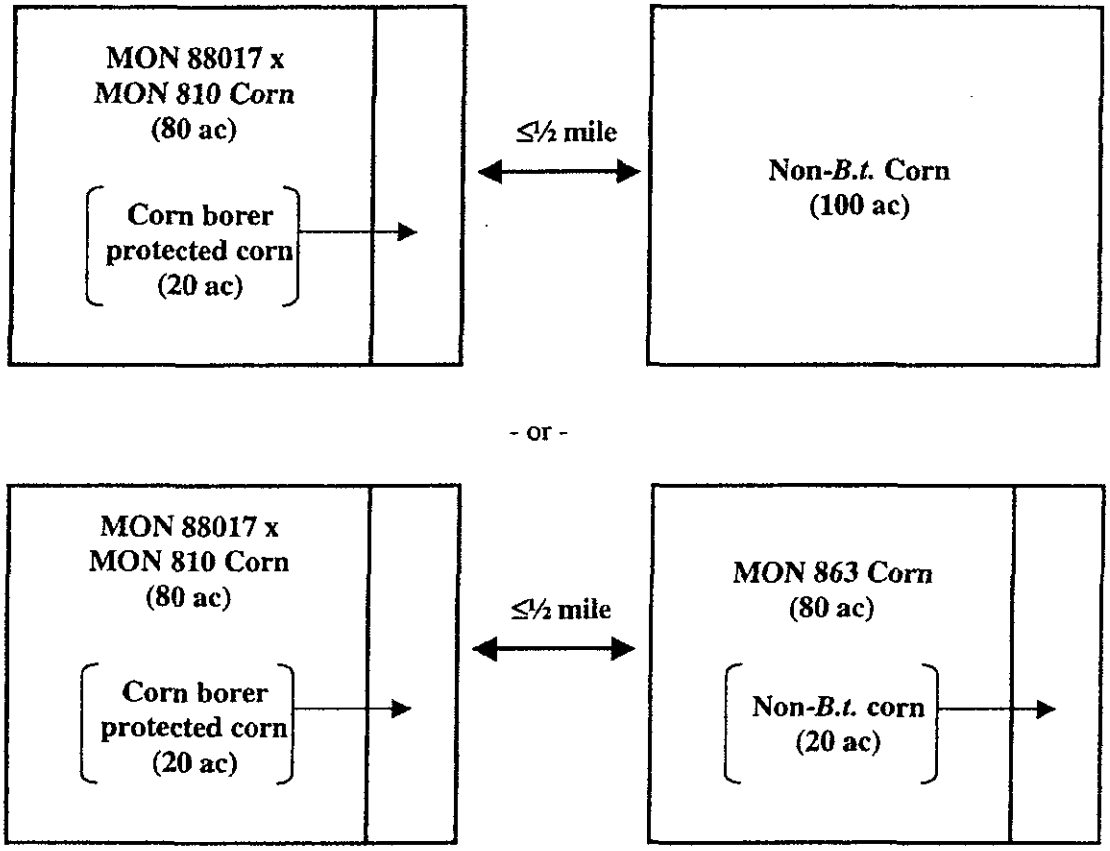
Common Refuge



The second option is planting separate refuge areas (e.g., two refuge areas, double refuge areas, paired refuge areas) for corn borers and corn rootworms. The corn borer refuge must be planted with corn that is not a lepidopteran-protected *B.t.* hybrid, must represent at least 50% of the grower's corn acres (i.e., must contain 50 acres of corn for every 50 acres of lepidopteran-protected corn planted), and must be planted within ½ mile of the MON 88017 x MON 810 field. The corn borer refuge can be treated with an insecticide for corn rootworm larval control, or a non-*B.t.* 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, etc.).

The corn rootworm refuge must be planted with corn that is not a rootworm-protected *B.t.* hybrid, but can be planted with *B.t.* 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 88017 x MON 810 corn planted) and be planted as a block within or adjacent to the MON 88017 x MON 810 field, strips around the field, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4, and preferably 6 consecutive rows wide. The corn rootworm refuge can be treated with an insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-*B.t.* foliar insecticide for control of late season pests; however, if rootworm adults are present at the time of foliar applications then the MON 88017 x MON 810 field must be treated in a similar manner. Schematics for two separate-refuge options with the corn rootworm refuge planted as a block within the MON 88017 x MON 810 field and the corn borer refuge planted as a block within a ½ mile of the MON 88017 x MON 810 field are shown below:

Separate -Refuge Options
{Two-Refuge Options, Double-Refuge Options, Paired Refuge Options}



Grower agreements will specify that growers must adhere to the refuge requirements that will be described in the Technology Use Guide (IRM Guide) for MON 88017 x MON 810 corn or other applicable product use documents. Growers who fail to comply with the IRM requirements risk losing access to the product.

These refuge requirements do not apply to operations engaged in the propagation of inbred and hybrid seed corn.

CORN INSECTS CONTROLLED OR SUPPRESSED

Field corn has been genetically transformed to produce the *B.t.* Cry1Ab and Cry3Bb1 proteins for the control or suppression of the following lepidopteran and coleopteran insects, respectively:

European corn borer (*Ostrinia nubilalis*)
Southwestern corn borer (*Diatraea grandiosella*)
Southern cornstalk borer (*Diatraea crambidoides*)
Sugarcane cornstalk borer (*Diatraea saccharalis*)
Corn earworm (*Helicoverpa zea*)
Fall armyworm (*Spodoptera frugiperda*)
Stalk borer (*Papaipema nebris*)

Western corn rootworm (*Diabrotica virgifera virgifera*)
Northern corn rootworm (*Diabrotica barberi*)
Mexican corn rootworm (*Diabrotica virgifera zeae*)

MON 88017 x MON 810 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: 4,940,835, 5,164,316, 5,188,642, 5,196,525, 5,322,938, 5,352,605, 5,359,142, 5,424,412, 5,484,956, 5,633,435, 5,641,876, 5,717,084, 5,728,925, 5,804,425, 5,859,347, 5,593,874, 6,331,665, and 6,501,009.