

524-545

10/10/2008

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1/9

OCT 10 2008

Ms. Margaret Wideman
Regulatory Affairs Manager
Monsanto Company
800 North Lindbergh Blvd
St. Louis, MO 63167

Dear Ms. Wideman:

Subject: Your February 15, 2008 Amendment Requests to Remove the Expiration Dates for YieldGard, YieldGard Plus Corn, and MON 88017 x MONB 810
EPA Registration Nos. 524-489, 524-545, and 524-552

The amendments referred to above, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, are acceptable subject to the following comments.

1) For EPA Registration Numbers 524-489, 524-545, and 524-552:

a) The subject plant-incorporated protectant 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 plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

b) The subject registration will automatically expire on midnight September 30, 2010.

We are currently unaware of any issues that would preclude a decision to remove the expiration date in the future. However, due to other statutory priorities, BPPD's review of the data and information submitted as conditions of registration is ongoing. Therefore, the expiration date is being extended to match that of corn rootworm resistant Bt corn as an interim measure.

c) Refuge requirements do not apply to seed propagation of inbred and hybrid corn seed corn up to a total of 20,000 acres per county and up to a combined U.S. total of 250,000 acres per PIP active ingredient per registrant per year.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of Cry1Ab corn constitutes acceptance of these conditions.

CONCURRENCES

SYMBOL	7511P	7511P					
SURNAME	Murphy	Wideman					
DATE	10/8/08	10/10/08					

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

Sincerely,

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

CONCURRENCES

SYMBOL		2					
SURNAME			2				
DATE							

MON 863 x MON 810

Rootworm- and Corn Borer-Protected Corn Seed
(OECD Unique Identifier: MON-ØØ863-5 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 ZMIR13L) in event MON 863 corn (OECD Unique Identifier: MON- ØØ863-5).....0.003 - 0.016%

Bacillus thuringiensis Cry1Ab delta-endotoxin and the genetic material necessary for its production (Vector PV-ZMCT01) in corn0.002 - 0.005%

Other Ingredients:

Substance produced by a marker gene and the genetic material necessary for its production (Vector ZMIR13L) in event MON 863 corn (OECD Unique Identifier: MON- ØØ863-5)..... 0.00005 - 0.0001%

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

CAUTION

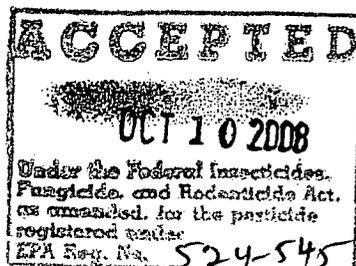
KEEP OUT OF REACH OF CHILDREN

NET CONTENTS _____

EPA Registration No. 524-545

EPA Establishment No. 524-MO-002

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63198



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 863 x MON 810 Technology Use Guide (IRM Guide).

This plant-incorporated protectant 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 plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

MON 863 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 863 x MON 810 corn, an insect-resistance management plan must be implemented which includes planting of a structured refuge.

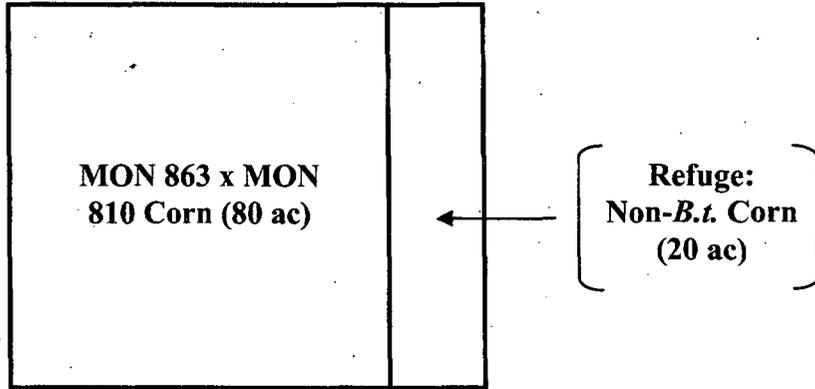
INSECT RESISTANCE MANAGEMENT

Corn Belt / Noncotton Growing Region Refuge Requirements

For MON 863 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 863 x MON 810 acres and refuge acres; refuge area must contain 20 acres of corn for every 80 acres of MON 863 x MON 810 corn planted). It can be planted as a block within or adjacent (e.g., across the road) to the MON 863 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 (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 863 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

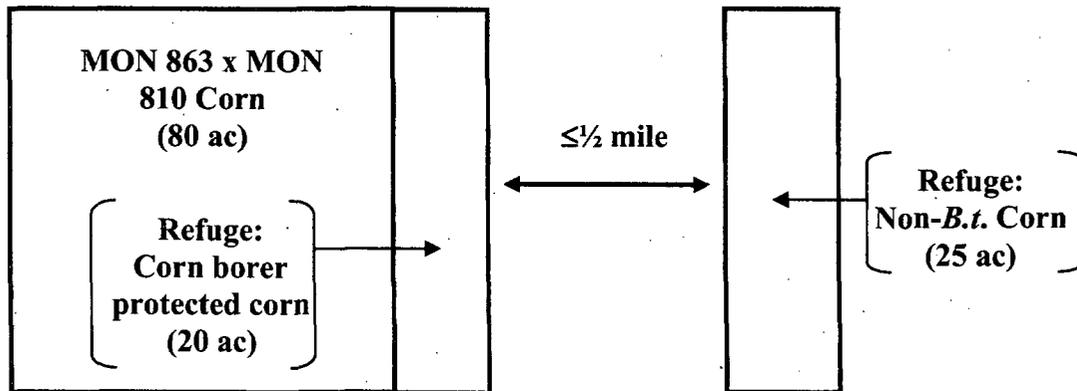


The second option is planting separate refuge areas (e.g., two refuge areas, a double refuge, paired refuge areas) for corn borers and corn rootworms. The corn borer refuge must be planted with corn that is not a lepidoteran-protected *B.t.* hybrid, must represent at least 20% of the grower's corn acres, and must be planted within ½ mile of the MON 863 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 863 x MON 810 corn planted) and can be planted as a block within or adjacent to the MON 863 x MON 810 field, strips around the field, or in-field strips. 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 863 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 863 x MON 810 field is shown below:

Separate-Refuge Option

{Two-Refuge Option, Double-Refuge Option, Paired-Refuge Option}

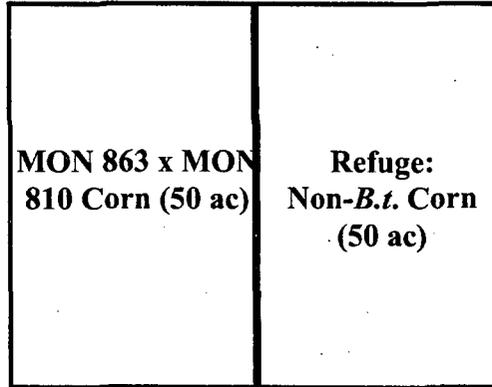


Corn/Cotton Growing Area (Cotton Growing Area) Refuge Requirements

For MON 863 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, Greenville, 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 863 x MON 810 corn planted). It can be planted as a block within or adjacent to the MON 863 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 (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 863 x MON 810 field must be treated in a similar manner. A schematic of one common refuge deployment option is shown below:

Common Refuge

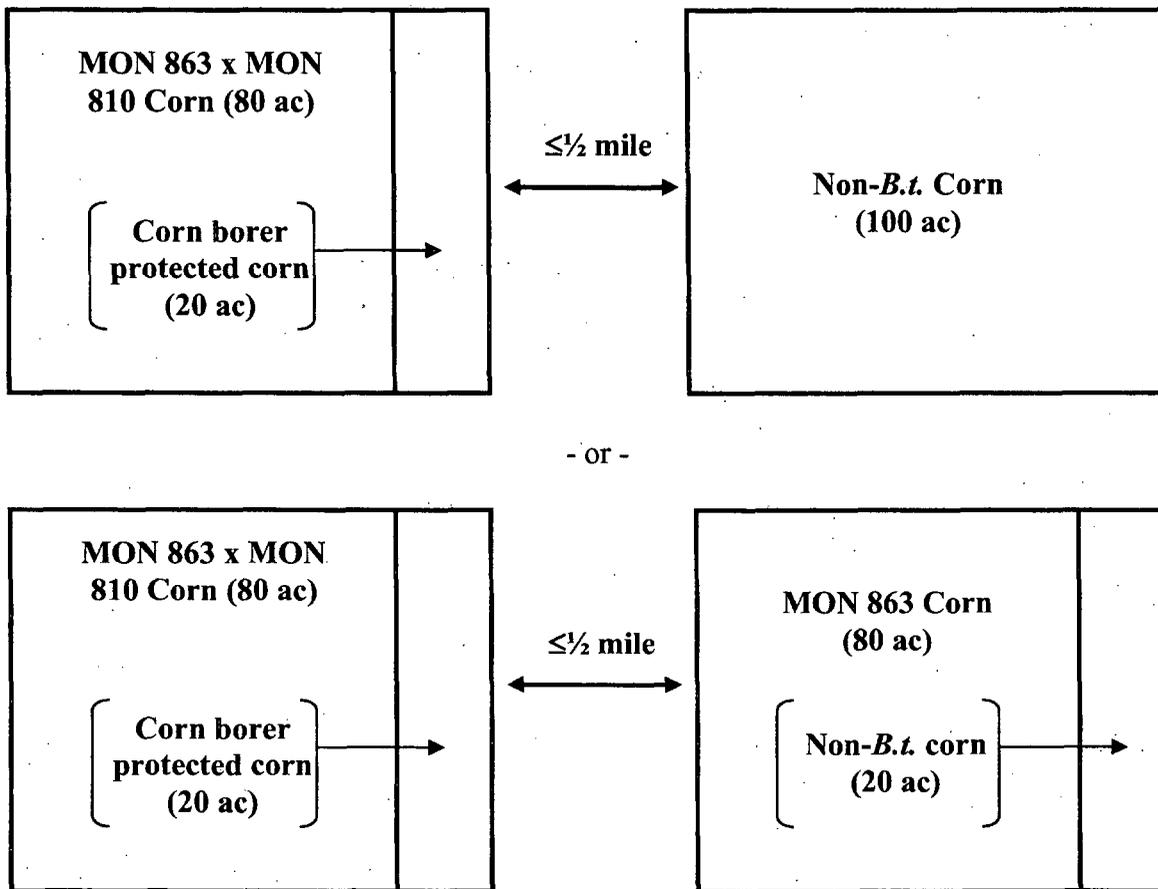


The second option is planting separate refuge areas (e.g., two refuge areas, double refuge areas, paired refuge areas) for corn borers and corn rootworms. The corn borer refuge must be planted with corn that is not a lepidopteran-protected *B.t.* hybrid, must represent at least 50% of the grower's corn acres (i.e., must contain 50 acres of corn for every 50 acres of lepidopteran-protected corn planted), and must be planted within 1/2 mile of the MON 863 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 863 x MON 810 corn planted) and be planted as a block within or adjacent to the MON 863 x MON 810 field, strips around the field, or in-field strips. 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 863 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 863 x MON 810 field and the corn borer refuge planted as a block within a 1/2 mile of the MON 863 x MON 810 field are shown below:

Separate-Refuge Option

{Two-Refuge Option, Double-Refuge Option, Paired-Refuge Option}



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 863 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 seed propagation of inbred and hybrid corn seed up to a total of 20,000 acres per county and up to a combined U.S. total of 250,000 acres per PIP active ingredient per registrant per year.

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 zea*)

MON 863 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: 5,023,179, 5,110,732, 5,352,605, 5,424,412, 5,484,956, 5,859,347, 5,593,874, 6,063,597, 6,174,724, 6,331,665,, 6,501,009, 7,064,248 and 7,227,056.