

67979-12

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
Washington, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Dr. Tichafa Munyikwa  
Regulatory Affairs Manager  
Syngenta Seeds, Inc.  
P. O. Box 12257  
Research Triangle Park, NC 27709

Subject: Syngenta's Amendment Request to Add Sweet Corn  
EPA Registration No. 67979-12

Dear Dr. Munyikwa:

The amendment referred to above, submitted in connection with registration under Section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable provided that you comply with the following terms and conditions.

1] Term and Condition number 2 is amended as follows. The subject registration will be limited to Cry1Ab (*Bacillus thuringiensis* Cry1Ab delta- endotoxin protein and the genetic material necessary for its production [via elements of vector pZO1502] in Event Bt11 corn [OECD Unique Identifier: SYN-BTØ11-1]) x Vip3Aa20 (*Bacillus thuringiensis* Vip3Aa20 insecticidal protein and the genetic material necessary for its production [via elements of vector pNOV1300] in Event MIR162 maize [OECD Unique Identifier: SYN-IR162-4]) for use in field and sweet corn.

2] Term and Condition number 6 a) Refuge Requirements for Bt11 x MIR162 Field Corn is amended as follows:

6. a) Field Corn Refuge and Sweet Corn Post-Harvest Requirements for Bt11 x MIR 162 Corn

***Refuge Requirements for Bt11 x MIR162 Field Corn***

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 U.S. total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year.

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EPA Registration No. 67979-12

Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

- Specifically, growers must plant a structured refuge of at least 20% non-*Bt* corn and/or non-lepidopteran-resistant *Bt* corn that may be treated with insecticides, as detailed below, to control lepidopteran stalk-boring and other pests.
- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips, and strips across the field.
- External refuges must be planted within 1/2 mile.
- When planting the refuge as strips across the field or as perimeter strips, refuges must be at least four consecutive rows wide.
- Insecticide treatments for control of European corn borer (ECB), CEW, SWCB, and other lepidopteran pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran-resistant *Bt* corn refuges.

***Sweet Corn Post-Harvest Requirements***

Sweet corn is harvested long before field corn. Therefore, if the sweet corn stalks remaining in the field and any insects remaining in the stalks are destroyed shortly after harvest, a refuge is not needed as a part of the IRM program for sweet corn. Growers must adhere to the following types of crop destruction requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

1. Crop destruction must occur no later than 30 days following harvest, but preferably within 14 days.
2. The allowed crop destruction methods are: rotary mowing, discing, or plow-down. The crop destruction methods are intended to protect against development of insect resistance.
- 3] Term and Condition number 6. c) 6) is amended as follows:

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6. c) IRM Education and IRM Compliance Monitoring Program for Bt11 x MIR162 Corn

6) The IRM compliance assurance program shall include an annual survey, conducted by an independent third party, of a statistically representative sample of growers of Bt11 x MIR162 corn who plant the vast majority of all corn in the United States and in areas in which the selection intensity is the greatest. For field corn, the survey shall consider only those growers who plant 200 or more acres of corn in the Corn Belt or who plant 100 or more acres of corn in corn-cotton growing areas. For sweet corn, the survey shall include customers who purchase 5 or more bags of Bt11 x MIR 162 sweet corn. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from independent marketing research firms and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the United States.

4) Term and Condition number 6.d) Insect Resistance Monitoring and Remedial Action Plans for Bt11 x MIR162 Corn 1. i. is amended by adding the following regarding fall armyworm population sampling for sweet corn.

Syngenta will develop and ensure the implementation of a plan for resistance monitoring for *Spodoptera frugiperda* (fall armyworm or FAW) in counties in which Bt11, Bt11 x MIR 162, or combined Bt 11 and Bt11 x MIR162 sweet corn acreage exceeds 5,000 acres and the pest is capable of overwintering in that county. Syngenta should consult with academic and USDA experts in developing the monitoring plan and will provide EPA with a copy of its proposed resistance monitoring plan for EPA's approval prior to implementation. This proposed FAW monitoring plan must be submitted to EPA by January 31 of the year following that in which sweet corn acreage exceeds the trigger specified in this requirement (i.e. greater than 5,000 acres in any county in which FAW overwinters). The proposed plan must be implemented the season following the acreage trigger being met. The proposed plan will remain in place until an EPA approved plan can be implemented.

5) You must submit an updated Confidential Statement of Formula and label by December 19, 2009.

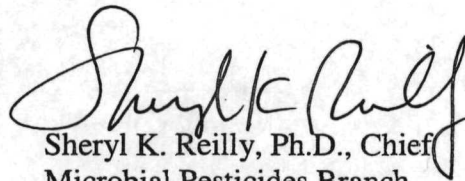
We note that under condition 6. c) IRM Education and IRM Compliance Monitoring Program for Bt11 x MIR162 Corn 3, you are required annually by January 31<sup>st</sup> to provide "any substantive changes to [your] grower education activities as part of the overall IRM compliance assurance program report." and that the addition of sweet corn triggers this requirement.

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If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). 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

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**ACCEPTED  
with COMMENTS  
In EPA Letter Dated  
NOV 18 2010**  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.  
67979-12

**Bt11 x MIR162 Corn**

[Alternate brand name: "Agrisure™ 2100"]

OECD Unique Identifier: SYN-BTØ11-1 x SYN-IR162-4

**Plant-incorporated protectant:**

**Cry1Ab and Vip3Aa20 proteins for control of corn borers and other lepidopteran pests**

This product is effective in controlling corn leaf, stalk, and ear damage caused by corn borers and certain lepidopteran pests.

**Active Ingredients:**

*Bacillus thuringiensis* Cry1Ab delta-endotoxin protein and the genetic material necessary for its production (via elements of vector pZO1502) in corn event Bt11 (SYN-BTØ11-1).....≤0.00204%\*

*Bacillus thuringiensis* Vip3Aa20 insecticidal protein and the genetic material necessary for its production (via elements of vector pNOV1300) in corn event MIR162 (SYN-IR162-4)..... ≤0.0087%\*

**Other Ingredients:**

A marker protein and the genetic material necessary for its production (via elements of vector pZO1502) in corn event Bt11 (SYN-BTØ11-1)..... ≤ 0.000086%\*

A marker protein and the genetic material necessary for its production (via elements of vector pNOV1300) in corn event MIR162 (SYN-IR162-4)..... ≤ 0.00042%\*

\*Percentage in whole plants on a dry weight basis

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

EPA Registration No. 67979-12  
EPA Establishment No. 66736-NC-01

Syngenta Seeds, Inc. - Field Crops - NAFTA  
P.O. Box 12257  
3054 East Cornwallis Rd.  
Research Triangle Park, NC 27709

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in any manner inconsistent with this labeling. All corn seed that contains the plant-incorporated protectant sold or distributed by Syngenta Seeds or its distributors must be accompanied by informational material (e.g., a bag

™ Agrisure is a trademark of a Syngenta Group company

tag) indicating the registration number (67979-12) and the active ingredients, and stipulating that growers read the Grower Guide (or equivalent guidance) prior to planting the seed.

This informational material will also include the following statements: [insert brand name for Bt11 x MIR162 sweet corn] Sweet Corn hybrids produce a protein that increases tolerance to glufosinate ammonium herbicides. Glufosinate ammonium is not registered or recommended for use on this hybrid. If you plant a glufosinate-resistant crop in the next growing season, please note that volunteer plants from this sweet corn hybrid may not be controlled by a glufosinate ammonium herbicide.”

**Insects Controlled or Suppressed**

Field corn has been genetically transformed to produce the insecticidal proteins, Cry1Ab and Vip3Aa20, for control or suppression of the following lepidopteran insects:

- European corn borer (*Ostrinia nubilalis*)
- Southwestern corn borer (*Diatraea grandiosella*)
- Southern cornstalk borer (*Diatraea crambidoides*)
- Corn earworm (*Helicoverpa zea*)
- Fall armyworm (*Spodoptera frugiperda*)
- Beet armyworm (*Spodoptera exigua*)
- Black cutworm (*Agrotis ipsilon*)
- Western bean cutworm (*Striacosta albicosta*)
- Sugarcane borer (*Diatraea saccharalis*)
- Common stalk borer (*Papaipema nebris*)
- Dingy Cutworm (*Feltia jaculifera*)

**Insect Resistance Management**

**Sweet Corn**

The following information regarding commercial production of Bt11 x MIR162 sweet corn must be included in the Grower Guide (or equivalent).

- Crop destruction must occur no later than 30 days following harvest, but preferably within 14 days.
- The allowed crop destruction methods are: rotary mowing, discing, or plow-down. Crop destruction methods should destroy any surviving resistant insects.

These plant-incorporated protectants 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.

**Field Corn**

The following information regarding commercial production of *Bt*11 x MIR162 corn must be included in the Grower Guide (or equivalent).

*Refuge Requirements for Bt11 x MIR162 Corn*

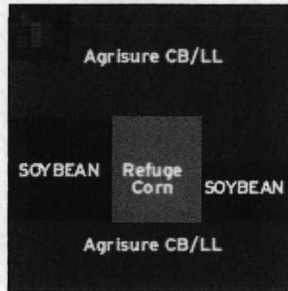
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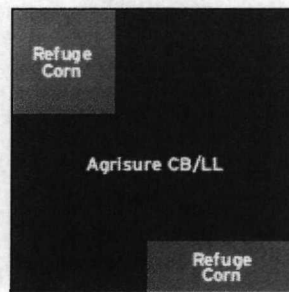
- Specifically, growers must plant a structured refuge of at least 20% non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn that may be treated with insecticides, as detailed below, to control lepidopteran stalk-boring and other pests.
- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips, and strips across the field (see diagrams below).
- External refuges must be planted within ½ mile.
- When planting the refuge as strips across the field or as perimeter strips, refuges must be at least 4 consecutive rows wide.
- Insecticide treatments for control of European corn borer, corn earworm, Southwestern corn borer, and other lepidopteran pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.

The following are schematics of the various refuge deployment options:

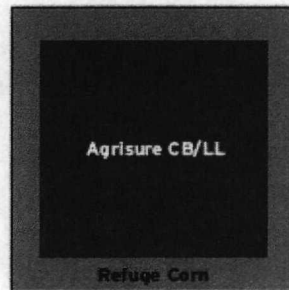
**Separate Fields**





**Blocks**



**Perimeter**



-  Agrisure CB/LL
-  Corn Borer Refuge