67979-13

02113/2009

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number:	Date of Issuance:
67979-13	2/13/09

Term of Issuance:
Conditional, Time-Limited

Name of Pesticide Product:
*Bt*11 x MIR162 x MIR604 Corn

NOTICE OF PESTICIDE:
_X_ Registration
___ Reregistration (under FIFRA, as amended)

Name and Address of Registrant (Include ZIP Code):

Syngenta Seeds, Inc. – Field Crops – NAFTA
P.O. Box 12257
3054 East Cornwallis Road
Research Triangle Park, NC 27709-2257

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product, always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide, and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

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

1. The subject registration will automatically expire at midnight on December 31, 2011.

Continued on page 2

Signature of Approving Official:

JZA see last page

Janet Andersen, Ph.D., Director
Biopesticides and Pollution Prevention Division (7511P)

Date:

2/13/09

EPA Form 8570-6 CONCURRENCES

SYMBOL ▶	7511P	7511P						
SURNAME ▶	KAUSCH	Reilly						
DATE ▶	03/16/2009	3/16/09						

EPA Form 1320-1A (1/90) *Printed on Recycled Paper* **OFFICIAL FILE COPY**

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

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2. 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 *Bt*11 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)] x mCry3A [modified Cry3A protein and the genetic material necessary for its production (via elements of vector pZM26) in Event MIR604 corn (OECD Unique Identifier SYN-IR6Ø4-5)] for use in field corn.

3. Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

4. Submit/cite all data required to support the individual plant-incorporated protectants in YieldGard® Insect Resistant Corn, MIR162 maize, and Agrisure® RW Rootworm-Protected Corn within the timeframes required by the terms and conditions of EPA Registration Numbers 67979-1, 67979-14, and 67979-5, respectively:

Study Type ****Registration**	**Required Data**	**Due Date**
Residue Analytical Method - Plants (OPPTS 860.1340) ****MIR162 maize**	The validation of the analytical method performed by Syngenta (as described in Standard Operating Procedure 2.91) must provide the following: 1) results as a concentration (i.e., gram/gram) as opposed to an optical density value and 2) testing on dilutions from corn samples, before grinding, instead of flour samples in order to address variability introduced by grinding and sample preparation. Additionally, you must provide to the EPA laboratory (Ft. Meade, Maryland) methodology and/or reagents necessary for validation of such analytical method within 6 months from the date that the Agency requests them.	November 1, 2009
Aquatic Invertebrate Toxicity (OPPTS 885.4240) ****MIR162 maize**	A 7-14 day *Daphnia* study as per the OPPTS 885.4240 guideline must be submitted as a condition of registration. Alternatively, a dietary study of the effects on an aquatic invertebrate, representing the functional group of a leaf shredder in headwater streams, can be performed and submitted in lieu of the 7-14 day *Daphnia* study.	November 1, 2009
Insect Resistance Management - Annual Reporting ****MIR162 maize**	Annual sales data, to include units sold and acres planted, must be reported and summed by state and county.	January 31st of each year, beginning in 2010
Simulated or Actual Field Tests - Non-Target Invertebrates ****Agrisure® RW Rootworm-Protected Corn**	Three (3) year full-scale field or semi-field studies for evaluation of mCry3A Event MIR604 corn exposure on non-target invertebrates must be conducted and a final report submitted. Full-scale field experiments must be appropriately designed to provide a measure of ecological impacts (larger fields, more replicates, more samples per plot based on recommendations of the August 2002 Scientific Advisory Panel (SAP) and the subsequent relevant research on appropriate study design).	January 31, 2011

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Study Type **Registration	Required Data	Due Date
Field Degradation Studies **Agrisure® RW Rootworm-Protected Corn	Field degradation studies evaluating accumulation and persistence of mCry3A in several soils and various strata must be conducted and a final report, regarding data from fields that have had three continuous years of cultivation of Event MIR604 corn, submitted. Representative fields must have been planted with mCry3A corn, include both conventional tillage and no-till samples, and be harvested under typical agronomic conditions. Sampling must continue until the limit of detection is reached. Studies should include soils with high levels of a variety of clays. Both ELISA and insect bioassays need to be conducted to determine if mCry3A is accumulating or persisting in soil samples.	January 31, 2011

5. You must submit the following data and/or information in the time frames listed:

Study Type	Required Data	Due Date
Insect Resistance Management - Dose	Because of the potential for synergistic interactions between plant-incorporated protectants in a stacked product, field efficacy studies and/or a protein expression report for Southwestern corn borer (SWCB), which show that *Bt*11 x MIR162 x MIR604 corn has the same dose profile as its single trait products, must be submitted as confirmatory data.	March 1, 2010
Insect Resistance Management - Grower Agreement	A copy of the grower agreement, associated stewardship documents, and written description of a system, which assure that growers will sign grower agreements and persons purchasing *Bt*11 x MIR162 x MIR604 corn will annually affirm that they are contractually bound to comply with the requirements of the insect resistance management (IRM) program, must be submitted.	Within 90 days of the date of registration
Insect Resistance Management - Compliance Monitoring Program	A compliance assurance program (CAP) for *Bt*11 x MIR162 x MIR604 corn must be submitted and must include a "phased compliance approach" that outlines instances of non-compliance to the IRM requirements and options of responding to non-compliant growers. This compliance assurance program should be harmonized with compliance assurance programs already in place for previously registered Syngenta *Bt* corn products.	Within 90 days of the date of registration
Insect Resistance Management - Resistance Monitoring	Baseline susceptibility and diagnostic concentration determinations for SWCB and corn earworm (CEW) to Vip3Aa20 must be submitted.	August 31, 2010
Insect Resistance Management - Resistance Monitoring	A detailed Vip3Aa20 resistance monitoring plan, integrating standard procedures developed by the Agricultural Biotechnology Stewardship Technical Committee (ABSTC) and similar in structure to those established for previously registered Syngenta *Bt* corn products, for the key target pests of CEW and SWCB must be submitted.	Within 90 days of the date of registration

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Study Type	Required Data	Due Date
Insect Resistance Management - Resistance Monitoring	A revised mCry3A resistance monitoring program that incorporates *Bt*11 x MIR162 x MIR604 corn must be submitted. Consideration for corn rootworm (CRW): In addition to mortality assays, consider utilizing sublethal bioassays (e.g., head capsule measurements) and molecular marker methods for CRW monitoring.	Within 90 days of the date of registration
Insect Resistance Management - Resistance Monitoring	Submit data generated by the following actions: a) initiate establishment of CRW strains that are resistant to mCry3A and investigate the nature, inheritance, and fitness costs of specific mechanisms of resistance to mCry3A, b) study the behavioral deterrence (avoidance) mechanism further, and c) continue studies on the biological impact of CRW adults surviving on corn expressing the mCry3A toxin.	January 31, 2010
Insect Resistance Management - Resistance Monitoring	Develop, validate, and submit an appropriate discriminating or diagnostic dose assay for the mCry3A resistance monitoring program.	January 31, 2010
Insect Resistance Management - Resistance Monitoring	Finalize and submit rootworm damage guidelines for the mCry3A resistance monitoring program.	January 31, 2010
Insect Resistance Management - Remedial Action Plan	A final remedial action plan for the Vip3Aa20 toxin expressed in *Bt*11 x MIR162 x MIR604 corn, integrating the standard procedures developed by the ABSTC and harmonized with remedial action plans established for previously registered Syngenta *Bt* corn products, must be submitted.	Within 90 days of the date of registration

6. The insect resistance management terms and conditions for *Bt*11 x MIR162 x MIR604 corn are as follows.

   The required IRM program for *Bt*11 x MIR162 x MIR604 corn must have the following elements:

   - Requirements relating to creation of a non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuge in conjunction with the planting of any acreage of *Bt*11 x MIR162 x MIR604 corn;

   - Requirements for Syngenta to prepare and require *Bt*11 x MIR162 x MIR604 corn users to sign "grower agreements," which impose binding contractual obligations on the grower to comply with the refuge requirements;

   - Requirements regarding programs to educate growers about IRM requirements;

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- Requirements regarding programs to evaluate and promote growers' compliance with IRM requirements;

- Requirements regarding programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to Vip3Aa20, Cry1Ab, and/or mCry3A proteins in the target insects;

- Requirements regarding a "remedial action plan," which contains measures Syngenta would take in the event that any field-relevant insect resistance was detected as well as to report on activity under the plan to EPA;

- Annual reports on units sold by state (units sold by county level will be made available to the Agency upon request), IRM grower agreements results, and the compliance assurance program including the educational program on or before January 31st each year, beginning in 2010.

a) Refuge Requirements for *Bt*11 x MIR162 x MIR604 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 United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year.

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.

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 rootworms or corn borers. The refuge area must represent at least 20% of the grower's corn acres (i.e., sum of *Bt*11 x MIR162 x MIR604 corn acres and refuge acres). It must be planted as a block adjacent to the *Bt*11 x MIR162 x MIR604 corn 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. If the common refuge is planted on rotated ground, then *Bt*11 x MIR162 x MIR604 corn must also be planted on rotated ground. If the common refuge is planted in continuous corn, the *Bt*11 x MIR162 x MIR604 corn field may be planted on either continuous or rotated land. 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 control of late season pests, if pest pressure

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reaches an economic threshold for damage; however, if rootworm adults are present at the time of foliar applications, then the *Bt*11 x MIR162 x MIR604 corn field 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 or crop consultants). Pests other than adult corn rootworms can be treated with an appropriate pest-labeled insecticide on the common refuge acres without treating the *Bt*11 x MIR162 x MIR604 corn acres only if treatment occurs when adult corn rootworms are not present. Pests on the *Bt*11 x MIR162 x MIR604 corn acres can be treated as needed without having to treat the common refuge.

The second option is planting separate refuge areas for corn borers and corn rootworms. The corn borer refuge must be planted with a non-*Bt*/lepidopteran-protected hybrid, must represent at least 20% of the grower's corn acres (i.e., sum of *Bt*11 x MIR162 x MIR604 corn acres and corn borer refuge acres), and must be planted within ½ mile of the *Bt*11 x MIR162 x MIR604 corn field. 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 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 or crop consultants).

The corn rootworm refuge must be planted with a non-*Bt*/corn rootworm-protected hybrid, but can be planted with *Bt* corn hybrids that control corn borers. The corn rootworm refuge must represent at least 20% of the grower's corn acres (i.e., sum of *Bt*11 x MIR162 x MIR604 corn acres and corn rootworm refuge acres) and must be planted as an adjacent block, perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. If the rootworm refuge is planted on rotated ground, then *Bt*11 x MIR162 x MIR604 corn must also be planted on rotated ground. If the rootworm refuge is planted in continuous corn, the *Bt*11 x MIR162 x MIR604 corn field may be planted on either continuous or rotated land. More generally, the rootworm refuge should utilize comparable agronomic practices as the *Bt*11 x MIR162 x MIR604 corn acres. 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 rootworm adults are present at the time of foliar applications, then the *Bt*11 x MIR162 x MIR604 corn field must be treated in a similar manner. Pests other than adult corn rootworms can be treated on the rootworm refuge acres without treating the *Bt*11 x MIR162 x MIR604 corn acres only if treatment occurs when adult corn rootworms are not present or if a pesticide without activity against adult corn rootworms is used. Pests on the *Bt*11 x MIR162 x MIR604 corn acres can be treated as needed without having to treat the rootworm refuge.

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b) Grower Agreement for *Bt*11 x MIR162 x MIR604 Corn

1) Persons purchasing *Bt*11 x MIR162 x MIR604 corn must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.

2) The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.

3) Syngenta must implement a system (equivalent to what is already approved for previously registered Syngenta *Bt* corn products), which is reasonably likely to assure that persons purchasing *Bt*11 x MIR162 x MIR604 corn will affirm annually that they are contractually bound to comply with the requirements of the IRM program. A description of the system must be submitted to EPA within 90 days from the date of registration.

4) Syngenta must use an approved grower agreement and must submit to EPA, within 90 days from the date of registration, a copy of that agreement and any specific stewardship documents referenced in the grower agreement. If Syngenta wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty days prior to implementing a proposed change, Syngenta must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of this registration.

5) Syngenta must implement an approved system (equivalent to what is already approved for previously registered Syngenta *Bt* corn products), which is reasonably likely to assure that persons purchasing *Bt*11 x MIR162 x MIR604 corn sign grower agreement(s). A description of the system must be submitted to EPA within 90 days from the date of registration.

6) Syngenta shall maintain records of all *Bt*11 x MIR162 x MIR604 corn grower agreements for a period of three years from December 31st of the year in which the agreement was signed.

7) Beginning on January 31, 2010 and annually thereafter, Syngenta shall provide EPA with a report on the number of units of *Bt*11 x MIR162 x MIR604 corn seed shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of a twelve-month period. Note: The first report shall contain the specified information from the time frame starting with the date of registration and extending through the 2009 growing season.

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8) Syngenta must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

c) IRM Education and IRM Compliance Monitoring Program for *Bt*11 x MIR162 x MIR604 Corn

1) Syngenta must design and implement a comprehensive, ongoing IRM education program designed to convey to *Bt*11 x MIR162 x MIR604 corn users the importance of complying with the IRM program. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by internet, radio, or television commercials. Copies of the materials will be provided to EPA for their records. The program shall involve at least one written communication annually to each *Bt*11 x MIR162 x MIR604 corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Syngenta shall coordinate its education program with the educational efforts of other registrants and other organizations, such as the National Corn Growers Association and state extension programs.

2) Annually, Syngenta shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraph 6 and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

3) Beginning January 31, 2010, Syngenta must provide a report to EPA summarizing the activities it carried out under its education program for the prior year. Annually thereafter, Syngenta must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. Syngenta must either submit a separate report or contribute to the report from the industry working group, Agricultural Biotechnology Stewardship Technical Committee (ABSTC).

4) Syngenta must design and implement an ongoing IRM compliance assurance program (CAP) designed to evaluate the extent to which growers purchasing *Bt*11 x MIR162 x MIR604 corn are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to *Bt*11 x MIR162 x MIR604 corn. Syngenta shall coordinate with other *Bt* corn registrants in designing and implementing its compliance assurance program and integrate this registration into the current compliance assurance program used for their other *Bt* corn PIPs. Syngenta must prepare and submit within 90 days of the date of registration a written description of the compliance assurance program. Other required features of the program are described in paragraphs 5 - 15 below.

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5) Syngenta must establish and publicize a "phased compliance approach," i.e., a guidance document that indicates how they will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers. While recognizing that for reasons of difference in business practices there are needs for flexibility between different companies, Syngenta must use a consistent set of standards for responding to non-compliance. The options shall include withdrawal of the right to purchase *Bt*11 x MIR162 x MIR604 corn for an individual grower or for all growers in a specific region. An individual grower found to be significantly out of compliance two years in a row would be denied sales of *Bt*11 x MIR162 x MIR604 corn the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell *Bt*11 x MIR162 x MIR604 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 *Bt*11 x MIR162 x MIR604 corn who plant the vast majority of all corn in the United States and in areas in which the selection intensity is the greatest. 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. 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.

7) The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.

8) The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.

9) Syngenta shall provide a final written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA by January 31st of each year, beginning with 2010. Syngenta shall confer with other registrants and EPA on the design and content of the survey prior to its implementation.

10) Annually, Syngenta shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey (required under paragraphs 6 through 8) and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. Syngenta must confer with the Agency prior to adopting any changes.

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11) Syngenta shall conduct an annual on-farm assessment program. Syngenta shall train its representatives who make on-farm visits with growers of *Bt*11 x MIR162 x MIR604 corn to perform assessments of compliance with IRM requirements. There is no minimum corn acreage size for this program. Therefore, growers will be selected for this program from across all farm sizes. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, Syngenta shall take appropriate action, consistent with its "phased compliance approach" to promote compliance.

12) Syngenta shall carry out a program for investigating legitimate "tips and complaints" that its growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, Syngenta shall take appropriate action, consistent with its "phased compliance approach."

13) If a grower, who purchases *Bt*11 x MIR162 x MIR604 corn for planting, was specifically identified as not being in compliance during the previous year, Syngenta shall visit with the grower and evaluate whether that grower is in compliance with the IRM program for the current year.

14) Beginning January 31, 2010 and annually thereafter, Syngenta shall provide a report to EPA summarizing the activities carried out under their compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken. Syngenta may elect to coordinate information with other registrants and report collectively the results of compliance assurance programs.

15) Syngenta and the seed corn dealers for Syngenta must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and license number of the growers will be protected.

d) Insect Resistance Monitoring and Remedial Action Plans for *Bt*11 x MIR162 x MIR604 Corn

1) The Agency is imposing the following conditions for the Cry1Ab toxin expressed in *Bt*11:

Syngenta will monitor for resistance to Cry1Ab expressed in *Bt*11 x MIR162 x MIR604 corn. The monitoring program shall consist of two approaches: (i) focused population sampling and laboratory testing and (ii) investigation of reports of less-than expected control of labeled insects. Should field-relevant resistance be confirmed, an appropriate resistance management action plan will be implemented.

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i) *Focused Population Sampling*

Syngenta shall annually sample and bioassay populations of the key target pests: *Ostrinia nubilalis* (European corn borer; ECB), *Diatraea grandiosella* (Southwestern corn borer; SWCB), and *Helicoverpa zea* (corn earworm; CEW). Sampling for the target pests will be focused in areas identified as those with the highest risk of resistance development (e.g., where lepidopteran-active *Bt* hybrids are planted on a high proportion of the corn acres, and where the insect species are regarded as key pests of corn). Bioassay methods must be appropriate for the goal of detecting field-relevant shifts in population response to *Bt*11 x MIR162 x MIR604 corn and/or changes in resistance-allele frequency in response to the use of *Bt*11 x MIR162 x MIR604 corn and, as far as possible, should be consistent across sampling years to enable comparisons with historical data.

The number of populations to be collected shall reflect the regional importance of the insect species as a pest, and specific collection regions will be identified for each pest. For ECB, a minimum of 12 populations across the sampling region will be targeted for collection at each annual sampling. For SWCB, the target will be a minimum of six populations. For CEW, the target will be a minimum of 10 populations. Pest populations should be collected from multiple corn-growing states reflective of different geographies and agronomic conditions. To obtain sufficient sensitivity to detect resistance alleles before they become common enough to cause measurable field damage, each population collection shall attempt to target 400 insect genomes (egg masses, larvae, mated females, and/or mixed-sex adults), but a successful population collection will contain a minimum of 100 genomes. It is recognized that it may not be possible to collect the target number of insect populations or genomes due to factors such as natural fluctuations in pest density, environmental conditions, and area-wide pest suppression.

The sampling program and geographic range of collections may be modified as appropriate based on changes in pest importance and for the adoption levels of *Bt*11 x MIR162 x MIR604 corn. The Agency shall be consulted prior to the implementation of such modifications.

Syngenta will report to the Agency by August 31st of each year, beginning in 2010, the results of the population sampling and bioassay monitoring program.

Any incidence of unusually low sensitivity to the Cry1Ab protein in bioassays shall be investigated as soon as possible to understand any field-relevance of such a finding. Such investigations shall proceed in a stepwise manner until the field-relevance can be either confirmed or refuted, and results of these shall be reported to the Agency annually before August 31st, beginning in 2010. The investigative steps will include:

1. Re-test progeny of the collected population to determine whether the unusual bioassay response is reproducible and heritable. If it is not reproducible and heritable, no further action is required.

2. If the unusual response is reproducible and heritable, progeny of insects that survive the diagnostic concentration will be tested using methods that are representative of exposure to *Bt*11 x MIR162 x MIR604 corn under field conditions. If progeny do not survive to adulthood, any suspected resistance is not field-relevant and no further action is required.

3. If insects survive steps 1 and 2, resistance is confirmed, and further steps will be taken to evaluate the resistance. These steps may include:

   - determining the nature of the resistance (i.e., recessive or dominant, and the level of functional dominance);
   - estimating the resistance-allele frequency in the original population;
   - determining whether the resistance-allele frequency is increasing by analyzing field collections in subsequent years sampled from the same site where the resistance allele(s) was originally collected;
   - determining the geographic distribution of the resistance allele by analyzing field collections in subsequent years from sites surrounding the site where the resistance allele(s) was originally collected.

Should field-relevant resistance be confirmed, and the resistance appears to be increasing or spreading, Syngenta will consult with the Agency to develop and implement a case-specific resistance management action plan.

ii) *Investigation of Reports of Unexpected Levels of Damage by the Target Pests*

Syngenta will follow up on grower, extension specialist or consultant reports of unexpected levels of damage by the lepidopteran pests listed on the pesticide label. Syngenta will instruct its customers to contact them if such incidents occur. Syngenta will investigate all legitimate reports submitted to the company or the company's representatives.

If reports of unexpected levels of damage lead to the suspicion of resistance in any of the key target pests (ECB, SWCB, and CEW), Syngenta will implement the actions described below, based on the following definitions of *suspected resistance* and *confirmed resistance.*

Suspected resistance

EPA defines *suspected resistance* to mean field reports of unexpected levels of insect feeding damage for which:

- the corn in question has been confirmed to be lepidopteran-active *Bt* corn;

- the seed used had the proper percentage of corn expressing *Bt* protein;
- the relevant plant tissues are expressing the expected level of *Bt* protein; and
- it has been ruled out that species not susceptible to the protein could be responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and that there could be no other reasonable causes for the damage.

The Agency does not interpret *suspected resistance* to mean grower reports of possible control failures or suspicious results from annual insect monitoring assays, nor does the Agency intend that extensive field studies and testing be undertaken to confirm scientifically the presence of insects resistant to *Bt*11 x MIR162 x MIR604 corn in commercial production fields before responsive measures are undertaken.

If resistance is *suspected,* Syngenta will instruct growers to do the following:

- Use alternative control measures in *Bt*11 x MIR162 x MIR604 corn fields in the affected region to control the target pest during the immediate growing season.
- Destroy *Bt*11 x MIR162 x MIR604 corn crop residues in the affected region within one month after harvest with a technique appropriate for local production practices to minimize the possibility of resistant insects over-wintering and contributing to the next season's target pest population.

Additionally, if possible, and prior to the application of alternative control measures or destruction of crop residue, Syngenta will collect samples of the insect population in the affected fields for laboratory rearing and testing. Such rearing and testing shall be conducted as expeditiously as practical.

Confirmed resistance

EPA defines *confirmed resistance* to mean, in the case of field reports of unexpected levels of damage from the key target pests, that all the following criteria are met:

- There is >30% insect survival and commensurate insect feeding in a bioassay, initiated with neonate larvae, that uses methods that are representative of exposure to *Bt* corn hybrids under field conditions (ECB and SWCB only).

- In standardized laboratory bioassays using diagnostic concentrations of the *Bt* protein suited to the target pest in question, the pest exhibits resistance that has a genetic basis and the level of survivorship indicates that there may be a resistance-allele frequency of ≥ 0.1 in the sampled population.

- In standardized laboratory bioassays, the LC_{50} exceeds the upper limit of the 95% confidence interval of the LC_{50} for susceptible populations surveyed both in the original baselines developed for this pest species and in previous years of field monitoring.

iii) *Response to Confirmed Resistance in a Key Target Pest as the Cause of Unexpected Levels of Damage in the Field*

When field resistance is *confirmed* (as defined above), the following steps will be taken by Syngenta:

- EPA will receive notification within 30 days of resistance confirmation;

- Affected customers and extension agents will be notified about confirmed resistance within 30 days;

- Monitoring will be increased in the affected area and local target pest populations will be sampled annually to determine the extent and impact of resistance;

- If appropriate (depending on the resistant pest species, the extent of resistance, the timing of resistance, and the nature of resistance, and the availability of suitable alternative control measures), alternative control measures will be employed to reduce or control target pest populations in the affected area. Alternative control measures may include advising customers and extension agents in the affected area to incorporate crop residues into the soil following harvest to minimize the possibility of over-wintering insects, and/or applications of chemical insecticides;

- Unless otherwise agreed with EPA, stop sale and distribution of the relevant lepidopteran-active *Bt* corn hybrids in the affected area immediately until an effective local mitigation plan approved by EPA has been implemented;

- Syngenta will develop a case-specific resistance management action plan within 90 days according to the characteristics of the resistance event and local agronomic needs. Syngenta will consult with appropriate stakeholders in the development of the action plan, and the details of such a plan shall be approved by EPA prior to implementation;

- Notify affected parties (e.g., growers, consultants, extension agents, seed distributors, university cooperators and state/federal authorities as appropriate) in the region of the resistance situation and approved action plan; and

- In subsequent growing seasons, maintain sales suspension and alternative resistance management strategies in the affected region(s) for the *Bt* corn hybrids that are affected by the resistant population until an EPA-approved local resistance management plan is in place to mitigate the resistance.

A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by August 31st each year, beginning in 2010, for the duration of the conditional registration.

2) The Agency is imposing the following conditions for the Vip3Aa20 toxin expressed in MIR162:

A detailed resistance monitoring program and final remedial action plan, integrating standard procedures developed by the Agricultural Biotechnology Stewardship Technical Committee (as outlined below) and harmonized with resistance monitoring programs and remedial action plans established for previously registered Syngenta *Bt* corn products, for the key target pests of CEW and SWCB must be submitted within 90 days of the date of registration.

Syngenta will monitor for resistance to Vip3Aa20 expressed in *Bt*11 x MIR162 x MIR604 corn. The monitoring program shall consist of two approaches: (i) focused population sampling and laboratory testing and (ii) investigation of reports of less-than expected control of labeled insects. Should field-relevant resistance be confirmed, an appropriate resistance management action plan will be implemented.

i) *Focused Population Sampling*

Syngenta shall annually sample and bioassay populations of the key target pests: *Diatraea grandiosella* (Southwestern corn borer; SWCB) and *Helicoverpa zea* (corn earworm; CEW). Sampling for the target pests will be focused in areas identified as those with the highest risk of resistance development (e.g., where lepidopteran-active *Bt* hybrids are planted on a high proportion of the corn acres, and where the insect species are regarded as key pests of corn). Bioassay methods must be appropriate for the goal of detecting field-relevant shifts in population response to *Bt*11 x MIR162 x MIR604 corn and/or changes in resistance-allele frequency in response to the use of *Bt*11 x MIR162 x MIR604 corn and, as far as possible, should be consistent across sampling years to enable comparisons with historical data.

The number of populations to be collected shall reflect the regional importance of the insect species as a pest, and specific collection regions will be identified for each pest. For SWCB, the target will be a minimum of six populations. For CEW, the target will be a minimum of 10 populations. Pest populations should be collected from multiple corn-growing states reflective of different geographies and agronomic conditions. To obtain sufficient sensitivity to detect resistance alleles before they become common enough to cause measurable field damage, each population collection shall attempt to target 400 insect genomes (egg masses, larvae, mated females, and/or mixed-sex adults), but a successful population collection will contain a minimum of 100 genomes. It is recognized that it may not be possible to collect the target number of insect populations or genomes due to factors such as natural fluctuations in pest density, environmental conditions, and area-wide pest suppression.

The sampling program and geographic range of collections may be modified as appropriate based on changes in pest importance and for the adoption levels of *Bt*11 x MIR162 x MIR604 corn. The Agency shall be consulted prior to the implementation of such modifications.

Syngenta will report to the Agency by August 31st of each year, beginning in 2010, the results of the population sampling and bioassay monitoring program.

Any incidence of unusually low sensitivity to the Vip3Aa20 protein in bioassays shall be investigated as soon as possible to understand any field-relevance of such a finding. Such investigations shall proceed in a stepwise manner until the field-relevance can be either confirmed or refuted, and results of these shall be reported to the Agency annually before August 31st, beginning in 2010. The investigative steps will include:

1. Re-test progeny of the collected population to determine whether the unusual bioassay response is reproducible and heritable. If it is not reproducible and heritable, no further action is required.

2. If the unusual response is reproducible and heritable, progeny of insects that survive the diagnostic concentration will be tested using methods that are representative of exposure to *Bt*11 x MIR162 x MIR604 corn under field conditions. If progeny do not survive to adulthood, any suspected resistance is not field-relevant and no further action is required.

3. If insects survive steps 1 and 2, resistance is confirmed, and further steps will be taken to evaluate the resistance. These steps may include:

   - determining the nature of the resistance (i.e., recessive or dominant, and the level of functional dominance);

   - estimating the resistance-allele frequency in the original population;

- determining whether the resistance-allele frequency is increasing by analyzing field collections in subsequent years sampled from the same site where the resistance allele(s) was originally collected;

- determining the geographic distribution of the resistance allele by analyzing field collections in subsequent years from sites surrounding the site where the resistance allele(s) was originally collected.

Should field-relevant resistance be confirmed, and the resistance appears to be increasing or spreading, Syngenta will consult with the Agency to develop and implement a case-specific resistance management action plan.

ii) *Investigation of Reports of Unexpected Levels of Damage by the Target Pests*

Syngenta will follow up on grower, extension specialist or consultant reports of unexpected levels of damage by the lepidopteran pests listed on the pesticide label. Syngenta will instruct its customers to contact them if such incidents occur. Syngenta will investigate all legitimate reports submitted to the company or the company's representatives.

If reports of unexpected levels of damage lead to the suspicion of resistance in any of the key target pests (SWCB and CEW), Syngenta will implement the actions described below, based on the following definitions of *suspected resistance* and *confirmed resistance.*

Suspected resistance

EPA defines *suspected resistance* to mean field reports of unexpected levels of insect feeding damage for which:

- the corn in question has been confirmed to be lepidopteran-active *Bt* corn;

- the seed used had the proper percentage of corn expressing *Bt* protein;

- the relevant plant tissues are expressing the expected level of *Bt* protein; and

- it has been ruled out that species not susceptible to the protein could be responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and that there could be no other reasonable causes for the damage.

The Agency does not interpret *suspected resistance* to mean grower reports of possible control failures or suspicious results from annual insect monitoring assays, nor does the Agency intend that extensive field studies and testing be undertaken to confirm scientifically the presence of insects resistant to *Bt*11 x MIR162 x MIR604 corn in commercial production fields before responsive measures are undertaken.

If resistance is *suspected,* Syngenta will instruct growers to do the following:

- Use alternative control measures in *Bt*11 x MIR162 x MIR604 corn fields in the affected region to control the target pest during the immediate growing season.

- Destroy *Bt*11 x MIR162 x MIR604 corn crop residues in the affected region within one month after harvest with a technique appropriate for local production practices to minimize the possibility of resistant insects over-wintering and contributing to the next season's target pest population.

Additionally, if possible, and prior to the application of alternative control measures or destruction of crop residue, Syngenta will collect samples of the insect population in the affected fields for laboratory rearing and testing. Such rearing and testing shall be conducted as expeditiously as practical.

Confirmed resistance

EPA defines *confirmed resistance* to mean, in the case of field reports of unexpected levels of damage from the key target pests, that all the following criteria are met:

- There is >30% insect survival and commensurate insect feeding in a bioassay, initiated with neonate larvae, that uses methods that are representative of exposure to *Bt* corn hybrids under field conditions (SWCB only).

- In standardized laboratory bioassays using diagnostic concentrations of the *Bt* protein suited to the target pest in question, the pest exhibits resistance that has a genetic basis and the level of survivorship indicates that there may be a resistance-allele frequency of ≥ 0.1 in the sampled population.

- In standardized laboratory bioassays, the LC_{50} exceeds the upper limit of the 95% confidence interval of the LC_{50} for susceptible populations surveyed both in the original baselines developed for this pest species and in previous years of field monitoring.

iii) *Response to Confirmed Resistance in a Key Target Pest as the Cause of Unexpected Levels of Damage in the Field*

When field resistance is *confirmed* (as defined above), the following steps will be taken by Syngenta:

- EPA will receive notification within 30 days of resistance confirmation;
- Affected customers and extension agents will be notified about confirmed resistance within 30 days;
- Monitoring will be increased in the affected area and local target pest populations will be sampled annually to determine the extent and impact of resistance;
- If appropriate (depending on the resistant pest species, the extent of resistance, the timing of resistance, and the nature of resistance, and the availability of suitable alternative control measures), alternative control measures will be employed to reduce or control target pest populations in the affected area. Alternative control measures may include advising customers and extension agents in the affected area to incorporate crop residues into the soil following harvest to minimize the possibility of over-wintering insects, and/or applications of chemical insecticides;
- Unless otherwise agreed with EPA, stop sale and distribution of the relevant lepidopteran-active *Bt* corn hybrids in the affected area immediately until an effective local mitigation plan approved by EPA has been implemented;
- Syngenta will develop a case-specific resistance management action plan within 90 days according to the characteristics of the resistance event and local agronomic needs. Syngenta will consult with appropriate stakeholders in the development of the action plan, and the details of such a plan shall be approved by EPA prior to implementation;
- Notify affected parties (e.g., growers, consultants, extension agents, seed distributors, university cooperators and state/federal authorities as appropriate) in the region of the resistance situation and approved action plan; and
- In subsequent growing seasons, maintain sales suspension and alternative resistance management strategies in the affected region(s) for the *Bt* corn hybrids that are affected by the resistant population until an EPA-approved local resistance management plan is in place to mitigate the resistance.

A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by August 31st each year, beginning in 2010, for the duration of the conditional registration.

3) The Agency is imposing the following conditions for the mCry3A toxin expressed in MIR604:

i) A revised mCry3A monitoring plan that incorporates *Bt*11 x MIR162 x MIR604 corn must be submitted to the Agency within 90 days of the date of registration. Syngenta must monitor for mCry3A resistance and/or trends in increased tolerance for corn rootworm. Sampling should be focused in those areas in which there is the highest risk of resistance development. In addition to mortality assays, consider utilizing sublethal bioassays (e.g., head capsule measurements) and molecular marker methods for corn rootworm monitoring.

ii) By January 31, 2010, submit data generated by the following actions: a) initiate establishment of CRW strains that are resistant to mCry3A and investigate the nature, inheritance, and fitness costs of specific mechanisms of resistance to mCry3A, b) study the behavioral deterrence (avoidance) mechanism further, and c) continue studies on the biological impact of CRW adults surviving on corn expressing the mCry3A toxin.

iii) Syngenta must develop and validate an appropriate discriminating or diagnostic dose assay by January 31, 2010.

iv) Syngenta must finalize rootworm damage guidelines and submit these to EPA by January 31, 2010.

v) Syngenta must follow-up on grower, extension specialist or consultant reports of unexpected damage or control failures for corn rootworm.

vi) Syngenta must provide EPA with an annual resistance monitoring report by August 31st each year, beginning in 2010, reporting on populations collected the previous year.

vii) The following program summary describes, in order or events, the steps that must be taken to implement a remedial action plan if resistance to corn rootworm is confirmed (this general process has been implemented for other lepidopteran and corn rootworm *Bt* corn products).

1. *Definition of Suspected Resistance.* Resistance will be suspected if investigations of unexpected damage reports show that:

   - implicated maize plant roots were expressing the mCry3A protein at the expected level;

- alternative causes of damage or lodging, such as non-target pest insect species, weather, physical damage, larval movement from alternate hosts, planting errors, and other reasonable causes for the observations, have been ruled out;

- the level of damage exceeds guidelines for expected damage.

If resistance is "suspected," Syngenta will instruct affected growers to use alternate pest control measures such as adulticide treatment, crop rotation the following year, or use of soil or seed insecticides the following year. These measures are intended to reduce the possibility of potentially resistant insects contributing to the following year's pest population.

2. *Confirmation of Resistance.* Resistance will be confirmed if all of the following criteria are met by progeny from the target pest species sampled from the area of "suspected resistance":

   - the proportion of larvae that can feed and survive on mCry3A roots from neonate to adult is significantly higher than the baseline proportion (currently being established);

   - the LC_{50} of the test population exceeds the upper limit of the 95% confidence interval for the LC_{50} of a standard unselected population and/or survival in the diagnostic assay is significantly greater than that of a standard unselected population, as established by the ongoing baseline monitoring program;

   - the ability to survive is heritable;

   - mCry3A plant assays determine that damage caused by surviving insects would exceed economic thresholds; and

   - the identified frequency of field resistance could lead to widespread product failure if subsequent collections in the affected field area(s) demonstrated similar bioassay results.

3. *Response to Confirmed Resistance.* When resistance is "confirmed," the following steps will be taken:

   - EPA will receive notification within 30 days of resistance confirmation;

   - affected customers and extension agents will be notified about confirmed resistance;

- affected customers and extension agents will be encouraged to employ alternative corn rootworm control measures;

- sale and distribution of mCry3A corn in the affected area will cease immediately; and

- a long-term resistance management action plan will be devised according to the characteristics of the resistance event and local agronomic needs. [The details of such a plan should be approved by approved by EPA and all appropriate stakeholders.]

e) Annual Reporting Requirements for *Bt*11 x MIR162 x MIR604 Corn

1) Annual Sales: reported and summed by state (county level data available by request) January 31st each year, beginning in 2010;

2) Grower Agreements: number of units of Bt11 x MIR162 x MIR604 corn seed shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements, January 31st each year, beginning in 2010;

3) Grower Education: substantive changes to education program completed previous year, January 31st each year, beginning in 2010;

4) Compliance Assurance Program: compliance assurance program activities and results for the prior year and plans for the compliance assurance program for the current year, January 31st each year, beginning in 2010;

5) Compliance Survey Results: results of annual surveys for the prior year and survey plans for the current year; full report January 31st each year, beginning in 2010;

6) Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, August 31st each year, beginning in 2010.

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 the product constitutes acceptance of these conditions.

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

Sincerely,

Janet Andersen, Ph.D., Director
Biopesticides and Pollution
Prevention Division (7511P)

Enclosures

Bt11 x MIR162 X MIR604 Corn

[Alternate brand name: *Agrisure™ 3100*]

OECD Unique Identifier: SYN-BTØ11-1 x SYN-IR162-4 x SYN-IR6Ø4-5

Plant-incorporated protectant:
Cry1Ab, Vip3Aa20 and mCry3A proteins for control of corn borers, other lepidopteran pests and corn rootworms

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

Active Ingredients:

Bacillus thuringiensis Cry1Ab delta-endotoxin protein and the genetic material necessary for its production (via elements of vector pZO1502) in *Bt*11 x MIR162 x MIR604 corn (SYN-BTØ11-1).....0.0014 – 0.0017%*

Bacillus thuringiensis Vip3Aa20 insecticidal protein and the genetic material necessary for its production (via elements of vector pNOV1300) in *Bt*11 x MIR162 x MIR604 corn (SYN-IR162-4).....0.0057 – 0.0088%*

Bacillus thuringiensis mCry3A protein and the genetic material necessary for its production (via elements of vector pZM26) in *Bt*11 x MIR162 x MIR604 corn (SYN-IR6Ø4-5).....0.0013 – 0.0021%*

Other Ingredients:

A marker protein and the genetic material necessary for its production (via elements of vector pZO1502) in *Bt*11 x MIR162 x MIR604 corn (SYN-BTØ11-1).....0.000075 – 0.000100%*

A marker protein and the genetic material necessary for its production (via elements of vectors pZM26 and pNOV1300) in *Bt*11 x MIR162 x MIR604 corn (SYN-IR6Ø4-5 and SYN-IR162-4).....0.00075 – 0.00095%*

*Percent in whole plants on a dry weight basis

KEEP OUT OF REACH OF CHILDREN
CAUTION

EPA Registration No. 67979-13
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

™ Agrisure is a trademark of a Syngenta Group company

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 tag) indicating the registration number (67979-13) and the active ingredients, and stipulating that growers read the Grower Guide (or equivalent guidance) prior to planting the seed.

Insects Controlled or Suppressed

Field corn has been genetically transformed to produce the insecticidal proteins, Cry1Ab, Vip3Aa20 and mCry3A, for control or suppression of the following lepidopteran and coleopteran 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*)
Western corn rootworm (*Diabrotica virgifera virgifera*)
Northern corn rootworm (*Diabrotica barberi*)
Mexican corn rootworm (*Diabrotica virgifera zeae*)
Common stalk borer (*Papaipema nebris*)

Insect Resistance Management

The following information regarding commercial production of *Bt*11 x MIR162 x MIR604 corn must be included in the Grower Guide (or equivalent).

Refuge Requirements for Bt11 x MIR162 x MIR604 Corn

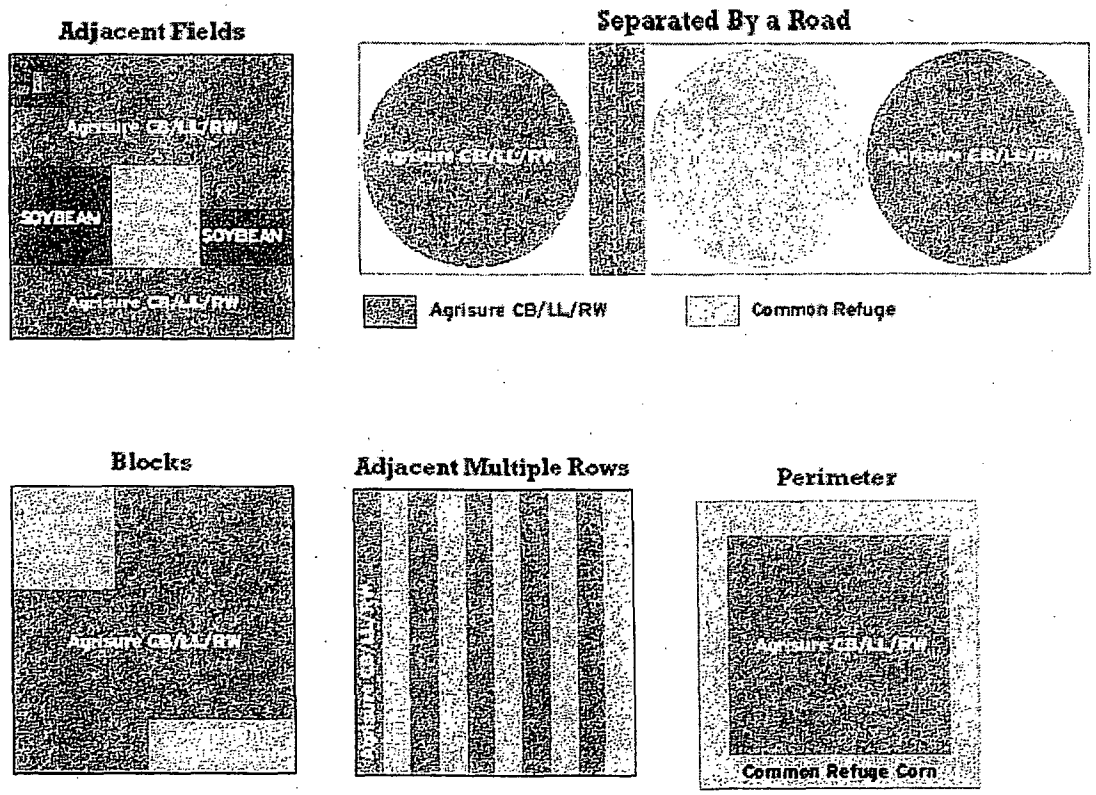
These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year.

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.

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 rootworms or corn borers. The refuge area must represent at least 20% of the grower's corn acres (i.e., sum of Bt11 x MIR162 x MIR604 corn acres and refuge acres). It must be planted as a block adjacent to the Bt11 x MIR162 x MIR604 corn 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. If the common refuge is planted on rotated ground, then Bt11 x MIR162 x MIR604 corn must also be planted on rotated ground. If the common refuge is planted in continuous corn, the Bt11 x MIR162 x MIR604 corn field may be planted on either continuous or rotated land. 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 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 Bt11 x MIR162 x MIR604 corn field 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 or crop consultants). Pests other than adult corn rootworms can be treated with an appropriate pest-labeled insecticide on the common refuge acres without treating the Bt11 x MIR162 x MIR604 corn acres only if treatment occurs when adult corn rootworms are not present. Pests on the Bt11 x MIR162 x MIR604 corn acres can be treated as needed without having to treat the common refuge.

The following is a schematic of common refuge deployment options:

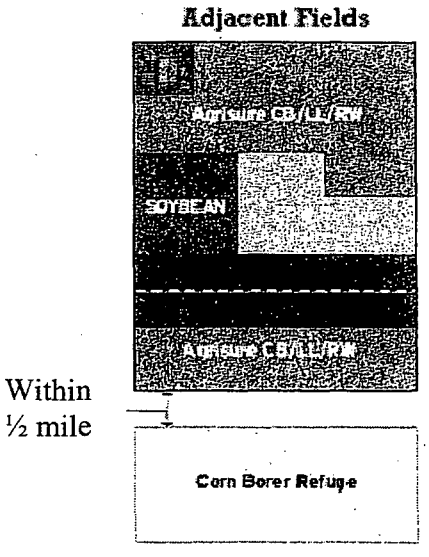


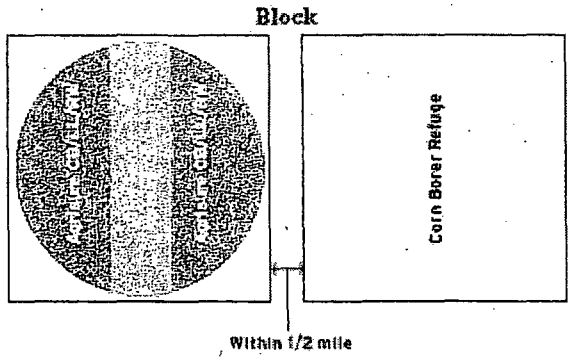
The second option is planting separate refuge areas for corn borers and corn rootworms. The corn borer refuge must be planted with a non-Bt/lepidopteran-protected hybrid, must represent at least 20% of the grower's corn acres (i.e., sum of Bt11 x MIR162 x MIR604 corn acres and corn borer refuge acres), and must be planted within ½ mile of the Bt11 x MIR162 x MIR604 corn field. 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 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 or crop consultants).

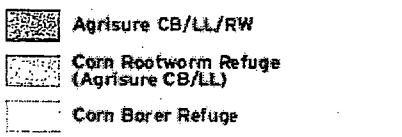
The corn rootworm refuge must be planted with a non-Bt/corn rootworm-protected hybrid, but can be planted with Bt corn hybrids that control corn borers. The corn rootworm refuge must represent at least 20% of the grower's corn acres (i.e., sum of Bt11 x MIR162 x MIR604 corn acres and corn rootworm refuge acres) and must be planted as an adjacent block, perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. If the rootworm refuge is planted on rotated ground, then Bt11 x MIR162 x MIR604 corn must also be planted on rotated ground. If the rootworm refuge is planted in continuous corn, the Bt11 x MIR162 x MIR604 corn field may be planted on either continuous or rotated land. More generally, the rootworm refuge should utilize comparable agronomic practices as the Bt11 x MIR162 x MIR604 corn acres. 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 rootworm adults are present at the time of foliar applications, then the Bt11 x MIR162 x MIR604 corn field must be treated in a similar manner. Pests other than adult corn rootworms can be treated on the rootworm refuge acres without treating the Bt11 x MIR162 x MIR604 corn acres only if treatment occurs when adult corn rootworms are not present or if a pesticide without activity against adult corn rootworms is used. Pests on the Bt11 x MIR162 x MIR604 corn acres can be treated as needed without having to treat the rootworm refuge.

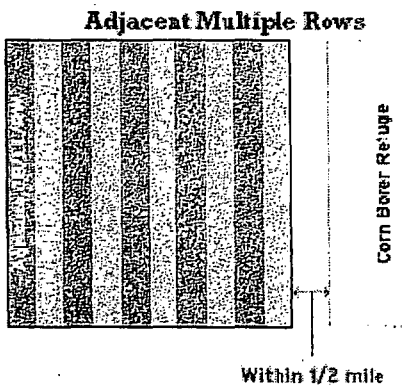
Growers who fail to comply with the IRM requirements risk losing access to Bt11 x MIR162 x MIR604 corn.

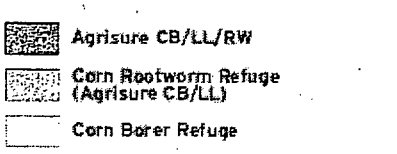
The following is a schematic of separate refuge deployment options:

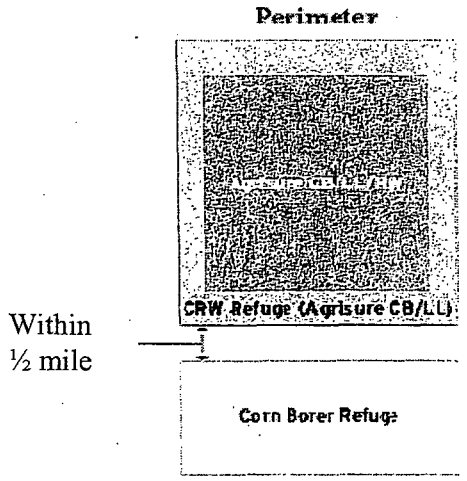

Adjacent Fields
Agrisure CB/LL/RW
SOYBEAN
Agrisure CB/LL/RW
Within
½ mile
Corn Borer Refuge


Block
Corn Borer Refuge
Within 1/2 mile


Agrisure CB/LL/RW
Corn Rootworm Refuge
(Agrisure CB/LL)
Corn Borer Refuge


Adjacent Multiple Rows
Corn Borer Refuge
Within 1/2 mile


Agrisure CB/LL/RW
Corn Rootworm Refuge
(Agrisure CB/LL)
Corn Borer Refuge


Perimeter
CRW Refuge (Agrisure CB/LL)
Within
½ mile
Corn Borer Refuge