

67979-15

3/29/2011

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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:  
67979-15

Date of Issuance:  
**MAR 29 2011**

Term of Issuance: Conditional, Time-Limited

NOTICE OF PESTICIDE:

Registration  
 Reregistration  
(under FIFRA, as amended)

Name of Pesticide Product:  
Bt11 x MIR162 x TC1507 Corn

Name and Address of Registrant (include ZIP Code):  
Syngenta Seeds, Inc. - Field Crops - NAFTA  
P.O. Box 12257  
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/reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or the Act). Registration is in no way to be construed as an endorsement or recommendation of this product by the Environmental Protection Agency (EPA or the Agency). In order to protect health and the environment, the Administrator, on her 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.

This product is conditionally registered pursuant to FIFRA section 3(c)(7)(A) provided that you comply with the following terms and conditions:

- 1) The subject registration will automatically expire on midnight March 29, 2023.
- 2) Submit/cite all data required for registration of your product under FIFRA section 3(c)(5) when EPA requires registrants of similar products to submit such data.

-Continued on Page 2-

Signature of Approving Official:  
  
Keith A. Matthews, Director  
Biopesticides and Pollution Prevention Division (7511P)

Date:  
March 29, 2011

EPA Form 8570-6

CONCURRENCES

SYMBOL	7511P	7511P	7511P				
SURNAME	KRUSCH	Holtz for S. Realty	Matthews				
DATE	03/28/2011	3/20/11	29 Mar 11				

EPA Form 1320-1A (1/90)

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3) 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 corn event Bt11 (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 corn event MIR162 (OECD Unique Identifier: SYN-IR162-4)] x Cry1F [*Bacillus thuringiensis* Cry1F protein and the genetic material necessary for its production (plasmid insert PHI8999A) in corn event TC1507 (OECD Unique Identifier: DAS-Ø15Ø7-1)].

4) Submit/cite all data, determined by EPA to be acceptable and required to support the individual plant-incorporated protectants in YieldGard® Insect Resistant Corn, MIR162 maize, and Herculex® RW Insect Protection, within the time frames required by the terms and conditions of EPA Registration Numbers 67979-1, 67979-14, and 68467-5, respectively.

5) Submit the following data and/or information, determined by EPA to be acceptable, in the time frames listed:

Study Type	Required Data	Due Date
Insect Resistance Management – Modeling	Syngenta Seeds, Inc. – Field Crops – NAFTA (Syngenta) must (1) submit a complete description of the model methodology (contained in MRID No. 480506-06), including a summary of all parameters included and their values, and (2) conduct an expanded modeling analysis, including worst case scenarios and/or sensitivity analyses for parameters such as survival (dose), dominance, initial resistance allele frequency, and cross resistance. Refer to the enclosed EPA memorandum (dated March 2, 2011) for additional information.	June 30, 2011

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

7) You must commit to do the following Insect Resistance Management (IRM) Program, consisting of the following elements:

- Requirements relating to creation of a non-*Bacillus thuringiensis* (*Bt*) corn and/or nonlepidopteran-resistant *Bt* corn refuge in conjunction with the planting of any acreage of Bt11 x MIR162 x TC1507 corn.

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- Requirements for Syngenta to prepare and require Bt11 x MIR162 x TC1507 corn users to sign grower agreements that impose binding contractual obligations on growers to comply with the refuge requirements.
- Requirements for Syngenta to develop, implement, and report to EPA on programs to educate growers about IRM requirements.
- Requirements for Syngenta to develop, implement, and report to EPA on programs to evaluate and promote growers' compliance with IRM requirements.
- Requirements for Syngenta to develop, implement, and report to EPA on monitoring programs to evaluate whether there are statistically significant and biologically relevant changes in susceptibility to the Cry1Ab, Vip3Aa20, and/or Cry1F proteins in the target insects.
- Requirements for Syngenta to develop and, if triggered, to implement a remedial action plan that would contain 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.
- Requirements for Syngenta, on or before January 31<sup>st</sup> of each year (beginning in 2012), to submit reports on units sold by state (units sold by county level will made available to EPA upon request), IRM grower agreement results, and the compliance assurance program, including the education program.
- Requirements for Syngenta, on or before August 31<sup>st</sup> of each year (beginning in 2012), to submit reports on resistance monitoring.

**a. Refuge Requirements for Bt11 x MIR162 x TC1507 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 PIP active ingredient per registrant per year.

When on-farm assessments identify non-compliance with refuge requirements for one or more *Bt* corn products, additional educational material and assistance will be provided by Syngenta to help these growers meet the refuge requirements across their farming operations.

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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 5% non-*Bt* corn (20% in cotton-growing areas\*) and/or nonlepidopteran-resistant *Bt* corn that may be treated with insecticides, as detailed below, to control lepidopteran stalk-boring and other pests.
- Refuge planting options include the following: separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips, and strips across the field.
- An external refuge must be planted within ½ mile of the Bt11 x MIR162 x TC1507 corn field.
- When planting the refuge as strips across the field or as perimeter strips, the refuge must be at least four (4) consecutive rows wide.
- Insecticide treatments for control of European corn borer (ECB), corn earworm (CEW), southwestern corn borer (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 (1) 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 nonlepidopteran-resistant *Bt* corn refuges.
- \*Cotton-growing areas (as identified by EPA) include the following states: Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard), North Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), South Carolina, 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), and Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex).

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**b. Grower Agreements for Bt11 x MIR162 x TC1507 Corn**

- 1) Persons purchasing Bt11 x MIR162 x TC1507 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 integrate this registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing Bt11 x MIR162 x TC1507 corn will affirm annually that they are contractually bound to comply with the requirements of the IRM program.
- 4) Syngenta must use an approved grower agreement and must submit to EPA, within ninety (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 (30) 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 integrate this registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing Bt11 x MIR162 x TC1507 corn sign grower agreement(s).
- 6) Syngenta shall maintain records of all Bt11 x MIR162 x TC1507 corn grower agreements for a period of three (3) years from December 31<sup>st</sup> of the year in which the agreement was signed.
- 7) Beginning on January 31, 2012 and annually thereafter, Syngenta shall provide EPA with a report showing the number of units of Bt11 x MIR162 x TC1507 corn seeds sold or 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 12-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 2011 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 numbers of the growers, will be protected.

**c. IRM Education and Compliance Monitoring Programs for Bt11 x MIR162 x TC1507 Corn**

- 1) Syngenta must implement and enhance (as set forth in paragraph 17 of this section) a comprehensive, ongoing IRM education program designed to convey to Bt11 x MIR162 x TC1507 corn users the importance of complying with the IRM program. The program shall include information encouraging Bt11 x MIR162 x TC1507 corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Bt11 x MIR162 x TC1507 corn fields. 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 its records. The program shall involve at least one (1) written communication annually to each Bt11 x MIR162 x TC1507 corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Syngenta shall coordinate its education programs with educational efforts of other registrants and 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 paragraphs 6–9 of this section, and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.
- 3) Beginning on January 31, 2012, 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). The required features of the compliance assurance program are described in paragraphs 4–22 of this section.

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4) Syngenta must implement and improve an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing Bt11 x MIR162 x TC1507 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 Syngenta's *Bt* corn products. Syngenta shall coordinate with other *Bt* corn registrants in improving its compliance assurance program and integrate this registration into the current compliance assurance program used for its other *Bt* corn plant-incorporated protectants. Other required features of the program are described in paragraphs 5–22 of this section.

5) Syngenta must maintain and publicize a phased compliance approach (i.e., a guidance document that indicates how it 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 after the first year of non-compliance). 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. An individual grower found to be significantly out of compliance two (2) years in a row would be denied access to Syngenta's *Bt* corn products 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* 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 x TC1507 corn who plant the vast majority of all corn in the United States and in areas in which the selection intensity is greatest. The survey shall consider only those growers who plant 200 or more acres of corn in the Corn Belt and who plant 100 or more acres of corn in corn-cotton 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.

- i. A third party is classified as a party other than Syngenta, the grower, or anyone else with a direct interest in IRM compliance for *Bt* corn.

7) The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of 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.

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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 on or before January 31<sup>st</sup> of each year, beginning in 2012. 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 6–9 of this section, and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. Syngenta must confer with EPA prior to adopting any changes.

11) Syngenta shall conduct an annual on-farm assessment program. Syngenta shall train its representatives who make on-farm visits with Bt11 x MIR162 x TC1507 corn growers 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 Bt11 x MIR162 x TC1507 corn 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 Bt11 x MIR162 x TC1507 corn for planting, was specifically identified as not being in compliance during the previous year, Syngenta shall visit with the grower and evaluate whether the grower is in compliance with the IRM program for the current year.

14) Beginning January 31, 2012 and annually thereafter, Syngenta shall provide a report to EPA summarizing the activities carried out under its compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. Within one (1) month of submitting this report to EPA, Syngenta shall meet with EPA to discuss its findings. 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. The report must inform EPA of the number of growers deemed ineligible to purchase *Bt* corn seed on the basis of continued non-compliance with the insect resistance management refuge requirements. Syngenta may elect to coordinate information with other registrants and report collectively the results of compliance assurance programs.



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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 grower license numbers of the growers, will be protected.

16) Syngenta shall revise and expand its existing compliance assurance program to include the following elements. Syngenta must prepare and submit, within ninety (90) days from the date of registration, a written description of its revised compliance assurance program. Syngenta may coordinate with other registrants in designing and implementing its compliance assurance program.

17) Syngenta will enhance the refuge education program throughout the seed delivery channel:

- i. Ensure sales representatives, licensees, seed dealers, and growers recognize the importance of correct refuge implementation and potential consequences of failure to plant the required refuge.
- ii. Include the refuge size requirement on all Bt11 x MIR162 x TC1507 corn seed bags or bag tags. The Bt11 x MIR162 x TC1507 corn label accepted by EPA must include how this information will be conveyed to growers via text and graphics. This requirement may be phased in over the next three (3) growing seasons. Revised Bt11 x MIR162 x TC1507 corn labels must be submitted by June 30, 2011, 50% implementation on the corn bags or bag tags must occur by the 2012 growing season, and full implementation must occur by the 2013 growing season.

18) Syngenta will focus the majority of on-farm assessments on regions with the greatest risk for resistance:

- i. Use *Bt* corn adoption, pest pressure information, and other available information to identify regions where the risk of resistance is greatest.
- ii. Focus approximately two-thirds of on-farm assessments on these regions, with the remaining assessments conducted across other regions where Bt11 x MIR162 x TC1507 corn is used.

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19) Syngenta will use its available Bt11 x MIR162 x TC1507 corn sales records and other information to refine grower lists for on-farm assessments of their compliance with refuge requirements:

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- i. Identify for potential on-farm assessment growers whose sales information indicates they have purchased Bt11 x MIR162 x TC1507 corn but may have purchased little or no refuge seed from Syngenta, licensees, or affiliated companies.

20) Syngenta will contract with third parties to perform on-farm assessments of compliance with refuge requirements:

- i. The third-party assessors will conduct all first-time on-farm assessments, as well as second-year on-farm assessments, of those growers found out of compliance in a first-time assessment.

21) Annually, Syngenta will refine the on-farm assessment program for Bt11 x MIR162 x TC1507 corn to reflect the adoption rate and level of refuge compliance for Bt11 x MIR162 x TC1507 corn.

22) Syngenta will follow up with growers who have been found significantly out of compliance under the on-farm assessment program and are found to be back in compliance the following year:

- i. All growers found to be significantly out of compliance in a prior year will annually be sent additional refuge assistance information for a minimum of two (2) years by Syngenta, a seed supplier, or a third-party assessor, after completing the assessment process.
- ii. Syngenta will conduct follow-up checks on growers found to be significantly out of compliance within three (3) years after they are found to be back in compliance.
- iii. A grower found with a second incident of significant non-compliance with refuge requirements for Bt11 x MIR162 x TC1507 corn within a 5-year period will be denied access to Syngenta's *Bt* corn products the next year.

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**d. Insect Resistance Monitoring and Remedial Action Plan for Bt11 x MIR162 x TC1507 Corn**

EPA is imposing the following conditions for the Cry1Ab, Vip3Aa20, and Cry1F toxins expressed in Bt11 x MIR162 x TC1507 corn:

Syngenta will monitor for resistance to Cry1Ab, Vip3Aa20, and Cry1F expressed in Bt11 x MIR162 x TC1507 corn. The monitoring program shall consist of two approaches: (1) focused population sampling and laboratory testing; and (2) 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.

Focused Population Sampling

Syngenta shall annually sample and bioassay populations of the key target pests: *Ostrinia nubilalis* (European corn borer; ECB) – Cry1Ab and Cry1F only, *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 Bt11 x MIR162 x TC1507 corn and/or changes in resistance allele frequency in response to the use of Bt11 x MIR162 x TC1507 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 twelve (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 (6) populations. For CEW, the target will be a minimum of ten (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 Bt11 x MIR162 x TC1507 corn. EPA shall be consulted prior to the implementation of such modifications.

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Syngenta will report to EPA, on or before August 31<sup>st</sup> of each year (beginning in 2012), the results of the population sampling and bioassay monitoring program.

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Any incidence of unusually low sensitivity to the Cry1Ab, Vip3Aa20, and/or Cry1F proteins 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 EPA annually on or before August 31<sup>st</sup>, beginning in 2012. The investigative steps will include the following:

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 Bt11 x MIR162 x TC1507 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 the following:
  - 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 EPA to develop and implement a case-specific resistance management action plan.

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### 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.

EPA does not interpret *suspected resistance* to mean grower reports of possible control failures or suspicious results from annual insect monitoring assays, nor does EPA intend that extensive field studies and testing be undertaken to confirm scientifically the presence of insects resistant to Bt11 x MIR162 x TC1507 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 Bt11 x MIR162 x TC1507 corn fields in the affected region to control the target pest during the immediate growing season.
- Destroy Bt11 x MIR162 x TC1507 corn crop residues in the affected region within one (1) 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.

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Additionally, if possible, and prior to the application of alternative control measures or destruction of crop residues, 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  $\geq 0.1$  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.

### 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 thirty (30) days of resistance confirmation;
- Affected customers and extension agents will be notified about confirmed resistance within thirty (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;

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- 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 ninety (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 EPA, on or before August 31<sup>st</sup> of each year (beginning in 2012), for the duration of the registration.

**e. Annual Reporting Requirements for Bt11 x MIR162 x TC1507 Corn**

- 1) Annual Sales: reported and summed by state (county level data available by request), on or before January 31<sup>st</sup> of each year, beginning in 2012.
- 2) Grower Agreement Results: number of units of Bt11 x MIR162 x TC1507 corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements, on or before January 31<sup>st</sup> of each year, beginning in 2012.
- 3) Grower Education: substantive changes to the education program completed during the previous year, on or before January 31<sup>st</sup> of each year, beginning in 2012.

Syngenta Seeds, Inc. – Field Crops – NAFTA  
EPA Registration No. 67979-15

- 4) Compliance Assurance Program: compliance assurance program activities and results for the previous year and plans for the compliance assurance program during the current year, on or before January 31<sup>st</sup> of each year, beginning in 2012.
- 5) Compliance Assurance Program Survey Results: survey results for the previous year and plans for the current year, on or before January 31<sup>st</sup> of each year, beginning in 2012.
- 6) Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, on or before August 31<sup>st</sup> of each year, beginning in 2012.

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 this product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Sincerely,



Keith A. Matthews, Director  
Biopesticides and Pollution  
Prevention Division (7511P)



MAR 29 2011

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 67979-15

Bt11 x MIR162 x TC1507 Corn

[Alternate brand name: Agrisure™ Viptera™ 3220 Refuge Renew]

OECD Unique Identifier: SYN-BT011-1.x.SYN-IR162-4.x.DAS-01507-1

Plant-incorporated protectant: Cry1Ab, Vip3Aa20 and Cry1F proteins for control of corn borers and other lepidopteran pests

This product is effective in controlling corn leaf, stalk, and ear damage caused by 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 Bt11 corn (SYN-BT011-1) .....≤0.00103%\*

Bacillus thuringiensis Vip3Aa20 insecticidal protein and the genetic material necessary for its production (via elements of vector pNOV1300) in MIR162 corn (SYN-IR162-4)..... ≤0.00256%\*

Bacillus thuringiensis Cry1F delta-endotoxin protein and the genetic material necessary for its production (plasmid insert PHI8999A) in TC 1507 corn (DAS-01507-1).....≤0.00077%\*

Other Ingredients:

A marker protein and the genetic material necessary for its production (via plasmid insert PHI8999A and elements of vector pZO1502) in TC 1507 corn (DAS-01507-1) and Bt11 corn (SYN-BT011-1) .....≤0.00017%\*

A marker protein and the genetic material necessary for its production (via elements of vector pNOV1300) in MIR162 corn (SYN-IR162-4).....≤0.00025%\*

\*Percent (wt/wt) of whole plant on a dry weight basis

KEEP OUT OF REACH OF CHILDREN CAUTION

EPA Registration No. 67979-15 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
™ Viptera 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 its labeling.

The subject registration will automatically expire on midnight March 29, 2023.

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

All corn seed that contains the plant-incorporated protectant sold or distributed by Syngenta Seeds, Inc. or its distributors must be accompanied by informational material (e.g., a bag tag) indicating the registration number (67979-15) 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 Cry1F, 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*)  
Lesser cornstalk borer (*Elasmopalpus lignosellus*)  
Dingy cutworm (*Feltia jaculifera*)  
Common stalk borer (*Papaipema nebris*)

### **Insect Resistance Management**

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.

**Refuge Requirements for Bt11 x MIR162 x TC1507 Corn**

The following information regarding commercial production of Bt11 x MIR162 x TC1507 corn must be included in the Grower Guide (or equivalent).

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.

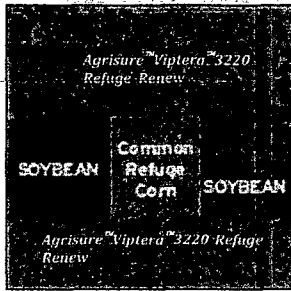
- Specifically, growers must plant a structured refuge of at least 5% non-Bt corn (20% in cotton -growing\* areas) and/or nonlepidopteran-resistant Bt corn that may be treated with insecticides, as detailed below, to control lepidopteran stalk-boring and other pests.
- Refuge planting options include the following: separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips, and strips across the field.
- An external refuge must be planted within 1/2 mile of the Bt11 x MIR162 x TC1507 corn field.
- When planting the refuge as strips across the field or as perimeter strips, the refuge must be at least four consecutive rows wide.
- Insecticide treatments for control of European corn borer (ECB), corn earworm (CEW), southwestern corn borer (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 nonlepidopteran-resistant Bt corn refuges.

**\*Cotton-Growing Areas (as Identified by EPA) Required to Plant 20% Refuge Corn**

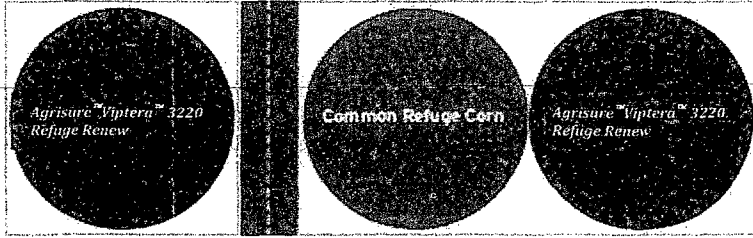
Alabama – all counties  
 Arkansas – all counties  
 Florida – all counties  
 Georgia – all counties  
 Louisiana – all counties  
 Mississippi – all counties  
 Missouri – counties of:  
 Dunklin Scott  
 New Madrid Stoddard  
 Pemiscot  
 North Carolina – all counties  
 Oklahoma – counties of:  
 Beckham Jackson  
 Caddo Kay  
 Comanche Kiowa  
 Custer Tillman  
 Greer Washita  
 Harmon  
 South Carolina – all counties  
 Tennessee – counties of:  
 Carroll Haywood  
 Chester Lake  
 Crockett Lauderdale

Dyer Lincoln  
 Fayette Madison  
 Franklin Obion  
 Gibson Rutherford  
 Hardeman Shelby  
 Hardin Tipton  
 Texas – all counties EXCEPT:  
 Carson Lipscomb  
 Dallam Moore  
 Hansford Ochiltree  
 Hartley Roberts  
 Hutchinson Sherman  
 (NOTE: these counties are  
 required to plant at least  
 5% refuge corn)  
 Virginia – counties of:  
 Dinwiddie Southampton  
 Franklin City Suffolk City  
 Greensville Surrey  
 Isle of Wight Sussex  
 Northampton

**Adjacent Fields**



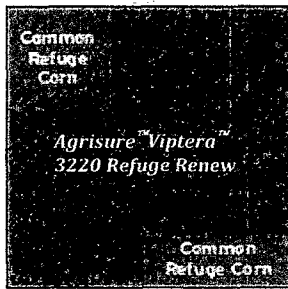
**Separated By a Road**



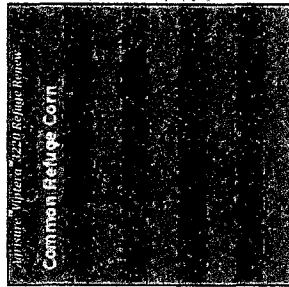
Agrisure™ Viptera™  
3220 Refuge Renew

Common Refuge

**Blocks**



**Adjacent Multiple Rows**



**Perimeter**

