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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 14, 2016

Katie P. Davis
Regulatory Affairs Manager, US
Syngenta Seeds, LLC – Field Crops – NAFTA
P.O. Box 12257, 3054 East Cornwallis Road
Research Triangle Park, NC 27709

Subject:

Product Name: Bt11xMIR162xMIR604xTC1507x5307 Corn
EPA Registration Number: 67979-23
Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendments – to amend compliance terms, amend reporting requirements, extend the registration expiration date and revise the label and confidential statement of formula (CSF)
Non-PRIA (Pesticide Registration Improvement Act) Labeling Notification – to add alternate brand names
Application Dates: Jan. 24, 2013, Oct. 23, 2013, Jan. 6, 2014 and Apr.14, 2016
OPP Decision Numbers: 474600, 485719, 487174, 516849

Dear Ms. Davis:

The amendments to the registration, labeling and CSF referred to above, submitted in connection with registration under § 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, are acceptable provided that you do the following terms and conditions.

1) The subject registration will automatically expire on midnight August 1, 2024.

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

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 protein and the genetic material necessary for their production (via elements of vector pNOV1300 in MIR162 corn (OECD Unique Identifier: SYN-IR162-4) x mCry3A [*Bacillus thuringiensis* mCry3A protein and the genetic material necessary for its production (via elements of vector pZM26) in corn event MIR604 (OECD Unique Identifier: SYN-IR6Ø4-5)] x Cry1F [*Bacillus thuringiensis* Cry1F protein and the genetic material necessary for its production (plasmid insert PHI8999) in corn event TC1507 (OECD Unique Identifier: DAS-Ø15Ø7-1)] x *Bacillus thuringiensis* eCry3.1Ab insecticidal

protein and the genetic material necessary for its production (via elements of vector PSYN12274) in 5307 Corn (SYN- Ø53Ø7-1).

4) Submit/cite all data, determined by EPA to be acceptable and required to support the individual plant-incorporated protectants within the time frames required by the terms and conditions of products bearing EPA Registration Numbers 67979-1, 67979-5, 67979-8, 67979-12, 67979-13, 67979-14, 67979-15, 67979-19, 67979-22, 67979-24, 67979-25, 67979-26 and 67979-27, respectively.

5) 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*) lepidopteran-protected hybrid corn refuge in cotton growing areas in conjunction with the planting of any acreage of Bt11xMIR162xMIR604xTC1507x5307 Corn.

- Requirements for Syngenta to prepare and require Bt11xMIR162xMIR604xTC1507x5307 Corn users to sign grower agreements that impose binding contractual obligations on growers to comply with the growing requirements.

- Requirements for Syngenta to develop, implement, and report to EPA on programs to educate growers about IRM.

- 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, mCry3A, Cry1F, and eCry3.1Ab 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 to maintain, and provide the Agency upon request, the number of units sold by state and county, IRM grower agreement results, and substantive changes to educational programs. Syngenta is required to submit reports within three months of the Agency's request.

- Requirements for Syngenta, on or before August 31st of each year, to submit reports on resistance monitoring.

- Bag Tag Requirements for Bt11xMIR162xMIR604xTC1507x5307 Corn

  Seed bags and/or bag tags for corn hybrids that contain plant-incorporated protectants produced in Bt11×MIR162×MIR604×TC1507×5307 Corn must display the registration number and active ingredients, and stipulate that growers read the Syngenta Stewardship Guide (or

equivalent guidance) prior to planting these hybrids. The refuge size requirement must be displayed on the bag or bag tag in both text and graphic format.

a. Refuge Requirements

The following information regarding commercial production of Bt11xMIR162xMIR604xTC1507x5307 Corn must be included in the Syngenta Stewardship Guide (or equivalent). Growers must plant a refuge when using this product. Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the Syngenta Stewardship guide/product use guide and/or in supplements to the Stewardship guide. Growers have two options for deployment of the refuge:

Refuge Option 1

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 pests. The refuge area must represent at least 5% (or 20% in cotton growing regions) of the grower's corn acres (*i.e.*, sum of Bt11xMIR162xMIR604xTC1507x5307 Corn acres and refuge acres). It must be planted as a block adjacent to the Bt11xMIR162xMIR604xTC1507x5307 Corn field, perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least four consecutive rows wide. If the common refuge is planted on rotated ground, then Bt11xMIR162xMIR604xTC1507x5307 Corn must also be planted on rotated ground. If the common refuge is planted in continuous corn, the Bt11xMIR162xMIR604x TC1507x5307 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 Bt11xMIR162xMIR604xTC1507x5307 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 Bt11x MIR162xMIR604xTC1507x5307 Corn acres only if treatment occurs when adult corn rootworms are not present. Pests on the Bt11xMIR162xMIR604xTC1507x5307 Corn acres can be treated as needed without having to treat the common refuge.

Refuge Option 2

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 5% (or 20% in cotton growing regions) of the grower's corn acres (*i.e.*, sum of Bt11xMIR162xMIR604xTC1507x5307 Corn acres and corn borer refuge acres), and must be planted within ½ mile of the Bt11xMIR162xMIR604x TC1507x5307 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 four 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 cannot be planted with a corn rootworm-protected *Bt* hybrid,

but can be planted with a non-*Bt* hybrid or a *Bt* corn hybrid that controls corn borers. The corn rootworm refuge must represent at least 5% (or 20% in cotton growing regions) of the grower's corn acres (*i.e.*, sum of Bt11xMIR162xMIR604xTC1507x5307 Corn acres and 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 four consecutive rows wide. If the rootworm refuge is planted on rotated ground, then Bt11xMIR162x MIR604xTC1507x5307 Corn must also be planted on rotated ground. If the rootworm refuge is planted in continuous corn, the Bt11xMIR162xMIR604xTC1507x5307 Corn field may be planted on either continuous or rotated land. More generally, the corn rootworm refuge should utilize comparable agronomic practices as the Bt11xMIR162x MIR604xTC1507x5307 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 Bt11xMIR162xMIR604xTC1507x 5307 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 Bt11xMIR162xMIR604xTC1507x 5307 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 Bt11xMIR162xMIR604xTC1507x5307 Corn acres can be treated as needed without having to treat the rootworm refuge.

Cotton-growing areas include the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, Stoddard).

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

b. Grower Agreements for Bt11xMIR162xMIR604xTC1507x5307 Corn

1) Persons purchasing Bt11xMIR162xMIR604xTC1507x5307 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 Bt11xMIR62x MIR604xTC1507x5307 Corn will affirm annually that they are contractually bound to comply with the requirements of the IRM program.

4) 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 Bt11xMIR162x MIR604xTC1507x5307 Corn sign grower agreement(s).

5) Syngenta shall maintain records of all Bt11xMIR162xMIR604xTC1507x5307 Corn grower agreements for a period of three (3) years from December 31st of the year in which the agreement was signed.

6) Syngenta shall make available to the Agency upon request records of the number of units of Bt11xMIR162x MIR604xTC1507x5307 Corn seed sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements for the previous growing season. Syngenta is required to submit reports within three months of the Agency's request.

7) 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 Bt11xMIR162xMIR604xTC1507x 5307 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 Bt11xMIR162xMIR604xTC1507x5307 Corn users the importance of complying with the IRM program, as well as product performance expectations and guidance to growers on actions to take when unexpected damage occurs. The program shall include information encouraging Bt11xMIR162xMIR604xTC1507x5307 Corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Bt11xMIR162xMIR604x TC1507x5307 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 Bt11xMIR162xMIR604xTC1507x5307 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) Upon EPA request, Syngenta shall provide copies of grower education materials and information on grower education activities including any substantive changes to these materials and activities conducted either individually or as part of the industry working group, Agricultural Biotechnology Stewardship Technical Committee (ABSTC). Syngenta is required to submit reports within three months of the

Agency's request. The required features of the compliance assurance program are described in paragraphs 4–22 of this section.

4) Syngenta must implement and improve an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing Bt11xMIR162xMIR604xTC1507x5307 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 the next year to Syngenta's *Bt* corn products for which the grower is required to plant a separate structured refuge. 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 Bt11xMIR162xMIR604x TC1507x5307 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.

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 31st of each year. 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 Bt11xMIR162xMIR604xTC1507x5307 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 Bt11xMIR162x MIR604xTC1507x5307 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 Bt11xMIR162xMIR604xTC1507x5307 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) Annually by January 31, 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.

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 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 Bt11xMIR162xMIR604xTC1507x5307 Corn seed bags or bag tags. The Bt11xMIR162xMIR604xTC1507x5307 Corn label accepted by EPA must include how this information will be conveyed to growers via text and graphics.

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 Bt11xMIR162xMIR604xTC1507x5307 Corn is used.

19) Syngenta will use its available Bt11xMIR162xMIR604xTC1507x5307 Corn sales records and other information to refine grower lists for on-farm assessments of their compliance with refuge requirements:

i. Identify for potential on-farm assessment growers whose sales information indicates they have purchased Bt11x MIR162 x MIR604xTC1507x5307 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 Bt11xMIR162xMIR604x TC1507x5307 Corn to reflect the adoption rate and level of refuge compliance for Bt11xMIR162x MIR604xTC1507x 5307 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 Bt11x MIR162xMIR604xTC1507x5307 Corn within a 5-year period will be denied access the next year to Syngenta's *Bt* corn products for which the grower is requested to plant a separate structured refuge.

d. Insect Resistance Monitoring and Remedial Action Plans for Bt11xMIR162xMIR604xTC1507x 5307 Corn

1] EPA is imposing the following conditions for the Cry1Ab, Cry1F, and Vip3Aa20 toxins expressed in Bt11x MIR162xMIR604xTC1507x5307 Corn:

Syngenta will monitor for resistance to Cry1Ab, Cry1F, and Vip3aA20 expressed in Bt11xMIR162x MIR604xTC1507x5307 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 remedial 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), *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 Bt11xMIR162xMIR604xTC1507x5307 Corn and/or changes in resistance allele frequency in response to the use of Bt11xMIR162xMIR604xTC1507x5307 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 Bt11xMIR162xMIR604xTC1507x5307 Corn. EPA shall be consulted prior to the implementation of such modifications.

Syngenta will report to EPA, on or before August 31st of each year, the results of the population sampling and bioassay monitoring program.

Any incidence of unusually low sensitivity to the Cry1Ab, Cry1F, and Vip3aA20 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 31st. 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 Bt11xMIR162x MIR604xTC1507x5307 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 remedial action plan.

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 and provide guidance to growers on product performance expectations and actions to take when unexpected damage occurs. Syngenta will investigate all legitimate reports submitted to Syngenta or Syngenta'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 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 Bt11xMIR162x MIR604xTC1507x5307 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 Bt11xMIR162xMIR604xTC1507x5307 Corn fields in the affected region to control the target pest during the immediate growing season.
- Destroy Bt11xMIR162xMIR604xTC1507x5307 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.

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 of 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.

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 remedial 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 EPA, on or before August 31st of each year, for the duration of the registration.

2] EPA is imposing the following conditions for the mCry3A and eCry3.1Ab toxins expressed in Bt11xMIR162xMIR604xTC1507x5307 Corn:

a) Investigation of Reports of Unexpected Levels of Damage (UXD) by Corn Rootworm (CRW): Performance Inquiries

1) Syngenta is required to investigate "performance inquiries" (i.e., reports of unexpected CRW damage to Bt11xMIR162xMIR604xTC1507x5307 Corn) from growers. Fields (defined as a tract separated by permanent boundaries such as fences, permanent waterways, woodlands, croplines not subject to change because of farming practices, or other similar features) with unexpected damage that meet both of the criteria below must be subjected to the follow-up actions in part 2) below:

    i. The affected plants are confirmed to be Bt11xMIR162xMIR604xTC1507x5307 Corn plants (take leaf samples to determine the presence of the CRW-active *Bt* protein); and
    ii. Corn rootworm feeding caused root damage with a Node Injury Score (NIS) > 0.5 on at least 50% of plants surveyed in a transect sampling of the damaged site(s) within the field.

2) Follow-up actions (performance inquiries). For Bt11xMIR162xMIR604xTC1507x5307 Corn fields meeting the criteria in part 1) above, Syngenta must take the following actions:

- Collect at least 250 (ideally 500 or more) CRW adult individuals from the damaged site within the field in question. Collections may be extended to the whole field, if necessary to obtain sufficient CRW adult individuals. Collected populations must be subjected to the steps described for "investigation of populations of concern" in section e(2)(b) below.
    - If collections are unsuccessful, visit affected farm or field the following year (assuming the grower continues to be a customer and repurchases seed and does not rotate the field to a non-host crop) and attempt to collect CRW adults. If beetles are not present the subsequent year, see section e(2)(b)(3)(c) below.
- Review with the grower their CRW management practices and provide CRW management recommendations including an assessment of corn fields with similar trait(s) adjacent to the affected corn field that are managed by the same grower.
- Use of single trait products containing the CRW traits in Bt11xMIR162xMIR604x TC1507x5307 Corn in fields with unexpected damage in previous years should be discouraged. Recommended management options include, but are not limited to, the following:
    - Primary option: Rotation to non-host crop (e.g., soybean)
    - Secondary options:
        - Use of pyramided *Bt* corn products one or more different CRW PIP trait(s)
        - Use of different single-CRW PIP traits (i.e., an alternative CRW-active PIP)

        - Use of non-*Bt* or non-CRW protected corn.
    - Tertiary options:
        - If additional pest management need is determined beyond the secondary options listed above, use of the same pyramided *Bt* corn product is acceptable if it is very unlikely that both of the traits are affected (e.g., the affected field experienced UXD to one of the traits in the product in the previous year, the NIS is less than 1.0, there has been no continuous use of the second trait in the product in the affected field, and Syngenta has not been informed of resistance to the second trait in the county)
        - Additional corn rootworm control tools (e.g., soil applied insecticides, chemigation) should be considered.
- If field(s) with UXD is/are planted to a non-host crop (e.g., soybean) the following year, then the area will be considered "mitigated" (as discussed in section e(2)(b)(3)(d) below) even if subsequent bioassay results show that the population was resistant. No further action will be required by Syngenta for the UXD case.

3) Syngenta must submit an annual report to EPA detailing activities related to investigations of unexpected damage (UXD). This report will include the information from the most recent and previous corn growing seasons:
    i. Information from the most recent season:
        - The number of UXD reports investigated.
        - Location (by county and state).
        - CRW sampling (number and location of populations collected).
    ii. Information from the previous season:
        - The final disposition of UXD fields from the previous season (i.e., the management practices employed in response to UXD if the grower continues to be a customer.
        - Results from bioassays conducted on CRW populations from UXD fields where the primary management option, rotation to non-host crop, was not used.
    iii. Grower information, such as farm addresses or other personally identifiable information, or other sensitive business/customer information must not be included in this report. This report must be submitted by November 30th each year.

<u>b) Investigation of Populations of Concern</u>

1) Syngenta must conduct investigations of all CRW populations collected as part of the performance inquiry process in section e(2)(a) above. These investigations must include the use of an EPA-approved bioassay to determine if sampled CRW populations are resistant to any of the CRW PIP toxins in Bt11xMIR162xMIR604xTC1507x5307 Corn. Acceptable assays must be able to function as diagnostic tools capable of distinguishing resistant populations from susceptible ones. Unless previously approved, Syngenta must consult with EPA on their bioassay prior to its use.

2) A CRW population will be considered by EPA to be resistant to a CRW PIP toxin if the following criteria are met and additional collections and testing are not deemed to be necessary (based on part 3) below):

a. An initial performance inquiry investigation results in a finding of Unexpected Damage; and
b. Where green tissues are available and if plants are unusually stressed due to agronomic and/or environmental factors, *Bt* protein levels in affected plants are found to be within the documented range for that hybrid (if data are available); and
c. Either (A): On-plant bioassays of insect collections from the UXD fields result in the following two statistically relevant comparisons:
    i. A statistically significant difference in measures of either mortality or sublethal effects (growth/development) between the field population and a relevant susceptible control population (i.e., one that responds as a typical susceptible field population) on *Bt* corn containing the single PIP and/or lack of a statistically significant difference in measures of mortality or sublethal effect between the field population and a resistant positive control population†; and
    ii. A lack of a statistically significant difference in the same measures of the field population raised on *Bt* corn containing the single PIP and non-*Bt* corn plants.

    Or (B): Sublethal seedling bioassay of insect collections from the UXD fields result in two statistically relevant comparisons.
    i. A statistically significant difference in measures of sublethal effects (growth/development) for populations on *Bt* corn containing the single PIP (normalized using non-*Bt*) seedlings between the field population and a relevant susceptible control population where available or historical field populations and/or lack of a statistically significant difference in measures between the field population and a resistant positive control population†; and
    ii. A lack of a statistically significant difference in the same measures of the field population raised on *Bt* corn seedlings containing the single PIP and non-*Bt* corn seedlings.

    Or (C): Diet-based bioassays of insect collections from the UXD fields result in two statistically relevant comparisons.
    i. A statistically significant difference in measures of lethal or sublethal effects (growth/development) on diet containing the *Bt* protein (diagnostic concentration or concentration-response measures) between the field population and a relevant susceptible control population where available or historical field populations and/or lack of a statistically significant difference in measures between field population and a resistant positive control population†; and
    ii. Either a lack of a statistically significant difference in the same measures of the field population exposed to diet containing the *Bt* protein (diagnostic concentration) and diet not containing the *Bt* protein and/or lack of a statistically significant difference in measures between the field population and a resistant positive control population, or lack of a statistically significant concentration and/or lack of a statistically significant difference in concentration response between the field and a resistant positive control population†.

† If a resistant positive control population is not available or accessible, Syngenta must consult with EPA prior to initiating bioassays and work to develop an appropriate resistant positive control population.

3) Mitigation, as detailed in section e(2)(c) below, is required for any CRW population that meets EPA's resistance criteria above for any of the CRW traits in Bt11xMIR162xMIR604xTC1507x 5307 Corn, unless the circumstances described below are applicable.

    a. To minimize the potential for incorrectly reaching a conclusion of resistance, another year of CRW adult collections and additional testing is needed to determine resistance if:
        i. The results of the bioassays are inconclusive (e.g., the results of the statistical analysis are unclear because of low sample sizes) or
        ii. Another reasonable explanation for the unexpected damage exists (e.g., high pest pressure and/or high plant stress).
    b. In these cases, Syngenta and EPA will discuss and align on next steps before reaching any resistance conclusion.
    c. If CRW collections are not possible in the current year or subsequent year due to successful management practices, then no further investigation is needed. The population would be considered "mitigated" meaning, in this case, that the population is suppressed or extirpated for the UXD field. However, EPA recommends that Syngenta continue to be vigilant in areas where CRW populations were successfully mitigated.
    d. If a UXD field receives non-host crop (e.g., soybean) rotation the following year as described in Section e(2)(a)(2) above, no additional mitigation is subsequently required.

<u>c) Mitigation of CRW Populations Meeting EPA's Resistance Criteria</u>

1) For any CRW population found to be resistant to one or more of the CRW traits in Bt11x MIR162xMIR604xTC1507x5307 Corn under EPA's criteria described in section e(2)(b) above, Syngenta must take the following steps:

    a. Syngenta must inform EPA of the results of the bioassays as soon as possible, but at least within 30 days if measures are triggered.
    b. The mitigation action area (MAA) is defined as the growers' farming operation up to a ½ mile radius from the damaged site that produced the resistant population.
    c. Within 30 days of informing EPA of the results of the bioassays, Syngenta must notify state extension agents and crop consultants who operate within the county in which resistance was identified. Information shared must include identification of the county in which resistance was detected and trait(s) affected.
    d. Within the MAA, Syngenta must do the following:
        i. Prior to finalizing the grower's seed order for the following season, inform the affected grower and other registrants that hold registrations containing the compromised trait(s). Syngenta must also inform neighboring growers if those growers are customers of Syngenta. Information shared must include identification of the county in which resistance was detected and trait(s) affected;
        ii. Discontinue sales/planting of products containing the compromised trait(s) without additional/alternative (i.e. non-compromised) CRW traits until resistance has been demonstrated to have been mitigated. Other *Bt* registrants selling such products in the MAA are encouraged, but cannot be required, to follow suit;

iii. Syngenta must monitor the resistant population in the MAA, as long as grower remains a customer of the company, until mitigation has been demonstrated as described in part e below unless otherwise agreed with EPA.

iv. Require any pyramids sold by Syngenta containing the compromised trait(s) be planted with a 20% refuge until resistance has been demonstrated to have been mitigated. Other *Bt* corn registrants selling such pyramided products in the MAA are encouraged, but cannot be required by this term of registration, to follow suit;

v. For Syngenta's affected customer's field(s), the mitigation goal is to control the resistant CRW population. Within the MAA Syngenta shall encourage the use of "Mitigation Practices" including:

1. Primary option: Rotation to a non-host crop (e.g., soybean);
2. Secondary options:
    a. Use of pyramided *Bt* corn products with different CRW PIP traits;
    b. Only in the case that the resistance definition for one of the CRW traits in the Bt11xMIR162xMIR604xTC1507x5307 Corn is not met, continued use of the product with a 20% refuge;
    c. Use of different single-CRW PIP traits (i.e., an alternative CRW-active PIP);
    d. Use of non-*Bt* corn or non-CRW protected corn (with/without soil-applied insecticide);
3. Tertiary options:
    a. If additional pest management need is determined beyond the secondary options listed above, additional CRW control tools (e.g., soil insecticides, seed-applied insecticides, chemigation) should be used.
    b. Use of foliar applications to control adults (when appropriate economic thresholds have been met) may be used in conjunction with one or more of the above;

e. A resistant CRW population in the MAA will be considered mitigated if one of the following criteria is met:

i. Corn fields within the MAA are rotated to a non-host crop (e.g. soybean) for one growing season.

ii. After implementation of mitigation practices (part d.v above), resistance monitoring (sampling) is conducted but few CRW are found (i.e., <0.1 adults per plant) and environmental conditions (e.g., weather) are unlikely to be responsible for the lack of adult CRW presence. If environmental conditions are a factor, then monitoring should continue for another season.

iii. After implementation practices (part d.v above), resistance monitoring (sampling) is conducted, CRW are found and collected, and bioassays (section e(2)(b)(2) above) show that the population susceptibility to the compromised trait(s) has returned to baseline levels.

f. The mitigation actions in part d above can be lifted, and growers can resume the use of Bt11xMIR162xMIR604xTC1507x5307 Corn as a primary tool for CRW management in the MAA, only when Syngenta demonstrates that successful mitigation as described in part e above has been achieved.

2) Based on further research to understand CRW resistance to *Bt* PIPs, EPA will consider refinements to the resistance mitigation program. Such research may include characterizing the genetics of resistance (e.g., number of genes, functional dominance, mechanism of resistance, and cross-resistance) and the biology of resistant insects (e.g., fitness in the presence and absence of the product), and other control tactics.

e. Annual Reporting Requirements for Bt11xMIR162xMIR604xTC1507x5307 Corn

1) Compliance Assurance Plan: Compliance Assurance Program activities, including IRM Grower Survey results and on-farm assessment results for the prior year and plans for the compliance assurance program for the current year, on or before January 31st each year.

2) Insect Resistance Monitoring Results (Cry1Ab, Vip3Aa20 and Cry1F only): results of monitoring and investigations of damage reports, on or before August 31st of each year.

3) IPM Stewardship Program (eCry3.1Ab and mCry3A only): Activities conducted under the IPM stewardship program, including an anonymous survey of grower practices, adoption levels of the various crop rotation options (if employed) and other elements of the stewardship program, on or before January 31st of each year.

4) Unexpected Damage Investigations (eCry3.1Ab and mCry3A only): Activities related to investigations of unexpected damage (UXD), including number and location of UXD cases, insect sampling, bioassays, and final disposition of UXD fields from the most recent and previous corn growing seasons, on or before November 30th of each year.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of this product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

Please note that the record for this product currently contains the following acceptable CSF:

- Basic CSF dated 07/06/2016

Any CSFs other than those listed above are superseded/no longer valid.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the U.S. Environmental Protection Agency (EPA). If the website is false or misleading, the product will be

considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Ann Sibold of my team by phone at (703) 305-6502 or via email at sibold.ann@epa.gov.

Sincerely,

Alan Reynolds, Team Leader
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure

Plant-incorporated Protectant Label

Bt11×MIR162×MIR604×TC1507×5307 Corn

Alternate Brand Names:
Agrisure® Duracade™ 5222 Refuge Renew
Agrisure® Duracade™ 5222A Refuge Renew

OECD Unique Identifier: SYN-BTØ11-1×SYN-IR162-4×
SYN-IR6Ø4-5×DAS-15Ø7-1×SYN-Ø53Ø7-1

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

Active Ingredients:

Bacillus thuringiensis Cry1Ab protein and the genetic material necessary for its production (via elements of vector pZO1502) in Bt11 corn (SYN-BTØ11-1) ..... ≤0.00495%*

Bacillus thuringiensis Vip3Aa20 protein and the genetic material necessary for its production (via elements of vector pNOV1300) in MIR162 corn (SYN-IR162-4) ..... ≤0.00431%*

Bacillus thuringiensis mCry3A protein and the genetic material necessary for its production (via elements of vector pZM26) in MIR604 corn (SYN-IR6Ø4-5) ..... ≤0.00060%*

Bacillus thuringiensis Cry1F protein and the genetic material necessary for its production (via elements of vector PHP8999) in TC1507 corn (DAS-Ø15Ø7-1) ..... ≤0.00122%*

Bacillus thuringiensis eCry3.1Ab protein and the genetic material necessary for its production (via elements of vector pSYN12274) in 5307 corn (SYN- Ø53Ø7-1) ..... ≤0.00261%*

Other Ingredients:

Phosphinothricin acetyltransferase marker protein and the genetic material necessary for its production (via elements of vector pZO1502) in Bt11corn (SYN-BTØ11-1) and (via elements of vector PHP8999) in TC1507 corn (DAS-Ø15Ø7-1) ..... ≤0.00020%*

Phosphomannose isomerase marker protein and the genetic material necessary for its production (via elements of vector pNOV1300) in MIR162 corn (SYN-IR162-4), (via elements of vector pZM26) in MIR604 corn (SYN-IR6Ø4-5), and (via elements of vector pSYN12274) in 5307 corn (SYN- Ø53Ø7-1) ..... ≤0.00179%*

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

KEEP OUT OF REACH OF CHILDREN
CAUTION

EPA Registration No. 67979-23
EPA Establishment No. 66736-NC-01

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

DIRECTIONS FOR USE

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

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 seed corn that contains the plant-incorporated protectant sold or distributed by Syngenta Seeds, LLC or its distributors must be accompanied by informational material (*e.g.* a bag tag) indicating the registration number and the active ingredients, and stipulating that growers read the Syngenta Stewardship Guide (or equivalent guidance) prior to planting the seed. The refuge size requirement must be displayed on the seed bag or bag tag in both text and graphic format.

Insects Controlled or Suppressed

Field corn has been genetically transformed to produce the insecticidal proteins, Cry1Ab, Vip3Aa20, mCry3A, Cry1F, and eCry3.1Ab for control or suppression of the following coleopteran and 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*)
True armyworm (*Pseudaletia unipuncta)*
Western corn rootworm (*Diabrotica virgifera virgifera*)
Northern corn rootworm (*Diabrotica barberi*)
Mexican corn rootworm (*Diabrotica virgifera zea*)

Insect Resistance Management

The following information regarding commercial production of Bt11×MIR162×MIR604×TC1507×5307 corn must be included in the Syngenta Stewardship Guide (or equivalent). Growers must plant a refuge when using this product. Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the Syngenta Stewardship guide/product use guide and/or in supplements to the Stewardship guide. Growers have two options for deployment of the refuge:

Refuge Option 1

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 pests. The refuge area must represent at least 5% (or 20% in cotton growing regions) of the grower's corn acres (*i.e.*, sum of Bt11×MIR162×MIR604×TC1507×5307 corn acres and refuge acres). It must be planted as a block adjacent to the Bt11×MIR162×MIR604× TC1507×5307 corn field, perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least four consecutive rows wide. If the common refuge is planted on rotated ground, then Bt11×MIR162×MIR604×TC1507×5307 corn must also be planted on rotated ground. If the common refuge is planted in continuous corn, the Bt11×MIR162×MIR604×TC1507×5307 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×MIR162×MIR604×TC1507×5307 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×MIR162×MIR604×TC1507×5307 corn acres only if treatment occurs when adult corn rootworms are not present. Pests on the Bt11×MIR162×MIR604× TC1507×5307 corn acres can be treated as needed without having to treat the common refuge.

Refuge Option 2

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 5% (or 20% in cotton growing regions) of the grower's corn acres (*i.e.*, sum of Bt11×MIR162×MIR604×TC1507×5307 corn acres and corn borer refuge acres), and must be planted within ½ mile of the Bt11×MIR162×MIR604×TC1507×5307 cornfield. 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 four 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).

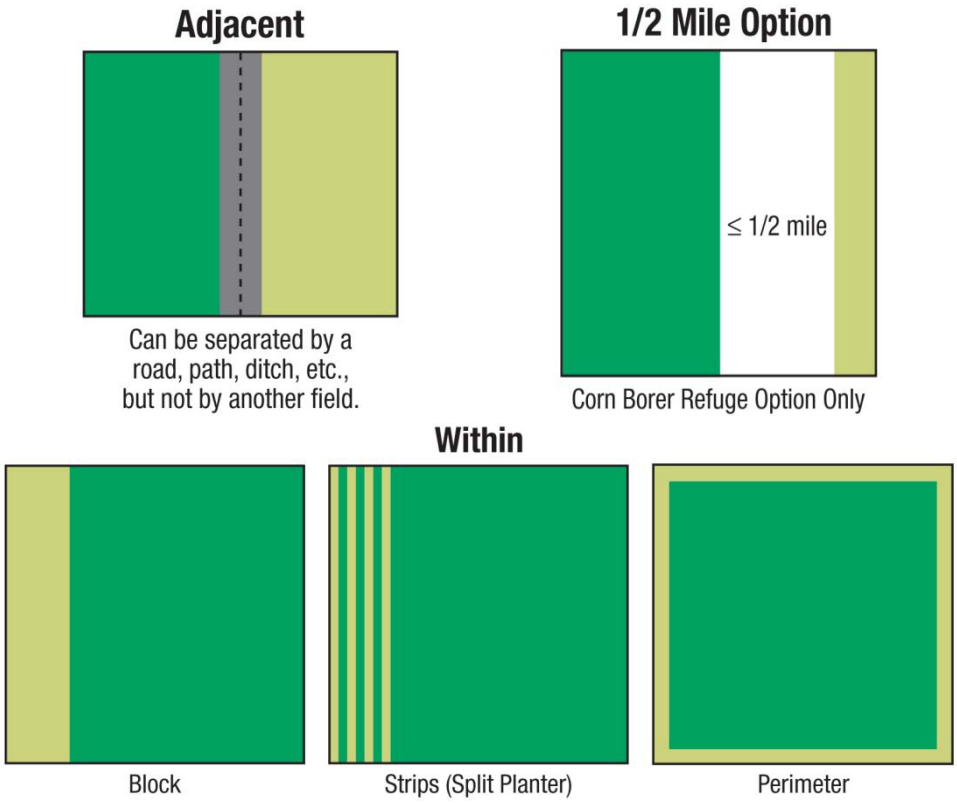
The corn rootworm refuge cannot be planted with a corn rootworm-protected Bt hybrid, but can be planted with a non-Bt hybrid or a Bt corn hybrid that controls corn borers. The corn rootworm refuge must represent at least 5% (or 20% in cotton growing regions) of the grower's corn acres (*i.e.*, sum of Bt11×MIR162×MIR604×TC1507×5307 corn acres and 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 four consecutive rows wide. If the rootworm refuge is planted on rotated ground, then Bt11×MIR162×MIR604×TC1507×5307 corn must also be planted on rotated ground. If the rootworm refuge is planted in continuous corn, the Bt11×MIR162×MIR604×TC1507×5307 cornfield may be planted on either continuous or rotated

land. More generally, the corn rootworm refuge should utilize comparable agronomic practices as the Bt11×MIR162×MIR604×TC1507×5307 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×MIR162×MIR604×TC1507×5307 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×MIR162×MIR604×TC1507×5307 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×MIR162×MIR604×TC1507×5307 corn acres can be treated as needed without having to treat the rootworm refuge.

Cotton-Growing Areas Requiring 20% Refuge Corn

State	Counties Identified by EPA as Cotton-Growing Areas				
Alabama	All Counties				
Arkansas	All Counties				
Florida	All Counties				
Georgia	All Counties				
Louisiana	All Counties				
Mississippi	All Counties				
Missouri	Dunklin	New Madrid	Pemiscot	Scott	Stoddard
North Carolina	All Counties				
Oklahoma	Beckham Harmon Washita	Caddo Jackson	Comanche Kay	Custer Kiowa	Greer Tillman
South Carolina	All Counties				
Tennessee	Carroll Franklin Lake Rutherford	Chester Gibson Lauderdale Shelby	Crockett Hardeman Lincoln Tipton	Dyer Hardin Madison	Fayette Haywood Obion
Texas	All counties with the exception of the following: Carson Lipscomb	Dallam Moore	Hansford Ochiltree	Hartley Roberts	Hutchinson Sherman
Virginia	Dinwiddie Southampton	Franklin City Suffock City	Greensville Surrey	Isle of Wright Sussex	Northampton

The following are schematics of the various refuge deployment options:



The following text and graphic indicating the refuge size requirement will appear on Bt11×MIR162×MIR604×TC1507×5307 seed corn bags or bag tags.

Important grower information.
This hybrid requires you to plant:

For more information please refer to the Syngenta Stewardship Guide.