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

EPA Reg. Number:

67979-25

Date of Issuance:

AUG 2 2013

Term of Issuance:

Conditional, Time-Limited

NOTICE OF PESTICIDE:

- Registration
 - Reregistration
- (under FIFRA, as amended)

Name of Pesticide Product:

Bt11 x MIR604 x TC1507 x 5307
5% Refuge Seed Blend 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 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 September 30, 2016.
- 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.

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Signature of Approving Official:

Robert McNally, Director
Biopesticides and Pollution Prevention Division (7511P)

Date:

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3) The subject registration will be limited to a seed mix of Cry1Ab [*Bacillus thuringiensis* Cry1Ab protein and the genetic material necessary for its production (via elements of vector pZO1502) in Bt11 corn (OECD Unique Identifier: SYN-BT011-1)] x mCry3A [*Bacillus thuringiensis* mCry3A protein and the genetic material necessary for its production (via elements of vector pZM26) in MIR604 corn (OECD Unique Identifier: SYN-IR604-5)] x Cry1F [*Bacillus thuringiensis* Cry1F protein and the genetic material necessary for its production (via elements of vector PHI8999) in TC1507 corn (OECD Unique Identifier: DAS-01507-1)] x eCry3.1Ab [*Bacillus thuringiensis* eCry3.1Ab protein and the genetic material necessary for its production (via elements of vector pSYN12274 in 5307 corn (OECD Unique Identifier: SYN-05307-1)] corn seed blended with not less than 5% non-*Bt* corn seed.

4) Submit/cite all data, determined by EPA to be acceptable and required to support the individual plant-incorporated protectants in Agrisure CB, Agrisure® RW, and 5307 Corn, as well as the block refuge product Bt11 x MIR604 x TC1507 x 5307 Corn, within the time frames required by the terms and conditions of EPA Registration Numbers 67979-1, 67979-5, 67979-22 and 67979-24 respectively.

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

- Requirements relating to a refuge assurance program for ensuring the correct refuge blend percentage.
- Requirements relating to creation of a non-*Bacillus thuringiensis* (*Bt*) corn refuge in cotton growing areas in conjunction with the planting of any acreage of Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn.
- Requirements for Syngenta to prepare and require Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend 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 for seed blends.
- 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, 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.

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- Requirements for Syngenta to make available to the Agency upon request records of the number of units of Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn 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, within three months of the request.
- Requirements for Syngenta, on or before August 31st of each year, to submit reports on resistance monitoring.
- Bag Tag Requirements for Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn. Seed bags and/or bag tags for corn hybrids that contain plant-incorporated protectants produced in Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend 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.

6) Submit a final report within two years providing the following data and information:

To address the potential for resistance development in Corn Earworm (CEW)

CEW can have up to six generations per year in the southern U.S. and may be at greater risk for resistance in a seed blend environment. Conduct biological research and/or submit CEW modeling for product durability that addresses the following concerns (refer to EPA’s review dated June 14, 2012 for additional information):

- a. CEW will encounter a mosaic of *Bt* expression in kernels of refuge corn ear as well as in *Bt* corn ear. Seed blends containing *Bt* and non-*Bt* seeds may actually accelerate resistance in ear-feeding Lepidoptera including corn earworm and fall armyworm. *Bt* ingestion has shown to promote wandering in larvae, and individuals that receive a sublethal dose may move to another kernel. Horner et al. 2003 evaluated feeding patterns of CEW in MON810 and non-*Bt* maize and determined that larvae had greater movement on *Bt* ears and essentially sampled kernels at greater frequency than their counterparts who fed exclusively and in a more compact fashion on non-*Bt* corn ears. This ability to move to another source of kernel in this mosaic of toxins (lethal vs. sublethal) and also to a non-toxin environment will give heterozygous individuals a great fitness advantage: the functional dominance of the resistance allele will increase. (Porter 2011, personal communication).
- b. Horner and Dively (2003) found that CEW exposed to Cry1Ab had reduced cannibalistic behavior which, they hypothesize, could serve as a mechanism to increase the selective differential between susceptible and resistant CEW and essentially lead to greater resistance evolution. (Cannibalistic behavior results “in partially resistant larvae feeding on nontoxic food [their fellow intoxicated larvae], thus temporarily providing escape from exposure to the *Bt* endotoxin.”)

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c. CEW development on *Bt* corn is delayed (Sims et al. 1996, Storer et al. 2001). This could enable a fraction of adult CEW to mate with CEW emerging from *Bt* cotton. Discretely breeding populations could become continuously breeding for part of the year in this scenario. This may be an important aspect to incorporate into IRM models of the south where corn and cotton are host plants of the same pest. Theoretical explorations are needed to assess effects of this delayed development on corn on the resistance evolution in CEW.

7) Implement the following Insect Resistance Management (IRM) Program for Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn:

a. Cotton-Growing Region Refuge Requirements

In cotton-growing regions where corn earworm is a significant pest:

- The 20% refuge must be planted with non-*Bt* corn hybrids.
- Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn and the 20% non-*Bt* refuge should be sown on the same day, or with the shortest window possible between planting dates.
- External refuges may be planted as an in-field or adjacent (e.g., across the road) refuge or as a separate block within 1/2 mile of the Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn field.
- In field refuge options include: blocks, perimeter strips (i.e., along the edges or headlands), or in-field strips.
- When planting the refuge in strips across the field, refuges must be at least four (4) rows wide.
- Insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, fall armyworm, black cutworm, western bean cutworm, lesser corn stalk borer, southern corn stalk borer, common stalk borer and sugarcane borer 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, crop consultants). Microbial *Bt* insecticides must not be applied to non-*Bt* corn refuge plants.
- 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

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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 Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn

- 1) Persons purchasing Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend 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 MIR604 x TC1507 x 5307 5% Refuge Seed Blend 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 Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn sign grower agreement(s).
- 5) Syngenta shall maintain records of all Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend 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 Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend 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, within three months of the 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.

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c. IRM Education and Compliance Monitoring Programs for Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend 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 MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn users the importance of complying with the IRM program, as well as seed blend product performance expectations and guidance to growers on actions to take when unexpected damage occurs. The program shall include information encouraging Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend 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). The program shall involve at least one (1) written communication annually to each Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend 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 a report from 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 Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend 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

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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 MIR604 x TC1507 x 5307 5% Refuge Seed Blend 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 Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn growers to perform

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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 MIR604 x TC1507 x 5307 5% Refuge Seed Blend 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 MIR604 x TC1507 x 5307 5% Refuge Seed Blend 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) 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 must prepare and submit 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.

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- ii. Include the refuge size requirement on all Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn seed bags or bag tags. The Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend 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 Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn is used.

19) Syngenta will use its available Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend 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 Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend 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 MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn to reflect the adoption rate and level of refuge compliance for Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend 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.

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- 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 MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn within a 5-year period will be denied access to Syngenta’s *Bt* corn products the next year.

d. Insect Resistance Monitoring and Remedial Action Plans for Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn

1) EPA is imposing the following conditions for the mCry3A and eCry3.1Ab toxins expressed in Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn:

- i. Syngenta must monitor for mCry3A and eCry3.1Ab resistance and/or trends in increased tolerance for corn rootworm. Sampling should be focused in those areas in which there is the highest risk of resistance development.
- ii. The resistance monitoring plan must include the following: baseline sensitivity data, sampling (number of locations, samples per locations), sampling methodology and life stage sampled, bioassay methodology, standardization procedures (including quality assurance/quality control provisions), detection technique and sensitivity, statistical analysis of the probability of detecting resistance, and a revised description of rootworm damage guidelines, including guidance specific for seed blends.
- iii. Syngenta must develop and utilize a functional “on-plant” diagnostic assay¹ for corn rootworm resistance monitoring to detect potentially resistant individuals and incorporate this assay into the annual resistance monitoring program.
- iv. Syngenta must develop a proactive resistance monitoring program for northern corn rootworm (*Diabrotica barberi*) by the 2014 season, with reporting in 2015. This program should include a proposal for annual sampling and testing of northern corn rootworm susceptibility to mCry3A and eCry3.1Ab toxins. As part of the effort, Syngenta may need to investigate novel techniques for rearing and conducting bioassays with northern corn rootworm.

¹ Examples of on-plant bioassays include:

Nowatzki T, Lefko SA, Binning RR, Thompson SD, Spencer TA, Siegfried BD. 2008. Validation of a novel resistance monitoring technique for corn rootworm (Coleoptera: Chrysomelidae) and event DAS-59122-7 maize. *J. Appl. Entomol.* 132:177–188 and

Gassmann A.J., J.L. Petzold-Maxwell, R.S. Keweshan, and M.W. Dunbar, 2011. Field-evolved resistance to *Bt* maize by western corn rootworm. *PLOS one*, Vol. 6 (7): 1-7.

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- v. Syngenta must submit revised corn rootworm damage guidelines (to characterize unexpected pest damage) that take into consideration seed blend impacts.
- vi. Syngenta must follow up on grower, extension specialist, or consultant reports of unexpected damage or control failures for corn rootworm.
- vii. Syngenta must provide EPA with a resistance monitoring report on or before August 31st of each year, reporting on populations collected the previous year.
- viii. The current remedial action plan approved for mCry3A and eCry3.1Ab must be used for corn rootworm with suspected and confirmed resistance to Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn. If corn rootworm resistance is confirmed, all acres of Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn and refuges in the affected area must be treated with insecticides targeted at corn rootworm adults and/or larvae.
- ix. You must submit an enhanced rootworm resistance monitoring plan for Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn that accounts for reports of suspected and/or confirmed resistance. The rootworm resistance monitoring plan and the revised definitions for suspected and confirmed resistance for Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn must be found acceptable to BPPD and utilized by Syngenta beginning in the 2014 season. This enhanced monitoring program should:
 - Be practical and adaptable and provide information on relevant changes in corn rootworm population sensitivity to Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn;
 - Be focused on areas where the potential for resistance is greatest for Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn and for the corn rootworm active single event components of Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn (mCry3A and eCry3.1Ab), based on available information on historical pest pressure, unexpected performance issues, historical suspected and/or confirmed resistance incidents as currently defined or as modified in EPA accepted enhanced monitoring programs, prevailing agronomic practices (e.g. crop rotation versus continuous corn), and academic and extension publications on Bt corn field performance;
 - Involve coordination to the extent possible with other stakeholders, such as academic and extension experts in the states where corn rootworm is a major pest, and other registrants of similar products, as appropriate;
 - Be responsive to incidents of suspected or confirmed resistance to the registrant's other products containing the same active ingredient(s), as well as to publicly available reports of suspected or

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confirmed resistance to other *Bt* protein toxins in Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn.

x. Remedial Action Plan for Corn Rootworm and Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn

Within one year of this registration, you must submit an enhanced remedial action plan for Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn that includes actions to be taken in response to both suspected and confirmed resistance. This remedial action plan must include a description of steps to be taken in response to customer product performance inquiries and annual reporting to the agency on the outcomes of investigations into any such inquiries that might indicate potential resistance. The program must include revised definitions of unexpected damage to Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn that could indicate potential suspected resistance. The enhanced remedial action plan must be found acceptable to BPPD and be utilized by Syngenta beginning in the 2014 season.

The remedial action plan is designed as a tiered approach for mitigating western and northern corn rootworm resistance development specifically due to the commercialization of Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn. The following program summary describes, in order of events, the steps that must be taken to implement a remedial action plan if resistance to target pests is confirmed.

1. Suspected Resistance from Population Monitoring

Definition of Suspected Resistance: Resistance will be suspected if investigations of target pest injury potential to Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn from the “on-plant” diagnostic assay show that:

- Injury potential of a target pest population obtained as part of the annual insect monitoring program has increased to a level representative of product failure in field conditions;
- The seeds used in the investigation of this population’s injury potential contain eCry3.1Ab and mCry3A at levels representative of (and in the same genetic background as) the benchmark study; and
- The change in injury potential has been documented as a heritable characteristic of the target pest population and not a result of experimental error.

If resistance is "suspected", Syngenta will inform growers in the area of the potential benefit of augmenting CRW control such as adulticide treatment and/or crop rotation or use of soil or seed-applied insecticides at rates providing corn rootworm control the following year. These measures are intended to educate growers of the

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potential for change in efficacy, reduce the possibility of grower loss from change in efficacy and reduce potentially resistant insects contributing to the following year's pest population.

2. Confirmed Resistance from Population Monitoring

Definition of Confirmed Resistance: Resistance will be confirmed if all of the following criteria are met by progeny from a subsequent rootworm population collected from the area of "suspected resistance" the following year:

- Injury potential of the subsequent field-collected rootworm population feeding on plants containing eCry3.1Ab and mCry3A remains at a level likely to produce repeated product failure in field conditions;
- The change in injury potential has been documented as a heritable characteristic of the target pest population;
- Greenhouse node-injury evaluation confirms product failure;
- Subsequent populations collected from the area and assayed show that the results are repeatable; and
- Continued monitoring of the area suggests that the change is spreading.

3. Suspected Resistance – Investigation of Field Reports

The registrant will follow up on grower, extension specialist or consultant reports of unexpected product performance due to corn rootworm species listed on the label. The registrants will instruct its customers to contact them if such incidents occur. The registrants will investigate all such reports submitted to the company or the company’s representatives to

- Confirm the corn in question is rootworm-active *Bt* corn;
- Confirm the field in question contains the correct blend rate of refuge corn;
- Confirm that species not susceptible to the protein are not responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and that all other reasonable causes based on historical experience for the observed root damage have been ruled out;
- If not due to other reasons, the registrant will conduct a thorough investigation of the factors known to affect the manifestation of corn rootworm feeding damage.

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The Agency recognizes that large corn rootworm populations, environmental conditions, and protein expression levels can influence corn root damage and may affect the definition of suspected CRW resistance. The Agency plans to work with the registrants to refine the definition of suspected resistance based on these factors. Until such time that the Agency accepts a modified definition of suspected resistance to corn rootworm, resistance will be suspected in cases where the average root damage in the Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn field is > 0.5 on the nodal injury scale (NIS) and the frequency of Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn with > 0.5 nodes destroyed exceeds 50% of the sampled plants.

If resistance is "suspected", Syngenta will inform growers in the area of the potential benefit of augmenting CRW control such as adulticide treatment, crop rotation the following year or use of soil or seed insecticides the following year. These measures are intended to educate growers of the potential for change in efficacy, reduce the possibility of grower loss from change in efficacy and reduce potentially resistant insects contributing to the following year's pest population.

Syngenta will collect insects as soon as possible from the area for laboratory studies to test for resistance by comparing with benchmark susceptibility data. These studies will be performed following the same laboratory protocols as used for the benchmark determination and monitoring programs.

4. Confirmed Resistance – Investigation of Field Reports

- Injury potential of the field-collected rootworm population feeding on plants containing eCry3.1Ab and mCry3A remains at a level likely to produce repeated product failure in field conditions;
- Subsequent populations collected from the area and assayed show that the results are repeatable;
- The change in injury potential has been documented as a heritable characteristic of the target pest population;
- Greenhouse node-injury evaluation confirms product failure; and
- Continued monitoring of the area suggests that the change is spreading.

5. Remedial Action

When resistance is "confirmed", the following steps will be taken:

- The EPA will receive notification within 30 days of confirmed resistance;

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- Affected customers and Extension specialists will be immediately notified about confirmed resistance;
- Affected customers and Extension specialists will be strongly encouraged to implement alternative CRW control measures such as adulticide treatment, crop rotation the following year, or use of soil or seed insecticides the following year;
- Sale and distribution of Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn in the affected area will cease immediately until an effective mitigation plan has been approved by EPA.

2) EPA is imposing the following conditions for the Cry1Ab and Cry1F toxins expressed in Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn:

Syngenta will monitor for resistance to Cry1Ab and Cry1F expressed in Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend 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 Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn and/or changes in resistance allele frequency in response to the use of Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend 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

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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 MIR604 x TC1507 x 5307 5% Refuge Seed Blend 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 and 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 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 Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend 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.

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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 and provide guidance to growers on seed blend product performance expectations and actions to take when unexpected damage occurs. 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 MIR604 x TC1507 x 5307 5% Refuge Seed Blend 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 MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn fields in the affected region to control the target pest during the immediate growing season.
- Destroy Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn crop residues in the affected region within one (1) month after harvest with a technique appropriate for local production practices to

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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

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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.

e. Annual Reporting Requirements for Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn

Syngenta must submit to the Agency the following information:

- 1) Compliance Assurance Program: compliance assurance program activities, including IRM Grower Survey 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 of each year;
- 2) Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, on or before August 31st of each year.
- 3) EZ Refuge Corn Manufacturing System Results: Documentation from qualification test runs that validate blend percentages from Syngenta’s third party contractors and Syngenta licensees that produce Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn must be provided along with the number of licensees using seed color to differentiate refuge and PIP seed provided, on or before January 31st of each year, beginning in 2014.

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f. Seed Blend Refuge Assurance Program for Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn

Syngenta must implement its EZ Refuge Corn Manufacturing System to ensure Bt11 x MIR604 x TC1507 x 5307 5% Refuge Seed Blend Corn products are formulated with the appropriate rate of refuge seeds.

All blending records must be maintained at the Syngenta blending facilities, third party contractors, and Syngenta licensees and must be available for EPA review upon request.

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.

The confidential statement of formula (CSF) dated July 17, 2013 is acceptable. A copy has been placed in the file jacket for this registration.

Sincerely,



Robert McNally, Director
Biopesticides and Pollution
Prevention Division (7511P)

Enclosure

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ACCEPTED
AUG 2 2013
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 67979-25

Plant-Incorporated Protectant Label

Bt11×MIR604×TC1507×5307 5% Refuge Seed Blend Corn

Alternate brand names: *Agrisure Duracade™ 5122 E-Z Refuge™ Corn*
Agrisure Duracade™ 5122A E-Z Refuge™ Corn

OECD Unique Identifier: SYN-BT011-1×SYN-IR604-5×DAS-01507-1×SYN-05307-1

This product is effective in limiting 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-BT011-1) ≤0.00460%*

Bacillus thuringiensis mCry3A protein and the genetic material necessary for its production (via elements of vector pZM26) in MIR604 corn (SYN-IR604-5) ≤0.00041%*

Bacillus thuringiensis Cry1F protein and the genetic material necessary for its production (via elements of vector PHI8999) in TC1507 corn (DAS-01507-1) ≤0.00103%*

Bacillus thuringiensis eCry3.1Ab protein and the genetic material necessary for its production (via elements of vector pSYN12274) in 5307 corn (SYN-05307-1) ≤0.00335%*

Other Ingredients:

Phosphinothricin acetyltransferase protein and the genetic material necessary for its production (via elements of vector pZO1502) in Bt11corn (SYN-BT011-1) and (via elements of vector PHI8999) in TC1507 corn (DAS-01507-1) ≤0.00022%*

Phosphomannose isomerase protein and the genetic material necessary for its production (via elements of vector pZM26) in MIR604 corn (SYN-IR604-5) and (via elements of vector pSYN12274) in 5307 corn (SYN-05307-1) ≤0.00132%*

*Percent (wt/wt) of dried whole plant

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET CONTENTS _____

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EPA Establishment No. 66736-NC-01

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

™ - Trademarks of Syngenta

67979-__ Label

July 17, 2013/ CR009-EPA-5

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DIRECTIONS FOR USE

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

Seed bags and/or bag tags for corn hybrids that contain plant-incorporated protectants produced in Bt11×MIR604×TC1507×5307 5% Refuge Seed Blend 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.

Insects Controlled or Suppressed

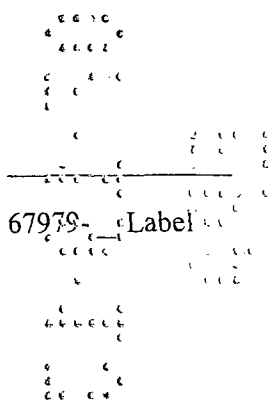
- European corn borer (*Ostrinia nubilalis*)
- Southwestern corn borer (*Diatraea grandiosella*)
- Southern cornstalk borer (*Diatraea crambidoides*)
- Corn earworm (*Helicoverpa zea*)
- Fall armyworm (*Spodoptera frugiperda*)
- Black cutworm (*Agrotis ipsilon*)
- Western bean cutworm (*Striacosta albicosta*)
- Sugarcane borer (*Diatraea saccharalis*)
- Lesser cornstalk borer (*Elasmopalpus lignosellus*)
- Common stalk borer (*Papaipema nebris*)
- Western corn rootworm (*Diabrotica virgifera virgifera*)
- Northern corn rootworm (*Diabrotica barberi*)
- Mexican corn rootworm (*Diabrotica virgifera zea*)

Insect Resistance Management

Each bag of Bt11×MIR604×TC1507×5307 5% Refuge Seed Blend Corn contains a blend of 95% Bt11×MIR604×TC1507×5307 seed and 5% non-Bt refuge seed.

IRM Requirements for Corn-Growing Areas of the U.S.

Refuge seed is blended into each bag of Bt11×MIR604×TC1507×5307 5% Refuge Seed Blend Corn. There is no requirement for growers to plant a separate structured refuge for managing resistance risk in corn-growing areas of the U.S. Corn-growing areas are those counties and states not defined below as comprising the cotton-growing areas of the U.S. Read the Syngenta Stewardship Guide.



IRM Requirements for Cotton-Growing Areas of the U.S.

In cotton-growing areas growers who plant Bt11×MIR604×TC1507×5307 5% Refuge Seed Blend Corn must plant a supplemental 20% structured refuge. The following table lists those states and counties identified by the Environmental Protection Agency (EPA) as cotton-growing areas.

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 Stoddard	New Madrid	Pemiscot	Scott
North Carolina	All Counties			
Oklahoma	Beckham Grèer Kiowa	Caddo Harmon Tillman	Comanche Jackson Washita	Custer Kay
South Carolina	All Counties			
Tennessee	Carroll Fayette Hardin Lincoln Shelby	Chester Franklin Haywood Madison Tipton	Crockett Gibson Lake Obion	Dyer Hardeman Lauderdale Rutherford
Texas	All counties with the exception of the following: Carson Hutchinson Roberts			
Virginia	Dinwiddie Northampton Sussex	Dallam Lipscomb Sherman	Hansford Moore	Hartley Ochiltree
		Franklin City Southampton	Greensville Suffolk City	Isle of Wight Surrey

The 20% supplemental refuge must be planted with hybrids that do not contain Bt technologies. The supplemental refuge can be planted as strips within the field, perimeter strips, a block within the field, a block adjacent to the field, or a separate block within ½ mile of the Bt11×MIR604×TC1507×5307 5% Refuge Seed Blend Corn field. If in-field or perimeter strips are implemented, the strips must be at least four consecutive rows wide.

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The supplemental refuge in cotton-growing areas can be protected from feeding damage by application of non-Bt microbial insecticides if the population of one or more lepidopteran pests exceeds economic thresholds. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). In addition, the supplemental refuge can be protected from corn rootworm feeding damage by use of an appropriate seed treatment or conventional insecticide. However, insecticides labeled for adult corn rootworm control must be avoided in the supplemental refuge during the period of corn rootworm adult emergence.

The following text and graphic indicating the supplemental refuge size requirement will appear on Bt11×MIR604×TC1507×5307 5% Refuge Seed Blend Corn bags or bag tags.

**Important grower information.
Supplemental refuge planting requirement.**



**For more information, please refer
to Syngenta Stewardship Guide.**