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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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JUN 05 2014

Product Name: Bt11 x DAS-59122-7 x MIR604 x TC1507 Corn
Company Name: Syngenta Seeds, Inc. - Field Crops - NAFTA
OPP Identification Number: 490501
EPA File Symbol: 67979-17
Amendment to change refuge requirement in cotton areas from 50% to 20%
EPA Receipt Date: April 29, 2014

Dear Ms. Jarrett,

The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(7)(A), is acceptable provided that you comply with the following terms and conditions:

- 1) The subject registration will automatically expire on midnight June 30, 2023.
- 2) Submit/cite all data required for registration of your product under FIFRA section 3(c)(5) when EPA requires registrants of similar products to submit such data.
- 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-BT011-1)] x Cry34/35Ab1 [*Bacillus thuringiensis* Cry34Ab1 and Cry35Ab1 delta-endotoxin proteins and the genetic material necessary for their production (via elements of vector PHP17662) in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7) 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-IR604-8)] x Cry1F [*Bacillus thuringiensis* Cry1F protein and the genetic material necessary for its production (plasmid insert PHI8999A) in corn event TC1507 (OECD Unique Identifier: DAS-01507-1)].
- 4) Submit/cite all data, determined by EPA to be acceptable and required to support the individual plant-incorporated protectants in YieldGard[®] Insect Resistant Corn, Herculex[®] RW Rootworm Protection, Agrisure[®] RW, and Herculex[®] I Insect Protection, within the time frames required by the terms and conditions of EPA Registration Numbers 67979-1, 68467-5, 67979-5, and 68467-2, respectively.

CONCURRENCES

SYMBOL	7511P	7511P	7511P					
SURNAME	Reynolds	Reynolds	Reynolds					
DATE	5/21/14	5/21/14	6/5/14					

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

6) Syngenta must commit to do the following Insect Resistance Management (IRM) Program for Bt11 x DAS-59122-7 x MIR604 x TC1507 Corn, consisting of the following elements:

- Requirements relating to creation of a refuge for the Cry1Ab, Cry34/35Ab1, mCry3A and Cry1F components that meets the requirements of the individual traits. The refuge for all traits may be combined by planting non-*Bacillus thuringiensis* (*Bt*) corn as the refuge, or the refuge for each trait may be planted separately. In the latter case, corn rootworm-resistant *Bt* corn may be planted in the lepidopteran refuge for the Cry1Ab and Cry1F components, and lepidopteran-resistant *Bt* corn may be planted in the corn rootworm refuge for the Cry34/35Ab1 and Cry1F components.
- Requirements for Syngenta to prepare and require Bt11 x DAS-59122-7 x MIR604 x TC1507 corn users to sign grower agreements that impose binding contractual obligations on growers to comply with the refuge requirements.
- Requirements regarding programs to educate growers about IRM requirements;
- Requirements regarding programs to evaluate and promote growers' compliance with IRM requirements;
- Requirements regarding programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to the Cry1Ab, Cry34/35Ab1, mCry3A and Cry1F proteins in the target insects.
- Requirements for Syngenta to develop, and if triggered, to implement a remedial action plan that would contain measures Syngenta would take in the event that any field-relevant insect resistance was detected, as well as to report on activity under the plan to EPA.
- Requirements for Syngenta to maintain and to make available to the Agency upon request the number of units of Bt11 x DAS-59122-7 x MIR604 x TC1507 Corn sold by state and county, IRM grower agreement results and substantive changes to education programs, within three months of the request;
- Requirements for Syngenta, on or before August 31st of each year, to submit reports on resistance monitoring.

a. Refuge Requirements for Bt11 x DAS-59122-7 x MIR604 x TC1507 Corn

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

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

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

The following information must be included on the product bag or bag-tag as sold per respective region and in the Grower Guide:

Corn Belt/Non-Cotton-Growing Area Refuge Requirements

For Bt11 x DAS-59122-7 x MIR604 x TC1507 corn grown in non-cotton-growing areas of the United States, two options for deployment of the refuge are available to growers.

The first option is planting a common refuge for both corn borers and corn rootworm. The common refuge must be planted with corn hybrids that do not contain *Bt* technologies for the control of corn borers or corn rootworm. The refuge area must represent at least 5% of the grower's corn acres (i.e., sum of Bt11 x DAS-59122-7 x MIR604 x TC1507 corn acres and refuge acres). It must be planted as a block within or adjacent (e.g., across the road) to the Bt11 x DAS-59122-7 x MIR604 x TC1507 corn field, perimeter strips (i.e., strips around the field), or in-field strips. ~~If perimeter or in-field strips are implemented, the strips must be at least 4~~ consecutive rows wide. The common refuge can be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-*Bt* foliar insecticide for control of late season pests if pest pressure reaches an economic threshold for damage; however, if rootworm adults are present at the time of foliar applications, then the Bt11 x DAS-59122-7 x MIR604 x TC1507 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).

The second option is planting separate refuge areas for corn borers and corn rootworms. The corn borer refuge must be planted with corn that is not a lepidopteran-protected *Bt* hybrid, must represent at least 5% of the grower's corn acres (i.e., sum of Bt11 x DAS-59122-7 x MIR604 x TC1507 corn acres and corn borer refuge acres), and must be planted within 1/2 mile of the Bt11 x DAS-59122-7 x MIR604 x TC1507 corn field. The corn borer refuge can be treated with a soil-applied or seed-applied insecticide for corn rootworm larval control, or a non-*Bt* foliar-applied insecticide for corn borer control, if pest pressure reaches an economic threshold for damage. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). The corn rootworm refuge must be planted with corn that is not a corn rootworm-protected *Bt* hybrid, must represent at least 5% of the grower's corn acres (i.e., sum of Bt11 x DAS-59122-7 x MIR604 x TC1507 corn acres and corn rootworm refuge acres), and must be planted as a block within or adjacent (e.g., across the road) to the Bt11 x DAS-59122-7 x MIR604 x TC1507 corn field, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. 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 if pest pressure reaches an economic threshold for damage; however, if rootworm adults are present at the time

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of foliar applications, then the Bt11 x DAS-59122-7 x MIR604 x TC1507 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).

Corn/Cotton-Growing Area (Cotton-Growing Area) Refuge Requirements

For Bt11 x DAS-59122-7 x MIR604 x TC1507 corn grown in cotton-growing areas of the United States, the common refuge and separate refuge options are also available; however, the refuge area is larger.

- 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).

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 borers or corn rootworms. The refuge area must represent at least 20% of the grower's corn acres (i.e., sum of Bt11 x DAS-59122-7 x MIR604 x TC1507 corn acres and refuge acres). It must be planted as a block within or adjacent (e.g., across the road) to the Bt11 x DAS-59122-7 x MIR604 x TC1507 corn field, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The common refuge can be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-*Bt* foliar insecticide for control of late season pests if pest pressure reaches an economic threshold for damage; however, if rootworm adults are present at the time of foliar applications, then the Bt11 x DAS-59122-7 x MIR604 x TC1507 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).

The second option is planting separate refuge areas for corn borers and corn rootworms. The corn borer refuge must be planted with corn that is not a lepidopteran-protected *Bt* hybrid, must represent at least 20% of the grower's corn acres (i.e., sum of Bt11 x DAS-59122-7 x MIR604 x TC1507 corn acres and corn borer refuge acres), and must be planted within ½ mile of the Bt11 x DAS-59122-7 x MIR604 x TC1507 corn field. The corn borer refuge can be treated with a soil-applied or seed-applied insecticide for corn rootworm larval control, or a non-*Bt* foliar-applied insecticide for corn borer control, if pest pressure reaches an economic threshold for damage. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). The corn rootworm refuge must be planted with corn that is not a corn rootworm-protected *Bt* hybrid, must represent at least 20% of the grower's corn acres (i.e., sum of Bt11 x DAS-59122-7 x MIR604 x TC1507 corn acres and corn rootworm refuge acres), and must be planted as a block within or adjacent (e.g.,

across the road) to the Bt11 x DAS-59122-7 x MIR604 x TC1507 corn field, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. 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 if pest pressure reaches an economic threshold for damage; however, if rootworm adults are present at the time of foliar applications, then the Bt11 x DAS-59122-7 x MIR604 x TC1507 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).

b. Grower Agreements for Bt11 x DAS-59122-7 x MIR604 x TC1507 Corn

- 1) Persons purchasing Bt11 x DAS-59122-7 x MIR604 x TC1507 corn must sign a grower agreement. The term grower agreement refers to any grower purchase contract, license agreement, or similar legal document.
- 2) The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.

- 3) Syngenta must integrate this registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing Bt11 x DAS-59122-7 x MIR604 x TC1507 corn will affirm annually that they are contractually bound to comply with the requirements of the IRM program.
- 4) If Syngenta wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty (30) days prior to implementing a proposed change, Syngenta must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of this registration.
- 5) Syngenta must integrate this registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing Bt11 x DAS-59122-7 x MIR604 x TC1507 corn sign grower agreement(s).
- 6) Syngenta shall maintain records of all Bt11 x DAS-59122-7 x MIR604 x TC1507 corn grower agreements for a period of three (3) years from December 31st of the year in which the agreement was signed.
- 7) Requirements for Syngenta to maintain and to make available to the Agency upon request the number of units of Bt11 x DAS-59122-7 x MIR604 x TC1507 Corn sold by state and county, IRM grower agreement results and substantive changes to education programs, within three months of the request.

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

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

- 1) Syngenta must implement and enhance (as set forth in paragraph 17 of this section) a comprehensive, ongoing IRM education program designed to convey to Bt11 x DAS-59122-7 x MIR604 x TC1507 corn users the importance of complying with the IRM program. The program shall include information encouraging Bt11 x DAS-59122-7 x MIR604 x TC1507 corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Bt11 x DAS-59122-7 x MIR604 x TC1507 corn fields. The education program shall involve the use of multiple media (e.g., face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials). Copies of the materials will be provided to EPA for its records. The program shall involve at least one (1) written communication annually to each Bt11 x DAS-59122-7 x MIR604 x TC1507 corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Syngenta shall coordinate its education programs with educational efforts of other registrants and organizations, such as the National Corn Growers Association and state extension programs.
- 2) Syngenta shall implement and enhance its education program to take into account the information collected through the compliance survey and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.
- 3) Syngenta must maintain and provide to the Agency upon request, substantive changes to educational programs within three months of the Agency's request.
- 4) Syngenta must implement and improve an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing Bt11 x DAS-59122-7 x MIR604 x TC1507 corn are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to Syngenta's *Bt* corn products. Syngenta shall coordinate with other *Bt* corn registrants in improving its compliance assurance program and integrate this registration into the current compliance assurance program used for its other *Bt* corn plant-incorporated protectants. Other required features of the program are described in paragraphs 5-21 of this section.
- 5) Syngenta must maintain and publicize a phased compliance approach (i.e., a guidance document that indicates how it will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers after the first year of non-compliance). While recognizing that for reasons of difference in business practices there are needs for flexibility between different companies, Syngenta must use a consistent set of standards for responding to non-compliance. An individual grower found to be significantly out of compliance two (2) years

in a row would be denied access to Syngenta's *Bt* corn products the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell *Bt* corn.

- 6) The IRM compliance assurance program shall include an annual survey, conducted by an independent third party, of a statistically representative sample of growers of Bt11 x DAS-59122-7 x MIR604 x TC1507 corn who plant the vast majority of all corn in the United States and in areas in which the selection intensity is greatest. The survey shall consider only those growers who plant 200 or more acres of corn in the Corn Belt and who plant 100 or more acres of corn in corn-cotton areas. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from independent marketing research firms and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the United States.
 - i. A third party is classified as a party other than Syngenta, the grower, or anyone else with a direct interest in IRM compliance for *Bt* corn.
 - ii. 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.

- 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 DAS-59122-7 x MIR604 x TC1507 corn growers to perform assessments of compliance with IRM requirements. There is no minimum corn acreage size for this program. Therefore, growers will be selected for this program from across all farm sizes. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, Syngenta shall take appropriate action, consistent with its phased compliance approach, to promote compliance.

12) Syngenta shall carry out a program for investigating legitimate tips and complaints that Bt11 x DAS-59122-7 x MIR604 x TC1507 corn growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, Syngenta shall take appropriate action, consistent with its phased compliance approach.

13) If a grower, who purchases Bt11 x DAS-59122-7 x MIR604 x TC1507 corn for planting, was specifically identified as not being in compliance during the previous year, Syngenta shall visit with the grower and evaluate whether the grower is in compliance with the IRM program for the current year.

14) Syngenta shall provide a report to EPA, on or before January 31st of each year, 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.

- 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 will enhance the refuge education program throughout the seed delivery channel:

- i. Ensure sales representatives, licensees, seed dealers, and growers recognize the importance of correct refuge implementation and potential consequences of failure to plant the required refuge.
- ii. Include the refuge size requirement on all Bt11 x DAS-59122-7 x MIR604 x TC1507 corn seed bags or bag tags. The PIP product label accepted by EPA must include how this information will be conveyed to growers via text and graphics. A revised PIP product label must be submitted by January 31, 2015. The purpose of this bag tag is to remind growers that Bt11 x DAS-59122-7 x MIR604 x TC1507 products require a separate 20% lepidopteran refuge in cotton growing areas.

17) 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 DAS-59122-7 x MIR604 x TC1507 corn is used.

18) Syngenta will use its available Bt11 x DAS-59122-7 x MIR604 x TC1507 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 DAS-59122-7 x MIR604 x TC1507 corn but may have purchased little or no refuge seed from Syngenta, licensees, or affiliated companies.

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

- i. A third party is classified as a party other than the registrant, the grower, or anyone else with a direct interest in IRM compliance for *Bt* corn.
- ii. The third-party assessors will conduct all first-time on-farm assessments for as well as second-year on-farm assessments of those growers found out of compliance in a first-time assessment.

20) Syngenta will annually refine the on-farm assessment program for Bt11 x DAS-59122-7 x MIR604 x TC1507 corn to reflect the adoption rate and level of refuge compliance for Bt11 x DAS-59122-7 x MIR604 x TC1507 corn.

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

- i. All growers found to be significantly out of compliance in a prior year will annually be sent additional refuge assistance information for a minimum of two (2) years by Syngenta, a seed supplier, or a third-party assessor, after completing the assessment process.
- ii. Syngenta will conduct follow-up checks on growers found to be significantly out of compliance within three (3) years after they are found to be back in compliance.
- iii. A grower found with a second incident of significant non-compliance with refuge requirements for Bt11 x DAS-59122-7 x MIR604 x TC1507 corn within a 5-year period will 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.

d. Insect Resistance Monitoring and Remedial Action Plans for Bt11 x DAS-59122-7 x MIR604 x TC1507 Corn

1) EPA is imposing the following conditions for the mCry3A and Cry34/35Ab1 toxins expressed in Bt11 x DAS-59122-7 x MIR604 x TC1507 corn:

- i. Syngenta must monitor for mCry3A and Cry34/35Ab1 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.
- iii. Syngenta must develop a functional diagnostic assay for corn rootworm resistance monitoring to detect potentially resistant individuals and incorporate this assay into the annual resistance monitoring program. As part of this effort, Syngenta must investigate the feasibility of using the Sublethal Seedling Assay¹ as a diagnostic assay.
- iv. Syngenta must develop a proactive resistance monitoring program for northern corn rootworm (*Diabrotica barberi*). This program should include a proposal for annual sampling and testing of northern corn rootworm susceptibility to mCry3A and Cry34/35Ab1 toxins. As part of the effort, Syngenta may need to investigate novel techniques for rearing and conducting bioassays with northern corn rootworm.

- v. Syngenta must submit revised corn rootworm damage guidelines (to characterize unexpected pest damage) that take into consideration the comments and recommendations from EPA's June 30, 2010 review of the rootworm resistance monitoring program for mCry3A and Cry34/35Ab1, or coordinate with other registrations (or registrants) subject to the same requirements.
- 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 Cry34/35Ab1 must be used for corn rootworm suspected and confirmed resistance in Bt11 x DAS-59122-7 x MIR604 x TC1507 corn. If corn rootworm resistance is confirmed, all acres of Bt11 x DAS-59122-7 x MIR604 x TC1507 corn and refuges must be treated with insecticides targeted at corn rootworm adults and larvae.

2) EPA is imposing the following conditions for the Cry1Ab and Cry1F toxins expressed in Bt11 x DAS-59122-7 x MIR604 x TC1507 corn:

Syngenta will monitor for resistance to Cry1Ab and Cry1F expressed in Bt11 x DAS-59122-7 x MIR604 x TC1507 corn. The monitoring program shall consist of two approaches: (1) focused

¹ 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.

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population sampling and laboratory testing; and (2) investigation of reports of less-than expected control of labeled insects. Should field-relevant resistance be confirmed, an appropriate resistance management action plan will be implemented.

Focused Population Sampling

Syngenta shall annually sample and bioassay populations of the key target pests: *Ostrinia nubilalis* (European corn borer; ECB), *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 DAS-59122-7 x MIR604 x TC1507 corn and/or changes in resistance allele frequency in response to the use of Bt11 x DAS-59122-7 x MIR604 x TC1507 corn and, as far as possible, should be consistent across sampling years to enable comparisons with historical data.

The number of populations to be collected shall reflect the regional importance of the insect species as a pest, and specific collection regions will be identified for each pest. For ECB, a minimum of twelve (12) populations across the sampling region will be targeted for collection at each annual sampling. For SWCB, the target will be a minimum of six (6) populations. For CEW, the target will be a minimum of ten (10) populations. Pest populations should be collected from multiple corn-growing states reflective of different geographies and agronomic conditions. To obtain sufficient sensitivity to detect resistance alleles before they become common enough to cause measurable field damage, each population collection shall attempt to target 400 insect genomes (egg masses, larvae, mated females, and/or mixed-sex adults), but a successful population collection will contain a minimum of 100 genomes. It is recognized that it may not be possible to collect the target number of insect populations or genomes due to factors such as natural fluctuations in pest density, environmental conditions, and area-wide pest suppression.

The sampling program and geographic range of collections may be modified as appropriate based on changes in pest importance and for the adoption levels of Bt11 x DAS-59122-7 x MIR604 x TC1507 corn. EPA shall be consulted prior to the implementation of such modifications.

Syngenta will report to the Agency before August 31 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 before August 31st. The investigative steps will include:

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

- 2) If the unusual response is reproducible and heritable, progeny of insects that survive the diagnostic concentration will be tested using methods that are representative of exposure to Bt11 x DAS-59122-7 x MIR604 x TC1507 corn under field conditions. If progeny do not survive to adulthood, any suspected resistance is not field relevant and no further action is required.
- 3) If insects survive steps 1 and 2, resistance is confirmed, and further steps will be taken to evaluate the resistance. These steps may include the following:
 - determining the nature of the resistance (i.e., recessive or dominant, and the level of functional dominance);
 - estimating the resistance allele frequency in the original population;
 - determining whether the resistance-allele frequency is increasing by analyzing field collections in subsequent years sampled from the same site where the resistance allele(s) was originally collected;
 - determining the geographic distribution of the resistance allele by analyzing field collections in subsequent years from sites surrounding the site where the resistance allele(s) was originally collected.

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

Investigation of Reports of Unexpected Levels of Damage by the Target Pests

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

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

Suspected Resistance

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

- the corn in question has been confirmed to be lepidopteran-active *Bt* corn;
- the seed used had the proper percentage of corn expressing *Bt* protein;
- the relevant plant tissues are expressing the expected level of *Bt* protein; and

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

The Agency does not interpret *suspected resistance* to mean grower reports of possible control failures or suspicious results from annual insect monitoring assays, nor does the Agency intend that extensive field studies and testing be undertaken to confirm scientifically the presence of insects resistant to Bt11 x DAS-59122-7 x MIR604 x TC1507 corn in commercial production fields before responsive measures are undertaken.

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

- Use alternative control measures in Bt11 x DAS-59122-7 x MIR604 x TC1507 corn fields in the affected region to control the target pest during the immediate growing season.
- Destroy Bt11 x DAS-59122-7 x MIR604 x TC1507 corn crop residues in the affected region within one (1) month after harvest with a technique appropriate for local production practices to minimize the possibility of resistant insects over-wintering and contributing to the next season's target pest population.

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 resistance management action plan within 90 days according to the characteristics of the resistance event and local agronomic needs. Syngenta will consult with appropriate stakeholders in the development of the action plan, and the details of such a plan shall be approved by EPA prior to implementation;
- Notify affected parties (e.g., growers, consultants, extension agents, seed distributors, university cooperators, and state/federal authorities as appropriate) in the region of the resistance situation and approved action plan; and
- In subsequent growing seasons, maintain sales suspension and alternative resistance management strategies in the affected region(s) for the *Bt* corn hybrids that are affected by the resistant population until an EPA-approved local resistance management plan is in place to mitigate the resistance.

A report on results of resistance monitoring and investigations of damage reports must be submitted to EPA, on or before August 31st of each year, for the duration of the registration.

e. Annual Reporting Requirements for Bt11 x DAS-59122-7 x MIR604 x TC1507 Corn

- 1) Grower Agreement Results: number of units of Bt11 x DAS-59122-7 x MIR604 x TC1507 corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements, on or before January 31st of each year.
- 2) 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 each year.
- 3) Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, on or before August 31st of each year.

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

Sincerely,



Kimberly Nesci, Branch Chief
Biopesticides and Pollution Prevention Division (7511P)

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Bt11×DAS-59122-7×MIR604×TC1507 Corn

[Alternate brand name: *Agrisure*[™] 3122]

**Plant-incorporated protectant:
Cry1Ab, Cry34Ab1, Cry35Ab1, mCry3A and Cry1F insecticidal proteins**

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

Active Ingredients:

Bacillus thuringiensis Cry1Ab delta-endotoxin protein and the genetic material necessary for its production (via elements of vector pZO1502) in corn event Bt11 (SYN-BT011-1) ≤0.006392%*

Bacillus thuringiensis Cry34Ab1 delta-endotoxin protein and the genetic material necessary for its production (via elements of vector PHP17662) in corn event DAS 59122-7 (DAS-59122-7)... ≤0.02162%*

Bacillus thuringiensis Cry35Ab1 delta-endotoxin protein and the genetic material necessary for its production (via elements of vector PHP17662) in corn event DAS 59122-7 (DAS-59122-7)... ≤0.004242%*

Bacillus thuringiensis mCry3A insecticidal protein and the genetic material necessary for its production (via elements of vector pZM26) in MIR604 corn (SYN-IR604-8) ≤0.0004888%*

Bacillus thuringiensis Cry1F delta-endotoxin protein and the genetic material necessary for its production (via elements of vector PHI8999A) in TC1507 corn (DAS-01507-1) ≤0.001071%*

Other Ingredients:

A marker protein and the genetic material necessary for its production (via plasmid insert PHI8999A and elements of vector pZO1502) in corn events TC1507 (DAS-01507-1) and Bt11 (SYN-BT011-1) ≤0.000837%*

A marker protein and the genetic material necessary for its production (via elements of vector pNOV1300) in corn event MIR604 (SYN-IR604-8) ≤0.000444%*

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

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

EPA Registration No. 67979-17
EPA Establishment No. 66736-NC-01

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

™ - Trademark of Syngenta

ACCEPTED

JUN 05 2014

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 67979-17

17/21

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its 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, Inc. or its distributors must be accompanied by informational material (e.g. a bag tag) indicating the registration number (67979-17) and the active ingredients, and stipulating that growers read the Syngenta Stewardship Guide (or equivalent guidance) prior to planting the seed.

Insects Controlled or Suppressed

Field corn has been genetically transformed to produce the insecticidal proteins, Cry1Ab, Cry34Ab1, Cry35Ab1, mCry3A, and Cry1F 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*)
- Western corn rootworm (*Diabrotica virgifera virgifera*)
- Northern corn rootworm (*Diabrotica barberi*)
- Mexican corn rootworm (*Diabrotica virgifera zea*)

Insect Resistance Management

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

Refuge Requirements for Bt1x-DAS-59122-7xMIR604xTC1507 Corn

ACCEPTED
JUN 2 2014

EPA Reg. No. 67979-17
the pesticide registered under
and Rodenticide Act, as amended, for
Under the Federal Insecticide, Fungicide

18/21

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.

The following information regarding commercial production of Bt11×DAS-59122-7×MIR604×TC1507 Corn must be included in the Grower Guide (or equivalent). Growers must plant a refuge when using this product.

Two options for deployment of the refuge are allowed:

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 Bt11×DAS-59122-7×MIR604×TC1507 Corn acres and refuge acres). It must be planted as a block adjacent to the Bt11×DAS-59122-7×MIR604×TC1507 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×DAS-59122-7×MIR604×TC1507 Corn must also be planted on rotated ground. If the common refuge is planted in continuous corn, the Bt11×DAS-59122-7×MIR604×TC1507 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×DAS-59122-7×MIR604×TC1507 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 Bt11×DAS-59122-7×MIR604×TC1507 Corn acres only if treatment occurs when adult corn rootworms are not present. Pests on the Bt11×DAS-59122-7×MIR604×TC1507 Corn acres can be treated as needed without having to treat the common refuge.

The second option is planting separate refuge areas for corn borers and corn rootworms. The corn borer refuge must be planted with a non-Bt/lepidopteran-protected hybrid, must represent at least 5% (or 20% in cotton growing regions) of the grower's corn acres (i.e., sum of Bt11×DAS-59122-7×MIR604×TC1507 Corn acres and corn borer refuge acres), and must be planted within ½ mile of the Bt11×DAS-59122-7×MIR604×TC1507 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).

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The corn rootworm refuge must be planted with a non-Bt/corn rootworm-protected Bt hybrid, but can be planted with 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×DAS-59122-7×MIR604×TC1507 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×DAS-59122-7×MIR604×TC1507 corn must also be planted on rotated ground. If the rootworm refuge is planted in continuous corn, the Bt11×DAS-59122-7×MIR604×TC1507 cornfield may be planted on either continuous or rotated land.

More generally, the corn rootworm refuge should utilize comparable agronomic practices as the Bt11×DAS-59122-7×MIR604×TC1507 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×DAS-59122-7×MIR604×TC1507 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×DAS-59122-7×MIR604×TC1507 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 Bt11×DAS-59122-7×MIR604×TC1507 corn acres can be treated as needed without having to treat the rootworm refuge.

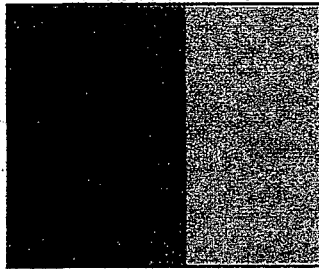
20/21

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 Dallam Hansford Hartley Hutchinson Lipscomb Moore Ochiltree Roberts Sherman					
Virginia	Dinwiddie Southampton	Franklin City Suffolk City	Greensville Surrey	Isle of Wright Sussex	Northampton	

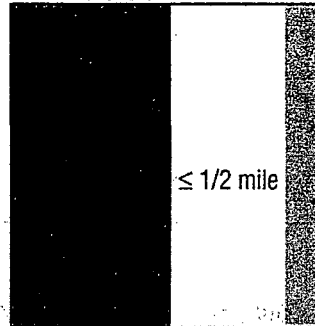
The following are schematics of the various refuge deployment options:

Adjacent



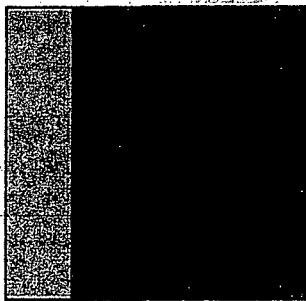
Can be separated by a road, path, ditch, etc., but not by another field.

1/2-Mile Option

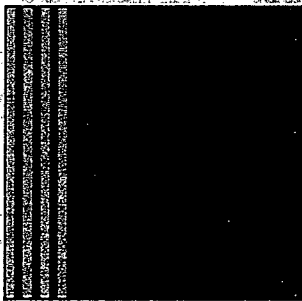


Corn Borer Refuge Option Only

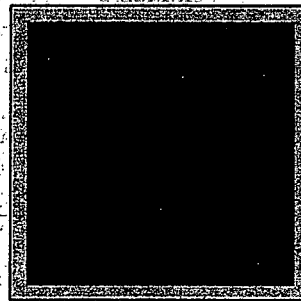
Within



Block



Strips (Split Planter)



Perimeter

The following text and graphic indicating the refuge size requirement will appear on Bt11×DAS-59122-7×MIR604×TC1507 seed corn bags or bag tags.

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



or



For more information, please refer to Syngenta Stewardship Guide.