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

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OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Ms. Sydney Jarrett
Regulatory Affairs Specialist
Syngenta Seeds, Inc. - Field Crops - NAFTA
P.O. Box 12257, 3054 East Cornwallis Road
Research Triangle Park, NC 27709

Re: Bt11 x MIR604 Corn
EPA Registration No. 67979-8
Application to amend reporting requirements, submission dated 1/6/14
Application to amend refuge requirements, submission dated 1/24/13
Notification to add pests and graphics to label, submission dated 11/25/13
Decision Nos. 489964, 474594 & 485899

Dear Ms. Jarrett:

The amendment referred to above, submitted in connection with registration under Section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable provided that you comply with the updated terms and conditions as described in this letter.

1] As stated in the amendment approval letter dated 9/29/2010, the subject registration will automatically expire on midnight September 30, 2015.

2] The subject registration will be limited to mCry3A (MIR604) corn with modified Cry3A protein and the genetic material necessary for its production (via elements of vector pZM26) in corn SYN-IR6Ø4-5 and *Bacillus thuringiensis* Cry1Ab delta-endotoxin protein (Bt11) and the genetic material necessary for its product (via elements of vector pZO1502 in corn (SYN-BTØ11-1)

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

4] The subject 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 plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

5] Three (3) year full-scale field or semi-field studies for evaluation of mCry3A Event MIR604 corn exposure on non-target invertebrates must be conducted. Full-scale field experiments must be appropriately designed to provide a measure of ecological impacts (larger fields, more replicates, more samples per plot based on recommendations of the August, 2002 SAP and subsequent relevant research on appropriate study design).

6] Submit/cite all data, determined by the Agency to be acceptable, required to support the individual plant-incorporated protectants in Event MIR 604 with modified Cry3A (Agrisure RW) corn and *Bacillus thuringiensis* corn Event *Bt*11 with Cry 1Ab for use in field corn within the timeframes required by the terms and conditions of EPA Registration Numbers 67979-5 and 67979-1.

7] Syngenta shall maintain, and provide the Agency upon request, the number of units sold by state and count, IRM grower agreement results, and substantive changes to educational programs. Syngenta is required to submit reports within three months of the Agency's request.

8] Syngenta must commit to do the following Insect Resistance Management Program:

a. Refuge Requirements

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.

Corn Belt/Non-Cotton-Growing Area Refuge Requirements

For Bt11 x MIR604 Field Corn (expressing Cry1Ab and mCry3A proteins) 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 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 MIR604 acres and refuge acres). It must be planted as a block within or adjacent (e.g., across the road) to the Bt11 x MIR604 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 MIR604 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 MIR604 acres and corn borer refuge acres), and must be planted within ½ mile of the Bt11 x MIR604 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 MIR604 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 MIR604 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 MIR604 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).

Growers who fail to comply with the IRM requirements risk losing access to Syngenta corn PIP products.

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

For Bt11 x MIR604 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, Florida, Georgia, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and 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, and Sussex), and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and 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 50% of the grower's corn acres (i.e., sum of Bt11 x MIR604 acres and refuge acres). It must be planted as a block within or adjacent (e.g., across the road) to the Bt11 x MIR604 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 MIR604 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 50% of the grower's corn acres (i.e., sum of Bt11 x MIR604 acres and corn borer refuge acres), and must be planted within

½ mile of the Bt11 x MIR604 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 MIR604 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 MIR604 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 MIR604 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).

Growers who fail to comply with the IRM requirements risk losing access to Syngenta corn PIP products.

b. **Grower Agreements**

1) Persons purchasing the *Bt* corn product 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 continue to integrate this amended 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 corn product will affirm annually that they are contractually bound to comply with the requirements of the IRM program.

4) Syngenta must continue to use its current grower agreement for Bt11 x MIR604 corn product. 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 amended registration.

5) Syngenta must continue to integrate this amended 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 corn product sign grower agreement(s).

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

7) Syngenta shall make available to the Agency upon request records of the number of units of Bt11 x MIR604 corn seeds sold or shipped and not returned, and the number of such units that were sold to persons

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who have signed grower agreements for the previous growing season. Syngenta is required to submit reports within three months of the Agency's request.

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

c. IRM Education and IRM Compliance Monitoring Programs

1) Syngenta must continue to implement and enhance (as set forth in paragraph 16 of this section) a comprehensive, ongoing IRM education program designed to convey to Bt11 x MIR604 corn product users the importance of complying with the IRM program. The program shall include information encouraging Bt11 x MIR604 corn product users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Bt11 x MIR604 corn product 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 written communication annually to each Bt11 x MIR604 corn product 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 6-8 of this section and from other sources. Syngenta shall identify deficiencies in grower compliance and revise the education program to address those deficiencies

3) Upon EPA request, Syngenta shall provide copies of grower education materials and information on grower education activities including any substantive changes to these materials and activities conducted either individually or as part of the industry working group Agricultural Biotechnology Stewardship Technical Committee (ABSTC). Syngenta is required to submit reports within three months of the Agency's request. The required features of the compliance assurance program are described in paragraphs 4-21 below.

4) Syngenta must continue to implement and improve an ongoing IRM Compliance Assurance Program (CAP) designed to evaluate the extent to which growers purchasing Bt11 x MIR604 corn product 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 corn PIP products. Syngenta shall coordinate with other *Bt* corn registrants in improving its Compliance Assurance Program and continue to integrate this amended 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.

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 noncompliance. While recognizing that for reasons of difference in business practices there are needs for flexibility between different companies, all *Bt* corn registrants must use a consistent set of standards for responding to non-compliance. An individual grower found to be significantly out of compliance 2 years in

a row would be denied access the next year to Syngenta's *Bt* corn products for which the grower is required to plant a separate structured refuge. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell *Bt* corn.

6) The IRM compliance assurance program shall include an annual survey conducted by an independent third party of a statistically representative sample of growers of *Bt* corn products who plant the vast majority of all corn in the U.S. 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 the independent marketing research firm 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 U.S.

   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 the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.

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

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

10) Annually, Syngenta shall revise, and expand as necessary, its Compliance Assurance Program to take into account the information collected through the compliance survey required under paragraphs 6 through 8 and from other sources. The registrant shall identify deficiencies in grower compliance and revise the education program to address those deficiencies. Syngenta must confer with the Agency 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 growers of their *Bt* corn products to perform assessments of compliance with IRM requirements. There is no minimum corn acreage size for this program. Therefore, growers will be selected for this program from across all farm sizes. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, Syngenta shall take appropriate action, consistent with its "phased compliance approach," to promote compliance.

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

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

14) Syngenta shall annually provide a report to EPA summarizing the activities carried out under their compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken. 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 and report collectively the results of their compliance assurance programs. Within one month of submitting this report to EPA, the registrant shall meet with EPA to discuss its findings.

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 number of the growers will be protected.

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

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 *Bt* 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. This requirement may be phased in over the next three growing seasons.

17) Syngenta will focus the majority of on-farm assessments on regions with the greatest risks for resistance and will:

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 the product is used.

18) Syngenta will use its available *Bt* 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 the *Bt* corn product but may have purchased little or no refuge seed from Syngenta, licensee, or affiliated company.

19) 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.

20) Syngenta will annually refine the on-farm assessment program for the *Bt* corn product to reflect the adoption rate and level of refuge compliance for the product.

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 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 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 corn product within a 5-year period will be denied access the next year to Syngenta's *Bt* corn products for which the grower is required to plant a separate structured refuge.

d. Insect Resistance Monitoring and Remedial Action Plan (mCry3A – Corn Rootworm)

The Agency is imposing the following conditions for the mCry3A toxin expressed in this product:

1) Syngenta must monitor for mCry3A resistance and/or trends in increased tolerance for corn rootworm. Sampling should be focused in those areas in which there is the highest risk of resistance development.

2) The resistance monitoring plan must include: baseline sensitivity data, sampling (number of locations, samples per locations), sampling methodology and life-stage sampled, bioassay methodology, standardization procedures (including QA/QC provisions), detection technique and sensitivity, the statistical analysis of the probability of detecting resistance, and an interim description of rootworm damage guidelines.

3) 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 Assay (Nowatzki et al. 2008)[1] as a diagnostic assay.

4) 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 toxin. As part of the effort, Syngenta may need to investigate novel techniques for rearing and conducting bioassays with northern corn rootworm.

[1] Reference: Nowatzki, T., S.A. Lefko, R.R. Binning, S.D. Thompson, T.A. Spencer, B.D. Siegfried, 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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5) Syngenta must submit revised corn rootworm damage guidelines (to characterize unexpected pest damage). The revised guidelines must take into consideration the comments and recommendations from EPA's June 30, 2010, review of the rootworm resistance monitoring program for mCry3A.

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

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

e. Remedial Action Plans

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 (this general process has been implemented for other lepidopteron and CRW *Bt* corn products).

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

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

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

iii. the level of damage exceeds guidelines for expected damage.

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

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

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

ii. the LC50 of the test population exceeds the upper limit of the 95% confidence interval for the LC50 of a standard unselected population and/or survival in the diagnostic assay is significantly greater than that of a standard unselected population, as established by the ongoing baseline monitoring program;

iii. the ability to survive is heritable;

iv. mCry3A plant assays determine that damage caused by surviving insects would exceed economic thresholds;

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

4) Response to Confirmed Resistance: When resistance is "confirmed", the following steps will be taken:

i. EPA will receive notification within 30 days of resistance confirmation;

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

iii. affected customers and extension agents will be encouraged to employ alternative CRW control measures;

iv. sale and distribution of mCry3A maize in the affected area will cease immediately;

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

f. Insect Resistance Monitoring and Remedial Action Plan (Cry1Ab – Corn Borer)

The Agency is imposing the following conditions for the Cry1Ab toxin expressed in this product:

Syngenta will continue to monitor for resistance to its lepidopteran-resistant *Bt* corn. The monitoring program shall consist of two approaches: (1) focused population sampling and laboratory testing; and (2) investigation of reports of less-than expected control of labeled insects. Should field-relevant resistance be confirmed, an appropriate resistance management action plan will be implemented.

1) 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 lepidopteran resistant *Bt* corn and/or changes in resistance allele frequency in response to the use of *Bt* corn and, as far as possible, should be consistent across sampling years to enable comparisons with historical data.

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

target number of insect populations or genomes due to factors such as natural fluctuations in pest density, environmental conditions, and area-wide pest suppression.

The sampling program and geographic range of collections may be modified as appropriate based on changes in pest importance and for the adoption levels of lepidopteran-resistant *Bt* corn. The Agency 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 *Bt* protein in bioassays shall be investigated as soon as possible to understand any field relevance of such a finding. Such investigations shall proceed in a stepwise manner until the field relevance can be either confirmed or refuted, and results of these shall be reported to the Agency annually before August 31. The investigative steps will include:

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

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

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

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

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

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

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

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

2) Investigation of Reports of Unexpected Levels of Damage by the Target Pests:

Syngenta will continue to 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 that there could be no other reasonable causes for the damage.

The Agency does not interpret *suspected resistance* to mean grower reports of possible control failures or suspicious results from annual insect monitoring assays, nor does the Agency intend that extensive field studies and testing be undertaken to confirm scientifically the presence of insects resistant to *Bt* 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 the *Bt* corn fields in the affected region to control the target pest during the immediate growing season.
- Destroy *Bt* corn crop residues in the affected region within one month after harvest with a technique appropriate for local production practices to minimize the possibility of resistant insects over-wintering and contributing to the next season's target pest population.

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

Confirmed resistance

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

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

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

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

3) 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, 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;

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

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

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g. Annual Reporting Requirements

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

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

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of Bt11 x MIR604 corn constitutes acceptance of these conditions. A copy of the stamped label is enclosed.

Sincerely,

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

Enclosure (1):
-Accepted Bt11 x MIR604 corn Label

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Plant-incorporated Protectant Label

Bt11 × MIR604 Corn

Alternate brand names:

Agrisure® CB/LL/RW Corn
Agrisure® 3000GT Corn
Agrisure Artesian 3011A

OECD Unique Identifier: SYN-BTØ11-1 × SYN-IR6Ø4-5

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

Active Ingredients:

Bacillus thuringiensis Cry1Ab delta-endotoxin protein and the genetic material necessary for its production (via elements of vector pZO1502) in corn (SYN-BTØ11-1)	≤ 0.0029%*
Modified Cry3A protein and the genetic material necessary for its production (via elements of vector pZM26) in corn (SYN-IR6Ø4-5)	≤ 0.0069%*

Inert Ingredients:

Phosphinothricin acetyltransferase and the genetic material necessary for its production (via elements of vector pZO1502) in corn (SYN-BTØ11-1)	≤ 0.00002%*
Phosphomannose isomerase and the genetic material necessary for its production (via elements of vector pZM26) in corn (SYN-IR6Ø4-5)	≤ 0.0013%*

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

KEEP OUT OF REACH OF CHILDREN
CAUTION

EPA Registration No. 67979-8
EPA Establishment No. 66736-NC-01

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

® Trademarks of Syngenta

DIRECTIONS FOR USE

It is a violation of federal law to use this product in any manner inconsistent with this labeling. This registration will automatically expire on midnight September 30, 2015. All commercial corn seed that contains the plant-incorporated protectant sold or distributed by Syngenta Seeds or its distributors must be accompanied by informational material stipulating that growers read the IRM Stewardship Guide (or equivalent guidance) prior to planting the seed. The refuge size and requirement must be displayed on the seed bag or bag tag in both text and graphic format as shown below.

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Important grower information.
This hybrid requires you to plant:

For more information please refer to the Syngenta Stewardship Guide.

Insects Controlled or Suppressed

Field corn has been genetically transformed to produce the insecticidal proteins Cry1Ab and mCry3A for control or suppression of the following lepidopteran and coleopteran insects:

European corn borer (*Ostrinia nubilalis*)
Southwestern corn borer (*Diatraea grandiosella*)
Southern cornstalk borer (*Diatraea crambidoides*)
Lesser cornstalk borer (*Elasmopalpus lignosellus*)
Corn earworm (*Helicoverpa zea*)
Fall armyworm (*Spodoptera frugiperda*)
True armyworm (*Pseudelatia unipuncta*)
Sugarcane borer *(Diatraea saccharalis)*
Common stalk borer *(Papaipema nebris)*
Western corn rootworm (*Diabrotica virgifera virgifera*)
Northern corn rootworm (*Diabrotica barberi*)
Mexican corn rootworm (*Diabrotica virgifera zeae*)

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.

The following information regarding commercial production of Bt11 × MIR604 corn must be included in the Grower Guide (or equivalent).

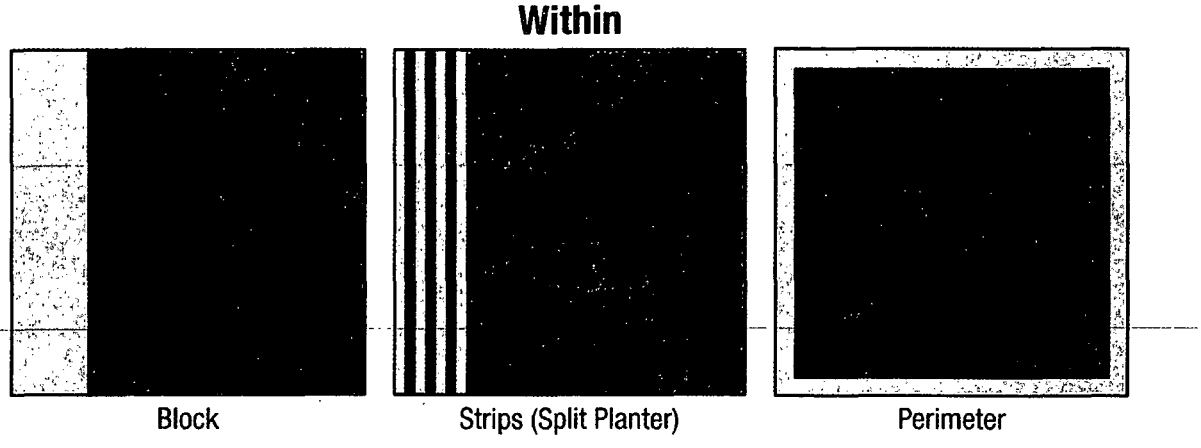
Corn Belt / Non-Cotton Growing Region Refuge Requirements

For Bt11 × MIR604 field corn (expressing Cry1Ab and mCry3A proteins) 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 rootworms. The common refuge must be planted with corn hybrids that do not contain Bt technologies for the

control of corn rootworms or corn borers. The refuge area must represent at least 20% of the grower's corn acres (i.e., sum of Bt11 × MIR604 acres and refuge acres). It must be planted as a block within or adjacent (e.g., across the road) to the Bt11 × MIR604 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 × MIR604 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, crop consultants, etc.). The following is a schematic of common refuge-deployment options:



The second option is planting separate refuge areas for corn borers and corn rootworms. The corn borer refuge must be planted with 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 × MIR604 acres and corn borer refuge acres), and must be planted within ½ mile of the Bt11 × MIR604 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 × MIR604 acres and corn rootworm refuge acres), and must be planted as a block within or adjacent (e.g., across the road) to the Bt11 × MIR604 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×MIR604 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).

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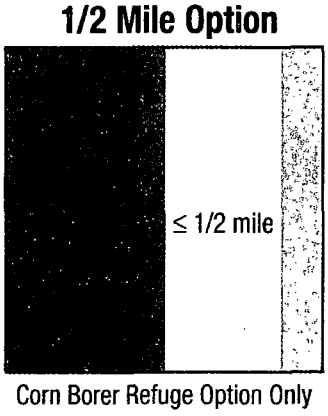
The following is a schematic of one separate refuge option with the corn rootworm refuge planted as a block within the field and the corn borer refuge planted within a ½ mile of the Bt11 ×MIR604 field:



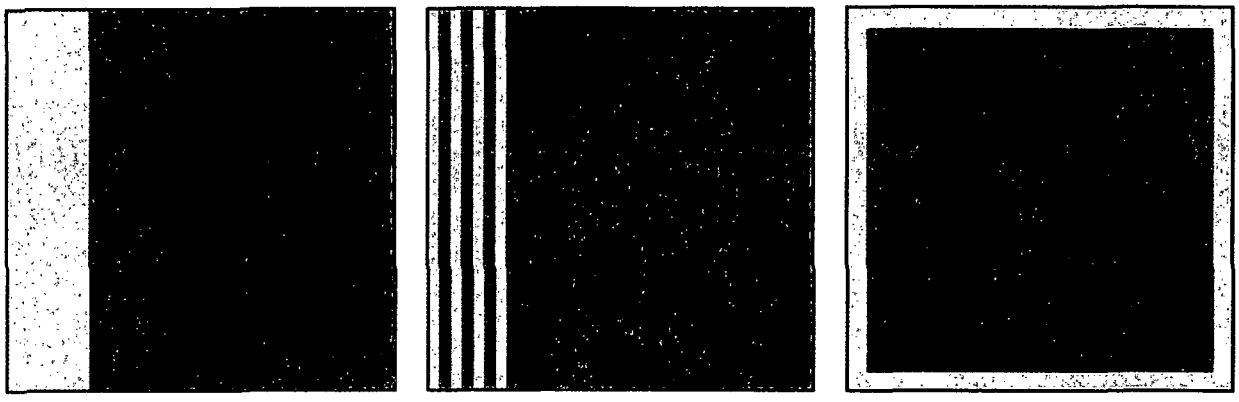
Cotton-Growing Area Refuge Requirements

For Bt11 × MIR604 corn grown in cotton-growing areas 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, Florida, Georgia, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and 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, and Sussex), and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and 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 rootworms or corn borers. The refuge area must represent at least 50% of the grower's corn acres (i.e., sum of Bt11 × MIR604 acres and refuge acres). It must be planted as a block within or adjacent (e.g., across the road) to the Bt11×MIR604 field, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter strips 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 × MIR604 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 following is a schematic of common refuge-deployment options:

Within

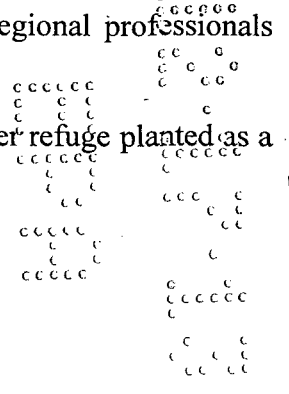


Block Strips (Split Planter) Perimeter

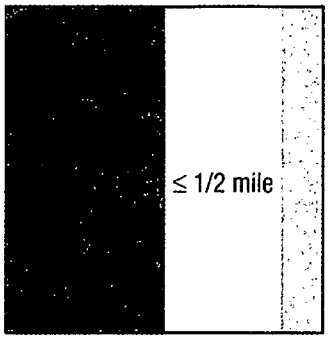
The second option is planting separate refuge areas for corn borers and corn rootworms. The corn borer refuge must be planted with corn that is not a lepidopteran-protected *Bt* hybrid, must represent at least 50% of the grower's corn acres (i.e., sum of Bt11 × MIR604 acres and corn borer refuge acres), and must be planted within ½ mile of the Bt11 × MIR604 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×MIR604 acres and corn rootworm refuge acres), and must be planted as a block within or adjacent (e.g., across the road) to the Bt11×MIR604 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×MIR604 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 following is a schematic for a separate-refuge option with the corn borer refuge planted as a block within a ½ mile of the Bt11 × MIR604 field:

Separate -Refuge Option



1/2 Mile Option



Corn Borer Refuge Option Only

Grower agreements will specify that growers must adhere to the refuge requirements that will be described in the IRM Stewardship Guide for Bt11 ×MIR604 corn or other applicable product use documents.