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

NOTICE OF PESTICIDE:
_X_ Registration
___ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	**Date of Issuance:**
67979-33	4/17/2017

Term of Issuance:
Unconditional

Name of Pesticide Product:
Bt11 x TC1507 Corn

Name and Address of Registrant (include ZIP Code):

Syngenta Seeds, LLC - Field Crops - NAFTA
9 Davis Drive
Research Triangle Park, NC 27709

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product, always refer to the above EPA Registration Number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or the Act).

Registration is in no way to be construed as an endorsement or recommendation of this product by the U.S. Environmental Protection Agency (EPA). In order to protect health and the environment, the Administrator, on his or her motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under the Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration or registration review of Bt11 x TC1507 Corn when the EPA requires all registrants of similar products to submit such data.

2. The subject registration will automatically expire at midnight on April 30, 2029.

Signature of Approving Official:

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

Date:

4/17/2017

EPA Form 8570-6

3. Make the following labeling change before you release this product for shipment:
   - Revise the EPA Registration Number to read, "EPA Reg. No. 67979-33."
4. The subject registration will be limited to field corn Bt11 [containing *Bacillus thuringiensis* Cry1Ab and phosphinothricin acetyltransferase proteins and the genetic material (plasmid insert pZO1502) necessary for their production] x TC1507 [containing *Bacillus thuringiensis* Cry1F and phosphinothricin acetyltransferase proteins and the genetic material (plasmid insert PHP8999) necessary for their production] in Bt11 x TC1507 Corn [OECD Unique Identifier: SYN-BTØ11-1 x DAS-Ø15Ø7-1].
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. You must commit to implementing the following Insect Resistance Management (IRM) Program, consisting of the following elements for Bt11 x TC1507 Corn:

   a. Requirements for Syngenta Seeds, LLC - Field Crops - NAFTA (Syngenta) relating to creation of a non-*Bacillus thuringiensis (Bt)* corn and/or non-lepidopteran-resistant *Bt* corn refuge in conjunction with the planting of any acreage of Bt11 x TC1507 Corn.

   b. Requirements for Syngenta to prepare and require Bt11 x TC1507 Corn users to sign "grower agreements," that impose binding contractual obligations on the grower to comply with the refuge requirements.

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

   d. Requirements for Syngenta to develop, implement, and report to EPA on programs to evaluate and promote growers' compliance with IRM requirements.

   e. Requirements for Syngenta to develop, implement, and report to EPA on programs to evaluate whether there are statistically significant and biologically relevant changes in susceptibility to Cry1Ab and Cry1F proteins in the target insects.

   f. Requirements for Syngenta to submit reports on units sold by state (units sold by county level will be made available to the Agency upon request), IRM grower agreement results, and the compliance assurance program including the education program upon request of the Agency, within 3 months of the request.

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

A. Refuge Requirements for Bt11 x TC1507 Corn

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total 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.

1. Corn Belt Refuge Requirements

For Bt11 x TC1507 Corn field corn grown outside cotton-growing areas (e.g., the Corn Belt), grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

- Specifically, growers must plant a structured refuge of at least 5% non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn that may be treated with insecticides, as detailed below, to control lepidopteran stalk-boring and other pests.
- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips, and strips across the field.
- External refuges must be planted within 1/2 mile.
- When planting the refuge as strips across the field or as perimeter strips, refuges must be at least 4 consecutive rows wide.
- Insecticide treatments for control of ECB, CEW, SWCB, and other lepidopteran target pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.

2. Cotton-Growing Area Refuge Requirements

For Bt11 x TC1507 Corn field corn grown in cotton-growing areas, grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

- Specifically, growers in these areas must plant a structured refuge of at least 20% non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn that may be treated with insecticides, as detailed below, to control lepidopteran stalk-boring and other pests.

- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips, and strips across the field.
- External refuges must be planted within 1/2 mile.
- When planting the refuge as strips across the field or as perimeter strips, refuges must be at least 4 consecutive rows wide.
- Insecticide treatments for control of ECB, CEW, SWCB, and other lepidopteran target pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.
- 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, 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).

3. Grower Agreements for Bt11 x TC1507 Corn

I. Persons purchasing Bt11 x TC1507 Corn must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.

II. 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.

III. 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 TC1507 Corn will affirm annually that they are contractually bound to comply with the requirements of the IRM program.

IV. 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 of this registration.

V. Syngenta shall maintain records of all Bt11 x TC1507 Corn grower agreements for a period of three years from December 31st of the year in which the agreement was signed.

VI. Syngenta shall make available upon request records of the number of units of Bt11 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 for the previous growing season, within three months of the request.

VII. 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.

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

I. Syngenta must implement a comprehensive, ongoing IRM education program designed to convey to Bt11 x TC1507 Corn users the importance of complying with the IRM program. The program shall include information encouraging Bt11 x TC1507 Corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Bt11 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 written communication annually to each Bt11 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 program with the educational efforts of other registrants and other organizations, such as the National Corn Growers Association and state extension programs.

II. Annually, Syngenta shall revise, and expand as necessary, 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.

III. Within three months of EPA request, Syngenta shall provide copies of grower education materials and information on grower education activities including any substantive changes to these materials and activities conducted either individually or as part of a report from the industry working group, the Agricultural Biotechnology Stewardship Technical Committee (ABSTC).

IV. Syngenta must implement an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing Bt11 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 PIP products. Syngenta shall coordinate with other *Bt* corn registrants in improving its compliance assurance program and continue to 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 V-XXIII below.

V. Syngenta must maintain and publicize a "phased compliance approach," i.e., a guidance document that indicates how Syngenta 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 two 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.

VI. 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 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.

VII. 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.

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

IX. 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.

X. 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 VI through VIII and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. Syngenta must confer with the Agency prior to adopting any changes.

XI. Syngenta shall conduct an annual on-farm assessment program. Syngenta shall train its representatives who make on-farm visits with growers of Bt11 x TC1507 Corn 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.

XII. 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."

XIII. If a grower, who purchases Bt11 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.

XIV. Annually, Syngenta shall 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. Within one month of submitting this report to EPA, Syngenta shall meet with EPA to discuss its findings. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of noncompliance, 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.

XV. 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.

XVI. Syngenta may coordinate with other registrants in designing and implementing its Compliance Assurance Program.

XVII. Syngenta will enhance the refuge education program throughout the seed delivery channel:

a. 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;
b. 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.

XVIII. Syngenta will focus the majority of on-farm assessments on regions with the greatest risks for resistance:

a. Use *Bt* corn adoption, pest pressure information, and other available information to identify regions where the risk of resistance is greatest;
b. Focus approximately two-thirds of on-farm assessments on these regions, with the remaining assessments conducted across other regions where the product is used.

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

a. Identify for potential on-farm assessment growers whose sales information indicates they have purchased the Bt11 x TC1507 Corn product but may have purchased little or no refuge seed from the registrant, licensee, or affiliated company.

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

a. 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.

XXI. Annually, Syngenta will refine the on-farm assessment program for the Bt11 x TC1507 Corn product to reflect the adoption rate and level of refuge compliance for Bt11 x TC1507 Corn.

XXII. 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:

a. 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 years by Syngenta, a seed supplier, or third party assessor, after completing the assessment process;
b. Syngenta will conduct follow-up checks on growers found to be significantly out of compliance within three years after they are found to be back in compliance;
c. A grower found with a second incident of significant non-compliance with refuge requirements for Bt11 x TC1507 Corn within a five-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.

XXIII. Syngenta will conduct and support grower education (e.g. corn clinics, certified crop advisor training, etc.) that demonstrates the economic and technology – preserving value of crop rotation as a best agronomic practice. Syngenta will submit to EPA a report on the grower education program (specifically including the number of education sessions/trainings held, locations, number of attendees, examples of presentation materials and grower survey results if available) upon the request of the agency within three months of the request.

C. Insect Resistance Monitoring and Remedial Action Plan for Bt11 x TC1507 Corn

EPA is imposing the following terms for the Cry1Ab and Cry1F proteins, expressed in Bt11 x TC1507 Corn:

Syngenta will monitor for resistance to Cry1Ab and Cry1F proteins, expressed in Bt11 x TC1507 Corn. The monitoring program shall consist of two approaches: (1) focused population sampling and laboratory testing; and (2) investigation of reports of less-than expected control of labeled insects. Should field-relevant resistance be confirmed, an appropriate resistance management action plan will be implemented.

Focused Population Sampling

Annually, Syngenta shall 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 TC1507 Corn and/or changes in resistance-allele frequency in response to the use of

Bt11 x TC1507 Corn and, as far as possible, should be consistent across sampling years to enable comparisons with historical data. Each protein in Bt11 x TC1507 Corn must be tested separately, rather than a mixture of the proteins, because resistance to one protein could be masked by the activity of the other. 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 com-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 TC1507 Corn. The Agency shall be consulted prior to the implementation of such modifications. Syngenta will report to the Agency by August 31st of each year, the results of the population sampling and bioassay monitoring program.

Any incidence of unusually low sensitivity to the Cry1Ab and Cry1F proteins in bioassays shall be investigated as soon as possible to understand any field relevance of such a finding. Such investigations shall proceed in a stepwise manner until the field relevance can be either confirmed or refuted, and results of these shall be reported to the Agency 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 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 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.

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, CEW and FAW), 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* com;
- the seed used had the proper percentage of corn expressing *Bt* protein;
- the relevant plant tissues are expressing the expected level of *Bt* protein; and
- it has been ruled out that species not susceptible to the protein could be responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and that there could be no other reasonable causes for the damage.

EPA does not interpret *suspected resistance* to mean grower reports of possible control failures or suspicious results from annual insect monitoring assays, nor does the Agency intend that extensive field studies and testing be undertaken to confirm scientifically the presence of insects, resistant to Bt11 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 TC1507 Corn fields in the affected region to control the target pest during the immediate growing season.
- Destroy Bt11 x TC1507 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 LC50 exceeds the upper limit of the 95% confidence interval of the LC50 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 the Agency annually by August 31st each year for the duration of the unconditional registration.

D. Annual Reporting Requirements for Bt11 x TC1507 Corn

The following annual reports must be submitted:

1. Compliance Assurance Plan: Compliance Assurance Program activities, including IRM Grower Survey and on-farm assessment results as required by this registration, for the previous year and plans for the compliance assurance program during the current year, on or before January 31st of each year.
2. Insect Resistance Monitoring Results: Results of monitoring and investigations of damage reports as required by this registration, on or before August 31st of each year.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6. A stamped copy of the labeling is enclosed for your records. Please also note that the record for this product currently contains the following acceptable Confidential Statement of Formula (CSF):

- Basic CSF dated 04/06/2017

Any CSFs other than those listed above are superseded.

If you have any questions, please contact Wiebke Tapken of my team by phone at (703) 347-0556 or via email at tapken.wiebke@epa.gov.

Sincerely,

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

Enclosure: Stamped Label

Plant-incorporated Protectant Label

Bt11 × TC1507 Corn
Agrisure® 3120 Refuge Renew ™
Agrisure® 3120A Refuge Renew ™

OECD Unique Identifier: SYN-BTØ11-1 × DAS-Ø15Ø7-1

Plant-incorporated protectants:
Cry1Ab and Cry1F insecticidal proteins

This product is effective in controlling corn leaf, stalk, and ear damage caused by corn borers and other lepidopteran pests

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Active Ingredients:
Bacillus thuringiensis Cry1Ab protein and the genetic material necessary for its production (via elements of vector pZO1502) in Bt11 corn (SYN-BTØ11-1)..... ≤0.0183%*

Bacillus thuringiensis Cry1F protein and the genetic material necessary for its production (via elements of vector PHP8999) in TC1507 corn (DAS-Ø15Ø7-1) ..... ≤0.00234%*

Other Ingredients:
Phosphinothricin acetyltransferase protein and the genetic material necessary for its production (via elements of vector pZO1502) in Bt11 corn (SYN-BTØ11-1) and (via elements of vector PHP8999) in TC1507 corn (DAS-Ø15Ø7-1)..... ≤0.000814%*

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

CAUTION
KEEP OUT OF REACH OF CHILDREN

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

Syngenta Seeds, LLC – Field Crops – NAFTA
9 Davis Drive
Research Triangle Park, NC 27709

DIRECTIONS FOR USE

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

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

PIP must be accompanied by informational material (*e.g.* a bag tag) indicating the EPA registration number and the active ingredients, and stipulating that growers read the Syngenta Stewardship Guide (or equivalent guidance) prior to planting their seed. The refuge size requirement must be displayed on the seed bag or bag tag in both text and graphic format.

Insects Controlled or Suppressed

Bt11 × TC1507 Corn has been genetically transformed to produce the insecticidal proteins Cry1Ab and Cry1F for control or suppression of the following lepidopteran insects:

European corn borer (*Ostrinia nubilalis*)
Southwestern corn borer (*Diatraea grandiosella*)
Southern cornstalk borer (*Diatraea crambidoides*)
Corn earworm (*Helicoverpa zea*)
Fall armyworm (*Spodoptera frugiperda*)
Black cutworm (*Agrotis ipsilon*)
Western bean cutworm (*Striacosta albicosta*)
Sugarcane borer (*Diatraea saccharalis*)
Lesser cornstalk borer (*Elasmopalpus lignosellus*)
Common stalk borer (*Papaipema nebris*)
Dingy cutworm (*Feltia jaculifera*)
Beet armyworm (*Spodoptera exigua*)
True armyworm (*Pseudaletia unipuncta)*

Insect Resistance Management

Each bag of Bt11 × TC1507 Corn contains 100% Bt11 × TC1507 Corn seed. The following information regarding commercial production of Bt11 × TC1507 Corn must be included in the Syngenta Stewardship Guide (or equivalent).

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

In corn-growing areas, growers who plant Bt11 × TC1507 Corn must plant a 5% structured refuge. Corn-growing areas are those counties and states not defined below as comprising the cotton-growing areas of the U.S. Read the Syngenta Stewardship Guide or refer to the Table below.

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

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

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

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

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

The following text and graphic indicating the refuge size requirement will appear on Bt11 × TC1507 Corn bags or bag tags.

Important grower information.
Supplemental refuge planting requirement.

For more information, please refer to Syngenta Stewardship Guide.

The following are schematics of the various refuge deployment options: