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:
☒Registration
☐Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	**Date of Issuance:**
67979-15	10/22/2021

Term of Issuance:
Unconditional

Name of Pesticide Product:
Bt11 x MIR162 x TC1507 Corn

Name and Address of Registrant (include ZIP Code):

Syngenta Seeds, LLC -Field Crops- NAFTA
P.O. Box 12257
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 comply with the following terms:

1. Submit and/or cite all data required for registration or registration review of Bt11 x MIR162 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 May 29, 2023.

Signature of Approving Official:

Alan Reynolds, Team Leader
Emerging Technologies Branch
Biopesticides and Pollution Prevention Division (7511P)

Date:
October 22, 2021

3. The subject registration will be limited to Cry1Ab [*Bacillus thuringiensis* Cry1Ab delta-endotoxin protein and the genetic material (vector pZ01502) necessary for its production in corn event Bt11 (OECD Unique Identifier: SYN-BTØ11-1), *Bacillus thuringiensis* Vip3Aa20 insecticidal protein and the genetic material (vector pNOV1300) necessary for its production in corn event MIR162 (OECD Unique Identifier: SYN-IR162-4), *Bacillus thuringiensis* Cry1F delta-endotoxin and the genetic material (plasmid insert PHP899A) necessary for its production in TC 1507 (OECD Unique Identifier: DAS-Ø15Ø7-1) for use in field corn.

4. 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.

5. Syngenta Seeds, LLC (Syngenta) must commit to do the following Insect Resistance Management (IRM) Program, consisting of the following elements:

    - Requirements relating to creation of a lepidopteran refuge (consisting of corn that does not contain any *Bt* trait for lepidopteran control) in conjunction with the planting of any acreage of Bt11 x MIR162 x TC1507 Corn;

    - Requirements for Syngenta to prepare and require Bt11 x MIR162 x TC1507 Corn users to sign grower agreements that impose binding contractual obligations on growers to comply with the refuge requirements.

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

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

    - Requirements for Syngenta to develop, implement, and report to EPA on monitoring programs to evaluate whether there are statistically significant and biologically relevant changes in susceptibility to the Cry1Ab, Vip3Aa20, and Cry1F proteins in the target insects.

    - Requirements for Syngenta to develop, and if triggered, to implement a remedial action plan that would contain measures Syngenta would take in the event that any field-relevant insect resistance to Cry1Ab, Vip3Aa20, and Cry1F was detected, as well as to report on activity under the plan to EPA.

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

    - Bag Tag Requirements for Bt11 x MIR162 x TC1507 Corn. Seed bags and/or bag tags for corn hybrids that contain plant- incorporated protectants produced in Bt11 x MIR162 x TC1507 Corn must display the registration number and active ingredients, and stipulate that growers read the Syngenta Stewardship Guide (or equivalent guidance) prior to planting these hybrids. The refuge size requirement must be displayed on the bag or bag tag in both text and graphic

format.

- Requirements for Syngenta, on or before August 31st of each year, to submit reports on Cry1Ab, Vip3Aa20, and Cry1F resistance monitoring.

a. Refuge Requirements for Bt11 x MIR162 x TC1507 Corn

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid Bt11 x MIR162 x MIR604 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 registrant per year.

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

1. IRM Requirements for corn-growing areas and other non-corn/cotton growing areas of the U.S.:

   The use of Bt11 x MIR162 x TC1507 Corn requires an accompanying 5% structured refuge consisting of non-*Bt* corn or corn that is not a lepidopteran-protected *Bt* hybrid. Corn-growing areas are those counties and states not defined in the table below as comprising the cotton-growing areas of the U.S.

2. IRM Requirements for cotton-growing areas of the U.S.:

   The use of Bt11 x MIR162 x TC1507 Corn requires an accompanying 20% structured refuge consisting of non-*Bt* corn or corn that is not a lepidopteran-protected *Bt* hybrid. The following table lists those states and counties identified by the Environmental Protection Agency (EPA) as cotton-growing areas.

State	**Counties Identified by EPA as Cotton-Growing Areas**			
Alabama	All Counties			
Arkansas	All Counties			
Florida	All Counties			
Georgia	All Counties			
Louisiana	All Counties			
Mississippi	All Counties			
Missouri	Dunklin Stoddard	New Madrid	Pemiscot	Scott
North Carolina	All Counties			
Oklahoma	Beckham Greer Kiowa	Caddo Harmon Tillman	Comanche Jackson Washita	Custer Kay
South Carolina	All Counties			
Tennessee	Carroll Fayette	Chester Franklin	Crocket Gibson	Dyer Hardeman

	Hardin	Haywood	Lake	Lauderdale
	Lincoln	Madison	Obion	Rutherford
	Shelby	Tipton		
Texas	All counties except for the following:			
	Carson	Dallam	Hansford	Hartley
	Hutchinson	Lipscomb	Moore	Ochiltree
	Roberts	Sherman		
Virginia	Dinwiddle	Franklin City	Greensville	Isle of Wight
	Northampton	Southampton	Suffolk City	Surrey
	Sussex			

3. Refuge Location
   a. The lepidopteran refuge can be planted in a separate field not more than ½ miles from the Bt11 x MIR162 x TC1507 Corn field;
   b. The lepidopteran refuge can be planted within the Bt11 x MIR162 x TC1507 Corn field as blocks (e.g., along the edges or headlands);
   c. The lepidopteran refuge can be planted within the Bt11 x MIR162 x TC1507 Corn field as strips across the field at least four (4) consecutive rows wide.

4. Refuge Management

   Insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, fall armyworm, black cutworm, western bean cutworm, lesser corn stalk borer, southern corn stalk borer, stalk borer and sugarcane borer may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). 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.

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

b. Grower Agreements for Bt11 x MIR162 x TC1507 Corn

1. Persons purchasing Bt11 x MIR162 x TC1507 Corn must sign a grower agreement. The term grower agreement refers to any grower purchase contract, license agreement, or similar legal document.

2. The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.

3. Syngenta must continue to 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 MIR162 x TC1507 Corn 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 MIR162 x TC1507 Corn. 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, then 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 shall maintain records of all Bt11 x MIR162 x TC1507 Corn grower agreements for a period of three (3) years from December 31st of the year in which the agreement was signed.

6. Syngenta shall make available to the Agency upon request records of the number of units of Bt11 x MIR162 x TC1507 Corn seed sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements for the previous growing season. Syngenta is required to submit reports within three months of the Agency's request.

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

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

1. Syngenta must implement and enhance (as set forth in paragraph 17 of this section) a comprehensive, ongoing IRM education program designed to convey to Bt11 x MIR162 x TC1507 Corn users the importance of complying with the IRM program. The program shall include information encouraging Bt11 x MIR162 x TC1507 Corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Bt11 x MIR162 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. The program shall involve at least one written communication annually to each Bt11 x MIR162 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.

2. Syngenta shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey, required under paragraphs 6–9 of this section, and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

3. Upon EPA request, Syngenta shall provide copies of grower education materials and information on grower education activities including any substantive changes to these materials and activities conducted either individually or as part of the industry working group Agricultural Biotechnology Stewardship Technical Committee (ABSTC). Syngenta is required to submit reports within three months of the Agency's request. The required features of the compliance assurance program are described in paragraphs 4–22 of this section.

4. Syngenta must implement and improve an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing Bt11 x MIR162 x TC1507 Corn are compliant

with the IRM program, and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to Syngenta's *Bt* corn products. Syngenta shall coordinate with other *Bt* corn registrants in improving its compliance assurance program and integrate this registration into the current compliance assurance program used for its other *Bt* corn plant-incorporated protectants. Other required features of the program are described in paragraphs 5–22 of this section.

5. Syngenta must maintain and publicize a phased compliance approach (i.e., a guidance document that indicates how it will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers after the first year of non-compliance). While recognizing that for reasons of difference in business practices there are needs for flexibility between different companies, Syngenta must use a consistent set of standards for responding to non-compliance. An individual grower found to be significantly out of compliance two (2) years in a row would be denied access the next year to Syngenta's *Bt* corn products for which the grower is required to plant a separate structured refuge. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell *Bt* corn.

6. The IRM compliance assurance program shall include an annual survey, conducted by an independent third party, of a statistically representative sample of growers Bt11 x MIR162 x TC1507 Corn. The survey shall be conducted in odd-numbered years beginning in 2021 and shall include growers who plant 100 or more acres of corn in the Southern U.S. corn-cotton areas. Syngenta may collaborate with other registrants of *Bt* corn [for example, through the industry working group the Agricultural Biotechnology Stewardship Technical Committee (ABSTC)] to conduct the survey.

   In the U.S. Corn Belt, no anonymous grower survey is required for Bt11 x MIR162 x TC1507 Corn if Syngenta can demonstrate that the industry-wide adoption of integrated refuge products (i.e., refuge seed blends) is equal to or greater than 70% of *Bt* corn acres in the Corn Belt. If industry- wide adoption of integrated refuge products (i.e., refuge seed blends) falls below 70% of *Bt* corn acres in the Corn Belt, an anonymous grower survey shall also be conducted in this region during the next growing season using a statistically representative sample of growers who plant 200 or more acres of corn, and grower surveys shall be continued every odd-numbered year until the industry-wide adoption of integrated refuge products (i.e., refuge seed blends) is again equal to or greater than 70% of *Bt* corn acres in this region. Syngenta may collaborate with other registrants of *Bt* corn (for example, through the industry working group the ABSTC) to compile the integrated refuge adoption data and to conduct the surveys.

   Alternatively, if Syngenta is not a participant of an industry working group (e.g., the ABSTC) and Syngenta's sales of integrated refuge products are equal to or greater than 70% of Syngenta's total *Bt* corn sales in the prior year, then no anonymous grower survey is required in the U.S. Corn Belt. If Syngenta's sales of integrated refuge products fall below 70% of Syngenta's total *Bt* corn sales, an anonymous grower survey shall also be conducted in this region during the next growing season using a statistically representative sample of growers who plant 200 or more acres of corn, and grower surveys shall be continued every odd-numbered year until sales of integrated refuge products (i.e., refuge seed blends) are again equal to or greater than 70% of Syngenta's total *Bt* corn sales in this region.

   - A third party is classified as a party other than the registrant, the grower, or anyone else with a

direct interest in IRM compliance for *Bt* corn.

7. The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of survey results must include the reasons, extent, and potential biological significance of any implementation deviations.

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

9. In years in which the survey is conducted, Syngenta shall provide a final written summary of the results of the survey (together with a description of the regions, the methodology used, and the supporting data) to EPA on or before January 31st of the following year. Syngenta shall confer with other registrants and EPA on the design and content of the survey prior to its implementation.

10. Syngenta shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey, required under paragraphs 6–9 of this section, and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. Syngenta must confer with EPA prior to adopting any changes.

11. Syngenta shall conduct and enhance an annual on-farm assessment program. Syngenta shall train its representatives who make on-farm visits with Bt11 x MIR162 x TC1507 Corn growers to perform assessments of compliance with IRM requirements. There is no minimum corn acreage size for this program. Therefore, growers will be selected for this program from across all farm sizes. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, Syngenta shall take appropriate action, consistent with its phased compliance approach, to promote compliance.

12. Syngenta shall implement a program for investigating legitimate tips and complaints that Bt11 x MIR162 x TC1507 Corn growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, Syngenta shall take appropriate action, consistent with its phased compliance approach.

13. If a grower, who purchases Bt11 x MIR162 x TC1507 Corn for planting, was specifically identified as not being in compliance during the previous year, Syngenta shall visit with the grower and evaluate whether the grower is in compliance with the IRM program for the current year.

14. Annually, by January 31st each year, Syngenta must provide a report to EPA summarizing the Bt11 x MIR162 x TC1507 Corn compliance assurance program activities and results for the prior year and plans for the Bt11 x MIR162 x TC1507 Corn compliance assurance program for the current year. Within one month of submitting this report to EPA, the registrant shall meet with EPA to discuss its findings. The report must inform EPA of the number of growers deemed ineligible to purchase *Bt* corn seed on the basis of continued non-compliance with the insect resistance management refuge requirements. Syngenta may elect to coordinate information with other registrants and report collectively the results of compliance assurance programs.

15. Syngenta and the seed corn dealers for Syngenta must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license numbers of the growers, will be protected.

16. Syngenta shall revise and expand its existing Compliance Assurance Program to include the following elements. The registrant may coordinate with other registrants in designing and implementing its Compliance Assurance Program.

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

    - 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.

    - Implement a "bag tag" that will be attached to all bags of Bt11 x MIR162 x TC1507 Corn seed sold and delivered. The purpose of this bag tag is to remind growers that Bt11 x MIR162 x TC1507 Corn products require a separate 20% lepidopteran refuge in cotton growing areas. The PIP product label accepted by EPA must include how this information will be conveyed to growers via text and graphics.

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

    - Use *Bt* corn adoption, pest pressure information, and other available information to identify regions where the risk of resistance is greatest.

    - Focus approximately two-thirds of on-farm assessments on these regions, with the remaining assessments conducted across other regions where Bt11 x MIR162 x TC1507 Corn is used.

19. Syngenta will use its available Bt11 x MIR162 x TC1507 Corn sales records and other information to refine grower lists for on-farm assessments of their compliance with refuge requirements:

    - Identify for potential on-farm assessment growers whose sales information indicates they have purchased Bt11 x MIR162 x TC1507 Corn product but may have purchased little or no refuge seed from the registrant, licensee, or affiliated company.

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

    - The third-party assessors will conduct all first-time on-farm assessments as well as second-year on-farm assessments of those growers found out of compliance in a first- time assessment.

21. Syngenta will annually refine the on-farm assessment program for the Bt11 x MIR162 x TC1507 Corn product to reflect the adoption rate and level of refuge compliance for the product.

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

    - 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, seed supplier, or third party assessor, after completing the assessment process;

- 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;

- A grower found with a second incident of significant non-compliance with refuge requirements for the *Bt* corn product within a five-year period will be denied access to Syngenta's *Bt* corn products the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell *Bt* corn.

d. Insect Resistance Monitoring and Mitigation Plan for Bt11 x MIR162 x TC1507 Corn

1. <u>EPA is imposing the following conditions for the Cry1Ab, Vip3Aa20, and Cry1F toxins expressed in Bt11 x MIR162 x TC1507 Corn</u>

Syngenta will monitor for resistance to Cry1Ab, Vip3Aa20, and Cry1F expressed in Bt11 x MIR162 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.

<u>Focused Population Sampling</u>

Syngenta shall annually sample and bioassay populations of the key target pests: Ostrinia nubilalis (European corn borer; ECB), Diatraea grandiosella (southwestern corn borer; SWCB), and Helicoverpa zea (corn earworm; CEW). Sampling for the target pests will be focused in areas identified as those with the highest risk of resistance development (e.g., where lepidopteran active *Bt* hybrids are planted on a high proportion of the corn acres, and where the insect species are regarded as key pests of corn). Bioassay methods must be appropriate for the goal of detecting field-relevant shifts in population response to Bt11 x MIR162 x TC1507 Corn and/or changes in resistance allele frequency in response to the use of Bt11 x MIR162 x TC1507 Corn and, as far as possible, should be consistent across sampling years to enable comparisons with historical data.

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

The sampling program and geographic range of collections may be modified as appropriate based on changes in pest importance and for the adoption levels of Bt11 x MIR162 x TC1507 Corn. EPA shall be consulted prior to the implementation of such modifications.

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

Any incidence of unusually low sensitivity to the Cry1Ab, Vip3Aa20, and Cry1F proteins in bioassays shall be investigated as soon as possible to understand any field relevance of such a finding. Such investigations shall proceed in a stepwise manner until the field relevance can be either confirmed or refuted, and results of these shall be reported to EPA annually on or before August 31st. The investigative steps will include the following:

i. 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.

ii. 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 MIR162 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.

iii. If insects survive steps 1 and 2, resistance is confirmed, and further steps will be taken to evaluate the resistance. These steps may include the following:
    a. Determining the nature of the resistance (i.e., recessive or dominant, and the level of functional dominance);
    b. Estimating the resistance allele frequency in the original population;
    c. 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;
    d. Determining the geographic distribution of the resistance allele by analyzing field collections in subsequent years from sites surrounding the site where the resistance allele(s) was originally collected.

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

<u>Investigation of Reports of Unexpected Levels of Damage by the Target Pests</u>

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

If reports of unexpected levels of damage lead to the suspicion of resistance in any of the key

target pests (ECB, SWCB, and CEW), Syngenta will implement the actions described below, based on the following definitions of ***suspected resistance*** and ***confirmed resistance***.

Suspected Resistance

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

- The corn in question has been confirmed to be lepidopteran-active *Bt* corn;
- The seed used had the proper percentage of corn expressing *Bt* protein;
- The relevant plant tissues are expressing the expected level of *Bt* protein; and
- It has been ruled out that species not susceptible to the protein could be responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and
- That there could be no other reasonable causes for the damage.

EPA does not interpret ***suspected resistance*** to mean grower reports of possible control failures or suspicious results from annual insect monitoring assays, nor does EPA intend that extensive field studies and testing be undertaken to confirm scientifically the presence of insects resistant to Bt11 x MIR162 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 MIR162 x TC1507 Corn fields in the affected region to control the target pest during the immediate growing season.
- Destroy Bt11 x MIR162 x TC1507 Corn crop residues in the affected region within one (1) month after harvest with a technique appropriate for local production practices to minimize the possibility of resistant insects over- wintering and contributing to the next season's target pest population.

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

Confirmed Resistance

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

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

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

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

Response to Confirmed Resistance in a Key Target Pest as the Cause of Unexpected Levels of Damage in the Field

When field resistance is ***confirmed*** (as defined above), the following steps will be taken by Syngenta:

- EPA will receive notification within 30 days of resistance confirmation;

- Affected customers and extension agents will be notified about confirmed resistance within 30 days;

- Monitoring will be increased in the affected area and local target pest populations will be sampled annually to determine the extent and impact of resistance;

- If appropriate (depending on the resistant pest species, the extent of resistance, the timing of resistance, and the nature of resistance, and the availability of suitable alternative control measures), alternative control measures will be employed to reduce or control target pest populations in the affected area. Alternative control measures may include advising customers and extension agents in the affected area to incorporate crop residues into the soil following harvest to minimize the possibility of over-wintering insects, and/or applications of chemical insecticides;

- Unless otherwise agreed with EPA, stop sale and distribution of the relevant lepidopteran-active *Bt* corn hybrids in the affected area immediately until an effective local mitigation plan, approved by EPA, has been implemented;

- Syngenta will develop a case-specific resistance management action plan within 90 days according to the characteristics of the resistance event and local agronomic needs. Syngenta will consult with appropriate stakeholders in the development of the action plan, and the details of such a plan shall be approved by EPA prior to implementation;

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

in place to mitigate the resistance.

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

e. Annual Reporting Requirements for Bt11 x MIR162 x TC1507 Corn

The following annual reports must be submitted:

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

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

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

Your release for shipment of this product constitutes acceptance of these conditions. If you fail to satisfy these terms and conditions, the EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e).

A stamped copy of the label is enclosed for your records. A previously approved Confidential Statement of Formula dated March 22, 2011 is on file for this product.

If you have any questions, please contact Matt Weiner by phone at (703) 347-0333 or via email at weiner.matthew@epa.gov.

Sincerely,

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

Enclosure

ACCEPTED
10/22/2021
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 67979-15

Plant-incorporated Protectant Label

Bt11 × MIR162 × TC1507 Corn

Alternate brand names:
Agrisure Viptera® 3220 Refuge Renew™
Agrisure Viptera® 3220A Refuge Renew™

OECD Unique Identifier: SYN-BTØ11-1 x SYN-IR162-4 x DAS-Ø15Ø7-1

Plant-incorporated protectants:
Cry1Ab, Vip3Aa20 and Cry1F proteins for control of corn borers and other lepidopteran pests

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

Active Ingredients:	
Bacillus thuringiensis Cry1Ab delta-endotoxin protein and the genetic material necessary for its production (via elements of vector pZO1502) in corn event Bt11 (SYN-BTØ11-1) …….....	≤ 0.00103%*
Bacillus thuringiensis Vip3Aa20 insecticidal protein and the genetic material necessary for its production (via elements of vector pNOV1300) in corn event MIR162 (SYN-IR162-4)	≤ 0.00256%*
Bacillus thuringiensis Cry1F delta-endotoxin protein and the genetic material necessary for its production (plasmid insert PHP8999A in TC 1507 corn (DAS-Ø15Ø7-1)	≤0.00077%*
Other Ingredients:	
Phosphinothricin acetyltransferase marker protein and the genetic material necessary for its production (via plasmid insert PHP8999A and elements of vector pZO1502) in TC1507 corn (DAS-Ø15Ø7-1) and Bt11 corn (SYN-BTØ11-1) …..	≤0.00017%*
Phosphomannose isomerase marker protein and the genetic material necessary for its production (via elements of vector pNOV1300) in corn event MIR162 (SYN-IR162-4)	≤ 0.00025%*

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*Percent in whole plants on a dry weight basis

KEEP OUT OF REACH OF CHILDREN
CAUTION

EPA Registration No. 67979-15
EPA Establishment No. 66736-NC-01

Syngenta Seeds, LLC -Field Crops-NAFTA
P.O. Box 12257
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 its labeling.

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

All corn seed that contains this PIP must be accompanied by informational material (e.g., a bag tag) indicating the registration number (67979-15) and the active ingredients, and stipulating that growers read the Grower Guide (or equivalent guidance) prior to planting the seed. The refuge size requirement must be displayed on the seed bag or bag tag in both text and graphic format.

Insects Controlled or Suppressed

Bt11 × MIR162 × TC1507 Field corn has been genetically transformed to produce the insecticidal proteins, Cry1Ab, Vip3Aa20 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*)
Beet armyworm (*Spodoptera exigua*)
True armyworm (*Pseudelatia unipuncta*)
Black cutworm (*Agrotis ipsilon*)
Western bean cutworm (*Striacosta albicosta*)
Sugarcane borer (*Diatraea saccharalis*)
Lesser cornstalk borer (*Elasmopalpus lignosellus)*
Dingy Cutworm (*Feltia jaculifera*)
Common stalk borer (*Papaipema nebris*)

Insect Resistance Management

Each bag of Bt11 × MIR162 × TC1507 Corn contains 100% Bt11 × MIR162 × TC1507 Corn seed. The following information regarding commercial production of Bt11 × MIR162 × 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 × MIR162 × 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 × MIR162 × 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 × MIR162 × 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 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 × MIR162 × TC1507 seed corn bags or bag tags.

Important grower information.
This hybrid requires you to plant:

For more information please refer to the Syngenta Stewardship Guide.

The following are schematics of the various refuge deployment options: