



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

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

February 13, 2017

Tanya Markham  
Regulatory Affairs Manager  
Syngenta Seeds, LLC – Field Crops – NAFTA  
9 Davis Drive  
Research Triangle Park, NC 27709

Subject: Non-PRIA (Pesticide Registration Improvement Act) Amendment to 1) modify the conditions of registration for home garden uses and the annual grower survey requirements, and 2) update the product label for home garden uses  
Product Name: Bt11 x MIR162 Corn  
EPA Registration Number: 67979-12  
Application Date: 8/10/2016  
OPP Decision Number: 520414

Dear Ms. Markham:

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), to revise the conditions of the current time-limited registration is acceptable provided that you comply with the updated conditions as described in this letter.

- 1) The subject registration will automatically expire at midnight on December 31, 2023.
- 2) The subject registration will be limited to Cry1Ab [*Bacillus thuringiensis* Cry1Ab delta-endotoxin protein and the genetic material necessary for its production (via elements of vector pZO1502) in corn event Bt11 (OECD Unique Identifier: SYN-BT011-1)] x Vip3Aa20 [*Bacillus thuringiensis* Vip3Aa20 insecticidal protein and the genetic material necessary for its production (via elements of vector pNOV1300) in corn event MIR162 (OECD Unique Identifier: SYN-IR162-4)] for use in field and sweet corn.
- 3) Submit/cite all data required for registration of your product under FIFRA section 3(c)(5) when the Environmental Protection Agency (EPA or Agency) requires registrants of similar products to submit such data.
- 4) Submit/cite all data and/or information, which are required to support individual plant-incorporated protectants in Bt11 Insect Resistant Corn and MIR162 maize within the time frames required by the terms and/or conditions of EPA Registration Numbers 67979-1 and 67979-14, respectively. These data and/or information must be determined by EPA to be acceptable.

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

6) You must commit to do the following IRM Program, consisting of the following elements:

- Requirements 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 MIR162 field corn.
- Requirements (except for sweet corn home garden or educational use, i.e., marketed to home gardeners or educators for use on less than 20 acres) for Syngenta Seeds, LLC – Field Crops – NAFTA (Syngenta) to prepare and require Bt11 x MIR162 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 and/or Vip3Aa20 proteins in the target insects.
- Requirements for Syngenta to develop, and if triggered, to implement a remedial action plan that would contain measures Syngenta would take in the event that any field-relevant insect resistance was detected, as well as to report on activity under the plan to EPA.
- Requirements for Syngenta to maintain, and 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.
- For home garden or educational use, Syngenta will maintain, and provide the Agency upon request, the total number of estimated acres sold, and substantive changes to educational programs. Syngenta is required to submit results within three months of the Agency's request.
- Requirements for Syngenta, on or before August 31<sup>st</sup> of each year, to submit reports on resistance monitoring.

## **a. Field Corn Refuge and Sweet Corn Postharvest Requirements for Bt11 x MIR162 Corn**

### Refuge Requirements for Bt11 x MIR162 Field Corn

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States total of 250,000 acres per plant-incorporated protectant 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.

- Specifically, growers 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 the following: separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips, and strips across the field.
- An external refuge must be planted within ½ mile of the Bt11 x MIR162 Corn field.
- When planting the refuge as strips across the field or as perimeter strips, the refuge must be at least four (4) consecutive rows wide.
- Insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, and other lepidopteran pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one (1) 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.

### Postharvest Requirements for Bt11 x MIR162 Sweet Corn

Sweet corn is harvested long before field corn. Therefore, if the sweet corn stalks remaining in the field and any insects remaining in the stalks are destroyed shortly after harvest, a refuge is not needed as a part of the IRM program for sweet corn. Growers must adhere to the following types of crop destruction requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide, and in the case of home gardeners, on the seed packet, in seed catalogues, and on websites offering Bt11 x MIR162 sweet corn hybrids for sale to home gardeners:

- Crop destruction must occur no later than thirty (30) days following harvest, but preferably within fourteen (14) days.
- The allowed crop destruction methods are rotary mowing, discing, or plow down or (for home garden use) by chopping up the stalks using home garden tools such as a hoe. The crop destruction methods are intended to protect against development of insect resistance.

**b. Grower Agreements for Bt11 x MIR162 Corn**

*The following conditions do not apply to Bt11 x MIR162 sweet corn home garden use or educational use (i.e., marketed to home gardeners or educators for use on less than 20 acres).*

- 1) Persons purchasing Bt11 x MIR162 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 implement a system, which is reasonably likely to assure that persons purchasing Bt11 x MIR162 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 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, 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 conditions of this registration.
- 5) Syngenta must continue to implement an approved system, which is reasonably likely to assure that persons purchasing Bt11 x MIR162 Corn sign grower agreement(s).
- 6) Syngenta shall maintain records of all Bt11 x MIR162 Corn grower agreements for a period of three (3) years from December 31<sup>st</sup> 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 MIR162 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.
- 8) Syngenta must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license numbers of the growers, will be protected.

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

1) Syngenta must continue to 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 corn users the importance of complying with the IRM program. The program shall include information encouraging Bt11 x MIR162 Corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Bt11 x MIR162 Corn fields. The education program shall involve the use of multiple media (e.g., face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials). Copies of the materials will be provided to EPA for its records. The program shall involve at least one (1) written communication annually to each Bt11 x MIR162 Corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Syngenta shall coordinate its education programs with educational efforts of other registrants and organizations, such as the National Corn Growers Association and state extension programs.

2) Annually, Syngenta shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey, required under paragraphs 6–9a & 9b 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 continue to implement and improve an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing Bt11 x MIR162 corn are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to Syngenta's *Bt* corn products. Syngenta shall coordinate with other *Bt* corn registrants in improving its compliance assurance program and 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 5–22 of this section.

***For sweet corn: The following IRM education and IRM compliance monitoring programs apply to all growers who plant more than 20 acres of Bt11 x MIR162 sweet corn. Annual grower survey requirements 6b and 9b for Bt11 x MIR162 sweet corn shall not require any action by Syngenta until a combined U.S. total of 50,000 acres per year have been planted of Attribute® Insect-Protected Sweet Corn (EPA Reg. No. 65268-1) and Bt11 x MIR162 sweet corn (Attribute® II Sweet Corn, EPA Reg. No. 67979-12).***

***For field corn: Requirements in the following IRM education and IRM compliance monitoring programs apply to Bt11 x MIR162 field corn without acreage limitations.***

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.

6a) Bt11 x MIR162 field corn: 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 MIR162 field corn who plant the vast majority of all corn in the United States and in areas in which the selection intensity is greatest. The survey shall consider only those growers who plant 200 or more acres of corn in the Corn Belt and who plant 100 or more acres of corn in corn-cotton areas. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from independent marketing research firms and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the United States.

i. A third party is defined as a party other than Syngenta, the grower, or anyone else with a direct interest in IRM compliance for *Bt* corn.

6b) Bt11 x MIR162 sweet corn: The IRM compliance assurance program shall include an annual survey of all Bt11 x MIR162 sweet corn customers who purchase five (5) or more bags of Bt11 x MIR162 sweet corn. The survey shall measure the degree of compliance with the IRM program, identify the response rate (e.g., the percent of Bt11 x MIR162 sweet corn acres covered by the responses), and consider the potential impact of non-response. An independent third party will participate in the design and implementation of the survey. Data and information derived from the annual survey will be audited by an independent third party.

i. A third party is defined as a party other than Syngenta, the grower, or anyone else with a direct interest in IRM compliance for *Bt* corn.

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

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

9a) Bt11 x MIR162 Field Corn: 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 31<sup>st</sup> of each year. Syngenta shall confer with other registrants and EPA on the design and content of the survey prior to its implementation.

9b) Bt11 x MIR162 Sweet Corn: Syngenta shall provide a final written summary of the results of the prior year's survey (together with a description of the methodology used and the supporting data) to EPA, on or before January 31<sup>st</sup> of each year. Syngenta shall confer with other registrants and EPA on the design and content of the survey prior to its implementation.

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

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

12) Syngenta shall carry out a program for investigating legitimate tips and complaints that Bt11 x MIR162 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 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, Syngenta shall provide a report to EPA summarizing the activities carried out under its compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. Within one (1) month of submitting this report to EPA, Syngenta shall meet with EPA to discuss its findings. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken. The report must inform EPA of the number of growers deemed ineligible to purchase *Bt* corn seed on the basis of continued non-compliance with the insect resistance management refuge requirements. Syngenta may elect to coordinate information with other registrants and report collectively the results of compliance assurance programs.

15) Syngenta and the seed corn dealers for Syngenta must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential

business information, including the names, personal information, and grower license numbers of the growers, will be protected.

16) Syngenta shall revise and expand its existing compliance assurance program to include the following elements. Syngenta must prepare and submit a written description of its revised compliance assurance program. Syngenta may coordinate with other registrants in designing and implementing its compliance assurance program.

***For sweet corn: Requirements 17-22 do not apply to Bt11 x MIR 162 sweet corn uses.***

***For field corn: Requirements 17-22 apply to Bt11 x MIR162 field corn without acreage limitations.***

17) 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 Bt11 x MIR162 corn seed bags or bag tags. The Bt11 x MIR162 corn label accepted by EPA must include how this information will be conveyed to growers via text and graphics.

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

- i. Use *Bt* corn adoption, pest pressure information, and other available information to identify regions where the risk of resistance is greatest.
- ii. Focus approximately two-thirds of on-farm assessments on these regions, with the remaining assessments conducted across other regions where Bt11 x MIR162 corn is used.

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

- i. Identify for potential on-farm assessment growers whose sales information indicates they have purchased Bt11 x MIR162 Corn but may have purchased little or no refuge seed from Syngenta, licensees, or affiliated companies.

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

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

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



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

- i. All growers found to be significantly out of compliance in a prior year will annually be sent additional refuge assistance information for a minimum of two (2) years by Syngenta, a seed supplier, or a third-party assessor, after completing the assessment process.
- ii. Syngenta will conduct follow-up checks on growers found to be significantly out of compliance within three (3) years after they are found to be back in compliance.
- iii. A grower found with a second incident of significant non-compliance with refuge requirements for Bt11 x MIR162 corn 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 for Bt11 x MIR162 Corn**

EPA is imposing the following conditions for the Cry1Ab and Vip3Aa20 toxins expressed in Bt11 x MIR162 Corn:

Syngenta will monitor for resistance to the Cry1Ab and Vip3Aa20 toxins expressed in Bt11 x MIR162 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

Syngenta will develop and ensure the implementation of a plan for resistance monitoring for *Spodoptera frugiperda* (fall armyworm; FAW) in counties in which Bt11, Bt11 x MIR162, or combined Bt11 and Bt11 x MIR162 sweet corn acreage exceeds 5,000 acres and the pest is capable of overwintering in that county. Syngenta should consult with academic and United States Department of Agriculture (USDA) experts in developing the monitoring plan and will provide EPA with a copy of its proposed resistance monitoring plan for EPA's approval prior to implementation. This proposed FAW monitoring plan must be submitted to EPA by January 31<sup>st</sup> of the year following that in which sweet corn acreage exceeds the trigger specified in this requirement (i.e., greater than 5,000 acres in any county in which FAW overwinters). The proposed plan must be implemented the season following the acreage trigger being met. The proposed plan will remain in place until an EPA-approved plan can be implemented.

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 Corn and/or changes in resistance allele frequency in response to the use of Bt11 x MIR162 Corn and, as far as possible, should be consistent across sampling years to enable comparisons with historical data. Monitoring for ECB is not required for the Vip3Aa20 toxin, since it is not active against this insect.

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 Corn. EPA shall be consulted prior to the implementation of such modifications.

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

Any incidence of unusually low sensitivity to the Cry1Ab and/or Vip3Aa20 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 31<sup>st</sup>. The investigative steps will include the following:

1. Re-test progeny of the collected population to determine whether the unusual bioassay response is reproducible and heritable. If it is not reproducible and heritable, no further action is required.
2. If the unusual response is reproducible and heritable, progeny of insects that survive the diagnostic concentration will be tested using methods that are representative of exposure to Bt11 x MIR162 Corn under field conditions. If progeny do not survive to adulthood, any suspected resistance is not field relevant and no further action is required.
3. If insects survive steps 1 and 2, resistance is confirmed, and further steps will be taken to evaluate the resistance. These steps may include the following:
  - determining the nature of the resistance (i.e., recessive or dominant, and the level of functional dominance);
  - estimating the resistance allele frequency in the original population;

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

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

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

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

If reports of unexpected levels of damage lead to the suspicion of resistance in any of the key target pests (ECB, SWCB, 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* 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 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 Corn fields in the affected region to control the target pest during the immediate growing season.
- Destroy Bt11 x MIR162 Corn crop residues in the affected region within one (1) month after harvest with a technique appropriate for local production practices to minimize the possibility of resistant insects over-wintering and contributing to the next season's target pest population.

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

### ***Confirmed Resistance***

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

- There is >30% insect survival and commensurate insect feeding in a bioassay, initiated with neonate larvae, that uses methods that are representative of exposure to *Bt* corn hybrids under field conditions (ECB and SWCB only).
- In standardized laboratory bioassays using diagnostic concentrations of the *Bt* protein suited to the target pest in question, the pest exhibits resistance that has a genetic basis and the level of survivorship indicates that there may be a resistance allele frequency of  $\geq 0.1$  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 thirty (30) days of resistance confirmation;
- Affected customers and extension agents will be notified about confirmed resistance within thirty (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 ninety (90) days according to the characteristics of the resistance event and local agronomic needs. Syngenta will consult with appropriate stakeholders in the development of the action plan, and the details of such a plan shall be approved by EPA prior to implementation;
- Notify affected parties (e.g., growers, consultants, extension agents, seed distributors, university cooperators, and state/federal authorities as appropriate) in the region of the resistance situation and approved action plan; and
- In subsequent growing seasons, maintain sales suspension and alternative resistance management strategies in the affected region(s) for the *Bt* corn hybrids that are affected by the resistant population until an EPA-approved local resistance management plan is in place to mitigate the resistance.

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

#### **e. Annual Reporting Requirements for Bt11 x MIR162 Corn**

- 1) Compliance Assurance Program: Compliance Assurance Program activities, including IRM Grower Survey results (if required) and on-farm assessment results for the prior year and plans for the compliance assurance program during the current year, on or before January 31<sup>st</sup> of each year.
- 2) Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, on or before August 31<sup>st</sup> 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

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EPA Reg. No. 67979-12  
OPP Decision Nos. 520414

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 these conditions are not complied with, the EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). A stamped copy of the product label is enclosed for your records.

If you have any questions, please feel free to contact me by phone at (703) 605-0515 or via email at [reynolds.alan@epa.gov](mailto:reynolds.alan@epa.gov).

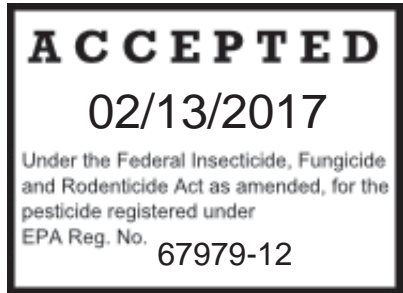
Sincerely,

A handwritten signature in black ink, appearing to read 'Alan Reynolds', with a long horizontal flourish extending to the right.

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

Enclosure

**Plant-incorporated Protectant Label**



**Bt11×MIR162 Corn**  
**Alternate brand names:**  
*Agrisure Viptera<sup>®</sup> 3110 Corn*  
*Agrisure Viptera<sup>®</sup> 3110A Corn*  
*Attribute<sup>®</sup> II Sweet Corn*

OECD Unique Identifier: SYN-BTØ11-1×SYN-IR162-4

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

**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) ..... ≤0.00233%\*

*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) ..... ≤0.0087%\*

**Other Ingredients:**

Phosphinothricin acetyltransferase marker protein and the genetic material necessary for its production (via elements of vector pZO1502) in corn event Bt11 (SYN-BTØ11-1) ..... ≤ 0.000101%\*

Phosphomannose isomerase marker protein and the genetic material necessary for its production (via elements of vector pNOV1300) in corn event MIR162 (SYN-IR162-4) ..... ≤ 0.00057%\*

\*Percentage in whole plants on a dry weight basis

**KEEP OUT OF REACH OF CHILDREN**  
**CAUTION**

EPA Reg. No. 67979-12  
EPA Est. No. 66736-NC-01

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

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## DIRECTIONS FOR USE

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

The subject registration will automatically expire at midnight on December 31, 2023.

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

All seed corn that contains the plant-incorporated protectant sold by Syngenta Seeds, LLC or its distributors 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 equivalence 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

Field and sweet corn have been genetically transformed to produce the insecticidal proteins, Cry1Ab and Vip3Aa20, 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 (*Pseudaletia unipuncta*)  
Black cutworm (*Agrotis ipsilon*)  
Western bean cutworm (*Striacosta albicosta*)  
Sugarcane borer (*Diatraea saccharalis*)  
Common stalk borer (*Papaipema nebris*)  
Lesser cornstalk borer (*Elasmopalpus lignosellus*)  
Dingy Cutworm (*Feltia jaculifera*)

### Insect Resistance Management

These insect resistance management requirements do not apply to breeding, research, or increase/propagation of inbred and hybrid Bt11×MIR162 seed corn up to a total of 20,000 acres per county and up to a combined United States (US) total of 250,000 acres per registrant per year.

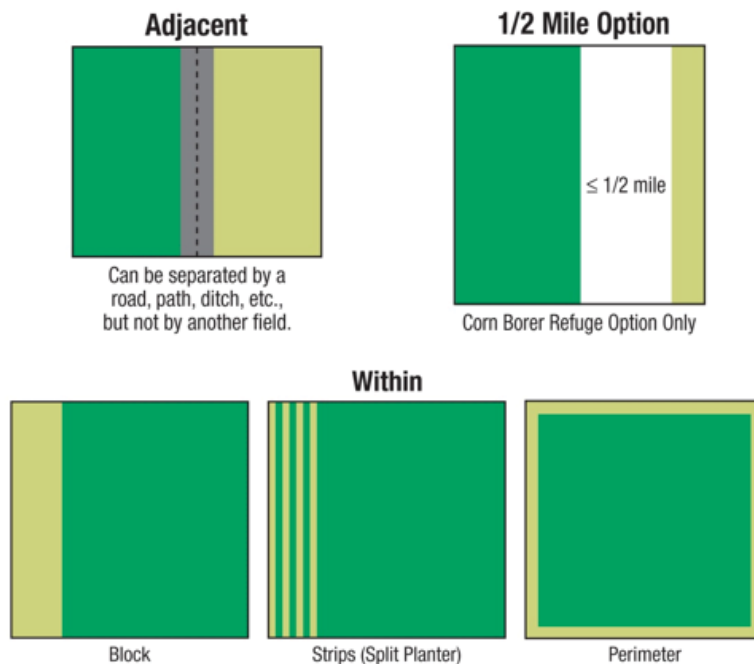
An IRM Stewardship Guide or equivalent guidance must be distributed to all customers planting this seed, with the exception of sweet corn home garden users. The guide will include instructions and recommendations regarding product use and insect resistance management. The following information regarding commercial production must be included in the IRM Stewardship Guide or equivalent guidance.



## **Bt11×MIR162 Field Corn**

- Growers must plant a structured refuge when using Bt11×MIR162 Field Corn. Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the Syngenta Stewardship Guide and/or in supplements to the Stewardship Guide.
- Growers must plant a 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 ½ mile of the Bt11×MIR162 corn field.
- If perimeter or in-field strips are implemented, the strips must be at least four consecutive rows wide.
- The refuge can be treated with an insecticide for control of European corn borer, corn earworm, Southwestern corn borer, and other lepidopteran pests listed on the label, 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). Microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.

The following are schematics of the various refuge deployment options:



The following text and graphic indicating the refuge size requirement must appear on Bt11×MIR162 seed bags or bag tags for field corn varieties.

**Important grower information.  
This hybrid requires you to plant:**



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

### **Bt11×MIR162 Sweet Corn**

- A refuge is not required for planting of sweet corn varieties. However, the crop must be destroyed within 30 days of harvest, preferably within 14 days of harvest.
- The allowed crop destruction methods for commercial plantings are: rotary mowing, discing, or plow-down. Crop destruction methods should destroy any surviving insects.

For home garden or educational use of Bt11×MIR162 sweet corn, the following informational material will appear on individual seed packets:

- This seed is for home garden and/or educational use only (total Bt11×MIR162 sweet corn planted must be less than 20 acres).
- Within 30 days of harvesting ears of corn, but preferably 14 days, corn plants must be chopped with a hoe or other garden tool to ensure that sweet corn insect pests do not develop resistance to this product.

In addition, IRM educational information will be available in seed catalogues and on websites offering Bt11×MIR162 sweet corn hybrids for sale to home gardeners.