



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

SEP 29 2010

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Dr. Demetra Vlachos  
Senior Regulatory Affairs Manager  
Syngenta Seeds, Inc. - Field Crops - NAFTA  
P.O. Box 12257, 3054 East Cornwallis Road  
Research Triangle Park, NC 27709

Re: Agrisure® RW (MIR604) Rootworm-Protected Corn  
EPA Registration No. 67979-5  
Application to amend the September 30, 2010 expiration date  
Submission dated 7/19/2010  
Decision No. 437600

Dear Dr. Vlachos:

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

- 1] The subject registration will automatically expire on midnight September 30, 2015.
- 2] The subject registration will be limited to Agrisure® RW (MIR604) Rootworm-Protected (MIR604) Corn with modified Cry3A protein and the genetic material necessary for its production (via elements of vector pZM26) in corn SYN-IR604-5.
- 3] Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires registrants of similar products to submit such data.
- 4] Three (3) year full-scale field or semi-field studies for evaluation of mCry3A Event MIR604 corn exposure on non-target invertebrates must be conducted. Full-scale field experiments must be appropriately designed to provide a measure of ecological impacts (larger fields, more replicates, more samples per plot based on recommendations of the August, 2002 SAP and subsequent relevant research on appropriate study design). A protocol is due within 90 days of the date of registration. A final report is due January 31, 2011.

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- 5] The subject plant-incorporated protectant may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.
- 6] You must commit to do the following Insect Resistance Management Program:

a. **Refuge Requirements.**

These refuge requirements do not apply to seed propagation of inbred and hybrid corn seed corn up to a total of 20,000 acres per county and up to a combined U.S. total of 250,000 acres per 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 are provided by Syngenta to help these growers meet the refuge requirements across their farming operations.

- 1) 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.
- 2) Specifically, growers must plant a structured refuge of at least 20% non-corn rootworm protected *Bt* corn that may be treated with insecticides as needed to control corn rootworm larvae. Growers will not be permitted to apply CRW labeled insecticides to the refuge for control of insect pests while adult corn rootworms are present unless the Agrisure® RW (MIR604) Rootworm-Protected Corn field is treated in a similar manner.
- 3) Refuge planting options include: refuge acres should be planted as blocks adjacent to Agrisure® RW (MIR604) Rootworm-Protected Corn Rootworm-Protected Corn fields, perimeter strips, or as in-field strips.
- 4) External refuges must be planted adjacent to (e.g., across the road from) Agrisure® RW (MIR604) Rootworm-Protected Corn fields.
- 5) When planting the refuge in strips across the field, refuges must be at least 4 consecutive rows wide.
- 6) Insecticide treatments for control of corn rootworm larvae may be applied. Instructions to growers will specify that insecticides labeled for control of corn rootworm adults cannot be applied while adults are present in the refuge unless the Agrisure® RW (MIR604) Rootworm-Protected Corn field is treated in a similar manner.

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- 7) If the refuge is planted in a field that is in a crop rotation system, then Agrisure® RW (MIR604) Rootworm-Protected Corn must also be planted in a field that is in a crop rotation system.
- 8) If the refuge is planted on continuous corn, then the Agrisure® RW (MIR604) Rootworm-Protected Corn field may be planted on either continuous or in a field that is in a crop rotation system.

**b. Grower Agreements**

- 1) Persons purchasing the *Bt* corn product must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.
- 2) The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
- 3) Syngenta must continue to integrate this amended registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing Agrisure® RW (MIR604) Rootworm-Protected Corn product will affirm annually that they are contractually bound to comply with the requirements of the IRM program.
- 4) Syngenta must continue to use its current grower agreement for Agrisure® RW (MIR604) Rootworm-Protected Corn product. If Syngenta wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty (30) days prior to implementing a proposed change, Syngenta must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of this amended registration.
- 5) Syngenta must continue to integrate this amended registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing Agrisure® RW (MIR604) Rootworm-Protected Corn product sign grower agreement(s).
- 6) Syngenta shall maintain records of all *Bt* corn grower agreements for a period of three years from December 31st of the year in which the agreement was signed.
- 7) Annually Syngenta shall provide EPA with a report showing the number of units of its *Bt* Agrisure® RW (MIR604) Rootworm-Protected Corn seeds sold or shipped and

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not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the twelve-month period covering the prior August through July.

- 8) Annually Syngenta shall submit annual 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 on or before January 31<sup>st</sup> each year.
- 9) Syngenta must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

**c. IRM Education and IRM Compliance Monitoring Programs**

- 1) Syngenta must continue to implement and enhance (as set forth in paragraph 17 of this section) a comprehensive, ongoing IRM education program designed to convey to Agrisure® RW (MIR604) Rootworm-Protected Corn product users the importance of complying with the IRM program. The program shall include information encouraging Agrisure® RW (MIR604) Rootworm-Protected Corn product users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Agrisure® RW (MIR604) Rootworm-Protected Corn product fields. The education program shall involve the use of multiple media (e.g., face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials). Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each Agrisure® RW (MIR604) Rootworm-Protected Corn product user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Syngenta shall coordinate its education programs with educational efforts of other registrants and organizations, such as the National Corn Growers Association and state extension programs.
- 2) Annually, Syngenta shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraph 6) and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.
- 3) Annually, Syngenta must provide a report to EPA summarizing the activities carried out under the education program for the prior year and any substantive changes to its grower education activities as part of the overall IRM Compliance Assurance Program (CAP) report. The required features of the Compliance Assurance Program are described in paragraphs 4 to 22 below.

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- 4) Syngenta must continue to implement and improve an ongoing IRM Compliance Assurance Program designed to evaluate the extent to which growers purchasing Agrisure® RW (MIR604) Rootworm-Protected Corn product are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to Syngenta corn PIP products. Syngenta shall coordinate with other *Bt* corn registrants in improving its Compliance Assurance Program and continue to integrate this amended registration into the current Compliance Assurance Program used for its other *Bt* corn plant-incorporated protectants. Other required features of the program are described in paragraphs 5–22.
- 5) Syngenta must maintain and publicize a “phased compliance approach,” i.e., a guidance document that indicates how it will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers after the first year of noncompliance. While recognizing that for reasons of difference in business practices there are needs for flexibility between different companies, all *Bt* corn registrants must use a consistent set of standards for responding to non-compliance. An individual grower found to be significantly out of compliance 2 years in a row would be denied access to the registrant’s *Bt* corn products the next year. Additionally, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell *Bt* corn.
- 6) The IRM Compliance Assurance Program shall include an annual survey conducted by an independent third party of a statistically representative sample of growers of *Bt* corn products who plant the vast majority of all corn in the U.S. and in areas in which the selection intensity is greatest. The survey shall consider only those growers who plant 200 or more acres of corn in the Corn-Belt and who plant 100 or more acres of corn in corn-cotton areas. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from the independent marketing research firm and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the U.S.
  - (a) A third party is classified as a party other than Syngenta, the grower, or anyone else with a direct interest in IRM compliance for *Bt* corn.
- 7) The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.
- 8) The survey shall be designed to obtain grower feedback on the usefulness of specific

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educational tools and initiatives.

- 9) Syngenta shall provide a final written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA by January 31.
- 10) Annually, Syngenta shall revise, and expand as necessary, its Compliance Assurance Program to take into account the information collected through the compliance survey required under paragraphs 6 through 8 and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. Syngenta must confer with the Agency prior to adopting any changes to a previously approved CAP.
- 11) Syngenta shall conduct an annual on-farm assessment program. Syngenta shall train its representatives who make on-farm visits with growers of their *Bt* corn products to perform assessments of compliance with IRM requirements. There is no minimum corn acreage size for this program. Therefore, growers will be selected for this program from across all farm sizes. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, Syngenta shall take appropriate action, consistent with its "phased compliance approach," to promote compliance.
- 12) Syngenta shall carry out a program for investigating legitimate "tips and complaints" that its growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, Syngenta shall take appropriate action, consistent with its "phased compliance approach."
- 13) If a grower, who purchases Agrisure® RW (MIR604) Rootworm-Protected *Bt* corn for planting, was specifically identified as not being in compliance during the previous year, Syngenta shall visit with the grower and evaluate whether that the grower is in compliance with the IRM program for the current year.
- 14) Each registrant shall annually provide a report to EPA summarizing the activities carried out under their compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken. The report must inform EPA of the number of growers deemed ineligible to purchase *Bt* corn seed on the basis of continued non-compliance with the insect resistance management refuge requirements. The registrants may elect to coordinate information and report collectively the results of their compliance assurance programs. Within one month of submitting this report to EPA, the registrant shall meet with EPA to discuss its findings.

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- 15) Syngenta and the seed corn dealers for Syngenta must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license number of the growers will be protected.
- 16) Syngenta shall revise and expand its existing Compliance Assurance Program to include the following elements. Syngenta must prepare and submit by January 31, 2011, a written description of its revised Compliance Assurance Program. Syngenta 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 to:
  - (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. This requirement may be phased in over the next three growing seasons. Revised PIP product labels must be submitted by January 31, 2011; 50% implementation on the *Bt* corn seed bags or bag tags must occur by the 2012 growing season; and full implementation must occur by the 2013 growing season.
- 18) Syngenta will focus the majority of on-farm assessments on regions with the greatest risks for resistance and will:
  - (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.
- 19) Syngenta will use its available *Bt* sales records and other information to refine grower lists for on-farm assessments of grower compliance with refuge requirements:
  - (a) Identify for potential on-farm assessment growers whose sales information indicates they have purchased the *Bt* corn product but may have purchased little or no refuge seed from Syngenta, licensee, or affiliated company.
- 20) Syngenta will contract with third parties to perform on-farm assessments of compliance with refuge requirements:

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- (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.
- 21) Syngenta will annually refine the on-farm assessment program for the *Bt* corn product to reflect the adoption rate and level of refuge compliance for the product.
- 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:
  - (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 2 years by Syngenta, a seed supplier, or a 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 3 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 Agrisure® RW (MIR604) Rootworm-Protected Corn product within a 5-year period will be denied access to and/or sales of the registrant's *Bt* corn products the next year.

**d. Insect Resistance Monitoring and Remedial Action Plan**

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

- 1) Syngenta must monitor for mCry3A resistance and/or trends in increased tolerance for corn rootworm. Sampling should be focused in those areas in which there is the highest risk of resistance development.
- 2) The resistance monitoring plan must include: baseline sensitivity data, sampling (number of locations, samples per locations), sampling methodology and life-stage sampled, bioassay methodology, standardization procedures (including QA/QC provisions), detection technique and sensitivity, the statistical analysis of the probability of detecting resistance, and an interim description of rootworm damage guidelines.
- 3) Syngenta must develop a functional diagnostic assay for corn rootworm resistance monitoring to detect potentially resistant individuals and incorporate this assay into the annual resistance monitoring program by the 2011 season with reporting in 2012. As part of this effort, Syngenta must investigate the feasibility of using the Sublethal



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Seedling Assay (Nowatzki et al. 2008)<sup>1</sup> as a diagnostic assay. A report on Syngenta's progress towards this requirement must be submitted to EPA within six (6) months from the date of this amended registration.

- 3) Syngenta must develop a proactive resistance monitoring program for northern corn rootworm (*Diabrotica barberi*) by the 2012 season with reporting in 2013. This program should include a proposal for annual sampling and testing of northern corn rootworm susceptibility to mCry3A toxin. As part of the effort, Syngenta may need to investigate novel techniques for rearing and conducting bioassays with northern corn rootworm. A report on Syngenta's progress towards this requirement must be submitted within one year (12 months) from the date of this amended registration.
- 4) Syngenta must submit revised corn rootworm damage guidelines (to characterize unexpected pest damage). The revised guidelines must take into consideration the comments and recommendations from EPA's June 30, 2010, review of the rootworm resistance monitoring program for mCry3A. A report on this requirement must be submitted to the Agency within six (6) months from the date of the amended registration.
- 5) Syngenta must follow-up on grower, extension specialist or consultant reports of unexpected damage or control failures for corn rootworm.
- 6) Syngenta must provide EPA with an annual resistance monitoring report by August 31st of each year, reporting on populations collected the previous year.

e. **Remedial Action Plans**

The following program summary describes, in order of events, the steps that must be taken to implement a remedial action plan if resistance to target pests is confirmed (this general process has been implemented for CRW *Bt* corn products).

- 1) **Definition of Suspected Resistance:** Resistance will be suspected if investigations of unexpected damage reports show that:
  - (a) implicated maize plant roots were expressing the mCry3A protein at the expected level;
  - (b) alternative causes of damage or lodging, such as non-target pest insect species, weather, physical damage, larval movement from alternate hosts, planting errors, and other reasonable causes for the observations, have been ruled out;

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<sup>1</sup> Reference: Nowatzki, T., S.A. Lefko, R.R. Binning, S.D. Thompson, T.A. Spencer, B.D. Siegfried, 2008. Validation of a novel resistance monitoring technique for corn rootworm (Coleoptera: Chrysomelidae) and event DAS-59122-7 maize. *J. Appl. Entomol.* 132: 177-188.

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- (c) the level of damage exceeds guidelines for expected damage.
- 2) If resistance is “suspected”, Syngenta will instruct affected growers to use alternate pest control measures such as adulticide treatment, crop rotation the following year, or use of soil or seed insecticides the following year. These measures are intended to reduce the possibility of potentially resistant insects contributing to the following year’s pest population.
- 3) **Confirmation of Resistance:** Resistance will be confirmed if all of the following criteria are met by progeny from the target pest species sampled from the area of “suspected resistance:”
- (a) the proportion of larvae that can feed and survive on mCry3A roots from neonate to adult is significantly higher than the baseline proportion (currently being established);
  - (b) the  $LC_{50}$  of the test population exceeds the upper limit of the 95% confidence interval for the  $LC_{50}$  of a standard unselected population and/or survival in the diagnostic assay is significantly greater than that of a standard unselected population, as established by the ongoing baseline monitoring program;
  - (c) the ability to survive is heritable;
  - (d) mCry3A plant assays determine that damage caused by surviving insects would exceed economic thresholds;
  - (e) the identified frequency of field resistance could lead to widespread product failure if subsequent collections in the affected field area(s) demonstrated similar bioassay results.
- 4) **Response to Confirmed Resistance:** When resistance is “confirmed”, the following steps will be taken:
- (a) EPA will receive notification within 30 days of resistance confirmation;
  - (b) affected customers and extension agents will be notified about confirmed resistance;
  - (c) affected customers and extension agents will be encouraged to employ alternative CRW control measures;
  - (d) sale and distribution of mCry3A maize in the affected area will cease immediately;

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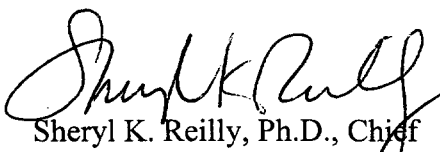
(e) a long-term resistance management action plan will be devised according to the characteristics of the resistance event and local agronomic needs. The details of such a plan should be approved by EPA and all appropriate stakeholders.

**f. Annual Reporting Requirements**

- 1) Annual Sales: reported and summed by state (county level data available by request), January 31st each year;
- 2) Grower Agreement: number of units of *Bt* corn seeds shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements, January 31st each year;
- 3) Grower Education: substantive changes to education program completed previous year, January 31st each year;
- 4) Compliance Assurance Plan: Compliance Assurance Program activities and results, January 31st each year;
- 5) Compliance: to include annual survey results and plans for the next year; full report January 31st each year;
- 6) Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, August 31st each year.

The confidential statement of formula dated July 9, 2010 is acceptable. A copy has been placed in the file jacket for this registration.

Sincerely,

  
 Sheryl K. Reilly, Ph.D., Chief  
 Microbial Pesticides Branch  
 Biopesticides and Pollution  
 Prevention Division (7511P)

Enclosure (1):  
Accepted Agrisure® RW (MIR604) Rootworm-Protected Corn Label

120813

# Agrisure® RW Rootworm-Protected Corn

[Alternate brand name: Agrisure® GT/RW Corn]

## Plant-Incorporated Protectant: Modified Cry3A Protein for Corn Rootworm Control

This product is effective in controlling or suppressing damage caused by larvae of some corn rootworm species feeding on corn roots.

### Active Ingredient:

Modified Cry3A protein and the genetic material necessary for its production (via elements of vector pZM26) in corn (SYN-IR6Ø4-5)..... ≤ 0.0029%\*

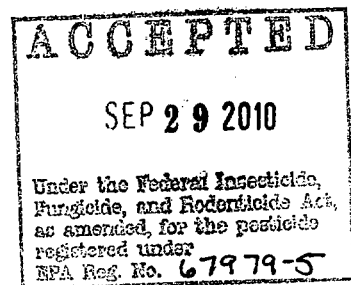
### Other Ingredients:

Phosphomannose isomerase and the genetic material necessary for its production (via elements of vector pZM26) in corn (SYN-IR6Ø4-5)..... ≤ 0.00025%\*

\*Percentage in whole plants on a dry-weight basis.

Keep Out of Reach of Children

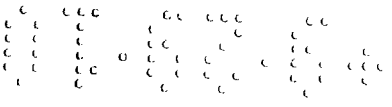
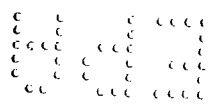
**CAUTION**



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EPA Establishment No. 66736-NC-001

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



### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This registration will automatically expire on midnight September 30, 2015.

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.

The following information regarding commercial planting must be included in the Grower Guide for Agrisure® RW Rootworm-Protected Corn.

#### Insect Resistance Management

Growers of Agrisure® RW Rootworm-Protected Corn must plant a structured refuge of at least 20% non-corn-rootworm-protected Bt corn that may be treated with insecticides as needed to control corn rootworm larvae. Growers will not be permitted to apply corn-rootworm-labeled insecticides to the refuge for control of insect pests while adult corn rootworm are present unless the Agrisure® RW Rootworm-Protected Corn field is treated in a similar manner.

Refuge planting options include: refuge acres should be planted as blocks adjacent to Agrisure® RW Rootworm-Protected Corn fields, perimeter strips, or as in-field strips.

External refuges must be planted adjacent to (e.g., across the road from) Agrisure® RW Rootworm-Protected Corn fields.

When planting the refuge in strips across the field, refuges must be at least 4 consecutive rows wide.

Insecticide treatments for control of corn rootworm larvae may be applied. Instructions to growers will specify that insecticides labeled for control of corn rootworm adults cannot be applied while adults are present in the refuge unless the Agrisure® RW Rootworm-Protected Corn field is treated in a similar manner.

If the refuge is planted in a field that is in a crop rotation system, then Agrisure® RW Rootworm-Protected Corn must also be planted in a field that is in a crop rotation system.

If the refuge is planted on continuous corn, then the Agrisure® RW Rootworm-Protected Corn field may be planted on either continuous corn or in a field that is in a crop rotation system.

These refuge requirements do not apply to seed propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined U.S. total of 250,000 acres per PIP active ingredient per registrant per year.

#### Corn Insects Controlled or Suppressed

Corn has been genetically transformed to produce a modified Cry3A protein for control or suppression of the following coleopteran insects:

- Western corn rootworm (*Diabrotica virgifera virgifera*)
- Northern corn rootworm (*Diabrotica longicornis barberi*)
- Mexican corn rootworm (*Diabrotica virgifera zea*)

