UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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

SEP 29 2010

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Dr. Laura A. Tagliani
Global Regulatory Leader
Mycogen Seeds c/o Dow AgroSciences LLC
9330 Zionsville Road
Indianapolis, IN 46268

Re: Mycogen Seeds c/o Dow AgroSciences LLC; Herculex® RW Insect Protection
EPA Registration No. 68467-5
Amendment to convert Herculex® RW Insect Protection corn from a conditional, time-limited registration to an unconditional registration with no expiration date
Submission dated 03/22/2010
Decision No. 431072

Dear Dr. Tagliani:

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 Cry34Ab1 and Cry35Ab1 [*Bacillus thuringiensis* Cry34Ab1 and Cry35Ab1 proteins and the genetic material necessary for their production (PHP17662 T-DNA) in event DAS-59122-7 corn (OECD Unique Identifier: DAS-59122-7)] for use in field corn.

3) Submit/cite all data required for registration of your product under FIFRA section 3(c)(5) when the Environmental Protection Agency (EPA) requires registrants of similar products to submit such data.

CONCURRENCES								
SYMBOL ▶	7511P	7511P	7511P					
SURNAME ▶	KAVSCH	Reynolds	Hill					
DATE ▶	09/29/2010	9/29/10	9/29/10					

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) Should you wish to amend the refuge treatment option to allow independent treatment of the refuge for pests other than corn rootworms, data would be required regarding the impact of independent treatment of the refuge for other pests (not corn rootworm, e.g., corn borers, spider mites) on corn rootworm resistance management.

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

- Requirements relating to creation of a non-(corn rootworm-protected PIP) corn refuge in conjunction with the planting of any acreage of commercial Herculex® RW Insect Protection corn.

- Requirements for Mycogen Seeds c/o Dow AgroSciences LLC (DAS) to prepare and require Herculex® RW Insect Protection corn users to sign grower agreements that impose binding contractual obligations on growers to comply with the refuge requirements.

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

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

- Requirements for DAS 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 Cry34Ab1 and Cry35Ab1 proteins in the target insects.

- Requirements for DAS to develop, and if triggered, to implement a remedial action plan that would contain measures DAS 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 DAS, on or before January 31st of each year, to submit reports on units sold by state (units sold by county level will made available to EPA upon request), IRM grower agreement results, and the compliance assurance program, including the education program.

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

Dr. Laura A. Tagliani
EPA Registration No. 68467-5

a. Refuge Requirements for Herculex® RW Insect Protection 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 (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 *Bacillus thuringiensis* (*Bt*) corn products, additional educational material and assistance will be provided by DAS to help these growers meet the refuge requirements across their farming operations.

Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

1) *Refuge size.* The use of Herculex® RW Insect Protection corn from event DAS-59122-7 requires an accompanying 20% refuge.

2) *Refuge location.* The rootworm refuge is required to be planted within or adjacent (e.g., across the road) to the Herculex® RW Insect Protection corn field.

3) *Refuge management options.* The rootworm refuge may be managed in such a way that there is little or no yield loss to rootworms, but must be managed in a way that it is sufficiently productive of susceptible rootworm adults.

- The in-field refuge options must be planted as a single block or as a series of strips measuring at least four (4) consecutive crop rows wide.
- Seed mixtures of Herculex® RW Insect Protection and refuge corn are not permitted.
- If the refuge is planted on rotated ground, then Herculex® RW Insect Protection corn must also be planted on rotated ground.
- If the refuge is planted in continuous corn, the Herculex® RW Insect Protection corn field may be planted on either continuous or rotated land (option encouraged where western corn rootworm rotation-resistant biotype may be present).
- Application of soil insecticide is permitted in the refuge.
- Seed treatment is permitted in the refuge, either at a rate for rootworm protection or at a rate for controlling secondary soil pests.

- If aerial insecticides are applied to the refuge for control of corn rootworm adults, the same treatment must also be applied in the same time frame to Herculex® RW Insect Protection corn.

- Pests other than adult corn rootworms can only be treated with corn rootworm-labeled insecticides on the refuge acres without treating the Herculex® RW Insect Protection corn acres if treatment occurs when adult corn rootworms are not present. Pests on the Herculex® RW Insect Protection corn acres can be treated as needed without having to treat the refuge.

- The rootworm refuge can be planted to any corn hybrid that does not express plant-incorporated protectants for rootworm control (e.g., lepidopteran-protected *Bt* corn, herbicide-tolerant corn, or conventional corn).

- The refuge and Herculex® RW Insect Protection corn should be sown on the same day, or with the shortest window possible between planting dates, to ensure that corn root development is similar among varieties.

- Growers are encouraged to plant the rootworm refuge in the same location each year, as it allows the rootworm population to remain high and the durability of the trait is extended. This option may be preferable to growers who wish to only think of their refuge design once and for growers who grow continuous corn; however, for those growers who need to employ crop rotation, a fixed refuge would be impractical.

b. Grower Agreements for Herculex® RW Insect Protection Corn

1) Persons purchasing Herculex® RW Insect Protection 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) DAS 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 Herculex® RW Insect Protection corn will affirm annually that they are contractually bound to comply with the requirements of the IRM program.

4) DAS must continue to use its current grower agreement for Herculex® RW Insect Protection corn. If DAS 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, DAS 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) DAS 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 Herculex® RW Insect Protection corn sign grower agreement(s).

6) DAS shall maintain records of all Herculex® RW Insect Protection corn grower agreements for a period of three (3) years from December 31st of the year in which the agreement was signed.

7) Annually, DAS shall provide EPA with a report showing the number of units of Herculex® RW Insect Protection corn seeds sold or shipped and 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 12-month period covering the prior August through July.

8) DAS 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 Herculex® RW Insect Protection Corn

1) DAS 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 Herculex® RW Insect Protection corn users the importance of complying with the IRM program. The program shall include information encouraging Herculex® RW Insect Protection corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Herculex® RW Insect Protection corn fields. The education program shall involve the use of multiple media (e.g., face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials). Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each Herculex® RW Insect Protection corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. DAS 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, DAS shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey, required under paragraph 6–8 of this section, and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

3) Annually, DAS must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. DAS must either submit a separate report or contribute to the report from the industry working group, Agricultural Biotechnology Stewardship Technical Committee (ABSTC). The required features of the compliance assurance program are described in paragraphs 4–22 of this section.

4) DAS must continue to implement and improve an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing Herculex® RW Insect Protection 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 DAS' *Bt* corn products. DAS 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 of this section.

5) DAS 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, DAS 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 to DAS' *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.

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 Herculex® RW Insect Protection 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 classified as a party other than DAS, 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) DAS shall provide a final written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA on or before January 31st of each year. DAS shall confer with other registrants and EPA on the design and content of the survey prior to its implementation.

10) Annually, DAS shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey, required under paragraphs 6–8 of this section, and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. DAS must confer with EPA prior to adopting any changes.

11) DAS shall conduct an annual on-farm assessment program. DAS shall train its representatives who make on-farm visits with Herculex® RW Insect Protection 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, DAS shall take appropriate action, consistent with its phased compliance approach, to promote compliance.

12) DAS shall carry out a program for investigating legitimate tips and complaints that Herculex® RW Insect Protection 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, DAS shall take appropriate action, consistent with its phased compliance approach.

13) If a grower, who purchases Herculex® RW Insect Protection corn for planting, was specifically identified as not being in compliance during the previous year, DAS shall visit with the grower and evaluate whether the grower is in compliance with the IRM program for the current year.

14) Annually, DAS 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, DAS 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. DAS may elect to coordinate information with other registrants and report collectively the results of compliance assurance programs.

15) DAS and the seed corn dealers for DAS 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) DAS shall revise and expand its existing compliance assurance program to include the following elements. DAS must prepare and submit, on or before January 31, 2011, a written description of its revised compliance assurance program. DAS may coordinate with other registrants in designing and implementing its compliance assurance program.

17) DAS will enhance the refuge education program throughout the seed delivery channel:

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 Herculex® RW Insect Protection corn seed bags or bag tags. The Herculex® RW Insect Protection corn 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 (3) growing seasons. Revised Herculex® RW Insect Protection corn labels must be submitted by January 31, 2011, 50% implementation on the Herculex® RW Insect Protection corn bags or bag tags must occur by the 2012 growing season, and full implementation must occur by the 2013 growing season.

18) DAS 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 Herculex® RW Insect Protection corn is used.

19) DAS will use its available Herculex® RW Insect Protection corn sales records and other information to refine grower lists for on-farm assessments of their compliance with refuge requirements:

i. Identify for potential on-farm assessment growers whose sales information indicates they have purchased Herculex® RW Insect Protection corn but may have purchased little or no refuge seed from DAS, licensees, or affiliated companies.

20) DAS 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, DAS will refine the on-farm assessment program for Herculex® RW Insect Protection corn to reflect the adoption rate and level of refuge compliance for Herculex® RW Insect Protection corn.

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

i. All growers found to be significantly out of compliance in a prior year will annually be sent additional refuge assistance information for a minimum of 2 years by DAS, a seed supplier, or a third-party assessor, after completing the assessment process.

ii. DAS 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 Herculex® RW Insect Protection corn within a 5-year period will be denied access to DAS' *Bt* corn products the next year.

d. Insect Resistance Monitoring and Remedial Action Plan for Herculex® RW Insect Protection Corn

EPA is imposing the following conditions for the Cry34Ab1 and Cry35Ab1 toxins expressed in Herculex® RW Insect Protection corn:

1) DAS must monitor for Cry34/35Ab1 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 the following: baseline sensitivity data, sampling (number of locations, samples per locations), sampling methodology and life stage sampled, bioassay methodology, standardization procedures (including quality assurance/quality control provisions), detection technique and sensitivity, statistical analysis of the probability of detecting resistance, and a revised description of rootworm damage guidelines.

3) DAS 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, DAS must investigate the feasibility of using the Sublethal Seedling Assay[1] as a diagnostic assay. A report of DAS' progress towards this requirement must be submitted to EPA within six (6) months from the date of this amended registration.

4) DAS 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 Cry34/35Ab1. As part of the effort, DAS may need to investigate novel techniques for rearing and conducting bioassays with northern corn rootworm. A report on DAS' progress towards this requirement must be submitted within one (1) year from the date of this amended registration.

5) DAS must submit revised corn rootworm damage guidelines (to characterize unexpected pest damage) that take into consideration the comments and recommendations from EPA's June 30, 2010 review of the rootworm resistance monitoring program for Cry34/35Ab1 within six (6) months from the date of this amended registration.

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

7) DAS must provide EPA with a resistance monitoring report on or before August 31st of each year, reporting on populations collected the previous year.

---

[1] Nowatzki T, Lefko SA, Binning RR, Thompson SD, Spencer TA, Siegfried BD. 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.

8) The remedial action plan is designed as a tiered approach for mitigating *Diabrotica virgifera virgifera* (western corn rootworm; WCRW), *Diabrotica barberi* (northern corn rootworm; NCRW), and *Diabrotica virgifera zeae* (Mexican corn rootworm; MCRW) resistance development to the Cry34Ab1 and Cry35Ab1 proteins. The following program summary describes, in order of events, the steps that must be taken to implement a remedial action plan if resistance to the target pests is confirmed.

Definition of Suspected Resistance

Resistance will be ***suspected*** if investigations of unexpected damage reports show the following:

i. implicated corn plant roots were expressing the Cry34Ab1 and Cry35Ab1 proteins at the expected levels;

ii. the seed used was not mixed with non-Cry34/35Ab1 seed;

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

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

If resistance is ***suspected***, DAS 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.

Confirmation of Resistance

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

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

ii. 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;

iii. the ability to survive is heritable;

iv. Herculex® RW Insect Protection corn plant assays determine that damage caused by surviving insects would exceed economic thresholds; and

v. if subsequent collections in the affected field area demonstrate similar bioassay results.

Response to Confirmed Resistance

When resistance is ***confirmed***, the following steps will be taken:

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

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

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

iv. sale and distribution of Herculex® RW Insect Protection corn in the affected area will cease immediately; and

v. a long-term resistance management action plan will be devised according to the characteristics of the resistance event and local agronomic needs.

e. Annual Reporting Requirements for Herculex® RW Insect Protection Corn

1) Annual Sales: reported and summed by state (county level data available by request), on or before January 31st of each year.

2) Grower Agreement Results: number of units of Herculex® RW Insect Protection corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements, on or before January 31st of each year.

3) Grower Education: substantive changes to the education program completed during the previous year, on or before January 31st of each year.

4) Compliance Assurance Program: compliance assurance program activities and results for the previous year and plans for the compliance assurance program during the current year, on or before January 31st of each year.

5) Compliance Assurance Program Survey Results: survey results for the previous year and plans for the current year, on or before January 31st of each year.

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

Dr. Laura A. Tagliani
EPA Registration No. 68467-5

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

Sincerely,

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

Enclosure (1):
-Accepted Herculex® RW Insect Protection Label

Herculex® RW Insect Protection

OECD Unique Identifier: DAS-59122-7

Active Ingredients:

Bacillus thuringiensis Cry34Ab1 protein and the genetic material (PHP17662-T-DNA) necessary for its production in corn event DAS-59122-7 ..... ≤ 0.0088%*

Bacillus thuringiensis Cry35Ab1 protein and the genetic material (PHP17662-T-DNA) necessary for its production in corn event DAS-59122-7 ..... ≤ 0.00181%*

Other Ingredient:

Phosphinothricin acetyltransferase (PAT) protein and the genetic material (PHP17662-T-DNA) necessary for its production in corn event DAS-59122-7..... ≤ 0.000058%*

*% total protein on a dry weight basis in plant cells (whole plant)

KEEP OUT OF REACH OF CHILDREN
CAUTION

EPA REGISTRATION NUMBER: 68467-5

EPA ESTABLISHMENT NUMBER: 62719-IN-1

Mycogen Seeds
c/o Dow AgroSciences LLC
9330 Zionsville Road
Indianapolis IN 46268

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 on midnight September 30, 2015.

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.

The plant-incorporated protectant must be used as specified in the terms and conditions of the registration.

Herculex® RW Insect Protection corn has been transformed to express the *Bacillus thuringiensis* (*B.t.*) strain PS149B1 Cry34/35Ab1 insecticidal crystal proteins (ICPs) for the control of western corn rootworm (*Diabrotica virgifera virgifera*), northern corn rootworm (*Diabrotica barberi*), and Mexican corn rootworm (*Diabrotica virgifera zeae*) pests.

Routine applications of insecticides to control western corn rootworm, northern corn rootworm, or Mexican corn rootworm are unnecessary for corn containing the *B.t.* Cry34/35Ab1 ICPs.

INSECT RESISTANCE MANAGEMENT

Growers are instructed to read information on insect resistance management.

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year.

The following information regarding refuge placement for commercial production must be included in the Growing Guide.

1. *Refuge size.* The use of Herculex® RW Insect Protection corn from event DAS-59122-7 requires an accompanying 20% refuge.

2. *Refuge location.* The rootworm refuge is required to be planted within or adjacent (e.g., across the road) to the Herculex® RW Insect Protection corn field.

3. *Refuge management options.* The rootworm refuge may be managed in such a way that there is little or no yield loss to rootworms, but must be managed in a way that it is sufficiently productive of susceptible rootworm adults.
    - The in-field refuge options must be planted as a single block or as a series of strips measuring at least four (4) consecutive crop rows wide.
    - Seed mixtures of Herculex® RW Insect Protection and refuge corn are not permitted.
    - If the refuge is planted on rotated ground, then Herculex® RW Insect Protection corn must also be planted on rotated ground.
    - If the refuge is planted in continuous corn, the Herculex® RW Insect Protection corn field may be planted on either continuous or rotated land (option encouraged where WCRW rotation-resistant biotype may be present).
    - Application of soil insecticide is permitted in the refuge.
    - Seed treatment is permitted in the refuge, either at a rate for rootworm protection or at a rate for controlling secondary soil pests.

- If aerial insecticides are applied to the refuge for control of CRW adults, the same treatment must also be applied in the same time-frame to Herculex® RW Insect Protection corn.
- Pests other than adult corn rootworms can only be treated with CRW-labeled insecticide on the refuge acres without treating the Herculex® RW Insect Protection corn acres only if treatment occurs when adult corn rootworms are not present. Pests on the Herculex® RW Insect Protection corn acres can be treated as needed without having to treat the refuge.
- The rootworm refuge can be planted to any corn hybrid that does not express PIPs for rootworm control (e.g., lepidopteran-protected *B.t.* corn, herbicide-tolerant corn, or conventional corn).
- The refuge and Herculex® RW Insect Protection corn should be sown on the same day, or with the shortest window possible between planting dates, to ensure that corn root development is similar among varieties.
- Growers are encouraged to plant the rootworm refuge in the same location each year, as it allows the rootworm population to remain high and the durability of the trait is extended. This option may be preferable to growers who wish to only think of their refuge design once and for growers who grow continuous corn. However, for those growers who need to employ crop rotation, a fixed refuge would be impractical.

USE PATTERN

CROP	PESTS
field corn	western corn rootworm northern corn rootworm Mexican corn rootworm

EPA Accepted: __/__/____