

68467-6

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1 of 26

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® XTRA Insect Protection  
EPA Registration No. 68467-6  
Amendment to convert Herculex® XTRA Insect Protection corn from a  
conditional, time-limited registration to an unconditional registration with no  
expiration date  
Submission dated 03/22/2010  
Decision No. 431070

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 Cry1F [*Bacillus thuringiensis* Cry1F protein and the genetic material necessary for its production (plasmid insert PHP8999A) in event TC1507 corn (OECD Unique Identifier: DAS-Ø15Ø7-1)] x 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

YMBOL	7511P	7511P	7511P				
URNAM	KAUSEH	Reynolds	Quilley				
DATE	09/29/2010	9/29/10	9/29/10				

Dr. Laura A. Tagliani  
EPA Registration No. 68467-6

4) Submit/cite all data, determined by EPA to be acceptable and required to support the individual plant-incorporated protectants in Herculex® I Insect Protection and Herculex® RW Insect Protection, within the time frames required by the terms and conditions of EPA Registration Numbers 68467-2 and 68467-5, respectively.

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

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

- Requirements relating to creation of a refuge for the Cry1F and Cry34/35Ab1 components that meets the requirements of the individual traits. The refuge for both traits may be combined by planting non-*Bacillus thuringiensis* (*Bt*) corn as the refuge, or the refuge for each trait may be planted separately. In the latter case, corn rootworm-resistant *Bt* corn may be planted in the lepidopteran refuge for the Cry1F component, and lepidopteran-resistant *Bt* corn may be planted in the corn rootworm refuge for the Cry34/35Ab1 component.
- Requirements for Mycogen Seeds c/o Dow AgroSciences LLC (DAS) to prepare and require Herculex® XTRA 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 Cry1F and Cry34/35Ab1 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 31<sup>st</sup> 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.

Dr. Laura A. Tagliani  
EPA Registration No. 68467-6

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

**a. Refuge Requirements for Herculex® XTRA 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 *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.

The use of Herculex® XTRA Insect Protection corn requires accompanying refuge corn for both the Cry1F and Cry34/35Ab1 components that meets the requirements of the individual traits, as described below. The refuge for both traits may be combined by planting non-*Bt* corn as the refuge (see the “Combined Refuge Option” section), or the refuge for each trait may be planted separately (see the “Lepidopteran Refuge for the Cry1F Component” and “Corn Rootworm Refuge for the Cry34/35Ab1 Component” sections).

For the separate refuges, corn rootworm-resistant *Bt* corn (e.g., Herculex® RW Insect Protection) may be planted in the lepidopteran refuge for the Cry1F component, and lepidopteran-resistant *Bt* corn (e.g., Herculex® I Insect Protection) may be planted in the corn rootworm refuge for the Cry34/35Ab1 component. Depending on cropping practices, pest problems, and pest management options employed on any given farm, growers may need to choose different refuge arrangements for different fields. Two refuge blocks (one for rootworm, one for Lepidoptera) can be planted within one field, or strips can be used for either refuge. Alternatively, a block of Herculex® RW Insect Protection corn can serve as an in-field lepidopteran refuge for one field planted to Herculex® XTRA Insect Protection corn and an external lepidopteran refuge for separate fields planted to Herculex® XTRA Insect Protection corn, while the rootworm refuge is planted as Herculex® I Insect Protection corn in an external adjacent field. In all options, size and management of each individual refuge must be followed as described in the “Lepidopteran Refuge for the Cry1F Component” and “Corn Rootworm Refuge for the Cry34/35Ab1 Component” sections.

Other refuge designs and combinations are permissible as long as, in all cases, the size and management of each refuge are described in the “Lepidopteran Refuge for the Cry1F Component,” “Corn Rootworm Refuge for the Cry34/35Ab1 Component,” or “Combined Refuge Option” sections.

Dr. Laura A. Tagliani  
EPA Registration No. 68467-6

Lepidopteran Refuge for the Cry1F Component

1) *Refuge size, Corn-growing areas (Corn Belt and other non-corn/cotton-growing areas).* The use of Herculex® XTRA Insect Protection corn requires an accompanying 20% refuge consisting of non-*Bt* corn or corn that is not a lepidopteran-protected *Bt* hybrid.

2) \**Refuge size, Corn/cotton-growing areas.* The use of Herculex® XTRA Insect Protection corn requires an accompanying 50% refuge consisting of non-*Bt* corn or corn that is not a lepidopteran-protected *Bt* hybrid.

3) *Refuge location.*

- The lepidopteran refuge can be planted in a separate field not more than ½ mile from the Herculex® XTRA Insect Protection corn field.
- The lepidopteran refuge can be planted within the Herculex® XTRA Insect Protection corn field as blocks (e.g., along the edges or headlands).
- The lepidopteran refuge can be planted within the Herculex® XTRA Insect Protection corn field as strips across the field at least four (4) consecutive rows wide.

4) *Refuge management.*

Insecticide treatment for European corn borer (ECB), corn earworm (CEW), southwestern corn borer (SWCB), 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 refuges consisting of non-*Bt* corn or corn that is not a lepidopteran-protected *Bt* hybrid.

\*Cotton-growing areas include the following states: Alabama, Arkansas, Florida, Georgia, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex), and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

Dr. Laura A. Tagliani  
EPA Registration No. 68467-6

### Corn Rootworm Refuge for the Cry34/35Ab1 Component

- 1) *Refuge size.* The use of Herculex® XTRA Insect Protection corn requires an accompanying 20% refuge consisting of non-*Bt* corn or corn that is not a rootworm-protected *Bt* hybrid.
- 2) *Refuge location.* The rootworm refuge is required to be planted within or adjacent (e.g., across the road) to the Herculex® XTRA Insect Protection corn field.
- 3) *Refuge management options.* The rootworm refuge can 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 rootworm 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® XTRA Insect Protection and rootworm refuge corn are not permitted.
  - If the rootworm refuge is planted on rotated ground, then Herculex® XTRA Insect Protection corn must also be planted on rotated ground.
  - If the rootworm refuge is planted in continuous corn, the Herculex® XTRA 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 rootworm refuge.
  - Seed treatment is permitted in the rootworm refuge, either at a rate for rootworm protection or at a rate for controlling secondary soil pests.
  - If aerial insecticides are applied to the rootworm refuge for control of corn rootworm adults, the same treatment must also be applied in the same time frame to Herculex® XTRA Insect Protection corn.
  - Pests other than adult corn rootworms can be treated on the rootworm refuge acres without treating the Herculex® XTRA Insect Protection corn acres only if treatment occurs when adult corn rootworms are not present or if pesticide without activity against adult corn rootworms is used. Pests on the Herculex® XTRA Insect Protection corn acres can be treated as needed without having to treat the rootworm 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).

Dr. Laura A. Tagliani  
EPA Registration No. 68467-6

- The rootworm refuge and Herculex® XTRA 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.

Combined Refuge Option

For the combined refuge option (i.e., the lepidopteran refuge combined with the rootworm refuge by planting non-Bt corn), the refuge must be planted and managed such that it is consistent with the requirements of the individual traits, Cry1F and Cry34/35Ab1.

- 1) *Refuge size.* The use of Herculex® XTRA Insect Protection corn requires an accompanying 20% refuge in corn-growing areas and 50% refuge in cotton-growing areas consisting of non-Bt corn. For the latter, see the list of states labeled with "\*" in the "Lepidopteran Refuge for the Cry1F Component" section.
- 2) *Refuge location.* The combined refuge is required to be planted within or adjacent (e.g., across the road) to the Herculex® XTRA Insect Protection corn field.
- 3) *Refuge management options.*
  - The in-field combined 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® XTRA Insect Protection and combined refuge corn are not permitted.
  - If the combined refuge is planted on rotated ground, then Herculex® XTRA Insect Protection corn must also be planted on rotated ground.
  - If the combined refuge is planted in continuous corn, the Herculex® XTRA 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 for corn rootworm control is permitted in the combined refuge.
  - Seed treatment is permitted in the combined refuge, either at a rate for rootworm protection or at a rate for controlling secondary soil pests.

70924

Dr. Laura A. Tagliani  
EPA Registration No. 68467-6

- If aerial insecticides are applied to the combined refuge for control of corn rootworm adults, the same treatment must also be applied in the same time frame to Herculex® XTRA Insect Protection corn.
- Insecticide treatments in the combined refuge for control of ECB, CEW, SWCB, 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). These pests can be treated with corn rootworm-labeled insecticide on the combined refuge acres without treating the Herculex® XTRA Insect Protection corn acres only if treatment occurs when adult corn rootworms are not present. Instructions to growers will specify that microbial *Bt* insecticides must not be applied to the combined refuges.
- Pests other than adult corn rootworms can be treated with corn rootworm-labeled insecticide on the combined refuge acres without treating the Herculex® XTRA Insect Protection corn acres only if treatment occurs when adult corn rootworms are not present. Pests on the Herculex® XTRA Insect Protection corn acres can be treated as needed without having to treat the combined refuge.
- The combined refuge can be planted to any corn hybrid that does not express plant-incorporated protectants for lepidopteran or rootworm control (i.e., herbicide-tolerant corn or conventional corn).
- The combined refuge and Herculex® XTRA 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.

**b. Grower Agreements for Herculex® XTRA Insect Protection Corn**

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

Dr. Laura A. Tagliani  
EPA Registration No. 68467-6

- 4) DAS must continue to use its current grower agreement for Herculex® XTRA 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® XTRA Insect Protection corn sign grower agreement(s).
- 6) DAS shall maintain records of all Herculex® XTRA Insect Protection 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) Annually, DAS shall provide EPA with a report showing the number of units of Herculex® XTRA 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® XTRA 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® XTRA Insect Protection corn users the importance of complying with the IRM program. The program shall include information encouraging Herculex® XTRA Insect Protection corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Herculex® XTRA 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® XTRA 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.



Dr. Laura A. Tagliani  
EPA Registration No. 68467-6

- 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® XTRA 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® XTRA 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.

Dr. Laura A. Tagliani  
EPA Registration No. 68467-6

- 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 31<sup>st</sup> 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® XTRA 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® XTRA 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® XTRA 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.

Dr. Laura A. Tagliani  
EPA Registration No. 68467-6

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

Dr. Laura A. Tagliani  
EPA Registration No. 68467-6

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® XTRA Insect Protection corn is used.

19) DAS will use its available Herculex® XTRA 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® XTRA 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® XTRA Insect Protection corn to reflect the adoption rate and level of refuge compliance for Herculex® XTRA 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 two (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® XTRA Insect Protection corn within a 5-year period will be denied access to DAS' *Bt* corn products the next year.

Dr. Laura A. Tagliani  
EPA Registration No. 68467-6

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

1) EPA is imposing the following conditions for the Cry1F toxin expressed in Herculex® XTRA Insect Protection corn:

DAS will monitor for resistance to Cry1F expressed in Herculex® XTRA Insect Protection 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

DAS 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 Herculex® XTRA Insect Protection corn and/or changes in resistance allele frequency in response to the use of Herculex® XTRA Insect Protection corn and, as far as possible, should be consistent across sampling years to enable comparisons with historical data.

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

The sampling program and geographic range of collections may be modified as appropriate based on changes in pest importance and for the adoption levels of Herculex® XTRA Insect Protection corn. EPA shall be consulted prior to the implementation of such modifications.

DAS 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.

Dr. Laura A. Tagliani  
EPA Registration No. 68467-6

Any incidence of unusually low sensitivity to the Cry1F protein 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 Herculex® XTRA Insect Protection 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, DAS 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

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

If reports of unexpected levels of damage lead to the suspicion of resistance in any of the key target pests (ECB, SWCB, and CEW), DAS will implement the actions described below, based on the following definitions of *suspected resistance* and *confirmed resistance*.

Dr. Laura A. Tagliani  
EPA Registration No. 68467-6

***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 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 Herculex® XTRA Insect Protection corn in commercial production fields before responsive measures are undertaken.

If resistance is ***suspected***, DAS will instruct growers to do the following:

- Use alternative control measures in Herculex® XTRA Insect Protection corn fields in the affected region to control the target pest during the immediate growing season.
- Destroy Herculex® XTRA Insect Protection 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, DAS 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.

Dr. Laura A. Tagliani  
EPA Registration No. 68467-6

***Confirmed Resistance***

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

- There is >30% insect survival and commensurate insect feeding in a bioassay, initiated with neonate larvae, that uses methods that are representative of exposure to *Bt* corn hybrids under field conditions (ECB and SWCB only).
- In standardized laboratory bioassays using diagnostic concentrations of the *Bt* protein suited to the target pest in question, the pest exhibits resistance that has a genetic basis and the level of survivorship indicates that there may be a resistance allele frequency of  $\geq 0.1$  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 DAS:

- EPA will receive notification within 30 days of resistance confirmation;
- Affected customers and extension agents will be notified about confirmed resistance within 30 days;
- Monitoring will be increased in the affected area and local target pest populations will be sampled annually to determine the extent and impact of resistance;
- If appropriate (depending on the resistant pest species, the extent of resistance, the timing of resistance, and the nature of resistance, and the availability of suitable alternative control measures), alternative control measures will be employed to reduce or control target pest populations in the affected area. Alternative control measures may include advising customers and extension agents in the affected area to incorporate crop residues into the soil following harvest to minimize the possibility of over-wintering insects, and/or applications of chemical insecticides;
- Unless otherwise agreed with EPA, stop sale and distribution of the relevant lepidopteran-active *Bt* corn hybrids in the affected area immediately until an effective local mitigation plan, approved by EPA, has been implemented;



Dr. Laura A. Tagliani  
EPA Registration No. 68467-6

- DAS will develop a case-specific resistance management action plan within 90 days according to the characteristics of the resistance event and local agronomic needs. DAS 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.

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

- i. 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.
- ii. 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.
- iii. 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<sup>1</sup> 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.

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<sup>1</sup> 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.

Dr. Laura A. Tagliani  
EPA Registration No. 68467-6

- iv. 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.
- v. 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.
- vi. DAS must follow-up on grower, extension specialist, or consultant reports of unexpected damage or control failures for corn rootworm.
- vii. DAS must provide EPA with a resistance monitoring report on or before August 31<sup>st</sup> of each year, reporting on populations collected the previous year.
- viii. 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 zea* (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.

Dr. Laura A. Tagliani  
EPA Registration No. 68467-6

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® XTRA Insect Protection corn roots from neonate to adult is significantly higher than the baseline proportion (currently being established);
- ii. the LC<sub>50</sub> of the test population exceeds the upper limit of the 95% confidence interval for the LC<sub>50</sub> 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® XTRA 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® XTRA 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.

Dr. Laura A. Tagliani  
EPA Registration No. 68467-6

**e. Annual Reporting Requirements for Herculex® XTRA Insect Protection Corn**

- 1) Annual Sales: reported and summed by state (county level data available by request), on or before January 31<sup>st</sup> of each year.
- 2) Grower Agreement Results: number of units of Herculex® XTRA 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 31<sup>st</sup> of each year.
- 3) Grower Education: substantive changes to the education program completed during the previous year, on or before January 31<sup>st</sup> 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 31<sup>st</sup> 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 31<sup>st</sup> of each year.
- 6) Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, on or before August 31<sup>st</sup> of each year.

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® XTRA Insect Protection Label

**Herculex® XTRA Insect Protection**  
OECD Unique Identifier: DAS-Ø15Ø7-1 x DAS-59122-7

Active Ingredients:

*Bacillus thuringiensis* Cry1F protein and the genetic material (plasmid insert PHI8999A) necessary for its production in corn event DAS-Ø15Ø7-1..... ≤ 0.00174%\*

*Bacillus thuringiensis* Cry34Ab1 protein and the genetic material (PHP17662-T-DNA) necessary for its production in corn event DAS-59122-7 ..... ≤ 0.01684%\*

*Bacillus thuringiensis* Cry35Ab1 protein and the genetic material (PHP17662-T-DNA) necessary for its production in corn event DAS-59122-7 ..... ≤ 0.00676%\*

Other Ingredient:

Phosphinothricin acetyltransferase (PAT) protein and the genetic material (plasmid insert PHI8999A and PHP17662-T-DNA) necessary for its production in corn events DAS-Ø15Ø7-1 and DAS-59122-7 ..... ≤ 0.00151%\*

\*% total protein on a dry wt. basis as expressed in corn plant cells (whole plant)

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

EPA Registration Number 68467-6

EPA Establishment Number 62719-IN-1

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

® Registered Trademark of Dow AgroSciences LLC

**ACCEPTED**

SEP 29 2010

**Under the Federal Insecticide, Fungicide,  
and Rodenticide Act, as amended, for  
the pesticide registered under  
EPA Reg. No. 68467-6**

220x24

## 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.

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

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.

Herculex® XTRA Insect Protection corn (Herculex® XTRA) combines the insect protection features of Herculex® I and Herculex® RW in the same corn hybrid (inbred). Herculex® XTRA hybrids protect corn crops from leaf, stalk and ear damage caused by Lepidopteran corn pests such as the European corn borer, and root damage caused by corn rootworm larvae. In order to minimize the risk of the corn pests developing resistance to Herculex® XTRA corn, an insect resistance management plan must be implemented.

Grower agreements will specify that growers must adhere to the refuge requirements that will be described in the Product Use Guide for Herculex® XTRA corn or other applicable product use documents.

## 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.

The use of Herculex® XTRA Insect Protection corn requires accompanying refuge corn for both the Cry1F and Cry34/35Ab1 components that meets the requirements of the individual traits, described below. The refuge for both traits may be combined by planting non-*Bacillus thuringiensis* (*Bt*) corn as the refuge (see C. below), or the refuge for each trait may be planted separately (see A. and B. below)

For the separate refuges, corn rootworm-resistant *Bt* corn (e.g., Herculex® RW Insect Protection) may be planted in the lepidopteran refuge for the Cry1F component and lepidopteran-resistant *Bt* corn (e.g., Herculex® I Insect Protection) may be planted in the corn rootworm refuge for the Cry34/35Ab1 component. Depending on cropping practices, pest problems, and pest management options employed on any given farm, growers may need to choose different refuge arrangements for different fields. Two refuge blocks (one for rootworm, one for Lepidoptera) can be planted within one field, or strips can be used for either refuge. Alternatively, a block of Herculex® RW Insect Protection corn can serve as an in-field lepidopteran refuge for one field planted to Herculex® XTRA and an external lepidopteran refuge for separate fields planted to Herculex® XTRA, while the rootworm refuge is planted as Herculex® I Insect Protection corn in an external adjacent field. In all options, size and management of each individual refuge must be followed as described in A. and B. below.

Other refuge designs and combinations are permissible as long as, in all cases, the size and management of each refuge are described in A., B., and C., below.

23 of 26

## A. Lepidopteran refuge for the Cry1F component.

1. *Refuge size, Corn-Growing Areas* (Corn Belt and other non-corn/cotton-growing regions). The use of Herculex® XTRA corn requires an accompanying 20% refuge consisting of non-*Bt* corn or corn that is not a lepidopteran-protected *Bt* hybrid.
2. *Refuge size, (Corn/Cotton-growing areas)*. \* The use of Herculex® XTRA corn requires an accompanying 50% refuge consisting of non-*Bt* corn or corn that is not a lepidopteran-protected *Bt* hybrid.
3. *Refuge location.*
  - The lepidopteran refuge can be planted in a separate field not more than ½ mile from the Herculex® XTRA corn field.
  - The lepidopteran refuge can be planted within the Herculex® XTRA corn field as blocks (e.g., along the edges or headlands)
  - The lepidopteran refuge can be planted within the Herculex® XTRA corn field as strips across the field at least four consecutive rows wide.
4. *Refuge management.*
  - Insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer and other lepidopteran target pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service Agents, crop consultants). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to refuges consisting of non-*Bt* corn or corn that is not a lepidopteran-protected *Bt* hybrid.

\* Cotton-growing areas consist of the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

## B. Corn rootworm refuge for the Cry34/35Ab1 component.

1. *Refuge size.* The use of Herculex® XTRA corn requires an accompanying 20% refuge consisting of non-*Bt* corn or corn that is not a rootworm-protected *Bt* hybrid.
2. *Refuge location.* The rootworm refuge is required to be planted within or adjacent (e.g., across the road) to the Herculex® XTRA corn field.
3. *Refuge management options.* The rootworm refuge can 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 rootworm 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® XTRA corn and rootworm refuge corn are not permitted.
  - If the rootworm refuge is planted on rotated ground, then Herculex® XTRA corn must also be planted on rotated ground.

- If the rootworm refuge is planted in continuous corn, the Herculex® XTRA 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 rootworm refuge.
- Seed treatment is permitted in the rootworm refuge, either at a rate for rootworm protection or at a rate for controlling secondary soil pests.
- If aerial insecticides are applied to the rootworm refuge for control of CRW adults, the same treatment must also be applied in the same time-frame to Herculex® XTRA corn.
- Pests other than adult corn rootworms can be treated on the rootworm refuge acres without treating the Herculex® XTRA corn acres only if treatment occurs when adult corn rootworms are not present or if a pesticide without activity against adult corn rootworms is used. Pests on the Herculex® XTRA corn acres can be treated as needed without having to treat the rootworm refuge.
- The rootworm refuge can be planted to any corn hybrid that does not express PIPs for rootworm control (e.g., lepidopteran-protected *Bt* corn, herbicide-tolerant corn, or conventional corn).
- The rootworm refuge and Herculex® XTRA 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.

C. For the combined refuge option (i.e. the lepidopteran refuge combined with the rootworm refuge by planting non-*Bt* corn), the refuge must be planted and managed such that it is consistent with the requirements of the two individual traits, as follows:

1. *Refuge size* shall be 20% in corn-growing areas and 50% in cotton-growing areas (see list of states labeled with " \* " under A.).
2. *Refuge location*. The combined refuge is required to be planted within or adjacent (e.g., across the road) to the Herculex® XTRA corn field.
3. *Refuge management options*.
  - 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® XTRA and refuge corn are not permitted.
  - If the combined refuge is planted on rotated ground, then the Herculex® XTRA corn must also be planted on rotated ground.
  - If the combined refuge is planted on continuous corn, the Herculex® XTRA 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 for corn rootworm control is permitted in the combined refuge.
  - Seed treatment is permitted in the combined refuge, either at a rate for rootworm protection or at a rate for controlling secondary soil pests.
  - If aerial insecticides are applied to the combined refuge for control of CRW adults, the same treatment must also be applied in the same timeframe to Herculex® XTRA corn.
  - Insecticide treatments in the combined refuge 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 or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service Agents, crop consultants). These pests can be treated with CRW-labeled insecticide on the



250x26

combined refuge acres without treating the Herculex® XTRA Insect Protection corn acres only if treatment occurs when adult corn rootworms are not present. Instructions to growers will specify that microbial *Bt* insecticides must not be applied to the combined refuges.

- Pests other than adult corn rootworms can be treated with CRW-labeled insecticide on the combined refuge acres without treating the Herculex® XTRA corn acres only if treatment occurs when adults corn rootworms are not present. Pests on the Herculex® XTRA corn acres can be treated as needed without having to treat the refuge.
- The combined refuge can be planted to any corn hybrid that does not express PIPs for lepidopteran or rootworm control (i.e. herbicide-tolerant corn or conventional corn).
- The combined refuge and Herculex® XTRA 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.

26 of 26

**Use Pattern**

<b>Crop</b>	<b>Pests</b>
Field corn	black cutworm corn earworm European corn borer fall armyworm Mexican corn rootworm northern corn rootworm southwestern corn borer western bean cutworm western corn rootworm lesser corn stalk borer southern corn stalk borer sugarcane borer

EPA Accepted:   /  /