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

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OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mr. Jamie Staley
Pioneer Hi-Bred International, Inc.
7100 N.W. 62nd Ave.
P.O. Box 1000
Johnston, IA 50131-1000

Re: 1507x59122xMON810
EPA Registration No. 29964-8
Amendment to reduce to 20% refuge requirements in cotton growing areas
Submission dated 7/16/2010, as amended 11/29/2010
Decision No. 437395

Dear Mr. Staley:

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 amendment 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 October 31, 2015.
2. The subject registration will be limited to *Bacillus thuringiensis* Cry1F protein and the genetic material (PHI8999A) necessary for its production in corn event TC 1507 (OECD Unique Identifier DAS-Ø15Ø7-1) x *Bacillus thuringiensis* Cry34Ab1 protein and the genetic material (PHP17662 T-DNA) necessary for its production in corn event 59122 (OECD Unique Identifier DAS-59122-7) x *Bacillus thuringiensis* Cry35Ab1 protein and the genetic material (PHP17662 T-DNA) necessary for its production in corn event 59122 (OECD Unique Identifier DAS-59122-7) x *Bacillus thuringiensis* Cry1Ab protein and the genetic material (vector PV-ZMBK07) necessary for its production in corn event MON 810 (OECD Unique Identifier MON-ØØ81Ø-6) for use in field corn.
3. Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Environmental Protection Agency (EPA) requires all registrants of similar products to submit such data.

4. Submit/cite all data determined by EPA to be acceptable and required to support the PIP registrations of the individual parental events: TC1507 (DAS-Ø15Ø7-1), 59122 (DAS-59122-7), and MON810 (MON-ØØ81Ø-6) in corn, as well as the combination PIP product TC1507 (DAS-Ø15Ø7-1) x DAS-59122-7, within the time frames required by the terms and conditions of EPA Registration Numbers 29964-3, 29964-4, 524-489 and 29964-5, 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, Cry1Ab and Cry34/35Ab1 components that meets the requirements of the individual traits. The refuge for all three traits may be combined by planting non-*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 and Cry1Ab component(s) and lepidopteran-resistant *Bt* corn may be planted in the corn rootworm refuge for the Cry34/35Ab1 component;
 - Requirements for Pioneer to prepare and require 1507x59122xMON810 corn users to sign grower agreements which impose binding contractual obligations on the grower to comply with the refuge requirements;
 - Requirements for Pioneer to develop, implement, and report to EPA on programs to educate growers about IRM requirements;
 - Requirements for Pioneer to develop, implement, and report to EPA on programs to evaluate and promote growers compliance with IRM requirements;
 - Requirements for the registrants to develop, implement, and report to EPA on programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to Cry1F, Cry1Ab and Cry34/35Ab1 proteins in the target insects;
 - Requirements for the registrants to develop, and if triggered, to implement a remedial action plan, which would contain measures Pioneer would take in the event that any insect resistance was detected as well as to report on activity under the plan to EPA;

- Requirements for Pioneer, on or before January 31st each year to submit annual reports on units sold by state (units sold by county level will be made available to EPA upon request), IRM grower agreement results, and the compliance assurance program including the education program;
- Requirements for Pioneer, on or before August 31st of each year, to submit reports on resistance monitoring.

I. Refuge Requirements

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 Pioneer 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 1507x59122xMON810 corn (Cry1F x Cry34/35Ab1 x Cry1Ab) corn requires accompanying corn refuge(s) for the Cry1F, Cry1Ab and Cry34/35Ab1 components that meets the requirements of the individual traits, described below. The refuge(s) for all three traits may be combined by planting non-*Bt* corn as the refuge (see C. below), or the refuges for the lepidopteran resistant traits and the corn rootworm-resistant traits may be planted separately (see A. and B. below).

For the separate refuges, corn rootworm-resistant *Bt* corn may be planted in the lepidopteran refuge for the Cry1F and Cry1Ab component and lepidopteran-resistant *Bt* corn 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. Possible options include: 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 rootworm resistant corn can serve as an in-field lepidopteran refuge for one field planted to 1507x59122xMON810 corn and an external lepidopteran refuge for separate fields planted to 1507x59122xMON810 corn, while the rootworm refuge is planted as a lepidopteran-resistant *Bt* 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.

A. Lepidopteran refuge for the Cry1F and Cry1Ab component.

1. *Refuge size.* In all corn-growing areas, the use of 1507x59122xMON810 corn requires an accompanying 20% refuge consisting of non-Bt corn or non-lepidopteran resistant *Bt* corn.
2. *Refuge location.*
 - i. The lepidopteran refuge can be planted in a separate field not more than ½ mile (1/4 mile preferred) of the 1507x59122xMON810 field.
 - ii. The lepidopteran refuge can be planted within the 1507x59122xMON810 field as blocks (e.g. along the edges or headlands).
 - iii. The lepidopteran refuge can be planted within the 1507x59122xMON810 field as strips across the field at least four rows wide.
3. *Refuge management.* Insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, fall armyworm, black cutworm, western bean cutworm, lesser corn stalk borer, sugarcane borer and southern corn stalk borer may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g. Extension Service Agents, crop consultants). Microbial *Bt* insecticides must not be applied to lepidopteran resistant refuges.

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

1. *Refuge size.* The use of 1507x59122xMON810 corn requires an accompanying 20% refuge consisting of non-Bt corn or non-corn rootworm-resistant *Bt* corn.
2. *Refuge location.* The rootworm refuge is required to be planted within or adjacent (e.g. across the road) to the 1507x59122xMON810 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.
 - i. The in-field rootworm refuge options may be planted as a single block or as a series of strips measuring at least four (4) crop rows wide.
 - ii. Seed mixtures of 1507x59122xMON810 and rootworm refuge corn are not permitted.
 - iii. If the rootworm refuge is planted on rotated ground, then 1507x59122xMON810 corn must also be planted on rotated ground.
 - iv. If the rootworm refuge is planted in continuous corn, the 1507x59122xMON810 field may be planted on either continuous or rotated land (option encouraged where WCRW rotation-resistant biotype may be present).
 - v. Application of soil insecticide is permitted in the rootworm refuge.

- vi. Seed treatment is permitted in the rootworm refuge, either at a rate for rootworm protection or at a rate for controlling secondary soil pests.
- vii. 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 1507x59122xMON810 corn.
- viii. Pests other than adult corn rootworms can be treated on the rootworm refuge acres without treating the 1507x59122xMON810 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 1507x59122xMON810 acres can be treated as needed without having to treat the rootworm refuge.
- ix. 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).
- x. The rootworm refuge and 1507x59122xMON810 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.
- xi. 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 individual traits (Cry1F, Cry 34/35Ab1, and Cry1Ab), as follows:

1. *Refuge management options.*

2. *Refuge size* shall be 20% refuge in all corn-growing areas.

3. *Refuge location.* The combined refuge is required to be planted within or adjacent (e.g. across the road) to the 1507x59122xMON810 corn field.

- i. The in-field refuge options must be planted as a single block or as a series of strips measuring at least four (4) rows wide.
- ii. Seed mixtures of 1507x59122xMON810 and refuge corn are not permitted.
- iii. If the combined refuge is planted on rotated ground, then the 1507x59122xMON810 corn must also be planted on rotated ground.
- iv. If the combined refuge is planted on continuous corn, the 1507x59122xMON810 field may be planted on either continuous or rotated land (option encouraged where WCRW rotation-resistant biotype may be present).

- v. Application of soil insecticide for corn rootworm control is permitted in the combined refuge.
- vi. Seed treatment is permitted in the combined refuge, either at a rate for rootworm protection or at a rate for controlling secondary soil pests.
- vii. 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 1507x59122xMON810 corn.
- viii. Insecticide treatments in the combined refuge for control of European corn borer, corn earworm, southwestern corn borer, fall armyworm, black cutworm, western bean cutworm, sugarcane borer, lesser corn stalk borer, or southern corn stalk borer may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g. Extension Service Agents, crop consultants). These pests can be treated with CRW-labeled insecticide on the combined refuge acres without treating the 1507x59122xMON810 acres only if treatment occurs when adult corn rootworms are not present. Microbial *Bt* insecticides must not be applied to the common refuges.
- ix. Pests other than adult corn rootworms can be treated with CRW-labeled insecticide on the combined refuge acres without treating the 1507x59122xMON810 acres only if treatment occurs when adult corn rootworms are not present. Pests on the 1507x59122xMON810 acres can be treated as needed without having to treat the refuge.
- x. 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).
- xi. The combined refuge and 1507x59122xMON810 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.
- xii. The description of the refuge requirements in the grower guide must be consistent with the preceding requirements.

II. Grower Agreement

- A. Persons purchasing 1507x59122xMON810 corn must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.

- B. The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program as revised by this amendment. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
- C. Pioneer 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 1507x59122xMON810 corn will affirm annually that they are contractually bound to comply with the requirements of the IRM program.
- D. Pioneer must submit to EPA by May 1, 2011, a copy of the grower agreement revised to incorporate the refuge change and any specific stewardship documents referenced in the revised grower agreement. Pioneer must continue to use this grower agreement in subsequent years.
- E. If Pioneer 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 days prior to implementing a proposed change, Pioneer must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of this amended registration.
- F. Pioneer 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 1507x59122xMON810 corn sign grower agreement(s).
- G. Pioneer shall maintain records of all 1507x59122xMON810 corn grower agreements for a period of three years from December 31st of the year in which the agreement was signed.
- H. Annually, Pioneer shall provide EPA with a report on the number of units of 1507x59122xMON810 corn seed 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 prior twelve-month period, August through July.
- I. Pioneer must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

III. IRM Education and IRM Compliance Monitoring Program

- A. Pioneer must continue to implement and enhance (as set forth in paragraph R. of this section) a comprehensive, ongoing IRM education program designed to convey to 1507x59122xMON810 corn users the importance of complying with the IRM program.

The program must inform growers of their obligation to implement the revised refuge requirements.

- B. The program shall include information encouraging 1507x59122xMON810 corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to 1507x59122xMON810 corn fields, and must inform growers of their obligation to implement the revised refuge requirements. 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 their records. The program shall involve at least one written communication annually to each 1507x59122xMON810 corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Pioneer shall coordinate its education program with the educational efforts of other registrants and other organizations, such as the National Corn Growers Association and state extension programs.
- C. Annually, Pioneer shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraphs G.-I. of this section, and from other sources. The registrant shall identify deficiencies in grower compliance and revise the education program to address those deficiencies.
- D. Annually, Pioneer must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. Pioneer 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 E.-W. of this section.
- E. Pioneer must continue to implement and improve an ongoing IRM compliance assurance program (CAP) designed to evaluate the extent to which growers purchasing 1507x59122xMON810 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 Pioneer's *Bt* corn products. Pioneer 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 PIP products. Other required features of the program are described in paragraphs F.-W. below.
- F. Pioneer must maintain and publicize a "phased compliance approach" (i.e., a guidance document that indicates how they 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, Pioneer must use a consistent set of standards for responding to non-compliance. An individual grower found to be significantly out of compliance two years in a row would be denied Pioneer's *Bt* corn products the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell *Bt* corn.

- G. The IRM compliance assurance program shall include an annual survey, conducted by an independent third party, of a statistically representative sample of growers of 1507x59122xMON810 corn who plant the vast majority of all corn in the United States and in areas in which the selection intensity is the greatest. The survey shall consider only those growers who plant 200 or more acres of corn in the Corn-Belt or who plant 100 or more acres of corn in corn-cotton growing 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 Pioneer, the grower, or anyone else with a direct interest in IRM compliance for *Bt* corn.
- H. The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.
- I. The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.
- J. Pioneer 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. Pioneer shall confer with other registrants and EPA on the design and content of the survey prior to its implementation.
- K. Annually, Pioneer shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey (required under paragraphs G through I) and from other sources. The registrant shall identify deficiencies in grower compliance and revise the education program to address those deficiencies. Pioneer must confer with the Agency prior to adopting any changes.
- L. Pioneer shall conduct an annual on-farm assessment program. Pioneer shall train its representatives who make on-farm visits with growers of 1507x59122xMON810 corn 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

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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, Pioneer shall take appropriate action, consistent with its "phased compliance approach" to promote compliance.

- M. Pioneer shall carry out a program for investigating legitimate "tips and complaints" that 1507x59122xMON810 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, Pioneer shall take appropriate action, consistent with its "phased compliance approach."
- N. If a grower, who purchases 1507x59122xMON810 corn for planting, was specifically identified as not being in compliance during the previous year, Pioneer shall visit with the grower and evaluate whether that grower is in compliance with the IRM program for the current year.
- O. Annually, Pioneer shall provide a report to EPA summarizing the activities carried out under their compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. Within one (1) month of submitting this report to EPA, Pioneer 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. Pioneer may elect to coordinate information with other registrants and report collectively the results of compliance assurance programs.
- P. Pioneer and the seed corn dealers for Pioneer 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 license number of the growers will be protected.
- Q. Pioneer shall revise and expand its existing compliance assurance program to address the amended refuge requirement. Pioneer must prepare and submit by May 1, 2011, a written description of its revised compliance assurance program. Pioneer may coordinate with other registrants in designing and implementing its compliance assurance program.
- R. Pioneer 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 requirements, as revised, on all 1507x59122xMON810 corn seed bags or bag tags. The 1507x59122xMON810 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 1507x59122xMON810 corn labels must be submitted by May 1, 2011. 50% implementation on the 1507x59122xMON810 corn seed bags or bag tags must occur by the 2012 growing season, and full implementation must occur by the 2013 growing season.
- S. Pioneer 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 1507x59122xMON810 corn is used.
- T. Pioneer will use its available 1507x59122xMON810 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 1507x59122xMON810 corn but may have purchased little or no refuge seed from Pioneer, licensees, or affiliated companies.
- U. Pioneer 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.
- V. Annually, Pioneer will refine the on-farm assessment program for 1507x59122xMON810 corn to reflect the adoption rate and level of refuge compliance for 1507x59122xMON810 corn.
- W. Pioneer 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

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- (2) years by Pioneer, a seed supplier, or a third-party assessor, after completing the assessment process.
- ii. Pioneer 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 1507x59122xMON810 corn within a 5-year period will be denied access to Pioneer's *Bt* corn products the next year.

IV. Insect Resistance Monitoring and Remedial Action Plans

- A. **Lepidopteran Resistance Monitoring.** The Agency is imposing the following conditions for the Cry1Ab and Cry1F toxins expressed in 1507x59122xMON810 corn:

Pioneer will monitor for resistance to Cry1Ab and Cry1F toxins expressed in 1507x59122xMON810 corn. The monitoring program shall consist of two approaches: (i) focused population sampling and laboratory testing and (ii) 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.

1. Focused Population Sampling

Pioneer 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 1507x59122xMON810 corn and/or changes in resistance-allele frequency in response to the use of 1507x59122xMON810 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 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 populations. For CEW, the target will be a minimum of 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

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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 1507x59122xMON810 corn. The Agency shall be consulted prior to the implementation of such modifications.

Pioneer will report to the Agency, by August 31st of each year, the results of the population sampling and bioassay monitoring program.

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

- i. Re-test progeny of the collected population to determine whether the unusual bioassay response is reproducible and heritable. If it is not reproducible and heritable, no further action is required.
- ii. If the unusual response is reproducible and heritable, progeny of insects that survive the diagnostic concentration will be tested using methods that are representative of exposure to 1507x59122xMON810 corn under field conditions. If progeny do not survive to adulthood, any suspected resistance is not field-relevant and no further action is required.
- iii. If insects survive steps i. and ii., resistance is confirmed, and further steps will be taken to evaluate the resistance. These steps may include:
 - 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, Pioneer will consult with the Agency to develop and implement a case-specific resistance management action plan.

2. *Investigation of Reports of Unexpected Levels of Damage by the Target Lepidopteran Pests*

Pioneer will follow up on grower, extension specialist or consultant reports of unexpected levels of damage by the lepidopteran pests listed on the pesticide label. Pioneer will instruct its customers to contact them if such incidents occur. Pioneer 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), Pioneer will implement the actions described below, based on the following definitions of *suspected resistance* and *confirmed resistance*.

3. *Suspected resistance*

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

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

The Agency does not interpret *suspected resistance* to mean grower reports of possible control failures or suspicious results from annual insect monitoring assays, nor does the Agency intend that extensive field studies and testing be undertaken to confirm scientifically the presence of insects resistant to 1507x59122xMON810 corn in commercial production fields before responsive measures are undertaken.

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

- i. Use alternative control measures in 1507x59122xMON810 corn fields in the affected region to control the target pest during the immediate growing season.
- ii. Destroy 1507x59122xMON810 corn crop residues in the affected region within one 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 residue, Pioneer 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.

4. *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:

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

5. *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 Pioneer:

- i. EPA will receive notification within 30 days of resistance confirmation;
- ii. Affected customers and extension agents will be notified about confirmed resistance within 30 days;
- iii. 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;
- iv. 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;

- v. Unless otherwise agreed with EPA, Pioneer will 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;
- vi. Pioneer will develop a case-specific resistance management action plan within 90 days according to the characteristics of the resistance event and local agronomic needs. Pioneer 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;
- vii. Pioneer will notify affected parties (e.g., growers, consultants, extension agents, seed distributors, university cooperators and state/federal authorities as appropriate) in the region of the resistance situation and approved action plan; and
- viii. In subsequent growing seasons, Pioneer will 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.

B. Insect Resistance Monitoring and Remedial Action Plan for 1507x59122xMON810 corn.
EPA is imposing the following conditions for the Cry34Ab1 and Cry35Ab1 corn rootworm toxins expressed in 1507x59122xMON810 corn:

1. Pioneer 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 QA/QC provisions), detection technique and sensitivity, statistical analysis of the probability of detecting resistance, and a revised description of rootworm damage guidelines.
3. Pioneer 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, Pioneer must investigate the feasibility of using the Sublethal Seedling Assay¹ as a diagnostic assay. A report of Pioneer's progress towards this requirement must be submitted to EPA within six (6) months from the date of this amended registration.

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.

4. Pioneer 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, Pioneer may need to investigate novel techniques for rearing and conducting bioassays with northern corn rootworm. A report on Pioneer's progress towards this requirement must be submitted within one (1) year from the date of this amended registration.
5. Pioneer 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. Pioneer must follow-up on grower, extension specialist or consultant reports of unexpected damage or control failures for corn rootworm.
7. Pioneer must provide EPA with a resistance monitoring report on or before August 31st of each year, reporting on populations collected the previous year.
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 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.
 - i. *Definition of Suspected Resistance.* Resistance will be **suspected** if investigations of unexpected damage reports show the following:
 - implicated corn plant roots were expressing the Cry34/35Ab1 proteins at the expected level;
 - the seed used was not mixed with non-Cry34/35Ab1 seed;
 - alternative causes of damage or lodging, such as non-target pest insect species, weather, physical damage, larval movement from alternate hosts, planting errors, and other reasonable causes for the observations, have been ruled out; and
 - the level of damage exceeds guidelines for expected damage.

If resistance is **suspected**, Pioneer 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.

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- ii. *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**:
- the proportion of larvae that can feed and survive on 1507x59122xMON810 corn roots from neonate to adult is significantly higher than the baseline proportion (currently being established);
 - 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;
 - the ability to survive is heritable;
 - 1507x59122xMON810 corn plant assays determine that damage caused by surviving insects would exceed economic thresholds; and
 - if subsequent collections in the affected field area(s) demonstrated similar bioassay results.
- iii. *Response to Confirmed Resistance.* When resistance is **confirmed**, the following steps will be taken:
- EPA will receive notification within 30 days of resistance confirmation;
 - affected customers and extension agents will be notified about confirmed resistance;
 - affected customers and extension agents will be encouraged to employ alternative corn rootworm control measures;
 - sale and distribution of 1507x59122xMON810 corn in the affected area will cease immediately; and
 - a long-term resistance management action plan will be devised according to the characteristics of the resistance event and local agronomic needs.

V. Annual Reporting Requirements

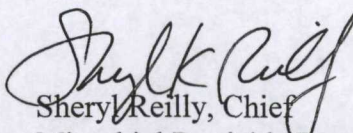
- 1) Annual Sales: reported and summed by state (county level data available by request) on or before January 31st each year;

- 2) Grower Agreement Results: number of units of 1507x59122xMON810 corn seed shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements, on or before January 31st each year;
- 3) Grower Education: substantive changes to education program completed previous year, on or before January 31st each year;
- 4) Compliance Assurance Program: compliance assurance program activities and results for the prior year and plans for the compliance assurance program for the current year, on or before January 31st 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 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 the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,


Sheryl Reilly, Chief
Microbial Pesticide Branch
Biopesticides and Pollution
Prevention Division (7511P)

Enclosure

1507x59122xMON810

(OECD Unique Identifier: DAS-Ø15Ø7-1xDAS-59122-7xMON-ØØ81Ø-6)

Active Ingredients:

Bacillus thuringiensis Cry1F protein and the genetic material (plasmid insert PHI8999A) necessary for its production in corn event DAS-Ø15Ø7-1 <0.0011%*

<i>Bacillus thuringiensis</i> Cry34Ab1 protein and the genetic material (PHP17662 T-DNA) necessary for its production in corn event DAS-59122-7	<0.0054%
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Bacillus thuringiensis Cry35Ab1 protein and the genetic material (PHP17662 T-DNA) necessary for its production in corn event DAS-59122-7 <0.0042%*

Bacillus thuringiensis Cry1Ab protein and the genetic material (vector PV-ZMBK07) necessary for its production in corn event MON-00810-6 <0.0015%*

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.....<0.0013%*

* Percentage (wt/wt) on a dry wt. basis for whole plant (forage).

KEEP OUT OF REACH OF CHILDREN

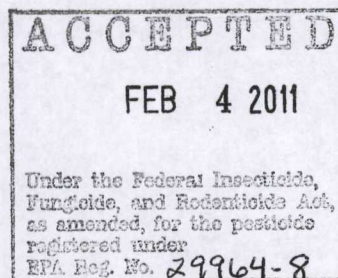
CAUTION

NET CONTENTS

EPA REGISTRATION NUMBER: 29964-8

EPA ESTABLISHMENT NUMBER: 029964-IA-001

Pioneer Hi-Bred International, Inc.
7300 NW 62nd Avenue
Johnston, IA 50131



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DIRECTIONS FOR USE

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

The subject registration automatically expires on midnight October 31, 2015.

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

1507x59122xMON810 corn combines the insect protection features of Herculex^{®1} XTRA Insect Protection (EPA Reg. No.: 29964-5) and Yieldgard² Corn Borer (EPA Reg. No.: 524-489) in the same corn hybrid or inbred. 1507x59122xMON810 corn 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 1507x59122xMON810 corn, an insect resistance management plan must be implemented.

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 active ingredient per registrant per year.

Growers are instructed to read information on insect resistance management. The following information regarding refuge placement for commercial production must be included in the Grower Guide:

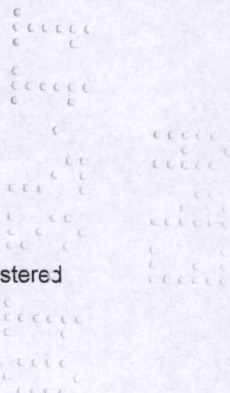
The use of 1507x59122xMON810 corn requires accompanying refuge corn for the Cry1F, Cry1Ab and Cry34/35Ab1 components that meets the requirements of the individual traits, described below. The refuge(s) for these traits may be combined by planting non-*Bacillus thuringiensis* (*Bt*) corn as the refuge (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[®] Rootworm Insect Protection; EPA Reg. No.: 29964-4) may be planted in the lepidopteran refuge for the Cry1F and Cry1Ab components and lepidopteran-resistant *Bt* corn (e.g., Herculex[®] I Insect Protection; EPA Reg. No.: 29964-3) 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. Possible options include: 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[®] Rootworm Insect Protection (EPA Reg. No.: 29964-4) corn can serve as an in-field lepidopteran refuge for one field planted to 1507x59122xMON810 corn and an external lepidopteran refuge for separate fields planted to 1507x59122xMON810 corn, while the rootworm refuge is planted as lepidopteran-resistant *Bt* corn (e.g., Herculex[®] I Insect Protection; EPA Reg. No.: 29964-3) 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.

¹ Herculex[®] Insect Protection technology by Dow AgroSciences and Pioneer Hi-Bred. [®]Herculex is a registered trademark of Dow AgroSciences LLC.

² Yieldgard is a registered trademark used under the license from Monsanto Company.



A. Lepidopteran refuge for the Cry1F and Cry1Ab components.

1. *Refuge size.* In all Corn-growing Areas the use of 1507x59122xMON810 corn requires an accompanying 20% refuge consisting of non-*Bt* corn or corn that is not a lepidopteran-protected *Bt* hybrid.
2. *Refuge location.*
 - The lepidopteran refuge can be planted in a separate field within a ½ mile of the 1507x59122xMON810 field.
 - The lepidopteran refuge can be planted within the 1507x59122xMON810 field as blocks (e.g. along the edges or headlands).
 - The lepidopteran refuge can be planted within the 1507x59122xMON810 field as strips across the field at least four (4) consecutive crop rows wide.
3. *Refuge management.*
 - Insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, fall armyworm, black cutworm, western bean cutworm, lesser corn stalk borer, sugarcane borer, stalk borer and southern corn stalk borer may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g. Extension Service Agents, crop consultants). Microbial *Bt* insecticides must not be applied to refuges consisting of non-*Bt* corn or corn that is not a lepidopteran-protected *Bt* hybrid.

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

1. *Refuge size.* The use of 1507x59122xMON810 corn requires an accompanying 20% refuge consisting of non-*Bt* corn or non-corn rootworm-resistant *Bt* corn.
2. *Refuge location.* The rootworm refuge is required to be planted within or adjacent (e.g. across the road) to the 1507x59122xMON810 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 may be planted as a single block or as a series of strips measuring at least four (4) consecutive crop rows wide.
 - Seed mixtures of 1507x59122xMON810 and rootworm refuge corn are not permitted.
 - If the rootworm refuge is planted on rotated ground, then 1507x59122xMON810 corn must also be planted on rotated ground.
 - If the rootworm refuge is planted in continuous corn, the 1507x59122xMON810 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 1507x59122xMON810 corn.
 - Pests other than adult corn rootworms can be treated on the rootworm refuge acres without treating the 1507x59122xMON810 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 1507x59122xMON810 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 1507x59122xMON810 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 individual traits, as follows:

1. *Refuge size* shall be 20% in all corn-growing areas.
2. *Refuge location.* The combined refuge is required to be planted within or adjacent (e.g. across the road) to the 1507x59122xMON810 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 1507x59122xMON810 and refuge corn are not permitted.
 - If the combined refuge is planted on rotated ground, then the 1507x59122xMON810 corn must also be planted on rotated ground.
 - If the combined refuge is planted on continuous corn, the 1507x59122xMON810 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 1507x59122xMON810 corn.
 - Insecticide treatments in the combined refuge for control of European corn borer, corn earworm, southwestern corn borer, fall armyworm, black cutworm, western bean cutworm, sugarcane borer, lesser corn stalk borer, stalk borer or southern corn stalk borer may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g. Extension Service Agents, crop consultants). These pests can be treated with CRW-labeled insecticide on the combined refuge acres without treating the 1507x59122xMON810 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 1507x59122xMON810 acres only if treatment occurs when adult corn rootworms are not present. Pests on the 1507x59122xMON810 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 1507x59122xMON810 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.

Use Pattern

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