29964-8 02/24/2010 1/23

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number:	Date of Issuance:
29964-8	FEB 2 4 2010

Term of Issuance: Conditional, Time-Limited

Name of Pesticide Product: 1507x59122xMON810

NOTICE OF PESTICIDE:
X Registration
___ Reregistration (under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Pioneer Hi-Bred International, Inc.
2450 Southeast Oak Tree Court
Ankeny, Iowa 50021

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product, always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide, and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

The registration application referred to above, submitted in connection with registration under Section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable provided that you comply with the following terms and conditions.

1. The subject registration will automatically expire October 31, 2010.

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Signature of Approving Official:

Keith A. Matthews, Acting Director
Biopesticides and Pollution Prevention Division (7511P)

Date: 24 February 2010

EPA Form 8570-6

2. The subject registration will be limited to *Bacillus thuringiensis* Cry1F protein and the genetic material (PHI8999) 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) necessary for its production in corn event 59122 (OECD Unique Identifier DAS-59122-7) x *Bacillus thuringiensis* Cry35Ab1 protein and the genetic material (PHP17662) necessary for its production in corn event 59122 (OECD Unique Identifier DAS-59122-7) x *Bacillus thuringiensis* Cry1Ab protein and the genetic material (PV-ZMBK07) necessary for it 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 Agency requires all registrants of similar products to submit such data.

4. The data submitted by Pioneer are sufficient to support registration for the combination PIP corn product: 1507x59122xMON810, provided that the registrant submits/cites any data 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. You must submit the following data and/or information in the time frames listed:

Study Type	Required Data	Due Date
Insect Resistance Management - Grower Agreement	A copy of the grower agreement, associated stewardship documents, and written description of a system, which assure that growers will sign grower agreements and persons purchasing 1507x59122xMON810 corn will annually affirm that they are contractually bound to comply with the requirements of the insect resistance management (IRM) program, must be submitted.	Within 90 days of the date of registration

6. The insect resistance management terms and conditions for 1507x59122xMON810 corn are as follows.

   The required IRM program for 1507x59122xMON810 corn must have 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 the registrants to prepare and require *Bt* corn users to sign grower agreements which impose binding contractual obligations on the grower to comply with the refuge requirements;

- Requirements for the registrants to develop, implement, and report to EPA on programs to educate growers about IRM requirements;

- Requirements for the registrants to develop, implement, and report to EPA on programs to evaluate and promote growers compliance with IRM requirements (the 1507x59122xMON810 Compliance Assurance Program (CAP) must integrate with the CAPS for the individually registered and combination products expressing Cry1F, Cry34/35Ab1 and Cry1Ab);

- 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 the registrants would take in the event that any insect resistance was detected as well as to report on activity under the plan to EPA;

- Submit annual reports on units sold by state (units sold by county level will be made available to the Agency upon request), IRM grower agreements results, and compliance assurance program including the education program, on or before January 31st each year, and for resistance monitoring, on or before January 31st each year for Cry1F and Cry1Ab beginning in 2011 and on or before August 31st each year for Cry34/35Ab1, beginning in 2010.

I. Refuge Requirements

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 (e.g., Herculex RW) may be planted in the lepidopteran refuge for the Cry1F and Cry1Ab component and lepidopteran-resistant *Bt* corn (e.g, Herculex I or YieldGard) 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 RW corn can serve as an in-field lepidopteran refuge for one field planted to Cry1F x Cry34/35Ab1 x Cry1Ab and an external lepidopteran refuge for separate fields planted to Cry1F x Cry34/35Ab1x Cry1Ab, while the rootworm refuge is planted as Herculex I corn or YieldGard 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,* Corn-Growing Areas (i.e., cornbelt and other non corn/cotton-growing regions). The use of 1507x59122xMON810 corn requires an accompanying 20% refuge consisting of non-Bt corn or non-lepidopteran resistant *Bt* corn.

2. *Refuge size,* Corn/Cotton-growing areas*. The use of 1507x59122xMON810 corn requires an accompanying 50% refuge consisting of non-*Bt* corn or non-lepidopteran resistant *Bt* corn.

3. *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 (six preferred).

4. *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.

* 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, 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, Sussex) and Missouri (only the counties of Dunkin, New Madrid, Pemiscot, Scott, Stoddard).

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 two individual traits, as follows:

1. *Refuge size* shall be 20% in corn-growing areas and 50% in cotton-growing areas (see list 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 1507x59122xMON810 corn field.

3. *Refuge management options*
   - 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 (six rows preferred).
   - 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. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.

C. Pioneer must implement a system equivalent to what is already approved for previously registered *Bt* corn products containing the previously registered events 1507, 59122 and MON810, 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. A description of the system must be submitted to EPA within 90 days from the date of registration

D. Pioneer must use an approved grower agreement and must submit to EPA, within 90 days from the date of registration, a copy of that agreement and any specific stewardship documents referenced in the grower agreement. 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 registration.

E. Pioneer must implement an approved system equivalent to what is already approved for previously registered *Bt* corn products containing the previously registered events 1507, 59122 and MON810), which is reasonably likely to assure that persons purchasing 1507x59122xMON810 corn sign grower agreement(s). A description of the system must be submitted to EPA within 90 days from the date of registration.

F. 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.

G. Beginning on January 31, 2011, and annually thereafter, 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 a twelve-month period. Note: The first report shall contain the specified information from the time frame starting with the date of registration and extending through the 2010 growing season.

H. 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 maintain a comprehensive, ongoing IRM education program designed to convey to 1507x59122xMON810 corn users the importance of complying with the IRM program for all *Bt* corn products containing the Cry1F, Cry1Ab and Cry34/45Ab1events. 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. 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.

B. Annually, Pioneer shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraph F and from other sources. The registrant shall identify deficiencies in grower compliance and revise the education program to address those deficiencies.

C. Beginning January 31, 2011, Pioneer must provide a report to EPA summarizing the activities it carried out under its education program for the prior year. Annually thereafter, 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).

D. Pioneer must maintain an ongoing IRM compliance assurance program (CAP) equivalent to what is already approved for previously registered Pioneer *Bt* corn products, 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 1507x59122xMON810 corn. Pioneer shall coordinate with other Bt corn registrants in designing and implementing its compliance assurance program and integrate this registration into the current compliance assurance program used for their other Bt corn PIPs. Pioneer must prepare and submit within 90 days of the date of registration a written description of the compliance assurance program. Other required features of the program are described in paragraphs E through O below.

E. Pioneer must maintain and publicize a "phased compliance approach" 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. It must be equivalent to what is already approved for previously registered Pioneer *Bt* corn products. 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. The options shall include withdrawal of the right to purchase 1507x59122xMON810 corn for an individual grower or for all growers in a specific region. An individual grower found to be significantly out of compliance two years in a row would be denied sales of 1507x59122xMON810 corn 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 1507x59122xMON810 corn.

F. 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.

G. 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.

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

I. 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 by January 31st of each year, beginning with 2011. Pioneer shall confer with other registrants and EPA on the design and content of the survey prior to its implementation.

J. 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 F through H) 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.

K. 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 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.

L. Pioneer shall carry out a program for investigating legitimate "tips and complaints" that its growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, Pioneer shall take appropriate action, consistent with its "phased compliance approach."

M. 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.

N. Beginning January 31, 2011, and annually thereafter, 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. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, education programs, grower meetings and letters), the extent of non-compliance, corrective measures to address the

non-compliance, and any follow-up actions taken. Pioneer may elect to coordinate information with other registrants and report collectively the results of compliance assurance programs.

O. 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.

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

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, beginning in 2010, 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, beginning in 2010. 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 1 and 2, 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. Corn Rootworm Monitoring. The Agency is imposing the following conditions for the Cry34/35Ab1 toxin expressed in 1507x59122xMON810:

Pioneer must monitor for Cry34/35Ab1 resistance and/or trends in increased tolerance for corn rootworm using the existing corn rootworm monitoring program developed for previously registered Pioneer *Bt* corn products. Sampling should be focused in those areas in which there is the highest risk of resistance development. In addition to mortality assays, consider utilizing sublethal bioassays (e.g., head capsule measurements) and molecular marker methods for corn rootworm monitoring.

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

2. Pioneer must provide EPA with an annual resistance monitoring report by August 31st each year, beginning in 2010, reporting on populations collected the previous year.

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

i. *Definition of Suspected Resistance*. Resistance will be suspected if investigations of unexpected damage reports show that:

- implicated maize plant roots were expressing the Cry34/35Ab1 protein at the expected level;
- 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;
- 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.

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 Cry34/35Ab1 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;
- Cry34/35Ab1 plant assays determine that damage caused by surviving insects would exceed economic thresholds; and
- the identified frequency of field resistance could lead to widespread product failure if subsequent collections in the affected field area(s) demonstrated similar bioassay results.

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 Cry34/35Ab1 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. The details of such a plan should be approved by approved by EPA and all appropriate stakeholders.

V. Annual Reporting Requirements

1) Annual Sales: reported and summed by state (county level data available by request) January 31st each year, beginning in 2011;

2) Grower Agreements: 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, January 31st each year, beginning in 2011;

3) Grower Education: substantive changes to education program completed previous year, January 31st each year, beginning in 2011;

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, January 31st each year, beginning in 2011;

5) Compliance Survey Results: results of annual surveys for the prior year and survey plans for the current year; full report January 31st each year, beginning in 2011;

6) Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, August 31st each year, beginning in 2011.

Pioneer Hi-Bred International, Inc.
EPA Reg. No. 29964-8

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,

Keith A. Matthews, Acting Director
Biopesticides and Pollution
Prevention Division (7511P)

Enclosures

1507x59122xMON810

Corn Borer- and Rootworm-Protected Corn Seed
(OECD Unique Identifier: DAS-Ø15Ø7-1xDAS-59122-7xMON-ØØ81Ø-6)

Active Ingredients:

Bacillus thuringiensis Cry1F protein and the genetic material (PHI8999) necessary for its production in corn event DAS-Ø15Ø7-1 ..... ≤0.0011%*

Bacillus thuringiensis Cry34Ab1 protein and the genetic material (PHP17662) necessary for its production in corn event DAS-59122-7 ..... ≤0.0054%

Bacillus thuringiensis Cry35Ab1 protein and the genetic material (PHP17662) necessary for its production in corn event DAS-59122-7 ..... ≤0.0042%*

Bacillus thuringiensis Cry1Ab protein and the genetic material (PV-ZMBK07) necessary for its production in corn event MON-ØØ81Ø-6 ..... ≤0.0015%*

Inert Ingredient:

Phosphinothricin acetyltransferase (PAT) produced by the *pat* gene and the genetic material necessary for its production in corn ..... ≤0.0013%*

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

CAUTION

KEEP OUT OF REACH OF CHILDREN

NET CONTENTS _____

EPA REGISTRATION NUMBER: 29964-

EPA ESTABLISHMENT NUMBER: 029964-IA-001

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

DIRECTIONS FOR USE

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

The subject registration automatically expires at midnight on October 31, 2010.

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* and *Yieldgard*[2] *Corn Borer* 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.

Grower agreements will specify that growers must adhere to the refuge requirements that will be described in the Product Use Guide for *1507x59122xMON810* corn or other applicable product use documents.

Growers are instructed to read information on insect resistance management. Information regarding commercial production consistent with the following must be included in the Grower Guide:

The use of Cry1FxCry34/35Ab1xCry1Ab 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 for both traits may be combined by planting non-*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[1] RW) may be planted in the lepidopteran refuge for the Cry1F and Cry1Ab components and lepidopteran-resistant *Bt* corn (e.g., Herculex[1] I) 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[1] RW corn can serve as an in-field lepidopteran refuge for one field planted to Cry1FxCry34/35Ab1xCry1Ab corn and an external lepidopteran refuge for separate fields planted to Cry1FxCry34/35Ab1xCry1Ab corn, while the rootworm refuge is planted as Herculex[1] I or Yieldgard[2] Corn Borer 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 components.

1. *Refuge size,* Corn-Growing Areas (= corn belt and other non corn/cotton-growing regions). The use of Cry1FxCry34/35Ab1xCry1Ab corn requires an accompanying 20% refuge consisting of non-Bt corn or non-lepidopteran resistant *Bt* corn.

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[1] Herculex Insect Protection technology by Dow AgroSciences and Pioneer Hi-Bred. Herculex and the HX logo are registered trademarks of Dow AgroSciences LLC.

[2] Yieldgard and the Yieldgard Corn Borer design are registered trademarks used under the license from Monsanto Company.

2. *Refuge size* (Corn/Cotton-growing areas). ** The use Cry1FxCry34/35Ab1xCry1Ab corn requires an accompanying 50% refuge consisting of non-Bt corn or non-lepidopteran resistant *Bt* corn.

3. *Refuge location.*
   - The lepidopteran refuge can be planted in a separate field within a ½ mile of the Cry1FxCry34/35Ab1xCry1Ab field.
   - The lepidopteran refuge can be planted within the Cry1FxCry34/35Ab1xCry1Ab field as blocks (e.g. along the edges or headlands).
   - The lepidopteran refuge can be planted within the Cry1FxCry34/35Ab1xCry1Ab field as strips across the field at least four rows wide.

4. *Refuge management.*
   - Foliar 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 lepidopteran resistant refuges.

** 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, 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, Sussex) and Missouri (only the counties of Dunkin, New Madrid, Pemiscot, Scott, Stoddard).

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

1. *Refuge size.* The use of Cry1FxCry34/35Ab1xCry1Ab 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 Cry1FxCry34/35Ab1xCry1Ab 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) crop rows wide.
   - Seed mixtures of Cry1FxCry34/35Ab1xCry1Ab and rootworm refuge corn are not permitted.
   - If the rootworm refuge is planted on rotated ground, then Cry1FxCry34/35Ab1xCry1Ab corn must also be planted on rotated ground.
   - If the rootworm refuge is planted in continuous corn, the Cry1FxCry34/35Ab1xCry1Ab 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 Cry1FxCry34/35Ab1xCry1Ab corn.
- Pests other than adult corn rootworms can be treated on the rootworm refuge acres without treating the Cry1FxCry34/35Ab1xCry1Ab 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 Cry1FxCry34/35Ab1xCry1Ab 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 Cry1FxCry34/35Ab1xCry1Ab 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 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 Cry1FxCry34/35Ab1xCry1Ab 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) rows wide.
   - Seed mixtures of Cry1FxCry34/35Ab1xCry1Ab and refuge corn are not permitted.
   - If the combined refuge is planted on rotated ground, then the Cry1FxCry34/35Ab1xCry1Ab corn must also be planted on rotated ground.
   - If the combined refuge is planted on continuous corn, the Cry1FxCry34/35Ab1xCry1Ab 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 Cry1FxCry34/35Ab1xCry1Ab corn.
   - Foliar 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 Cry1FxCry34/35Ab1xCry1Ab acres only if treatment occurs when adult corn rootworms are not present. Microbial *Bt* insecticides must not be applied to the common refuges.

- Pests other than adult corn rootworms can be treated with CRW-labeled insecticide on the combined refuge acres without treating the Cry1FxCry34/35Ab1xCry1Ab acres only if treatment occurs when adult corn rootworms are not present. Pests on the Cry1FxCry34/35Ab1xCry1Ab 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 Cry1FxCry34/35Ab1xCry1Ab 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