

U S ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Biopesticides and Pollution
Prevention Division (7511P)
Ariel Rios Building
1200 Pennsylvania Ave, NW
Washington D C 20460

EPA Reg Number

Date of Issuance

29964 14

MAR 07 2012

NOTICE OF PESTICIDE

Registration
 Reregistration
(under FIFRA as amended)

Term of Issuance Conditional

Name of Pesticide Product

Optimum® Intrasect™ XTreme

Name and Address of Registrant (include ZIP Code)

Pioneer Hi Bred International Inc
7100 N W 62nd Avenue
P O Box 1000
Johnston Iowa 50131 1000

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/reregistered 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

This product is conditionally registered in accordance with FIFRA Section 3(c)(7)(A) of the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) as amended provided that you do the following terms and conditions

- 1] The subject registration will automatically expire on midnight April 1 2020
- 2] The subject registration will be limited to TC1507 (Cry1F) x DAS 59122 7 (Cry34Ab1/Cry35Ab1) x MON810 (Cry1Ab) x MIR604 (mCry3A) corn for use in field corn
- 3] Submit/cite all data required for registration of your product under FIFRA section 3(c)(5) when the Environmental Protection Agency (EPA) requires registrants of similar products to submit such data
- 4] Submit/cite all data determined by EPA to be acceptable and required to support the individual plant incorporated protectants in TC1507 (Cry1F) DAS 59122 7 (Cry34Ab1/Cry35Ab1) MON810 (Cry1Ab) and MIR604 (mCry3A) within the time frames required by the terms and conditions of EPA Registration Numbers 29964 3 29964 4 524 489 and 67979 5 respectively

Signature of Approving Official

W A S

Date

MAR 07 2012

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 Cry34/35Ab1 and mCry3A components The refuge for these traits may be combined by planting non *Bacillus thuringiensis* (*Bt*) corn as the refuge or the refuge for each trait may be planted separately In the latter case corn rootworm resistant *Bt* corn may be planted in the lepidopteran refuge for the Cry1F and Cry1Ab components and lepidopteran resistant *Bt* corn may be planted in the corn rootworm refuge for the mCry3A and Cry34/35Ab1 components

Requirements for Pioneer Hi Bred International Incorporated (Pioneer) to prepare and require Optimum® Intrasect™ XTreme users to sign grower agreements that impose binding contractual obligations on growers 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 Pioneer to develop implement and report to EPA on monitoring programs to evaluate whether there are statistically significant and biologically relevant changes in susceptibility to the Cry1F Cry1Ab Cry34/35Ab1 and mCry3A proteins in the target insects

Requirements for Pioneer to develop and if triggered to implement a remedial action plan that would contain measures Pioneer would take in the event that any field relevant insect resistance was detected as well as to report on activity under the plan to EPA

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

Requirements for Pioneer on or before August 31st of each year to submit reports on resistance monitoring

a) Refuge Requirements for Optimum® Intrasect™ XTreme

These refuge requirements do not apply to seed propagation of inbred and hybrid corn seed up to a total of 20 000 acres per county and up to a combined U S total of 250 000 acres per PIP active ingredient per registrant per year Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the following refuge requirements as described in the

grower guide/product use guide and/or in supplements to the grower guide/product use guide

The following information must be included on the product bag or bag tag as sold per respective region and in the Grower Guide

A common refuge must be planted for both corn borers and corn rootworms. The refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. The refuge and Optimum® Intrasect™ XTreme 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. If the refuge is planted on rotated ground, then the Optimum® Intrasect™ XTreme corn must also be planted on rotated ground. If the combined refuge is planted on continuous corn, the Optimum® Intrasect™ XTreme field may be planted on either continuous or rotated land (option encouraged where WCRW rotation resistant biotype may be present). Refuge options are based on the planting of Optimum® Intrasect™ XTreme in cotton or non cotton growing regions and the insect pressure present in those locations. The refuge sizes for these regions are either 20% in cotton growing regions (i.e. 20 acres of non Bt corn for every 80 acres Optimum® Intrasect™ XTreme planted) or 5% in non cotton growing regions (5 acres of non Bt corn for every 95 acres of Optimum® Intrasect™ XTreme planted). If corn rootworms are significant within a region, the structured refuge must be planted as an in field or adjacent refuge using corn hybrids that do not contain Bt technologies for the control of corn borers or corn rootworms. It can be planted as a block within or adjacent (e.g. across the road) to the Optimum® Intrasect™ XTreme corn perimeter strips (i.e. strips around the field) or in field strips. If perimeter or in field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non Bt insecticides if the population of one or more target lepidopteran pests of Optimum® Intrasect™ XTreme in the refuge exceeds economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide, however, insecticides labeled for adult CRW control must be avoided in the refuge during the period of CRW adult emergence. If insecticides are applied to the refuge for control of CRW adults, the same treatment must also be applied in the same timeframe to Optimum® Intrasect™ XTreme. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g. Extension Service agents, crop consultants). If corn rootworms are not significant within a region, the structured refuge may be planted as an in field or adjacent refuge or as a separate block that is within 1/2 mile of the Optimum® Intrasect™ XTreme field. The structured refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn borers or corn rootworms. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g. Extension Service agents, crop consultants).

Region	Refuge size	In field or adjacent refuge is allowed	Refuge separated by up to 1/2 mile is allowed
Cotton growing where CEW is a significant pest and WCRW, NCRW and MCRW are not significant. AR, NC, SC, GA, FL, TN (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin)	20% non Bt corn	Yes	Yes

Region	Refuge size	In field or adjacent refuge is allowed	Refuge separated by up to 1/2 mile is allowed
Haywood Lake Lauderdale Lincoln Madison Obion Rutherford Shelby and Tipton) AL MS LA VA (only the counties of Dinwiddie Franklin City Greenville Isle of Wight Northampton Southampton Suffolk City Surrey and Sussex)			
Cotton growing where CEW is a significant pest and WCRW NCRW and/or MCRW are significant TX (except the counties of Carson Dallam Hansford Hartley Hutchinson Lipscomb Moore Ochiltree Roberts and Sherman) OK (only the counties of Beckham Caddo Comanche Custer Greer Harmon Jackson Kay Kiowa Tillman and Washita) MO (only the counties of Dunkin New Madrid Pemiscot Scott and Stoddard)	20% non Bt corn	Yes	No
Cotton growing where CEW is not a significant pest and WCRW NCRW and MCRW are not significant NM AZ CA NV	5% non Bt corn	Yes	Yes
Non cotton growing where WCRW NCRW and MCRW are not significant OR WA ID MT WY UT VA (except the counties of Dinwiddie Franklin City Greenville Isle of Wight Northampton Southampton Suffolk City Surrey and Sussex) WV PA MD DE CT RI NJ NY ME MA NH VT HI AK TN(except the counties of Carroll Chester Crockett Dyer Fayette Franklin Gibson Hardeman Hardin Haywood Lake Lauderdale Lincoln Madison Obion Rutherford Shelby and Tipton)	5% non Bt corn	Yes	Yes
Non cotton growing where WCRW NCRW and/or MCRW are significant KS NE SD ND MN IA MO (except the counties of Dunkin New Madrid Pemiscot Scott and Stoddard) IL WI MI IN OH KY CO OK (except the counties of Beckham Caddo Comanche Custer Greer Harmon Jackson Kay	5% non Bt corn	Yes	No

Region	Refuge size	In field or adjacent refuge is allowed	Refuge separated by up to 1/2 mile is allowed
Kiowa Tillman and Washita) TX (only the counties of Carson Dallam Hansford Hartley Hutchinson Lipscomb Moore Ochiltree Roberts and Sherman)			

a Grower Agreements for Optimum® Intrasect™ XTreme

1] Persons purchasing Optimum® Intrasect™ XTreme must sign a grower agreement The term grower agreement refers to any grower purchase contract license agreement or similar legal document

2] The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program By signing the grower agreement a grower must be contractually bound to comply with the requirements of the IRM program

3] Pioneer must continue to integrate this registration into the current system used for its other *Bt* corn plant incorporated protectants which is reasonably likely to assure that persons purchasing Optimum® Intrasect™ XTreme will affirm annually that they are contractually bound to comply with the requirements of the IRM program

4] Pioneer must submit its grower agreement for Optimum® Intrasect™ XTreme corn within six (6) months of this registration 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 (30) 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

5] Pioneer must integrate this registration into the current system used for its other *Bt* corn plant incorporated protectants which is reasonably likely to assure that persons purchasing Optimum® Intrasect™ XTreme sign grower agreement(s)

6] Pioneer shall maintain records of all Optimum® Intrasect™ XTreme corn grower agreements for a period of three (3) years from December 31st of the year in which the agreement was signed

7] Annually Pioneer shall provide EPA with a report showing the number of units of Optimum® Intrasect™ XTreme seeds sold or shipped and not returned and the number of such units that were sold to persons who have signed grower agreements The report shall cover the time frame of the 12 month period covering the prior September through August

8] 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 numbers of the growers will be protected

c IRM Education and Compliance Monitoring Programs for Optimum® Intrasect™ XTreme Corn

1] Pioneer must continue to implement and enhance (as set forth in paragraph 17 of this section) a comprehensive ongoing IRM education program designed to convey to Optimum® Intrasect™ XTreme corn users the importance of complying with the IRM program The program shall include information encouraging Optimum® Intrasect™ XTreme users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Optimum® Intrasect™ XTreme fields The education program shall involve the use of multiple media (e g face to face meetings mailing written materials EPA reviewed language on IRM requirements on the bag or bag tag and electronic communications such as by Internet radio or television commercials) Copies of the materials will be provided to EPA for its records The program shall involve at least one written communication annually to each Optimum® Intrasect™ XTreme user separate from the grower technical guide The communication shall inform the user of the current IRM requirements Pioneer shall coordinate its education programs with educational efforts of other registrants and organizations such as the National Corn Growers Association and state extension programs

Pioneer must design and immediately implement a bag tag that will be attached to all bags of Optimum® Intrasect™ XTreme Corn seed sold and delivered for the 2013 growing season and annually thereafter The purpose of this bag tag is to remind growers that Optimum® Intrasect™ XTreme Corn products require a separate 20% lepidopteran refuge in cotton growing areas The PIP product label accepted by EPA must include how this information will be conveyed to growers via text and graphics A revised PIP product label must be submitted by April 1 2012

2] 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 6–8 of this section and from other sources The changes shall address aspects of grower compliance that are not sufficiently high

3] 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 4–22 of this section

4] Pioneer must continue to implement and improve an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing Optimum® Intrasect™ XTreme 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 integrate this registration into the current compliance assurance program used for its other *Bt* corn plant incorporated protectants Other required features of the program are described in paragraphs 5–22 of this section

5] Pioneer must maintain and publicize a phased compliance approach (i.e. a guidance document that indicates how it will address instances of non compliance with the terms of the IRM program and general criteria for choosing among options for responding to any noncompliant 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 A grower found with a second incident of significant non compliance with refuge requirements for the *Bt* corn product within a five year period will be denied access to Pioneer Hi Bred'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*

6) The IRM compliance assurance program shall include an annual survey conducted by an independent third party of a statistically representative sample of growers of Optimum® Intrasect™ XTreme corn who plant the vast majority of all corn in the United States and in areas in which the selection intensity is greatest The survey shall consider only those growers who plant 200 or more acres of corn in the Corn Belt and who plant 100 or more acres of corn in corn/cotton areas The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non response The sample size and geographical resolution may be adjusted annually based upon input from independent marketing research firms and academic scientists to allow analysis of compliance behavior within regions or between regions The sample size must provide a reasonable sensitivity for comparing results across the United States

1 A third party is classified as a party other than the registrant the grower or anyone else with a direct interest in IRM compliance for *Bt* corn

7] The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements An analysis of the survey results must include the reasons extent and potential biological significance of any implementation deviations

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

9] 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

10] 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 6–8 of this section and from other sources The changes shall address aspects of grower compliance that are not sufficiently high Pioneer must confer with EPA prior to adopting any changes

11] Pioneer shall conduct an annual on farm assessment program Pioneer shall train its representatives who make on farm visits with Optimum® Intrasect™ XTreme growers to perform assessments of compliance with IRM requirements There is no minimum corn acreage size for this program Therefore growers will be selected for this program from across

all farm sizes In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program Pioneer shall take appropriate action consistent with its phased compliance approach to promote compliance

12] Pioneer shall carry out a program for investigating legitimate tips and complaints that Optimum® Intract™ XTreme 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

13] If a grower who purchases Optimum® Intract™ XTreme for planting was specifically identified as not being in compliance during the previous year Pioneer shall visit with the grower and evaluate whether that the grower is in compliance with the IRM program for the current year

14] Annually Pioneer shall provide a report to EPA summarizing the activities carried out under its compliance assurance program for the prior year and the plans for the compliance assurance program during the current year Within one (1) month of submitting this report to EPA 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

15] 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 grower license numbers of the growers will be protected

16] Pioneer shall revise and expand its existing compliance assurance program to include the following elements Pioneer must prepare and submit on or before January 31 2013 a written description of its revised compliance assurance program Pioneer may coordinate with other registrants in designing and implementing its compliance assurance program

17] 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 requirement on all Optimum® Intract™ XTreme corn seed bags or bag tags Pioneer must submit a revised Optimum® Intract™ XTreme label by April 1 2012 that includes how this information will be conveyed to growers via text and graphics Insect Protection corn seed bags or bag tags must occur by the 2013 growing season

18] 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 Optimum® Intrasect™ XTreme corn is used

19] Pioneer will use its available Optimum® Intrasect™ XTreme 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 Optimum® Intrasect™ XTreme but may have purchased little or no refuge seed from the registrant licensees or affiliated companies

20] 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

21] Annually Pioneer will refine the on farm assessment program for Optimum® Intrasect™ XTreme corn to reflect the adoption rate and level of refuge compliance for Optimum® Intrasect™ XTreme corn

22] 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 (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 Optimum® Intrasect™ XTreme within a 5 year period will be denied access to Pioneer's *Bt* corn products the next year

d Insect Resistance Monitoring and Remedial Action Plan for Optimum® Intrasect™ XTreme Corn

1] EPA is imposing the following conditions for the Cry1F and Cry1Ab toxins expressed in Optimum® Intrasect™ XTreme corn

Pioneer will monitor for resistance to Cry1F and Cry1Ab expressed in Optimum® Intrasect™ XTreme corn. The monitoring program shall consist of two approaches: (1) focused population sampling and laboratory testing, and (2) investigation of reports of less than expected control of labeled insects. Should field relevant resistance be confirmed, an appropriate resistance management action plan will be implemented.

Focused Population Sampling

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 Optimum® Intrasect™ XTreme and/or changes in resistance allele frequency in response to the use of Optimum® Intrasect™ XTreme corn, and as far as possible, should be consistent across sampling years to enable comparisons with historical data.

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

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

Pioneer will report to EPA on or before August 31st of each year the results of the population sampling and bioassay monitoring program.

Any incidence of unusually low sensitivity to the Cry1F and Cry1Ab 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 EPA annually on or before August

31st The investigative steps will include the following

1 Re test progeny of the collected population to determine whether the unusual bioassay response is reproducible and heritable. If it is not reproducible and heritable, no further action is required.

2 If the unusual response is reproducible and heritable, progeny of insects that survive the diagnostic concentration will be tested using methods that are representative of exposure to Optimum® Intrasect™ XTreme under field conditions. If progeny do not survive to adulthood, any suspected resistance is not field relevant and no further action is required.

3 If insects survive steps 1 and 2, resistance is confirmed, and further steps will be taken to evaluate the resistance. These steps may include the following:

determining the nature of the resistance (i.e., recessive or dominant, and the level of functional dominance); estimating the resistance allele frequency in the original population;

determining whether the resistance allele frequency is increasing by analyzing field collections in subsequent years sampled from the same site where the resistance allele(s) was originally collected;

determining the geographic distribution of the resistance allele by analyzing field collections in subsequent years from sites surrounding the site where the resistance allele(s) was originally collected.

Should field relevant resistance be confirmed, and the resistance appears to be increasing or spreading, Pioneer will consult with EPA to develop and implement a case specific resistance management action plan.

Investigation of Reports of Unexpected Levels of Damage by the Target Pests

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*.

Suspected Resistance

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

the corn in question has been confirmed to be lepidopteran active *Bt* corn

the seed used had the proper percentage of corn expressing *Bt* protein

the relevant plant tissues are expressing the expected level of *Bt* protein and

it has been ruled out that species not susceptible to the protein could be responsible for the damage that no climatic or cultural reasons could be responsible for the damage and that there could be no other reasonable causes for the damage

EPA does not interpret ***suspected resistance*** to mean grower reports of possible control failures or suspicious results from annual insect monitoring assays nor does EPA intend that extensive field studies and testing be undertaken to confirm scientifically the presence of insects resistant to Optimum® Intrasect™ XTreme in commercial production fields before responsive measures are undertaken

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

Use alternative control measures in Optimum® Intrasect™ XTreme fields in the affected region to control the target pest during the immediate growing season

Destroy Optimum® Intrasect™ XTreme crop residues in the affected region within one (1) month after harvest with a technique appropriate for local production practices to minimize the possibility of resistant insects over wintering and contributing to the next season's target pest population

Additionally if possible and prior to the application of alternative control measures or destruction of crop residues 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

Confirmed Resistance

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

There is >30% insect survival and commensurate insect feeding in a bioassay initiated with neonate larvae that uses methods that are representative of exposure to *Bt* corn hybrids under field conditions (ECB and SWCB only)

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

In standardized laboratory bioassays the LC_{50} exceeds the upper limit of the 95% confidence interval of the LC_{50} for susceptible populations surveyed both in the original baselines developed for this pest species and in previous years of field monitoring

Response to Confirmed Resistance in a Key Target Pest as the Cause of Unexpected Levels of Damage in the Field

When field resistance is **confirmed** (as defined above) the following steps will be taken by Pioneer

EPA will receive notification within 30 days of resistance confirmation

Affected customers and extension agents will be notified about confirmed resistance within 30 days

Monitoring will be increased in the affected area and local target pest populations will be sampled annually to determine the extent and impact of resistance

If appropriate (depending on the resistant pest species the extent of resistance the timing of resistance and the nature of resistance and the availability of suitable alternative control measures) alternative control measures will be employed to reduce or control target pest populations in the affected area Alternative control measures may include advising customers and extension agents in the affected area to incorporate crop residues into the soil following harvest to minimize the possibility of over wintering insects and/or applications of chemical insecticides

Unless otherwise agreed with EPA stop sale and distribution of the relevant lepidopteran active *Bt* corn hybrids in the affected area immediately until an effective local mitigation plan approved by EPA has been implemented

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

Notify affected parties (e.g. growers consultants extension agents seed distributors university cooperators and state/federal authorities as appropriate) in the region of the resistance situation and approved action plan and

In subsequent growing seasons maintain sales suspension and alternative resistance management strategies in the affected region(s) for the *Bt* corn hybrids that are affected by the resistant population until an EPA approved local resistance management plan is in place to mitigate the resistance

A report on results of resistance monitoring and investigations of damage reports must be submitted to EPA on or before August 31st of each year for the duration of the registration

2] EPA is imposing the following conditions for the mCry3A Cry34Ab1 and Cry35Ab1 toxins expressed in Optimum® Intrasect™ XTreme

1 Pioneer must monitor for mCry3A and 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

11 The resistance monitoring plan must include the following baseline sensitivity data

sampling (number of locations samples per locations) sampling methodology and life stage sampled bioassay methodology standardization procedures (including quality assurance/quality control provisions) detection technique and sensitivity statistical analysis of the probability of detecting resistance and a revised description of rootworm damage guidelines

iii 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 2012 season with reporting in 2013 As part of this effort Pioneer must investigate the feasibility of using the

Within one year of this registration you must submit an enhanced rootworm resistance monitoring plan for 1507 x 59122 x MON810 x MIR604 that accounts for reports of suspected and/or confirmed resistance The rootworm resistance monitoring plan and the revised definitions for suspected and confirmed resistance for 1507 x 59122 x MON810 x MIR604 must be found acceptable to BPPD and utilized by Pioneer beginning in the 2013 season This enhanced monitoring program should

- o Be practical and adaptable and provide information on relevant changes in corn rootworm population sensitivity to 1507 x 59122 x MON810 x MIR604
- o Be focused on areas where the potential for resistance is greatest for 1507 x 59122 x MON810 x MIR604 and for the corn rootworm active single event components of 1507 x 59122 x MON810 x MIR604 (mCry3A and Cry34Ab1/Cry35Ab1) based on available information on historical pest pressure unexpected performance issues historical suspected and/or confirmed resistance incidents as currently defined or as modified in EPA accepted enhanced monitoring programs prevailing agronomic practices (e.g. crop rotation versus continuous corn) and academic and extension publications on Bt corn field performance
- o Involve coordination to the extent possible with other stakeholders such as academic and extension experts in the states where corn rootworm is a major pest and other registrants of similar products as appropriate
- o Be responsive to incidents of suspected or confirmed resistance to the registrant's other products containing the same active ingredient(s) as well as to publicly available reports of suspected or confirmed resistance to other *Bt* protein toxins in 1507 x 59122 x MON810 x MIR604

iv Pioneer must develop a proactive resistance monitoring program for northern corn rootworm (*Diabrotica barberi*) by the 2013 season with reporting in 2014 This program should include a proposal for annual sampling and testing of northern corn rootworm susceptibility to mCry3A and 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) month from the date of this registration (This information has been submitted and is being evaluated by the Agency)

v Pioneer must follow up on grower extension specialist or consultant reports of unexpected damage or control failures for corn rootworm

v1 Pioneer must provide EPA with a resistance monitoring report on or before August 31st of each year reporting on populations collected the previous year

v11 Within one year of this registration you must submit an enhanced remedial action plan for Optimum® AcreMax® XTreme that includes actions to be taken in response to both suspected and confirmed resistance This remedial action plan must include a description of steps to be taken in response to customer product performance inquiries and annual reporting to the agency on the outcomes of investigations into any such inquiries that might indicate potential resistance The program must include revised definitions of unexpected damage to Optimum® AcreMax® XTreme Corn that could indicate potential suspected resistance The enhanced remedial action plan must be found acceptable to BPPD and implemented by Pioneer in the 2013 growing season

Definition of Suspected Resistance

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

- i implicated corn plant roots were expressing the mCry3A Cry34Ab1 and Cry35Ab1 proteins at the expected levels
- ii the seed used was not mixed with non Bt seed
- iii alternative causes of damage or lodging such as nontarget pest insect species weather physical damage larval movement from alternate hosts planting errors and other reasonable causes for the observations have been ruled out

The Agency recognizes that large corn rootworm populations environmental conditions and protein expression levels can influence corn root damage and may affect the definition of suspected CRW resistance The Agency plans to work with the registrants to refine the definition of suspected resistance based on these factors Until such time that the Agency accepts a modified definition of suspected resistance to corn rootworm resistance will be suspected in cases where the average root damage in the 1507 x 59122 x MON810 x MIR604 field is > 0.5 on the nodal injury scale (NIS) and the frequency of 1507 x 59122 x MON810 x MIR604 with > 0.5 nodes destroyed exceeds 50% of the sampled plants

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

Confirmation of Resistance

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

- i the proportion of larvae that can feed and survive on Optimum® Intrasect™ XTreme corn roots from neonate to adult is significantly higher than the baseline proportion (currently being established)
- ii the LC₅₀ of the test population exceeds the upper limit of the 95% confidence interval for the LC₅₀ of a standard unselected population and/or survival in the diagnostic assay is significantly greater than that of a standard unselected population as established by the ongoing baseline monitoring program
- iii the ability to survive is heritable
- iv Optimum® Intrasect™ XTreme plant assays determine that damage caused by surviving insects would exceed economic thresholds and
- v if subsequent collections in the affected field area demonstrate similar bioassay results

Response to Confirmed Resistance

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

- i EPA will receive notification within 30 days of confirming resistance
- ii affected customers and extension agents will be notified about confirmed resistance
- iii affected customers and extension agents will be encouraged to employ alternative corn rootworm control measures
- iv sale and distribution of Optimum® Intrasect™ XTreme in the affected area will cease immediately until an effective mitigation plan has been approved by EPA and
- v a long term resistance management action plan will be devised according to the characteristics of the resistance event and local agronomic needs

e Annual Reporting Requirements for Optimum® Intrasect™ XTreme

- 1) Annual Sales reported and summed by state (county level data available by request) on or before January 31st of each year
- 2) Grower Agreement Results number of units of Optimum® Intrasect™ XTreme seeds sold or shipped and not returned and the number of such units that were sold to persons who have signed grower agreements on or before January 31st of each year

- 3) Grower Education substantive changes to the education program completed during the previous year on or before January 31st of each year
- 4) Compliance Assurance Program compliance assurance program activities and results for the previous year and plans for the compliance assurance program during the current year on or before January 31st of each year
- 5) Compliance Assurance Program Survey Results survey results for the previous year and plans for the current year on or before January 31st of each year
- 6) Insect Resistance Monitoring Results results of monitoring and investigations of damage reports on or before August 31st of each year

A copy of the stamped label is enclosed for your records

Sincerely


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

Optimum® Intrasect™ XTreme

(OECD Unique Identifier DAS Ø15Ø7 1xDAS 59122 7xMON ØØ81Ø 6xSYN IR6Ø4 5)

Active Ingredients

- Bacillus thuringiensis* Cry1F protein and the genetic material (plasmid insert PHI8999A) necessary for its production in corn event DAS Ø15Ø7 1 ≤0 0018%
- Bacillus thuringiensis* Cry34Ab1 protein and the genetic material (PHP17662 T DNA) necessary for its production in corn event DAS 59122 7 ≤0 0082%
- Bacillus thuringiensis* Cry35Ab1 protein and the genetic material (PHP17662 T DNA) necessary for its production in corn event DAS 59122 7 ≤0 0060%
- Bacillus thuringiensis* Cry1Ab protein and the genetic material (vector PV ZMBK07) necessary for its production in corn event MON ØØ81Ø 6 ≤0 0011%
- Bacillus thuringiensis* mCry3A protein and the genetic material (via elements of pZM26) necessary for its production in corn event SYN IR6Ø4 5 ≤0 0018%

Inert Ingredients

- 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 0024%
- Phosphomannose isomerase (PMI) protein and the genetic material (via elements of pZM26) necessary for its production in corn event SYN IR6Ø4 5 ≤0 00084 /

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

KEEP OUT OF REACH OF CHILDREN

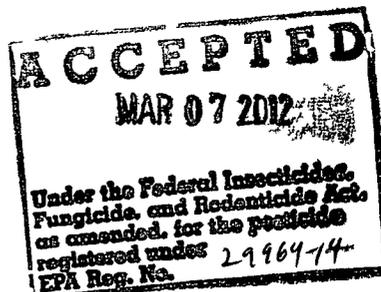
CAUTION

NET CONTENTS _____

EPA REGISTRATION NUMBER 29964 ~~8~~14

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

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

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

Optimum[®] Intrasect XTreme combines the insect protection features of 1507x59122xMON810 and Agrisure[®] RW in the same corn hybrid (inbred) Optimum Intrasect XTreme 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 Optimum Intrasect XTreme 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 Optimum Intrasect XTreme requires accompanying refuge corn for the Cry1F Cry34/35Ab1 Cry1Ab and mCry3A components as described in the table below

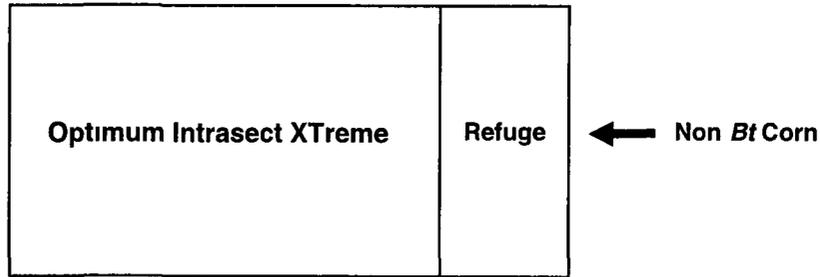
Region	Refuge size	In field or adjacent refuge allowed*	Refuge separated by up to ½ mile allowed
Non cotton growing where WCR NCR and MCR are not significant AK OR WA ID MT WY UT VA (except the counties of Dinwiddie Franklin City Greensville Isle of Wight Northampton Southampton Suffolk City Surrey and Sussex) WV PA MD DE CT RI NJ NY ME MA NH VT HI TN (except the counties of Carroll Chester Crockett Dyer Fayette Franklin Gibson Hardeman Hardin Haywood Lake Lauderdale Lincoln Madison Obion Rutherford Shelby and Tipton)	5% non <i>Bt</i> maize	Yes	Yes

Region	Refuge size	In field or adjacent refuge allowed	Refuge separated by up to 1/2 mile allowed
Non cotton growing where WCR NCR and/or MCR are significant KS NE SD ND MN IA MO (except the counties of Dunkin New Madrid Pemiscot Scott and Stoddard) IL WI MI IN OH KY CO OK (except the counties of Beckham Caddo Comanche Custer Greer Harmon Jackson Kay Kiowa Tillman and Washita) TX (only the counties of Carson Dallam Hansford Hartley Hutchinson Lipscomb Moore Ochiltree Roberts and Sherman)	5% non <i>Bt</i> maize	Yes	No
Cotton growing where CEW is not a significant pest and WCR NCR and MCR are not significant NM AZ CA NV	5% non <i>Bt</i> maize	Yes	Yes
Cotton growing where CEW is a significant pest and WCR NCR and MCR are not significant NC SC GA FL TN (only the counties of Carroll Chester Crockett Dyer Fayette Franklin Gibson Hardeman Hardin Haywood Lake Lauderdale Lincoln Madison Obion Rutherford Shelby and Tipton) AL MS LA AR VA (only the counties of Dinwiddie Franklin City Greenville Isle of Wight Northampton Southampton Suffolk City Surrey and Sussex)	20% non <i>Bt</i> maize	Yes	Yes
Cotton growing where CEW is a significant pest and WCR NCR and/or MCR are significant TX (except the counties of Carson Dallam Hansford Hartley Hutchinson Lipscomb Moore Ochiltree Roberts and Sherman) OK (only the counties of Beckham Caddo Comanche Custer Greer Harmon Jackson Kay Kiowa Tillman and Washita) MO (only the counties of Dunkin New Madrid Pemiscot Scott and Stoddard)	20% non <i>Bt</i> maize	Yes	No

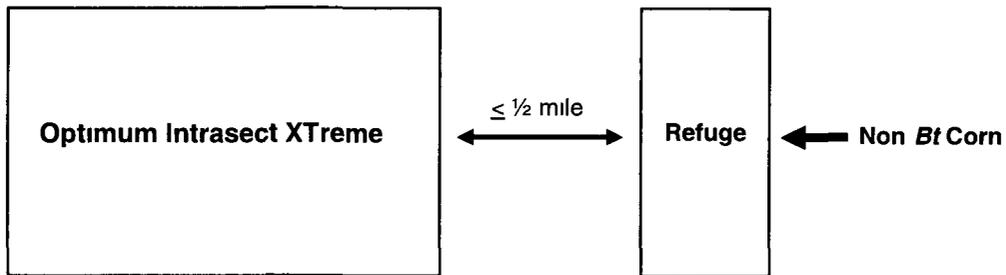
The common refuge can be separated by a ditch or a road but not by another field. The refuge must be owned or managed by the same grower. A neighbor's field cannot be used as the refuge.

If corn rootworms are significant within a region, the block/strip refuge must be planted as an in field or adjacent refuge using non *Bt* corn hybrids. It can be planted as block within or adjacent (e.g. across the road) to the Optimum Intrasect XTreme field perimeter strips (i.e. strips around the field) or in field strips that are at least one (1) row wide. The refuge can be protected from lepidopteran damage use of non *Bt* insecticides if the population of one or more target lepidopteran pests of Optimum Intrasect XTreme in the refuge exceeds economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide, however insecticides labels for adult CRW control must be avoided in the refuge during the period of CRW adult emergence. Economic threshold will be determined using method recommended by local or

regional professionals (e.g. Extension Service agents, crop consultants). A schematic of one common refuge deployment option is shown below.



If corn rootworms are not significant within a region, the block/strip refuge may be planted as an in-field or adjacent refuge, or as a separate block that is within a 1/2 mile of the Optimum Intrasect XTreme field. The block/strip refuge must be planted using non Bt corn hybrids. Economic threshold will be determined using the method recommended by local or regional professionals (e.g. Extension Service agents, crop consultants). A schematic of one refuge deployment option with the refuge planted within a 1/2 mile of the Optimum Intrasect XTreme field is shown below.



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 sugarcane borer stalk borer western bean cutworm western corn rootworm northern corn rootworm Mexican corn rootworm