29964-13 9/30/2011 1/23

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 13	SEP 30 2011

Term of Issuance: Conditional

NOTICE OF PESTICIDE
_x_ Registration
___ Reregistration
(under FIFRA as amended)

Name of Pesticide Product
Optimum® TRIsect™

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 September 30 2015

2] The subject registration will be limited to Cry1F [*Bacillus thuringiensis* Cry1F protein and the genetic material necessary for its production (plasmid insert PHP8999A) in event TC1507 corn (OECD Unique Identifier DAS Ø15Ø7 1)] x [mCry3A (MIR604) corn with modified Cry3Aprotein and the genetic material necessary for its production (via elements of vector pZM26) in corn SYN IR6Ø4 5] 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 Herculex® I Insect Protection and in Event MIR 604 with modified Cry3A (Agrisure RW) corn within the time frames required by the terms and conditions of EPA Registration Numbers 29964 3 and 67979 5 respectively

Signature of Approving Official	Date
[signature]	30 Sept 2011

EPA Form 8570 6

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

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

Requirements relating to creation of a refuge for the Cry1F and MCry3A components that meets the requirements of the individual traits The refuge for both traits may be combined by planting non *Bacillus thuringiensis* (*Bt*) corn as the refuge or the refuge for each trait may be planted separately In the latter case corn rootwormresistant *Bt* corn may be planted in the lepidopteran refuge for the Cry1F component and lepidopteran resistant *Bt* corn may be planted in the corn rootworm refuge for the MCry3A component

Requirements for Pioneer Hi Bred International Incorporated (Pioneer) to prepare and require Optimum® TRIsect™corn 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 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® TRIsect™Corn

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

When on farm assessments identify non compliance with refuge requirements for one or more *Bt* corn products additional educational material and assistance will be provided by Pioneer to help these growers meet the refuge requirements across their farming operations

Grower agreements (also known as stewardship agreements) will specify that growers must

adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide

The use of Optimum® TRIsect™ corn requires accompanying refuge corn for both the Cry1F and MCry3A components that meets the requirements of the individual traits as described below The refuge for both traits may be combined by planting non *Bt* corn as the refuge (see the Combined Refuge Option section) or the refuge for each trait may be planted separately (see the Lepidopteran Refuge for the Cry1F Component and Corn Rootworm Refuge for the MCry3A Component sections)

For the separate refuges corn rootworm resistant *Bt* corn (e g Herculex® Rootworm Insect Protection) may be planted in the lepidopteran refuge for the Cry1F component and lepidopteran resistant *Bt* corn (e g Herculex® I Insect Protection) may be planted in the corn rootworm refuge for the MCry3A component Depending on cropping practices pest problems and pest management options employed on any given farm growers may need to choose different refuge arrangements for different fields Two refuge blocks (one for rootworm one for Lepidoptera) can be planted within one field or strips can be used for either refuge Alternatively a block of Herculex® Rootworm Insect Protection corn can serve as an in field lepidopteran refuge for one field planted to Optimum® TRIsect™corn and an external lepidopteran refuge for separate fields planted to Optimum® TRIsect™ corn while the rootworm refuge is planted as Herculex® I Insect Protection corn in an external adjacent field In all options size and management of each individual refuge must be followed as described in the Lepidopteran Refuge for the Cry1F Component and Corn Rootworm Refuge for the MCry3A Component sections

Other refuge designs and combinations are permissible as long as in all cases the size and management of each refuge are described in the Lepidopteran Refuge for the Cry1F Component Corn Rootworm Refuge for the MCry3A Component or Combined Refuge Option sections

<u>Lepidopteran Refuge for the Cry1F Component</u>

1] *Refuge size Corn growing areas (Corn Belt and other non corn/cotton growing areas)* The use of Optimum® TRIsect™corn requires an accompanying 20% refuge consisting of non *Bt* corn or corn that is not a lepidopteran protected *Bt* hybrid

2] **Refuge size Corn/cotton growing areas* The use of Optimum® TRIsect™ corn requires an accompanying 50% refuge consisting of non *Bt* corn or corn that is not a lepidopteran protected *Bt* hybrid

3] *Refuge location*

The lepidopteran refuge can be planted in a separate field not more than ½ mile from the Optimum® TRIsect™corn field

The lepidopteran refuge can be planted within the Optimum® TRIsect™ corn field as blocks (e g along the edges or headlands)

The lepidopteran refuge can be planted within the Optimum® TRIsect™ corn field as strips across the field at least four (4) consecutive rows wide

4] *Refuge management*

Insecticide treatment for European corn borer (ECB) corn earworm (CEW) southwestern corn borer (SWCB) and other lepidopteran pests listed on the label grower guides or other educational material may be applied only if economic thresholds are reached for 1 or more of these target pests Economic thresholds will be determined using methods recommended by local or regional professionals (e g Extension Service agents or crop consultants) Instructions to growers will specify that microbial *Bt* insecticides must not be applied to refuges consisting of non *Bt* corn or corn that is not a lepidopteran protected *Bt* hybrid

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

<u>Corn Rootworm Refuge for the MCry3A Component</u>

1] *Refuge size* The use of Optimum® TRIsect™corn requires an accompanying 20% refuge consisting of non *Bt* corn or corn that is not a rootworm protected *Bt* hybrid

2] *Refuge location* The rootworm refuge is required to be planted within or adjacent (e g across the road) to the Optimum® TRIsect™corn field

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

The in field rootworm refuge options must be planted as a single block or as a series of strips measuring at least four (4) consecutive crop rows wide
Seed mixtures of Optimum® TRIsect™and rootworm refuge corn are not permitted

5/23

If the rootworm refuge is planted on rotated ground then Optimum® TRIsect™ corn must also be planted on rotated ground

If the rootworm refuge is planted in continuous corn the Optimum® TRIsect™ corn field may be planted on either continuous or rotated land (option encouraged where western corn rootworm rotation resistant biotype may be present)

Application of soil insecticide is permitted in the rootworm refuge

Seed treatment is permitted in the rootworm refuge either at a rate for rootworm protection or at a rate for controlling secondary soil pests

If aerial insecticides are applied to the rootworm refuge for control of corn rootworm adults the same treatment must also be applied in the same time frame to Optimum® TRIsect™ corn

Pests other than adult corn rootworms can be treated on the rootworm refuge acres without treating the Optimum® TRIsect™corn acres only if treatment occurs when adult corn rootworms are not present or if pesticide without activity against adult corn rootworms is used Pests on the Optimum® TRIsect™corn acres can be treated as needed without having to treat the rootworm refuge

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

The rootworm refuge and Optimum® TRIsect™corn should be sown on the same day or with the shortest window possible between planting dates to ensure that corn root development is similar among varieties

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

Combined Refuge Option

For the combined refuge option (i e the lepidopteran refuge combined with the rootworm refuge by planting non *Bt* corn) the refuge must be planted and managed such that it is consistent with the requirements of the individual traits Cry1F and MCry3A

1] *Refuge size* The use of Optimum® TRIsect™corn requires an accompanying 20% refuge in corn growing areas and 50% refuge in cotton growing areas consisting of non *Bt* corn For the latter see the list of states labeled with * in the Lepidopteran Refuge for the Cry1F Component section

2] *Refuge location* The combined refuge is required to be planted within or adjacent (e g across the road) to the Optimum® TRIsect™corn field

3] *Refuge management options*

The in field combined refuge options must be planted as a single block or as a series of strips measuring at least four (4) consecutive crop rows wide

Seed mixtures of Optimum® TRIsect™and combined refuge corn are not permitted

If the combined refuge is planted on rotated ground then Optimum® TRIsect™ corn must also be planted on rotated ground

If the combined refuge is planted in continuous corn the Optimum® TRIsect™ corn field may be planted on either continuous or rotated land (option encouraged where western corn rootworm rotation resistant biotype may be present)

Application of soil insecticide for corn rootworm control is permitted in the combined refuge

Seed treatment is permitted in the combined refuge either at a rate for rootworm protection or at a rate for controlling secondary soil pests

If aerial insecticides are applied to the combined refuge for control of corn rootworm adults the same treatment must also be applied in the same time frame to Optimum® TRIsect™ corn

Insecticide treatments in the combined refuge for control of ECB CEW SWCB and other lepidopteran pests listed on the label grower guides or other educational material may be applied only if economic thresholds are reached for one (1) or more of these target pests Economic thresholds will be determined using methods recommended by local or regional professionals (e g Extension Service agents or crop consultants) These pests can be treated with corn rootworm labeled insecticide on the combined refuge acres without treating the Optimum® TRIsect™corn acres only if treatment occurs when adult corn rootworms are not present Instructions to growers will specify that microbial *Bt* insecticides must not be applied to the combined refuges

Pests other than adult corn rootworms can be treated with corn rootworm labeled insecticide on the combined refuge acres without treating the Optimum® TRIsect™ corn acres only if treatment occurs when adult corn rootworms are not present
Pests on the Optimum® TRIsect™corn acres can be treated as needed without having to treat the combined refuge

The combined refuge can be planted to any corn hybrid that does not express plantincorporated protectants for lepidopteran or rootworm control (i e herbicide tolerant corn or conventional corn)

The combined refuge and Optimum® TRIsect™corn should be sown on the same day or with the shortest window possible between planting dates to ensure that corn root development is similar among varieties

b Grower Agreements for Optimum® TRIsect™Corn

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

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

3] 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® TRIsect™corn 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® TRIsect™ 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® TRIsect™corn sign grower agreement(s)

6] Pioneer shall maintain records of all Optimum® TRIsect™ 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® TRIsect™corn seeds sold or shipped and not returned and the number of such units that were sold to persons who have signed grower agreements The report shall cover the time frame of the 12 month period covering the prior August through July

8] 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® TRIsect™ 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® TRIsect™ corn users the importance of complying with the IRM program The program shall include information encouraging Optimum® TRIsect™corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Optimum® TRIsect™corn fields The education program shall involve the use of multiple media (e g face to face meetings mailing written materials EPA reviewed language on IRM requirements on the bag or bag tag and electronic communications such as by Internet radio or television commercials) Copies of the materials will be provided to EPA for its records The program shall involve at least one written communication annually to each Optimum® TRIsect™corn 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

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® TRIsect™ 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 An individual grower found to be significantly out of compliance two (2) years in a row would be denied access to Pioneer s *Bt* corn products the next year Similarly seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell *Bt* corn

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® TRIsect™ 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 corncotton 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® TRIsect™corn growers to perform assessments of compliance with IRM requirements There is no minimum corn acreage size for this program Therefore growers will be selected for this program from across all farm sizes In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program 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® TRIsect™corn growers are not in compliance with the IRM program Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program Pioneer shall take appropriate action consistent with its phased compliance approach

13] If a grower who purchases Optimum® TRIsect™corn for planting was

10/23

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 2011 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® TRIsect™ corn seed bags or bag tags Pioneer must submit a revised Optimum® TRIsect™corn label within three (3) weeks 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 2012 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® TRIsect™ corn is used

19] Pioneer will use its available Optimum® TRIsect™corn sales records and other information

to refine grower lists for on farm assessments of their compliance with refuge requirements

ı Identify for potential on farm assessment growers whose sales information indicates they have purchased Optimum® TRIsect™corn 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

ı 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® TRIsect™ corn to reflect the adoption rate and level of refuge compliance for Optimum® TRIsect™ 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

ı 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

ıı 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
ııı A grower found with a second incident of significant non compliance with refuge requirements for Optimum® TRIsect™corn 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® TRIsect™ Corn

1] EPA is imposing the following conditions for the Cry1F toxin expressed in Optimum® TRIsect™ corn

Pioneer will monitor for resistance to Cry1F expressed in Optimum® TRIsect™ 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 lepidopteranactive

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® TRIsect™corn and/or changes in resistance allele frequency in response to the use of Optimum® TRIsect™ 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® TRIsect™ 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 protein in bioassays shall be investigated as soon as possible to understand any field relevance of such a finding Such investigations shall proceed in a stepwise manner until the field relevance can be either confirmed or refuted and results of these shall be reported to EPA annually on or before August 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® TRIsect™corn under field conditions If progeny do not survive to adulthood any suspected resistance is not field relevant and no further action is required

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

determining the nature of the resistance (i e recessive or dominant and the level of

functional dominance) estimating the resistance allele frequency in the original population

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

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

Should field relevant resistance be confirmed and the resistance appears to be increasing or spreading 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 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® TRIsect™corn in commercial production fields before responsive measures are undertaken

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

14/23

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

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

Additionally if possible and prior to the application of alternative control measures or destruction of crop residues 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 $\geq 0\ 1$ in the sampled population

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

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

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 Cry34Ab1 and Cry35Ab1 toxins expressed in Optimum® TRIsect™corn

i Pioneer must monitor for MCry3A resistance and/or trends in increased tolerance for corn rootworm Sampling should be focused in those areas in which there is the highest risk of resistance development

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

iii Pioneer must develop a functional diagnostic assay for corn rootworm resistance monitoring to detect potentially resistant individuals and incorporate this assay into the annual resistance monitoring program by the 2011 season with reporting in 2012 As part of this effort Pioneer must investigate the feasibility of using the

Sublethal Seedling Assay1 as a diagnostic assay A report of Pioneer s progress

---

1 Nowatzki T Lefko SA Binning RR Thompson SD Spencer TA Siegfried BD 2008 Validation of a novel resistance monitoring technique for corn rootworm (Coleoptera Chrysomelidae) and event DAS 59122 7 maize *J*

towards this requirement must be submitted to EPA within one (1) month from the date of this registration

iv Pioneer must develop a proactive resistance monitoring program for northern corn rootworm (*Diabrotica barberi*) by the 2012 season with reporting in 2013 This program should include a proposal for annual sampling and testing of northern corn rootworm susceptibility to MCry3A 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

v Pioneer must submit revised corn rootworm damage guidelines (to characterize unexpected pest damage) that take into consideration the comments and recommendations from EPA s June 30 2010 review of the rootworm resistance monitoring program for MCry3A within one (1) month from the date of this registration

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

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

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

Definition of Suspected Resistance

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

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

ii the seed used was not mixed with non MCry3A seed

iii alternative causes of damage or lodging such as nontarget pest insect species weather physical damage larval movement from alternate hosts planting errors and

other reasonable causes for the observations have been ruled out and

iv the level of damage exceeds guidelines for expected damage

If resistance is ***suspected*** 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® TRIsect™ corn roots from neonate to adult is significantly higher than the baseline proportion (currently being established)

ii the LC_{50} of the test population exceeds the upper limit of the 95% confidence interval for the LC_{50} of a standard unselected population and/or survival in the diagnostic assay is significantly greater than that of a standard unselected population as established by the ongoing baseline monitoring program

iii the ability to survive is heritable

iv Optimum® TRIsect™corn plant assays determine that damage caused by surviving insects would exceed economic thresholds and

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

Response to Confirmed Resistance

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

i EPA will receive notification within 30 days of confirming resistance

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

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

iv sale and distribution of Optimum® TRIsect™corn in the affected area will cease immediately and

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

e Annual Reporting Requirements for Optimum® TRIsect™Corn

1) Annual Sales reported and summed by state (county level data available by request) on or

before January 31st of each year

2) Grower Agreement Results number of units of Optimum® TRIsect™corn seeds sold or shipped and not returned and the number of such units that were sold to persons

who have signed grower agreements on or before January 31st of each year

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

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

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

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

A copy of the stamped label is enclosed for your records

Sincerely

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

19/23

Optimum® TRIsect™

(OECD Unique Identifier DAS Ø15Ø7 1xSYN 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 0016%
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) necessary for its production in corn event DAS Ø15Ø7 1	<0 00046%
Phosphomannose isomerase (PMI) protein and the genetic material (via elements of pZM26) necessary for its production in corn event SYN IR6Ø4 5	<0 0010%

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

KEEP OUT OF REACH OF CHILDREN

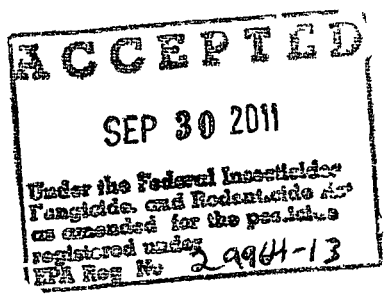
CAUTION

NET CONTENTS _____

EPA REGISTRATION NUMBER 29964 13

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® TRIsect combines the insect protection features of Herculex®[1] I and Agrisure®[2] RW in the same corn hybrid (inbred) Optimum TRIsect 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 (CRW) larvae In order to minimize the risk of the corn pests developing resistance to Optimum TRIsect an insect resistance management plan must be implemented

INSECT RESISTANCE MANAGEMENT

Growers are instructed to read information on insect resistance management

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

Corn seed bags or bag tags for products containing Optimum TRIsect must include the refuge size requirement in text and graphical format

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

The use of Optimum TRIsect requires accompanying refuge corn for the Cry1F and mCry3A components that meets the requirements of the individual traits described below The refuge for both traits may be combined by planting non *Bacillus thuringiensis* (*Bt*) corn as the refuge (see C below) or the refuge for each trait may be planted separately (see A and B below)

For the separate refuges CRW resistant *Bt* corn (e g Herculex® Rootworm) may be planted in the lepidopteran refuge for the Cry1F component and lepidopteran resistant *Bt* corn (e g Herculex® I) may be planted in the CRW refuge for the mCry3A component Depending on cropping practices pest problems and pest management options employed on any given farm growers may need to choose different refuge arrangements for different fields Two refuge blocks (one for CRW one for Lepidoptera) can be planted within one field or strips can be used for either refuge Alternatively a block of CRW resistant *Bt* corn (e g Herculex® Rootworm) can serve as an in field lepidopteran refuge for one field planted to Optimum TRIsect and an external lepidopteran refuge for separate fields planted to Optimum TRIsect while the CRW refuge is planted as lepidopteran resistant *Bt* corn (e g Herculex®) in an external adjacent field In all options size and management of each individual refuge must be followed as described in A and B below

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

---

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

[2] Agrisure® is a trademark of and used under license from a Syngenta Group Company Agrisure® technology incorporated into these seeds is commercialized under a license from Syngenta Crop protection AG

A Lepidopteran refuge for the Cry1F and mCry3A components

1 *Refuge size* Corn Growing Areas (= Corn Belt and other non corn/cotton growing regions) The use of Optimum TRIsect requires an accompanying 20% refuge consisting of non *Bt* corn or corn that is not a lepidopteran protected *Bt* hybrid

2 *Refuge size* (Corn/Cotton growing areas) * The use Optimum TRIsect requires an accompanying 50% refuge consisting of non *Bt* corn or corn that is not a lepidopteran protected *Bt* hybrid

3 *Refuge location*
- The lepidopteran refuge can be planted in a separate field within a ½ mile of the Optimum TRIsect field
- The lepidopteran refuge can be planted within the Optimum TRIsect field as blocks (e g along the edges or headlands)
- The lepidopteran refuge can be planted within the Optimum TRIsect field as strips across the field at least four (4) consecutive crop rows wide

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) Instructions to growers will specify that microbial *Bt* insecticides must not be applied to refuges consisting of non *Bt* corn or corn that is not a lepidopteran protected *Bt* hybrid

Cotton growing areas consist of the following states Alabama Arkansas Georgia Florida Louisiana North Carolina Mississippi South Carolina Oklahoma (only the counties of Beckham Caddo Comanche Custer Greer Harmon Jackson Kay Kiowa Tillman 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 Dunklin New Madrid Pemiscot Scott Stoddard)

B Corn rootworm refuge for the mCry3A component

1 *Refuge size* The use of Optimum TRIsect requires an accompanying 20% refuge consisting of non *Bt* corn or corn that is not a CRW protected *Bt* hybrid

2 *Refuge location* The CRW refuge is required to be planted within or adjacent (e g across the road) to the Optimum TRIsect field

3 *Refuge management options* The CRW refuge can be managed in such a way that there is little or no yield loss to CRW but must be managed in a way that it is sufficiently productive of susceptible CRW adults
- The in field CRW refuge options may be planted as a single block or as a series of strips measuring at least four (4) consecutive crop rows wide
- Seed mixtures of Optimum TRIsect and CRW refuge corn are not permitted
- If the CRW refuge is planted on rotated ground then Optimum TRIsect must also be planted on rotated ground

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

3 *Refuge management options*
   - The in field refuge options must be planted as a single block or as a series of strips measuring at least four (4) consecutive crop rows wide
   - Seed mixtures of Optimum TRIsect and refuge corn are not permitted
   - If the combined refuge is planted on rotated ground then the Optimum TRIsect corn must also be planted on rotated ground
   - If the combined refuge is planted on continuous corn the Optimum TRIsect 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 CRW control is permitted in the combined refuge
   - Seed treatment is permitted in the combined refuge either at a rate for CRW 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 Optimum TRIsect corn
   - Insecticide treatments in the combined refuge for control of European corn borer corn earworm southwestern corn borer fall armyworm black cutworm western bean cutworm sugarcane borer lesser corn stalk borer 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) These pests can be treated with CRW labeled insecticide on the combined refuge acres without treating the Optimum TRIsect acres only if

treatment occurs when adult CRW are not present Instructions to growers will specify that microbial *Bt* insecticides must not be applied to the combined refuges

- Pests other than adult CRW can be treated with CRW labeled insecticide on the combined refuge acres without treating the Optimum TRIsect acres only if treatment occurs when adult CRW are not present Pests on the Optimum TRIsect 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 CRW control (i e herbicide tolerant corn or conventional corn)
- The combined refuge and Optimum TRIsect 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 sugarcane borer western bean cutworm western corn rootworm northern corn rootworm Mexican corn rootworm