29964-23 11/5/2013 1/18

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:
29964-23	NOV 0 5 2013

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

Term of Issuance: Unconditional

Name of Pesticide Product:
Optimum® AcreMax® 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 unconditionally registered in accordance with FIFRA Section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, provided that you do the following terms.

1] The subject registration will automatically expire on midnight September 30, 2015.

2] Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires registrants of similar products to submit such data.

-Continued on Page 2-

Signature of Approving Official:
RMcNally

Robert McNally, Director
Biopesticides and Pollution Prevention Division (7511P)

Date:
11/5/13

EPA Form 8570-6

2/18

3] The subject registration will be limited to a seed mix of Cry1F [*Bacillus thuringiensis* Cry1F protein and the genetic material (plasmid insert PHI8999A) necessary for its production in corn event DAS-Ø15Ø7-1] x Cry1Ab [*Bacillus thuringiensis* Cry 1Ab protein and the genetic material (vector PV-ZMBK07) necessary for its production in corn event MON- ØØ81Ø-6] x mCry3A [*Bacillus thuringiensis* mCry3Ab protein and the genetic material (via elements of pZM26) necessary for its production in corn event SYNIR6 Ø4-5] blended with not less than 10% non-*Bt* corn seed.

4] Submit/cite all data determined by EPA to be acceptable and required to support the individual plant-incorporated protectant 1507 in Optimum® AcreMax® TRIsect® within the timeframes required by the terms and conditions of EPA Registration Numbers 29964-3.

5] Pioneer must implement an Insect Resistance Management Program for Optimum® AcreMax® TRIsect® consisting of the following elements:

- Requirements relating to a refuge assurance program for ensuring the correct refuge blend percentage.
- Requirements relating to creation of a lepidopteran refuge (consisting of corn that does not contain any *Bt* trait for lepidopteran control) in cotton growing regions in conjunction with the planting of any acreage of Optimum® AcreMax® TRIsect®;
- Requirements for Pioneer to prepare and require Optimum® AcreMax® TRIsect® users to sign "grower agreements," that impose binding contractual obligation on the grower to comply with the refuge requirements in cotton growing regions;
- Requirements regarding programs to educate growers about IRM requirements;
- Requirements regarding programs to evaluate and promote growers' compliance with IRM requirements;
- Requirements regarding programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to Cry1F, Cry1Ab and mCry3A proteins in the target insects;
- Requirements regarding a "remedial action plan," that contains 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 to maintain and to make available to the Agency upon request the number of units of Optimum® AcreMax® TRIsect® sold by state and county, IRM grower agreement results and substantive changes to education programs, within three months of the request;
- Bag Tag Requirements for Optimum® AcreMax® TRIsect®. Seed bags and/or bag tags for corn hybrids that contain plant-incorporated protectants produced in Optimum® AcreMax® TRIsect® must display the registration number and active ingredients, and stipulate that growers read the Pioneer Stewardship Guide (or equivalent guidance) prior to planting these hybrids. The refuge size requirement must be displayed on the bag or bag tag in both text and graphic format.

a) Refuge requirements for Optimum® AcreMax® TRIsect®

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

Corn-Belt/Non-Cotton Growing Areas

Optimum® AcreMax® TRIsect® contains a Lepidopteran and corn rootworm refuge that is "in the bag" and is automatically implemented when the grower plants the product. No additional refuge is required when planting this product.

Foliar insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, fall armyworm, black cutworm, western bean cutworm, lesser corn stalk borer, southern corn stalk borer, stalk borer and sugarcane borer may be applied only if economic thresholds are reached for one or more of these target pests. Foliar insecticide treatments are also permitted for control of corn rootworm adults if economic thresholds are reached. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

Cotton-Growing Region Refuge Requirements

In cotton-growing regions where corn earworm is a significant pest:

- The 20% refuge must be planted with non-*Bt* corn hybrids.
- Optimum® AcreMax® TRIsect® and the 20% non-*Bt* refuge should be sown on the same day, or with the shortest window possible between planting dates.
- External refuges may be planted as an in-field or adjacent (e.g., across the road) refuge or as a separate block within 1/2 mile of the Optimum® AcreMax® TRIsect® field.
- In field refuge options include: blocks, perimeter strips (i.e., along the edges or headlands), or in-field strips.
- When planting the refuge in strips across the field, refuges must be at one (1) row wide.
- Insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, fall armyworm, black cutworm, western bean cutworm, lesser corn stalk borer, southern corn stalk borer, stalk borer and sugarcane borer may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Microbial *Bt* insecticides must not be applied to non-*Bt* corn refuge plants.
- Cotton-growing areas include 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

4/18

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).

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

b) Grower agreement for Optimum® AcreMax® TRIsect®

1. Persons purchasing Optimum® AcreMax® TRIsect® 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 integrate this registration into the current system used for previously registered Pioneer *Bt* corn products, which is reasonably likely to assure that persons purchasing Optimum® AcreMax® TRIsect® will affirm annually that they are contractually bound to comply with the requirements of the IRM program.

4. Pioneer must integrate this registration into the current system which is used for its other *Bt* corn plant-incorporated protectants and which is reasonably likely to assure that persons purchasing Optimum® AcreMax® TRIsect® sign grower agreement(s).

5. Pioneer shall maintain records of all Optimum® AcreMax® TRIsect® grower agreements for a period of three years from December 31st of the year in which the agreement was signed.

6. Pioneer shall maintain and make available to the Agency upon request records of the number of units of Optimum® AcreMax® TRIsect® seed sold by state and county, and the number of such units that were sold to persons who have signed grower agreements within three months of the request.

7. Pioneer must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

c) IRM Education and IRM Compliance Monitoring Program for Optimum® AcreMax® TRIsect® in EPA-designated cotton counties

1. Pioneer must implement and enhance a comprehensive, ongoing IRM education program designed to convey to Optimum® AcreMax® TRIsect® users the importance of complying with the IRM program. The program must also address unexpected pest damage and guidance for growers in this area. The education program shall involve the use of multiple media, *e.g.* face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the

bag or bag tag, and electronic communications such as by internet, radio, or television commercials. Copies of the materials will be provided to EPA for their records. The program shall involve at least one written communication annually to each Optimum® AcreMax® TRIsect® user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements and specifically the need to plant a lepidopteran refuge in cotton growing regions. Pioneer shall coordinate its education program with the educational efforts of other registrants and other organizations, such as the National Corn Growers Association and state extension programs.

2. Pioneer must design and immediately implement a "bag tag" that will be attached to all bags of Optimum® AcreMax® TRIsect® seed sold and delivered for the 2014 growing season and annually thereafter. The purpose of this bag tag is to remind growers that Optimum® AcreMax® TRIsect® 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 January 31, 2014.

3. Pioneer must conduct targeted, on-farm compliance assessments for growers who purchase Optimum® AcreMax® TRIsect® seed to ensure growers are compliant with the requirement of a 20% refuge for lepidopteran pests in cotton growing areas. Results of these on-farm surveys must be reported separately from non-seed blended products.

   Pioneer must provide, in conjunction with other Pioneer PIP products, a report to EPA summarizing the Optimum® AcreMax® TRIsect® compliance assurance program activities and results for the prior year and plans for the Optimum® AcreMax® TRIsect® compliance assurance program for the current year, by January 31, 2014, and annually thereafter. Within one month of submitting this report to EPA, Pioneer shall meet with EPA to discuss its findings. 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.

4. Pioneer shall implement and enhance its education program to take into account the information collected through the compliance survey and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

5. Pioneer must maintain and provide to the Agency upon request, substantive changes to educational programs within three months of the Agency's request.

6. Pioneer shall revise and expand its existing Compliance Assurance Program to include the following elements: Pioneer must prepare and submit a written description of its revised Compliance Assurance Program. Pioneer may coordinate with other registrants in designing and implementing its Compliance Assurance Program.

7. 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. Pioneer must design and immediately implement a "bag tag" that will be attached to all bags of Optimum® AcreMax® TRIsect® seed sold and delivered for the 2014 growing season and annually thereafter. The purpose of this bag tag is to remind growers that Optimum® AcreMax® TRIsect® 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 January 31, 2014.

8. Pioneer will focus the majority of on-farm assessments on regions with the greatest risks 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 Optimum® AcreMax® TRIsect® is used.

9. Pioneer will use its available Optimum® AcreMax® TRIsect® 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 the Optimum® AcreMax® TRIsect® but may have purchased little or no refuge seed from the registrant, licensee, or affiliated companies.

10. Pioneer will contract with third parties to perform on-farm assessments of compliance with refuge requirements:

    i. 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.

    ii. The third-party assessors will conduct all first-time on-farm assessments for as well as second-year on-farm assessments of those growers found out of compliance in a first-time assessment.

11. Pioneer will annually refine the on-farm assessment program for the Optimum® AcreMax® TRIsect® to reflect the adoption rate and level of refuge compliance for Optimum® AcreMax® TRIsect®.

12. 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 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 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® AcreMax® TRIsect® within a five-year period will 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.

d) Insect Resistance Monitoring and Remedial Action Plan for Optimum® AcreMax® TRIsect®

EPA is imposing the following conditions for the Cry1F and Cry1Ab toxins expressed in Optimum® AcreMax® TRIsect®:

Pioneer will monitor for resistance to its lepidopteran-resistant *Bt* 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.

(1) Focused Population Sampling

Pioneer shall annually sample and bioassay populations of the key target pests *Ostrinia nubilalis* (European corn borer; ECB), *Diatraea grandiosella* (Southwestern corn borer; SWCB), and *Helicoverpa zea* (corn earworm; CEW). Sampling for the target pests will be focused in areas identified as those with the highest risk of resistance development (e.g., where lepidopteran-active *Bt* hybrids are planted on a high proportion of the corn acres, and where the insect species are regarded as key pests of corn). Bioassay methods must be appropriate for the goal of detecting field-relevant shifts in population response to lepidopteran resistant *Bt* corn and/or changes in resistance allele frequency in response to the use of *Bt* corn and, as far as possible, should be consistent across sampling years to enable comparisons with historical data.

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

The sampling program and geographic range of collections may be modified as appropriate based on changes in pest importance and for the adoption levels of lepidopteran-resistant *Bt* corn. The Agency shall be consulted prior to the implementation of such modifications.

The registrant will report to the Agency before August 31 each year the results of the population sampling and bioassay monitoring program.

Any incidence of unusually low sensitivity to the *Bt* 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

8/18

manner until the field relevance can be either confirmed or refuted, and results of these shall be reported to the Agency annually before August 31. The investigative steps will include:

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 *Bt* corn hybrids 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:

- 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, the registrant will consult with the Agency to develop and implement a case-specific resistance management action plan.

(2) Investigation of Reports of Unexpected Levels of Damage by the Target Pests:

The registrant will follow up on grower, extension specialist or consultant reports of unexpected levels of damage by the lepidopteran pests listed on the pesticide label. The registrant will instruct its customers to contact them if such incidents occur. The registrant 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), the registrant 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;

9/18

- 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.

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

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

- Use alternative control measures in the *Bt* corn fields in the affected region to control the target pest during the immediate growing season.

- Destroy *Bt* corn crop residues in the affected region within one month after harvest with a technique appropriate for local production practices to minimize the possibility of resistant insects over-wintering and contributing to the next season's target pest population.

Additionally, if possible, and prior to the application of alternative control measures or destruction of crop residue, the registrant 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.

(3) 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 the registrant:

- EPA will receive notification within 30 days of resistance confirmation;

10/18

- 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;

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

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- 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 the Agency annually by August 31st each year for the duration of the conditional registration.

EPA is imposing the following conditions for the mCry3A toxin expressed in Optimum® AcreMax® TRIsect®:

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.

11/18

iii. Pioneer must develop and utilize a functional "on-plant" diagnostic assay[1] for corn rootworm resistance monitoring to detect potentially resistant individuals and incorporate this assay into the annual resistance monitoring program.

iv. Pioneer must submit an enhanced rootworm resistance monitoring plan for Optimum® AcreMax® TRIsect® 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 Optimum® AcreMax® TRIsect® must be found acceptable to BPPD and utilized by Pioneer beginning in the 2015 season. This enhanced monitoring program should:

o Be practical and adaptable and provide information on relevant changes in corn rootworm population sensitivity to Optimum® AcreMax® TRIsect®;

o Be focused on areas where the potential for resistance is greatest for Optimum® AcreMax® TRIsect® and for the corn rootworm active single event component of Optimum® AcreMax® TRIsect® (mCry3A), 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 Optimum® AcreMax® TRIsect®.

v. Pioneer must develop a proactive resistance monitoring program for northern corn rootworm (*Diabrotica barberi*). 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. (This information has been submitted and is being evaluated by the Agency).

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. Remedial Action Plan for Corn Rootworm and Optimum® AcreMax® TRIsect®

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[1] Examples of on-plant bioassays include:
Nowatzki T, Lefko SA, Binning RR, Thompson SD, Spencer TA, Siegfried BD. 2008. Validation of a novel resistance monitoring technique for corn rootworm (Coleoptera: Chrysomelidae) and event DAS-59122-7 maize. *J. Appl. Entomol.* 132:177–188 and
Gassmann A.J., J.L. Petzold-Maxwell, R.S. Keweshan, and M.W. Dunbar, 2011. Field-evolved resistance to *Bt* maize by western corn rootworm. *PLOS one*, Vol. 6 (7): 1-7.

12/18

The current remedial action plan approved for mCry3A must be used for corn rootworm with suspected and confirmed resistance to Optimum® AcreMax® TRIsect®. If corn rootworm resistance is confirmed, all acres of Optimum® AcreMax® TRIsect® and refuges in the affected area must be treated with insecticides targeted at corn rootworm adults and/or larvae.

Within one year of this registration, Pioneer must submit an enhanced remedial action plan for Optimum® AcreMax® TRIsect® 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® TRIsect® that could indicate potential suspected resistance. The enhanced remedial action plan must be found acceptable to BPPD and implemented by Pioneer beginning in the 2014 growing season.

The remedial action plan is designed as a tiered approach for mitigating western and northern corn rootworm resistance development specifically due to the commercialization of Optimum® AcreMax® TRIsect®. The following program summary describes, in order of events, the steps that must be taken to implement a remedial action plan if resistance to target pests is confirmed.

1. **Suspected Resistance from Population Monitoring**

Definition of Suspected Resistance - Resistance will be suspected if investigations of target pest injury potential to Optimum® AcreMax® TRIsect® from the Sublethal Seedling Assay show that:

- Injury potential of a target pest population obtained as part of the annual insect monitoring program has increased to a level representative of product failure in field conditions;
- The seeds used in the investigation of this population's injury potential contain mCry3A at levels representative of (and in the same genetic background as) the benchmark study; and
- The change in injury potential has been documented as a heritable characteristic of the target pest population and not a result of experimental error.

If resistance is "suspected", Pioneer will inform growers in the area of the potential benefit of augmenting CRW control such as adulticide treatment and/or crop rotation or use of soil or seed-applied insecticides at rates providing corn rootworm control the following year. These measures are intended to educate growers of the potential for change in efficacy, reduce the possibility of grower loss from change in efficacy and reduce potentially resistant insects contributing to the following year's pest population.

2. **Confirmed Resistance from Population Monitoring**

Definition of Confirmed Resistance - Resistance will be confirmed if all of the following criteria are met by progeny from a subsequent rootworm population collected from the area of "suspected resistance" the following year:

- Injury potential of the subsequent field-collected rootworm population feeding on plants containing mCry3A remains at a level likely to produce repeated product failure in field conditions;

- The change in injury potential has been documented as a heritable characteristic of the target pest population;
- Greenhouse node-injury evaluation confirms product failure;
- Subsequent populations collected from the area and assayed show that the results are repeatable; and
- Continued monitoring of the area suggests that the change is spreading.

3. Suspected Resistance – Investigation of Field Reports

The registrant will follow up on grower, extension specialist or consultant reports of unexpected product performance due to corn rootworm species listed on the label. The registrants will instruct its customers to contact them if such incidents occur. The registrants will investigate all such reports submitted to the company or the company's representatives to:

- Confirm the corn in question is rootworm-active *Bt* corn;
- Confirm the field in question contains the correct blend rate of refuge corn;
- Confirm that species not susceptible to the protein are not responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and that all other reasonable causes based on historical experience for the observed root damage have been ruled out;
- If not due to other reasons, the registrant will conduct a thorough investigation of the factors known to affect the manifestation of corn rootworm feeding damage.

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 Optimum® AcreMax® TRIsect® field is > 0.5 on the nodal injury scale (NIS) and the frequency of Optimum® AcreMax® TRIsect® corn with > 0.5 nodes destroyed exceeds 50% of the sampled plants.

If resistance is "suspected", Pioneer will inform growers in the area of the potential benefit of augmenting CRW control such as adulticide treatment, crop rotation the following year or use of soil or seed insecticides the following year. These measures are intended to educate growers of the potential for change in efficacy, reduce the possibility of grower loss from change in efficacy and reduce potentially resistant insects contributing to the following year's pest population.

Pioneer will collect insects as soon as possible from the area for laboratory studies to test for resistance by comparing with benchmark susceptibility data. These studies will be performed following the same laboratory protocols as used for the benchmark determination and monitoring programs.

4. Confirmed Resistance – Investigation of Field Reports

- Injury potential of the field-collected rootworm population feeding on plants containing mCry3A remains at a level likely to produce repeated product failure in field conditions;
- Subsequent populations collected from the area and assayed show that the results are repeatable;
- The change in injury potential has been documented as a heritable characteristic of the target pest population;
- Greenhouse node-injury evaluation confirms product failure; and
- Continued monitoring of the area suggests that the change is spreading.

5. Remedial Action

When resistance is "confirmed", the following steps will be taken:

- The EPA will receive notification within 30 days of confirmed resistance;
- Affected customers and Extension specialists will be immediately notified about confirmed resistance;
- Affected customers and Extension specialists will be strongly encouraged to implement alternative CRW control measures such as adulticide treatment, crop rotation the following year, or use of soil or seed insecticides the following year;
- Sale and distribution of Optimum® AcreMax® TRIsect® in the affected area will cease immediately until an effective mitigation plan has been approved by EPA.

f) Refuge Assurance Program for Optimum® AcreMax® TRIsect®

Pioneer must implement a Blended Seed Refuge Assurance Program designed to ensure Optimum® AcreMax® TRIsect® products are formulated with the appropriate rate of refuge seeds. The program must include the following four elements:

1. Trait purity check on seed lots prior to blending;
2. ISO 9000 Standard Operating Procedures for the blending process;
3. Calibration of blending equipment; and
4. Records and data retention records for seed blend products.

- Calibration records - Pioneer will retain documentation for a specified period of time on the equipment calibration including the procedure, when it was conducted and the results.

15/18

- Blend proportion records (weight and kernel based) - Pioneer will retain documentation for a specified period of time on the kernel per pound data of the components, the calculations to determine the proportions based on weight and the actual weights that are blended together to make up an Optimum® AcreMax® TRIsect® product by seed lot.

All records must be maintained at the Pioneer blending facility and must be available for the EPA review upon request.

g) Annual Reporting Requirements Optimum® AcreMax® TRIsect®

1. Compliance Assurance Program: compliance assurance program activities, including IRM Grower Survey and on-farm assessment results for the prior year and plans for the compliance assurance program for the current year, on or before January 31st each year beginning in 2014;

2. Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, on or before August 31st each year.

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

The basic confidential statement of formula (CSF) dated 9/16/13 is acceptable. It supersedes all previously submitted basic CSFs. A copy has been placed in the file jacket for this registration.

Sincerely,

Robert McNally, Director
Biopesticides and Pollution
Prevention Division (7511P)

Enclosure

16/18

Optimum® AcreMax® TRIsect®

(OECD Unique Identifier: DAS-Ø15Ø7-1xMON-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 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) necessary for its production in corn event DAS-Ø15Ø7-1 ..... ≤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%*

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* 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-xx

EPA ESTABLISHMENT NUMBER: 029964-IA-001

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

17/18

DIRECTIONS FOR USE

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

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

Optimum® AcreMax® TRIsect® consists of 90% 1507xMON810xMIR604 maize and 10% non-*Bt* seed blended together in a bag of seed. This product controls above- and below-ground pests of maize, and the blended non-*Bt* plants provide refuge for both lepidopteran and corn rootworm pests.

INSECT RESISTANCE MANAGEMENT

Growers are instructed to read information on insect resistance management.

Corn seed bags or bag tags for products containing 1507xMON810xMIR604 maize 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:

Corn Belt/Non-Cotton Growing Regions

Optimum AcreMax TRIsect contains a lepidopteran and corn rootworm refuge that is integrated and automatically implemented when the grower plants the product. No additional refuge is required when planting this product where corn earworm is not a significant pest. An external 20% lepidopteran refuge is required in cotton-growing regions where corn earworm is a significant pest.

Cotton-Growing Region Refuge Requirements

In cotton-growing regions where corn earworm is a significant pest:

- The 20% refuge must be planted with non-*Bt* corn hybrids.
- Optimum AcreMax TRIsect and the 20% non-*Bt* refuge should be sown on the same day, or with the shortest window possible between planting dates
- External refuges may be planted as an in-field or adjacent (e.g., across the road) refuge or as a separate block within 1/2 mile of the Optimum AcreMax TRIsect corn field.
- In field refuge options include: blocks, perimeter strips (i.e., along the edges or headlands), or in-field strips.
- When planting the refuge in strips across the field, refuges must be at least four (4) rows wide.
- Insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, fall armyworm, black cutworm, western bean cutworm, lesser corn stalk borer, southern corn stalk borer, and sugarcane borer may be applied only if economic thresholds are reached for one or more of these target pests. 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. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Microbial *Bt* insecticides must not be applied to non-*Bt* corn refuge plants.
- Cotton-growing areas include 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).

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