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

SEP 3 0 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mr. Jamie Staley
U.S. Registration Manager
Pioneer Hi-Bred International, Inc.
7100 NW 62nd Avenue, P.O. Box 1000
Johnston, IA 50131-1000

Subject: Optimum®AcreMax® RW Insect Protection
EPA Registration No. 29964-10
Submission dated 9/23/2013 to amend reporting requirements
Submission dated 5/13/2014 to extend expiration date
Decision Nos. 483756 & 491424

Dear Mr. Staley:

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

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

2) Submit and/or cite all data required for registration/ registration review of your product under FIFRA section 3(c)(2)(B) when the Agency requires all registrants of similar products to submit such data.

3) Submit or cite all data required to support the Herculex RW plant-incorporated protectant products within the timeframes required by the terms and conditions of EPA Registration Number 29964-4.

4) The subject registration will be limited to a seed mix of DAS-59122-7 [*Bacillus thuringiensis* Cry34Ab1 and Cry35Ab1 proteins and the genetic material necessary for their production (PHP17662 T-DNA) in event DAS-59122-7 corn (OECD Unique Identifier: DAS-59122-7)] corn seed blended with a minimum of 10% non-*Bt* corn seed.

Targeted on-farm compliance assessments are neither necessary nor required for OAMRW Insect Protection corn because the refuge is automatically implemented when planting this product.

OAMRW Insect Protection corn may be used as the Lepidopteran refuge for Optimum®AcreMax® 1 (OAM1) Insect Protection corn (EPA Registration Number 29964-6). In this case, on-farm assessments to ensure that the Lepidopteran refuge is planted and placed appropriately would be covered by OAM1 Insect Protection corn's grower education, targeted on-farm assessments and stewardship documents.

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5) Pioneer must commit to do the following Insect Resistance Management Program for OAMRW Insect Protection corn.

The required IRM program for OAMRW Insect Protection corn must have the following elements:

Requirements regarding programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to Cry34/Cry35Ab1 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 provide the Agency upon request, the number of units sold by state and county, IRM grower agreement results, and substantive changes to educational programs. Pioneer is required to submit reports within three months of the Agency's request.

a) IRM Education Program for OAMRW Corn

1. Pioneer must continue to implement and enhance a comprehensive, ongoing IRM education program designed to convey to OAMRW corn users the importance of complying with the IRM program, seed blend product performance expectations and guidance to growers on actions to take when unexpected damage occurs. The education program shall involve the use of multiple media, *e.g.* face-to-face meetings, mailing written materials, 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 OAMRW corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Pioneer shall coordinate its education program with the educational efforts of other registrants and other organizations, such as the National Corn Growers Association and state extension programs.

2. Upon EPA request, Pioneer shall provide copies of grower education materials and information on grower education activities including any substantive changes to these materials and activities conducted either individually or as part of the industry working group Agricultural Biotechnology Stewardship Technical Committee (ABSTC). Pioneer is required to submit reports within three months of the Agency's request.

b) Grower Agreements for OAMRW Corn

1. Persons purchasing OAMRW 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 use its current grower agreement for OAMRW corn. 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 of 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 submitted to EPA the text of such changes to ensure that it is consistent with the terms and conditions of this amended registration.

4. 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 OAMRW corn will affirm annually that they are contractually bound to comply with the requirements of the IRM program.

5. Pioneer shall maintain records of all OAMRW corn grower agreements for a period of three (3) years from December 31st of the year in which the agreement was signed.

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6. Pioneer must allow a review of grower agreements and grower agreement records by EPA or 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.

7. Pioneer shall make available to the Agency upon request records of the number of units of OAMRW Insect Protection corn seed sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements for the previous growing season. Pioneer is required to submit reports within three months of the Agency's request.

c) **Insect Resistance Monitoring and Remedial Action Plan for Corn Rootworm and OAMRW Corn Insect Resistance Monitoring**

In addition to the existing two-pronged approach to insect resistance monitoring (monitoring insect populations using the diet bioassay and investigations of field reports) that are required for Cry34/35Ab1 for Herculex Rootworm (EPA Reg. No. 29964-4), Pioneer must also conduct enhanced monitoring using the Sublethal Seedling Assay as a complement to the diet bioassay method.

1. Pioneer must continue to monitor for Cry34/35Ab1 resistance and/or trends in increased tolerance for corn rootworm. Sampling should be focused in those areas in which there is the highest risk of resistance development.

2. The resistance monitoring plan must include the following: baseline sensitivity data, sampling (number of locations, samples per locations), sampling methodology and life stage sampled, bioassay methodology, standardization procedures (including 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.

3. Pioneer must continue to utilize a functional "on-plant" diagnostic assay[1] for annual Cry34/35Ab1 corn rootworm resistance monitoring to detect potentially resistant individuals.

4. Pioneer must continue to implement and enhance a rootworm resistance monitoring plan for OAMRW Insect Protection corn 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 OAMRW Insect Protection corn must be found acceptable to BPPD and utilized by Pioneer for the 2015 growing season. This enhanced monitoring program should:

- Be practical and adaptable and provide information on relevant changes in corn rootworm population sensitivity to OAMRW Insect Protection corn;

- Be focused on areas where the potential for resistance is greatest for OAMRW Insect Protection corn and for the corn rootworm active single event component of OAMRW Insect Protection corn (Cry34/35Ab1), 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;

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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.

- 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;

- Be responsive to incidents of suspected or confirmed resistance to the registrant's other products containing the same active ingredient, as well as to publicly available reports of suspected or confirmed resistance to other *Bt* protein toxins in OAMRW Insect Protection corn.

5. Pioneer must continue to attempt to develop a proactive resistance monitoring program for northern corn rootworm (*Diabrotica barberi*). Any progress towards developing a resistance monitoring program should be reported to EPA.

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

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

Remedial Action Plan for Corn Rootworm and OAMRW Corn

Pioneer must continue and enhance a remedial action plan for OAMRW corn 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 OAMRW corn that could indicate potential suspected resistance. If corn rootworm resistance is confirmed, all acres of OAMRW corn and refuges in the affected area must be treated with insecticides targeted at corn rootworm adults and/or larvae.

The remedial action plan is designed as a tiered approach for mitigating western and northern com rootworm resistance development specifically due to the commercialization of OAMRW com. 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 OAMRW corn from a bioassay (diet or on-plant bioassay) 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 Cry34/35Abl 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 com 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

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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 Cry34/35Ab1 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

Suspected Resistance is defined as: (1) an initial performance inquiry investigation resulting in a find of Unexpected Damage (a field having an overall average CRW NIS rating of 1.0 or greater for planting containing event DAS-59122-7 (1.5 or greater under exceedingly high corn rootworm pressure); (2) protein levels in green plant tissue of affected plants found to be within the documented range for that hybrid (if data are available); and (3) bioassays of insects collected from the affected fields showing statistically significantly lower sensitivity (e.g. elevation of the LC50 or EC50) compared with the historical baseline and laboratory susceptible populations for corn rootworm-active protein in OAM1 Insect Protection corn products.

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

- Confirm the com 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, Pioneer will conduct a thorough investigation of the factors known to affect the manifestation of corn rootworm feeding damage.
- If the investigation fails to rule out target pest resistance as the cause, resistance is suspected.

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.

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4. Confirmed Resistance – Investigation of Field Reports

Resistance is confirmed when:

- Injury potential of the field-collected rootworm population feeding on plants containing Cry34/35Ab1 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:

- EPA will receive notification from Pioneer 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;
- Unless otherwise agreed with EPA, sale and distribution of OAMRW corn in the affected area will cease immediately until an effective mitigation plan has been approved by EPA.

d) Refuge Assurance Program for OAMRW Corn

Pioneer must implement a Blended Seed Refuge Assurance Program designed to ensure OAMRW 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.
- 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 OAMRW product by seed lot.

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

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e) Annual Reporting Requirements for OAMRW Corn

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

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA Section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

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

Sincerely,

Kimberly Nesci, Chief
Microbial Pesticide Branch
Biopesticides and Pollution
Prevention Division (7511P)

Enclosure

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Optimum® AcreMax® RW Insect Protection

Active Ingredient(s)

Bacillus thuringiensis Cry34Ab1 protein and the genetic material (PHP17662 T-DNA) necessary for its production in corn event DAS-59122-7 ..... ≤0.0088%*

Bacillus thuringiensis Cry35Ab1 protein and the genetic material (PHP17662 T-DNA) necessary for its production in corn event DAS-59122-7 ..... ≤0.00181%*

Inert Ingredient(s)

Phosphinothricin acetyltransferase (PAT) protein and the genetic material (PHP17662 T-DNA) necessary for its production in corn event DAS-59122-7 ..... ≤0.000058%*

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*% total protein on a dry wt. basis as expressed in whole plant tissue

KEEP OUT OF REACH OF CHILDREN

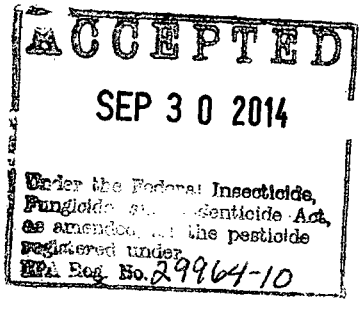
CAUTION

NET CONTENTS _____

EPA REGISTRATION NUMBER: 29964-10

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 a manner inconsistent with its labeling.

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

Optimum® AcreMax® RW Insect Protection consists of up to 90% 59122 maize and a minimum of 10% non-*Bt* seed blended together in a single lot of seed. This product controls corn rootworm pests of maize and the blended non-*Bt* plants provide refuge for the corn rootworm pests.

INSECT RESISTANCE MANAGEMENT

Optimum® AcreMax® RW Insect Protection contains a 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.

USE PATTERN

Crop	Pests
Field corn	western corn rootworm northern corn rootworm Mexican corn rootworm