29964-10 4/30/2010 1/9

UNIT[illegible] STATES ENVIRONMENTAL PROTECTIO[illegible] AGENCY

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:
29964-10	APR 30 2010

Term of Issuance: Conditional

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

Name of Pesticide Product:
Optimum AcreMax RW Insect Protection

Name and Address of Registrant (include ZIP Code):

Pioneer Hi-Bred International, Inc.
7100 NW 62nd Avenue
Johnston, IA 50131

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 Sec. 3(c)(7)(A) provided you do the following terms and conditions.

1) Submit and/or cite all data required for registration/ registration review of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

2) The subject registration will automatically expire on midnight September 30, 2010.

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 (Cry34Ab1/Cry35Ab1) corn seed blended with not less than 10% non-Bt corn seed.

CONCURRENCES								
SYMBOL	▶ 2511P							
SURNAME	▶ [illegible]							
DATE	▶ 4/30/10							

Signature of Approving Official: [illegible] Date: APR 30 2010

EPA Form 8570-6

☆ U.S. Government Printing Office: 2005 206-899 (mac)

Because OAMRW controls corn rootworm pests and contains an integrated corn rootworm refuge, no additional refuge is required. When a grower plants a bag of OAMRW, all refuge requirements are fully and automatically met for this product. Therefore, grower agreements (demonstrating persons purchasing OAMRW corn will annually affirm that they are contractually bound to comply with requirements of the insect resistance management (IRM) program) and other associated stewardship documents are neither necessary nor required.

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

OAMRW may be used as the Lepidopteran refuge for OAM1. In this case, on-farm assessments to ensure that the Lepidopteran refuge is planted and placed appropriately would be covered by OAM1 grower education, targeted on-farm assessments and stewardship documents.

5) Submit the following data in the timeframes listed:

Study Type	Required Data	Due Date
Insect Resistance Management	Pioneer must implement an enhanced resistance monitoring plan for OAMRW. Pioneer must provide the Agency with a baseline (benchmark) study that shows the susceptibility of western corn rootworm populations (WCRW) in the Sublethal Seedling Assay prior to the large-scale introduction of OAMRW. Although northern corn rootworm (NCRW) is difficult to rear, Pioneer must attempt to obtain benchmark susceptibility data for NCRW as well.	12/1/2010 for WCRW 12/1/11 for NCRW
Insect Resistance Management	Pioneer must submit a detailed OAMRW-specific resistance monitoring and remedial action plan, including an analysis to determine the expected field performance criteria for OAMRW products so that unexpected damage can be benchmarked. Pioneer will update the plan by 12/1/2012, if needed, based on continued field evaluation of OAM1 performance.	12/1/2010

6) Pioneer must commit to do the following Insect Resistance Management Program for OAMRW.

The required IRM program for OAMRW 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 Cry34Ab1/Cry35Ab1 proteins in the target insects;

Requirements regarding a "remedial action plan," which 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;

Annual reports on units sold by state (units sold by county level will be made available to the Agency upon request) on or before January 31st of each year, beginning in 2011.

a) Insect Resistance Monitoring for OAMRW Corn

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 currently takes place for Cry34/35 for Herculex Rootworm (29964-4), Pioneer must also conduct enhanced monitoring using the Sublethal Seedling Assay as a complement to the diet bioassay method. Pioneer must submit a detailed OAM1/OAMRW-specific resistance monitoring plan to the Agency by December 1, 2010.

With respect to the implementation of the Sublethal Seedling Assay:

1. Pioneer must monitor for resistance and or changes in target pest susceptibility that will lead to increased injury potential in western and northern corn rootworm feeding on the rootworm component of OAMRW products. Sampling must be focused in the four regions of highest risk of resistance development: Region – 1 (Illinois, Indiana); Region 2 (Iowa, Missouri), Region 3 (Nebraska and Kansas), Region 4 (Minnesota, South Dakota and Wisconsin).

2. Pioneer must provide the EPA its detailed western corn rootworm resistance monitoring plan for approval by December 1, 2010 and its northern corn rootworm resistance monitoring plan for approval by December 1, 2011. These plans will include baseline (benchmark) susceptibility data and an enhanced annual resistance monitoring plan. The reports will contain:

    - Sampling scheme: annual collection should target a range of 16-20 western and/or northern rootworm populations (4-5 per region), with a minimum number of 2,000 beetles collected per population.
    - Bioassay methodology (precision, detection level, etc.). Pioneer must bioassay a target of 3000 larvae on 59122 plants for each population.
    - A description of how monitoring results relate to and are predictive of changes in field efficacy, and change in injury potential to DAS-59122-7 constituting product failure and development of a remedial action plan.

3. Pioneer will provide the EPA with an annual OAMRW resistance monitoring report by August 31st of each year beginning with 2011 for western corn rootworm and 2012 for northern corn rootworm, reporting on populations collected the previous year.

In addition to screening of wide-area corn rootworm populations as outlined above, for the second prong of resistance monitoring Pioneer must investigate grower, extension specialist or consultant reports of less-than-expected efficacy or field performance of OAMRW products.

b) Remedial Action Plan for Corn Rootworm and OAMRW Corn

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 OAMRW corn. 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.
Pioneer will complete a benchmark study of susceptibility of western corn rootworm using the Sublethal Seedling Assay and analyze field efficacy data to set a benchmark for expected levels of damage to finalize the OAMRW remedial action plan by December 1, 2010, so that decision points regarding crop damage and target pest resistance are established, and a remedial action plan can be initiated when needed. Although northern corn rootworm is difficult to rear in the laboratory, Pioneer will attempt to complete a benchmark study for susceptibility of northern corn rootworm using the Sublethal Seedling Assay as well.

1. Suspected Resistance from Population Monitoring

Definition of Suspected Resistance - Resistance will be suspected if investigations of target pest injury potential to OAMRW maize 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 Cry34/Cry35Ab1 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 DAS-59122-7 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.

- 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.
- 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.

4. Confirmed Resistance – Investigation of Field Reports

- Injury potential of the field-collected rootworm population feeding on plants containing DAS-59122-7 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:

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- The EPA will receive notification within 30 days of confirmed resistance;
- Affected customers and Extension specialists will be notified about confirmed resistance;
- Affected customers and Extension specialists will be 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;
- Pioneer and EPA will jointly determine the extent of the mitigation needed and determine whether sales should be stopped on an appropriate geographic (i.e., county or regional) basis; and
- Pioneer will develop a case-specific resistance mitigation 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 the EPA prior to implementation. The resistance management plan could include such measures layering additional technologies in future OAMRW products.

c) 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 the EPA review upon request.

d) Annual Reporting Requirements for OAMRW Corn

1. Annual Sales: reported and summed by state (county level data available by request) January 31st each year, beginning in 2011;
2. Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, August 31st each year, beginning in 2011 for western corn rootworm and 2012 for northern corn rootworm.

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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,

W. Michael McDavit

W. Michael McDavit, Acting Director
Biopesticides and Pollution
Prevention Division (7511P)

Enclosure

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Optimum® AcreMax™RW Insect Protection*

Active Ingredients:

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

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

Inert Ingredient:

Phosphinothricin acetyltransferase (PAT) protein and the genetic material necessary for its production in corn ..... <0.000058%**

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*Optimum® AcreMax™RW Insect Protection contains 90% Herculex[1] Rootworm seed and 10% non-Bt seed blended together in a single container of seed.

**% total protein on a dry wt. basis as expressed in whole plant tissue in DAS-59122-7 plants.

CAUTION

KEEP OUT OF REACH OF CHILDREN

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

ACCEPTED
APR 30 2010
Under the Federal Insecticides, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 29964-10

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[1] Herculex Rootworm Protection technology by Dow AgroSciences and Pioneer Hi-Bred. ®Herculex is a registered trademark of Dow AgroSciences LLC.

DIRECTIONS FOR USE

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

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

Corn has been transformed to express *Bacillus thuringiensis* strain PS149B1 Cry34/35Ab1 insecticidal crystal proteins (ICP) for the control of western corn rootworm (*Diabrotica vigifera*), northern corn rootworm (*Diabrotica berberi*) and Mexican corn rootworm (*Diabrotica virgifera zeae*) pests.

Routine application of insecticides to control western corn rootworm, northern corn rootworm or Mexican corn rootworm are unnecessary for corn containing *B.t.* Cry34/35Ab1 ICP.

Refuge Requirements for Optimum® AcreMax™RW Insect Protection

Optimum® AcreMax™RW Insect Protection contains a "built-in" 10% corn rootworm refuge by virtue of the blended non-Bt refuge seed in the bag. No further corn rootworm refuge is required to minimize the risk of corn rootworm developing resistance.

USE PATTERN

CROP	PESTS
Field corn	western corn rootworm northern corn rootworm Mexican corn rootworm