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:
29964-11	AUG 26 2011

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

Term of Issuance: Conditional

Name of Pesticide Product:
Optimum AcreMax Xtra

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 1, 2012.

2] The subject registration will be limited to a seed mix of TC1507 (Cry1F) xDAS-59122-7 (Cry34Ab1/Cry35Ab1) x Cry1Ab corn seed blended with not less than 10% non-Bt corn seed.

3] 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.

4] This plant-incorporated protectant 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.

5] Submit or cite all data required to support 1507x MON810x59122 within the timeframes required by the terms and conditions of EPA Registration Number 29964-8.

Signature of Approving Official:	Date:
[signature]	26 Aug 2011

6] The following seed blend related IRM data is being required to support a longer term analysis of the potential for insect resistance developing from the use of two toxin based Bt corn seed blends targeting European corn borer and southwestern corn borer. Provided the registration expiration date is extended, submit an interim report on the following data within one year and a final report within two years.

a) Ovipositional behavior in seed blends under, for example, increased pest pressure;
b) The potential and degree of crowding out refuge plants by Bt protected plants in blends expressing corn rootworm traits under different environmental conditions and higher pest pressure;
c) Adult movement (related to mating and movement from refuges), larval movement, larval feeding (i.e., selective feeding within corn ears or on pollen), survival of heterozygote genotypes on OAM (markers may need to be determined for heterozygotes), and the potential for epistatic mechanisms of resistance (particularly with older instars).

7] In order to improve the strength of modeling, you must incorporate the following into your model and clarify certain assumptions utilized within 120 days of the date of this registration:

a) Non-uniform oviposition for both generations of lepidoptera in a 10% seed blend (OAM Xtra);
b) Non-uniform oviposition for the second generation of lepidoptera in a 5% seed blend without a corn rootworm trait; and
c) Increased female (SWCB) pre-ovipositional dispersal out of seed blends.
d) How was fecundity increased in seed blends? Does the 6-fold (and 4-fold) increase refer to the fecundity of susceptible insects on refuge plants relative to fecundity on Bt plants?
e) How was uniform oviposition dealt with in the model code? The methodology should be explained. Do adults form one big random mating pool in seed blends, and eggs are uniformly applied across the field (or else)?
f) How was non-uniform oviposition dealt with in the model code of the sensitivity analysis? Pioneer/DuPont should explain the methodology used.

8] Pioneer must implement the following Insect Resistance Management Program:

The required IRM program for OAM Xtra corn must have the following elements:

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 OAM Xtra corn;

Requirements for Pioneer to prepare and require OAM XTRA users to sign "grower agreements," that impose binding contractual obligation on the grower to comply with the refuge requirements;

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 and Cry34Ab1/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;

Annual reports on units sold by state (units sold by county level will be made available to the Agency upon request), IRM grower agreements results, and the compliance assurance program including the educational program on or before January 31st of each year, beginning in 2012.

a) Refuge requirements for OAM XTRA

Corn-Belt/Non-Cotton Growing Areas

Optimum® AcreMax™ Xtra Insect Protection 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, 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™ Xtra 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™ Xtra 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 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, 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).

These refuge requirements do not apply to seed propagation of inbred and hybrid corn seed corn up to a total of 20,000 acres per county and up to a combined U.S. total of 250,000 acres per PIP active ingredient per registrant per year.

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 the registrant to help these growers meet the refuge requirements across their farming operations.

b) Grower Agreement for OAM XTRA Corn

1. Persons purchasing OAM XTRA 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 implement a system equivalent to what is already approved for previously registered Pioneer *Bt* corn products, which is reasonably likely to assure that persons purchasing OAM XTRA corn will affirm annually that they are contractually bound to comply with the requirements of the IRM program. A description of the system must be submitted to EPA within 90 days from the date of registration. (This information has been submitted and is being evaluated by the Agency.)

4. Pioneer must use a grower agreement and must submit to EPA, within 90 days from the date of registration, a copy of that agreement and any specific stewardship documents referenced in the grower agreement. (This information has been submitted and is being evaluated by the Agency.)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, 30 days prior to implementing a proposed change, Pioneer must submit to EPA the text of such changes to ensure it is consistent with the terms and conditions of this registration.

5. Pioneer shall maintain records of all OAM XTRA corn grower agreements for a

period of three years from December 31st of the year in which the agreement was signed.

6. Beginning on January 31, 2013, and annually thereafter, Pioneer shall provide EPA with a report on the number of units of OAM XTRA corn seed 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 a twelve-month period. Note: The first report shall contain the specified information from the time frame starting with the date of registration and extending through the 2012 growing season.

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 OAM XTRA Corn

1. Pioneer must design and implement a comprehensive, ongoing IRM education program designed to convey to OAM XTRA corn 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 OAM XTRA corn 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 OAM XTRA seed sold and delivered for the 2011 growing season and annually thereafter. The purpose of this bag tag is to remind growers that OAM XTRA 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, 2012.

3. Pioneer must conduct targeted, on-farm compliance assessments for growers who purchase OAM XTRA seed to ensure growers are compliant with the requirement of a 20% refuge for lepidopteran pests in cotton growing areas. For the 2012 growing season and thereafter, Pioneer must conduct on-farm assessments or roughly half the number of assessments that Pioneer will contribute to the 2012 Agricultural Biotechnology Stewardship Technical Committee (ABSTC) compliance assurance program assessment for corn borer and stacked products. Pioneer must contract with

an independent third party to conduct these compliance assessments. The table below reflects the relative number of on-farm assessments for OAM XTRA based on Pioneer's contribution to the ABSTC compliance assurance program report and is subject to change with time as appropriate.

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.

Pioneer must provide a report to EPA summarizing the OAM XTRA compliance assurance program activities and results for the prior year and plans for the OAM XTRA compliance assurance program for the current year, by January 31, 2013, and annually thereafter. Within one month of submitting this report to EPA, the registrant 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. Annually, Pioneer shall revise, and expand as necessary, 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. Beginning January 31, 2013, Pioneer must provide a report to EPA summarizing the activities it carried out under its education program for the prior year. Annually thereafter, 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, ABSTC.

6. The registrant shall revise and expand its existing Compliance Assurance Program to include the following elements. The registrant must prepare and submit by January 31, 2012, a written description of its revised Compliance Assurance Program. The registrant may coordinate with other registrants in designing and implementing its Compliance Assurance Program.

7. The registrant 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 OAM XTRA seed sold and delivered for the 2012 growing season and annually thereafter. The purpose of this bag tag is to remind growers that OAM XTRA 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, 2012.

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8. The registrant 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 where the product is used.

9. The registrant will use its available *Bt* sales records and other information to refine grower lists for on-farm assessments of their compliance with refuge requirement:

i. Identify for potential on-farm assessment growers whose sales information indicates they have purchased the *Bt* corn product but may have purchased little or no refuge seed from the registrant, licensee, or affiliated company.

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

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

11. The registrant will annually refine the on-farm assessment program for the *Bt* corn product to reflect the adoption rate and level of refuge compliance for the product.

12. The registrant 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 the registrant, seed supplier, or third party assessor, after completing the assessment process;

ii. The registrant 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 the *Bt* corn product within a five-year period will be denied access to Pioneer Hi-Bred's *Bt* corn products the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell *Bt* corn.

d) Insect Resistance Monitoring and Remedial Action Plan for OAM XTRA Corn

The Agency is imposing the following conditions for this lepidopteran toxin:

The registrant 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

The registrant shall annually sample and bioassay populations of the key target pests *Ostrinia nubilalis* (European corn borer; ECB), *Diatraea grandiosella* (Southwestern corn borer; S WCB), 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 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;

- 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

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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;

- Affected customers and extension agents will be notified about confirmed resistance

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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
- 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.

The Agency is imposing the following conditions for this corn rootworm toxin:

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 Cry34/35 for Herculex Rootworm Insect Protection (29964-4) and Herculex Xtra Insect Protection (29964-5), Pioneer must also conduct enhanced monitoring using the Sublethal Seedling Assay as a complement to the diet bioassay method. Pioneer must submit a detailed OAM XTRA/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 OAM XTRA 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), and 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 OAM XTRA 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 OAM XTRA products.

e) Remedial Action Plan for Corn Rootworm and OAM XTRA 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 OAM XTRA 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 OAM XTRA 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.

1. Suspected Resistance from Population Monitoring

Definition of Suspected Resistance - Resistance will be suspected if investigations of target pest injury potential to OAM XTRA 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:

- 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;
- Within 60 days of notification, 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 OAM XTRA products.

f) Remedial Action Plan for lepidopteran pests and OAM XTRA Corn

When field resistance is confirmed (as previously defined), the following steps will be taken by the registrant:

• 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;
• 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

• 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.

g) Refuge Assurance Program for OAM XTRA Corn

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

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

h) Annual Reporting Requirements for OAM XTRA Corn

1. Annual Sales: reported and summed by state (county level data available by request) January 31st each year, beginning in 2012;
2. Grower Agreements: number of units of OAM XTRA corn seed shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements, January 31st each year, beginning in 2012;
3. Grower Education: substantive changes to education program completed previous year, January 31st each year, beginning in 2012;
4. Compliance Assurance Program: compliance assurance program activities and results for the prior year and plans for the compliance assurance program for the current year, January 31st each year, beginning in 2012;
5. Compliance Survey Results: results of annual surveys for the prior year and survey plans for the current year; full report January 31st each year, beginning in 2013;
6. Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, August 31st each year, beginning in 2013 for western corn rootworm and northern corn rootworm.

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

Sincerely,

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

17/19

Optimum® AcreMax™ Xtra Insect Protection

(OECD Unique Identifier: DAS-Ø15Ø7-1xDASx59122-7xMON-ØØ81Ø-6)

Active Ingredients:

Bacillus thuringiensis var. aizawai Cry1F protein and the genetic material (PHI8999) necessary for its production in corn event DAS-Ø15Ø7-1 ..... <0.0011%*

Bacillus thuringiensis Cry34Ab1 protein and the genetic material (PHP17662) necessary for its production in corn event DAS-59122-7) ..... <0.0054%

Bacillus thuringiensis Cry35Ab1 protein and the genetic material (PHP17662) necessary for its production in corn event DAS-59122-7 ..... <0.0042%*

Bacillus thuringiensis subsp. kurstaki Cry1Ab protein and the genetic material (PV-ZMBK07) necessary for its production in corn event MON-ØØ81Ø-6 ..... <0.0015%*

Inert Ingredient:

Phosphinothricin acetyltransferase (PAT) marker protein and the genetic material necessary for its production in corn ..... <0.0013%*

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* Percentage (wt/wt) on a dry wt. basis for whole plant tissue of 1507x59122xMON810 plants.

CAUTION

KEEP OUT OF REACH OF CHILDREN

NET CONTENTS _____

EPA REGISTRATION NUMBER: 29964-11

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 must be used as specified in the terms and conditions of the registration.

This product may be combined or produced 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.

Optimum® AcreMax™ Xtra Insect Protection consists of 90% 1507x59122xMON810 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.

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.

The following information regarding commercial production must be included in the grower guides for cotton and non-cotton growing areas:

Corn seed bags or bag tags for products containing Optimum® AcreMax™ Xtra must include the refuge size requirement in text and graphical format.

Corn-Belt/Non-Cotton Growing Areas

Optimum® AcreMax™ Xtra Insect Protection 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, 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™ Xtra 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™ Xtra 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 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, 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