29964-6 9/29/2010 1 of 21

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

SEP 29 2010

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: Pioneer Hi-Bred's Amendment Request to Extend the Optimum AcreMax 1 Insect Protection Registration; Submission dated 05/5/2010
EPA Registration No. 29964-6

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, 2012.

2] The subject registration will be limited to a seed mix of DAS-Ø15Ø7-1 (Cry1F) x DAS-59122-7 (Cry34Ab1/Cry35Ab1) corn seed blended with not less than 10% DAS-Ø15Ø7-1 (Cry1F) 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 the following data in the timeframes listed:

7 5 11
9/29/10

Study Type	Required Data	Due Date
Insect Resistance Management	Pioneer must provide the Agency with a copy of the grower agreement, associated stewardship documents, and written description of a system, which assures that growers will sign grower agreements and persons purchasing OAM1 corn will annually affirm that they are contractually bound to comply with requirements of the insect resistance management (IRM) program. (This information has been submitted and is being evaluated by the Agency.)	90 days from the date of registration
Insect Resistance Management	Pioneer must implement an enhanced resistance monitoring plan for OAM1. 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 OAM1. Although northern corn rootworm (NCRW) is difficult to rear, Pioneer must attempt to obtain benchmark susceptibility data using the Sublethal Seedling Assay for NCRW as well.	12/1/2010 for WCRW 12/1/11 for NCRW
Insect Resistance Management	Pioneer must submit a detailed OAM1-specific resistance monitoring and remedial action plan, including an analysis to determine the expected field performance criteria for OAM1 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 implement the following Insect Resistance Management Program:

The required IRM program for OAM1 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 conjunction with the planting of any acreage of OAM1 corn;

Requirements for Pioneer to prepare and require OAM1 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 2011.

a) Refuge requirements for OAM1

Because the refuge for corn rootworm is blended in each bag or box of OAM1 seed, no additional corn rootworm refuge is required. A refuge must be planted for corn borers. The refuge must be planted with corn hybrids that do not contain *Bt* technologies for the control of corn borers. Refuge options are based on the planting of OAM1 in cotton or non-cotton growing regions and insect pressure present in those locations. The refuge sizes for these regions are either 50% in cotton-growing regions (*i.e.,* 50 acres of corn that does not contain *Bt* technology for the control of corn borers for every 50 acres of OAM1) or 20% in non-cotton growing regions (*i.e.,* 20 acres of corn that does not contain *Bt* technology for the control of corn borers for every 80 acres of OAM1). Refuge planting options include: separate fields, blocks within fields (*e.g.,* along the edges or headlands), and strips across the field. Cotton-growing regions consist of the following states Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma(only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott and Stoddard.

External refuges must be planted within ½ mile. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-*Bt* insecticides if the population of one or more of the target lepidopteran pests of OAM1 in the refuge exceeds economic thresholds. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

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 OAM1 Corn

1. Persons purchasing OAM1 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 OAM1 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 OAM1 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, 2011, and annually thereafter, Pioneer shall provide EPA with a report on the number of units of OAM1 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 2010 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 OAM1 Corn

1. Pioneer must design and implement a comprehensive, ongoing IRM education program designed to convey to OAM1 corn users the importance of complying with the IRM program. 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 OAM1 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. 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 OAM1 seed sold and delivered for the 2011 growing season and annually thereafter. The purpose of this bag tag is to remind growers that OAM1 products require a separate 20% lepidopteran refuge, and a 50% refuge requirement 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, 2011.

3. Pioneer must conduct targeted, on-farm compliance assessments for growers who purchase OAM1 seed to ensure growers are compliant with the requirement of a 20% refuge for lepidopteran pests. For the 2010 growing season, Pioneer must conduct at least 500 on-farm assessments or roughly half the number of assessments that Pioneer will contribute to the 2010 Agricultural Biotechnology Stewardship Technical Committee (ABSTC) compliance assurance program assessment for corn borer and stacked products. Beginning in 2011 and annually thereafter, Pioneer will contract with an independent third party to conduct these compliance assessments and target twice the number of on-farm assessments for OAM1 as Pioneer conducts for corn borer and stacked products on an annual basis. The table below reflects the relative number of on-farm assessments for OAM1 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.

Number of on-farm assessments conducted by Pioneer

Products	Year: 2010	Year: 2011, annually thereafter
Corn Borer and Stacked Products	1000	1000
OAM1	500	2000
Total	1500	3000

Pioneer must provide a report to EPA summarizing the OAM1 compliance assurance program activities and results for the prior year and plans for the OAM1 compliance assurance program for the current year, by January 31, 2011, 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, 2011, 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 Compliance Assurance Program to include the following elements. The registrant must prepare and submit by January 31, 2011, 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. As stated in 6)c)2), Pioneer must design and immediately implement a "bag tag" that will be attached to all bags of OAM1 seed sold and delivered for the 2011 growing season and annually

thereafter. The purpose of this bag tag is to remind growers that OAM1 products require a separate 20% lepidopteran refuge, and a 50% refuge requirement 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, 2011.

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 OAM1 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 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 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 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 OAM1 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 OAM1 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 OAM1 products.

e) Remedial Action Plan for Corn Rootworm and OAM1 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 OAM1 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 OAM1 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 OAM1 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

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

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 OAM1 products.

f) Remedial Action Plan for lepidopteran pests and OAM1 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 OAM1 Corn

Pioneer must implement a Blended Seed Refuge Assurance Program designed to ensure OAM1 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 OAM1 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 OAM1 Corn

1. Annual Sales: reported and summed by state (county level data available by request) January 31st each year, beginning in 2011;
2. Grower Agreements: number of units of OAM1 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 2011;
3. Grower Education: substantive changes to education program completed previous year, January 31st each year, beginning in 2011;
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 2011;
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 2011;
6. 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.

Mr. Jamie Staley
EPA Registration No. 29964-6

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). A stamped copy of the label is enclosed for your records.

Sincerely,

Sheryl K. Reilly, Ph.D., Chief
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

Enclosure

Optimum® AcreMax™1 Insect Protection

Active Ingredients of Component 1 (Herculex* XTRA): 90% of maize kernels

Bacillus thuringiensis Cry1F protein and the genetic material (plasmid insert PHI8999A) necessary for its production in corn event DAS-Ø15Ø7-1 ..... ≤0.00174**

Bacillus thuringiensis Cry34Ab1 protein and the genetic material (PHP17662 T-DNA) necessary for its production in corn event DAS-59122-7 ..... ≤0.01684**

Bacillus thuringiensis Cry35Ab1 protein and the genetic material (PHP17662 T-DNA) necessary for its production in corn event DAS-59122-7 ..... ≤0.00676**

Other Ingredient:

Phosphinothricin acetyltransferase (PAT) protein and the genetic material (plasmid insert PHI8999A and PHP17662 T-DNA) necessary for its production in corn events DAS-Ø15Ø7-1 and DAS-59122-7 ..... ≤0.00151%**

Active Ingredient of Component 2 (Herculex* I): 10% of maize kernels

Bacillus thuringiensis Cry1F protein and the genetic material (plasmid insert PHI8999A) necessary for its production in corn event DAS-Ø15Ø7-1 ..... ≤0.0123%**

Other Ingredient:

Phosphinothricin acetyltransferase (PAT) protein and the genetic material (plasmid insert PHI8999A) necessary for its production in corn event DAS-Ø15Ø7-1 ..... ≤0.0020%**

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

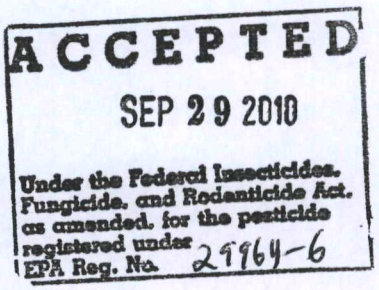
KEEP OUT OF REACH OF CHILDREN

CAUTION

NET CONTENTS _____

EPA REGISTRATION NUMBER: 29964-6

EPA ESTABLISHMENT NUMBER: 029964-IA-001
Pioneer Hi-Bred International, Inc.
7300 NW 62 Avenue
Johnston, IA 50131



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* Herculex Insect 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 subject registration automatically expires on midnight September 30, 2012.

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

Optimum® AcreMax™1 Insect Protection (Optimum® AcreMax™ 1) combines the insect protection features of Herculex® XTRA Insect Protection and Herculex® I Insect Protection in a single seed bag. Optimum® AcreMax™ 1 protects corn crops from leaf, stalk and ear damage caused by corn borers and root damage caused by corn rootworm larvae. In order to minimize the risk of corn pests developing resistance to Optimum® AcreMax™ 1 corn, an insect resistance management plan must be implemented.

Optimum® AcreMax™ 1 contains a "built-in" 10% corn rootworm refuge by virtue of the blended refuge seed in the bag. No further corn rootworm refuge is required to minimize the risk of corn rootworm developing resistance.

The use of Optimum® AcreMax™ 1 corn does require an accompanying lepidopteran refuge. .

INSECT RESISTANCE MANAGEMENT

Corn-Belt/Non-Cotton Growing Areas

Optimum® AcreMax™ 1 corn grown outside cotton-growing areas (e.g., the Corn Belt), growers must adhere to the following refuge requirements:

- Growers must plant a structured refuge of at least 20% non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn which may be treated with insecticides as needed to control lepidopteran stalk-boring and other pests.
- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field.
- External refuges must be planted within 1/2 mile.
- When planting the refuge in strips across the field, refuges must be at least four (4) consecutive crop rows wide.
- Insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, fall armyworm, black cutworm, western bean cutworm, lesser corn stalk borer, southern corn stalk borer, and sugarcane borer may be applied only if economic thresholds are reached for one or more of these target pests. 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 and/or non-lepidopteran resistant *Bt* corn refuges.

Cotton-Growing Areas

Optimum® AcreMax™ 1 corn grown in cotton-growing areas:

- Growers must plant a structured refuge of 50% non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn that may be treated with insecticides as needed to control lepidopteran stalk-boring and other pests.
- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field.
- External refuges must be planted within 1/2 mile.

- When planting the refuge in strips across the field, refuges must be at least four (4) consecutive crop rows wide.
- Insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, fall armyworm, black cutworm, western bean cutworm, lesser corn stalk borer, southern corn stalk borer, and sugarcane borer may be applied only if economic thresholds are reached for one or more of these target pests. 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 and/or non-lepidopteran resistant *Bt* corn refuges.
- 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 western bean cutworm western corn rootworm northern corn rootworm Mexican corn rootworm

Herculex® Insect Protection technology by Dow AgroSciences and Pioneer Hi-Bred offers unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5,484,956; 5,489,520; 5,510,474; 5,550,318; 5,919,675; 6,020,190; 6,218,188; 6,258,999; 6,573,240; 6,737,273; 6,943,282; 6,083,499; 6,127,180; 6,340,593; 6,548,291; 6,624,145; and 6,893,872.