29964-6 9/30/2014 1/17

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

SEP 3 0 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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

Subject: Optimum®AcreMax®1 Insect Protection
EPA Registration No. 29964-6
Submission dated 9/23/2013 to amend reporting requirements
Submission dated 5/13/2014 to extend expiration date
Decision Nos. 483749 & 491423

Dear Mr. Staley:

The amendments 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, are acceptable provided that you comply with the following terms and conditions.

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

2] The subject registration will be limited to a seed mix of Cry1F [*Bacillus thuringiensis* Cry1F protein and the genetic material necessary for its production (plasmid insert PHP8999A) in event TC1507 corn (OECD Unique Identifier: DAS-Ø15Ø7-1)] x Cry34Ab1 and Cry35Ab1 [*Bacillus thuringiensis* Cry34Ab1 and Cry35Ab1 proteins and the genetic material necessary for their production (PHP17662 T-DNA) in event DAS-59122-7 corn (OECD Unique Identifier: DAS-59122-7)] corn seed blended with a minimum of 10% Cry1F [*Bacillus thuringiensis* Cry1F protein and the genetic material necessary for its production (plasmid insert PHP8999A) in event TC1507 corn (OECD Unique Identifier: DAS-Ø15Ø7-1)] corn seed.

3] Submit/cite all data required for registration of Optimum®AcreMax®1 (OAM1) Insect Protection corn within the timeframes required by the terms and conditions of EPA Registration numbers 29964-3, 29964-4 and 29964-5.

4] In order to improve the strength of modeling, you must address and incorporate the uncertainties (described in the 2/15/2012 J. Martinez insect resistance management review) into your ECB and CEW models. This information has been submitted and reviewed.

2/17

5] Pioneer must implement an Insect Resistance Management Program for OAM1 consisting of 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 OAM1 Insect Protection corn;

- Requirements for Pioneer to prepare and require OAM1 Insect Protection corn 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 Cry34/35Ab1 proteins in the target insects;

- Requirements regarding a "remedial action plan," that contains measures Pioneer would take in the event that any field-relevant insect resistance was detected as well as to report on activity under the plan to EPA;

- Requirements for Pioneer to maintain, and provide the Agency upon request, the number of units sold by state and county, IRM grower agreements results, and substantive changes to educational programs. Pioneer is required to submit reports within three months of the Agency's request.

- Requirements for a "bag tag" that will be attached to all bags of OAM1 Insect Protection corn seed sold and delivered. The purpose of this bag tag is to remind growers that OAM1 Insect Protection corn products require a separate 20% lepidopteran refuge in non-cotton growing areas, and a 50% 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) Refuge requirements for OAM1Insect Protection corn

Because the refuge for corn rootworm is blended in each bag or box of OAM1 Insect Protection corn 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 Insect Protection corn 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 Insect Protection corn) 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 Insect Protection corn). 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 Insect Protection corn in the refuge exceeds economic

3/17

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

b) Grower Agreement for OAM1 Insect Protection corn

1. Persons purchasing OAM1 Insect Protection corn must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.

2. The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.

3. Pioneer must continue to integrate this registration into the current system used for its other *Bt* corn products, which is reasonably likely to assure that persons purchasing OAM1 Insect Protection corn will affirm annually that they are contractually bound to comply with the requirements of the IRM program.

4. Pioneer must continue to use its current grower agreement for OAM1 Insect Protection corn. If Pioneer wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program 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 amended registration.

5. Pioneer shall maintain records of all OAM1 Insect Protection corn grower agreements for a period of three years from December 31st of the year in which the agreement was signed.

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

7. Pioneer shall make available to the Agency upon request records of the number of units of OAM1 Insect Protection corn seed sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements for the previous growing season. Pioneer is required to submit reports within three months of the Agency's request.

c) IRM Education and IRM Compliance Monitoring Program

1. Pioneer must continue to implement and enhance (as set forth in paragraph 16 of this section) a comprehensive, ongoing IRM education program designed to convey to OAM1 Insect Protection corn users the importance of complying with the IRM program, seed blend product performance expectations and guidance to growers on actions to take when unexpected damage occurs. The program shall include information encouraging OAM1 Insect Protection corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to OAM1 Insect Protection corn fields. 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

4/17

shall involve at least one written communication annually to each OAM1 Insect Protection 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 shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey (required under paragraphs 6-9), and from other sources. Pioneer shall identify deficiencies in grower compliance, and revise the education program to address those deficiencies.

3. Upon EPA request, Pioneer shall provide copies of grower education materials and information on grower education activities, including any substantive changes to these materials and activities conducted either individually or as part of the industry working group Agricultural Biotechnology Stewardship Technical Committee (ABSTC). Pioneer is required to submit reports within three months of the Agency's request. The required features of the compliance assurance program are described in paragraphs 4-21 of this section.

4. Pioneer must continue to implement an ongoing IRM Compliance Assurance Program (CAP) designed to evaluate the extent to which growers purchasing OAM1 Insect Protection corn are complying with the IRM program, and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to Pioneer *Bt* corn products. Pioneer shall coordinate with other *Bt* corn registrants in improving its compliance assurance program and continue to integrate this amended registration into the current compliance assurance program used for Pioneer's other *Bt* corn PIPs. Other required features of the program are described in paragraphs 5-21 below.

5. Pioneer must continue to maintain and publicize a "phased compliance approach," i.e., a guidance document that indicates how Pioneer will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers after the first year of non-compliance. While recognizing that for reasons of difference in business practices there are needs for flexibility between different companies, Pioneer must use a consistent set of standards for responding to non-compliance. An individual grower found to be significantly out of compliance two years in a row would be denied access the next year to Pioneer's Bt corn products for which the grower is required to plant a separate structured refuge. 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.

6. Pioneer must maintain an IRM Compliance Assurance Program (CAP) which shall include an annual survey conducted by an independent third party of a statistically representative sample of growers of OAM1 Insect Protection field corn who plant the vast majority of all corn in the U.S. and in areas in which the selection intensity is greatest. The survey shall consider only those growers who plant 200 or more acres of corn in the Corn-Belt and who plant 100 or more acres of corn in corn-cotton areas. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from the independent marketing research firm and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the U.S.

i. A third party is classified as a party other than Pioneer, the grower, or anyone else with a direct interest in IRM compliance for *Bt* corn.

7. The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.

8. The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.

5/17

9. Pioneer shall provide a written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA by January 31st of each year. Pioneer shall confer with other registrants and EPA on the design and content of the survey prior to its implementation.

10. Annually, Pioneer shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey and from other sources. Pioneer shall identify deficiencies in grower compliance and revise the education program to address those deficiencies. Pioneer must confer with the Agency prior to adopting any changes.

11. Pioneer shall continue to conduct and enhance an annual on-farm assessment program. Pioneer shall train its representatives who make on-farm visits with growers of OAM1 Insect Protection corn to perform assessments of compliance with IRM requirements. There is no minimum corn acreage size for this program. Therefore, growers will be selected for this program from across all farm sizes. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, Pioneer shall take appropriate action, consistent with its "phased compliance approach," to promote compliance.

12. Pioneer shall continue to implement a program for investigating legitimate "tips and complaints" that its growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, the registrant shall take appropriate action, consistent with its "phased compliance approach."

13. If a grower who purchases OAM1 Insect Protection corn for planting was specifically identified as not being in compliance during the previous year, Pioneer shall visit with the grower and evaluate whether that the grower is in compliance with the IRM program for the current year.

14. Annually, Pioneer shall provide a report to EPA summarizing the activities carried out under their compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. Within one month of submitting this report to EPA, Pioneer shall meet with EPA to discuss its findings. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken. 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. Pioneer may elect to coordinate information and report collectively the results of their compliance assurance programs.

15. Pioneer and the seed corn dealers for Pioneer must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license number of the growers will be protected.

16. Pioneer will enhance the refuge education program throughout the seed delivery channel to:

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 continue to implement a "bag tag" that will be attached to all bags of OAM1 Insect Protection corn seed sold and delivered. The purpose of this bag tag is to remind growers that OAM1 products require a separate 20% lepidopteran refuge in non-cotton growing areas, 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.

17. Pioneer will focus the majority of on-farm assessments on regions with the greatest risks for resistance:

6/17

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 OAM1 Insect Protection corn is used.

18. Pioneer will use its available OAM1 Insect Protection corn 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 OAM1 Insect Protection corn product but may have purchased little or no refuge seed from the registrant, licensee, or affiliated companies.

19. Pioneer 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.

20. Pioneer will annually refine the on-farm assessment program for OAM1 Insect Protection corn to reflect the adoption rate and level of refuge compliance for OAM1 Insect Protection corn.

21. Pioneer will follow up with growers who have been found significantly out of compliance under the on-farm assessment program and are found to be back in compliance the following year:

i. All growers found to be significantly out of compliance in a prior year will annually be sent additional refuge assistance information for a minimum of two years by Pioneer, a seed supplier, or a third party assessor, after completing the assessment process;

ii. Pioneer will conduct follow-up checks on growers found to be significantly out of compliance within three years after they are found to be back in compliance;

iii. A grower found with a second incident of significant non-compliance with refuge requirements for the *Bt* corn product within a five-year period will be denied access the next year to Pioneer's *Bt* corn products for which the grower is required to plan a separate structured refuge. 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:

Pioneer will monitor for resistance to its lepidopteran-resistant *Bt* corn. The monitoring program shall consist of two approaches: (1) focused population sampling and laboratory testing; and (2) investigation of reports of less-than expected control of labeled insects. Should field-relevant resistance be confirmed, an appropriate resistance management action plan will be implemented.

(1) Focused Population Sampling

Pioneer shall annually sample and bioassay populations of the key target pests *Ostrinia nubilalis* (European corn borer; ECB), *Diatraea grandiosella* (Southwestern corn borer; SWCB), and *Helicoverpa zea* (corn earworm; CEW). Sampling for the target pests will be focused in areas identified as those with the highest risk of resistance development (e.g., where lepidopteran-active *Bt* hybrids are planted on a high proportion of the corn acres, and where the insect species are

7/17

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.

Pioneer 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.

8/17

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

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

9/17

- 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, Pioneer will 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;

- Pioneer will develop a case-specific resistance management 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 EPA prior to implementation;

- Pioneer will 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, Pioneer will 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 Cry34Ab1 and Cry35Ab1 toxins expressed in OAM1 Insect Protection corn:

10/17

In addition to the existing two-pronged approach to insect resistance monitoring (monitoring insect populations using the diet bioassay and investigations of field reports) that are required for Cry34/35Ab1 for Herculex Rootworm 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.

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

2. The resistance monitoring plan must include the following: baseline sensitivity data, sampling (number of locations, samples per locations), sampling methodology and life stage sampled, bioassay methodology, standardization procedures (including quality assurance/quality control provisions), detection technique and sensitivity, statistical analysis of the probability of detecting resistance, and a revised description of rootworm damage guidelines.

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

4. Pioneer must continue to implement and enhance a rootworm resistance monitoring plan for OAM1 Insect Protection corn that accounts for reports of suspected and/or confirmed resistance. The rootworm resistance monitoring plan and the revised definitions for suspected and confirmed resistance for OAM1 Insect Protection corn must be found acceptable to BPPD and utilized by Pioneer for the 2015 growing season. This enhanced monitoring program should:

- Be practical and adaptable and provide information on relevant changes in corn rootworm population sensitivity to OAM1 Insect Protection corn;

- Be focused on areas where the potential for resistance is greatest for OAM1 Insect Protection corn and for the corn rootworm active single event component of OAM1 Insect Protection corn (Cry34/35Ab1), based on available information on historical pest pressure, unexpected performance issues, historical suspected and/or confirmed resistance incidents as currently defined or as modified in EPA accepted enhanced monitoring programs, prevailing agronomic practices (e.g.crop rotation versus continuous corn), and academic and Extension publications on Bt corn field performance;

- Involve coordination to the extent possible with other stakeholders, such as academic and extension experts in the states where corn rootworm is a major pest, and other registrants of similar products, as appropriate;

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[1] Examples of on-plant bioassays include:

Nowatzki T, Lefko SA, Binning RR, Thompson SD, Spencer TA, Siegfried BD. 2008. Validation of a novel resistance monitoring technique for corn rootworm (Coleoptera: Chrysomelidae) and event DAS-59122-7 maize. *J. Appl. Entomol.* 132:177–188 and

Gassmann A.J., J.L. Petzold-Maxwell, R.S. Keweshan, and M.W. Dunbar, 2011. Field-evolved resistance to *Bt* maize by western corn rootworm. *PLOS one*, Vol. 6 (7): 1-7.

11/17

- Be responsive to incidents of suspected or confirmed resistance to the registrant's other products containing the same active ingredient, as well as to publicly available reports of suspected or confirmed resistance to other Bt protein toxins in OAM1 Insect Protection corn.

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

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

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

Remedial Action Plan for Corn Rootworm in OAM1 Insect Protection corn

Pioneer must continue and enhance a remedial action plan for OAM1 Insect Protection corn that includes actions to be taken in response to both suspected and confirmed resistance. This remedial action plan must include a description of steps to be taken in response to customer product performance inquiries and annual reporting to the agency on the outcomes of investigations into any such inquiries that might indicate potential resistance. The program must include revised definitions of unexpected damage to OAM1 Insect Protection corn that could indicate potential suspected resistance. If corn rootworm resistance is confirmed, all acres of OAM1 Insect Protection corn and refuges in the affected area must be treated with insecticides targeted at corn rootworm adults and/or larvae.

The remedial action plan is designed as a tiered approach for mitigating western and northern corn rootworm resistance development specifically due to the commercialization of OAM1 Insect Protection 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.

1. **Suspected Resistance from Population Monitoring**

Definition of Suspected Resistance: Resistance will be suspected if investigations of target pest injury potential to OAM1 Insect Protection corn from a bioassay (diet or on-plant bioassay) show that:

- Injury potential of a target pest population obtained as part of the annual insect monitoring program has increased to a level representative of product failure in field conditions;

- The seeds used in the investigation of this population's injury potential contain Cry34/35Ab1 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.

12/17

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 Cry34/35Ab1 remains at a level likely to produce repeated product failure in field conditions;
- The change in injury potential has been documented as a heritable characteristic of the target pest population;
- Greenhouse node-injury evaluation confirms product failure;
- Subsequent populations collected from the area and assayed show that the results are repeatable; and
- Continued monitoring of the area suggests that the change is spreading.

3. Suspected Resistance – Investigation of Field Reports

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

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

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

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

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

13/17

4. Confirmed Resistance – Investigation of Field Reports

Resistance is confirmed when:

- Injury potential of the field-collected rootworm population feeding on plants containing Cry 34/35Ab1 remains at a level likely to produce repeated product failure in field conditions;
- Subsequent populations collected from the area and assayed show that the results are repeatable;
- The change in injury potential has been documented as a heritable characteristic of the target pest population;
- Greenhouse node-injury evaluation confirms product failure; and
- Continued monitoring of the area suggests that the change is spreading.

5. Remedial Action

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

- The EPA must receive notification from Pioneer within 30 days of confirmed resistance;
- Affected customers and Extension specialists will be immediately notified about confirmed resistance;
- Affected customers and Extension specialists will be strongly encouraged to implement alternative CRW control measures such as adulticide treatment, crop rotation the following year, or use of soil or seed insecticides the following year;
- Unless otherwise agreed with EPA, sale and distribution of OAM1 Insect Protection corn in the affected area will cease immediately until an effective mitigation plan has been approved by EPA.

e) Refuge Assurance Program for OAM1 Insect Protection Corn

Pioneer must implement a Blended Seed Refuge Assurance Program designed to ensure OAM1 Insect Protection corn 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 Insect Protection corn product by seed lot.

14/17

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 Insect Protection corn

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

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

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

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

Sincerely,

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

Enclosure

15/17

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**

Inert 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%**

Inert 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

ACCEPTED
SEP 3 0 2014
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 29964-6

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* Herculex® Insect Protection technology by Dow AgroSciences and Pioneer Hi-Bred. ® Herculex is a registered trademark of Dow AgroSciences LLC.

16/17

DIRECTIONS FOR USE

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

The plant-incorporated protectant 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.

17/17

- 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).
- Seed bags or bag tags will prominently display the refuge size requirements using graphics accompanied by text. For seed distributed outside cotton-growing areas the information will indicate that the product requires a 20% structured refuge lepidopteran pests, and for seed distributed within cotton-growing areas the information will indicated that the product requires a 50% structured refuge for lepidopteran pests.

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.