

29964-9

1/29/2016

1/13



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 29, 2016

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

Subject: Herculex® RW Insect Protection
EPA Registration No. 29964-4
Submission to amend the expiration date of the registration
Submission dated December 14, 2015
Decision No. 513006

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), is acceptable only as an extension to the current conditional, time-limited registration and provided that you comply with the updated terms and conditions as described in this letter.

- 1) The subject registration will automatically expire on midnight March 31, 2016.
- 2) The subject registration will be limited to 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)] for use in field corn.
- 3) Submit/cite all data required for registration of your product under FIFRA section 3(c)(2)(B) when the Environmental Protection Agency (EPA) requires registrants of similar products to submit such data.
- 4) This plant-incorporated protectant (PIP) 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) Should you wish to amend the refuge treatment option to allow independent treatment of the refuge for pests other than corn rootworms, data would be required regarding the impact of independent treatment of the refuge for other pests (not corn rootworm, e.g., corn borers, spider mites) on corn rootworm resistance management.
- 6) You must commit to do the following Insect Resistance Management (IRM) Program, consisting of the following elements:

Mr. Jamie Staley
EPA Registration No. 29964-4

- Requirements for Pioneer Hi-Bred International, Inc. (Pioneer) to implement an IPM-based stewardship program designed to reduce selection pressure for corn rootworm (CRW) resistance.
- Requirements relating to creation of a non-CRW-protected PIP corn refuge in conjunction with the planting of any acreage of commercial Herculex® RW Insect Protection corn.
- Requirements for Pioneer to prepare and require Herculex® RW Insect Protection corn users to sign “grower agreements” that impose binding contractual obligations on growers to comply with the refuge requirements.
- Requirements for Pioneer to educate growers about IRM requirements.
- Requirements for Pioneer to evaluate and promote growers’ compliance with IRM requirements.
- Requirements for Pioneer to investigate reports of unexpected CRW damage to Herculex® RW Insect Protection corn from growers (“performance inquiries”) and sample CRW to determine if the insects are resistant to Cry34Ab1 and Cry35Ab1.
- Requirements for Pioneer to recommend CRW management options to growers in response to cases of unexpected CRW damage to Herculex® RW Insect Protection corn.
- Requirements regarding mitigation and notification actions that Pioneer would take in the event that CRW resistance was detected.
- Requirements for Pioneer to maintain, and provide the Agency upon request, the number of units sold by state and county, IRM grower agreement results, and substantive changes to educational programs. Pioneer is required to submit reports within three months of the Agency’s request.

a. Integrated Pest Management Stewardship Program

1) Pioneer must implement an IPM-based stewardship program for Herculex® RW Insect Protection corn. This program must be designed to reduce selection pressure for corn rootworm (CRW) resistance by encouraging growers to engage in a multi-year crop rotation strategy involving the use of one or more of the following: a non-CRW host crop (e.g., soybean), pyramided Bt corn Plant Incorporated Protectants (PIPs), other PIP corn products with different modes of action, and/or non-Bt or non-CRW protected Bt corn. As part of the stewardship program, Pioneer must update the technology use guide/grower guide and other grower educational materials to indicate that the use of soil-applied insecticides (SAI) with Herculex® RW Insect Protection corn is not recommended for control of CRW except under limited circumstances and in consultation with extension, crop consultants or other local experts. A copy of the revised grower educational materials must be provided to EPA by January 31, 2017 (provided the registration is extended beyond this date). As part of the stewardship program, Pioneer must promote the ABSTC/NCGA Best Management Practices (BMPs) for CRW control. Implementation of the IPM strategy can include:

- Grower education initiatives or incentives;
- Outreach to extension and consultant groups.

Mr. Jamie Staley
EPA Registration No. 29964-4

2) Pioneer must submit an annual report to EPA documenting activities conducted under the IPM stewardship program. This report must include an anonymous survey of grower practices, including adoption levels of the various crop rotation options (if employed) and other elements of the stewardship program. Pioneer may combine this product with other registered products to submit one annual report. The report must be submitted by January 31st each year, beginning in 2017 (provided the registration is extended beyond this date). The 2017 report will serve as a baseline unless Pioneer wishes to submit a separate baseline report prior to January 31, 2017.

b. Refuge Requirements for Herculex® RW Insect Protection Corn

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

When on-farm assessments identify non-compliance with refuge requirements for one or more *Bacillus thuringiensis (Bt)* corn products, additional educational material and assistance will be provided by Pioneer to help these growers meet the refuge requirements across their farming operations.

Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

- 1) *Refuge size.* The use of Herculex® RW Insect Protection corn from event DAS-59122-7 requires an accompanying 20% refuge.
- 2) *Refuge location.* The CRW refuge is required to be planted within or adjacent (e.g., across the road) to the Herculex® RW Insect Protection corn field.
- 3) *Refuge management options.* The CRW refuge may be managed in such a way that there is little or no yield loss to CRW, but must be managed in a way that it is sufficiently productive of susceptible CRW adults.
 - The in-field refuge options must be planted as a single block or as a series of strips measuring at least four (4) consecutive crop rows wide.
 - Seed mixtures of Herculex® RW Insect Protection and refuge corn are not permitted.
 - If the refuge is planted on rotated ground, then Herculex® RW Insect Protection corn must also be planted on rotated ground.
 - If the refuge is planted in continuous corn, the Herculex® RW Insect Protection corn field may be planted on either continuous or rotated land (option encouraged where western corn rootworm rotation-resistant biotype may be present).
 - Application of soil insecticide is permitted in the refuge.

9/13

Mr. Jamie Staley
EPA Registration No. 29964-4

- Seed treatment is permitted in the refuge, either at a rate for CRW protection or at a rate for controlling secondary soil pests.
- If aerial insecticides are applied to the refuge for control of CRW adults, the same treatment must also be applied in the same time frame to Herculex® RW Insect Protection corn.
- Pests other than adult CRW can only be treated with CRW-labeled insecticides on the refuge acres without treating the Herculex® RW Insect Protection corn acres if treatment occurs when adult CRW are not present. Pests on the Herculex® RW Insect Protection corn acres can be treated as needed without having to treat the refuge.
- The CRW refuge can be planted to any corn hybrid that does not express plant-incorporated protectants for CRW control (e.g., lepidopteran-protected *Bt* corn, herbicide-tolerant corn, or conventional corn).
- The refuge and Herculex® RW Insect Protection corn should be sown on the same day, or with the shortest window possible between planting dates, to ensure that corn root development is similar among varieties.
- Growers are encouraged to plant the CRW refuge in the same location each year, as it allows the CRW population to remain high and the durability of the trait is extended. This option may be preferable to growers who wish to only think of their refuge design once and for growers who grow continuous corn; however, for those growers who need to employ crop rotation, a fixed refuge would be impractical.

c. Grower Agreements for Herculex® RW Insect Protection Corn

- 1) Persons purchasing Herculex® RW 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 amended registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing Herculex® RW 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 Herculex® RW 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, thirty (30) days prior to implementing a proposed change, Pioneer must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of this amended registration.
- 5) Pioneer must continue to integrate this amended registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing Herculex® RW Insect Protection corn sign grower agreement(s).

Mr. Jamie Staley
EPA Registration No. 29964-4

- 6) Pioneer shall maintain records of all Herculex® RW Insect Protection corn grower agreements for a period of three (3) years from December 31st of the year in which the agreement was signed.
- 7) Pioneer shall make available to the Agency upon request records of the number of units of Herculex® RW 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.
- 8) 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 numbers of the growers, will be protected.

d. IRM Education and Compliance Monitoring Programs for Herculex® RW Insect Protection Corn

- 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 Herculex® RW Insect Protection corn users the importance of complying with the IRM program. The program shall include information encouraging Herculex® RW Insect Protection corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Herculex® RW 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 its records. The program shall involve at least one written communication annually to each Herculex® RW Insect Protection corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Pioneer shall coordinate its education programs with educational efforts of other registrants and organizations, such as the National Corn Growers Association and state extension programs.
- 2) Annually, Pioneer shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey, required under paragraphs 6–8 of this section, 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 and improve an ongoing IRM Compliance Assurance Program (CAP) designed to evaluate the extent to which growers purchasing Herculex® RW 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's *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 its

Mr. Jamie Staley
EPA Registration No. 29964-4

other *Bt* corn plant-incorporated protectants. Other required features of the program are described in paragraphs 5–21 of this section.

5) Pioneer must maintain and publicize a phased compliance approach (i.e., a guidance document that indicates how it 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 (2) years in a row would be denied access to Pioneer’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.

6) Pioneer must maintain and enhance an IRM compliance assurance program which shall include an annual survey conducted by an independent third party of a statistically representative sample of growers of Herculex® RW Insect Protection corn who plant the vast majority of all corn in the United States 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 independent marketing research firms 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 United States.

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 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.

9) Pioneer shall provide a final 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 on or before 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 required under paragraphs 6–8 of this section and from other sources. The registrant shall identify deficiencies in grower compliance and revise the education program to address those deficiencies. Pioneer must confer with EPA prior to adopting any changes.

11) Pioneer shall conduct an annual on-farm assessment program. Pioneer shall train its representatives who make on-farm visits with Herculex® RW Insect Protection corn growers 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

Mr. Jamie Staley
EPA Registration No. 29964-4

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 carry out a program for investigating legitimate tips and complaints that Herculex® Rootworm Insect Protection corn 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, Pioneer shall take appropriate action, consistent with its phased compliance approach.

13) If a grower, who purchases Herculex® RW 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 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 its compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. Within one (1) 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 with other registrants and report collectively the results of 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 numbers 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. Include the refuge size requirement on all Herculex® RW Insect Protection corn seed bags or bag tags. The Herculex® RW Insect Protection corn 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 risk 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 Herculex® Rootworm Insect Protection corn is used.

18) Pioneer will use its available Herculex® Rootworm Insect Protection corn sales records and other information to refine grower lists for on-farm assessments of their compliance with refuge requirements:

8/13

Mr. Jamie Staley
EPA Registration No. 29964-4

i. Identify for potential on-farm assessment growers whose sales information indicates they have purchased Herculex® RW Insect Protection corn but may have purchased little or no refuge seed from Pioneer, licensees, 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) Annually, Pioneer will refine the on-farm assessment program for Herculex® RW Insect Protection corn to reflect the adoption rate and level of refuge compliance for Herculex® RW 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 2 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 (3) 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 Herculex® RW Insect Protection corn within a 5-year period will be denied access to Pioneer's Bt corn products the next year.

e. Insect Resistance Monitoring and Mitigation Plan for Herculex® RW Insect Protection Corn

EPA is imposing the following terms and conditions for the Cry34Ab1 and Cry35Ab1 toxins expressed in Herculex® RW Insect Protection corn:

1) Investigation of Reports of Unexpected Levels of Damage (UXD) by Corn Rootworm (CRW): Performance Inquiries

a) Pioneer is required to investigate "performance inquiries" (i.e., reports of unexpected CRW damage to Herculex® RW Insect Protection corn) from growers. Fields (defined as a tract separated by permanent boundaries such as fences, permanent waterways, woodlands, croplines not subject to change because of farming practices, or other similar features) with unexpected damage that meet both of the criteria below must be subjected to the follow-up actions in part b) below:

- i. The affected plants are confirmed to be Herculex® RW Insect Protection corn plants (take leaf samples to determine the presence of the CRW-active Bt protein); and
- ii. Corn rootworm feeding caused root damage with a Node Injury Score (NIS) > 1.0 on at least 50% of plants surveyed in a transect sampling of the damaged site(s) within the field.

9/13

Mr. Jamie Staley
EPA Registration No. 29964-4

b) Follow-up actions (performance inquiries). For Herculex® RW Insect Protection corn fields meeting the criteria in part a) above, Pioneer must take the following actions:

- Collect at least 250 (ideally 500 or more) CRW adult individuals from the damaged site within the field in question. Collections may be extended to the whole field, if necessary to obtain sufficient CRW adult individuals. Collected populations must be subjected to the steps described for "investigation of populations of concern" in section e(2) below.
 - If collections are unsuccessful, visit affected farm or field the following year (assuming the grower continues to be a customer and repurchases seed and does not rotate the field to a non-host crop) and attempt to collect CRW adults. If beetles are not present the subsequent year, see section e(2)(c)(3) below.
- Review with the grower their CRW management practices and provide CRW management recommendations including an assessment of corn fields with similar trait(s) adjacent to the affected corn field that are managed by the same grower.
- Use of single trait products containing the CRW trait in fields with unexpected damage in previous years should be discouraged. Recommended management options include, but are not limited to, the following:
 - Primary option: Rotation to non-host crop (e.g., soybean)
 - Secondary options:
 - Use of pyramided Bt corn products with multiple CRW PIP traits
 - Use of different single-CRW PIP traits (i.e., an alternative CRW-active PIP)
 - Use of non-Bt or non-CRW protected corn
 - Tertiary options: If additional pest management need is determined beyond the secondary options listed above, additional CRW control tools (e.g., soil insecticides, seed-applied insecticides, chemigation) should be used
- If field(s) with UXD is/are planted to a non-host crop (e.g., soybean) the following year, then the area will be considered "mitigated" (as discussed in section e(2)(c)(4) below) even if subsequent bioassay results show that the population was resistant. No further action will be required by Pioneer for the UXD case.

c) Pioneer must submit an annual report to EPA detailing activities related to investigations of unexpected damage (UXD). This report will include the information from the most recent and previous corn growing seasons:

- i. Information from the most recent season:
 - The number of UXD reports investigated.
 - Location (by county and state).
 - CRW sampling (number and location of populations collected).
- ii. Information from the previous season:
 - The final disposition of UXD fields from the previous season (i.e., the management practices employed in response to UXD if the grower continues to be a customer.
 - Results from bioassays conducted on CRW populations from UXD fields where the primary management option, rotation to non-host crop, was not used.
- iii. Grower information, such as farm addresses or other personally identifiable information, or other

Mr. Jamie Staley
EPA Registration No. 29964-4

sensitive business/customer information must not be included in this report. This report must be submitted by November 30th each year.

2) Investigation of Populations of Concern

- a) Pioneer must conduct investigations of all CRW populations collected as part of the performance inquiry process in section e(1) above. These investigations must include the use of an EPA-approved bioassay to determine if sampled CRW populations are resistant to Cry34Ab1 and Cry35Ab1. Acceptable assays must be able to function as diagnostic tools capable of distinguishing resistant populations from susceptible ones. Unless previously approved, Pioneer must consult with EPA on their bioassay prior to its use.
- b) A CRW population will be considered by EPA to be resistant to Cry34Ab1 and Cry35Ab1 if the following criteria are met and additional collections and testing are not deemed to be necessary (based on part c) below):
1. An initial performance inquiry investigation results in a finding of Unexpected Damage; and
 2. Where green tissues are available and if plants are unusually stressed due to agronomic and/or environmental factors, Bt protein levels in affected plants are found to be within the documented range for that hybrid (if data are available); and
 3. Either (A): On-plant bioassays of insect collections from the UXD fields result in the following two statistically relevant comparisons
 - i. A statistically significant difference in measures of either mortality or sublethal effects (growth/development) between the field population and a relevant susceptible control population (i.e., one that responds as a typical susceptible field population) on Bt corn and/or lack of a statistically significant difference in measures of mortality or sublethal effect between the field population and a resistant positive control population[†]; and
 - ii. A lack of a statistically significant difference in the same measures of the field population raised on Bt corn and non-Bt corn plants.
- Or (B): Sublethal seedling bioassay of insect collections from the UXD fields result in two statistically relevant comparisons
- i. A statistically significant difference in measures of sublethal effects (growth/development) for populations on Bt corn (normalized using non-Bt) seedlings between the field population and a relevant susceptible control population where available or historical field populations and/or lack of a statistically significant difference in measures between the field population and a resistant positive control population[†]; and
 - ii. A lack of a statistically significant difference in the same measures of the field population raised on Bt corn seedlings and non-Bt corn seedlings.
- Or (C): Diet-based bioassays of insect collections from the UXD fields result in two statistically relevant comparisons
- i. A statistically significant difference in measures of lethal or sublethal effects (growth/development) on diet containing the Bt protein (diagnostic concentration or

[†] If a resistant positive control population is not available or accessible, Pioneer must consult with EPA prior to initiating bioassays and work to develop an appropriate resistant positive control population.

Mr. Jamie Staley
EPA Registration No. 29964-4

concentration-response measures) between the field population and a relevant susceptible control population where available or historical field populations and/or lack of a statistically significant difference in measures between field population and a resistant positive control population[†]; and

- ii. Either a lack of a statistically significant difference in the same measures of the field population exposed to diet containing the Bt protein (diagnostic concentration) and diet not containing the Bt protein and/or lack of a statistically significant difference in measures between the field population and a resistant positive control population, or lack of a statistically significant concentration and/or lack of a statistically significant difference in concentration response between the field and a resistant positive control population[†].

c) Mitigation, as detailed in section e(3) below, is required for any CRW population that meets EPA's resistance criteria above, unless the circumstances described below are applicable.

- 1. To minimize the potential for incorrectly reaching a conclusion of resistance, another year of CRW adult collections and additional testing is needed to determine resistance if:
 - i. The results of the bioassays are inconclusive (e.g., the results of the statistical analysis are unclear because of low sample sizes) or
 - ii. Another reasonable explanation for the unexpected damage exists (e.g., high pest pressure and/or high plant stress).
- 2. In these cases, Pioneer and EPA will discuss and align on next steps before reaching any resistance conclusion.
- 3. If CRW collections are not possible in the current year or subsequent year due to successful management practices, then no further investigation is needed. The population would be considered "mitigated" meaning, in this case, that the population is suppressed or extirpated for the UXD field. However, EPA recommends that Pioneer continue to be vigilant in areas where CRW populations were successfully mitigated.
- 4. If a UXD field receives non-host crop (e.g., soybean) rotation the following year as described in Section e(1)(b) above, no additional mitigation is subsequently required.

3) Mitigation of CRW Populations Meeting EPA's Resistance Criteria

a) For any CRW population found to be resistant under EPA's criteria described in section e(2) above, Pioneer must take the following steps:

- 1. Pioneer must inform EPA of the results of the bioassays as soon as possible, but at least within 30 days if measures are triggered.
- 2. The mitigation action area (MAA) is defined as the growers' farming operation up to a 1/2 mile radius from the damaged site that produced the resistant population.
- 3. Within 30 days of informing EPA of the results of the bioassays, Pioneer must notify state extension agents and crop consultants who operate within the county in which resistance was identified. Information shared must include identification of the county in which resistance was detected and trait(s) affected.

Mr. Jamie Staley
EPA Registration No. 29964-4

4. Within the MAA, Pioneer must do the following:
 - i. Prior to finalizing the grower's seed order for the following season, inform the affected grower and other registrants that hold registrations containing the affected trait. Pioneer must also inform neighboring growers if those growers are customers of Pioneer. Information shared must include identification of the county in which resistance was detected and trait(s) affected;
 - ii. Discontinue sales/planting of single trait product containing the compromised trait until resistance has been demonstrated to have been mitigated;
 - iii. Pioneer must monitor the resistant population in the MAA, as long as grower remains a customer of the company, until mitigation has been demonstrated as described in part 5 below unless otherwise agreed with EPA.
 - iv. Require any pyramids sold by Pioneer containing the compromised trait be planted with a 20% refuge until resistance has been demonstrated to have been mitigated. Other Bt registrants selling pyramided products in the MAA are encouraged, but cannot be required by this term of registration, to follow suit;
 - v. For Pioneer's affected customer's field(s), the mitigation goal is to control the resistant CRW population. Within the MAA Pioneer shall encourage the use of "Mitigation Practices" including:
 1. Primary option: Rotation to a non-host crop (e.g., soybean);
 2. Secondary options:
 - a. Use of pyramided Bt corn products with multiple CRW PIP traits;
 - b. Use of different single-CRW PIP traits (i.e., an alternative CRW-active PIP);
 - c. Use of non-Bt corn or non-CRW protected corn (with/without soil-applied insecticide);
 3. Tertiary options:
 - a. If additional pest management need is determined beyond the secondary options listed above, additional CRW control tools (e.g., soil insecticides, seed-applied insecticides, chemigation) should be used.
 - b. Use of foliar applications to control adults (when appropriate economic thresholds have been met) may be used in conjunction with one or more of the above;
5. A resistant CRW population in the MAA will be considered mitigated if one of the following criteria is met:
 - i. Corn fields within the MAA are rotated to a non-host crop (e.g. soybean) for one growing season.
 - ii. After implementation of mitigation practices (part 4.v above), resistance monitoring (sampling) is conducted but few CRW are found (i.e., <0.1 adults per plant) and environmental conditions (e.g., weather) are unlikely to be responsible for the lack of adult CRW presence. If environmental conditions are a factor, then monitoring should continue for another season.
 - iii. After implementation practices (part 4.v above), resistance monitoring (sampling) is conducted, CRW are found and collected, and bioassays (section e(2)(b) above) show that the population susceptibility to the identified trait has returned to baseline levels.

Mr. Jamie Staley
EPA Registration No. 29964-4

- 6. The mitigation actions in part 4 above can be lifted, and growers can resume the use of Herculex® RW Insect Protection Corn as a primary tool for CRW management in the MAA, only when Pioneer demonstrates that successful mitigation as described in part 5 above has been achieved.
- b) Based on further research to understand CRW resistance to Bt PIPs, EPA will consider refinements to the resistance mitigation program. Such research may include characterizing the genetics of resistance (e.g., number of genes, functional dominance, mechanism of resistance, and cross-resistance) and the biology of resistant insects (e.g., fitness in the presence and absence of the product), and other control tactics.

f. Annual Reporting Requirements for Herculex® RW Insect Protection Corn

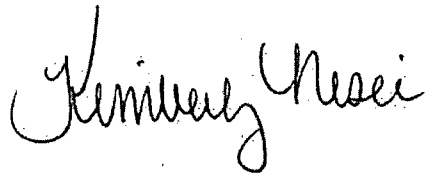
The following annual reports must be submitted, provided the registration is extended beyond the current registration expiration date.

- 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 of each year.
- 2) IPM Stewardship Program: Activities conducted under the IPM stewardship program, including an anonymous survey of grower practices, adoption levels of the various crop rotation options (if employed) and other elements of the stewardship program, on or before January 31st of each year.
- 3) Unexpected Damage Investigations: Activities related to investigations of unexpected damage (UXD), including number and location of UXD cases, insect sampling, bioassays, and final disposition of UXD fields from the most recent and previous corn growing seasons, on or before November 30th of 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 this product constitutes acceptance of these conditions.

This amendment does not affect the last approved label (dated September 29, 2015) for this product.

Sincerely,



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