

29964-10

1/29/2016

1/10



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 62<sup>nd</sup> Avenue, P.O. Box 1000  
Johnston, IA 50131-1000

Subject: Optimum<sup>®</sup>AcreMax<sup>®</sup> RW  
EPA Registration No. 29964-10  
Submission to amend the expiration date of the registration  
Submission dated December 14, 2015  
Decision No. 513112

Dear Mr. Staley:

The amendment referred to above, submitted in connection with registration under Section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable provided that you comply with the following terms and conditions.

- 1) The subject registration will automatically expire on midnight March 31, 2016.
- 2) Submit and/or cite all data required for registration/ registration review of your product under FIFRA section 3(c)(2)(B) when the Agency requires all registrants of similar products to submit such data.
- 3) Submit or cite all data required to support the Herculex RW plant-incorporated protectant products within the timeframes required by the terms and conditions of EPA Registration Number 29964-4.
- 4) The subject registration will be limited to a seed mix of DAS-59122-7 [*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% non-*Bt* corn seed.
- 5) Targeted on-farm compliance assessments are neither necessary nor required for Optimum<sup>®</sup>AcreMax<sup>®</sup> RW (OAMRW) corn because the refuge is automatically implemented when

planting this product. OAMRW corn may be used as the Lepidopteran refuge for Optimum<sup>®</sup> AcreMax<sup>®</sup> 1 (OAM1) corn (EPA Registration Number 29964-6). In this case, on-farm assessments to ensure that the Lepidopteran refuge is planted and placed appropriately would be covered by OAM1 corn's grower education, targeted on-farm assessments and stewardship documents.

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

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

- 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 for Pioneer to investigate reports of unexpected CRW damage to OAMRW 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 OAMRW 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 OAMRW 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 OAMRW 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.

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 31<sup>st</sup> 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) IRM Education Program for OAMRW Corn**

1. Pioneer must continue to implement and enhance a comprehensive, ongoing IRM education program designed to convey to OAMRW 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 education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, and electronic communications such as by internet, radio, or television commercials. Copies of the materials will be provided to EPA for their records. The program shall involve at least one written communication annually to each OAMRW corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. 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. 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.

**c) Grower Agreements for OAMRW Corn**

1. Persons purchasing OAMRW 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 use its current grower agreement for OAMRW 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.
4. Pioneer must continue to integrate this registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing

OAMRW corn will affirm annually that they are contractually bound to comply with the requirements of the IRM program.

5. Pioneer shall maintain records of all OAMRW corn grower agreements for a period of three (3) years from December 31<sup>st</sup> 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 OAMRW 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.

**d) Insect Resistance Monitoring and Mitigation Plan for Corn Rootworm and OAMRW Corn Insect Resistance Monitoring**

EPA is imposing the following terms and conditions for the Cry34Ab1 and Cry35Ab1 toxins expressed in OAMRW 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 OAMRW 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 OAMRW 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.
- b) Follow-up actions (performance inquiries). For OAMRW 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 d(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 d(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 d(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 sensitive business/customer information must not be included in this report. This report must be submitted by November 30<sup>th</sup> 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 d(1) above. These investigations must include the use of an EPA-

6/10

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<sup>†</sup>; 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<sup>†</sup>; 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 concentration-response measures) between the field population and a relevant susceptible control population where available or historical field populations

---

<sup>†</sup> 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.

- and/or lack of a statistically significant difference in measures between field population and a resistant positive control population<sup>†</sup>; 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<sup>†</sup>.
- c) Mitigation, as detailed in section d(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 d(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 d(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 ½ 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.
  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 d(2)(b) above)



show that the population susceptibility to the identified trait has returned to baseline levels.

6. The mitigation actions in part 4 above can be lifted, and growers can resume the use of OAMRW 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.

**e) Refuge Assurance Program for OAMRW Corn**

Pioneer must implement a Blended Seed Refuge Assurance Program designed to ensure OAMRW products are formulated with the appropriate rate of refuge seeds. The program must include the following four elements:

1. Trait purity check on seed lots prior to blending;
  2. ISO 9000 Standard Operating Procedures for the blending process;
  3. Calibration of blending equipment; and
  4. Records and data retention records for seed blend products.
- Calibration records - Pioneer will retain documentation for a specified period of time on the equipment calibration including the procedure, when it was conducted and the results.
  - Blend proportion records (weight and kernel based) - Pioneer will retain documentation for a specified period of time on the kernel per pound data of the components, the calculations to determine the proportions based on weight and the actual weights that are blended together to make up an OAMRW product by seed lot.

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

**f) Annual Reporting Requirements for OAMRW Corn**

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

- 1) 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 31<sup>st</sup> of each year.

Mr. Jamie Staley  
EPA Registration No. 29964-10

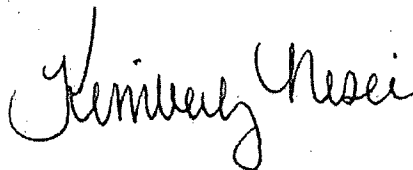
10/10

2) 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 30<sup>th</sup> 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 the product constitutes acceptance of these conditions.

This amendment does not affect the last approved label (dated September 28, 2015) for this product.

Sincerely,



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