29964-19 1/25/2013 1/17

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

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

EPA Reg. Number:	Date of Issuance:
29964-19	JAN 25 2013

Term of Issuance:
Unconditional, Time-Limited

Name of Pesticide Product:
Optimum® Intrasect™ Leptra™

Name and Address of Registrant (include ZIP Code):

Pioneer Hi-Bred International, Inc.
7100 NW 62nd Avenue
Johnston, Iowa 50131

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or the Act). Registration is in no way to be construed as an endorsement or recommendation of this product by the Environmental Protection Agency (EPA or the Agency). To protect health and the environment, the Administrator, on her motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This registration does not eliminate the need for continual reassessment of the pesticide. If EPA determines at any time that additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under section 3(c)(2)(B) of FIFRA.

This product is unconditionally registered in accordance with Section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and is subject to the following terms:

1. The subject registration will automatically expire January 31, 2121.

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Signature of Approving Official:

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

Date: 25 Jan 2013

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2. The subject registration is limited to *Bacillus thuringiensis* Cry1F protein and the genetic material (plasmid insert PHI8999A) necessary for its production in corn event TC 1507 (OECD Unique Identifier DAS-Ø15Ø7-1) x *Bacillus thuringiensis* Cry1Ab protein and the genetic material (vector PV-ZMBK07) necessary for its production in corn event MON 810 (OECD Unique Identifier MON-ØØ81Ø-6) x *Bacillus thuringiensis* Vip3Aa20 protein and the genetic material (via elements of pNOV1300) necessary for its production in corn event MIR162 (OECD Unique Identifier SYN-IR162-4) for use in field corn.

3. Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

4. The data submitted by Pioneer are sufficient to support registration for the combination PIP corn product: Optimum® Intrasect™ Leptra™ (1507xMON810xMIR162), provided that the registrant submits/cites any data required to support the PIP registrations of the individual parental events: TC1507 (DAS-Ø15Ø7-1), MON810 (MON-ØØ81Ø-6) and MIR 162 (SYN-IR162-4) in corn, within the time frames required by the terms and conditions of EPA Registration Numbers 29964-3, 524-489 and 67979-14, respectively as well as the combination PIP product TC1507 (DAS-Ø15Ø7-1) x MON810 (MON-ØØ81Ø-6) within the time frames required by the terms and conditions of EPA Registration Number 29964-7.

5. This plant-incorporated protectant may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination through conventional breeding with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

6. You must submit the following data and/or information in the time frames listed:

Study Type	Required Data	Due Date
Insect Resistance Management - Grower Agreement	A copy of the grower agreement, associated stewardship documents, and written description of a process, that assures that growers will sign grower agreements and persons purchasing 1507xMON810xMIR 162 corn will annually affirm that they are contractually bound to comply with the requirements of the insect resistance management (IRM) program.	Within 90 days of the date of registration

7. You must commit to an Insect Resistance Management (IRM) Program consisting of the following elements:

- Requirements relating to creation of a non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuge in conjunction with the planting of any acreage of corn;

- Requirements for Pioneer Hi-Bred International, Inc. (Pioneer) to prepare and require Optimum® Intrasect™ Leptra™ corn users to sign "grower agreements" that impose binding contractual obligations on the grower to comply with the refuge requirements;

- Requirements for Pioneer to develop, implement, and report to EPA on programs to educate growers about IRM requirements;

- Requirements for Pioneer to develop, implement, and report to EPA on programs to evaluate and promote growers' compliance with IRM requirements;

- Requirements for Pioneer to develop, implement, and report to EPA on programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to Cry1F, Cry1Ab, and Vip3Aa20 proteins in the target insects;

- Requirements for Pioneer to develop and, if triggered, to implement 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 submit reports on units sold by state (units sold by county level will be made available to the Agency upon request), IRM grower agreement results, and the compliance assurance program, including the educational program, on or before January 31st each year.

I. Refuge Requirements

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (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 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. Corn Belt Refuge Requirements for *Bt* corn. For Optimum® Intrasect™ Leptra™ field corn grown outside cotton-growing areas (e.g., the Corn Belt), 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.

    i. Specifically, growers must plant a structured refuge of at least 5% non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn that may be treated with insecticides as detailed below, to control lepidopteran stalk-boring and other pests.

    ii. Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field.

    iii. External refuges must be planted within ½ mile of the *Bt* fields.

iv. When planting the refuge as strips across the field or as perimeter strips, refuges must be at least 4 consecutive rows wide.

v. Insecticide treatments for control of ECB, CEW, Southwestern corn borer (SWCB) and other lepidopteran target pests listed on the label, grower guides, or other educational material 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 or crop consultants). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.

2. Cotton-Growing Area Refuge Requirements for *Bt* Corn. For *Bt* field corn grown in cotton-growing areas, 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. In order to inform growers of their obligation to implement the revised refuge requirements described below, Pioneer must revise and update its grower guide. A copy of the revised grower guide must be submitted to EPA by May 1, 2013.

i. Specifically, growers in these areas must plant a structured refuge of at least 20% 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.

ii. Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field.

iii. External refuges must be planted within ½ mile of the *Bt* fields.

iv. When planting the refuge in strips across the field, refuges must be at least 4 consecutive rows wide.

v. Insecticide treatments for control of ECB, CEW, Southwestern corn borer (SWCB), and other lepidopteran target pests listed on the label, grower guides, or other educational material 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). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.

vi. 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,

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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).

II. Grower Agreement

1. Persons purchasing Optimum® Intrasect™ Leptra™ 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 plant-incorporated protectants, which is reasonably likely to assure that persons purchasing the Optimum® Intrasect™ Leptra™ corn will affirm annually that they are contractually bound to comply with the requirements of the IRM program.

4. Pioneer must submit to EPA within 90 days a copy of the grower agreement and any specific stewardship documents referenced in the grower agreement. Pioneer must continue to use this grower agreement in subsequent years.

5. 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, then thirty 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 of this registration.

6. Pioneer must continue to integrate this registration into the current system used for its other *Bt* corn plant incorporated protectant products, which is reasonably likely to assure that persons purchasing Optimum® Intrasect™ Leptra™ corn sign grower agreement(s).

7. Pioneer shall maintain records of all Optimum® Intrasect™ Leptra™ corn grower agreements for a period of three years from December 31st of the year in which the agreement was signed.

8. Beginning on January 31, 2014, and annually thereafter, Pioneer shall provide EPA with a report showing the number of units of its *Bt* corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the preceding twelve-month period.

9. Pioneer must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential

business information, including names, personal information, and grower license number, will be protected.

III. IRM Education and IRM Compliance Monitoring Program

1. Pioneer must continue to implement and enhance (as set forth in paragraph 18 of this section) a comprehensive, ongoing IRM education program designed to convey to Optimum® Intrasect™ Leptra™ corn users the importance of complying with the IRM program. The program must inform growers of their obligation to implement the refuge requirements.

2. The program shall include information encouraging Optimum® Intrasect™ Leptra™ corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Optimum® Intrasect™ Leptra™ corn fields. The program must inform growers of their obligation to implement the refuge requirements. 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 Optimum® Intrasect™ Leptra™ 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 other organizations, such as the National Corn Grower Association and state extension programs.

3. Annually, Pioneer shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraph 7 and from other sources. The registrant shall identify deficiencies in grower compliance and revise the education program to address those deficiencies.

4. Annually, Pioneer must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. Pioneer must either submit a separate report or contribute to the report from the industry working group, Agricultural Biotechnology Stewardship Technical Committee (ABSTC). The required features of the compliance assurance program are described in paragraphs 5–23 of this section.

5. Pioneer must continue to implement and improve an ongoing IRM compliance assurance program (CAP) designed to evaluate the extent to which growers purchasing Optimum® Intrasect™ Leptra™ 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 corn PIP products. Pioneer shall coordinate with other *Bt* corn registrants in improving its compliance assurance program and continue to integrate this registration into the current compliance assurance program used for their other *Bt* corn PIPs. Other required features of the program are described in paragraphs 6 - 23 below.

6. Pioneer must maintain 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 noncompliance. While recognizing that for reasons of difference in business practices there are needs for flexibility between different companies, all *Bt* corn registrants 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 sales of 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.

7. 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 Optimum® Intrasect™ Leptra™ 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 the registrant, the grower, or anyone else with a direct interest in IRM compliance for *Bt* corn.

8. 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.

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

10. 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 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.

11. Annually, Pioneer shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey (required by paragraphs 7 through 9) 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 the Agency prior to adopting any changes.

12. Pioneer shall conduct an annual on-farm assessment program. Pioneer shall train its representatives who make on-farm visits with growers of Optimum® Intrasect™ Leptra™ 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.

13. Pioneer shall carry out 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."

14. If a grower, who purchases Optimum® Intrasect™ Leptra™ 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.

15. 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.

16. 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.

17. Pioneer shall maintain and continue to use its existing Compliance Assurance Program (CAP) to address the refuge requirement. The registrant may coordinate with other registrants in designing and implementing its Compliance Assurance Program.

18. Pioneer will enhance the IRM refuge education program throughout the seed delivery channel:

    i. Ensure sales representatives, licensees, seed dealers, and growers recognize the importance of correct refuge implementation, and potential consequences of failure to plant the required refuge;

    ii. Include the refuge size requirements on all Optimum® Intrasect™ Leptra™ corn seed bags or bag tags. The Optimum® Intrasect™ Leptra™ corn label accepted by EPA must include how this information will be conveyed to growers via text and graphics. This requirement may be phased in over the next three growing seasons. Revised Optimum® Intrasect™ Leptra™ corn labels must be submitted by 90 days from the date of this registration. 50% implementation on the Optimum® Intrasect™ Leptra™ corn seed bags or bag tags must

occur by the 2013 growing season, and full implementation must occur by the 2014 growing season.

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

    i. Use *Bt* corn adoption, pest pressure information, and other available information to identify regions where the risk of resistance is greatest;

    ii. Focus approximately two-thirds of on-farm assessments on these regions, with the remaining assessments conducted across other regions where the product is used.

20. Pioneer will use its available Optimum® Intrasect™ Leptra™ sales records and other information to refine grower lists for on-farm assessments of their compliance with refuge requirements:

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

21. 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.

22. Annually, Pioneer will refine the on-farm assessment program for the Optimum® Intrasect™ Leptra™ corn product to reflect the adoption rate and level of refuge compliance for Optimum® Intrasect™ Leptra™ corn.

23. 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 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 Optimum® Intrasect™ Leptra™ corn within a five-year period will be denied access to and/or sales of Pioneer's Bt corn products the next year.

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IV. Insect Resistance Monitoring and Remedial Action Plans

1. The Agency is imposing the following conditions for the Cry1F, Cry1Ab, and Vip3Aa20 toxins expressed in Optimum® Intrasect™ Leptra™ corn:

   i. Pioneer must monitor for resistance to the Cry1F, Cry1Ab, and Vip3Aa20 toxins expressed in Optimum® Intrasect™ Leptra™ corn.

   ii. The resistance monitoring program must include the following 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 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 Optimum® Intrasect™ Leptra™ corn. The Agency shall be consulted prior to the implementation of such modifications.

Pioneer will report to the Agency before August 31st each year the results of the population sampling and bioassay monitoring program.

Any incidence of unusually low sensitivity to the Cry1F, Cry1Ab and Vip3Aa20 proteins in bioassays shall be investigated as soon as possible to understand any field relevance of such a finding. Such investigations

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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 31st. 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 Optimum® Intrasect™ Leptra™ corn 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; and
- 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, Pioneer will consult with the Agency to develop and implement a case-specific resistance management action plan.

2. Investigation of Reports of Unexpected Levels of Damage by the Target Pests

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* proteins;
- the relevant plant tissues are expressing the expected level of *Bt* proteins; 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 Optimum® Intrasect™ Leptra™ 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 Optimum® Intrasect™ Leptra™ corn fields in the affected region to control the target pest during the immediate growing season.
- Destroy Optimum® Intrasect™ Leptra™ 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).
- 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 Pioneer:

- 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, the registrant 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;
- The registrant 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, the registrant 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 unconditional registration.

V. Annual Reporting Requirements

1. Annual Sales: reported and summed by state (county level data available by request) on or before January 31st each year;

2. Grower Agreement Results: number of units of Optimum® Intrasect™ Leptra™ corn seed shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements, on or before January 31st of each year;

3. Grower Education: substantive changes to education program completed previous year, on or before January 31st of each year;

4. Compliance Assurance Program: Compliance Assurance Program activities and results for the previous year and plans for the Compliance Assurance Program for the current year, on or before January 31st of each year;.

5. Compliance Survey Results: to include annual survey results and plans for the next year; on or before January 31st of each year;

6. 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,

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

15/17

Optimum® Intrasect™ Leptra™

(OECD Unique Identifier: DAS-Ø15Ø7-1xMON-ØØ81Ø-6xSYN-IR162-4)

Active Ingredients

Bacillus thuringiensis Cry1F protein and the genetic material (plasmid insert PHI8999A) necessary for its production in corn event DAS-Ø15Ø7-1	≤0.0017%*
Bacillus thuringiensis Cry1Ab protein and the genetic material (vector PV-ZMBK07) necessary for its production in corn event MON-ØØ81Ø-6	≤0.0013%*
Bacillus thuringiensis Vip3Aa20 protein and the genetic material (via elements of pNOV1300) necessary for its production in corn event SYN-IR162-4	≤0.02%*

Inert Ingredients

Phosphinothricin acetyltransferase (PAT) protein and the genetic material (plasmid insert PHI8999A) necessary for its production in corn events DAS-Ø15Ø7-1	≤0.00046%*
Phosphomannose isomerase (PMI) protein and the genetic material (via elements of pNOV1300) necessary for its production in corn event SYN-IR162-4	≤0.00048%*

* Percentage (wt/wt) on a dry wt. basis for whole plant (forage).

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET CONTENTS _____

EPA REGISTRATION NUMBER: 29964-xx

EPA ESTABLISHMENT NUMBER: 029964-IA-001

Pioneer Hi-Bred International, Inc.
7300 NW 62nd Avenue
Johnston, IA 50131

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.

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.

Optimum® Intrasect™ Leptra™ combines the insect protection features of 1507xMON810 and Agrisure® Viptera (MIR162) in the same corn hybrid (inbred). Optimum® Intrasect™ Leptra™ hybrids protect corn crops from leaf, stalk and ear damage caused by lepidopteran corn pests such as the European corn borer and other lepidopteran pests. In order to minimize the risk of the corn pests developing resistance to Optimum® Intrasect™ Leptra™, an insect resistance management plan must be implemented.

INSECT RESISTANCE MANAGEMENT

Growers are instructed to read information on insect resistance management.

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

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

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

Corn-Belt/Non-Cotton Growing Areas

Optimum® Intrasect™ Leptra™ 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 5% 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 of the *Bt* cornfield(s).
- When planting the refuge in strips across the field, refuges must be at least four (4) rows wide.
- Foliar insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, fall armyworm, black cutworm, stalk borer, western bean cutworm, lesser corn stalk borer, southern corn stalk borer, sugarcane borer, beet armyworm and dingy cutworm 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® Intrasect™ Leptra™ grown in cotton-growing areas:

- Growers must plant a structured refuge of 20% 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 of the *Bt* cornfield(s).
- When planting the refuge in strips across the field, refuges must be at least four (4) rows wide.
- Foliar insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, fall armyworm, black cutworm, stalk borer, western bean cutworm, lesser corn stalk borer, southern corn stalk borer, sugarcane borer, beet army worm and dingy cutworm 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).

Crop	Pests
Field Corn	black cutworm beet armyworm corn earworm dingy cutworm European corn borer fall armyworm southwestern corn borer western bean cutworm lesser corn stalk borer southern corn stalk borer stalk borer sugarcane borer