BIOPESTICIDES REGISTRATION ACTION DOCUMENT

Optimum® AcreMax™ B.t. Corn Seed Blends

U.S. Environmental Protection Agency (EPA)
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (BPPD)

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I. BACKGROUND

Active Ingredients:

Bacillus thuringiensis Cry34Ab1 and Cry35Ab1 proteins and the genetic material necessary for their production (plasmid insert PHP 17662) in Event DAS-59122-7 corn

Bacillus thuringiensis Cry1F protein and the genetic material necessary for its production (plasmid insert PHI8999) in Event TC1507 corn

Trade & Other Names:

HERCULEX® I => Cry1F Corn

HERCULEX® RW (Rootworm) => Cry34/35Ab1 Corn

HERCULEX® XTRA => Cry1F + Cry34/35Ab1 Corn

Optimum® AcreMax™ 1 (OAM 1) => Seed Blend of 90% HERCULEX® XTRA and 10% HERCULEX® I

OAM RW => Seed Blend of 90% HERCULEX® RW and 10% Non-*B.t.* Corn

OPP Chemical Codes: 006490 (Cry34/35Ab1 corn) and 006481 (Cry 1F corn)

Type of Pesticide: Plant-Incorporated Protectants (PIPs)

Product Profile:

HERCULEX® I

The registration for Cry1F Event TC1507 (Event DAS-01507-1), also known as HERCULEX® I, was first granted by the Agency on May 18, 2001. HERCULEX® I expresses the Cry1F insecticidal crystal protein as well as the PAT (phosphinothrin acetyl transferase) protein, which confers tolerance to the herbicidal active ingredient glufosinate-ammonium. Cry1F is efficacious against lepidopteran pests, and the primary target pest of HERCULEX® I is the European corn borer (ECB, *Ostrinia nubilalis*); other target pests are corn earworm (CEW, *Helicoverpa zea*), southwestern cornborer (SWCB, *Diatrea grandiosella*), fall armyworm (FAW, *Spodoptera frugiperda*), western bean cutworm (WBCW, *Richia albicosta*), and black cutworm (BCW, *Agrotis ipsilon*). The main target pests for which insect resistance management (IRM) requirements apply are ECB, CEW, and SWCB.

HERCULEX® RW
The registration for Event DAS-59122-7, also known as HERCULEX® RW, was granted by the Agency in August, 2005. HERCULEX® RW expresses *B.t.* toxins Cry34Ab1 and Cry35Ab1, which are efficacious against coleopteran pests. The primary target pests of HERCULEX® RW are western corn rootworm and northern corn rootworm (CRW, *Diabrotica* species). Maize containing Event 59122-7 has been modified to express the PAT protein, which confers tolerance to gluphosinate-aluminum herbicide.

HERCULEX® XTRA
The registration for HERCULEX® XTRA (Event TC1507 x DAS59122-7) was granted in October 2005. HERCULEX® XTRA is the result of a conventional breeding cross between HERCULEX® I and HERCULEX® RW and is considered a stacked PIP because it targets two different kinds of pests (Lepidoptera and Coleoptera) and contains two separate PIP active ingredients.

OAM 1: EPA File Symbol 29964-A
In February, 2008, Pioneer Hi-Bred International, Inc. submitted an application to register Optimum® AcreMax™ 1 Insect Protection, a new blended seed product that contains two different kinds of seeds of the already registered products HERCULEX® XTRA and HERCULEX® I. The new product incorporates the CRW refuge into the seed bag. The seed blend percentage was amended to 90% HERCULEX® XTRA and 10% HERCULEX® I.

OAM RW: EPA File Symbol 29964-RN
In November 2009, Pioneer Hi-Bred International, Inc. submitted an application to register Optimum® AcreMax™ RW Insect Protection, a seed blend consisting of 90% HERCULEX® RW and 10% non-*B.t.* Corn. The new product incorporates the CRW refuge into the seed bag and also can serve as a refuge for the Cry1F portion of OAM 1.

Pioneer's Projected Use in 2010, 2011, and 2012

Pioneer's forecast for OAM 1 U.S. acreage in the 2010, 2011, and 2012 growing seasons is listed below. Pioneer states that "[t]hese estimates have been divided into high-pressure areas for corn rootworm (i.e., the Red Zone) and non-Red Zone acres (i.e., the remaining U.S. corn acreage outside the Red Zone). The Red Zone is defined by Pioneer as 90 counties that have a 100% chance of corn rootworm infestation in any given year. These counties are primarily located in northeastern Illinois, northwestern Indiana and, to a lesser extent, southeastern Wisconsin and southwestern Michigan. Because of the strong selection pressure present in the Red Zone, it is considered a potential area for corn rootworm resistance to develop. The percentages are based on general USDA acreage projections, which project a total of 90 million corn acres in the U.S. in 2010, 2011, and 2012."

Growing season	Red Zone geography	Non-Red Zone geography
2010	~0.077%	~0.042%
2011	~5.8%	~8.2%
2012	~8%	~12%

II. INSECT RESISTANCE MANAGEMENT

FIFRA Scientific Advisory Panel (SAP)

Pioneer/Dupont's initial registration application for OAM 1 consisted of a seed blend of 95% HERCULEX® XTRA and 5% [3.5% (±1.5)] HERCULEX® I. The HERCULEX® I was intended to serve as the IRM refuge for the corn rootworm active component of HERCULEX® XTRA. The proposed seed blend strategy and reduction in refuge from 20% to 2% to 5% represented a significant paradigm shift for the *B.t.* IRM strategy that has been employed for over 15 years. BPPD conducted a risk assessment and presented preliminary conclusions to the Scientific Advisory Panel for peer review on February 23 to 24, 2009.

The SAP (2009) expressed concern about the proposed refuge reduction. The Panel concluded that there was no compelling evidence, either in the data provided by Pioneer or in the public literature, to support a 5% blended refuge for this particular product. The Panel noted, however, that the biology of the corn rootworm makes it susceptible to successful control and mitigation by a seed blend methodology, if the refuge is of sufficient size.

Current Submissions

OAM 1 is a blended seed product that contains 90% HERCULEX® XTRA seeds (Cry34/35Ab1 x Cry1F) and 10% HERCULEX® I seeds (Cry1F).

OAM RW is a blended seed product that contains 90% HERCULEX® RW seeds (Cry34/35Ab1) and 10% non-*B.t.* Corn.

Seed Blending

Pioneer submitted information and analyses supporting their claim that refuge plants will be randomly distributed throughout the field, including information indicating that the expected error of mixing the refuge seed is ±1.5% (using the seed mixing technology described in their submission) and that the standard deviation for planting the correct percentage of refuge is ±1%.

IRM Modeling

EPA Model Description

EPA'S POPGEN (Population Genetics) simulation models are a series of generalized, flexible population genetics modeling systems modeling the evolution of resistance to conventional pesticides and transgenic crops. The programs are capable of simulating complex landscapes that vary spatially as well as temporally over the course of a growing season.

POPGEN-D

The deterministic model POPGEN-D is a relatively simple frequency-based model that incorporates non-compliance estimates, non-random mating in refuge fields, and larval movement. The model permits modeling of both block refuges and blended seed-mixture refuges.

POPGEN-S2

The stochastic model POPGEN-S2 is a modification of an earlier stochastic, spatially explicit, dual locus, simulation model designed to evaluate the development of resistance in crop pests to insecticides. (Caprio et al 2006).

POPGEN-SM

The stochastic model POPGEN-SM is a modification of an earlier stochastic, spatially explicit, dual locus, simulation model designed to evaluate development of resistance in crop pests to insecticides and incorporating multi loci. (Caprio et al 2006).

To incorporate uncertainty in the parameters used in the deterministic model, distributions, based on data for the lowest and maximum possible values, were developed as well as a most likely value. These values were used in PERT distributions based on a beta distribution with the most likely value weighted by 4 (Vose 2001).

5% Seed Blend

Subsequent to the February 2009, FIFRA Scientific Advisory Panel meeting, Pioneer submitted revised modeling that incorporated new corn rootworm movement data. EPA fully evaluated this modeling, including assessing the new corn rootworm movement data. In addition, using the POPGEN model developed by EPA ORD, EPA conducted an independent modeling analysis of Pioneer's proposed seed blend using both deterministic and stochastic models. EPA concluded that a number of critical input parameters to the Pioneer modeling were not supported by data or were inadequate to support a rational basis for regulatory decisionmaking. Therefore, BPPD concluded that the results of the Pioneer modeling indicating that the proposed 5% seed blend is superior to a 20% block refuge deployment strategy for OAM 1 and corn rootworm were not scientifically

supported.

EPA had concerns regarding Pioneer's assumptions about short range insect dispersal because the data (Nowatzki et al. 2003) were limited, and were derived from only one location in the cornbelt. This was a critical factor because the adult insect dispersal input is a sensitive parameter for modeling the durability of block refuges. Parameter inputs representing a shorter dispersal range lowered the resulting effectiveness of a block refuge. Using a range of representative parameter values and assumptions to predict the durability of a 20% block refuge versus Pioneer's proposed 5% blended refuge, EPA's deterministic modeling showed that the predicted durability for the 20% block refuge was superior to a 5% seed blend strategy (11.95 years vs. 8.1 years).

In addition to the 5% seed blend, EPA modeled other blend percentages for comparison. A 10% seed blend was predicted to have a durability of 11.3 years, which was slightly less durable (5.4%) relative to a 20% block refuge based on EPA's assumptions. EPA concluded, however, that these results were of limited actual utility because a number of parameter inputs to the original Pioneer model did not reflect actual variability and/or uncertainty. Therefore, to assess the current application for a 10% blended refuge, EPA conducted modeling using a range of representative input parameters.

10% Seed Blend

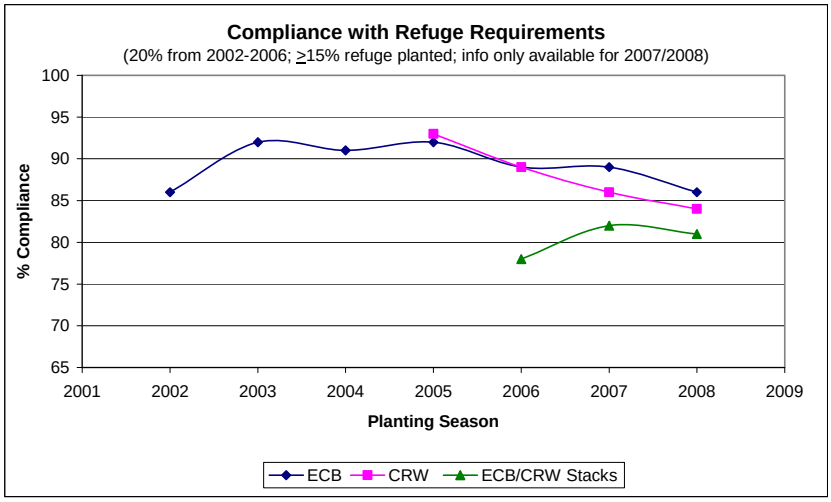
In the latest modeling, EPA incorporated uncertainty by using probabilistic distributions of critical data that we determined to be variable and/or uncertain. The distributions were developed based on acceptable data for the minimum, maximum, and most likely, possible values. These values were developed as PERT distributions. Each model was run 2,000 times, and each run utilized input parameters drawn from the PERT distributions. "Resistance" was defined as the resistance allele exceeding 50%, and EPA measured the mean, 25^{th,} and 75th percentiles of the time to "resistance." EPA also determined the proportion of simulations where the time to resistance exceeded 11 years. (The SAP has advised that 15 years with no resistance is a reasonable goal for an IRM program applicable to a single-gene toxin. The Cry34/35 transgenic toxin has been in use for four years. Therefore, we believe it relevant to assess how many of the model runs indicate that either the 20% block or the 10% blend will delay development of resistance for 11 or more years.) The data from these model simulations indicate comparative durability values of 11.3 years for the 10% blended refuge and 20.2 years for the 20% block refuge. Thus, the 10% blend was 45% less durable than the 20% block refuge currently required for single trait CRW PIPs.

IRM Refuge Compliance

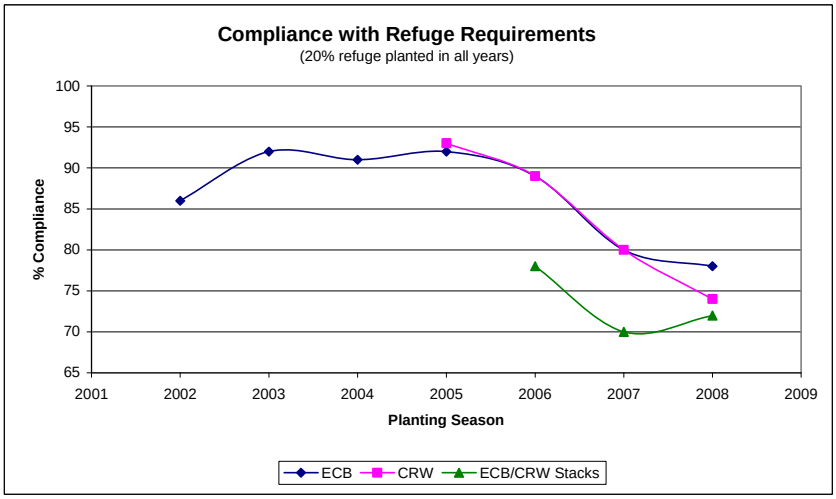
Critical to an assessment of the likely efficacy of an IRM mitigation program is the level of compliance with that program. Data received by EPA from the Agricultural Biotechnology Stewardship Technical Committee (ABSTC) indicate that compliance with the paradigmatic 20% block refuge requirement for most *B.t.* corn crops has been steadily decreasing. As noted by a number of commenters, this decreased compliance increases the risk of resistance development (see, e.g., *Complacency on the Farm*, CSPI 2009, and *Impact of Genetically Engineered Crops on Farm Sustainability in the United States*, NAS 2010*).*

For the 2002 to 2008 planting seasons, ABSTC reported refuge compliance either as 'all compliant' (i.e., always planting a 20% refuge, within the proper distance) or 'out-of-compliance' (i.e., not having either a 20% refuge, or having the refuge not located exactly where required, or neither). In 2007 and 2008, ABSTC began to also report if growers at least planted a 15% refuge or/and if most of a grower's *B.t.* fields met the refuge distance requirement. (Reporting these additional data reflects that there may be degrees of noncompliance, for example, a grower may be inadvertently out of compliance with distance requirements by a degree that does not materially affect the efficacy of the refuge. Also, while, admittedly, a 15% refuge is not compliant with a 20% refuge requirement, it has a much different field impact than does a 0% refuge.)

The graphs below compare "out of compliance" versus "almost compliant" data. The upper graph is adjusted for 'almost compliant' growers in 2007 to 2008; the lower graph is the compiled out-of-compliance data from the ABSTC for 2007 and 2008. These data indicate that the unadjusted "out-of-compliance" values may not accurately reflect the actual impact of growers who are, technically, not compliant with the refuge requirements. Therefore, it may be that the "out of compliance" numbers reported recently may indicate a greater degree of risk of resistance developing than is actually the case.



	ECB	CRW	ECB/CRW Stacks
2002	86		
2003	92		
2004	91		
2005	92	93	
2006	89	89	78
2007	89	86	82
2008	86	84	81



	ECB	CRW	ECB/CRW Stacks
2002	86		
2003	92		
2004	91		
2005	92	93	
2006	89	89	78
2007	80	80	70
2008	78	74	72

III. BENEFITS

We expect OAM 1 to have the following benefits: (1) Reduced pesticide use in the refuge. Currently, the 20% block refuge may be sprayed with pesticide to mitigate pest damage. The blended in-field refuge will not be sprayable. (2) Significantly less complicated refuge deployment for the corn rootworm active ingredient. Currently, to be fully compliant with the refuge requirements, growers must accurately calculate 20% of the field, accurately determine the proper distance for the refuge field, and properly plant the required acreage in the correct location. Moreover, there are temporal concerns, as the refuge field must be planted at, essentially, the same time as the yield field so that emergence of refuge rootworms is contemporaneous with emergence of field rootworms. Anecdotal reports from growers make clear that meeting each of these requirements can be challenging in the actual on-farm environment. A product with the refuge blended with the field seed will ease deployment of the rootworm refuge. (3) Increased grower compliance with IRM requirements for the corn rootworm active ingredient. A seed

blend product incorporating an effective refuge in the seed bag would lead to 100% grower compliance for planting a refuge. This is a significant benefit, although perhaps not as great as the raw data on refuge compliance might suggest.

In addition, *indirect benefits* of introducing Optimum® AcreMax™ 1 may include reduced energy consumption for manufacture, transport, and application of chemical insecticides; reduced waste streams arising from pesticide manufacture; reduced disposal of pesticide waste containers; and reduced residues from pesticide applications.

Efficacy and Yield Benefits

Pioneer conducted a two year study (2006 to 2007) to assess efficacy and yield benefits of a blended seed refuge. The purpose of the study was to determine the effects of a blended refuge approach on field standability, root ratings, and yield (three effects measured at each treatment level). The 2006 experiment was replicated at eight different locations in a randomized block design with four replicates for all five treatments. The treatments were: (1) untreated control; (2) conventional seed treated with P1250; (3) 100% HXRW (HERCULEX® RW) seed treated with P250; (4) 10% seed mix of conventional seed treated with P250 and 90% HXRW seed treated with P250; and (5) 20% seed mix of conventional seed treated with P1250 and 80% HXRW seed treated with P250. During July 2006, five roots per plot were randomly selected, root damaged scored using the Iowa State 0-3 node injury scoring, and yield determined at end of the growing season. Under low insect pressure, Pioneer reports little difference in node injury or yields between treatments (no data provided). Under high insect pressure, all HXRW treatments had approximately equal grain yield and node injury and the 10% and 20% seed blends were equivalent to the control of 100% HXRW maize.

In 2007, the study was repeated with the addition of HX1 (HERCULEX® I) as refuge seed (treated with P250 and P1250). BPPD did not see statistically significant differences between node injury, % root lodging, and grain yields between any of the HXX (HERCULEX® XTRA) treatments except with respect to node for the 20% refuge with P250.

IV. REGULATORY RATIONALE

Section 3(c)(7)(A) of FIFRA provides for the registration or amendment of a pesticide when the pesticide and proposed use "…are identical or substantially similar to any currently registered pesticide and use thereof, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment, and (ii) approving the registration or amendment in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment." Unreasonable adverse effects on the environment are defined under Section 2(bb) of FIFRA as "… any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide…" Thus, pursuant to Section 3(c)(7)(A), EPA may conditionally register a

pesticide if (1) the pesticide and its proposed use are identical or substantially similar to a currently registered pesticide; or (2) the pesticide and its proposed use differ only in ways that would not significantly increase the risk of unreasonable adverse effects; and (3) approving the registration would not significantly increase the risk of any unreasonable adverse effect.

We find that OAM 1 and OAM RW meet criteria (2) and (3) of Section 3(c)(7)(A) for a time-limited registration to expire September 30, 2010. Optimum® AcreMax™ 1 is a seed blend consisting of two currently registered products, 90% HERCULEX® XTRA and 10% HERCULEX® I. Optimum® AcreMax™ RW is a seed blend consisting of an already registered product and non-PIP corn, 90% HERCULEX® RW and 10% non-*B.t.* Corn. Thus, both products are substantially similar to already registered PIPs in composition and use site (field corn). These products do not meet criteria (1), however, because the proposed use of OAM 1 and OAM RW that achieves the insect resistance management refuge via a seed mix rather than a block refuge is not substantially similar to any currently registered pesticide. Having the refuge in the bag of seeds is a novel approach.

We determine, however, that each of these products meets criteria (2) as, when used in accordance with the terms and conditions of a time-limited registration set to expire September 30, 2010, neither would significantly increase the risk of unreasonable adverse effects on the environment. Since OAM 1 and OAM RW are substantially similar to already registered PIPs in composition and use site, EPA's consideration of whether these new products would significantly increase the risk of any unreasonable adverse effect on the environment is limited to the change in insect resistance management refuge deployment and percentage, i.e., a 10% seed blend in the bag versus a 20% block refuge. The unreasonable adverse effect of concern is the development of resistance to Cry34/35Ab1 in corn. Thus, we consider: (1) how does the registration of OAM 1 and OAM RW contribute to the development of corn rootworm resistance to Cry34/35Ab1 corn; (2) should this resistance develop, what risk does it pose to man or the environment; and (3) taking into account the economic, social, and environmental costs and benefits, does this risk constitute an unreasonable adverse effect?

The Risk of OAM 1 and OAM RW Registrations Causing CRW Resistance to Cry34/35Ab1

The modeling used by EPA to assess IRM strategies utilizes comparative simulation models. The model durability outputs, years to resistance, is intended to be used for comparative purposes to evaluate different refuge options on a relative basis. The durability outputs that EPA has determined for the proposed 90% CRW protected seed/10% non-CRW protected seed blend, and a 20% block refuge are 11.3 years to resistance, and 20.2 years to resistance, respectively. Thus, our analysis indicates that, as modeled, the proposed seed blend is 45% less durable on a comparative basis than the 20% block refuge currently required for single trait CRW PIPs .

Besides the currently registered Pioneer PIPs, Cry34/35Ab1 corn is registered in a

number of other *B.t.* corn PIPs, including multi-CRW *B.t.* toxin products, by Monsanto and Dow AgroSciences. Should resistance develop to Cry34/35 in a OAM 1 seed blend, these other products could be adversely affected including potential loss of efficacy and viability as CRW control tools. We note, in particular, the recent statement of the National Research Council to the effect that ". . . results from simulation models and small-scale laboratory experiments indicate that the evolution of resistance to two-toxin cultivars is accelerated when plants that produce two *B.t.* toxins are grown near plants that produce just one toxin." National Academy of Sciences, *Impact of Genetically Engineered Crops on Farm Sustainability in the United States*, 2-37 (2010). Based on our current assessment, we conclude that significant acreage of a 10% seed blend with a single, non-high dose mode of action such as Cry 34/35Ab1 likely increases the risk of resistance for all *B.t.* corn products containing Cry34/35Ab1. But, the current time-limited registration will not likely increase the risk of resistance to Cry34/35Ab1.

Pioneer projects that the time-limited registrations being granted for the 2010 growing season will result in planting on only approximately 0.042% of acres of non-Red Zone geography corn acres; and only on approximately 0.077% of Red-Zone geography corn acres. In the context of 90 million acres of corn planted in the United States annually, we conclude that plantings on such limited acreage will not have effects on CRW resistance development.

Should Resistance Develop, What *Risk Does it Pose to Man or the Environment, and What Economic and Social Costs?*

Should Cry34/35Ab1 resistance develop, there would be an increase in conventional chemical insecticide use for U.S. corn production. Although there are other CRW controlling PIPs in the marketplace and under development, Cry34/35Ab1 resistance would not only impact OAM 1 and OAM RW, but also HERCULEX® RW, HERCULEX® XTRA, and Genuity™ SmartStax™. Increased use of conventional insecticides would increase impacts on the environment and man. There would also be indirect impacts in increased consumption for manufacture, transport, and application of chemical insecticides; increased waste streams arising from pesticide manufacture; and increased disposal of pesticide waste containers and residues from pesticide applications.

What are the Economic, Social, and Environmental Benefits of OAM 1 and OAM RW?

Both OAM 1 and OAM RW have been determined by EPA to be efficacious in their control of corn rootworm.

OAM 1 and OAM RW should increase grower compliance with CRW refuge requirements by providing a novel and effective way of simplifying the refuge deployment process for growers as the corn rootworm refuge is deployed as a seed blend rather than a separate block in the field.

OAM 1 and OAM RW should also reduce the insecticide use in the CRW refuge and in the CRW-PIP fields. Currently, corn rootworm PIP products require insecticide

treatment of the PIP acreage, even if economic thresholds are not reached. This use of insecticides solely to support the management of resistance has been required if aerial insecticides are applied to the refuge for control of CRW adults or if pests other than adult corn rootworms are treated with CRW-labeled insecticide on the refuge acres when adult corn rootworms are present. OAM 1 and OAM RW would reduce this IRM based use of insecticides. Indirect benefits of decreased insecticide use include reduced energy consumption for manufacture, transport, and application of chemical insecticides; reduced waste streams arising from pesticide manufacture; reduced disposal of pesticide waste containers and residues from pesticide applications.

OAM 1 and OAM RW should benefit growers by simplifying the planting process.

Registration Decision for 2010 Growing Season

We conclude that OAM 1 and OAM RW meet the criteria for registration under FIFRA Section 3(c)(7)(A). Our assessment supports the determination that these products are not likely to contribute towards the development of resistance of CRW to Cry34/35Ab1 during period of the time-limited registration in effect for the 2010 growing season. Our assessment of the likely impacts concerning ease of use, increased grower compliance, efficacy, and reduced insecticide use coupled with our determination that OAM 1 and OAM RW are not likely to increase the risk of resistance of CRW to Cry34/35Ab1 developing during the 2010 growing season support the conclusion that the criteria under FIFRA Section 3(c)(7)(A) are met such that registration of OAM 1 and OAM RW will not pose a risk of unreasonable adverse effects on the environment during this period.

On October 1, 2009, EPA announced a new policy to provide a more meaningful opportunity for the public to participate on major registration decisions before they occur. According to this new policy, EPA intends to provide a public comment period prior to making a registration decision for, at minimum, the following types of applications: new active ingredients; first food use; first outdoor use; first residential use; and other actions for which the Agency anticipates that there will be significant public interest.

Notwithstanding that the current actions on OAM 1 and OAM RW qualify as "actions for which the Agency anticipates that there will be significant public interest," EPA believes that it is in the best interests of the public and the environment to issue the registrations for OAM 1 and OAM RW without delay. The PRIA (Pesticide Registration Improvement Act) deadline date of May 1, 2010, is sufficiently late in the growing season that a 30-day delay would lessen the likelihood that significant acreage of these products could be planted in 2010. Given the potential benefits attendant to the blended refuge concept, EPA concludes that it is in the best interests of the public and the environment to issue the registrations for OAM 1 and OAM RW without delay for 2010 growing season. The registration is only effective for the current growing season. Therefore, consistent with the Agency's policy for making certain registration actions more transparent, EPA is issuing these time-limited registrations with an initial period to expire September 30, 2010, and, concurrent with their issuance, providing a 30-day public comment period on the time-limited registrations. EPA is registering this product

as a time-limited registration, with the understanding that public comments could bring to light new information or concerns that could inform EPA's initial decision. Any subsequent action taken on these registrations will be informed by any information received during the public comment period.

Proposed Registration Decisions for 2011 and 2012 Growing Seasons

We have also preliminarily concluded that our modeling analysis combined with the Pioneer sales projections for the 2011 and 2012 growing seasons support continued registration of OAM 1 and OAM RW for 2011 and 2012. We note that Pioneer predicts acreage to increase up to 8% of the Red Zone and 12% of the non-Red Zone. EPA invites comments during the 30-day comment period on the preliminary decision to register OAM 1 and OAM RW for the 2011 to 2012 growing seasons. Important to this preliminary decision is the fact that Pioneer has committed to the following additional elements of the IRM plan applicable to OAM 1 and OAM RW regarding insect resistance monitoring, remedial action should resistance be detected, and the refuge assurance program. These are all listed in detail in the terms and conditions of the OAM 1 and OAM RW registrations.

V. TERMS AND CONDITIONS OF THE REGISTRATION(S)

OAM 1

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

2) The subject registration will automatically expire on midnight September 30, 2010.

3) The subject registration will be limited to a seed mix of TC1507 (Cry1F) xDAS-59122-7 (Cry34Ab1/Cry35Ab1) corn seed blended with not less than 10% TC1507 (Cry1F) corn seed.

4) Submit or cite all data required to support the Herculex XTRA and the Herculex I plant-incorporated protectant products within the timeframes required by the terms and conditions of EPA Registration Numbers 29964-3 and 29964-5.

5) The subject registration will be limited to Submit the following data in the timeframes listed:

Study Type	Required Data	Due Date
Insect Resistance Management	Pioneer must provide the Agency with a copy of the grower agreement, associated stewardship documents, and written description of a system, which assures that growers will sign grower agreements and persons purchasing OAM1 corn will annually affirm that they are contractually bound to comply with requirements of the insect resistance management (IRM) program.	90 days from the date of registration
Insect Resistance Management	Pioneer must implement an enhanced resistance monitoring plan for OAM1. Pioneer must provide the Agency with a baseline (benchmark) study that shows the susceptibility of western corn rootworm populations (WCRW) in the Sublethal Seedling Assay prior to the large-scale introduction of OAM1. Although northern corn rootworm (NCRW) is difficult to rear, Pioneer must attempt to obtain benchmark susceptibility data using the Sublethal Seedling Assay for NCRW as well.	12/1/2010 for WCRW 12/1/11 for NCRW
Insect Resistance Management	Pioneer must submit a detailed OAM1-specific resistance monitoring and remedial action plan, including an analysis to determine the expected field performance criteria for OAM1 products so that unexpected damage can be benchmarked. Pioneer will update the plan by 12/1/2012, if needed, based on continued field evaluation of OAM1 performance.	12/1/2010

6) Pioneer must commit to do the following Insect Resistance Management Program for OAM1.

The required IRM program for OAM1 corn must have the following elements:

Requirements relating to creation of a lepidopteran refuge (consisting of corn that does not contain any *Bt* trait for lepidopteran control) in conjunction with the planting of any acreage of OAM1 corn;

Requirements for Pioneer to prepare and require OAM1 users to sign "grower agreements," which impose binding contractual obligation on the grower to comply with the refuge requirements;

Requirements regarding programs to educate growers about IRM requirements;

Requirements regarding programs to evaluate and promote growers' compliance with IRM requirements;

Requirements regarding programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to Cry1F and Cry34Ab1/Cry35Ab1 proteins in the target insects;

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

Annual reports on units sold by state (units sold by county level will be made available to the Agency upon request), IRM grower agreements results, and the compliance assurance program including the educational program on or before January 31st of each year, beginning in 2011.

a) Refuge requirements for OAM1

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

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

b) Grower Agreement for OAM1 Corn

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

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

3. Pioneer must implement a system (equivalent to what is already approved for previously registered Pioneer *Bt* corn products), which is reasonably likely to assure that persons purchasing OAM1 corn will affirm annually that they are contractually bound to comply with the requirements of the IRM program. A description of the system must be submitted to EPA within 90 days from the date of registration.

4. Pioneer must use a grower agreement and must submit to EPA, within 90 days from the date of registration, a copy of that agreement and any specific stewardship documents referenced in the grower agreement. If Pioneer wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, 30 days prior to implementing a proposed change, Pioneer must submit to EPA the text of such changes to ensure it is consistent with the terms and conditions of this registration.

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

6. Beginning on January 31, 2011 and annually thereafter, Pioneer shall provide EPA with a report on the number of units of OAM1 corn seed shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of a twelve-month period. Note: The first report shall contain the specified information from the time frame starting with the date of registration and extending through the 2010 growing season.

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

c) IRM Education and IRM Compliance Monitoring Program for OAM1 Corn

1. Pioneer must design and implement a comprehensive, ongoing IRM education program designed to convey to OAM1 corn users the importance of complying with the IRM program. The education program shall involve the use of multiple media, *e.g.* face-to-face meetings, mailing written materials, EPA-reviewed

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language on IRM requirements on the bag or bag tag, and electronic communications such as by internet, radio, or television commercials. Copies of the materials will be provided to EPA for their records. The program shall involve at least one written communication annually to each OAM1 corn user

separate from the grower technical guide. The communication shall inform the user of the current IRM requirements and specifically the need to plant a lepidopteran refuge. Pioneer shall coordinate its education program with the educational efforts of other registrants and other organizations, such as the National Corn Growers Association and state extension programs.

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

Number of on-farm assessments conducted by Pioneer

Products	Year: 2010	Year: 2011, annually thereafter
Corn Borer and Stacked Products	1000	750-1000
OAM1	500	1500-2000
Total	1500	2250-3000

Pioneer must provide a report to EPA summarizing the OAM1 compliance assurance program activities and results for the prior year and plans for the OAM1 compliance assurance program for the current year, January 31, 2011 and annually thereafter.

3. Annually, Pioneer shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

4. Beginning January 31, 2011, Pioneer must provide a report to EPA summarizing the activities it carried out under its education program for the prior year.

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Annually thereafter, Pioneer must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. Pioneer must either submit a separate report or contribute to the report from the industry working group, ABSTC.

d) Insect Resistance Monitoring for OAM1 Corn

In addition to the existing two-pronged approach to insect resistance monitoring (monitoring insect populations using the diet bioassay and investigations of field reports) that currently takes place for Cry34/35 for Herculex Rootworm Insect Protection (29964-4) and Herculex Xtra Insect Protection (29964-5), Pioneer must also conduct enhanced monitoring using the Sublethal Seedling Assay as a complement to the diet bioassay method. Pioneer must submit a detailed OAM1/OAMRW-specific resistance monitoring plan to the Agency by December 1, 2010.

With respect to the implementation of the Sublethal Seedling Assay:

1. Pioneer must monitor for resistance and or changes in target pest susceptibility that will lead to increased injury potential in western and northern corn rootworm feeding on the rootworm component of OAM1 products. Sampling must be focused in the four regions of highest risk of resistance development: Region – 1 (Illinois, Indiana); Region 2 (Iowa, Missouri), Region 3 (Nebraska and Kansas), Region 4 (Minnesota, South Dakota and Wisconsin).

2. Pioneer must provide the EPA its detailed western corn rootworm resistance monitoring plan for approval by December 1, 2010 and its northern corn rootworm resistance monitoring plan for approval by December 1, 2011. These plans will include baseline (benchmark) susceptibility data and an enhanced annual resistance monitoring plan. The reports will contain:

    - Sampling scheme: annual collection should target a range of 16-20 western and/or northern rootworm populations (4-5 per region), with a minimum number of 2,000 beetles collected per population.
    - Bioassay methodology (precision, detection level, etc.). Pioneer must bioassay a target of 3000 larvae on 59122 plants for each population.
    - A description of how monitoring results relate to and are predictive of changes in field efficacy, and change in injury potential to DAS-59122-7 constituting product failure and development of a remedial action plan.

3. Pioneer will provide the EPA with an annual OAM1 resistance monitoring report by August 31st of each year beginning with 2011 for western corn rootworm and 2012 for northern corn rootworm, reporting on populations collected the previous year.
In addition to screening of wide-area corn rootworm populations as outlined above, for the second prong of resistance monitoring Pioneer must investigate grower, extension specialist or consultant reports of less-than-expected efficacy or field performance of OAM1 products.

e) Remedial Action Plan for Corn Rootworm and OAM1 Corn

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The remedial action plan is designed as a tiered approach for mitigating western and northern corn rootworm resistance development specifically due to the commercialization of OAM1 corn. The following program summary describes, in order of events, the steps that must be taken to implement a remedial action plan if resistance to target pests is confirmed.

Pioneer will complete a benchmark study of susceptibility of western corn rootworm using the Sublethal Seedling Assay and analyze field efficacy data to set a benchmark for expected levels of damage to finalize the OAM1 remedial action plan by December 1, 2010, so that decision points regarding crop damage and target pest resistance are established, and a remedial action plan can be initiated when needed. Although northern corn rootworm is difficult to rear in the laboratory, Pioneer will attempt to complete a benchmark study for susceptibility of northern corn rootworm using the Sublethal Seedling Assay.

1. Suspected Resistance from Population Monitoring

Definition of Suspected Resistance - Resistance will be suspected if investigations of target pest injury potential to OAM1 maize from the Sublethal Seedling Assay show that:

- Injury potential of a target pest population obtained as part of the annual insect monitoring program has increased to a level representative of product failure in field conditions;
- The seeds used in the investigation of this population's injury potential contain Cry34/Cry35Ab1 at levels representative of (and in the same genetic background as) the benchmark study; and
- The change in injury potential has been documented as a heritable characteristic of the target pest population and not a result of experimental error.

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

2. Confirmed Resistance from Population Monitoring

Definition of Confirmed Resistance - Resistance will be confirmed if all of the following criteria are met by progeny from a subsequent rootworm population collected from the area of "suspected resistance" the following year:

- Injury potential of the subsequent field-collected rootworm population feeding on plants containing DAS-59122-7 remains at a level likely to produce repeated product failure in field conditions;
- The change in injury potential has been documented as a heritable characteristic of the target pest population;
- Greenhouse node-injury evaluation confirms product failure;
- Subsequent populations collected from the area and assayed show that the results

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are repeatable; and
- Continued monitoring of the area suggests that the change is spreading.

3. Suspected Resistance – Investigation of Field Reports

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

- Confirm the corn in question is rootworm-active Bt corn;
- Confirm the field in question contains the correct blend rate of refuge corn;
- Confirm that species not susceptible to the protein are not responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and that all other reasonable causes based on historical experience for the observed root damage have been ruled out;
- If not due to other reasons, the registrant will conduct a thorough investigation of the factors known to affect the manifestation of corn rootworm feeding damage.
- If the investigation fails to rule out target pest resistance as the cause, resistance is suspected.

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

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

4. Confirmed Resistance – Investigation of Field Reports

- Injury potential of the field-collected rootworm population feeding on plants containing DAS-59122-7 remains at a level likely to produce repeated product failure in field conditions;
- Subsequent populations collected from the area and assayed show that the results are repeatable;
- The change in injury potential has been documented as a heritable characteristic of the target pest population;
- Greenhouse node-injury evaluation confirms product failure; and
- Continued monitoring of the area suggests that the change is spreading.

5. Remedial Action

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

- The EPA will receive notification within 30 days of confirmed resistance;
- Affected customers and Extension specialists will be notified about confirmed resistance;
- Affected customers and Extension specialists will be encouraged to implement alternative CRW control measures such as adulticide treatment, crop rotation the following year, or use of soil or seed insecticides the following year;

- Pioneer and EPA will jointly determine the extent of the mitigation needed and determine whether sales should be stopped on an appropriate geographic (i.e., county or regional) basis; and
- Pioneer will develop a case-specific resistance mitigation action plan within 90 days according to the characteristics of the resistance event and local agronomic needs. Pioneer will consult with appropriate stakeholders in the development of the action plan, and the details of such a plan shall be approved by the EPA prior to implementation. The resistance management plan could include such measures layering additional technologies in future OAM1 products.

f) Remedial Action Plan for lepidopteran pests and OAM1 Corn

When field resistance is confirmed (as defined above), the following steps will he taken by the registrant:

• EPA will receive notification within 30 days of resistance confirmation;

• Affected customers and extension agents will be notified about confirmed resistance within 30 days;

• Monitoring will be increased in the affected area and local target pest populations will be sampled annually to determine the extent and impact of resistance;

• If appropriate (depending on the resistant pest species, the extent of resistance, the timing of resistance, and the nature of resistance, and the availability of suitable alternative control measures) , alternative control measures will be employed to reduce or control target pest populations in the affected area. Alternative control measures may include advising customers and extension agents in the affected area to incorporate crop residues into the soil following harvest to minimize the possibility of over-wintering insects, and/or applications of chemical insecticides;

• Unless otherwise agreed with EPA, stop sale and distribution of the relevant lepidopteran-active Bt corn hybrids in the affected area immediately until an effective local mitigation plan approved by EPA has been implemented;

• The registrant will develop a case-specific resistance management action plan within 90 days according to the characteristics of the resistance event and local agronomic needs. The registrant

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will consult with appropriate stakeholders in the development of the action plan. and the details of such a plan shall be approved by EPA prior to implementation;

• Notify affected part ies (e .g. growers, consultants, extension agents, seed distributors, university cooperators and state/ federal authorities as appropriate) in the region of the resistance situation and approved action plan; and

• In subsequent growing seasons, maintain sales suspension and alternative resistance management strategies in the affected region(s) for the Bt corn hybrids that are affected by the resistant population until an EPA-approved local resistance management plan is in place to mitigate the resistance.

A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by August 31st each year for the duration of the conditional registration.

g) Refuge Assurance Program for OAM1 Corn

Pioneer must implement a Blended Seed Refuge Assurance Program designed to ensure OAM1 products are formulated with the appropriate rate of refuge seeds. The program must include the following four elements:

1. Trait purity check on seed lots prior to blending;
2. ISO 9000 Standard Operating Procedures for the blending process;
3. Calibration of blending equipment; and
4. Records and data retention records for seed blend products.

- Calibration records - Pioneer will retain documentation for a specified period of time on the equipment calibration including the procedure, when it was conducted and the results.
- Blend proportion records (weight and kernel based) - Pioneer will retain documentation for a specified period of time on the kernel per pound data of the components, the calculations to determine the proportions based on weight and the actual weights that are blended together to make up an OAM1 product by seed lot.

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

h) Annual Reporting Requirements for OAM1 Corn

1. Annual Sales: reported and summed by state (county level data available by request) January 31st each year, beginning in 2011;
2. Grower Agreements: number of units of OAM1 corn seed shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements, January 31st each year, beginning in 2011;
3. Grower Education: substantive changes to education program completed

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previous year, January 31st each year, beginning in 2011;

4. Compliance Assurance Program: compliance assurance program activities and results for the prior year and plans for the compliance assurance program for the current year, January 31st each year, beginning in 2011;
5. Compliance Survey Results: results of annual surveys for the prior year and survey plans for the current year; full report January 31st each year, beginning in 2011;
6. Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, August 31st each year, beginning in 2011 for western corn rootworm and 2012 for northern corn rootworm.

OAM RW

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

2) The subject registration will automatically expire on midnight September 30, 2010.

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 (Cry34Ab1/Cry35Ab1) corn seed blended with not less than 10% non-Bt corn seed.

Because OAMRW controls corn rootworm pests and contains an integrated corn rootworm refuge, no additional refuge is required. When a grower plants a bag of OAMRW, all refuge requirements are fully and automatically met for this product. Therefore, grower agreements (demonstrating persons purchasing OAMRW corn will annually affirm that they are contractually bound to comply with requirements of the insect resistance management (IRM) program) and other associated stewardship documents are neither necessary nor required.

Targeted on-farm compliance assessments are neither necessary nor required for OAMRW because the refuge is automatically implemented when planting this product.

OAMRW may be used as the Lepidopteran refuge for OAM1. In this case, on-farm assessments to ensure that the Lepidopteran refuge is planted and placed appropriately would be covered by OAM1 grower education, targeted on-farm assessments and stewardship documents.

5) Submit the following data in the timeframes listed:

Study Type	Required Data	Due Date
Insect Resistance Management	Pioneer must implement an enhanced resistance monitoring plan for OAMRW. Pioneer must provide the Agency with a baseline (benchmark) study that shows the susceptibility of western corn rootworm populations (WCRW) in the Sublethal Seedling Assay prior to the large-scale introduction of OAMRW. Although northern corn rootworm (NCRW) is difficult to rear, Pioneer must attempt to obtain benchmark susceptibility data for NCRW as well.	12/1/2010 for WCRW 12/1/11 for NCRW
Insect Resistance Management	Pioneer must submit a detailed OAMRW-specific resistance monitoring and remedial action plan, including an analysis to determine the expected field performance criteria for OAMRW products so that unexpected damage can be benchmarked. Pioneer will update the plan by 12/1/2012, if needed, based on continued field evaluation of OAM1 performance.	12/1/2010

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

The required IRM program for OAMRW corn must have the following elements:
Requirements regarding programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to Cry34Ab1/Cry35Ab1 proteins in the target insects;

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

Annual reports on units sold by state (units sold by county level will be made available to the Agency upon request) on or before January 31st of each year, beginning in 2011.

a) Insect Resistance Monitoring for OAMRW Corn

In addition to the existing two-pronged approach to insect resistance monitoring (monitoring insect populations using the diet bioassay and investigations of field reports) that currently takes place for Cry34/35 for Herculex Rootworm (29964-4), Pioneer must also conduct enhanced monitoring using the Sublethal Seedling Assay as a complement to the diet bioassay method. Pioneer must submit a detailed OAM1/OAMRW-specific resistance monitoring plan to the Agency by December 1, 2010.

With respect to the implementation of the Sublethal Seedling Assay:

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1. Pioneer must monitor for resistance and or changes in target pest susceptibility that will lead to increased injury potential in western and northern corn rootworm feeding on the rootworm component of OAMRW products. Sampling must be focused in the four regions of highest risk of resistance development: Region – 1 (Illinois, Indiana); Region 2 (Iowa, Missouri), Region 3 (Nebraska and Kansas), Region 4 (Minnesota, South Dakota and Wisconsin).

2. Pioneer must provide the EPA its detailed western corn rootworm resistance monitoring plan for approval by December 1, 2010 and its northern corn rootworm resistance monitoring plan for approval by December 1, 2011. These plans will include baseline (benchmark) susceptibility data and an enhanced annual resistance monitoring plan. The reports will contain:

   - Sampling scheme: annual collection should target a range of 16-20 western and/or northern rootworm populations (4-5 per region), with a minimum number of 2,000 beetles collected per population.
   - Bioassay methodology (precision, detection level, etc.). Pioneer must bioassay a target of 3000 larvae on 59122 plants for each population.
   - A description of how monitoring results relate to and are predictive of changes in field efficacy, and change in injury potential to DAS-59122-7 constituting product failure and development of a remedial action plan.

3. Pioneer will provide the EPA with an annual OAMRW resistance monitoring report by August 31st of each year beginning with 2011 for western corn rootworm and 2012 for northern corn rootworm, reporting on populations collected the previous year.

In addition to screening of wide-area corn rootworm populations as outlined above, for the second prong of resistance monitoring Pioneer must investigate grower, extension specialist or consultant reports of less-than-expected efficacy or field performance of OAMRW products.

b) Remedial Action Plan for Corn Rootworm and OAMRW Corn

The remedial action plan is designed as a tiered approach for mitigating western and northern corn rootworm resistance development specifically due to the commercialization of OAMRW corn. The following program summary describes, in order of events, the steps that must be taken to implement a remedial action plan if resistance to target pests is confirmed.
Pioneer will complete a benchmark study of susceptibility of western corn rootworm using the Sublethal Seedling Assay and analyze field efficacy data to set a benchmark for expected levels of damage to finalize the OAMRW remedial action plan by December 1, 2010, so that decision points regarding crop damage and target pest resistance are established, and a remedial action plan can be initiated when needed. Although northern corn rootworm is difficult to rear in the laboratory, Pioneer will attempt to complete a benchmark study for susceptibility of northern corn rootworm using the Sublethal Seedling Assay as well.

1. Suspected Resistance from Population Monitoring

Definition of Suspected Resistance - Resistance will be suspected if investigations of target pest injury potential to OAMRW maize from the Sublethal Seedling Assay show that:

- Injury potential of a target pest population obtained as part of the annual insect monitoring program has increased to a level representative of product failure in field conditions;
- The seeds used in the investigation of this population's injury potential contain Cry34/Cry35Ab1 at levels representative of (and in the same genetic background as) the benchmark study; and
- The change in injury potential has been documented as a heritable characteristic of the target pest population and not a result of experimental error.

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

2. Confirmed Resistance from Population Monitoring

Definition of Confirmed Resistance - Resistance will be confirmed if all of the following criteria are met by progeny from a subsequent rootworm population collected from the area of "suspected
resistance" the following year:

- Injury potential of the subsequent field-collected rootworm population feeding on plants containing DAS-59122-7 remains at a level likely to produce repeated product failure in field conditions;
- The change in injury potential has been documented as a heritable characteristic of the target pest population;
- Greenhouse node-injury evaluation confirms product failure;
- Subsequent populations collected from the area and assayed show that the results are repeatable; and
- Continued monitoring of the area suggests that the change is spreading.

3. Suspected Resistance – Investigation of Field Reports

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

- Confirm the corn in question is rootworm-active Bt corn;
- Confirm the field in question contains the correct blend rate of refuge corn;

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- Confirm that species not susceptible to the protein are not responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and that all other reasonable causes based on historical experience for the observed root damage have been ruled out;
- If not due to other reasons, the registrant will conduct a thorough investigation of the factors known to affect the manifestation of corn rootworm feeding damage.
- If the investigation fails to rule out target pest resistance as the cause, resistance is suspected.

If resistance is "suspected", Pioneer will inform growers in the area of the potential benefit of augmenting CRW control such as adulticide treatment, crop rotation the following year or use of soil or seed insecticides the following year. These measures are intended to educate growers of the potential for change in efficacy, reduce the possibility of grower loss from change in efficacy and reduce potentially resistant insects contributing to the following year's pest population. Pioneer will collect insects as soon as possible from the area for laboratory studies to test for resistance by comparing with benchmark susceptibility data. These studies will be performed following the same laboratory protocols as used for the benchmark determination and monitoring programs.

4. Confirmed Resistance – Investigation of Field Reports

- Injury potential of the field-collected rootworm population feeding on plants containing DAS-59122-7 remains at a level likely to produce repeated product failure in field conditions;
- Subsequent populations collected from the area and assayed show that the results are repeatable;
- The change in injury potential has been documented as a heritable characteristic of the target pest population;
- Greenhouse node-injury evaluation confirms product failure; and
- Continued monitoring of the area suggests that the change is spreading.

5. Remedial Action

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

- The EPA will receive notification within 30 days of confirmed resistance;
- Affected customers and Extension specialists will be notified about confirmed resistance;
- Affected customers and Extension specialists will be encouraged to implement alternative CRW control measures such as adulticide treatment, crop rotation the following year, or use of soil or seed insecticides the following year;
- Pioneer and EPA will jointly determine the extent of the mitigation needed and determine whether sales should be stopped on an appropriate geographic (i.e., county or regional) basis; and
- Pioneer will develop a case-specific resistance mitigation action plan within 90

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days according to the characteristics of the resistance event and local agronomic needs. Pioneer will consult with appropriate stakeholders in the development of the action plan, and the details of such a plan shall be approved by the EPA prior to implementation. The resistance management plan could include such measures layering additional technologies in future OAMRW products.

c) 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 the EPA review upon request.

d) Annual Reporting Requirements for OAMRW Corn

1. Annual Sales: reported and summed by state (county level data available by request) January 31st each year, beginning in 2011;
2. Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, August 31st each year, beginning in 2011 for western corn rootworm and 2012 for northern corn rootworm.

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