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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D C 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

SEP 2 0 2012

Mr Jamie Staley
U S Registration Manager
Pioneer Hi Bred International Inc
7100 N W 62nd Avenue
P O Box 1000
Johnston IA 50131 1000

SUBJECT April 13 2012 Request to Amend the Expiration Date for Optimum® Acremax® 1 Insect Protection
EPA Reg No 29964 6

Dear Mr Staley

The amendment referred to above submitted in connection with registration under Section 3(c)(7)(A) of the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) as amended is acceptable subject to the following comments

1) The subject registration will automatically expire on midnight September 30 2014

2) In order to improve the strength of modeling, you must address and incorporate the following uncertainties (as described in the 2/15/2012 J Martinez insect resistance management review for Optimum® AcreMax® XTreme) into a new CEW model by April 1 2013

Corn Earworm (CEW) Modeling

CEW can have up to six generations per year in the southern U S and may be at greater risk for resistance in a seed blend environment Submit CEW modeling for product durability that addresses the following concerns

CEW will encounter a mosaic of *Bt* expression in kernels of refuge corn ear as well as in *Bt* corn ear Seed blends containing *Bt* and non *Bt* seeds may actually accelerate resistance in ear feeding Lepidoptera including corn earworm and fall armyworm *Bt* ingestion has shown to promote wandering in larvae and individuals that receive a sub lethal dose may move to another kernel Horner et al 2003 evaluated feeding patterns of CEW in MON810 and non *Bt* maize and determined that larvae had greater movement on *Bt* ears and essentially sampled kernels at greater frequency than their counterparts who fed exclusively and in a more compact fashion on non *Bt* corn ears This ability to move to another source of kernel in this mosaic of toxins (lethal vs sublethal) and non toxin environment will give heterozygous individuals a great fitness

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advantage the functional dominance of the resistance allele will increase (Porter 2011 personal communication)

Horner and Dively (2003) found that CEW exposed to Cry1Ab had reduced cannibalistic behavior which they hypothesize could serve as a mechanism to increase the selective differential between susceptible and resistant CEW and essentially lead to greater resistance evolution (Cannibalistic behavior results in partially resistant larvae feeding on nontoxic food [their fellow intoxicated larvae] thus temporarily providing escape from exposure to the *Bt* endotoxin ')

CEW development on Bt corn is delayed (Sims et al 1996 Storer et al 2001) This could enable a fraction of adult CEW to mate with CEW emerging from *Bt* cotton Discretely breeding populations could become continuously breeding for part of the year in this scenario This may be an important aspect to incorporate into IRM models of the south where corn and cotton are host plants of the same pest Theoretical explorations are needed to assess effects of this delayed development on corn on the resistance evolution in CEW

3) The corn rootworm portion of Condition 6 e) Remedial Action Plan for Corn Rootworm and OAM 1 Corn is modified as follows

e) Remedial Action Plan for Corn Rootworm and OAM1 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 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

1 Suspected Resistance from Population Monitoring

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

Confirmed Resistance is defined as (1) Unexpected Damage in OAM1 corn fields resulting from (2) a heritable significant reduction in sensitivity Cry34/35Ab1 proteins for a corn rootworm population that (3) persists in the field resulting in (4) increased survival of adults on OAM1 corn and (5) is field relevant resulting in economic root injury as defined in local extension recommendations

3 Suspected Resistance – Investigation of Field Reports

Suspected Resistance is defined as (1) an initial performance inquiry investigation resulting in a find of Unexpected Damage (a field having an overall average CRWNIS rating of 1 0 or greater for plants containing event DAS 59122 7 (1 5 or greater under exceedingly high corn rootworm pressure) (2) protein levels in green plant tissue of affected plants found to be within the documented range for that hybrid (if data are available) and (3) bioassays of insect collected from the affected fields showing statistically significantly lower sensitivity (e g elevation of the LC50 or EC50) compared with the historical baseline and laboratory susceptible populations for corn rootworm active protein in OAM1 products

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' as defined above the insect population will be characterized further to conform whether or not the corn rootworm population is resistant Pioneer will inform growers in the area of the potential benefit of crop rotation to a non host crop (preferred approach) Alternatively the use of additional corn rootworm control tools in combination with or in place of OAM1 products may be recommended For example soil insecticides seed applied insecticides or chemigation in combination with OAM1 products are expected to reduce the corn rootworm larval population Insecticides applied to corn rootworm adults during the period of adult emergence but before oviposition can be used as a

control measure Use of an alternative corn rootworm active plant incorporated protectant may also be used to reduce the local surviving population

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 must receive notification from Pioneer within 30 days of confirmed resistance
- Stakeholders in the Remedial Action Zone including customers Extension specialists and crop consultants will be informed so that best management practices can be followed and
- Management of resistant populations in the Remedial Action Zone will involve the integration of multiple pest management practices (i e IPM) such as crop rotation pest population monitoring soil applied and seed applied insecticides insecticides to control corn rootworm adults and alternative corn rootworm active traits

If these conditions are not complied with the registration will be subject to cancellation in accordance with FIFRA section 6(e) A stamped copy of the label is enclosed for your records

Sincerely

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

Enclosure

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Optimum® AcreMax™1 Insect Protection

Active Ingredients of Component 1 (Herculex® XTRA) 90% of maize kernels

Bacillus thuringiensis Cry1F protein and the genetic material (plasmid insert PHI8999A) necessary for its production in corn event DAS Ø15Ø7 1	≤0 00174
Bacillus thuringiensis Cry34Ab1 protein and the genetic material (PHP17662 T DNA) necessary for its production in corn event DAS 59122 7	≤0 01684
Bacillus thuringiensis Cry35Ab1 protein and the genetic material (PHP17662 T DNA) necessary for its production in corn event DAS 59122 7	≤0 00676

Other Ingredient

Phosphinothricin acetyltransferase (PAT) protein and the genetic material (plasmid insert PHI8999A and PHP17662 T DNA) necessary for its production in corn events DAS Ø15Ø7 1 and DAS 59122 7	≤0 00151%

Active Ingredient of Component 2 (Herculex® I) 10% of maize kernels

Bacillus thuringiensis Cry1F protein and the genetic material (plasmid insert PHI8999A) necessary for its production in corn event DAS Ø15Ø7 1	≤0 0123%

Other Ingredient

Phosphinothricin acetyltransferase (PAT) protein and the genetic material (plasmid insert PHI8999A) necessary for its production in corn event DAS Ø15Ø7 1	≤0 0020%

% total protein on a dry wt basis as expressed in whole plant tissue

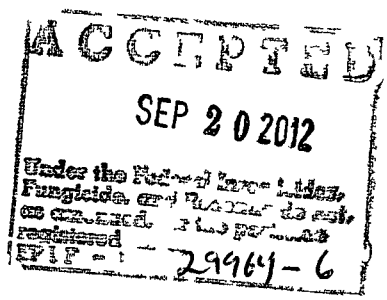
KEEP OUT OF REACH OF CHILDREN

CAUTION

NET CONTENTS _____

EPA REGISTRATION NUMBER 29964 6

EPA ESTABLISHMENT NUMBER 029964 IA 001
Pioneer Hi Bred International Inc
7300 NW 62 Avenue
Johnston IA 50131



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

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DIRECTIONS FOR USE

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

The subject registration automatically expires on midnight September 30 2014

The plant incorporated protectant must be used as specified in the terms and conditions of the registration

Optimum® AcreMax™1 Insect Protection (Optimum® AcreMax™ 1) combines the insect protection features of Herculex® XTRA Insect Protection and Herculex® I Insect Protection in a single seed bag Optimum® AcreMax™ 1 protects corn crops from leaf stalk and ear damage caused by corn borers and root damage caused by corn rootworm larvae In order to minimize the risk of corn pests developing resistance to Optimum® AcreMax™ 1 corn an insect resistance management plan must be implemented

Optimum® AcreMax™ 1 contains a built in 10% corn rootworm refuge by virtue of the blended refuge seed in the bag No further corn rootworm refuge is required to minimize the risk of corn rootworm developing resistance

The use of Optimum® AcreMax™ 1 corn does require an accompanying lepidopteran refuge

INSECT RESISTANCE MANAGEMENT

Corn Belt/Non Cotton Growing Areas

Optimum® AcreMax™ 1 corn grown outside cotton growing areas (e g the Corn Belt) growers must adhere to the following refuge requirements

- Growers must plant a structured refuge of at least 20% non *Bt* corn and/or non lepidopteran resistant *Bt* corn which may be treated with insecticides as needed to control lepidopteran stalk boring and other pests
- Refuge planting options include separate fields blocks within fields (e g along the edges or headlands) and strips across the field
- External refuges must be planted within 1/2 mile
- When planting the refuge in strips across the field refuges must be at least four (4) consecutive crop rows wide
  Insecticide treatments for control of European corn borer corn earworm southwestern corn borer fall armyworm black cutworm western bean cutworm lesser corn stalk borer southern corn stalk borer and sugarcane borer may be applied only if economic thresholds are reached for one or more of these target pests Economic thresholds will be determined using methods recommended by local or regional professionals (e g Extension Service agents crop consultants) Microbial *Bt* insecticides must not be applied to non *Bt* corn and/or non lepidopteran resistant *Bt* corn refuges

Cotton Growing Areas

Optimum® AcreMax™ 1 corn grown in cotton growing areas

- Growers must plant a structured refuge of 50% non *Bt* corn and/or non lepidopteran resistant *Bt* corn that may be treated with insecticides as needed to control lepidopteran stalk boring and other pests
- Refuge planting options include separate fields blocks within fields (e g along the edges or headlands) and strips across the field
- External refuges must be planted within 1/2 mile

When planting the refuge in strips across the field refuges must be at least four (4) consecutive crop rows wide
Insecticide treatments for control of European corn borer corn earworm southwestern corn borer fall armyworm black cutworm western bean cutworm lesser corn stalk borer southern corn stalk borer and sugarcane borer may be applied only if economic thresholds are reached for one or more of these target pests Economic thresholds will be determined using methods recommended by local or regional professionals (e g Extension Service agents crop consultants) Microbial *Bt* insecticides must not be applied to non *Bt* corn and/or non lepidopteran resistant *Bt* corn refuges
Cotton growing areas include the following states Alabama Arkansas Georgia Florida Louisiana North Carolina Mississippi South Carolina Oklahoma (only the counties of Beckham Caddo Comanche Custer Greer Harmon Jackson Kay Kiowa Tillman Washita) Tennessee (only the counties of Carroll Chester Crockett Dyer Fayette Franklin Gibson Hardeman Hardin Haywood Lake Lauderdale Lincoln Madison Obion Rutherford Shelby and Tipton) Texas (except the counties of Carson Dallam Hansford Hartley Hutchinson Lipscomb Moore Ochiltree Roberts and Sherman) Virginia (only the counties of Dinwiddie Franklin City Greensville Isle of Wight Northampton Southampton Suffolk City Surrey Sussex) and Missouri (only the counties of Dunklin New Madrid Pemiscot Scott Stoddard)

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

Use Pattern

Crop	Pests
Field corn	black cutworm corn earworm European corn borer fall armyworm lesser corn stalk borer southern corn stalk borer southwestern corn borer sugarcane borer western bean cutworm western corn rootworm northern corn rootworm Mexican corn rootworm

Herculex® Insect Protection technology by Dow AgroSciences and Pioneer Hi Bred offers unique genetic characteristics for specific grower needs and may be protected by one or more of the following U S patents 5 484 956 5 489 520 5 510 474 5 550 318 5 919 675 6 020 190 6 218 188 6 258 999 6 573 240 6 737 273 6 943 282 6 083 499 6 127 180 6 340 593 6 548 291 6 624 145 and 6 893 872