

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 20 2003

Dr. Larry Zeph  
Registration Manager  
Pioneer Hi-Bred International, Inc.  
Regulatory Science & Registration  
P.O. Box 552  
Johnston, IA 50131-0552

Dear Dr. Zeph:

Subject: Herculex I Insect Protection; Your March 20, 2003 and August 13, 2003 Letters Requesting to Amend the Label by Adding Western Bean Cutworm; WBCW Stewardship Plan Dated March 7, 2003  
EPA Registration No. 29964-3

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

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Modify the label ingredients statement by adding the following Other Ingredient section: Other Ingredient: Substance produced by a marker gene and its controlling sequences in corn .....< 0.0020%
3. Modify the label directions for use by changing "plant pesticide" to "plant-incorporated protectant."
4. Modify the label directions for use by modifying the statement "Insecticide treatments for control....may be applied only if economic thresholds are reached..." by adding Western bean cutworm (WBCW) to the list of pests in both places where this statement appears on the label.
5. The specific Insect Resistance Management terms and conditions cited below (that were previously set forth in the Agency's October 15, 2001, letter) are modified as follows.

CONCURRENCES							
SYMBOL	7711	2511C					
SURNAME	M... ..	S... ..					
DATE	8/20/03	8-20-03					

a) Section 4) of d. Insect Resistance Monitoring:

The registrant must follow up on grower, extension specialist or consultant reports of less than expected results or control failures for the target lepidopteran pests listed on the label, grower guides or other educational materials. The registrant will instruct its customers (growers and seed distributors) to contact them (e.g., via toll-free customer service number) if incidents of unexpected levels of damage occurs from the target pests. the registrant will investigate all damage reports submitted to the company or the company's representatives. See Remedial Action Plans section below (in October 15, 2001 letter).

b) Section 1) of a. Refuge Requirements, the 5<sup>th</sup> bullet::

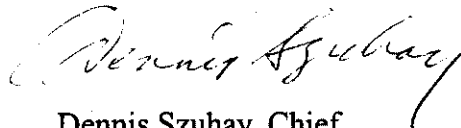
Insecticide treatments for control of lepidopteran target pests listed on the label, grower guides or other educational materials may be applied only if economic thresholds are reached for one or more of the target pests. Economic thresholds will be determined using methods recommended by local or regional 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 refuges.

c) Section 2) of a. Refuge Requirements, the 5<sup>th</sup> bullet:

Insecticide treatments for control of lepidopteran target pests listed on the label, grower guides or other educational materials may be applied only if economic thresholds are reached for one or more of the 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 refuges.

A stamped copy of the label is enclosed for your records. Submit a final copy of the label for the record.

Sincerely,



Dennis Szuhay, Chief  
 Microbial Pesticides Branch  
 Biopesticides and Pollution  
 Prevention Division (7511C)

Enclosure

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

### Herculex\* I Insect Protection

Pure form of the plant-pesticide, *Bacillus thuringiensis* subsp. *aizawai* delta endotoxin protein as produced in corn cells. For control of European corn borer, Southwestern corn borer, Black cutworm, Fall armyworm, Southwestern corn borer, Corn earworm and Western bean curworm.

**Active Ingredient:**

*Bacillus thuringiensis* Cry1F protein and the genetic material necessary for its production (plasmid insert PHI8999) in corn. ....<0.0010 – 0.235 %

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\*% total protein on a dry wt. basis as expressed in corn plant cells (whole plant)

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

EPA REG NO.: 29964-3

EPA ESTABLISHMENT NUMBER: 029964-LA-001.

Pioneer Hi-Bred International, Inc.  
Regulatory Science and Registration  
7250 NW 62<sup>nd</sup> Avenue  
Johnston, IA 50131

**RECEIVED**  
**WITH COMMENTS**  
**In EPA Letter Dated**  
**AUG 20 2003**  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No. 29964-3

Herculex I *Insect Protection* technology by Dow AgroSciences and Pioneer Hi-Bred  
\*Herculex is a trademark of Dow AgroSciences LLC

## DIRECTIONS FOR USE

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

The subject registration will automatically expire on midnight October 15, 2008.

The plant-pesticide product should be used as specified in the terms and conditions of the registration.

Corn has been transformed to express a *Bacillus thuringiensis* subsp.  *aizawai*  (*B.t.a.*) delta-endotoxin protein for control of the European corn borer (*Ostrinia nubilalis*) and other lepidopteran pests.

Routine applications of insecticides to control European corn borer are unnecessary when corn containing the *B.t.a.* delta-endotoxin protein is planted.

Growers are instructed to read information on insect resistance management. The following information regarding commercial production must be included in the grower guide for cotton and non-cotton growing areas:

### Corn-Belt/Non-Cotton Growing Areas

For Cry1F field corn grown outside cotton-growing areas (e.g., the Corn Belt), growers guides must specify that growers must adhere to the following refuge requirements.

- Growers must plant a structured refuge of at least 20% non-*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 ½ mile (1/4 mile or closer preferred).
- When planting the refuge in strips across the field, refuges must be at least 4 rows wide, preferably 6 rows wide.
- Insecticide treatments for control of ECB, CEW, Southwestern corn borer (SWCB), fall armyworm (FAAW), and black cutworm (BCW) 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 refuges.

### Cotton-Growing Area Refuge Requirements for *Bt* Corn

For *Bt* field corn grown in cotton-growing areas:

- Growers must plant a structured refuge of 50% non-*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 ½ mile (1/4 mile or closer preferred).
- When planting the refuge in strips across the field, refuges must be at least 4 rows wide, preferably 6 rows wide.

5/5

- Insecticide treatments for control of ECB, CEW, Southwestern corn borer (SWCB), fall armyworm (FAAW), and black cutworm (BCW) 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 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 Dunkin, New Madrid, Pemiscot, Scott, Stoddard).

CROP	INSECTS CONTROLLED
Field corn	Black cutworm Corn earworm European corn borer Fall armyworm Southwestern corn borer Western bean cutworm

EPA Accepted: \_\_\_\_\_