UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV 22 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Dr. Laura Tagliani
Regulatory Leader
Mycogen Seeds c/o Dow AgroSciences LLC
9330 Zionsville Road
Indianapolis, Indiana 46268-1054

Subject: SmartStax (MON 89034 x TCI507 x MON 88017 x DAS-59122-7) Label Amendment
EPA Registration No. 68467-7

Dear Dr. Tagliani:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. A stamped copy of the label is enclosed for your records.

Sincerely,

Sheryl K. Reilly, Ph.D.
Chief, Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

Enclosure

S2J / MON 89034 x TC1507 x MON 8801 JAS 59122 7 / MSTR LBL FPL / 02 03 10
Title MON 89034 x TC1507 x MON 88017 x DAS 59122 7 / 68467 7 / 02 03 10doc

Plant-Incorporated Protectant Label

SmartStax™ (MON 89034 x TC1507 x MON 88017 x DAS-59122-7)
Insect-Protected, Herbicide-Tolerant Corn
(Alternate brand name SmartStax™)

Dow AgroSciences *Bacillus thuringiensis (B t)* CRY1A 105 CRY2Ab2 CRY1F CRY3Bb1, CRY34/35Ab1
PROTEINS AND THE GENETIC MATERIAL NECESSARY FOR THEIR PRODUCTION IN MON 89034 ×
TC1507 × MON 88017 × DAS-59122-7 (*SMARTSTAX*™) CORN

(OECD Unique Identifier MON-89Ø34-3 × DAS- Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)

Active Ingredients

Active Ingredients
Bacillus thuringiensis Cry1A 105 protein and the genetic material necessary (vector PV-ZMIR245) for its
production in corn event MON 89034 ≤0 0026%*

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary (vector PV-ZMIR245) for its
production in corn event MON 89034 ≤0 0053%*

Bacillus thuringiensis Cry1F protein and the genetic material necessary (vector PHP8999) for its
production in corn event TC1507 ≤0 0012%*

Bacillus thuringiensis Cry3Bb1 protein and the genetic material necessary (vector PV-ZMIR39) for its
production in corn event MON 88017 ≤0 0079%*

Bacillus thuringiensis Cry34Ab1 protein and the genetic material necessary (vector PHP17662) for its
production in corn event DAS-59122-7 ≤0 0194%*

Bacillus thuringiensis Cry35Ab1 protein and the genetic material necessary (vector PHP17662) for its
production in corn event DAS-59122-7 ≤0 0042%*

Inert Ingredients
CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material necessary
(vector PV-ZMIR39) for its production in corn event MON 88017 ≤0 0052%*

PAT protein (phosphinothricin acetyl transferase) and the genetic material necessary (vectors PHP17622
and PHP8999) for its production in corn event TC1507 and DAS-59122-7 ≤0 00045%*

*Maximum percent (wt/wt) of dry forage

ACCEPTED
with COMMENTS
In EPA Letter Dated

NOV 22 2010

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg No
664 67-7

™ Trademark of Monsanto Company

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CAUTION

KEEP OUT OF REACH OF CHILDREN

NET CONTENTS_____

EPA Registration No 68467-7

EPA Establishment No 62719-IN-001

Mycogen Seeds c/o Dow AgroSciences LLC
9330 Zionsville Road
Indianapolis, IN 46268

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling Information regarding commercial production reflected here and in the terms and conditions of this registration must be included in the Product Use Guide

SmartStax™ (MON 89034 × TC1507 × MON 88017 × DAS-59122-7) 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 these pests developing resistance to SmartStax (MON 89034 × TC1507 × MON 88017 × DAS-59122-7) corn, an insect resistance management plan must be implemented which includes planting of a structured refuge   Growers who fail to comply with the IRM requirements risk losing access to Mycogen's corn PIP products

These refuge requirements do not apply to seed propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined US total of 250,000 acres per PIP active ingredient per year

A common refuge must be planted for both corn borers and corn rootworms   The refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers   The refuge and SmartStax (MON 89034 × TC1507 × MON 88017 × DAS-59122-7) corn should be sown on the same day, or with the shortest window possible between planting dates to ensure that corn root development is similar among varieties   If the refuge is planted on rotated ground, then the SmartStax (MON 89034 × TC1507 × MON 88017 × DAS-59122-7) corn must also be planted on rotated ground   If the combined refuge is planted on continuous corn, the SmartStax (MON 89034 × TC1507 × MON 88017 × DAS-59122-7) field may be planted on either continuous or rotated land (option encouraged where WCRW rotation resistant biotype may be present)   Refuge options are based on the planting of SmartStax (MON 89034 × TC1507 × MON 88017 × DAS-59122-7) in cotton or non-cotton growing regions and the insect pressure present in those locations

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If insecticides are applied to the refuge for control of CRW adults, the same treatment must also be applied in the same time frame to SmartStax (MON 89034 × TC1507 × MON 88017 × DAS-59122-7)

Several options for deployment of the refuge for SmartStax (MON 89034 × TC1507 × MON 88017 × DAS-59122-7) are available to growers   These options are based on the planting of SmartStax (MON 89034 × TC1507 × MON 88017 × DAS-59122-7) in cotton or non-cotton growing regions and the insect pressure present in those locations   The refuge sizes for these regions are either 5% (i e 5 acres of non-Bt corn for every 95 acres SmartStax (MON 89034 × TC1507 × MON 88017 × DAS-59122-7) planted) or 20% (20 acres of non-Bt corn for every 80 acres of SmartStax (MON 89034 × TC1507 × MON 88017 × DAS-59122-7) planted), and are presented in the table below

Region	Refuge size	In-field or adjacent refuge allowed	Refuge separated by up to ½ mile allowed
Cotton growing where CEW is a significant pest and WCRW, NCRW and MCRW are not significant NC, SC, GA, FL, TN (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), AL, MS, LA, AR, VA (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex)	20% non-Bt corn	Yes	Yes
Cotton growing where CEW is a significant pest and WCRW, NCRW, and/or MCRW are significant TX (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), OK (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), MO (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard)	20% non-Bt corn	Yes	No

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Cotton growing where CEW is not a significant pest and WCRW, NCRW and MCRW are not significant NM, AZ, CA, NV	5% non-Bt corn	Yes	Yes
Non-cotton growing where WCRW, NCRW and MCRW are not significant OR, WA, ID, MT, WY, UT, VA (except the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex), WV, PA, MD, DE, CT, RI, NJ, NY, ME, MA, NH, VT, HI, AK, TN (except the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton)	5% non-Bt corn	Yes	Yes
Non-cotton-growing where WCRW, NCRW and/or MCRW are significant KS, NE, SD, ND, MN, IA, MO (except the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard), IL, WI, MI, IN, OH, KY, CO, OK (except the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), TX (only the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman)	5% non-Bt corn	Yes	No

If corn rootworms are significant within a region, the structured refuge must be planted as an in-field or adjacent refuge using corn hybrids that do not contain Bt technologies for the control of corn borers or corn rootworms It can be planted as a block within or adjacent (e g , across the road) to the SmartStax (MON 89034 × TC1507 × MON 88017 × DAS-59122-7), perimeter strips (i e , strips around the field), or in-field strips 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 target lepidopteran pests of SmartStax (MON 89034 × TC1507 × MON 88017 × DAS-59122-7) in the refuge exceeds economic thresholds In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide, however, insecticides labeled for adult CRW control must be avoided in the refuge during the period of CRW adult emergence Economic thresholds will be determined using methods recommended by local or regional professionals (e g , Extension Service agents, crop consultants) A schematic of one common refuge deployment option is shown below

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Structured Refuge

SmartStax (MON 89034 x
TC1507 x MON 88017 x
DAS 59122 7)
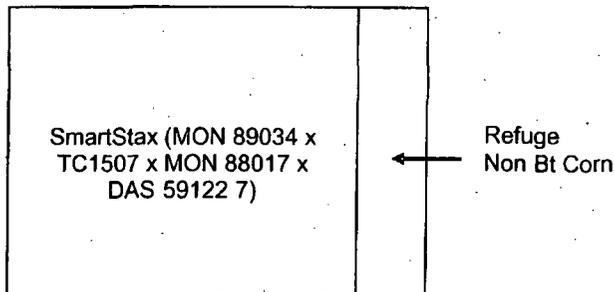
← Refuge
Non Bt Corn

If corn rootworms are not significant within a region, the structured refuge may be planted as <u>an in-field or adjacent refuge, or as a separate block</u> that is within ½ mile of the SmartStax (MON 89034 × TC1507 × MON 88017 × DAS-59122-7) field   The structured refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn borers or corn rootworms   Economic thresholds will be determined using methods recommended by local or regional professionals (e g , Extension Service agents, crop consultants)   A schematic of one refuge option with the refuge planted within a ½ mile of the SmartStax (MON 89034 × TC1507 × MON 88017 × DAS-59122-7) field is shown below

Separated Structured Refuge

SmartStax (MON 89034 x
TC1507 x MON 88017 x
DAS 59122 7)

≤½ mile ↔

← Refuge
Non Bt corn
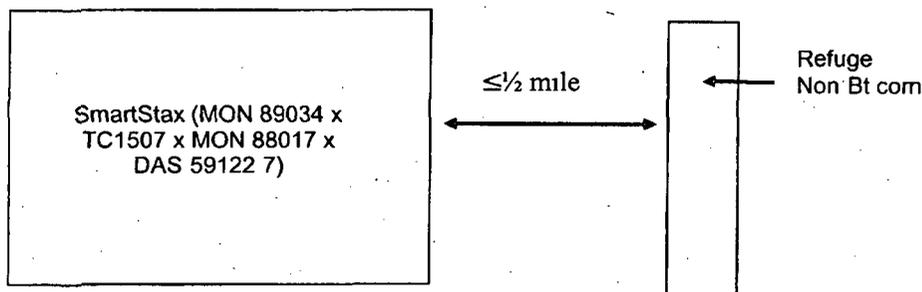
Corn Insects Controlled or Suppressed

European corn borer (ECB)	*Ostrinia nubilalis*
Southwestern corn borer (SWCB)	*Diatraea grandiosella*
Southern cornstalk borer (SCSB)	*Diatraea crambidoides*
Corn earworm (CEW)	*Helicoverpa zea*
Fall armyworm (FAW)	*Spodoptera frugiperda*
Stalk borer	*Papaipema nebris*
Lesser corn stalk borer	*Elasmopalpus lignosellus*
Sugarcane borer (SCB)	*Diatraea saccharalis*
Western bean cutworm (WBC)	*Richia albicosta*
Black cutworm	*Agrotis ipsilon*
Western corn rootworm (WCRW)	*Diabrotica virgifera virgifera*
Northern corn rootworm (NCRW)	*Diabrotica barberi*
Mexican corn rootworm (MCRW)	*Diabrotica virgifera zeae*

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Sales of corn hybrids that contain Mycogen's Bt corn plant pesticide must be accompanied by a Product Use Guide which includes information on planting, production and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted

SmartStax (MON 89034 × TC1507 × MON 88017 × DAS-59122-7) is a product of Monsanto's and Dow AgroSciences' research programs, offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U S patents 5023179, 5110732, 5164316, 5196525, 5322938, 5352605, 5359142, 5378619, 5424412, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6962705, 7064249, 7227056, and 7250501

EPA Accepted   __/__/__