

68467-16

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

4 / 22 / 2014

1/8

Mr. Gregory Orr
Global Regulatory Leader
Mycogen Seeds c/o Dow AgroSciences LLC
9300 Zionsville Rd.
Indianapolis, IN 46268

APR 22 2014

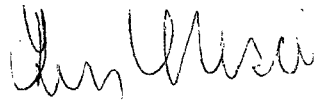
Re: Product Name – SmartStax Refuge Advanced and PowerCore Refuge Advanced
EPA Reg. No. 68467-16 and 68467-21
Your application dated March 27, 2014 to add alternate brand names (SmartStax Refuge
Advanced and PowerCore Refuge Advanced),
Pesticide Registration (PR) Notice 98-10
Decision No. D-489635 and D--489636

Dear Mr. Orr:

The Biopesticides and Pollution Prevention Division is in receipt of your applications, as indicated above, for notification under PR Notice 98-10. A preliminary screen of this request has been conducted for its applicability under PR Notice 98-10, and it has been determined that the action requested falls within the scope of this document. Our records have been duly noted, and the labels submitted with this application has been stamped "Notification Accepted" and will be placed accordingly in our records. Submit two (2) copies of final printed labeling before the product, as modified, is sold or distributed [40 C.F.R. § 156.10(a)(6)].

Questions concerning this action should be directed to Dr. Kenneth Haymes by phone (703-347-0398) or email (haymes.kenenth@epa.gov).

Sincerely,



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

CONCURRENCES

SYMBOL	▶ 7511P	7511P	7511P					
SURNAME	▶ Haymes	Reynolds	Nesci					
DATE	▶ 4/15/14	4/15/14	4/18/14					

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United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier
Number

Application for Pesticide – Section I

1. Company/Product Number Dow AgroSciences/ 68467-16	2. EPA Product Manager Ann Sibold	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
Company/Product (Name) Dow AgroSciences/SmartStax® Refuge Advanced ABN for Refuge Advanced Powered by SmartStax®		PM # 92
5. Name and Address of Applicant (Include ZIP Code) Mycogen Seeds c/o Dow AgroSciences LLC 9300 Zionsville Rd. Indianapolis, IN 46268 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(B)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section – II

<input type="checkbox"/> Amendment – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification – Explain below.	<input type="checkbox"/> Other – Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Application to amend the Registration of the Plant-Incorporated Protectant, Refuge Advanced Powered By SmartStax®. We would like to make SmartStax® Refuge Advanced the primary name for the product (68467-16). This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section – III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per Container	If "Yes" Package wgt.	No. per Container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container Various		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Other <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

Section – IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Gregory L. Orr	Title Global Regulatory Leader	Telephone No. (Include Area Code) (317) 337-3692
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Global Regulatory Leader	
4. Typed Name Gregory L. Orr	5. Date March 27, 2014	



Dow AgroSciences

Notification Accepted

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Date: 4/22/2014

Reviewer: LMM

Dow AgroSciences LLC
9330 Zionsville Road, Indianapolis, IN 46268-1054

dowagro.com

308/2E
March 27, 2014

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Attn: Ann Sibold (7511P)

**REFUGE ADVANCED POWERED BY SMARTSTAX®
EPA REGISTRATION NUMBER: 68467-16
NOTIFICATION OF ALTERNATE BRAND NAME PER PR NOTICE 98-10**

Enclosed please find labeling for the notification action of Refuge Advanced Powered by SmartStax®. The following change has been made by notification:

1. Make SmartStax® Refuge Advanced the primary name
2. Make Refuge Advanced Powered by SmartStax® an Alternate Brand Name

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Contents of the Submission

- Transmittal document (this letter)
- Application for Pesticide, EPA Form 8570-1
- Label entitled S2J/SmartStax® Refuge Advanced /FPL/27March2014 (redlined copy)
- Label entitled S2J/SmartStax® Refuge Advanced /FPL/27March2014 (clean copy)

If you require additional information about this product, please contact me at 317-337-3081 or Greg Ort, Global Regulatory Manager for Biotech Corn, at 317-337-3692.

Sincerely,

Heidi Reistad
Biotechnology Regulatory & Government Affairs Specialist
317-337-3081

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Plant-Incorporated Protectant Label

SmartStax® Refuge Advanced

(Alternate Brand Name MON 89034 x TC1507 x MON 88017 x DAS-59122-7)

Insect Protected Herbicide-Tolerant Corn With An Interspersed Refuge)

(Alternate Brand Name Refuge Advanced Powered by SmartStax®)

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

Active Ingredients:

Bacillus thuringiensis Cry1A.105 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3) ≤ 0.0026%*

Bacillus thuringiensis Cry2Ab2 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3) ≤ 0.0053%*

Bacillus thuringiensis Cry1F protein and the genetic material (vector PHP8999) necessary for its production in corn event TC1507 (OECD Unique Identifier: DAS- Ø15Ø7-1) ≤ 0.0012%*

Bacillus thuringiensis Cry3Bb1 protein and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017 (OECD Unique Identifier: MON-88Ø17-3) ≤ 0.0079%*

Bacillus thuringiensis Cry34Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7) ≤ 0.0194%*

Bacillus thuringiensis Cry35Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7) ≤ 0.0042%*

Other Ingredients:

CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017 ≤ 0.0052%*

PAT protein (phosphinothricin acetyl transferase) and the genetic material (vectors PHP17662 and PHP8999) necessary for its production in corn events TC1507 and DAS-59122-7 ≤ 0.00045%*

*Maximum percent (wt/wt) of dry forage

‡ SmartStax® seed with this refuge configuration contains 95% MON 89034 x TC1507 x MON 88017 x DAS-59122-7 mixed with at least 5% non-*Bt* corn within a single lot of seed.

™Trademark of Dow AgroSciences LLC

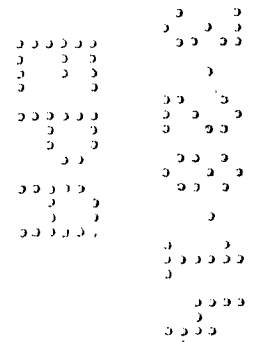
KEEP OUT OF REACH OF CHILDREN

CAUTION

NET CONTENTS _____

**EPA Registration No. 68467-16
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. The plant-incorporated protectant (PIP) product must be used as specified in the terms and conditions of the registration.

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

SmartStax® Refuge Advanced™ protects corn crops from leaf, stalk, and ear damage caused by lepidopteran corn pests listed on this label and root damage caused by corn rootworm larvae listed on this label. In order to minimize the risk of these pests developing resistance to SmartStax® Refuge Advanced™, an insect resistance management plan must be implemented as defined in the registration terms and conditions.

Grower agreements will specify that growers must adhere to the refuge requirements that will be described in the Product Use Guide for SmartStax® Refuge Advanced™ or other applicable product use documents.

Sales of corn hybrids that contain Mycogen's *Bt* corn plant-incorporated pesticide(s) 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.

Corn seed bags or bag tags for products containing SmartStax® Refuge Advanced™ must include the refuge size requirement in text and graphical format.

INSECT RESISTANCE MANAGEMENT

Growers are instructed to read information on insect resistance management.

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

The following information regarding refuge placement for commercial production must be included in the Product Use Guide.

This product includes refuge that is interspersed within the field by planting a licensed seed-mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-PIP seed. **The seed mix refuge option for SmartStax® Refuge Advanced™ satisfies the refuge requirements in all regions other than in cotton growing regions where corn earworm is a significant pest as defined below.**

The seed producer must ensure a minimum of 5% non-PIP refuge seed is included with the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 in each lot of seed corn.

The interspersed refuge can only be used by planting seed corn specifically generated by qualified seed producers/conditioners licensed by the registrant. The refuge seed in the seed mixture may not be treated with seed-applied insecticides for corn rootworm (CRW) control unless the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 seed in the seed mixture receives the same treatment. Insecticidal treatments labeled for adult CRW control are discouraged during the time of adult CRW emergence.

Additional refuge requirements in cotton-growing regions where corn earworm is a significant pest

In cotton-growing regions where corn earworm is a significant pest, as defined below, the seed-mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-PIP seed requires the planting of an additional 20% structured refuge (i.e. 20 acres of non-Bt corn for every 80 acres of SmartStax® Refuge Advanced™ planted).

The 20% 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 the SmartStax® Refuge Advanced™ 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. The structured refuge may be planted as an in-field or adjacent (e.g., across the road) refuge, or as a separate block that is within ½ mile of the SmartStax® Refuge Advanced™. In-field refuge options include blocks, 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).

The cotton-growing region requiring this additional 20% refuge consists 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, and 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, Ochiltrie, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

The following language will be included on the seed bag tags for SmartStax® Refuge Advanced™:

Management Guidelines

This product consists of a licensed seed-mixture/seed-blend containing 95% SmartStax® seed and a minimum of 5% seed that does not contain B.t. technologies for the control of corn borers or corn rootworms. When planted, the refuge will be interspersed within the field.

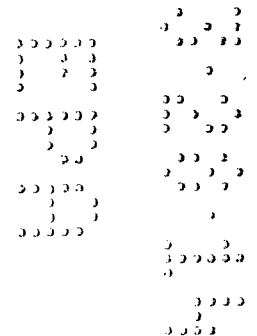
The interspersed refuge configuration in SmartStax® Refuge Advanced™ fulfills the grower's refuge requirements for this product in non-cotton growing regions and in cotton growing regions where corn earworm is not a significant pest (i.e. the same regions where the minimum refuge size is 5% under SmartStax® registration 68467-7).

The interspersed refuge in SmartStax® Refuge Advanced™ corn is not sufficient to meet IRM requirements in regions that currently require a 20% structured refuge for SmartStax® (cotton growing regions and non-cotton growing regions where corn earworm is a significant pest). In these regions growers are required to plant a structured 20% corn refuge for corn earworm.

In the SmartStax 20% structured refuge areas, the structured refuge may be planted as an in-field or adjacent (e.g., across the road) refuge or as a separate block that is within ½ mile of the Refuge Advanced field. In-field refuge options include blocks, perimeter strips (i.e., strips around the field) or in-field strips. If perimeter strips or in-field strips are implemented, the strips must be at least four consecutive rows of corn wide.

Cotton Growing Region

The cotton-growing region requiring this additional 20% refuge consists 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, and 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, Ochiltrie, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard)



Corn Insects Controlled or Suppressed

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

SmartStax® Refuge Advanced™ 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:

Dow AgroSciences Patent Rights: 6,083,499; 6,127,180; 6,218,188; 6,340,593; 6,548,291; 6,624,145; 6,893,872; 6,900,371; 6,943,282; 7,790,961 and 7,956,246; Monsanto Patent Rights: 5,717,084; 5,728,925; 6,025,545; 6,051,753; 6,063,597; 6,083,878; 6,489,542; 6,645,497; 6,713,063; 6,962,705; 7,064,249; 7,070,982; 7,250,501; 7,304,206; 7,544,862; 7,618,942; 7,700,830; 7,927,598; 8,034,997; and 8,212,113.

EPA Accepted: / / .

