



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

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

April 26, 2023

Ashley Young  
U.S. Seeds Regulatory Specialist  
Corteva Agriscience LLC  
9330 Zionsville Road  
Indianapolis, IN 46268

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment –Revision to the Name of the Company  
Product Name: SmartStax Enlist  
EPA Registration Number: 68467-7  
EPA Receipt Date: February 16, 2023  
Action Case Number: 00432995

Dear Ms. Young:

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

The primary company name of this product has been changed from Mycogen Seeds c/o Dow Agrosiences LLC to Corteva Agriscience LLC, and our records have been updated accordingly. This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR § 152.3.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the U.S. Environmental Protection Agency (EPA). If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should EPA find or if it is brought to our attention that a website contains statements or claims substantially differing from statements or claims made in connection with obtaining a FIFRA

section 3 registration, the website will be referred to EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Leslie Paul via email at [paul.leslie@epa.gov](mailto:paul.leslie@epa.gov).

Sincerely,

 Digitally signed by  
ALAN REYNOLDS  
Date: 2023.04.26  
14:46:37 -04'00'

Alan Reynolds, Team Leader  
Emerging Technologies Branch  
Biopesticides and Pollution  
Prevention Division (7511M)  
Office of Pesticide Programs

Enclosure: Final Stamped Label

**ACCEPTED**

04/26/2023

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 68467-7

**Plant-Incorporated Protectant Label**

**SmartStax<sup>®</sup> Enlist<sup>™</sup>**

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

**Insect Protected Herbicide-Tolerant Corn)**

(Alternate Brand Name SmartStax<sup>®</sup>)

(OECD Unique Identifier: MON-89034-3 × DAS- 01507-1 × MON-88017-3 × 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-89034-3) ..... ≤ 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-89034-3) ..... ≤ 0.0053%\*

*Bacillus thuringiensis* Cry1F protein and the genetic material (vector PHP8999) necessary for its production in corn event TC1507 (OECD Unique Identifier: DAS- 01507-1) ..... ≤ 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-88017-3) ..... ≤ 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

KEEP OUT OF REACH OF CHILDREN

**CAUTION**

NET CONTENTS \_\_\_\_\_

**EPA Registration No. 68467-7**

**EPA Establishment No. 62719-IN-001**

Corteva Agriscience LLC  
9330 Zionsville Road  
Indianapolis, IN 46268

*SmartStax<sup>®</sup> multi-event technology developed by Corteva Agriscience and Monsanto.*

*<sup>®</sup>SmartStax is a registered trademark of Bayer Group.*

*Enlist<sup>™</sup> is a trademark of Corteva Agriscience and its affiliated companies.*

## 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 Grower Guide.

SmartStax® Enlist™ 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® Enlist™ 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 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® Enlist™ 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® Enlist™ corn must also be planted on rotated ground. If the combined refuge is planted on continuous corn, the SmartStax® Enlist™ 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 MON 89034 × TC1507 × MON 88017 × DAS-59122-7 in cotton or non-cotton growing regions and the insect pressure present in those locations.

If insecticides are applied to the refuge for control of CRW adults, the same treatment must also be applied in the same timeframe to SmartStax® Enlist™.

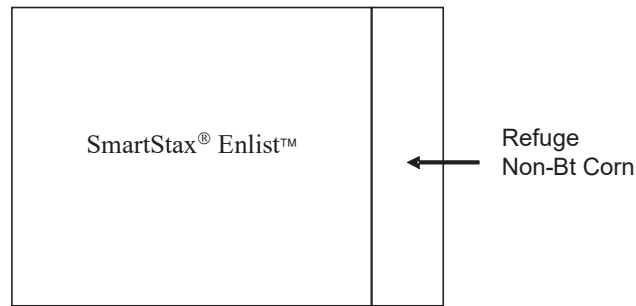
Several options for deployment of the refuge for SmartStax® Enlist™ are available to growers. These options are based on the planting of SmartStax® Enlist™ in cotton or non-cotton growing regions and the insect pressure present in those locations. The refuge sizes for these regions are either 5% (i.e. 5 acres of non-Bt corn for every 95 acres of SmartStax® Enlist™ planted) or 20% (20 acres of non-Bt corn for every 80 acres of SmartStax® Enlist™ 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  | 20% non-Bt corn | Yes                                 | No                                       |

|   |                |     |     |
|---|----------------|-----|-----|
| 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)  |                |     |     |
| 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  |

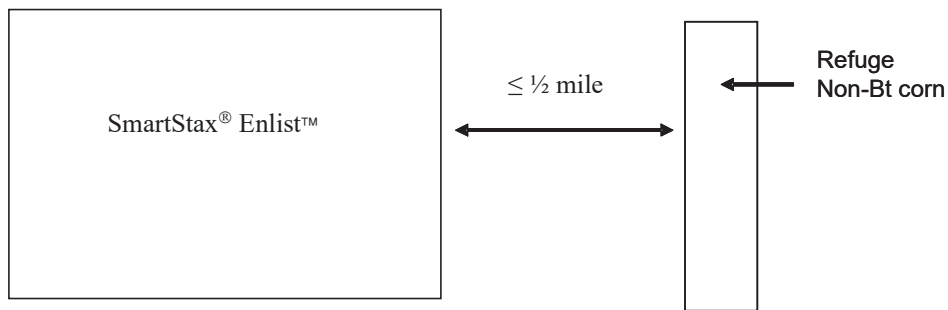
If corn rootworms are significant within a region, the structured refuge must be planted as an in-field or adjacent refuge using corn hybrids that do not contain Bt technologies for the control of corn borers or corn rootworms. It can be planted as a block within or adjacent (e.g., across the road) to the SmartStax® Enlist™, 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® Enlist™ 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:

### Structured Refuge



If corn rootworms are not significant within a region, the structured refuge may be planted as an in-field or adjacent refuge, or as a separate block that is within ½ mile of the SmartStax® Enlist™ 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® Enlist™ field is shown below:

### Separated Structured Refuge



### 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>       |

Sales of corn hybrids that contain Bt corn plant pesticide must be accompanied by a IRM/Grower 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.

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

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