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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 5, 2018

David Chi
Regulatory Affairs Manager
Monsanto Company
800 North Lindbergh Blvd.
St. Louis, Missouri 63167

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment –

- Remove Western bean cutworm (*R. albicosta)* as a target pest;
- Replace "524-YYY" with "524-632;"
- Modify designations for the active and inactive ingredients;
- Remove SmartStax® Pro as an Alternate Brand Name;
- Make minor changes to the Directions for Use.

Product Name: MON 89034 x TC1507 x MON 87411 x DAS-59122-7
EPA Registration Number: 524-632
Application Dates: 3/29/2018
OPP Decision Numbers: 542192

Dear Mr. Chi:

In an application dated March 29, 2018, you notified the U.S. Environmental Protection Agency (EPA) that you requested to modify the designations for the active and inactive ingredients, to remove SmartStax® Pro as an Alternate Brand Name, to remove Western bean cutworm (*R. albicosta)* as a target pest, to replace "524-YYY" with "524-632", and to make minor changes to the Directions for Use. Subsequently, the EPA determined that the actions requested do not fall under the scope of Pesticide Registration Notice (PRN) 98-10 and therefore converted the notification to a non-PRIA amendment (OPP Decision No. 542192). The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

Additionally, the alternate brand name SmartStax® Pro has been removed from the registration. 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 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 the 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 the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the 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 Matt Weiner by phone at 703-347-0333 or via email at weiner.matthew@epa.gov.

Sincerely,

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

Enclosure

Plant-Incorporated Protectant Label

MON 89034 × TC1507 × MON 87411 × DAS-59122-7

Insect-Protected, Herbicide-Tolerant Corn
(OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7)

Active Ingredients:

dsRNA transcript comprising a DvSnf7 inverted repeat sequence derived from *Diabrotica virgifera virgifera*, and the genetic material (vector PV-ZMIR10871) necessary for its production in MON 89034 × TC1507 × MON 87411 × DAS-59122-7 (OECD Unique Identifier MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7) .....≤ 0.00000044%*

Bacillus thuringiensis Cry1A.105 protein and the genetic material (vector PV-ZMIR245) necessary for its production in MON 89034 × TC1507 × MON 87411 × DAS-59122-7 (OECD Unique Identifier MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7)..... .....≤ 0.0088%*

Bacillus thuringiensis Cry2Ab2 protein and the genetic material (vector PV-ZMIR245) necessary for its production in MON 89034 × TC1507 × MON 87411 × DAS-59122-7 (OECD Unique Identifier MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7) ....≤ 0.0048%*

Bacillus thuringiensis Cry1F protein and the genetic material (vector PHP8999) necessary for its production in MON 89034 × TC1507 × MON 87411 × DAS-59122-7 (OECD Unique Identifier MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7) .....≤ 0.00096%*

Bacillus thuringiensis Cry3Bb1 protein and the genetic material (vector PV-ZMIR10871) necessary for its production in MON 89034 × TC1507 × MON 87411 × DAS-59122-7 (OECD Unique Identifier MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7)..... .....≤ 0.0041%*

Bacillus thuringiensis Cry34Ab1 protein and the genetic material (vector PHP17662) necessary for its production in MON 89034 × TC1507 × MON 87411 × DAS-59122-7 (OECD Unique Identifier MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7).. ….....≤ 0.012%*

Bacillus thuringiensis Cry35Ab1 protein and the genetic material (vector PHP17662) necessary for its production in MON 89034 × TC1507 × MON 87411 × DAS-59122-7 (OECD Unique Identifier MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7)…....≤ 0.0026%*

Other Ingredients:

The marker protein CP4 EPSPS and the genetic material (vector PV-ZMIR10871) necessary for its production in MON 89034 × TC1507 × MON 87411 × DAS-59122-7 (OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS 59122 7) .....≤ 0.036%*

The marker protein PAT and the genetic material (vector PHP17662) necessary for its production in MON 89034 × TC1507 × MON 87411 × DAS-59122-7 (OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7) ..... ≤ 0.0001%*

*Percentage (wt/wt) on a dry weight basis for forage tissue of MON 89034 × TC1507 × MON 87411 × DAS-59122-7 plants

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET CONTENTS_____

EPA Registration No. 524-632

EPA Establishment No. 524-MO-002

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167

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 as specified in the terms and conditions of this registration must be included in the Technology Use Guide.

MON 89034 × TC1507 × MON 87411 × DAS-59122-7 protects corn crops from leaf, stalk, and ear damage caused by corn borers and from root damage caused by corn rootworm larvae.

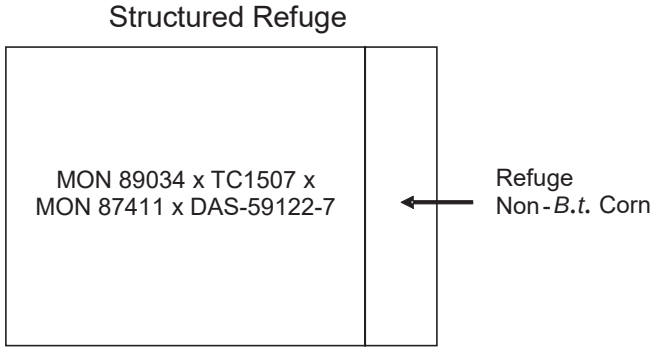
In order to minimize the risk of these pests developing resistance to MON 89034 × TC1507 × MON 87411 × DAS-59122-7 corn, an insect resistance management plan must be implemented which includes planting of a structured refuge. Growers who fail to comply with the IRM requirements risk losing access to Monsanto's corn PIP products.

For the sole purpose of manufacturing and small scale research trials for observation, 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.

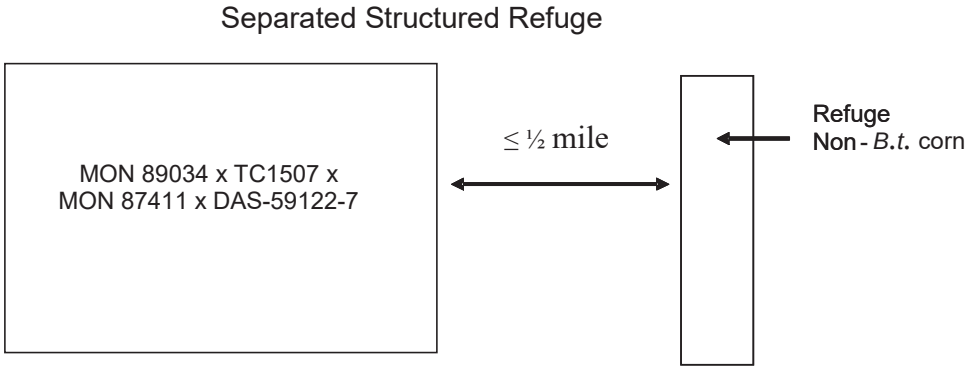
Several options for deployment of the refuge for MON 89034 × TC1507 × MON 87411 × DAS-59122-7 are available to growers. These options are based on the planting of MON 89034 × TC1507 × MON 87411 × DAS-59122-7 in cotton or non-cotton growing regions and the insect pressure present in those locations. The refuge sizes for these regions are either 5% (i.e. 5 acres of non-*B.t.* corn for every 95 acres MON 89034 × TC1507 × MON 87411 × DAS-59122-7 planted) or 20% (20 acres of non- *B.t.* corn for every 80 acres of MON 89034 × TC1507 × MON 87411 × DAS-59122-7 planted) and are presented in the table below:

Region	Refuge size	In-field or adjacent refuge	Refuge separated by up to ½ mile
Cotton belt where CEW is a significant pest and WCRW, NCRW and MCRW are not significant: NC, SC, GA, FL, TN, AL, MS, LA, AR, northern TX	20% non-*B.t.* corn	Yes	Yes
Cotton belt where CEW is a significant pest and MCRW is significant: southern TX	20% non-*B.t.* corn	Yes	No
Cotton belt where CEW is not a significant pest and WCRW, NCRW and MCRW are not significant: NM, AZ, CA, NV Non-cotton states where WCRW, NCRW and MCRW are not significant: OR, WA, ID, MT, WY, UT, CO, OK, VA, WV, PA, MD, DE, CT, RI, NJ, NY, ME, MA, NH, VT, HI, AK	5% non-*B.t.* corn	Yes	Yes
Non-cotton states where WCRW, NCRW and/or MCRW are significant: KS, NE, SD, ND, MN, IA, MO, IL, WI, MI, IN, OH, KY	5% non-*B.t.* 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 *B.t.* 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 MON 89034 × TC1507 × MON 87411 × 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 four (4) consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-*B.t.* insecticides if the population of one or more target lepidopteran pests of MON 89034 × TC1507 × MON 87411 × DAS-59122-7 in the refuge exceeds economic threshold. 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 should 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:



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 MON 89034 × TC1507 × MON 87411 × DAS-59122-7 field. The structured refuge must be planted with corn hybrids that do not contain *B.t.* 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 MON 89034 × TC1507 × MON 87411 × DAS-59122-7 field is shown below:



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*
Black cutworm	*Agrotis ipsilon*
Western corn rootworm (WCRW)	*Diabrotica virgifera virgifera*
Northern corn rootworm (NCRW)	*Diabrotica barberi*
Mexican corn rootworm (MCRW)	*Diabrotica virgifera zeae*

MON 89034 × TC1507 × MON 87411 × DAS-59122-7 is a product of Monsanto's research program offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents that can be found at http://www.monsantotechnology.com