



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511M)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

524-631

Date of Issuance:

6/14/2022

NOTICE OF PESTICIDE:

Registration

Reregistration

(under FIFRA, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product:

MON 89034 x TC1507 x MON 87411
x DAS-59122-7 Seed Blend

Name and Address of Registrant (include ZIP Code):

Bayer CropScience LP
700 Chesterfield Parkway West
Chesterfield, Missouri 63017

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product, always refer to the above EPA Registration Number.

On the basis of information furnished by the registrant, the above-named pesticide is hereby registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or the Act).

Registration is in no way to be construed as an endorsement or recommendation of this product by the U.S. Environmental Protection Agency (EPA). In order to protect health and the environment, the Administrator, on his or her motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under the Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you comply with the following terms:

1. The subject registration will automatically expire at midnight on June 30, 2023.

Signature of Approving Official:

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

Date:

6/14/2022

2. The subject registration will be limited to *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 proteins and the genetic material necessary for their production (vector PV-ZMIR245) in MON 89034 corn (OECD Unique Identifier: MON-89034-3), *Bacillus thuringiensis* Cry1F protein and the genetic material necessary for its production (vector PHP8999) in TC1507 corn (OECD Unique Identifier: DAS-01507-1), *Bacillus thuringiensis* Cry34Ab1/Cry35Ab1 proteins and the genetic material necessary for their production (vector PHP17662) in DAS-59122-7 corn (OECD Unique Identifier: DAS-59122-7), *DvSnf7* dsRNA [Double-stranded ribonucleic acid transcript comprising a *DvSnf7* inverted repeat sequence derived from western corn rootworm (*Diabrotica virgifera virgifera*)], *Bacillus thuringiensis* Cry3Bb1 protein and the genetic material necessary for their production (vector PV-ZMIR10871) in MON 87411 corn (OECD Unique Identifier: MON-87411-9), and a minimum of 5% non-PIP corn seed for use in field corn.
3. Submit/cite all data required for registration of your product under FIFRA section 3(c)(5) when the Environmental Protection Agency (EPA) requires registrants of similar products to submit such data.
4. This plant-incorporated protectant (PIP) may be combined 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.
5. Bayer CropScience LP (Bayer) must commit to do the following Insect Resistance Management (IRM) Program, consisting of the following elements:
 - Requirements for Bayer to implement an IPM-based stewardship program designed to reduce selection pressure for corn rootworm (CRW) resistance.
 - Requirements relating to a refuge assurance program for ensuring the correct refuge blend percentage.
 - Requirements relating to creation of a lepidopteran refuge (consisting of corn that does not contain any *Bt* trait for lepidopteran control) in cotton growing regions in conjunction with the planting of MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn;
 - Requirements for Bayer to prepare and require MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn users to sign grower agreements that impose binding contractual obligations on growers to comply with the refuge requirements.
 - Requirements for Bayer to develop, implement, and report to EPA on programs to educate growers about IRM requirements.
 - Requirements for Bayer to develop, implement, and report to EPA on programs to evaluate and promote growers' compliance with IRM requirements.
 - Requirements for Bayer to develop, implement, and report to EPA on monitoring programs to evaluate whether there are statistically significant and biologically relevant changes in susceptibility to the Cry1A.105, Cry2Ab2, and Cry1F proteins in the target insects.
 - Requirements for Bayer to develop, and if triggered, to implement a remedial action plan that would contain measures Bayer would take in the event that any field-relevant insect resistance to

Cry1A.105, Cry2Ab2, and Cry1F was detected, as well as to report on activity under the plan to EPA.

- Requirements for Bayer to investigate reports of unexpected CRW damage to MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn from growers (“performance inquiries”) and sample CRW to determine if the insects are resistant to Cry34/35Ab1, DvSnf7 dsRNA, or Cry3Bb1.
- Requirements for Bayer to recommend CRW management options to growers in response to cases of unexpected CRW damage to MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn.
- Requirements regarding mitigation and notification actions that Bayer would take in the event that CRW resistance was detected.
- Requirements for Bayer to maintain, and provide the Agency upon request, the number of units sold by state and county, IRM grower agreement results, and substantive changes to educational programs. Bayer is required to submit reports within three months of the Agency’s request.
- Bag Tag Requirements for MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn. Seed bags and/or bag tags for corn hybrids that contain plant- incorporated protectants produced in MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn must display the registration number and active ingredients, and stipulate that growers read the Bayer Stewardship Guide (or equivalent guidance) prior to planting these hybrids. The refuge size requirement must be displayed on the bag or bag tag in both text and graphic format.
- Requirements for Bayer to submit reports on CRW IPM Stewardship and resistance monitoring within the time frames specified in this letter.

a. Integrated Pest Management Stewardship Program

1. Bayer must implement an IPM-based stewardship program for MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn. This program must be designed to reduce selection pressure for corn rootworm (CRW) resistance by encouraging growers to engage in a multi-year crop rotation strategy involving the use of one or more of the following: a non-CRW host crop (e.g., soybean), pyramided *Bt* corn Plant Incorporated Protectants (PIPs), other PIP corn products with different modes of action, and/or non-PIP or non-CRW protected *Bt* corn. As part of the stewardship program, Bayer must update the technology use guide/grower guide and other grower educational materials to indicate that application of an insecticide to the soil surface, in furrows, and/or incorporated into the soil (referred to as “soil applied insecticide”, “soil insecticide” or “SAI”) with MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn is not recommended for control of CRW except under limited circumstances and in consultation with extension, crop consultants or other local experts. Grower education materials should also state that SAIs should not be necessary for CRW control with pyramided CRW trait *Bt* corn product(s). As part of the stewardship program, Bayer must promote the ABSTC/NCGA Best Management Practices (BMPs) for CRW control. Implementation of the IPM strategy can include:

- Grower education initiatives or incentives;
- Outreach to extension and consultant groups.

2. Bayer must submit an annual report to EPA documenting activities conducted under the IPM stewardship program. This report must include an anonymous survey of grower practices, including adoption levels of the various crop rotation options (if employed) and other elements of the stewardship program. Bayer may combine this product with other registered products to submit one annual report. The report must be submitted by January 31st each year.

b. Refuge Requirements for MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend

The following information must be included on the product bag or bag-tag as sold per respective region and in the Grower Guide:

Corn-Belt/Non-Cotton Growing Areas

MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn contains a Lepidopteran and corn rootworm refuge that is “in the bag” and is automatically implemented when the grower plants the product. No additional refuge is required when planting this product.

Foliar insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, fall armyworm, black cutworm, western bean cutworm, lesser corn stalk borer, southern corn stalk borer, stalk borer, and sugarcane borer may be applied only if economic thresholds are reached for one or more of these target pests. Foliar insecticide treatments are also permitted for control of corn rootworm adults if economic thresholds are reached. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service Agents, crop consultants).

Cotton-Growing Region Refuge Requirements

These refuge requirements do not apply to planting of inbred/hybrid corn seed productions, breeding, and small-scale research trials on 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. Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

In cotton-growing regions where corn earworm is a significant pest:

- The 20% refuge must be planted with non-PIP hybrids.
- MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend and the 20% non-PIP refuge should be sown on the same day, or with the shortest window possible between planting dates.
- External refuges may be planted as an in-field or adjacent (e.g., across the road) refuge or as a separate block within 1/2 mile of the MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn field.
- In field refuge options include blocks, perimeter strips (i.e., along the edges or headlands), or infield strips.
- When planting the refuge in strips across the field, refuges must be at least four (4) rows wide.

- Foliar insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, fall armyworm, black cutworm, western bean cutworm, lesser corn stalk borer, southern corn stalk borer, stalk borer and sugarcane borer 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-PIP corn refuge plants.
- 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, 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, Ochiltree, 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).

c. Grower Agreements for MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend

1. Persons purchasing MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn must sign a grower agreement. The term grower agreement refers to any grower purchase contract, license agreement, or similar legal document.
2. The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
3. Bayer must continue to integrate this registration into the current system used for its other *Bt* corn plant- incorporated protectants, which is reasonably likely to assure that persons purchasing MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn will affirm annually that they are contractually bound to comply with the requirements of the IRM program.
4. Bayer must continue to use its current grower agreement for MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn. If Bayer wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, then thirty (30) days prior to implementing a proposed change, Bayer must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of this amended registration.
5. Bayer shall maintain records of all MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn grower agreements for a period of three (3) years from December 31st of the year in which the agreement was signed.
6. Bayer shall make available to the Agency upon request records of the number of units of MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn seed sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements for the previous growing season. Bayer is required to submit reports within three months of the Agency's request.

7. Bayer must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license numbers of the growers, will be protected.

d. IRM Education and IRM Compliance Monitoring Program for MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend in EPA-designated Cotton Counties

1. Bayer must implement and enhance (as set forth in paragraph 17 of this section) a comprehensive, ongoing IRM education program designed to convey to MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn users the importance of complying with the IRM program, as well as seed blend product performance expectations and guidance to growers on actions to take when unexpected damage occurs. The program shall include information encouraging MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn fields. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by internet, radio, or television commercials. The program shall involve at least one written communication annually to each MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements and specifically the need to plant a lepidopteran refuge in cotton growing regions. Bayer shall coordinate its education program with the educational efforts of other registrants and other organizations, such as the National Corn Growers Association and state extension programs.
2. Bayer shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey, required under paragraphs 6–9 of this section, and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.
3. Upon EPA request, Bayer shall provide copies of grower education materials and information on grower education activities including any substantive changes to these materials and activities conducted either individually or as part of the industry working group Agricultural Biotechnology Stewardship Technical Committee (ABSTC). Bayer is required to submit reports within three months of the Agency's request. The required features of the compliance assurance program are described in paragraphs 4–22 of this section.
4. Bayer must implement and improve an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn are compliant with the requirement of a 20% refuge for lepidopteran pests in cotton growing areas, and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to Bayer's *Bt* corn products. Bayer shall coordinate with other *Bt* corn registrants in improving its compliance assurance program and integrate this registration into the current compliance assurance program used for its other *Bt* corn plant-incorporated protectants. Other required features of the program are described in paragraphs 5–22 of this section.
5. Bayer must maintain and publicize a phased compliance approach (i.e., a guidance document that indicates how it will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers after the first year of non-compliance). While recognizing that for reasons of difference in business practices there

are needs for flexibility between different companies, Bayer must use a consistent set of standards for responding to non-compliance. A grower found with a second incident of significant non-compliance with refuge requirements for the *Bt* corn product within a five-year period will be denied access the next year to Bayer's *Bt* corn products. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell *Bt* corn.

6. The IRM compliance assurance program shall include an annual survey, conducted by an independent third-party, of a statistically representative sample of growers MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn. The survey shall be conducted in odd-numbered years beginning in 2023 and shall include growers who plant 100 or more acres of corn in the Southern U.S. corn-cotton areas. Bayer may collaborate with other registrants of *Bt* corn [for example, through the industry working group the Agricultural Biotechnology Stewardship Technical Committee (ABSTC)] to conduct the survey.

In the U.S. Corn Belt, no anonymous grower survey is required for MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn if Bayer can demonstrate that the industry-wide adoption of integrated refuge products (i.e., refuge seed blends) is equal to or greater than 70% of *Bt* corn acres in the Corn Belt. If industry-wide adoption of integrated refuge products (i.e., refuge seed blends) falls below 70% of *Bt* corn acres in the Corn Belt, an anonymous grower survey shall also be conducted in this region during the next growing season using a statistically representative sample of growers who plant 200 or more acres of corn, and grower surveys shall be continued every odd-numbered year until the industry-wide adoption of integrated refuge products (i.e., refuge seed blends) is again equal to or greater than 70% of *Bt* corn acres in this region. Bayer may collaborate with other registrants of *Bt* corn (for example, through the industry working group the ABSTC) to compile the integrated refuge adoption data and to conduct the surveys.

Alternatively, if Bayer is not a participant of an industry working group (e.g., the ABSTC) and Bayer's sales of integrated refuge products are equal to or greater than 70% of Bayer's total *Bt* corn sales in the prior year, then no anonymous grower survey is required in the U.S. Corn Belt. If Bayer's sales of integrated refuge products fall below 70% of Bayer's total *Bt* corn sales, an anonymous grower survey shall also be conducted in this region during the next growing season using a statistically representative sample of growers who plant 200 or more acres of corn, and grower surveys shall be continued every odd-numbered year until sales of integrated refuge products (i.e., refuge seed blends) are again equal to or greater than 70% of Bayer's total *Bt* corn sales in this region.

- A third-party is classified as a party other than the registrant, the grower, or anyone else with a direct interest in IRM compliance for *Bt* corn.

7. The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of survey results must include the reasons, extent, and potential biological significance of any implementation deviations.
8. The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.
9. In years in which the survey is conducted, Bayer shall provide a final written summary of the results of the survey (together with a description of the regions, the methodology used, and the supporting data) to EPA on or before January 31st of the following year. Bayer shall confer with other registrants and EPA on the design and content of the survey prior to its implementation.

10. Bayer shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey, required under paragraphs 6–9 of this section, and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. Bayer must confer with EPA prior to adopting any changes.
11. Bayer shall conduct and enhance an annual on-farm assessment program. Bayer shall train its representatives who make on-farm visits with MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn growers to perform assessments of compliance with IRM requirements. There is no minimum corn acreage size for this program. Therefore, growers will be selected for this program from across all farm sizes. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, Bayer shall take appropriate action, consistent with its phased compliance approach, to promote compliance.
12. Bayer shall implement a program for investigating legitimate tips and complaints that MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, Bayer shall take appropriate action, consistent with its phased compliance approach.
13. If a grower, who purchases MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn for planting, was specifically identified as not being in compliance during the previous year, Bayer shall visit with the grower and evaluate whether the grower is in compliance with the IRM program for the current year.
14. Annually, by January 31st each year, Bayer must provide a report to EPA summarizing the MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend compliance assurance program activities and results for the prior year and plans for the MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend compliance assurance program for the current year. Within one month of submitting this report to EPA, the registrant shall meet with EPA to discuss its findings. The report must inform EPA of the number of growers deemed ineligible to purchase *Bt* corn seed on the basis of continued non-compliance with the insect resistance management refuge requirements. Bayer may elect to coordinate information with other registrants and report collectively the results of compliance assurance programs.
15. Bayer and the seed corn dealers for Bayer must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license numbers of the growers, will be protected.
16. Bayer shall revise and expand its existing Compliance Assurance Program to include the following elements. The registrant may coordinate with other registrants in designing and implementing its Compliance Assurance Program.
17. Bayer will enhance the refuge education program throughout the seed delivery channel:
 - Ensure sales representatives, licensees, seed dealers, and growers recognize the importance of correct refuge implementation and potential consequences of failure to plant the required refuge.
 - Implement a “bag tag” that will be attached to all bags of MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend seed sold and delivered. The purpose of this bag tag is to remind growers that MON 89034 x TC1507 x MON 87411 x DAS- 59122-7 Seed Blend products

require a separate 20% lepidopteran refuge in cotton growing areas. The PIP product label accepted by EPA must include how this information will be conveyed to growers via text and graphics.

18. Bayer will focus the majority of on-farm assessments on regions with the greatest risks for resistance:

- Use *Bt* corn adoption, pest pressure information, and other available information to identify regions where the risk of resistance is greatest;
- Focus approximately two-thirds of on-farm assessments on these regions, with the remaining assessments conducted across other regions where MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend is used.

19. Bayer will use its available MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend sales records and other information to refine grower lists for on-farm assessments of their compliance with refuge requirements:

- Identify for potential on-farm assessment growers whose sales information indicates they have purchased MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn product but may have purchased little or no refuge seed from the registrant, licensee, or affiliated company.

20. Bayer will contract with third parties to perform on-farm assessments of compliance with refuge requirements:

- The third-party assessors will conduct all first-time on-farm assessments as well as second-year on-farm assessments of those growers found out of compliance in a first-time assessment.

21. Bayer will annually refine the on-farm assessment program for the MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn product to reflect the adoption rate and level of refuge compliance for the product.

22. Bayer will follow up with growers who have been found significantly out of compliance under the on-farm assessment program and are found to be back in compliance the following year:

- All growers found to be significantly out of compliance in a prior year will annually be sent additional refuge assistance information for a minimum of two years by Bayer, seed supplier, or third-party assessor, after completing the assessment process;
- Bayer will conduct follow-up checks on growers found to be significantly out of compliance within three years after they are found to be back in compliance;
- A grower found with a second incident of significant non-compliance with refuge requirements for the *Bt* corn product within a five-year period will be denied access to Bayer's *Bt* corn products the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell *Bt* corn.

e. Insect Resistance Monitoring and Mitigation Plan for MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend

1. EPA is imposing the following conditions for the Cry1A.105, Cry2Ab2, and Cry1F toxins expressed in MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend

Bayer will monitor for resistance to Cry1A.105, Cry2Ab2, and Cry1F expressed in MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn. The monitoring program shall consist of two approaches: (1) focused population sampling and laboratory testing; and (2) investigation of reports of less-than expected control of labeled insects. Should field-relevant resistance be confirmed, an appropriate resistance management action plan will be implemented.

Focused Population Sampling

Bayer shall annually sample and bioassay populations of the key target pests: *Ostrinia nubilalis* (European corn borer; ECB), *Diatraea grandiosella* (southwestern corn borer; SWCB), and *Helicoverpa zea* (corn earworm; CEW). Sampling for the target pests will be focused in areas identified as those with the highest risk of resistance development (e.g., where lepidopteran active *Bt* hybrids are planted on a high proportion of the corn acres, and where the insect species are regarded as key pests of corn). Bioassay methods must be appropriate for the goal of detecting field-relevant shifts in population response to MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn and/or changes in resistance allele frequency in response to the use of MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn and, as far as possible, should be consistent across sampling years to enable comparisons with historical data.

The number of populations to be collected shall reflect the regional importance of the insect species as a pest, and specific collection regions will be identified for each pest. For ECB, a minimum of twelve (12) populations across the sampling region will be targeted for collection at each annual sampling. For SWCB, the target will be a minimum of six (6) populations. For CEW, the target will be a minimum of ten (10) populations. Pest populations should be collected from multiple corn-growing states reflective of different geographies and agronomic conditions. To obtain sufficient sensitivity to detect resistance alleles before they become common enough to cause measurable field damage, each population collection shall attempt to target 400 insect genomes (egg masses, larvae, mated females, and/or mixed-sex adults), but a successful population collection will contain a minimum of 100 genomes. It is recognized that it may not be possible to collect the target number of insect populations or genomes due to factors such as natural fluctuations in pest density, environmental conditions, and area-wide pest suppression.

The sampling program and geographic range of collections may be modified as appropriate based on changes in pest importance and for the adoption levels of MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn. EPA shall be consulted prior to the implementation of such modifications.

Bayer will report to EPA, on or before January 31st of each year, the results of the population sampling and bioassay monitoring program.

Any incidence of unusually low sensitivity to the Cry1A.105, Cry2Ab2, and Cry1F proteins in

bioassays shall be investigated as soon as possible to understand any field relevance of such a finding. Such investigations shall proceed in a stepwise manner until the field relevance can be either confirmed or refuted, and results of these shall be reported to EPA annually on or before January 31st. The investigative steps will include the following:

- i. Re-test progeny of the collected population to determine whether the unusual bioassay response is reproducible and heritable. If it is not reproducible and heritable, no further action is required.
- ii. If the unusual response is reproducible and heritable, progeny of insects that survive the diagnostic concentration will be tested using methods that are representative of exposure to MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn under field conditions. If progeny do not survive to adulthood, any suspected resistance is not field relevant and no further action is required.
- iii. If insects survive steps 1 and 2, resistance is confirmed, and further steps will be taken to evaluate the resistance. These steps may include the following:
 - a. Determining the nature of the resistance (i.e., recessive or dominant, and the level of functional dominance);
 - b. Estimating the resistance allele frequency in the original population;
 - c. Determining whether the resistance allele frequency is increasing by analyzing field collections in subsequent years sampled from the same site where the resistance allele(s) was originally collected;
 - d. Determining the geographic distribution of the resistance allele by analyzing field collections in subsequent years from sites surrounding the site where the resistance allele(s) was originally collected.

Should field-relevant resistance be confirmed, and the resistance appears to be increasing or spreading, Bayer will consult with EPA to develop and implement a case-specific resistance management action plan.

Investigation of Reports of Unexpected Levels of Damage by the Target Pests

Bayer will follow up on grower, extension specialist, or consultant reports of unexpected levels of damage by the lepidopteran pests listed on the pesticide label. Bayer will instruct its customers to contact them if such incidents occur. Bayer will investigate all legitimate reports submitted to the company or the company's representatives.

If reports of unexpected levels of damage lead to the suspicion of resistance in any of the key target pests (ECB, SWCB, and CEW), Bayer will implement the actions described below, based on the following definitions of *suspected resistance* and *confirmed resistance*.

Suspected Resistance

EPA defines *suspected resistance* to mean field reports of unexpected levels of insect-feeding

damage for which:

- The corn in question has been confirmed to be lepidopteran-active *Bt* corn;
- The seed used had the proper percentage of corn expressing *Bt* protein;
- The relevant plant tissues are expressing the expected level of *Bt* protein; and
- It has been ruled out that species not susceptible to the protein could be responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and
- That there could be no other reasonable causes for the damage.

EPA does not interpret *suspected resistance* to mean grower reports of possible control failures or suspicious results from annual insect monitoring assays, nor does EPA intend that extensive field studies and testing be undertaken to confirm scientifically the presence of insects resistant to MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn in commercial production fields before responsive measures are undertaken.

If resistance is *suspected*, Bayer will instruct growers to do the following:

- Use alternative control measures in MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn fields in the affected region to control the target pest during the immediate growing season.
- Destroy MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn crop residues in the affected region within one (1) month after harvest with a technique appropriate for local production practices to minimize the possibility of resistant insects over-wintering and contributing to the next season's target pest population.

Additionally, if possible, and prior to the application of alternative control measures or destruction of crop residues, Bayer will collect samples of the insect population in the affected fields for laboratory rearing and testing. Such rearing and testing shall be conducted as expeditiously as practical.

Confirmed Resistance

EPA defines *confirmed resistance* to mean, in the case of field reports of unexpected levels of damage from the key target pests, that all the following criteria are met:

- There is >30% insect survival and commensurate insect feeding in a bioassay, initiated with neonate larvae, that uses methods that are representative of exposure to *Bt* corn hybrids under field conditions (ECB and SWCB only).
- In standardized laboratory bioassays using diagnostic concentrations of the *Bt* protein suited to the target pest in question, the pest exhibits resistance that has a genetic basis and the level of survivorship indicates that there may be a resistance allele frequency of ≥ 0.1 in the sampled population.

- In standardized laboratory bioassays, the LC_{50} exceeds the upper limit of the 95% confidence interval of the LC_{50} for susceptible populations surveyed both in the original baselines developed for this pest species and in previous years of field monitoring.

Response to Confirmed Resistance in a Key Target Pest as the Cause of Unexpected Levels of Damage in the Field

When field resistance is *confirmed* (as defined above), the following steps will be taken by Bayer:

- EPA will receive notification within 30 days of resistance confirmation;
- Affected customers and extension agents will be notified about confirmed resistance within 30 days;
- Monitoring will be increased in the affected area and local target pest populations will be sampled annually to determine the extent and impact of resistance;
- If appropriate (depending on the resistant pest species, the extent of resistance, the timing of resistance, and the nature of resistance, and the availability of suitable alternative control measures), alternative control measures will be employed to reduce or control target pest populations in the affected area. Alternative control measures may include advising customers and extension agents in the affected area to incorporate crop residues into the soil following harvest to minimize the possibility of over-wintering insects, and/or applications of chemical insecticides;
- Unless otherwise agreed with EPA, stop sale and distribution of the relevant lepidopteran-active *Bt* corn hybrids in the affected area immediately until an effective local mitigation plan, approved by EPA, has been implemented;
- Bayer will develop a case-specific resistance management action plan within 90 days according to the characteristics of the resistance event and local agronomic needs. Bayer will consult with appropriate stakeholders in the development of the action plan, and the details of such a plan shall be approved by EPA prior to implementation;
- Bayer will notify affected parties (e.g., growers, consultants, extension agents, seed distributors, university cooperators, and state/federal authorities as appropriate) in the region of the resistance situation and approved action plan; and
- In subsequent growing seasons, maintain sales suspension and alternative resistance management strategies in the affected region(s) for the *Bt* corn hybrids that are affected by the resistant population until an EPA-approved local resistance management plan is in place to mitigate the resistance.

A report on results of resistance monitoring and investigations of damage reports must be submitted to EPA, on or before January 31st of each year, for the duration of the registration.

2. EPA is imposing the following conditions for the Cry34/35Ab1, DvSnf7 dsRNA, and Cry3Bb1 toxins expressed in MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend:

a) Investigation of Reports of Unexpected Levels of Damage (UXD) by Corn Rootworm (CRW): Performance Inquiries

- 1) Bayer is required to investigate "performance inquiries" (i.e., reports of unexpected CRW damage to MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn) from growers. Fields (defined as a tract separated by permanent boundaries such as fences, permanent waterways, woodlands, croplines not subject to change because of farming practices, or other similar features) with unexpected damage that meet both of the criteria below must be subjected to the follow-up actions in part 2) below:
 - a. The affected plants are confirmed to be MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn plants (take leaf samples to determine the presence of the CRW-active *Bt* protein); and
 - b. Corn rootworm feeding caused root damage with a Node Injury Score (NIS) > 0.5 on at least 50% of plants surveyed in a transect sampling of the damaged site(s) within the field.
- 2) Follow-up actions (performance inquiries). For MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn fields meeting the criteria in part 1) above, Bayer must take the following actions:
 - a. Collect at least 250 (ideally 500 or more) CRW adult individuals from the damaged site within the field in question. Collections may be extended to the whole field, if necessary to obtain sufficient CRW adult individuals. Collected populations must be subjected to the steps described for "investigation of populations of concern" in section e(2)(b) below.
 - If collections are unsuccessful, visit affected farm or field the following year (assuming the grower continues to be a customer and repurchases seed and does not rotate the field to a non-host crop) and attempt to collect CRW adults. If beetles are not present the subsequent year, see section e(2)(b)(3)(c) below.
 - b. Review with the grower their CRW management practices and provide CRW management recommendations including an assessment of corn fields with similar trait(s) adjacent to the affected corn field that are managed by the same grower.
 - c. Use of single trait products containing the CRW traits in MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend in fields with unexpected damage in previous years should be discouraged. Recommended management options include, but are not limited to, the following:
 - Primary option:
 - Rotation to non-host crop (e.g., soybean)
 - Secondary options:
 - Use of pyramided *Bt* corn products one or more different CRW PIP trait(s);

- Use of different CRW PIP traits (i.e., an alternative CRW-active PIP);
 - Use of non-PIP or non-CRW protected corn.
 - Tertiary options:
 - If additional pest management need is determined beyond the secondary options listed above, use of the same pyramided *Bt* corn product is acceptable if it is very unlikely that both of the traits are affected (e.g., the affected field experienced UXD to one of the traits in the product in the previous year, the NIS is less than 1.0, there has been no continuous use of the second trait in the product in the affected field, and Bayer has not been informed of resistance to the second trait in the county)
 - Additional corn rootworm control tools (e.g., soil applied insecticides, chemigation) should be considered
 - d. If field(s) with UXD is/are planted to a non-host crop (e.g., soybean) the following year, then the area will be considered “mitigated” (as discussed in section e(2)(b)(3)(d) below) even if subsequent bioassay results show that the population was resistant. No further action will be required by Bayer for the UXD case.
- 3) Bayer must submit an annual report to EPA detailing activities related to investigations of unexpected damage (UXD). This report will include the information from the most recent and previous corn growing seasons:
- a. Information from the most recent season:
 - The number of UXD reports investigated;
 - Location (by county and state);
 - CRW sampling (number and location of populations collected).
 - b. Information from the previous season:
 - The final disposition of UXD fields from the previous season (i.e., the management practices employed in response to UXD if the grower continues to be a customer.
 - Results from bioassays conducted on CRW populations from UXD fields where the primary management option, rotation to non-host crop, was not used.
 - c. Grower information, such as farm addresses or other personally identifiable information, or other sensitive business/customer information must not be included in this report. This report must be submitted by November 30th each year.

b) Investigation of Populations of Concern

- 1) Bayer must conduct investigations of all CRW populations collected as part of the performance

inquiry process in section e(2)(a) above. These investigations must include the use of an EPA-approved bioassay to determine if sampled CRW populations are resistant to any of the CRW PIP toxins in MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend. Acceptable assays must be able to function as diagnostic tools capable of distinguishing resistant populations from susceptible ones. Unless previously approved, Bayer must consult with EPA on their bioassay prior to its use.

- 2) A CRW population will be considered by EPA to be resistant to a CRW PIP toxin if the following criteria are met and additional collections and testing are not deemed to be necessary (based on part 3) below):
 - a. An initial performance inquiry investigation results in a finding of Unexpected Damage; and
 - b. Where green tissues are available and if plants are unusually stressed due to agronomic and/or environmental factors, *Bt* protein levels in affected plants are found to be within the documented range for that hybrid (if data are available); and
 - c. Either (A): On-plant bioassays of insect collections from the UXD fields result in the following two statistically relevant comparisons:
 - i. A statistically significant difference in measures of either mortality or sublethal effects (growth/development) between the field population and a relevant susceptible control population (i.e., one that responds as a typical susceptible field population) on *Bt* corn containing the single PIP and/or lack of a statistically significant difference in measures of mortality or sublethal effect between the field population and a resistant positive control population¹; and
 - ii. A lack of a statistically significant difference in the same measures of the field population raised on *Bt* corn containing the single PIP and non-PIP corn plants.

Or (B): Sublethal seedling bioassay of insect collections from the UXD fields result in two statistically relevant comparisons:

- i. A statistically significant difference in measures of sublethal effects (growth/development) for populations on *Bt* corn containing the single PIP (normalized using non-PIP) seedlings between the field population and a relevant susceptible control population where available or historical field populations and/or lack of a statistically significant difference in measures between the field population and a resistant positive control population¹; and
- ii. A lack of a statistically significant difference in the same measures of the field population raised on *Bt* corn seedlings containing the single PIP and non-PIP corn seedlings

Or (C): Diet-based bioassays of insect collections from the UXD fields result in two statistically relevant comparisons:

¹ If a resistant positive control population is not available or accessible, Bayer must consult with EPA prior to initiating bioassays and work to develop an appropriate resistant positive control population.

- i. A statistically significant difference in measures of lethal or sublethal effects (growth/development) on diet containing the *Bt* protein (diagnostic concentration or concentration-response measures) between the field population and a relevant susceptible control population where available or historical field populations and/or lack of a statistically significant difference in measures between field population and a resistant positive control population¹; and
 - ii. Either a lack of a statistically significant difference in the same measures of the field population exposed to diet containing the *Bt* protein (diagnostic concentration) and diet not containing the *Bt* protein and/or lack of a statistically significant difference in measures between the field population and a resistant positive control population, or lack of a statistically significant concentration and/or lack of a statistically significant difference in concentration response between the field and a resistant positive control population¹.
- 3) Mitigation, as detailed in section e(2)(c) below, is required for any CRW population that meets EPA's resistance criteria above for any of the CRW traits in MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend, unless the circumstances described below are applicable.
 - a. To minimize the potential for incorrectly reaching a conclusion of resistance, another year of CRW adult collections and additional testing is needed to determine resistance if:
 - i. The results of the bioassays are inconclusive (e.g., the results of the statistical analysis are unclear because of low sample sizes); or
 - ii. Another reasonable explanation for the unexpected damage exists (e.g., high pest pressure and/or high plant stress).
 - b. In these cases, Bayer and EPA will discuss and align on next steps before reaching any resistance conclusion.
 - c. If CRW collections are not possible in the current year or subsequent year due to successful management practices, then no further investigation is needed. The population would be considered "mitigated" meaning, in this case, that the population is suppressed or extirpated for the UXD field. However, EPA recommends that Bayer continue to be vigilant in areas where CRW populations were successfully mitigated.
 - d. If a UXD field receives non-host crop (e.g., soybean) rotation the following year as described in Section e(2)(a)(2) above, no additional mitigation is subsequently required.
- c) Mitigation of CRW Populations Meeting EPA's Resistance Criteria
 - 1) For any CRW population found to be resistant to one or more of the CRW traits in MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend under EPA's criteria described in section e(2)(b) above, Bayer must take the following steps:
 - a) Bayer must inform EPA of all the results of the bioassays as soon as possible, but at least within 30 days if measures are triggered.

- b) The mitigation action area (MAA) is defined as the growers' farming operation up to a ½ mile radius from the damaged site that produced the resistant population.
- c) Within 30 days of informing EPA of the results of the bioassays, Bayer must notify state extension agents and crop consultants who operate within the county in which resistance was identified. Information shared must include identification of the county in which resistance was detected and trait(s) affected.
- d) Within the MAA, Bayer must do the following:
 - i. Prior to finalizing the grower's seed order for the following season, inform the affected grower and other registrants that hold registrations containing the compromised trait(s). Bayer must also inform neighboring growers if those growers are customers of Bayer. Information shared must include identification of the county in which resistance was detected and trait(s) affected;
 - ii. Discontinue sales/planting of products containing the compromised trait(s) without additional/alternative (i.e. non-compromised) CRW traits until resistance has been demonstrated to have been mitigated. Other *Bt* registrants selling such products in the MAA are encouraged, but cannot be required, to follow suit;
 - iii. Bayer must monitor the resistant population in the MAA, as long as grower remains a customer of the company, until mitigation has been demonstrated as described in part e below unless otherwise agreed with EPA.
 - iv. Require any pyramids sold by Bayer containing the compromised trait(s) be planted with a 20% refuge until resistance has been demonstrated to have been mitigated. Other *Bt* corn registrants selling such pyramided products in the MAA are encouraged, but cannot be required by this term of registration, to follow suit;
 - v. For Bayer's affected customer's field(s), the mitigation goal is to control the resistant CRW population. Within the MAA Bayer shall encourage the use of "Mitigation Practices" including:
 - 1. Primary option: Rotation to a non-host crop (e.g., soybean);
 - 2. Secondary options:
 - a. Use of pyramided *Bt* corn products with different CRW PIP traits;
 - b. Only in the case that the resistance definition for one of the CRW traits in the MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend is not met, continued use of the product with a 20% refuge;
 - c. Use of different CRW PIP traits (i.e., an alternative CRW-active PIP);
 - d. Use of non-PIP corn or non-CRW protected corn (with/without soil-applied insecticide);

3. Tertiary options:

- a. If additional pest management need is determined beyond the secondary options listed above, additional CRW control tools (e.g., soil insecticides, seed-applied insecticides, chemigation) should be used.
 - b. Use of foliar applications to control adults (when appropriate economic thresholds have been met) may be used in conjunction with one or more of the above.
- e) A resistant CRW population in the MAA will be considered mitigated if one of the following criteria is met:
- i. Corn fields within the MAA are rotated to a non-host crop (e.g. soybean) for one growing season.
 - ii. After implementation of mitigation practices (part d.v above), resistance monitoring (sampling) is conducted but few CRW are found (i.e., <0.1 adults per plant) and environmental conditions (e.g., weather) are unlikely to be responsible for the lack of adult CRW presence. If environmental conditions are a factor, then monitoring should continue for another season.
 - iii. After implementation practices (part d.v above), resistance monitoring (sampling) is conducted, CRW are found and collected, and bioassays (section e(2)(b)(2) above) show that the population susceptibility to the compromised trait(s) has returned to baseline levels.
- f) The mitigation actions in part d above can be lifted, and growers can resume the use of MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn as a primary tool for CRW management in the MAA, only when Bayer demonstrates that successful mitigation as described in part e above has been achieved.

- 2) Based on further research to understand CRW resistance to *Bt* PIPs, EPA will consider refinements to the resistance mitigation program. Such research may include characterizing the genetics of resistance (e.g., number of genes, functional dominance, mechanism of resistance, and cross-resistance) and the biology of resistant insects (e.g., fitness in the presence and absence of the product), and other control tactics.

f. Refuge Assurance Program for MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend

Bayer must implement a Blended Seed Refuge Assurance Program designed to ensure MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn products are formulated with the appropriate rate of refuge seeds. The program must include the following four elements:

1. Trait purity check on seed lots prior to blending;
2. ISO 9000 Standard Operating Procedures for the blending process;
3. Calibration of blending equipment; and

4. Records and data retention records for seed blend products.
 - Calibration records - Bayer will retain documentation for a specified period of time on the equipment calibration including the procedure, when it was conducted and the results.
 - Blend proportion records (weight and kernel based) - Bayer will retain documentation for a specified period of time on the kernel per pound data of the components, the calculations to determine the proportions based on weight and the actual weights that are blended together to make up an MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend corn product by seed lot.

All records must be maintained at the Bayer blending facility and must be available for the EPA review upon request.

Should Bayer CropScience LP or its Licensees be notified by USDA/AMS or State Seed Control Officials that their seed blend products have been found to have a lower percentage of the refuge component than is represented on the label, they must notify EPA within 30 days. This would constitute information reportable under FIFRA 6(a)(2).

g. Annual Reporting Requirements for MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend

The following annual reports must be submitted:

1. Compliance Assurance Plan: Compliance Assurance Program activities, including IRM Grower Survey results and on-farm assessment results for the prior year and plans for the compliance assurance program for the current year, on or before January 31st each year.
2. Insect Resistance Monitoring Results (Cry1A.105, Cry2Ab2, and Cry1F only): results of monitoring and investigations of damage reports, January 31st of each year.
3. IPM Stewardship Program (Cry34/35Ab1, DvSnf7 dsRNA, and Cry3Bb1 only): Activities conducted under the IPM stewardship program, including an anonymous survey of grower practices, adoption levels of the various crop rotation options (if employed) and other elements of the stewardship program, on or before January 31st of each year.
4. Unexpected Damage Investigations (Cry34/35Ab1, DvSnf7 dsRNA, and Cry3Bb1 only): Activities related to investigations of unexpected damage (UXD), including number and location of UXD cases, insect sampling, bioassays, and final disposition of UXD fields from the most recent and previous corn growing seasons, on or before November 30th of each year.

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 and conditions. If you fail to satisfy these terms and conditions, the EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e).

A stamped copy of the labeling is enclosed for your records. Please also note that the record for this product currently contains the following acceptable Confidential Statement of Formula (CSF):

- Basic CSF dated 2/26/2016

If you have any questions, please contact Matt Weiner by phone at (202) 564-1509 or via email at weiner.matthew@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Alan Reynolds', with a stylized flourish at the end.

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

Enclosure

ACCEPTED

06/14/2022

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 524-631

Plant-Incorporated Protectant Label

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

Insect-Protected, Herbicide-Tolerant Corn

(OECD Unique Identifier: MON-89034-3 × DAS-01507-1 × 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-89034-3 × DAS-01507-1 × 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-89034-3 × DAS-01507-1 × 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-89034-3 × DAS-01507-1 × 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-89034-3 × DAS-01507-1 × 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-89034-3 × DAS-01507-1 × 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-89034-3 × DAS-01507-1 × 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-89034-3 × DAS-01507-1 × 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-89034-3 × DAS-01507-1 × 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-89034-3 × DAS-01507-1 × MON-87411-9 × DAS-59122-7) ≤ 0.0001%*

*Percentage (wt/wt) on a dry weight basis for forage tissue

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET CONTENTS _____

EPA Registration No. 524-631

EPA Establishment No. 524-MO-002

Bayer CropScience LP
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. This product must be used as specified in the terms and conditions of the registration.

This Plant-Incorporated Protectant (PIP) 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.

MON 89034 × TC1507 × MON 87411 × DAS-59122-7 seed blend 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 MON 89034 × TC1507 × MON 87411 × DAS-59122-7 seed blend, 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 on the bag or bag/tag for MON 89034 × TC1507 × MON 87411 × DAS-59122-7 seed blend or other applicable product use documents.

Sales of corn hybrids that contain Bayer's *Bt* corn plant-incorporated pesticide(s) must be accompanied by either an IRM/Grower Guide or information on the bag or bag-tag 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 *B.t.* proteins is planted.

Corn seed bags or bag tags for products containing MON 89034 × TC1507 × MON 87411 × DAS-59122-7 seed blend must include the refuge size requirement in text and graphical format.

INSECT RESISTANCE MANAGEMENT

Growers are instructed to read information on insect resistance management in the bag and/or bag-tag.

These refuge requirements do not apply to planting of inbred/hybrid corn seed productions, breeding, and small scale research trials on 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 seed producer must ensure a minimum of 5% non-PIP refuge seed is included with MON 89034 × TC1507 × MON 87411 × DAS-59122-7 in each lot of seed corn. 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 87411 × DAS-59122-7 seed in the seed mixture receives the same treatment.

The IRM/Grower Guide for MON 89034 × TC1507 × MON 87411 × DAS-59122-7 seed blend or comparable information presented on the product bag or bag-tag must contain the following information:

This product is a seed mixture containing MON 89034 × TC1507 × MON 87411 × DAS-59122-7 and a minimum of 5% non-*B.t.* seed that when planted creates an interspersed refuge within the field. There are no requirements for a separate structured refuge for MON 89034 × TC1507 × MON 87411 × DAS-59122-7 seed blend when planted in the U.S. corn-growing region, including Alaska and Hawaii, because the refuge seed is contained within the bag/container.

The interspersed refuge can only be used by planting seed corn specifically generated by qualified seed producers/conditioners licensed by the registrant. Insecticidal treatments labeled for adult CRW control are discouraged during the time of adult CRW emergence.

The seed mix refuge option for MON 89034 × TC1507 × MON 87411 × DAS-59122-7 seed blend satisfies the refuge requirements in all regions other than in the cotton-growing region where corn earworm is a significant pest as defined below.

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

In the cotton-growing region where corn earworm is a significant pest, as defined below, MON 89034 × TC1507 × MON 87411 × DAS-59122-7 seed blend requires the planting of an additional 20% structured refuge (i.e., 20 acres of non-*B.t.* corn for every 80 acres of MON 89034 × TC1507 × MON 87411 × DAS-59122-7 seed blend planted).

The 20% refuge must be planted with corn hybrids that do not contain *B.t.* technologies for the control of corn rootworms or corn borers. The refuge and the MON 89034 × TC1507 × MON 87411 × DAS-59122-7 seed blend 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 planted as a separate block that is within ½ mile of the MON 89034 × TC1507 × MON 87411 × DAS-59122-7 seed blend field. 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 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 seed blend 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 the 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, Ochiltree, 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>
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>

MON 89034 × TC1507 × MON 87411 × DAS-59122-7 seed blend is a product of Bayer'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>