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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 7, 2019

David Chi
Regulatory Affairs Manager
Monsanto Company
800 North Lindberg Blvd.
St. Louis, MO 63167

Subject: Pesticide Registration Improvement Act (PRIA) Amendment – B900 Amendment to extend the expiration date of the registration, update the registration terms, remove sweet corn as a use, and remove alternate brand names from the product label.
Product Name: MON 89034 x MON 88017
EPA Registration Number: 524-576
Submission Date: September 7, 2018
OPP Decision Number: 544525

Dear Mr. Chi:

The amendment referenced above, submitted in connection with registration under Section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable provided that you comply with the updated terms and conditions as described in this letter.

1. The subject registration will automatically expire at midnight on December 31, 2020.

2. Monsanto must adhere to the transition strategy detailed in its submission titled "Amended Phase Out Plan for MON 89034 x MON 88017 (VT Triple PRO®)" (dated September 7, 2018) (MRID: 506395-02).

3. The subject registration will be limited to the subject registration will be limited to *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 proteins and the genetic material necessary for their production (vector PVZMIR245) in MON 89034 corn (OECD Unique Identifier: MON-89∅34-3 x MON-88∅17-3) and *Bacillus thuringiensis* Cry3Bb1 protein and the genetic material necessary for its production (vector PV-ZMIR39) in MON 88017 corn (OECD Unique Identifier: MON-89∅34-3 x MON-88∅17-3) for use in field corn.

4. Submit and/or cite all data required for registration or registration review of MON 89034 x MON 88017 when the EPA requires all registrants of similar products to submit such data.

5. 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.

6. Monsanto must commit to do the following Insect Resistance Management (IRM) Program, consisting of the following elements:

    - Requirements for Monsanto to implement an IPM-based stewardship program designed to reduce selection pressure for corn rootworm (CRW) resistance.

    - Requirements relating to creation of a refuge for the Cry3Bb1, Cry1A.105, and Cry2Ab2 components that meets the requirements of the individual traits. The refuge for both traits may be combined by planting non-*Bacillus thuringiensis* (*Bt*) corn as the refuge, or the refuge for each trait may be planted separately. In the latter case, corn rootworm-resistant *Bt* corn may be planted in the lepidopteran refuge for the Cry1A.105 and Cry2Ab2 components, and lepidopteran-resistant *Bt* corn may be planted in the corn rootworm refuge for the Cry3Bb1 component.

    - Requirements for Monsanto to prepare and require MON 89034 x MON 88017 users to sign grower agreements that impose binding contractual obligations on growers to comply with the refuge requirements.

    - Requirements for Monsanto to develop, implement, and report to EPA on programs to educate growers about IRM requirements.

    - Requirements for Monsanto to develop, implement, and report to EPA on programs to evaluate and promote growers' compliance with IRM requirements.

    - Requirements for Monsanto 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 and Cry2Ab2 proteins in the target insects.

    - Requirements for Monsanto to develop, and if triggered, to implement a remedial action plan that would contain measures Monsanto would take in the event that any field-relevant insect resistance to Cry1A.105 and/or Cry2Ab2 was detected, as well as to report on activity under the plan to EPA.

    - Requirements for Monsanto to investigate reports of unexpected CRW damage to MON 89034 x MON 88017 from growers ("performance inquiries") and sample CRW to determine if the insects are resistant to Cry3Bb1.

    - Requirements for Monsanto to recommend CRW management options to growers in response to cases of unexpected CRW damage to MON 89034 x MON 88017.

    - Requirements regarding mitigation and notification actions that Monsanto would take in the event that CRW resistance is detected.

    - Requirements for Monsanto 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. Monsanto is required to submit reports within three months of the Agency's request.

- Bag Tag Requirements for MON 89034 x MON 88017. Seed bags and/or bag tags for corn hybrids that contain plant- incorporated protectants produced in MON 89034 x MON 88017 must display the registration number and active ingredients, and stipulate that growers read the Monsanto 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 Monsanto, on or before August 31st of each year, to submit reports on Cry1A.105 and Cry2Ab2 resistance monitoring.

a. Integrated Pest Management Stewardship Program

1. Monsanto must implement an IPM-based stewardship program for MON 89034 x MON 88017. 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-*Bt* or non-CRW protected *Bt* corn. As part of the stewardship program, Monsanto 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 MON 88017 is not recommended for control of CRW except under limited circumstances and in consultation with extension, crop consultants or other local experts. As part of the stewardship program, Monsanto 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. Monsanto 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. Monsanto 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 MON 88017

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.

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.

1) Corn-Belt Refuge Requirements

For MON 89034 x MON 88017 grown outside cotton-growing areas (e.g., the Corn Belt), 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. Two options for the deployment of the refuge are available to growers.

The first option is planting a common refuge for both corn borers and corn rootworms. The common refuge must be planted with corn hybrids that do not contain *Bt* technologies for the control of corn rootworms or corn borers. The refuge area must represent at least 20% of the grower's corn acres (i.e., sum of MON 89034 x MON 88017 acres and refuge acres). It must be planted as a block adjacent to the MON 89034 x MON 88017 field, perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The common refuge may be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge may also be treated with a non-*Bt* foliar insecticide for control of late season pests if pest pressure reaches an economic threshold for damage (determined using methods recommended by local or regional professionals); however, if rootworm adults are present at the time of foliar applications, then the MON 89034 x MON 88017 field must be treated in a similar manner.

The second option is planting separate refuge areas for corn borers and corn rootworms. The corn borer refuge must be planted with a non-*Bt*/lepidopteran-protected hybrid, must represent at least 5% of the grower's corn acres (i.e. sum of MON 89034 x MON 88017 acres and corn borer refuge acres), and must be planted within ½ mile of the MON 89034 x MON 88017 field. Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The corn borer refuge may be treated with a soil-applied or seed-applied insecticide for corn rootworm larval control or a non-*Bt* foliar-applied insecticide for corn borer control if pest pressure reaches an economic threshold for damage (determined using methods recommended by local or regional professionals). The corn rootworm refuge must be planted with a non-*Bt*/corn rootworm-protected hybrid but may be planted with *Bt* corn hybrids that control corn borers. The corn rootworm refuge must represent at least 20% of the grower's corn acres (i.e. sum of MON 89034 x MON 88017 acres and corn rootworm refuge acres) and must be planted as an adjacent block, perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The corn rootworm refuge may be treated with a soil-applied or seed- applied insecticide to control rootworm larvae and other soil pests. The refuge may also be treated with a non-*Bt* foliar insecticide for control of late season pests; however, if rootworm adults are present at the time of foliar applications, then the MON 89034 x MON 88017 field must be treated in a similar manner.

2) Cotton-Growing Area Refuge Requirements

For MON 89034 x MON 88017 grown in cotton-growing areas, 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.

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, 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, Sussex), and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

Two options for the deployment of the refuge are available to growers.

The first option is planting a common refuge for both corn borers and corn rootworms. The common refuge must be planted with corn hybrids that do not contain *Bt* technologies for the control of corn rootworms or corn borers. The refuge area must represent at least 20% of the grower's corn acres (i.e. sum of MON 89034 x MON 88017 acres and refuge acres). It must be planted as a block adjacent to the MON 89034 x MON 88017 field, perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The common refuge may be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge may also be treated with a non-*Bt* foliar insecticide for control of late season pests if pest pressure reaches an economic threshold for damage (determined using methods recommended by local or regional professionals); however, if rootworm adults are present at the time of foliar applications, then the MON 89034 x MON 88017 field must be treated in a similar manner.

The second option is planting separate refuge areas for corn borers and corn rootworms. The corn borer refuge must be planted with a non-*Bt*/lepidopteran-protected hybrid, must represent at least 20% of the grower's corn acres (i.e. sum of MON 89034 x MON 88017 acres and corn borer refuge acres), and must be planted within ½ mile of the MON 89034 x MON 88017 field.

Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The corn borer refuge may be treated with a soil- applied or seed-applied insecticide for corn rootworm larval control or a non-*Bt* foliar-applied insecticide for corn borer control if pest pressure reaches an economic threshold for damage (determined using methods recommended by local or regional professionals). The corn rootworm refuge must be planted with a non-*Bt*/corn rootworm-protected hybrid but may be planted with *Bt* corn hybrids that control corn borers. The corn rootworm refuge must represent at least 20% of the grower's corn acres (i.e. sum of MON 89034 x MON 88017 acres and corn rootworm refuge acres) and must be planted as an adjacent block, perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The corn rootworm refuge may be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge may also be treated with a non-*Bt* foliar insecticide for control of late season pests; however, if rootworm adults are present at the time of foliar applications then the MON 89034 x MON 88017 field must be treated in a similar manner.

c. Grower Agreements for MON 89034 x MON 88017

1. Persons purchasing MON 89034 x MON 88017 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. Monsanto 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 MON 88017 will affirm annually that they are contractually bound to comply with the requirements of the IRM program.

4. Monsanto must continue to use its current grower agreement for MON 89034 x MON 88017. If Monsanto 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, Monsanto 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. Monsanto shall maintain records of all MON 89034 x MON 88017 grower agreements for a period of three (3) years from December 31st of the year in which the agreement was signed.

6. Monsanto shall make available to the Agency upon request records of the number of units of MON 89034 x MON 88017 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. Monsanto is required to submit reports within three months of the Agency's request.

7. Monsanto 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 MON 88017

1. Monsanto 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 MON 88017 users the importance of complying with the IRM program and guidance to growers on actions to take when unexpected damage occurs. The program shall include information encouraging MON 89034 x MON 88017 users to pursue optional elements of the IRM program relating to refuge configuration and proximity to MON 89034 x MON 88017 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 MON 88017 user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Monsanto 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. Monsanto 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, Monsanto 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). Monsanto 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. Monsanto must implement and improve an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing MON 89034 x MON 88017 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 Monsanto's *Bt* corn products. Monsanto 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. Monsanto 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, Monsanto must use a consistent set of standards for responding to non-compliance. An individual grower found to be significantly out of compliance two (2) years in a row would be denied access the next year to Monsanto's *Bt* corn products for which the grower is required to plant a separate structured refuge. 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 MON 88017. The survey shall be conducted in odd-numbered years beginning in 2019 and shall include growers who plant 100 or more acres of corn in the Southern U.S. corn-cotton areas. Monsanto 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 MON 88017 if Monsanto 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. Monsanto 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 Monsanto is not a participant of an industry working group (e.g., the ABSTC) and Monsanto's sales of integrated refuge products are equal to or greater than 70% of Monsanto's total *Bt* corn sales in the prior year, then no anonymous grower survey is required in the U.S. Corn Belt. If Monsanto's sales of integrated refuge products fall below 70% of Monsanto'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 Monsanto'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, Monsanto 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. Monsanto shall confer with other registrants and EPA on the design and content of the survey prior to its implementation.

10. Monsanto 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. Monsanto must confer with EPA prior to adopting any changes.

11. Monsanto shall conduct and enhance an annual on-farm assessment program. Monsanto shall train its representatives who make on-farm visits with MON 89034 x MON 88017 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, Monsanto shall take appropriate action, consistent with its phased compliance approach, to promote compliance.

12. Monsanto shall implement a program for investigating legitimate tips and complaints that MON 89034 x MON 88017 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, Monsanto shall take appropriate action, consistent with its phased compliance approach.

13. If a grower, who purchases MON 89034 x MON 88017 for planting, was specifically identified as not being in compliance during the previous year, Monsanto 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, Monsanto must provide a report to EPA summarizing the MON 89034 x MON 88017 compliance assurance program activities and results for the prior year and plans for the MON 89034 x MON 88017 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. Monsanto may elect to coordinate information with other registrants and report collectively the results of compliance assurance programs.

15. Monsanto and the seed corn dealers for Monsanto 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. Monsanto 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. Monsanto 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 MON 88017 seed sold and delivered. The PIP product label accepted by EPA must include how this information will be conveyed to growers via text and graphics.

18. Monsanto 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 MON 88017 is used.

19. Monsanto will use its available MON 89034 x MON 88017 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 MON 88017 product but may have purchased little or no refuge seed from the registrant, licensee, or affiliated company.

20. Monsanto 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. Monsanto will annually refine the on-farm assessment program for the MON 89034 x MON 88017 product to reflect the adoption rate and level of refuge compliance for the product.

22. Monsanto 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 Monsanto, seed supplier, or third-party assessor, after completing the assessment process;

    - Monsanto 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 Monsanto'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 MON 88017

1. <u>EPA is imposing the following conditions for the Cry1A.105 and Cry2Ab2 toxins expressed in MON 89034 x MON 88017</u>

Monsanto must monitor for resistance to Cry1A.105 and Cry2Ab2 expressed in MON 89034 x MON 88017.

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.

<u>Focused Population Sampling</u>

Monsanto 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 MON 88017 and/or changes in resistance allele frequency in response to the use of MON 89034 x MON 88017 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 MON 88017. EPA shall be consulted prior to the implementation of such modifications.

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

Any incidence of unusually low sensitivity to the Cry1A.105 and/or Cry2Ab2 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 August 31st. The investigative steps will include the

following:

1. 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.

2. 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 MON 88017 under field conditions. If progeny do not survive to adulthood, any suspected resistance is not field relevant and no further action is required.

3. 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, Monsanto 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

Monsanto will follow up on grower, extension specialist, or consultant reports of unexpected levels of damage by the lepidopteran pests listed on the pesticide label. Monsanto will instruct its customers to contact them if such incidents occur. Monsanto 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), Monsanto 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 MON 88017 in commercial production fields before responsive measures are undertaken.

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

- Use alternative control measures in MON 89034 x MON 88017 fields in the affected region to control the target pest during the immediate growing season.

- Destroy MON 89034 x MON 88017 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, Monsanto 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 Monsanto:

- 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;

- Monsanto will develop a case-specific resistance management action plan within 90 days according to the characteristics of the resistance event and local agronomic needs. Monsanto 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;

- Monsanto 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 August 31st of each year, for the duration of the registration.

2. <u>EPA is imposing the following conditions for the Cry3Bb1 toxin expressed in MON 89034 x MON 88017:</u>

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

(1) Monsanto is required to investigate "performance inquiries" (i.e., reports of unexpected CRW damage to MON 89034 x MON 88017) 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 MON 88017 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) > 1.0 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 MON 88017 fields meeting the criteria in part 1) above, Monsanto 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 MON 88017 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 single-CRW PIP traits (i.e., an alternative CRW-active PIP)
  - Use of non-*Bt* or non-CRW protected corn
- Tertiary options:
  - If additional pest management need is determined beyond the secondary options listed above, additional corn rootworm control tools (e.g., soil insecticides, seed-applied insecticides, chemigation) should be used.

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 Monsanto for the UXD case.

(3) Monsanto 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 Population of Concern

1. Monsanto 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 Cry3Bb1. Acceptable assays must be able to function as diagnostic tools capable of distinguishing resistant populations from susceptible ones. Unless previously approved, Monsanto 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 population[1]; 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-*Bt* 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-*Bt*) 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 population[1]; 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-*Bt* corn seedlings

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

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 population[1]; 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 population[1].

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 MON 88017, 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

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

ii. Another reasonable explanation for the unexpected damage exists (e.g., high pest pressure and/or high plant stress).

b. In these cases, Monsanto 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 Monsanto 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 the Cry3Bb1 trait in MON 89034 x MON 88017 under EPA's criteria described in section e(2)(b) above, Monsanto must take the following steps:

a) Monsanto 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, Monsanto 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, Monsanto 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). Monsanto must also inform neighboring growers if those growers are customers of Monsanto. 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. Monsanto 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 Monsanto 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 Monsanto's affected customer's field(s), the mitigation goal is to control the resistant CRW population. Within the MAA Monsanto 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. Use of different single-CRW PIP traits (i.e., an alternative CRW-active PIP);

   c. Use of non-*Bt* 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 MON 88017 as a primary tool for CRW management in the MAA, only when Monsanto 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. Annual Reporting Requirements for MON 89034 x MON 88017

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 and Cry2Ab2 only): results of monitoring and investigations of damage reports, August 31st of each year.

3. IPM Stewardship Program (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 (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 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 label is enclosed for your records. A previously approved Confidential Statement of Formula dated July 2, 2013 is on file for this product.

If you have any questions, please contact Matthew Weiner by phone at (703) 347-0333 or by 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 × MON 88017

(OECD Unique Identifier: MON-89Ø34-3 × MON 88Ø17-3)

Active Ingredients:

Bacillus thuringiensis Cry1A.105 protein and the genetic material necessary for its production (vector PV-ZMIR245) in MON 89034 × MON 88017 corn (OECD Unique Identifier: MON-89Ø34-3 × MON-88Ø17-3).....≤ 0.0024%*

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary for its production (vector PV-ZMIR245) in MON 89034 × MON 88017 corn (OECD Unique Identifier: MON-89Ø34-3 × MON-88Ø17-3).....≤ 0.0057%*

Bacillus thuringiensis Cry3Bb1 protein and the genetic material necessary for its production (vector PV-ZMIR39) in MON 89034 × MON 88017 corn (OECD Unique Identifier: MON-89Ø34-3 × MON-88Ø17-3) .....≤ 0.0070%*

Other Ingredient:

CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and genetic material necessary for its production (vector PV-ZMIR39) in MON 89034 × MON 88017 corn (OECD Unique Identifier: MON-89Ø34-3 × MON-88Ø17-3) .....≤ 0.0069%*

*Percentage (wt/wt) on a dry weight basis whole plant (forage)

KEEP OUT OF REACH OF CHILDREN

CAUTION

EPA Registration No. 524-576
EPA Establishment No. 524-MO-002

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

NET CONTENTS_____

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with this labeling. This product must be used as specified in the terms and conditions of the registration.

MON 89034 × MON 88017 protects corn crops from leaf, stalk, and ear damage caused by corn borers and root damage caused by corn rootworm larvae.

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

1) Refuge Requirements for MON 89034 × MON 88017 Field Corn

In order to minimize the risk of corn borers and corn rootworms developing resistance to MON 89034 × MON 88017 corn, an insect resistance management (IRM) plan must be implemented which includes planting of a structured refuge.

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 PIP active ingredient per registrant per year. Furthermore, these refuge requirements do not apply to commercial hybrid sweet corn.

The refuge and MON 89034 × MON 88017 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 MON 89034 × MON 88017 corn must also be planted on rotated ground. If the combined refuge is planted on continuous corn, then MON 89034 × MON 88017 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 × MON 88017 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 MON 89034 × MON 88017.

a) Corn-Belt/Non-Cotton Growing Area Refuge Requirements

For MON 89034 × MON 88017 field corn grown outside cotton-growing areas (*e.g.*, the Corn Belt), two options for deployment of the refuge are available to growers.

The first option is planting a **common refuge** for both corn borers and corn rootworms. The common refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn borers or corn rootworms. The refuge area must represent at least 20% of the grower's corn acres (*i.e.*, sum of MON 89034 × MON 88017 acres and refuge acres; refuge area must contain 20 acres of corn for every 80 acres of MON 89034 × MON 88017 corn planted). It must be planted as block within or adjacent (*e.g.*, across the road) to the MON 89034 × MON 88017 field, 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 common refuge can be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-Bt foliar insecticide for the control of late season pests if pest pressure reaches an economic threshold for damage; however, if rootworm adults are present at the time of foliar applications then the MON 89034 × MON 88017 field (acres) must be treated in a similar manner. Economic thresholds will be determined

using methods recommended by local or regional professionals (*e.g.*, Extension Service agents, crop consultants, etc.

The second option is planting **separate refuge** areas (*e.g.*, two refuge areas, a double refuge, or paired refuge areas) for corn borers and corn rootworms. Refuge planting options include: separate fields, blocks within fields (*e.g.*, along the edges or headlands), perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The corn borer refuge must be planted with corn that is not a lepidopteran-protected Bt hybrid, must represent at least 5% of the grower's corn acres, and must be planted within ½ mile of the MON 89034 × MON 88017 field. The corn borer refuge can be treated with a soil-applied or seed-applied insecticide for corn rootworm larval control, or a non-Bt foliar applied insecticide for corn borer control if pest pressure reaches an economic threshold for damage. Economic thresholds will be determined using methods recommended by local or regional professionals (*e.g.*, Extension Service agents, crop consultants, etc.).

The corn rootworm refuge must be planted with corn that is not a corn rootworm-protected Bt hybrid, but can be planted with Bt hybrids that control corn borers. The corn rootworm refuge must represent at least 20% of the grower's corn acres (*i.e.*, corn rootworm refuge must contain 20 acres of corn for every 80 acres of MON 89034 × MON 88017 corn planted) and must be planted as a block within or adjacent to the MON 89034 × MON 88017 field, strips around the field, perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least four (4) consecutive rows wide. The corn rootworm refuge can be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-Bt foliar insecticide for control of late season pests; however, if corn rootworm adults are present at the time of foliar applications then the MON 89034 × MON 88017 field must be treated in a similar manner.

b) Cotton-Growing Area Refuge Requirements

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, 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, Sussex), and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, Stoddard).

For MON 89034 × MON 88017 field corn grown in cotton growing areas of the U.S. the common refuge and separate refuge options (*e.g.*, two-refuge options, double-refuge options, paired-refuge options) are available as specified below.

The first option is planting a **common refuge** for both corn borers and corn rootworms. The common refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn borers or corn rootworms. The refuge area must represent at least 20% of the grower's corn acres (*i.e.*, sum of MON 89034 × MON 88017 acres and refuge acres; refuge area must contain 20 acres of corn for every 80 acres of MON 89034 × MON 88017 corn planted). It must be planted as block within or adjacent (*e.g.*, across the road) to the MON 89034 × MON 88017 field, 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 common refuge can be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-Bt foliar

insecticide for the control of late season pests if pest pressure reaches an economic threshold for damage; however, if rootworm adults are present at the time of foliar applications then the MON 89034 × MON 88017 field (acres) must be treated in a similar manner. Economic thresholds will be determined using methods recommended by local or regional professionals (*e.g.*, Extension Service agents, crop consultants, etc.).

The second option is planting **separate refuge** areas (*e.g.*, two refuge areas, a double refuge, or paired refuge areas) for corn borers and corn rootworms. Refuge planting options include: separate fields, blocks within fields (*e.g.*, along the edges or headlands), perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The corn borer refuge must be planted with corn that is not a lepidopteran-protected Bt hybrid, must represent at least 20% of the grower's corn acres, and must be planted within ½ mile of the MON 89034 × MON 88017 field. The corn borer refuge can be treated with a soil-applied or seed-applied insecticide for corn rootworm larval control, or a non-Bt foliar applied insecticide for corn borer control if pest pressure reaches an economic threshold for damage. Economic thresholds will be determined using methods recommended by local or regional professionals (*e.g.*, Extension Service agents, crop consultants, etc.).

The corn rootworm refuge must be planted with corn that is not a corn rootworm-protected Bt hybrid, but can be planted with Bt hybrids that control corn borers. The corn rootworm refuge must represent at least 20% of the grower's corn acres (*i.e.*, corn rootworm refuge must contain 20 acres of corn for every 80 acres of MON 89034 × MON 88017 corn planted) and must be planted as a block within or adjacent to the MON 89034 × MON 88017 field, perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least four (4) consecutive rows wide. The corn rootworm refuge can be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-Bt foliar insecticide for control of late season pests; however, if corn rootworm adults are present at the time of foliar applications then the MON 89034 × MON 88017 field must be treated in a similar manner.

Corn Insects Controlled or Suppressed

European corn borer	*Ostrinia nubilalis*
Southwestern corn borer	*Diatraea grandiosella*
Southern cornstalk borer	*Diatraea crambidoides*
Corn earworm	*Helicoverpa zea*
Fall armyworm	*Spodoptera frugiperda*
Stalk borer	*Papaipema nebris*
Lesser corn stalk borer	*Elasmopappus lignosellus*
Sugarcane borer	*Diatraea saccharalis*
Western corn rootworm	*Diabrotica virgifera virgifera*
Northern corn rootworm	*Diabrotica barberi*
Mexican corn rootworm	*Diabrotica virgifera zeae*

Sales of corn hybrids that contain Monsanto's Bt corn plant incorporated protectants must be accompanied by either a Grower Guide or bag tag which includes information on planting, production and insect resistance management.

MON 89034 × MON 88017 is a product of Monsanto's research program offering unique genetic characteristics for specific grower needs and may be protected by one or more U.S. patents found at the following web page: www.monsantotechnology.com.