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

NOTICE OF PESTICIDE:
_X_ Registration
___ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	**Date of Issuance:**
524-658	3/8/2019

Term of Issuance:
Unconditional

Name of Pesticide Product:
MON 89034 x MON 88017 Sweet Corn

Name and Address of Registrant (include ZIP Code):

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

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 December 31, 2020.

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

Date:
March 8, 2019

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

3. Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Environmental Protection Agency (EPA) requires registrants of similar products to submit such data.

4. This plant-incorporated protectant 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. The subject registration is limited to a combined yearly total of 100,000 acres for commercial and breeding purposes, agronomic testing, and seed production in the United States and the Commonwealth of Puerto Rico.

6. You must commit to implement an Insect Resistance Management (IRM) Program, consisting of the following elements:

- Requirements (except for sweet corn home garden or educational use, i.e., marketed to home gardeners or educators for use on less than 20 acres) for Monsanto to prepare and require MON 89034 x MON 88017 Sweet Corn users to sign "grower agreements," that impose binding contractual obligations on the grower to comply with IRM 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 (except for sweet corn home garden or educational use, i.e., marketed to home gardeners or educators for use on less than 20 acres).

- Requirements for Monsanto to develop, implement and report to EPA on programs to evaluate whether there are statistically significant changes in target insect susceptibility to Cry1A.105 and Cry2Ab2 proteins in the target insects.

- Requirements for Monsanto to develop and, if triggered, to implement a "remedial action plan" that contains 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 Sweet Corn 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 Sweet Corn.

- Requirements regarding mitigation and notification actions that Monsanto would take in the event that a CRW population that meets EPA's resistance criteria (as defined herein) 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, for the previous growing season, within three months of the request.

- Requirements for Monsanto, on or before August 31st of each year, to submit reports on Cry1A.105 and Cry2Ab2 resistance monitoring.

a. Post-Harvest Requirements for MON 89034 x MON 88017 Sweet Corn

Sweet corn is harvested long before field corn. Therefore, if the sweet corn stalks remaining in the field and any insects remaining in the stalks are destroyed shortly after harvest, a refuge is not needed as a part of the IRM program for sweet corn. Growers must adhere to the following types of crop destruction requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide, and, in the case of home gardeners, on the seed packet, in seed catalogues, and on websites offering MON 89034 x MON 88017 Sweet Corn hybrids for sale to home gardeners.

1) Crop destruction must occur no later than 30 days following harvest, but preferably within 14 days.

2) The allowed crop destruction methods are: rotary mowing, discing, or plow down or (for the home garden use) by chopping up the stalks using home garden tools such as a hoe. Crop destruction methods should destroy any surviving resistant insects.

b. Grower Agreements for MON 89034 x MON 88017 Sweet Corn (except for sweet corn home garden use or educational use, i.e., marketed to home gardeners or educators for use on less than 20 acres).

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

4) Monsanto must use its current grower agreement for MON 89034 x MON 88017 Sweet Corn. 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, 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 Sweet Corn grower agreements for a period of three years from December 31st of the year in which the agreement was signed.

6) Monsanto make available upon request records of the number of units of MON 89034 × MON 88017 Sweet 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, within three months of the 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 number, will be protected.

c. IRM Education and IRM Compliance Monitoring Program for MON 89034 MON 88017 Sweet Corn

1) Monsanto must continue to 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 Sweet Corn users the importance of complying with the IRM program. The program shall include information encouraging MON 89034 x MON 88017 Sweet Corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to MON 89034 x MON 88017 Sweet 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 Internet, radio or television commercials.) Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each MON 89034 x MON 88017 Sweet Corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Monsanto shall coordinate its educational programs with educational efforts of other registrants and organizations, such as the National Corn Growers Association and state extension programs.

2) Annually, Monsanto shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraph 6-9 of this section and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

3) Within three months of EPA request, Monsanto shall provide copies of the grower education materials and information on grower education activities including any substantive changes to these materials and activities conducted either individually or as a part of a report from the industry working group, Agricultural Biotechnology Stewardship Technical Committee (ABSTC).

4) Monsanto must continue to implement and improve an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing MON 89034 x MON 88017 Sweet Corn are complying with the IRM program 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 corn PIP products (with exception of sweet corn home gardening or educational uses). Monsanto shall coordinate with other *Bt* corn registrants in improving its

compliance assurance program and continue to integrate this amended registration into a current compliance assurance program used for *Bt* corn plant-incorporated protectants. Other required features of the program are described in paragraph 5-16.

The following IRM Education and IRM Compliance Monitoring Programs (Paragraphs 5-16) apply to all sweet corn growers who plant more than 20 acres in a single growing season:

5) Monsanto must maintain and publicize a "phase compliance approach" i.e., a guidance document that indicates how the registrant 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, all *Bt* corn registrants must use a consistent set of standards for responding to non-compliance. An individual grower found to be significantly out of compliance two years in a row would be denied access the next year to Monsanto's *Bt* sweet 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 of all MON 89034 x MON 88017 Sweet Corn customers who purchase 5 or more bags of MON 89017 x MON 88017 Sweet Corn. The survey would measure the degree of compliance with the IRM program, identify the response rate (e.g., the percent of MON 89034 x MON 88017 Sweet Corn acres covered by the responses), and consider the potential impact of non-response. An independent third party* will participate in the design and implementation of the survey. Data and information derived from the annual survey will be audited by an independent third party.

7) The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the 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) Monsanto shall provide a written summary of the results of the prior year's survey (together with a description of the methodology used and the supporting data) to EPA on or before January 31st of each year. Monsanto shall confer with EPA on changes to design and content of the survey prior to its implementation.

10) Annually, Monsanto shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey required under paragraph 6 through 8 and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. Monsanto must confer with the Agency prior to adopting any changes.

11) Monsanto shall train its representatives who make on-farm visits with growers of MON 89034 x MON 88017 Sweet Corn to perform assessments of compliance with IRM requirements. In the

* 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.

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 carry out a program for investigating legitimate "tips and complaints" that its growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not 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 Sweet Corn for planting, was specifically identified as not being in compliance during the previous year, Monsanto shall visit the grower and evaluate whether the grower is in compliance with the IRM program for the current year.

14) Annually, Monsanto shall provide a report to EPA summarizing the activities carried out under their compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. Within one month of submitting this report to EPA, Monsanto shall meet with EPA to discuss findings. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken. 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 number of the growers will be protected.

16) Monsanto may coordinate with other registrants in designing and implementing its Compliance Assurance Program.

d. Insect Resistance Monitoring and Mitigation for MON 89034 x MON 88017 Sweet Corn

1) The Agency is imposing the following conditions for the Cry1A.105 and Cry2Ab2 toxins expressed in MON 89034 x MON 88017 Sweet Corn:

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

ii. The resistance monitoring program must include the following 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.

(a) Focused Population Sampling

Monsanto must develop and ensure the implementation of a plan for resistance monitoring for *Spodoptera frugiperda* (fall armyworm or FAW) in counties in which MON 89034 and/or MON 89034 x MON 88017 Sweet Corn acreage exceeds 5,000 acres and the pest is capable of overwintering in that county. Monsanto should consult with academic and United States Department of Agriculture (USDA) experts in developing

the monitoring plan and will provide EPA with a copy of its proposed resistance monitoring plan for EPA's approval prior to implementation. This proposed FAW monitoring plan must be submitted to EPA by January 31st of the year following that in which MON 89034 and/or MON 89034 x MON 88017 Sweet Corn acreage exceeds the trigger specified in this requirement (i.e., greater than 5,000 acres in any county in which FAW overwinters). The proposed plan must be implemented the season following the acreage trigger being met. The proposed plan will remain in place until an EPA approved plan can be implemented.

Annually, Monsanto shall 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 Sweet Corn and/or changes in resistance-allele frequency in response to the use of MON 89034 x MON 88017 Sweet Corn and, as far as possible, should be consistent across sampling years to enable comparisons with historical data. Each protein in MON 89034 must be tested separately, rather than a mixture of the two proteins, because resistance to one protein could be masked by the activity of the other.

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 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 populations. For CEW, the target will be a minimum of 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 Sweet Corn. The Agency shall be consulted prior to the implementation of such modifications.

Monsanto will report to the Agency, by 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 bioassay 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 the Agency annually before August 31st. The investigative steps will include:

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 Sweet Corn 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 taken to evaluate the resistance. These steps may include:

    - Determining the nature of the resistance (i.e., recessive or dominant, and the level of functional dominance);

    - Estimating the resistance-allele frequency in the original population;

    - 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;

    - 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 the Agency to develop and implement a case-specific resistance management action plan.

(b) Investigation of Reports of Unexpected Levels of Damage by Lepidopteran 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, CEW, and FAW), 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 the Agency 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 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 residue, 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.

(c) Response to Confirmed Resistance in a Lepidopteran 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;

- 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 the Agency annually by August 31st each year, for the duration of the conditional registration.

2) The Agency is imposing the following conditions for the Cry3Bb1 toxin expressed in MON 89034 x MON 88017 Sweet Corn:

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

1) Monsanto is required to investigate "performance inquiries" (i.e., reports of unexpected corn rootworm damage to MON 89034 x MON 88017 Sweet 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:

   i. The affected plants are confirmed to be MON 89034 x MON 88017 Sweet Corn plants (take leaf samples to determine the presence of the CRW-active Bt protein); and
   ii. 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 Sweet Corn fields meeting the criteria in part 1) above, Monsanto must take the following actions:

- 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 (d)(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 corn rootworm adults. If beetles are not present the subsequent year, see section (d)(2)(b)(3)(c) below.
- 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.
- Use of single trait products containing the CRW trait 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 with multiple CRW PIP traits
        - Use of different single-CRW PIP traits (i.e., an alternative corn rootworm-active PIP)
        - Use of non-Bt or non-corn rootworm 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.

- 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 (d)(2)(b)(3) 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:

    i. 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).
    ii. 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.
    iii. 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 September 30th each year.

b) Investigation of Populations of Concern

1) Monsanto must conduct investigations of all CRW populations collected as part of the performance inquiry process in section (d)(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 Cry3Bb1 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†; 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†; 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.

† 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.

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†; 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†.

3) Mitigation, as detailed in section (d)(2)(c) below, is required for any CRW population that meets EPA's resistance criteria above, 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, 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 (d)(2)(a)(2) above, no additional mitigation is subsequently required.

c) <u>Mitigation of CRW Populations Meeting EPA's Resistance Criteria</u>

1) For any CRW population found to be resistant under EPA's criteria described in section (d)(2)(b) above, Monsanto must take the following steps:

a. Monsanto must inform EPA of 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. 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 single trait product containing the compromised trait until resistance has been demonstrated to have been mitigated;
    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 be planted with a 20% refuge until resistance has been demonstrated to have been mitigated. Other Bt corn registrants selling 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 multiple CRW PIP traits;
            b. Use of different single-CRW PIP traits (i.e., an alternative corn rootworm-active PIP);
            c. Use of non-Bt corn or non-corn rootworm 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 corn rootworm 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 (d)(2)(b) above)

show that the population susceptibility to the compromised trait 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 Sweet Corn 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.

e. Annual Reporting Requirements for MON 89034 x MON 88017 Sweet Corn

The following annual reports must be submitted:

1) Compliance Assurance Plan: Compliance Assurance Program activities, including IRM Grower Survey and on-farm assessment results as required by this registration, for the previous year and plans for the compliance assurance program during the current year, on or before January 31st of each year.

2) Insect Resistance Monitoring Results (Cry1A.105 and Cry2Ab2 only): Results of monitoring and investigations of damage reports as required by this registration, on or before August 31st each year.

3) 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 September 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 these conditions are not complied with, 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. The Confidential Statement of Formula (basic formulation, dated 06/28/2018) has been added to the product file.

If you have any questions, please contact Stephanie Kelly by phone at (703) 347-0598 or via email at kelly.stephanie@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 Sweet Corn

Lepidopteran-and Rootworm-Protected Sweet Corn
(OECD Unique Identifier: MON-89Ø34-3 × MON 88Ø17-3)

Active Ingredients:

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

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

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

Other Ingredient:

CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and genetic material (vector PV-ZMIR39) necessary for its production in MON 89034 × MON 88017 (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-XXX
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. Information regarding commercial production must be included in the Technology Use Guide and/or Insect Resistance Management (IRM) Guide.

MON 89034 × MON 88017 sweet corn protects 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 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.

Refuge requirements do not apply to commercial hybrid MON 89034 × MON 88017 sweet corn or the increase/propagation of inbred and hybrid sweet corn seed.

Post-Harvest Requirements for MON 89034 × MON 88017 Sweet Corn

For MON 89034 × MON 88017 sweet corn, growers are required to destroy any MON 89034 × MON 88017 sweet corn stalks that remain in the field following harvest via rotary mowing, discing, or plow-down or (for home garden use) by chopping up the stalks using home garden tools such as a hoe within one (1) month of harvest, but preferably within 14 days.

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 cornstalk borer	*Elasmopalpus lignosellus*
Sugarcane borer	*Diatraea saccharalis*
Western corn rootworm	*Diabrotica virgifera virgifera*
Northern corn rootworm	*Diabrotica barberi*
Mexican corn rootworm	*Diabrotica virgifera zeae*

Sales of sweet corn hybrids that contain Monsanto's Bt corn plant incorporated protectants must be accompanied by a Technology Use Guide and/or Grower Guide which includes information on planting, production and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when sweet corn containing the Bt proteins is planted.

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 that can be found at http://www.monsantotechnology.com