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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

SEP 29 2010

Dr. Russell P. Schneider
Senior Director, Regulatory Affairs and Policy
Monsanto Company
1300 I Street, NW, Suite 450 East
Washington, DC 20005

Re: Monsanto Company; MON 89034
EPA Registration No. 524-575
Amendment to convert MON 89034 from a conditional, time-limited
registration to an unconditional registration with no expiration date
Submission dated 03/31/2010
Decision No. 431589

Dear Dr. Schneider:

The amendment referred to above, submitted in connection with registration under Section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable only as an extension to the current conditional, time-limited registration and provided that you comply with the updated terms and conditions as described in this letter.

- 1) The subject registration will automatically expire on midnight September 30, 2022.
- 2) The subject registration will be limited to MON 89034 [*Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 proteins and the genetic material necessary for their production (vector PV-ZMIR245) in event MON 89034 corn (OECD Unique Identifier: MON-89034-3) for use in field or sweet corn. Further, MON 89034 sweet corn may only be sold directly to processors or through commercial dealers to large growers. MON 89034 sweet corn must not be sold to small roadside or home growers.
- 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

CONCURRENCES

| SYMBOL | 7511P | 7511P | 7511P | | | | |
|---------|---------|----------|---------|--|--|--|--|
| SURNAME | Glenn | Reynolds | July | | | | |
| DATE | 9/29/10 | 9/29/10 | 9/29/10 | | | | |

Dr. Russell P. Schneider
EPA Registration No. 524-575

pesticidal traits.

5) Submit the following data in the time frames listed:

| OPPTS Guideline/ Study Type | Required Data | Due Date |
|--|--|-----------|
| Insect Resistance Management – Resistance Monitoring | Baseline susceptibility studies and/or a discriminating concentration assay are required for the Cry1A.105 protein against Southwestern corn borer (SWCB), and for the Cry2Ab2 protein against SWCB. These data were submitted and are being evaluated. | |
| Insect Resistance Management – Resistance Monitoring | To support sweet corn uses, baseline susceptibility studies must be conducted on fall armyworm (FAW) populations collected from sweet corn growing areas. Monitoring studies will be conducted on FAW populations collected from sweet corn distribution areas in states in which Monsanto MON 89034 and/or MON 89034 x MON 88017 sweet corn plantings exceed 5,000 acres. The collected populations of FAW will be monitored for changes in susceptibility to the Cry1A.105 and Cry2Ab2 proteins. | 4/1/2012* |

*Extensions were granted as listed in the above table.

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

- Requirements relating to creation of a non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuge in conjunction with the planting of any acreage of MON 89034 field corn.
- Requirements for Monsanto Company (Monsanto) to prepare and require MON 89034 users to sign “grower agreements,” that impose binding contractual obligations on the grower 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 programs to evaluate whether there are statistically significant and biologically relevant changes in 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

Dr. Russell P. Schneider
EPA Registration No. 524-575

insect resistance was detected as well as to report on activity under the plan to EPA;

- Requirements for Monsanto, on or before January 31st of each year, to submit reports on units sold by state (units sold by county level will be made available to the Agency upon request), IRM grower agreement results, and the compliance assurance program including the education program.
- Requirements for Monsanto, on or before August 31st of each year, to submit reports on resistance monitoring.

a) Refuge Requirements for MON 89034 Field Corn

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. Furthermore, these refuge requirements do not apply to commercial hybrid sweet corn.

When on-farm assessments identify non-compliance with refuge requirements for one or more *Bt* corn products, additional educational material and assistance will be provided by Monsanto to help these growers meet the refuge requirements across their farming operations.

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 field corn 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.

- Specifically, growers must plant a structured refuge of at least 5% non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn that may be treated with insecticides, as detailed below, to control lepidopteran stalk-boring and other pests.
- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips, and strips across the field.
- External refuges must be planted within ½ mile.
- When planting the refuge as strips across the field or as perimeter strips, refuges must be

at least 4 consecutive rows wide.

- Insecticide treatments for control of ECB, CEW, SWCB, and other lepidopteran target pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.

2) Cotton-Growing Area Refuge Requirements

For MON 89034 field corn 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.

- Specifically, growers in these areas must plant a structured refuge of at least 20% non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn that may be treated with insecticides, as detailed below, to control lepidopteran stalk-boring and other pests.
- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips, and strips across the field.
- External refuges must be planted within ½ mile.
- When planting the refuge as strips across the field or as perimeter strips, refuges must be at least 4 consecutive rows wide.
- Insecticide treatments for control of ECB, CEW, SWCB, and other lepidopteran target pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.
- 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),

5
21

Dr. Russell P. Schneider
EPA Registration No. 524-575

Virginia (only the counties of Dinwiddie, Franklin City, Greenville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, Sussex), and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

b) Post-Harvest Requirements for MON 89034 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.

- Crop destruction must occur no later than 30 days following harvest, but preferably within 14 days.
- The allowed crop destruction methods are: rotary mowing, discing, or plow-down. Crop destruction methods should destroy any surviving resistant insects.

c) Grower Agreements for MON 89034

- 1) Persons purchasing MON 89034 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 amended 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 corn 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 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 must continue to integrate this amended 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 corn sign grower agreement(s).
- 6) Monsanto shall maintain records of all MON 89034 grower agreements for a period of three years from December 31st of the year in which the agreement was signed.
- 7) Annually, Monsanto shall provide EPA with a report showing the number of units of MON 89034 corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the twelve-month period covering the prior August through July.
- 8) 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.

d) IRM Education and Compliance Monitoring Programs for MON 89034

- 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 corn users the importance of complying with the IRM program. The program shall include information encouraging MON 89034 corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to MON 89034 corn fields. The education program shall involve the use of multiple media (e.g., face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials). 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 corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Monsanto shall coordinate its education 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 paragraphs 6a or 6b and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.
- 3) Annually Monsanto must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. Monsanto must either submit a separate report or contribute to the report from the industry working group, Agricultural Biotechnology Stewardship Technical Committee (ABSTC). The

Dr. Russell P. Schneider
EPA Registration No. 524-575

required features of the compliance assurance program are described in paragraphs 4-22 of this section.

- 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 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 corn PIP products. Monsanto shall coordinate with other *Bt* corn registrants in improving its compliance assurance program and continue to integrate this amended 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.
- 5) Monsanto must maintain and publicize a "phased compliance approach," i.e., a guidance document that indicates how Monsanto 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 noncompliance. 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 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
- 6a) MON 89034 Field Corn: The IRM compliance assurance program shall include an annual survey, conducted by an independent third party, of a statistically representative sample of growers of MON 89034 field corn who plant the vast majority of all corn in the United States and in areas in which the selection intensity is greatest. The survey shall consider only those growers who plant 200 or more acres of corn in the Corn-Belt and who plant 100 or more acres of corn in corn-cotton areas. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from independent marketing research firms and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the United States.
 - i. 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.
- 6b) MON 89034 Sweet Corn: The IRM compliance assurance program shall include an annual survey of all MON 89034 sweet corn customers who purchase 5 or more bags of

MON 89034 sweet corn. The survey shall measure the degree of compliance with the IRM program, identify the response rate (e.g., the percent of MON 89034 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.
- 9a) MON 89034 Field Corn: Monsanto shall provide a final written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA on or before January 31st of each year. Monsanto shall confer with other registrants and EPA on the design and content of the survey prior to its implementation.
- 9b) MON 89034 Sweet Corn: 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 the 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 paragraphs 6a 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 conduct an annual on-farm assessment program. Monsanto shall train its representatives who make on-farm visits with growers of MON 89034 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 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 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 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, 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 its 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. 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 number of the growers will be protected.
- 16) Monsanto shall revise and expand its existing Compliance Assurance Program to include the following elements. The registrant must prepare and submit by January 31, 2011, a written description of its revised Compliance Assurance Program. The registrant may coordinate with other registrants in designing and implementing its Compliance Assurance Program.
- 17) The registrant will enhance the refuge education program throughout the seed delivery channel:
 - i. 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;
 - ii. Include the refuge size requirement on all *Bt* corn seed bags or bag tags. The PIP product label accepted by EPA must include how this information will be conveyed to growers via text and graphics. This requirement may be phased in over the next three growing seasons. Revised PIP product labels must be submitted by January 31, 2011, 50% implementation on the *Bt* corn seed bags or bag tags must occur by the 2012 growing season, and full implementation must occur by the 2013 growing season.
- 18) Monsanto will focus the majority of on-farm assessments on regions with the greatest risks for resistance:

Dr. Russell P. Schneider
EPA Registration No. 524-575

- i. Use *Bt* corn adoption, pest pressure information, and other available information to identify regions where the risk of resistance is greatest;
 - ii. Focus approximately two-thirds of on-farm assessments on these regions, with the remaining assessments conducted across other regions where the product is used.
- 19) Monsanto will use its available MON 89034 sales records and other information to refine grower lists for on-farm assessments of their compliance with refuge requirements:
- i. Identify for potential on-farm assessment growers whose sales information indicates they have purchased the MON 89034 corn 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:
- i. 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) Annually, Monsanto will refine the on-farm assessment program for the MON 89034 corn product to reflect the adoption rate and level of refuge compliance for MON 89034 .
- 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:
- i. 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, a seed supplier, or third party assessor, after completing the assessment process;
 - ii. 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;
 - iii. A grower found with a second incident of significant non-compliance with refuge requirements for MON 89034 corn within a five-year period will be denied access to and/or sales of Monsanto's *Bt* corn products the next year.

e) Insect Resistance Monitoring and Remedial Action Plan for MON 89034

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

Dr. Russell P. Schneider
EPA Registration No. 524-575

- i. Monsanto must monitor for resistance to Cry1A.105 and Cry2Ab2 expressed in MON 89034.
- 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.

(1) 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 and/or changes in resistance-allele frequency in response to the use of MON 89034 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

Dr. Russell P. Schneider
EPA Registration No. 524-575

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. 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 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 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 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.

(2) 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, 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 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 fields in the affected region to control the target pest during the immediate growing season.
- Destroy MON 89034 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.

(3) 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;
- 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, beginning in 2010, for the duration of the conditional registration.

f) Annual Reporting Requirements for MON 89034

- 1) Annual Sales: reported and summed by state (county level data available by request), on or before January 31st of each year.
- 2) Grower Agreement Results: number of units of MON 89034 seeds shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements, on or before January 31st of each year.
- 3) Grower Education: substantive changes to education program completed previous year, on or before January 31st of each year,.
- 4) Compliance Assurance Plan: Compliance Assurance Program activities and results, for the previous year and plans for the compliance assurance program during the current year, on or before January 31st of each year.

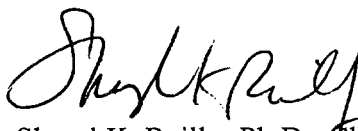
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Dr. Russell P. Schneider
EPA Registration No. 524-575

- 5) Compliance Assurance Plan Survey Results: to include annual survey results and plans for the next year; on or before January 31st of each year.
- 6) Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, on or before August 31st each year.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of this product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Sincerely,


Sheryl K. Reilly, Ph.D., Chief
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

Enclosure (1):
-Accepted MON 89034 Label

Plant-Incorporated Protectant Label

MON 89034

Lepidopteran-Protected Corn
(OECD Unique Identifier: MON-89Ø34-3)

This product is effective in controlling leaf, stalk, and ear damage caused by corn borers.

Active Ingredients:

Bacillus thuringiensis Cry1A.105 protein and the genetic material necessary for its production
(Vector PV-ZMIR245) in event MON 89034 corn (OECD Unique Identifier: MON-89Ø34-3)
..... ≤ 0.0056%*

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary for its production
(Vector PV-ZMIR245) in event MON 89034 corn (OECD Unique Identifier: MON-89Ø34-3)
..... ≤ 0.0055%*

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

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET CONTENTS _____

EPA Registration No. 524-575

EPA Establishment No. 524-MO-002

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

ACCEPTED

SEP 29 2010

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 524-575

DIRECTIONS FOR USE

It is a violation of Federal law to use this seed in any manner inconsistent with this labeling. Information regarding commercial production must be included in the Technology Use Guide and/or IRM Grower Guide.

The subject registration will automatically expire on midnight September 30, 2022.

MON 89034 can be used to protect corn plants from leaf, stalk, and ear damage caused by corn borers.

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.

1) Refuge Requirements for MON 89034 Field Corn

In order to minimize the risk of corn borers developing resistance to MON 89034 field corn, an insect resistance management 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 plant-incorporated protectant (PIP) active ingredient per registrant per year. Furthermore, these refuge requirements do not apply to commercial hybrid sweet corn.

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

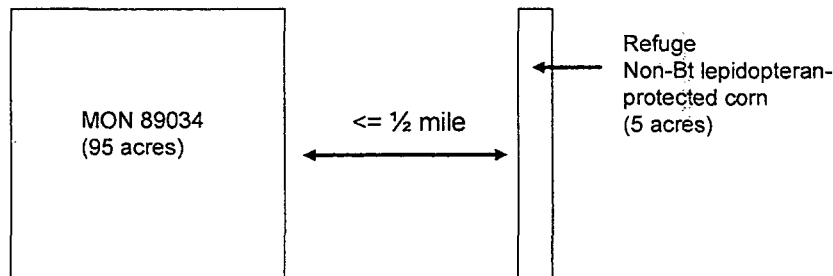
For MON 89034 field corn grown outside cotton-growing areas (e.g., the Corn Belt), grower guides must specify that growers must adhere to the following refuge requirements.

Growers must plant a structured refuge of at least 5% corn, which is not a lepidopteran-protected *B.t.* corn hybrid. The refuge may be treated with insecticides, as detailed below, to control lepidopteran stalk-boring and other pests.

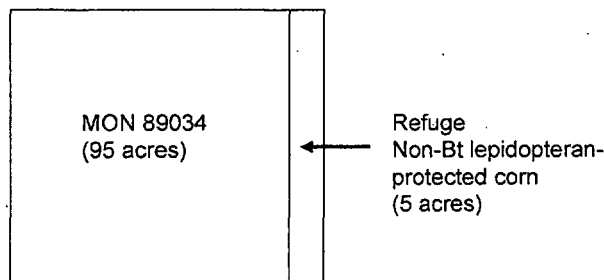
Insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, southern cornstalk borer, sugarcane borer, fall armyworm and corn stalk borer may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). Instructions to growers will specify that microbial *B.t.* insecticides must not be applied to non-*B.t.* corn refuges.

Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field.

External refuges must be planted within ½ mile.



When planting the refuge in strips across the field, refuges must be at least 4 consecutive rows wide.



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).

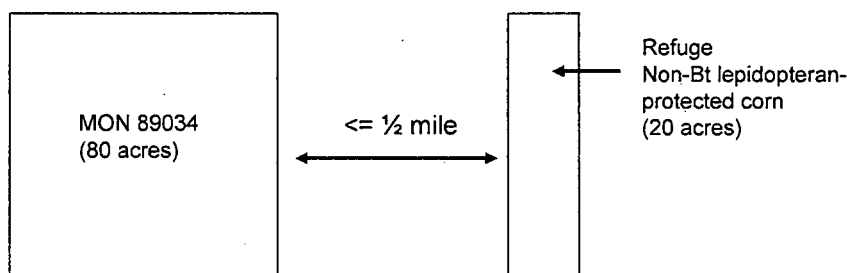
For MON 89034 field corn grown in cotton-growing areas, grower guides must specify that growers must adhere to the following refuge requirements.

Growers must plant a structured refuge of at least 20% corn which is not a lepidopteran-protected *B.t.* corn hybrid. The refuge may be treated with insecticides, as detailed below, to control lepidopteran stalk-boring and other pests.

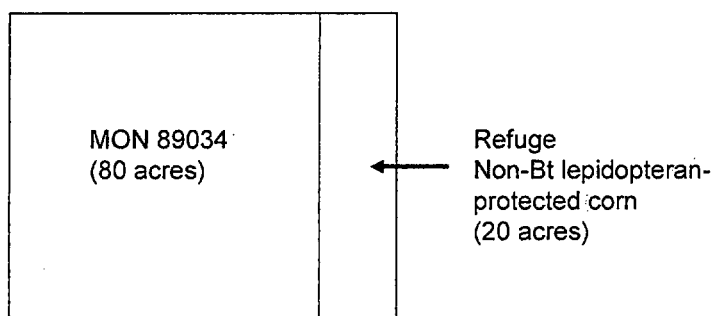
Insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, southern cornstalk borer, sugarcane borer, fall armyworm and corn stalk borer may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Instructions to growers will specify that microbial *B.t.* insecticides must not be applied to non-*B.t.* corn refuges.

Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field.

External refuges must be planted within ½ mile.



When planting the refuge in strips across the field, refuges must be at least 4 consecutive rows wide.



2) Post-Harvest Requirements for MON 89034 Sweet Corn

For MON 89034 sweet corn, growers are required to destroy any MON 89034 sweet corn stalks that remain in the field following harvest via rotary mowing, disking, or plow-down within one (1) month of harvest.

CORN INSECTS CONTROLLED

European corn borer
Southwestern corn borer
Southern cornstalk borer
Corn earworm

Ostrinia nubilalis
Diatraea grandiosella
Diatraea crambidoides
Helicoverpa zea

Fall armyworm
Corn stalk borer
Sugarcane borer

Spodoptera frugiperda
Papaipema nebris
Diatraea saccharalis

Sales of corn hybrids that contain Monsanto's *B.t.* corn plant incorporated protectant must be accompanied by a Grower Guide which includes information on planting, production and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the *B.t.* proteins is planted.

MON 89034 is a product of Monsanto's research program offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5322938, 5352605, 5378619, 5424412, 6051753, 6489542, 6645497, 6713063, 6962705, 7064249, 7070982, 7250501, 7304206, 7618942.