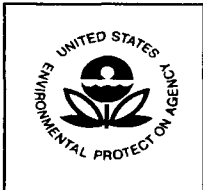



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|  <p align="center"><b>U S ENVIRONMENTAL PROTECTION AGENCY</b><br/> <b>Office of Pesticide Programs</b><br/> <b>Biopesticides and Pollution</b><br/> <b>Prevention Division (7511P)</b><br/> <b>Ariel Rios Building</b><br/> <b>1200 Pennsylvania Ave , NW</b><br/> <b>Washington, D C 20460</b></p> <p align="center">NOTICE OF PESTICIDE<br/> <input checked="" type="checkbox"/> Registration<br/> <input type="checkbox"/> Reregistration<br/>         (under FIFRA as amended)</p>  | EPA Reg Number<br>524 597                                | Date of Issuance<br><b>NOV 16 2011</b> |
|  | Term of Issuance <b>Conditional</b>                      |  |
|  | Name of Pesticide Product<br><b>MON 89034 Seed Blend</b> |  |
| Name and Address of Registrant (include ZIP Code)<br><b>Monsanto Company</b><br><b>800 North Lindbergh Blvd</b><br><b>St Louis MO 63167</b>  |  |  |
| <p><b>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</b></p> <p>On the basis of information furnished by the registrant the above named pesticide is hereby registered/reregistered under the Federal Insecticide Fungicide and Rodenticide Act Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency In order to protect health and the environment the Administrator on his 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 this 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</p> <p>This product is conditionally registered in accordance with FIFRA Section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, provided that you do the following terms and conditions</p> <ol style="list-style-type: none"> <li>1] The subject registration will automatically expire on midnight on November 16 2012</li> <li>2] The subject registration will be limited to a seed mix of MON 89034 field corn [<i>Bacillus thuringiensis</i> 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)] seed blended with not less than 5% non-Bt corn seed</li> <li>3] Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires registrants of similar products to submit such data</li> <li>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</li> <li>5] Submit or cite all data required to support MON 89034 within the timeframes required by the terms and conditions of EPA Registration Number 524-575</li> </ol> |  |  |
| Signature of Approving Official<br>   | Date<br>11/16/2011                                       |  |

6] Monsanto stated that the models used to analyze this product included non-uniform oviposition behavior but did not explain how this was accomplished in the models and what the ratio of non-uniform oviposition was between Bt and non-Bt plants This information must be provided to the Agency within six (6) months

7] Monsanto's deterministic model (also used for the 5% SmartStax RIB) explored effects of density-dependence and estimated that resistance in a 5% block with MON 89034 occurred around 4600 generations with a final r-frequency of 0.5 in non-compliant fields and approximately at 4900 generations in compliant fields yet with a final r-allele frequencies ranging from 0.7-0.93 (depending on adult dispersal assumptions) Monsanto did not explain why the final resistance allele frequency in compliant fields was so high when the cut-off (termination of model runs) was set for a frequency of 0.5 Since BPPD does not have access to Monsanto's model, it is unclear why the final resistance allele frequencies in compliant fields exceeded 0.5 (Monsanto's definition of resistance) One possible explanation is that the resistance allele frequency prior to the final run was slightly below 0.5 and then dramatically increased on the next and final run (based on the shape of resistance response) Whether this explanation is correct or not is unclear, therefore, Monsanto must provide an explanation

8] 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 cotton growing regions in conjunction with the planting of any acreage of MON 89034 Seed Blend field corn

Requirements for Monsanto Company (Monsanto) to prepare and require MON 89034 Seed Blend 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 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 31<sup>st</sup> of each year, to submit reports on resistance monitoring

**a) Refuge Requirements for MON 89034 Field 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.

Corn seed bags or bag tags for products containing MON 89034 Seed Blend must include the refuge size and distance requirements in text and graphical format.

**1) Corn-Belt Refuge Requirements**

There are no requirements for a separate structured refuge for MON 89034 Seed Blend corn when planted in the U.S. corn-growing region. The refuge seed of MON 89034 Seed Blend corn is contained in the bag resulting in a refuge configuration that is interspersed within the field.

**2) Cotton-Growing Area Refuge Requirements**

For MON 89034 Seed Blend 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), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, Sussex), and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard)

**b) Grower Agreements for MON 89034 Seed Blend**

- 1) Persons purchasing MON 89034 Seed Blend 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 Seed Blend 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 Seed Blend 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 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 Seed Blend corn sign grower agreement(s).
- 6) Monsanto shall maintain records of all MON 89034 Seed Blend 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 Seed Blend 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.

**c) IRM Education and Compliance Monitoring Programs for MON 89034 Seed Blend**

1) Monsanto must continue to implement and enhance 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 Seed Blend corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to MON 89034 Seed Blend corn fields. The education program shall involve the use of multiple media (e.g., face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials). 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 Seed Blend 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 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 Seed Blend 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.

6) MON 89034 Seed Blend 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 Seed Blend 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

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

7) The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements An analysis of 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) MON 89034 Seed Blend 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 31<sup>st</sup> of each year Monsanto shall confer with other registrants and EPA on 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 Seed Blend 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 Seed Blend 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 noncompliance, 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, 2012, 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

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

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 Seed Blend 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 Seed Blend corn product to reflect the adoption rate and level of refuge compliance for MON 89034 Seed Blend corn in cotton growing regions

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

#### **d) Insect Resistance Monitoring and Remedial Action Plan for MON 89034**

The Agency is imposing the following conditions for the Cry1A 105 and Cry2Ab2 toxins expressed in MON 89034

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***

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 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 31<sup>st</sup> 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 31<sup>st</sup>, 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 and CEW), Monsanto will implement the actions described below, based on the following definitions of *suspected resistance* and *confirmed resistance*.

### *Suspected resistance*

EPA defines *suspected resistance* to mean field reports of unexpected levels of insect feeding damage for which

the corn in question has been confirmed to be lepidopteran-active *Bt* corn,

the seed used had the proper percentage of corn expressing *Bt* protein

the relevant plant tissues are expressing the expected level of *Bt* protein, and

it has been ruled out that species not susceptible to the protein could be responsible for the damage, that no climatic or cultural reasons could be responsible for the damage and that there could be no other reasonable causes for the damage.

EPA does not interpret *suspected resistance* to mean grower reports of possible control failures or suspicious results from annual insect monitoring assays, nor does 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  $\geq 0.1$  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 31<sup>st</sup> each year, beginning in 2012, for the duration of the conditional registration

**e) Annual Reporting Requirements for MON 89034 Seed Blend**

- 1) Annual Sales reported and summed by state (county level data available by request) on or before January 31<sup>st</sup> of each year
- 2) Grower Agreement Results number of units of MON 89034 Seed Blend 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 31<sup>st</sup> of each year
- 3) Grower Education substantive changes to education program completed previous year, on or before January 31<sup>st</sup> 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 31<sup>st</sup> of each year
- 5) Compliance Assurance Plan Survey Results to include annual survey results and plans for the next year, on or before January 31<sup>st</sup> of each year
- 6) Insect Resistance Monitoring Results results of monitoring and investigations of damage reports, on or before August 31<sup>st</sup> each year

**f) Refuge Assurance Program for MON 89034 Seed Blend Corn**

Monsanto and Monsanto's seed company licensees must continue to implement a blended seed refuge assurance program designed to ensure MON 89034 Seed Blend corn products are formulated with the appropriate rate of refuge seeds

The program must include the following four elements

- 1 Trait purity check on seed lots prior to blending (Monsanto and Monsanto Licensees)
- 2 Standard Operating Procedures for the blending process,
- 3 Calibration of blending equipment, and
- 4 Records and data retention records for seed blend products
  - Calibration records – Monsanto and Monsanto's Licensees will retain documentation for three (3) years on the equipment calibration including the procedure, when it was conducted and the results
  - Blend proportion records (weight and kernel based) – Monsanto and Monsanto Licensees will retain documentation for three (3) years on the kernel per pound data of the components, the calculations to determine the proportions based on weight and the actual weights that are blended together to make up an MON 89034 seed blend corn product by seed lot All records must be maintained at the Monsanto or Monsanto Licensees seed blending facility and must be available for the EPA review upon request
  - Within one year of the date of registration Monsanto will collect documentation from

qualification test runs that validate blend percentages from their licensees/conditioners that produce MON 89034 seed blend corn and submit this data to the Agency Any licensee/conditioner that is unable to verify their blend accuracy will provide evidence demonstrating application and participation in the USDA USA Accredited Seed Conditioning Program (ASCP) as outlined in ARC 1005D Appendix, <http://www.ams.usda.gov/AMSV10/ams.fetchTemplateData.do?template=TemplateN&navID=AccreditedSeedPrograms&rightNav1=AccreditedSeedPrograms&topNav=&leftNav=&page=ASLProgram&resultType=&acct=audrevcom>

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

9] Monsanto must submit revised product labeling that indicates the actual seed tag language for use in both cotton and non-cotton growing areas within six months

10] Monsanto must report on how many of their licensees (by number and percentage) color seed January 31st each year, beginning in 2012

11] The labeling submitted is acceptable provided you add the phrase "Corn seed bags or bag tags for products containing MON 89034 Seed Blend must include the refuge size and distance requirements in text and graphical format" under the Refuge Requirements header on the second page of the stamped approved label

A copy of the stamped label is enclosed for your records

Sincerely,



Keith A. Matthews Director  
Biopesticides and Pollution  
Prevention Division (7511P)

Plant-Incorporated Protectant Label

MON 89034 Seed Blend

Lepidopteran-Protected Corn  
(OECD Unique Identifier MON-89034-3)

Alternate Brand Name Genuity® VT Double PRO™‡

Active Ingredients

*Bacillus thuringiensis* Cry1A 105 protein and the genetic material necessary for its production (vector PV-ZMIR245) in event MON 89034 corn 0 0020-0 0056%\*

*Bacillus thuringiensis* Cry2Ab2 protein and the genetic material necessary for its production (vector PV-ZMIR245) in event MON 89034 corn 0 0015-0 0055%\*

\*Percentage (wt/wt) on a dry weight basis whole plant (forage) of MON 89034 plants

The MON 89034 seed with this refuge configuration contains 95% MON 89034 mixed with 5% non-Bt corn within a single lot of seed

‡ Genuity® VT Double PRO™ seed with this refuge configuration contains 95% MON 89034 × NK603 mixed with 5% non-Bt corn within a single lot of seed

KEEP OUT OF REACH OF CHILDREN

Caution

NET CONTENTS \_\_\_\_\_

EPA Registration No 524-~~524~~ 597

EPA Establishment No 524-MO-002

Monsanto Company  
800 North Lindbergh Blvd  
St Louis, MO 63167

ACCEPTED  
with CONFIDENTIALITY TO  
In EPA Label Approval  
NOV 16 2011  
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the products registered with EPA Reg. No. 524-597

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

### Refuge Requirements

A refuge must consist of corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. This product achieves the required refuge as the refuge is interspersed within the field and occurs only by planting a licensed seed-mixture containing MON 89034 or MON 89034 stacked with other non-PIP technologies, with a minimum of 5% non-PIP seed. This refuge configuration complies with refuge requirements only in the U.S. Corn Belt.

The refuge requirements do not apply to seed propagation of inbred and hybrid seed corn under this registration, however, seed propagation over 20,000 acres per county and up to a combined U.S. total of 250,000 acres per PIP active ingredient per year would utilize the discrete or structured refuge options for MON 89034 under EPA registration 524-575.

The sufficiency of this refuge configuration is defined by geography, and ultimately is based on insect presence and species. **The seed mix refuge option for MON 89034 complies with refuge requirements only in the U.S. Corn Belt.**

The 95/5% MON 89034 seed mix product may be planted in cotton growing areas, however, planting the 95/5% MON 89034 seed mix in cotton growing areas still requires planting an additional 20% structured refuge (block, strips, or border) as defined for MON 89034 EPA registration 524-575. **The interspersed refuge option for MON 89034 does not alone comply with refuge requirements in cotton growing areas.**

Cotton-growing areas include the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltrie, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

The seed mix (interspersed) refuge option under this registration is limited to planting specifically licensed seed corn of MON 89034 and MON 89034 stacks with non-PIP corn.

With this option, the field containing an interspersed refuge may be treated with labeled insecticides to control additional corn pests, including larval or adult lepidopteran pests, because both the MON 89034 and refuge are treated in the same manner. 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). Microbial Bt insecticides must not be applied to the field containing a seed mix interspersed refuge.

**Corn Insects Controlled**

|                          |                              |
|--------------------------|------------------------------|
| European corn borer      | <i>Ostrinia nubilalis</i>    |
| Southwestern corn borer  | <i>Diatraea grandiosella</i> |
| Southern cornstalk borer | <i>Diatraea crambidoides</i> |
| Corn earworm             | <i>Helicoverpa zea</i>       |
| Fall armyworm            | <i>Spodoptera frugiperda</i> |
| Corn stalk borer         | <i>Papaipema nebris</i>      |
| Sugarcane borer          | <i>Diatraea saccharalis</i>  |

Sales of corn hybrids that contain Monsanto's Bt 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 Bt proteins is planted.

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.

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, and 7618942.