


524-528

02/24/2003

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 <p>U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Biopesticides and Pollution Prevention Division (7511C) 1200 Pennsylvania Avenue NW Washington, DC 20460</p> <p>NOTICE OF PESTICIDE: <u>X</u> Registration — Reregistration (under FIFRA, as amended)</p>	EPA Reg. Number: 524-528	Date of Issuance: FEB 24 2003
	Term of Issuance: Conditional	
	Name of Pesticide Product: Corn Event MON863	
Name and Address of Registrant (include ZIP Code): Monsanto Company 700 Chesterfield Parkway West St. Louis, MO 63017		
<p><b>Note:</b> 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.</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.</p> <p>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 her motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under 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>The registration application referred to above, submitted in connection with registration under § 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you implement the following terms and conditions.</p> <ol style="list-style-type: none"> <li>1) The subject registration will automatically expire on midnight May 1, 2004. The registration must expire on this date because this is the date of expiration of the tolerance exemption under 40 CFR 180.1214. When and if the Agency registers this product, it is our understanding that Monsanto intends to submit in the near future an amendment application to modify the expiration date and a petition to amend the tolerance exemption under 40 CFR 180.1214 so that its expiration date is removed. Based on the Agency's review of the data submitted and cited in support of this application, and provided that the Agency finalizes a rule which amends 40 CFR 180.1214 so that its expiration date is removed; the Agency anticipates at this time that an expiration date three years from the initial date of registration for this product would be appropriate.</li> <li>2) The subject registration will be limited to <i>Bacillus thuringiensis</i> Cry3Bb1 Protein and the Genetic Material Necessary for its Production (Vector ZMIR13L) in Event MON863 Corn use in field corn.</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> </ol>		
Signature of Approving Official: <i>JEA see last page</i>	Date:	

- 4) Submit production information for this product to Mr. Owen Beeder of Office of Pesticide Programs, Registration Division (mail code 7505C) for the fiscal year in which this product is conditionally registered, in accordance with FIFRA § 29. The fiscal year begins October 1 and ends September 30. Production information will be submitted to the Agency no later than December 15, following the end of the preceding fiscal year.
- 5) Submit independent laboratory method validation (under OPPTS Guidelines 860.1340) to complete the database for Cry3Bb1 corn within 12 months of the date of registration. Provide to the EPA laboratory (Ft. Meade, MD) methodology and/or reagents necessary for validation of a Cry3Bb1 analytical method within 6 months of the date of registration. The extraction and detection method as described for Cry3Bb1 protein appears to be adequate for analysis of Cry3Bb1 protein in corn grain. However, this method must be validated by both an independent laboratory and the EPA Biological and Economic Analysis Division laboratory before it can be considered a valid method. In addition, to assure that grain handlers have a test method in place prior to harvest, you must make available Cry3Bb1 strip tests to grain handlers and demonstrate to the Agency this provision prior to September 2003. EPA understands that these are 'qualitative' test kits and that you are in discussions with USDA/GIPSA about providing methodology and reagents for their use in developing a validated 'quantitative' method for MON 863 and that this transfer of materials will take place once registration occurs.
- 6) Submit expression data in terms of dry weight, as the amount of protein present in the given tissue. Tissues for which expression data must be provided include: leaf, root, pollen, seed, and whole plant. In addition, data for each of these tissues should be provided for young plants in rapid growth, during flowering, and mature plants before harvest when that part of the plant is present. Data obtained for roots should also include typical times when corn rootworm would be feeding. Data are due within 24 months of the date of registration, provided the registration is amended to extend the registration date.
- 7) Submit field degradation studies evaluating accumulation and persistence of Cry3Bb1 in several different soils in various strata. Representative fields must have been planted with MON863 and include both conventional tillage and no-till samples and be harvested under typical agronomic conditions. Sampling must continue until the limit of detection is reached. Studies should include soils with high levels of a variety of clays. Both ELISA and insect bioassays need to be conducted and compared to determine if Cry3Bb1 is accumulating or persisting in soil samples. A protocol is due within 90 days of the date of registration, and a progress report is due within one year of the date of registration. If the registration and tolerance exemption are amended to extend the expiration dates, a final report is due two years from the date of registration.
- 8) Submit laboratory toxicity tests with *Orius insidiosus* (minute pirate bug), carabid (ground beetle), and *Tetraopes* (red milkweed beetle) within 24 months of the date of registration, provided the registration is amended to extend the registration date. Protocols are due within 120 days of the date of registration.
- 9) Full-scale field or semi-field studies with appropriate end points and statistical power must be conducted. Submit intermediate and multi-year non-target organism field studies with statistical power. You must submit final results to field studies previously summarized in MRID No.456530-03 (the carabid and nematode data are of particular interest) and annual reports each year of this registration every April 30th.
- 10) Submit a six week broiler dietary study with 60% - 70% MON 863 corn in the diet that is of appropriate duration to represent the start and growing periods of the test species. Balanced diets should be formulated according to the National Research Council guidelines ("Nutrient Requirements of

Poultry," Ninth Revised Edition, 1994) with the energy requirements of the test species being met by the inclusion of corn in the diet to assess hazards from chronic exposure of wild or domesticated fowl. A protocol for poultry studies must be submitted within 90 days of the date of registration with a final report submitted 18 months after approval of the protocol.

11) Submit the following insect resistance management/pest biology data. Protocols and data sets identified in Monsanto's 12/13/2002 letter must be submitted within 90 days of the date of registration. A progress report must be submitted by January 31, 2004. Provided the registration is amended to extend the expiration date, the final reports must be submitted by January 31, 2006.

- Research regarding adult and larval movement and dispersal, mating habits, ovipositional patterns, number of times a female can mate and fecundity.
- Research to determine if IRM strategies designed for WCRW and NCRW are appropriate for MCRW
- Research regarding the mechanism of potential resistance of CRW to MON 863 is necessary to develop an appropriate long-term IRM strategy. Monsanto must attempt to develop resistant CRW colonies to aid in determining selection intensity.
- Research regarding the effect of WCRW ovipositing in soybean prior to overwintering and extended diapause in NCRW on an IRM strategy needs further investigation.
- Detailed summaries of the four data-sets identified in Monsanto's December 13, 2002 letter should be submitted to the Agency to support their conclusion that the initial resistance allele frequency is  $\leq 0.01$ .
- Baseline susceptibility studies currently underway should be continued for WCRW and initiated for NCRW and monitoring techniques such as discriminating dose concentration assays need to be thoroughly investigated for their feasibility as resistance monitoring tools.

12) BPPD strongly urges Monsanto to submit data and information cited in the benefits assessment (contained in the MON863 Biopesticides Regulatory Action Document) to help measure the impacts and potential benefits of the use of MON 863 corn on a wide scale. [Note that this is not a required term or condition of the registration.]

13) You must implement the following Insect Resistance Management Program:

The required IRM program for Cry3Bb1 *Bt* corn has the following elements:

- 1] Requirements relating to creation of a non-Cry3Bb1 *Bt* corn refuge in conjunction with the planting of any acreage of commercial Cry3Bb1 *Bt* corn;
- 2] Requirements for the registrants to prepare and require Cry3Bb1 *Bt* corn users to sign "grower agreements" which impose binding contractual obligations on the grower to comply with the refuge requirements;
- 3] Requirements for the registrants to develop, implement, and report to EPA on programs to educate growers about IRM requirements;

4] Requirements for the registrants to develop, implement, and report to EPA on programs to evaluate and promote growers' compliance with IRM requirements (the Cry3Bb1 Compliance Assurance Program (CAP) must integrate with the CAP already approved for MON810, EPA Registration Number 524-489);

5] Requirements for the registrants to develop, implement, and report to EPA on monitoring programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to Cry3Bb1 protein in the target insects;

6] Requirements for the registrants to develop, and if triggered, to implement a "remedial action plan" which would contain measures the registrants would take in the event that any insect resistance was detected as well as to report on activity under the plan to EPA;

7] Submit annual reports on sales(by state and county), IRM grower agreements results, compliance, and educational program on or before January 31<sup>st</sup> each year beginning in 2004.

a. Refuge Requirements

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 20% non-Cry3Bb1 *Bt* corn that may be treated with insecticides as needed to control corn rootworm larvae. Growers will not be permitted to apply CRW labeled insecticides to the refuge for control of insect pests while adult corn rootworm are present unless the Cry3Bb1 field is treated in a similar manner.
- Refuge planting options include: refuge acres should be planted as blocks adjacent to MON 863 corn fields or as in-field strips.
- External refuges must be planted adjacent to Cry3Bb1 MON 863 fields.
- When planting the refuge in strips across the field, refuges must be at least 6 rows wide, preferably 12 consecutive rows wide.
- Insecticide treatments for control of corn rootworm larvae may be applied. Instructions to growers will specify that insecticides labeled for control of corn rootworm adults cannot be applied while adults are present in the refuge unless the Cry3Bb1 field is treated in a similar manner.

b. Grower Agreements

1] Persons purchasing the *Bt* corn product 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] The registrant must develop a system (equivalent to what is already approved for MON 810, EPA Reg. No. 524-489) which is reasonably likely to assure that persons purchasing the *Bt* corn product will affirm

annually that they are contractually bound to comply with the requirements of the IRM program. The proposed system will be submitted to EPA within 90 days from the date of registration.

4] The registrant must use grower agreements and submit to EPA within 90 days from the date of registration a copy of that agreement and any specific stewardship documents referenced in the grower agreement. 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 days prior to implementing a proposed change, the registrant must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of the amendment.

5] The registrant must establish a system (equivalent to what is already approved for MON 810, EPA Reg. No. 524-489) which is reasonably likely to assure that persons purchasing the *Bt* corn sign grower agreement(s), and must provide within 90 days from the date of the registration a written description of that system.

6] The registrant shall maintain records of all *Bt* corn grower agreements for a period of three years from December 31st of the year in which the agreement was signed.

7] Beginning on January 31, 2004 and annually thereafter, the registrant shall provide EPA with a report showing the number of units of its *Bt* MON863 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] The registrant must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

#### c. IRM Education and IRM Compliance Monitoring Programs

1] Monsanto must design and implement a comprehensive, ongoing IRM education program designed to convey to *Bt* MON863 corn users the importance of complying with the IRM program. The program shall include information encouraging *Bt* MON863 corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to *Bt* MON863 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 *Bt* MON863 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 other organizations, such as the National Corn Growers Association and state extension programs.

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

3] Beginning January 31, 2004 and annually thereafter, the registrants must provide a report to EPA summarizing the activities carried out under the education program for the prior year and the plans for

their education program during the current year. The registrant must either submit a separate report or contribute to the report from the industry working group (ABSTC).

4] The registrant must design and implement an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing its MON863 *Bt* corn product 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 the MON863 *Bt* corn product. The registrant shall coordinate with other *Bt* corn registrants in designing and implementing its compliance assurance program and integrate the Cry3Bb1 CAP with the CAP already approved for MON810, EPA Registration Number 524-489. The registrant must prepare and submit within 90 days of the date of registration a written description of their compliance assurance program including a summary of the program implemented in the 2003 growing season. Other required features of the program are described in paragraphs 5] - 15] below.

5] The registrant must establish and publicize a "phased compliance approach," i.e., a guidance document that indicates how the registrant will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers. The options shall include withdrawal of the right to purchase MON863 *Bt* corn for an individual grower or for all growers in a specific region. An individual grower found to be significantly out of compliance two years in a row would be denied sales of the product 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 MON863 *Bt* corn.

6] The IRM compliance assurance program shall include an annual survey of a statistically representative sample of *Bt* corn growers conducted by an independent third party. 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 the independent marketing research firm 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 U.S.

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] The registrant shall provide a preliminary summary of their findings by November 15 and 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 by January 31 of each year. The registrant shall confer with EPA on the design and content of the survey prior to its implementation.

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

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11] The registrant shall train its representatives who make on-farm visits with MON863 *Bt* corn growers to perform assessments of compliance with IRM requirements. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, the registrant shall take appropriate action, consistent with its "phased compliance approach," to promote compliance.

12] The registrant 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, the registrant shall take appropriate action, consistent with its "phased compliance approach."

13] If a grower, who purchases MON863 *Bt* corn for planting, was specifically identified as not being in compliance during the previous year, the registrant shall visit with the grower and evaluate whether that the grower is in compliance with the IRM program for the current year.

14] Beginning January 31, 2004 and annually thereafter, 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. 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.

15] The registrant and the seed corn dealers for the registrant 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.

d. Insect Resistance Monitoring

The Agency is imposing the following conditions for this product:

- 1) The registrants will monitor for resistance and/or trends in increased tolerance for corn rootworm. Sampling should be focused in those areas in which there is the highest risk of resistance development. You must submit a protocol within 90 days of the date of registration.
- 2) The registrant shall provide to EPA a description of its resistance monitoring plan by January 31, 2004. The description shall include: sampling (number of locations and samples per locations), sampling methodology, bioassay methodology, standardization procedures, detection technique and sensitivity, and the statistical analysis of the probability of detecting resistance.
- 3) The registrant must follow up on grower, extension specialist or consultant reports of less than expected results or control failures for the corn rootworm. The registrant will instruct its customers (growers and seed distributors) to contact them (e.g., via a toll-free customer service number) if incidents of unexpected levels of damage occurs from these target pests. The registrant will investigate all damage reports submitted to the company or the company's representatives. See Remedial Action Plans section below.
- 5) A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by April 30<sup>th</sup> each year for the duration of the conditional registration.

e. Remedial Action Plans

A Remedial Action Plan covering both suspected and confirmed resistance for corn rootworm must be submitted by 1/31/2004. If resistance is confirmed, all MON863 acres (MON863 Bt fields and non-MON863 Bt refuges) must be treated with insecticides targeted at CRW adults as well as larvae.

**Annual Reports:**

The registrant will provide an annual reports to EPA on its Cry3Bb1 PIP expressed in corn based on the following table.

Report	Description	Due Date
Annual Sales	Reported by county and state summed by state	January 31 <sup>st</sup> each year beginning in 2004
Grower Agreement	Number of units of <i>Bt</i> corn seeds shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements	January 31 <sup>st</sup> each year beginning in 2004
Grower Education	Education program completed previous year and plan for next year	January 31 <sup>st</sup> each year beginning in 2004
Proposed Compliance Plan	Written description of Compliance Assurance Program	90 Days of the Date of Registration
Compliance Assurance Plan	Compliance Assurance Program Activities and Results	January 31 <sup>st</sup> each year starting in 2004
Compliance	To include annual survey results and plans for the next year	Preliminary survey report November 15 <sup>th</sup> each year and full report January 31 <sup>st</sup> each year thereafter
Insect Resistance Monitoring	Submission of protocol	90 Days of the Date of Registration
Insect Resistance Monitoring	Description of the program including sampling (number of locations and samples per locations), sampling methodology, bioassay methodology, standardization procedures, detection technique and sensitivity, and the statistical analysis of the probability of detecting resistance.	January 31, 2004



Additional reports are due as described in the following table:

IRM Grower Agreements	Proposed system to assure growers sign grower agreements	90 Days of the Date of Registration
IRM Affirmation Plan	System to assure annual affirmation by growers of their IRM obligations	90 Days of the Date of Registration
Changes to Grower Agreement and/or IRM documents	Current grower agreement(s) and any specific stewardship documents	At least 30 days before any changes related to IRM are expected to be imposed.
Insect Resistance Monitoring Results	Results of monitoring and investigations of damage reports	April 30 <sup>th</sup> each year

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,



Janet L. Andersen, Ph.D, Director  
Biopesticides and Pollution  
Prevention Division (7511C)

Enclosure

### Corn Event MON 863: Rootworm Protected Corn

[Alternate brand name: *YieldGard*<sup>®</sup> Rootworm: *Rootworm Protection*]

This product is effective in controlling damage caused by corn rootworm larval feeding on corn roots.

**Active Ingredient:**

*Bacillus thuringiensis* Cry3Bb1 protein and the genetic material necessary for its production (ZMIR13L) in event MON 863 corn.....0.001 - 0.006%

**Other Ingredients:**

Substance produced by a marker gene and the genetic material necessary for its production (ZMIR13L) in event MON 863 corn.....0.00002 – 0.00003%

Percentage (wt/wt) on a dry weight basis.

Keep Out of Reach of Children

### CAUTION

® YieldGard is a trademark of Monsanto Technology LLC

EPA Registration No. 524-528

EPA Establishment No. 524-MO-002

©2003 Monsanto Company  
700 Chesterfield Parkway West  
St. Louis, MO 63017

ACCEPTED  
with COMMENTS  
In EPA Letter dated  
Feb 24, 2003  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.  
524-528

### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling.

The following information regarding commercial production must be included in the Event MON 863 Technology Use Guide.

### **Insect Resistance Management**

Growers of Corn Event MON 863: Rootworm Protected Corn must adhere to the following refuge requirements. Growers must plant a structured refuge of at least 20% non-Event MON 863 corn.

Refuge planting options include: adjacent blocks or in-field strips. If blocks are implemented they must be adjacent to the Corn Event MON 863 field. If in-field strips within a corn field are implemented, then at least 6, and preferably 12 consecutive rows should be planted with non-event MON 863 corn.

The refuge and Corn Event MON 863 acres should be managed under comparable agronomic regimes. Refuge and Corn Event MON 863 acres should both be irrigated if irrigation is used. In regions where corn is cropped continuously, refuge and Corn Event MON 863 acres should be planted in a continuous cropping regime. The refuge may be placed only on first-year corn acres if the Event MON 863 corn is planted on first-year corn acres.

Growers have the option of applying conventional insecticides to the corn refuge for control of corn rootworm larvae. Growers are not permitted to apply agents for control of adult corn rootworm to the refuge as this would render the refuge less effective. If growers opt to treat for other insects present in the refuge while adult corn rootworm are present, then the Corn Event MON 863 acres must be treated in a like manner.

These refuge requirements do not apply to operations engaged in the propagation of inbred seed corn.

### **Corn Insects Controlled or Suppressed**

Corn has been genetically transformed to produce the *B.t.* protein, Cry3Bb1, for control or suppression of the following coleopteran insects:

- Western corn rootworm (*Diabrotica virgifera virgifera*)
- Northern corn rootworm (*Diabrotica barberi*)
- Mexican corn rootworm (*Diabrotica virgifera zea*)