Bacillus thuringiensis Cry3Bb1 protein and the genetic material necessary for its production (Vector ZMIR39) in Event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3) (006502) and Bacillus thuringiensis Cry1Ab Delta-Endotoxin and the Genetic Material Necessary for its Production in Corn (006430) Fact Sheet

I. Description of the Plant-Incorporated Protectant (PIP)

- **Pesticide Names:**

  Bacillus thuringiensis Cry3Bb1 protein and the genetic material necessary for its production (Vector ZMIR39) in Event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)

  Bacillus thuringiensis Cry3Bb1 protein and the genetic material necessary for its production (Vector ZMIR39) in Event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3) and *Bacillus thuringiensis* Cry1Ab Delta-Endotoxin and the Genetic Material Necessary for its Production in Corn

- **EPA Registration Number:** 524-545

- **Date Registered:** October 31, 2003

- **Trade and Other Names:** MON 88017 Corn, MON 88017 x MON 810

- **OPP Chemical Codes:** 006484 and 006430

- **Basic Manufacturer:**

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

- **Type of Pesticide:** Plant-Incorporated Protectant

- **Uses:** Field Corn

- **Pests Controlled or Suppressed**:

  - MON 88017 - Western Corn Rootworm, Northern Corn Rootworm, and Mexican Corn Rootworm

  - MON 88017 x MON 810 - European Corn Borer, Southwestern Corn Borer, Southwestern Cornstalk Borer, Southern Cornstalk Borer, Sugarcane Cornstalk Borer, Corn Earworm, Fall Armyworm, Stalk Borer, Western Corn Rootworm, Northern Corn Rootworm, and Mexican Corn Rootworm

II. Background

The Cry3Bb1 protein produced in MON 88017 corn is a variant of the wild-type Cry3Bb1 protein from *B.t.* subsp. *kumamotoensis* and it protects the roots of corn plants from feeding damage caused by the coleopteran pest, corn rootworm (*Diabrotica* sp.). The Cry3Bb1 protein in MON 88017 corn differs in its amino acid sequence by a single amino acid from the Cry3Bb1 protein in MON 863 corn (EPA Registration Number 524-528).

MON 88017 corn also expresses the 5-enolpyruvylshikimate-3-phosphate synthase protein from *Agrobacterium sp.* strain CP4 (CP4 EPSPS) which confers tolerance to the herbicide glyphosate.

MON 88017 x MON 810 corn was produced via traditional plant breeding of plants containing

MON 88017 and plants containing MON 810 (EPA Registration Number 524-489).

III. Terms and Conditions of the Registration

A. MON 88017, EPA Registration Number 524-551

1. The subject registration will automatically expire on midnight September 30, 2010.

2. The subject registration will be limited to Bacillus thuringiensis Cry3Bb1 protein and the genetic material necessary for its production (Vector ZMIR39) in MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3 for use in field corn.

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.

4. Submit all data required to support the individual plant-incorporated protectant in Event MON863 (YieldGard Rootworm), 524-528. In the event that the Agency concludes MON 863 (YieldGard Rootworm) studies do not sufficiently demonstrate a lack of significant adverse effects, additional data with MON 88017 corn must be submitted. This data may include a) laboratory toxicity testing with Orius insidiosus (minute pirate bug), b) laboratory toxicity testing with a carabid (ground beetle), c) long range effects testing on invertebrate populations in the field, and d) long range soil persistence testing.

5. You must commit to do the following Insect Resistance Management Program:

   a. **Refuge Requirements**

      These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn.

      1. 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.

      2. Specifically, growers must plant a structured refuge of at least 20% non-corn rootworm protected 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.

      3. Refuge planting options include: refuge acres should be planted as blocks adjacent to MON 88017 corn fields, perimeter strips, or as in-field strips.

4. External refuges must be planted adjacent (e.g., across the road) to Cry3Bb1 MON 88017 fields.

5. When planting the refuge in strips across the field, refuges must be at least 4 rows wide, preferably 6 consecutive rows wide.

6. 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.

7. If the refuge is planted in a field that is in a crop rotation system, then MON 88017 must also be planted in a field that is in a crop rotation system.

8. If the refuge is planted on continuous corn, then the MON 88017 field may be planted on either continuous or in a field that is in a crop rotation system.

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, 2007 and annually thereafter, the registrant shall provide EPA with a report showing the number of units of its Bt MON 88017 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 MON 88017 corn users the importance of complying with the IRM program. The program shall include information encouraging Bt MON 88017 corn

users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Bt MON 88017 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 MON 88017 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. On January 31, 2007, the registrant must provide a report to EPA summarizing the activities carried out under the education program for the prior year. Annually thereafter, the registrant must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. The required features of the compliance assurance program are described in paragraphs 4]-15] below.

4. The registrant must design and implement an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing its MON 88017 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 MON 88017 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. 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 MON 88017 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 MON 88017 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. The survey will include only growers planting at least 200 acres of corn in the Corn Belt or 100 acres of corn in corn/cotton growing regions.

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 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, beginning with 2007. 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 registrant must confer with the Agency prior to adopting any changes to a previously approved CAP.

11. The registrant shall train its representatives who make on-farm visits with MON 88017 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. This on-farm assessment program has no minimum acreage threshold for growers.

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 MON 88017 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, 2007 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:

The registrants must monitor for Cry3Bb1 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.

1. The registrant must provide EPA its resistance monitoring plan for approval. A revised monitoring plan must be submitted to the Agency with 3 months of the date of registration consisting of a description of the steps to be taken to establish corn rootworm baseline sensitivity and damage guidelines. A detailed resistance monitoring plan must be submitted to the Agency for review by January 31, 2008. This plan must include: baseline sensitivity data, sampling (number of locations, samples per locations), sampling methodology and life-stage sampled, bioassay methodology, standardization procedures (including QA/QC provisions), detection technique and sensitivity, the statistical analysis of the probability of detecting resistance, and an interim description of rootworm damage guidelines.

2. The registrant must develop and validate an appropriate discriminating or diagnostic dose assay by January 31, 2010.

3. You must finalize rootworm damage guidelines and submit these to BPPD by January 31, 2010.

4. The registrant must follow-up on grower, extension specialist or consultant reports of unexpected damage or control failures for corn rootworm.

5. The registrant must provide EPA with an annual resistance monitoring report by August 31st of each year beginning with 2007, reporting on populations collected the previous year.

e. **Remedial Action Plans**

Once a remedial action plan is approved for MON 863, it also must be used for corn rootworm suspected and confirmed resistance in MON 88017. If corn rootworm resistance is confirmed, all acres (MON 88017 and refuges) must be treated with insecticides targeted at CRW adults as well as larvae.

The annual reporting requirements are as follows:

1. Annual Sales: reported and summed by state (county level data available by request), January 31st each year;

2. Grower Agreement: number of units of Bt 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 31st each year;

3. Grower Education: substantive changes to education program completed previous year, January 31st each year;

4. Compliance Assurance Plan: Compliance Assurance Program activities and results, January 31st each year;

5. Compliance: to include annual survey results and plans for the next year; full report January 31st each year;

6. Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, August 31st each year.

B. MON 88017 x MON 810, EPA Registration Number 524-552

0. The subject registration will automatically expire on midnight October 15, 2008.

1. The subject registration will be limited to Cry3Bb1 [Bacillus thuringiensis Cry3Bb1 protein and the genetic material necessary for its production (Vector ZMIR39) in MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3)] X Cry1Ab [Bacillus thuringiensis Cry1Ab delta-endotoxin and the genetic material necessary for its production in corn] corn for use in field corn.

2. 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.

3. Submit all data required to support the individual plant-incorporated protectants in MON 810 (YieldGard), Event MON863 (YieldGard Rootworm), MON 88017 corn;

EPA Registration Nos. 524-489, 524-528. In the event that the Agency concludes MON 863 (YieldGard Rootworm) studies do not sufficiently demonstrate a lack of significant adverse effects, additional data with MON 88017 x MON 810 corn must be submitted. This data may include a) laboratory toxicity testing with Orius insidiosus (minute pirate bug), b) laboratory toxicity testing with a carabid (ground beetle), c) long range effects testing on invertebrate populations in the field, and d) long range soil persistence testing.

4. Submit expression level data regarding Cry1Ab protein levels in MON 810 and MON 88017 x MON 810 young root and forage root within 12 months of the date of registration.

5. You must commit to do the following Insect Resistance Management Program:

a. **Refuge Requirements**

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn.

Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the following refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

Corn Belt / Non-Cotton Growing Region Refuge Requirements

For corn grown in the US Corn Belt two options for deployment of the refuge are available to growers.

The first option is planting a common refuge for both corn borers and corn rootworms. The common refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. The refuge area must represent at least 20% of the grower's corn acres (i.e. sum of [MON 88017 x MON 810] acres and refuge acres). It can be planted as a block adjacent to the [MON 88017 x MON 810] field, perimeter strips, or in-field strips. If perimeter strips are implemented, the strips must be at least 4, and preferably 6 consecutive rows wide. If strips within the [MON 88017 x MON 810] field are implemented, then at least 4, and preferably 6 consecutive rows should be planted. The common refuge can be treated

with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-Bt foliar insecticide for control of late season pests if pest pressure reaches an economic threshold for damage; however, if rootworm adults are present at the time of foliar applications then the [MON 88017 x MON 810] field must be treated in a similar manner.

The first option is planting a common refuge for both corn borers and corn rootworms. The common refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. The refuge area must represent at least 20% of the grower's corn acres (i.e. sum of [MON 88017 x MON 810] acres and refuge acres). It can be planted as a block adjacent to the [MON 88017 x MON 810] field, perimeter strips, or in-field strips. If perimeter strips are implemented, the strips must be at least 4, and preferably 6 consecutive rows wide. If strips within the [MON 88017 x MON 810] field are implemented, then at least 4, and preferably 6 consecutive rows should be planted. The common refuge can be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-Bt foliar insecticide for control of late season pests if pest pressure reaches an economic threshold for damage; however, if rootworm adults are present at the time of foliar applications then the [MON 88017 x MON 810] field must be treated in a similar manner.

The second option is planting separate refuge areas for corn borers and corn rootworms. The corn borer refuge must be planted with a non-Bt/lepidopteran-protected hybrid, must represent at least 20% of the grower's corn acres (i.e. sum of [MON 88017 x MON 810] acres and corn borer refuge acres), and must be planted within ½ mile of the [MON 88017 x MON 810] field. The corn borer refuge can be treated with a soil-applied or seed-applied insecticide for corn rootworm larval control, or a non-Bt foliar-applied insecticide for corn borer control if pest pressure reaches an economic threshold for damage. The corn rootworm refuge must be planted with a non-Bt/corn rootworm-protected hybrid, but can be planted with Bt corn hybrids that control corn borers. The corn rootworm refuge must represent at least 20% of the grower's corn acres (i.e. sum of [MON 88017 x MON 810] acres and corn rootworm refuge acres) and can be planted as an adjacent block, perimeter strips, or in-field strips. The corn rootworm refuge can be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-Bt foliar insecticide for control of late season pests; however, if

rootworm adults are present at the time of foliar applications then the [MON 88017 x MON 810] field must be treated in a similar manner. Growers who fail to comply with the IRM requirements risk losing access to the product.

Cotton Growing Area Refuge Requirements

For [MON 88017 x MON 810] corn grown in cotton-growing areas the common refuge and separate refuge options are also available, however, the refuge area is larger. Cotton-growing areas include the following states: Alabama, Arkansas, Florida, Georgia, 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, Ochiltree, 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 Dunkin, New Madrid, Pemiscot, Scott, and Stoddard).

The first option is planting a common refuge for both corn borers and corn rootworms. The common refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. The refuge area must represent at least 50% of the grower's corn acres (i.e. sum of [MON 88017 x MON 810] acres and refuge acres). It can be planted as a block adjacent to the [MON 88017 x MON 810] field, perimeter strips, or in-field strips. If perimeter strips are implemented, the strips must be at least 4, and preferably 6 consecutive rows wide. If strips within the [MON 88017 x MON 810] field are implemented, then at least 4, and preferably 6 consecutive rows should be planted. The common refuge can be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-Bt foliar insecticide for control of late season pests if pest pressure reaches an economic threshold for damage; however, if rootworm adults are present at the time of foliar applications then the [MON 88017 x MON 810] field must be treated in a similar manner.

The second option is planting separate refuge areas for corn borers and corn rootworms. The corn borer refuge must be planted with a non-Bt/lepidopteran-protected hybrid, must represent at least 50% of the

grower's corn acres (i.e. sum of [MON 88017 x MON 810] acres and corn borer refuge acres), and must be planted within ½ mile of the [MON 88017 x MON 810] field. The corn borer refuge can be treated with a soil-applied or seed-applied insecticide for corn rootworm larval control, or a non-Bt foliar-applied insecticide for corn borer control if pest pressure reaches an economic threshold for damage. The corn rootworm refuge must be planted with a non-Bt corn/rootworm-protected hybrid, but can be planted with Bt corn hybrids that control corn borers. The corn rootworm refuge must represent at least 20% of the grower's corn acres (i.e. sum of [MON 88017 x MON 810] acres and corn rootworm refuge acres) and be planted as an adjacent block, perimeter strips, or in-field strips. The corn rootworm refuge can be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-Bt foliar insecticide for control of late season pests; however, if rootworm adults are present at the time of foliar applications then the [MON 88017 x MON 810] field must be treated in a similar manner. Growers who fail to comply with the IRM requirements risk losing access to the product.

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, 2007 and annually thereafter, the registrant shall provide EPA with a report showing the number of units of its [MON 88017 x MON 810] 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 [MON 88017 x MON 810] corn users the importance of complying with the IRM program. The program shall include information encouraging [MON 88017 x MON 810] corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to [MON 88017 x MON 810] 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 88017 x MON 810] 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. On January 31, 2007, the registrant must provide a report to EPA summarizing the activities carried out under the education program for the prior year. Annually thereafter, the registrant must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. The required features of the compliance assurance program are described in paragraphs 4]-15] below.

4. The registrant must design and implement an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing its [MON 88017 x MON 810] 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 [MON 88017 x MON 810] 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. 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 [MON 88017 x MON 810] 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 [MON 88017 x MON 810] 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. The survey will include only growers planting at least 200 acres of corn in the Corn Belt or 100 acres of corn in corn/cotton growing regions.

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 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, beginning with 2007. 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 registrant must confer with the Agency prior to adopting any changes to a previously approved CAP.

11. The registrant shall train its representatives who make on-farm visits with [MON 88017 x MON 810] 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. This on-farm assessment program will have no minimum acreage threshold for growers.

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 [MON 88017 x MON 810] 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, 2007 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. For the Cry1Ab portion of the product , the registrants will monitor for resistance and/or trends in increased tolerance for European

corn borer, Southwestern corn borer, and corn earworm. Sampling should be focused in those areas in which there is the highest risk of resistance development. Monitoring must be carried out under the same protocols used for the products MON 810 524-528. The registrants must monitor for Cry3Bb1 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.

2. For the Cry3Bb1 portion of the product, the registrant must provide EPA its resistance monitoring plan for approval. A revised monitoring plan must be submitted to the Agency with 3 months of the date of registration consisting of a description of the steps to be taken to establish corn rootworm baseline sensitivity and damage guidelines. A detailed resistance monitoring plan must be submitted to the Agency for review by January 31, 2008. This plan must include: baseline sensitivity data, sampling (number of locations, samples per locations), sampling methodology and life-stage sampled, bioassay methodology, standardization procedures (including QA/QC provisions), detection technique and sensitivity, the statistical analysis of the probability of detecting resistance, and an interim description of rootworm damage guidelines.

3. For the Cry3Bb1 portion of the product, the registrant must finalize rootworm damage guidelines and submit these to BPPD by January 31, 2010.

4. For the Cry3Bb1 portion of the product, the registrant must finalize rootworm damage guidelines and submit these to BPPD by January 31, 2010.

5. The registrant must follow-up on grower, extension specialist or consultant reports of unexpected damage or control failures for corn rootworm.

6. The registrant must provide EPA with annual resistance monitoring reports by April 30 th of each year for lepidopteran insects and by August 31st of each year for coleopteran insects, beginning with 2007, reporting on populations collected the previous year.

e. **Remedial Action Plans**

The October 15, 2001 Remedial Action Plan for Responding to Resistance in European Corn Borer, Corn Earworm and/or Southwestern Corn Borer must be used for suspected and confirmed resistance of these pests. Once a remedial action plan is approved for MON 863, it also must be used for corn rootworm suspected and confirmed resistance in [MON 88017 x MON 810]. If corn rootworm resistance is confirmed, all acres ([MON 88017 x MON 810] and refuges) must be treated with insecticides targeted at CRW adults as well as larvae.

A summary of required annual reports follows.

1. Annual Sales: reported and summed by state (county level data available by request), January 31st each year;

2. Grower Agreement: number of units of Bt 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 31st each year;

3. Grower Education: substantive changes to education program completed previous year, January 31st each year;

4. Compliance Assurance Plan: Compliance Assurance Program activities and results, January 31st each year;

5. Compliance: to include annual survey results and plans for the next year; full report January 31st each year;

6. Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, April 30th each year.

IV. Additional Contact Information:

Ombudsman, Biopesticides and Pollution Prevention Division (7511P)
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460