III. Terms and Conditions of the Registration

MON 863

Monsanto is required to do the following as terms and conditions of the registration.

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 ZMIR13L) in Event MON863 Corn 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 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 once requested by EPA's Ft. Meade laboratory. 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, Monsanto 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 Monsanto is 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. *Data requirement satisfied. Validation by EPA's Biological and Economic Analysis Division Laboratory pending.*

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 requirement satisfied.*

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. *Data requirement satisfied provided three (3) year YieldGard Plus (EPA Reg. No. 524-545) fate data submitted and found acceptable.*

8) Submit laboratory toxicity tests with Orius insidiosus (minute pirate bug), and carabid (ground beetle), within 24 months of the date of registration, provided the registration is amended to extend the registration date. *Data submitted and under review.* Protocols are due within 120 days of the date of registration. We note that further investigation of the biology and life cycle of the red milkweed beetle demonstrates that there will be little or no exposure of larvae under natural conditions. Although adults may be exposed to Bt corn pollen while feeding on milkweed leaves, Bt is typically less toxic to adults than larvae. There is also no protocol for rearing red milkweed beetles in the laboratory and the development of such a laboratory assay would be difficult due to the red milkweed beetle''s long development time. Therefore, on October 1, 2003, the Agency granted Monsanto's request and the *waived requirement for conducting a red milkweed beetle* study set forth in the notice 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. *Data submitted and under review.*

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. *Data submitted and under review.*

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. The final reports must be submitted by January 31, 2006. *Data requirement satisfied.*

- 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 ?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 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.] *No information submitted, but not required.*

13) Monsanto 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 units sold by state (units sold by county level will be made available to the Agency upon request), IRM grower agreements results, compliance and assurance program including the educational program on or before January 31st each year.

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 4 rows wide, preferably 6 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 registrant must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. 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 conducted by an independent third party of a statistically representative sample of growers of Bt corn protected products who plant the vast majority of all corn in the U.S. 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 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 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 31st of each year. The registrant shall confer with other registrants and 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 conduct an annual on-farm assessment program. The registrant shall train its representatives who make on-farm visits with growers of their Bt corn products 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, 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 August 31st 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 (including MON863 Bt fields and non-MON863 Bt refuges) must be treated with insecticides targeted at CRW adults as well as larvae. *Remedial Action Plan submitted and found acceptable.*

Annual Reports:

The registrant will provide annual reports to EPA by January 31st each year based on the following table.

Report	Description
Annual Sales	Reported by state
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
Grower Education	Significant changes in grower education plan
Compliance Assurance Plan	Compliance Assurance Program activities and results
Compliance	Annual survey results and plans for the next year

Additionally, at least 30 days before any changes related to IRM are expected to be imposed (e.g. grower agreement), a report of such changes must be submitted to EPA. Results of insect resistance monitoring and investigations of damage reports must be submitted by April 30th each year.

YieldGard Plus

Monsanto is required to do the following as terms and conditions of the registration.

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

2) The subject registration will be limited to the use of a) Bacillus thuringiensis Cry3Bb1 Protein and the Genetic Material Necessary for its Production (Vector ZMIR13L) in MON 863 corn and b) Bacillus thuringiensis Cry1Ab1 Protein and the Genetic Material Necessary for its Production in corn in YieldGard® Plus field corn produced via the conventional breeding of MON 810 and MON 863 corn.

3) Monsanto must submit/cite all data required for registration of their product under FIFRA§ 3(c)(5) when the Agency requires registrants of similar products to submit such data.

4) Monsanto must submit production information for this product to the Office of Pesticide Programs 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) Monsanto must submit all data required to support the individual plant-incorporated protectants in YieldGard® Corn Borer (MON 810) and YieldGard® Rootworm (MON 863) corn, EPA Registration Nos. 524-489 & 524-528.

6) Monsanto must submit small and large-scale field studies conducted with YieldGard® Plus Corn with appropriate end points and statistical power to verify there are no adverse ecological effects to non-target invertebrate populations. Monsanto must submit annual reports each year of this registration every April 30th, beginning in 2005, provided the registration expiration date is extended.

7) Monsanto must submit field degradation studies evaluating accumulation and persistence of Cry1Ab and Cry3Bb1 from YieldGard® Plus Corn in several different soils in various strata. Representative fields must have been planted with YieldGard® Plus Corn for at least three consecutive years and include both conventional tillage and no-till samples and be harvested under typical agronomic conditions. Sampling must begin after three consecutive years of YieldGard® Plus Corn planting and 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 Cry1Ab and Cry3Bb1 are accumulating or persisting in soil samples. A protocol is due within 120 days of the date of registration. Planting of YieldGard® Plus Corn for the study must begin in 2004, with sampling beginning after the 2006 growing season. Provided, the registration and tolerance exemption are amended to extend the expiration dates, a final report is due November 15, 2007.

8) Monsanto must do the following Insect Resistance Management Program:

The required IRM program for YieldGard Plus® Bt corn has the following elements:

1] Requirements relating to creation of either common or separate refuges for Cry3Bb1 and Cry1Ab in conjunction with the planting of any acreage of commercial YieldGard Plus® Bt corn;

2] Requirements for the registrant to prepare and require YieldGard Plus® 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 registrant to develop, implement, and report to EPA on programs to educate growers about IRM requirements;

4] Requirements for the registrant to develop, implement, and report to EPA on programs to evaluate and promote growers'' compliance with IRM requirements (the YieldGard Plus® Compliance Assurance Program (CAP) must integrate with the Cry1 and Cry3Bb1 CAPs);

5] Requirements for the registrant 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 or Cry1Ab proteins in the target insects;

6] Requirements for the registrant 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 units sold by state (units sold by county level will be made available to the Agency upon request), IRM grower agreements results, compliance and assurance program including the educational program on or before January 31st each year.

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 YieldGard Plus acres and refuge acres). It can be planted as a block adjacent to the YieldGard Plus 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 YieldGard Plus 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 YieldGard Plus 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/lepidoteran-protected hybrid, must represent at least 20% of the grower''s corn acres (i.e. sum of YieldGard Plus acres and corn borer refuge acres), and must be planted within ½ mile of the YieldGard Plus 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 YieldGard Plus 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 YieldGard Plus 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 YieldGard Plus 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 YieldGard Plus acres and refuge acres). It can be planted as a block adjacent to the YieldGard Plus 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 YieldGard Plus 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 YieldGard Plus 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 YieldGard Plus acres and corn borer refuge acres), and must be planted within ½ mile of the YieldGard Plus 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 YieldGard Plus 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 YieldGard Plus 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, 2005 and annually thereafter, the registrant shall provide EPA with a report showing the number of units of its YieldGard Plus® 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 YieldGard Plus corn users the importance of complying with the IRM program. The program shall include information encouraging YieldGard Plus corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to YieldGard Plus 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 YieldGard Plus 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 Grower 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, 2005 and 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 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 YieldGard® Plus 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 YieldGard® Plus Bt corn product. Monsanto shall ensure that the YieldGard® Plus compliance assurance program (CAP) will be consistent with and integrated with the CAPs for MON 863 and MON 810, EPA Registration Nos. 524-489 and 524-528. 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 to be implemented

in the 2004 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 YieldGard Plus 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 YieldGard Plus corn.

6] The IRM compliance assurance program shall include an annual survey conducted by an independent third party of a statistically representative sample of growers of Bt corn protected products who plant the vast majority of all corn in the U.S. 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 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 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 31st of each year. The registrant shall confer with other registrants and 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.

11] The registrant shall conduct an annual on-farm assessment program. The registrant shall train its representatives who make on-farm visits with growers of their Bt corn products 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, 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 YieldGard Plus 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, 2005 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 registrant will monitor for resistance and/or trends in increased tolerance for corn rootworm, 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 individual trait products MON 810 and MON 863, EPA Registration Nos. 524-489 and 524-528.

2) The registrant shall provide to EPA a description of its resistance monitoring plan by January 31, 2005. 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 all pests listed on the label and/or grower guide. 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.

4) A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by August 31st each year for the duration of the conditional registration, beginning in 2005.

e. Remedial Action Plans

A Remedial Action Plan covering both suspected and confirmed resistance for corn rootworm, European corn borer, southwestern corn borer, and corn earworm must be submitted by 1/31/2005. If resistance is confirmed, all acres (YieldGard Plus and refuges) should be treated with insecticides targeted at CRW adults as well as larvae.

Annual Reports:

The registrant will provide annual reports to EPA by January 31st each year based on the following table.

Report	Description
Annual Sales	Reported by state
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
Grower Education	Significant changes in grower education plan
Compliance Assurance Plan	Compliance Assurance Program activities and results
Compliance	Annual survey results and plans for the next year

Additionally, at least 30 days before any changes related to IRM are expected to be imposed (e.g. grower agreement), a report of such changes must be submitted to EPA. Results of insect resistance monitoring and investigations of damage reports must be submitted by April 30th each year.

MON 88017

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

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

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 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 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. 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.

9d. 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, April 30th each year.

MON 88017 x MON 810

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

2) 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.

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 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.

5) 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.

6) 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 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 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 [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. 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 develop and validate an appropriate discriminating or diagnostic dose assay 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 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

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.