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

OCT 13 2005

MEMORANDUM

SUBJECT: Review of proposed insect resistance management plan and benefits information submitted by Monsanto for MON 88017 x MON 810 Bt corn. EPA Reg. No. 524-LLE. DP Barcode: D302513. Decision: 339469. MRID#: 461850-01.

TO: Mike Mendelsohn, Regulatory Action Leader
Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division (7511C)

FROM: Alan Reynolds, Entomologist
Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division (7511C)

PEER REVIEW: Sharlene Matten, Ph.D., Biologist for:
Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division (7511C)

Action Requested

BPPD has been asked to review submitted information on insect resistance management (IRM) and benefits for MON 88017 x MON 810, a new Bt corn product that expresses Cry3Bb1 and Cry1Ab. The materials were submitted in a single volume ("Human Health and Environmental Assessment of the Plant-Incorporated Protectant *Bacillus thuringiensis* Cry3Bb1 and Cry1Ab Proteins Produced in MON 88017 x MON 810", MRID# 461850-01). The submitted volume also contains information on product characterization, human health, and environmental/non-target effects. The product characterization and human health aspects will be reviewed separately and only the environmental/non-target information pertinent to IRM and benefits will be reviewed in this document.

Background

MON 88017 x MON 810 expresses both the Cry3Bb1 and Cry1Ab Bt toxins and is targeted against corn rootworm (CRW) larvae (Cry3Bb) and European corn borer (ECB)/stalk boring lepidopteran larvae (Cry1Ab). The product was created by conventional breeding in which MON 88017 (EPA Reg. No. 524-LLR) was crossed with MON 810 (Yieldgard, EPA Reg. No. 524-489). The Cry3Bb1 toxin is the same as expressed by MON 863 corn (Yieldgard Rootworm, EPA Reg. No. 525-528), which was registered by Monsanto for the 2003 growing

season. A separate stacked product, Yieldgard Plus (EPA Reg. No. 524-545) also expresses Cry3Bb1 and Cry1Ab and was created by crossing MON 863 with MON 810. The Cry3Bb1 protein produced in MON 88017 and MON 863 is a variant of the wild-type Cry3Bb1 protein from *Bt* subsp. *kumamotoensis*, whereas the Cry1Ab toxin originated from *Bt* subsp. *kurstaki*. When compared by amino acid sequencing, the Cry3Bb1 protein expressed in MON 88017 has been reported to be 99.8% similar to the Cry3Bb1 protein expressed in MON 863. The primary difference between the hybrids (MON 863 and MON 863 x MON 810) is that MON 88017 (and hence MON 88017 x MON 810) also expresses a gene for resistance to glyphosate (Roundup) based herbicides. The proposed label for MON 88017 x MON 810 indicates that the product controls or suppresses western corn rootworm (*Diabrotica virgifera virgifera*), northern corn rootworm (*Diabrotica barberi*), Mexican corn rootworm (*Diabrotica virgifera zeae*), European corn borer (ECB, *Ostrinia nubilalis*), southwestern corn borer (SWCB, *Diatraea grandiosella*), southern cornstalk borer (*Diatraea crambidoides*), sugarcane cornstalk borer (*Diatraea saccharalis*), corn earworm (CEW, *Helicoverpa zea*), fall armyworm (FAW, *Spodoptera frugiperda*), and stalk borer (*Papaipema nebris*).

Conclusions and Recommendations

1) Both the Insect Resistance Management (IRM) and benefits materials submitted by Monsanto are acceptable to support registration of MON 88017 x MON 810. No additional data or information are needed at the present time.

2) Data submitted by Monsanto has shown that the Cry3Bb1 and Cry1Ab toxins expressed by MON 88017 x MON 810 are the functional equivalent of those expressed in the previously registered events MON 863 (Cry3Bb1), MON 810 (Cry1Ab1), and Yieldgard Plus (MON 863 x MON 810). This functional equivalence includes amino acid homology for Cry3Bb1 (99.8%), protein expression for both toxins, and efficacy against the major target pests (CRW and ECB). As such, the IRM plan developed for Yieldgard Plus is applicable to the MON 88017 x MON 810 registration.

3) The Monsanto submission provided only a cursory overview of the Yieldgard Plus IRM plan. It is recommended that all aspects of the Yieldgard Plus IRM plan be applied to the MON 88017 x MON 810 registration, including refuge requirements, resistance monitoring, compliance assurance, remedial action, and annual reports. However, one modification to the plan is discussed in #4 below. Several other modifications that have been proposed for the Yieldgard Plus plan (including grower education reports and compliance issues) should also be made for MON 88017 x MON 810. The specific IRM terms and conditions for Yieldgard Plus that should be applied to MON 88017 x MON 810 are detailed in the IRM Data Evaluation Report attached to this memorandum. Any changes that are subsequently made to the Yieldgard Plus IRM plan should be made for the MON 88017 plan as well.

4) BPPD recommends modification to the current minimum row width for in-field strip CRW refuges. Currently, the IRM plan for Yieldgard Plus requires 6 or more rows for in-field strips. However, to provide consistency among all refuge options and all Bt corn product targeting CRW, BPPD recommends that the minimum in-field strip width for CRW refuges in the MON 88017 x MON 810 IRM plan be adjusted to 4 or more rows. (A similar adjustment has been proposed for the MON 863, MON 88017 and Yieldgard Plus IRM plans.) Larval movement

data recently reviewed by BPPD suggest that 4 row or greater strips are scientifically justifiable for CRW in-field refuges. It is noted that in-field strip refuges of at least 4 rows (6 preferred) are still recommended for lepidopteran (ECB) refuges.

5) The current IRM plan for Yieldgard Plus allows for treatment of CRW adults in the refuge, provided the Bt field is treated in a similar manner. Should Monsanto wish to amend this refuge treatment option to allow independent treatment of the refuge for pests other than corn rootworms (e.g. corn borers, spider mites), it is recommended that data be submitted regarding the impact of independent treatment of the refuge on CRW resistance management.

6) The benefits of MON 88017 x MON 810 will be almost identical to those for Yieldgard Plus. The major benefits will include efficacy against the target pests (CRW and lepidoptera), reduced use of conventional insecticides, environmental benefits (reduced exposure of non-target insects), economic benefits (e.g. reduced costs, increased yields), and reduced incidences of mycotoxin infection from ECB feeding. Additional benefits may be derived from Roundup (glyphosate) tolerance, although these potential advantages were not fully quantified by Monsanto and could not be completely assessed.

7) It is noted that a public interest document (PID) was not submitted with the benefits information, therefore, a public interest determination (as is required for conditional FIFRA section 3c7 registrations) was not made in this review.

DATA EVALUATION RECORD

EPA Secondary Reviewer: Alan Reynolds, Entomologist

STUDY TYPE:	Insect Resistance Management (IRM)
MRID NO:	461850-01
TEST MATERIAL:	Transgenic corn events MON 88017 x MON 810
PROJECT STUDY NO:	MSL-18955
SPONSOR:	Monsanto Company
TESTING FACILITY:	Monsanto Company 800 North Lindbergh Boulevard St. Louis, MO 63167
TITLE OF REPORT:	Human Health and Environmental Assessment of the Plant-Incorporated Protectant *Bacillus thuringiensis* Cry3Bb1 and Cry1Ab Proteins Produced in Corn MON 88017 x MON 810
AUTHORS:	Ravinder S. Sidhu
STUDY COMPLETED:	January 22, 2004
CONCLUSION:	The Cry3Bb1 and Cry1Ab proteins expressed in MON 88017 x MON 810 corn are functionally and physiologically similar to that expressed in MON88017/MON 863 and MON 810 corn. The Cry3Bb1 proteins differ by only one amino acid of 653 (99.8% homology) and are expressed at comparable levels in the plant. The Cry1Ab protein (MON 810) was inserted by conventional breeding. Field efficacy data showed that the performance of both MON 88017 x MON 810 against the target pests was nearly identical to MON 88107 and MON 810 alone. As such, the IRM plan developed for Yieldgard Plus (MON 863 x MON 810), consisting of CRW (MON 863) and Lepidoptera (MON 810) components, is compatible with MON 88017 x MON 810 corn. It is recommended that all aspects of the Yieldgard Plus IRM plan (as outlined in the terms and conditions of registration) be applied to MON 88017 x MON 810.
CLASSIFICATION:	Acceptable
GOOD LABORATORY PRACTICE:	Not GLP compliant

I. SUMMARY OF PROPOSED IRM PLAN

Monsanto has submitted an IRM plan identical to the one implemented for MON 863 x MON 810 (Yieldgard Plus, EPA Reg. No. 524-545). Both MON 88017 x MON 810 and

Yieldgard Plus express the Cry3Bb1 and Cry1Ab toxins and are targeted against corn rootworm (CRW) and corn stalk boring lepidopteran larvae.

Dose Issues

Monsanto's submission indicates that the Cry3Bb1 and Cry1Ab toxins expressed in MON 88017 x MON 810 are "physiologically and functionally" equivalent to that expressed in MON 863, MON 88017, and MON 810. To demonstrate the physiological equivalence, Monsanto investigated the amino acid sequences of the Cry3B1 toxins produced in both MON 88017 and MON 863. The Cry3Bb1 proteins produced in MON 88017 and MON 863 share an amino acid sequence identity of >99.8%, differing from one another by only one of 653 amino acids. Since the Cry1Ab toxin was introduced using conventional breeding with MON 810, the toxins in MON 88017 x MON 810 and MON 810 should be identical. To test for functional equivalence, field efficacy tests were conducted against CRW and ECB larvae. Four treatments were used: MON 88017 x MON 810, MON 88017, MON 810 (crossed with a glyphosate tolerant hybrid), and a non-expressing control (a glyphosate-tolerant hybrid). For ECB, evaluations natural infestations were used, which were supplemented by artificial infestations at the whorl stage. Damage (efficacy) was determined by assessing leaf damage (LDR) using the Modified Guthrie Scale (0=no damage, 9=high damage). CRW efficacy was also evaluated with artificial infestations of western corn rootworm (WCRW), which was done at the second leaf stage (V2). Damage was assessed using a root damage rating (RDR) scale (Oelson Node Injury Scale). The results for ECB efficacy (tabulated after 21 days) showed that both MON 88017 x MON 810 and MON 810 alone had low amounts of leaf damage (LDR= 0.8 and 0.9 respectively), while the MON 88017 alone and non-expressing control had significantly higher levels of damage (LDR=2.7 for both). For WCRW (determined after 6-7 weeks), both MON 88017 x MON 810 and MON 88017 alone had significantly greater root protection (RDR=0.1 for both) than MON 810 alone or the non-expressing control (RDR=1.24 and 1.35 respectively). A summary of the submitted efficacy data is in table 2 at the end of this report.

In addition to the structural and functional analysis of the Cry3Bb1 and Cry1Ab toxins, Monsanto also determined protein expression levels in MON 88017 x MON 810 relative to those for MON 88017 and MON 810. (MON 88017 had been previously compared with MON 863 for Cry3Bb1 expression which was found to be almost identical). Using ELISA techniques, young leaf, young root (Cry3Bb1 only), pollen (Cry3Bb1 only), forage (leaf), forage root (Cry3Bb1 only), and grain tissues were analyzed for the amount of Cry3Bb1 and Cry1Ab protein both in dry weight and fresh weight tissues. The results showed that the Cry3Bb1 protein expression in MON 88017 x MON 810 was comparable to MON 88017 in all tissues. Expression in MON 88017 x MON 810 was slightly lower in young root and grain tissues and was higher in all other tested tissues, though none of the differences were statistically significant. Only the expression in silk was significantly different. For Cry1Ab, expression in MON 88017 x MON 810 was also comparable to MON 810, with only slight insignificant differences in young leaf, forage leaf, and grain tissues. Expression data are summarized in table 1 at the end of this report.

Based on the physiological and expression/efficacy (i.e. dose) information, Monsanto concluded that the IRM plan implemented for Yieldgard Plus (MON 863 x MON 810)

should be compatible with MON 88017 x MON 810.

IRM Strategy for MON 88017 x MON 810

Monsanto's proposed IRM plan for MON 88017 x MON 810 is identical to the one in place for Yieldgard Plus (MON 863 x MON 810) and consists of the following elements (paraphrased from Monsanto's submission):

Refuge: Growers planting MON 88017 x MON 810 corn will be required to plant either a "common" refuge for both CRW and ECB or two separate refuges to manage each pest individually.
Grower Agreements: All growers using MON 88017 x MON 810 will be required to sign a contract compelling them to adhere to the refuge requirements.

Grower Education: Monsanto will develop IRM educational materials for MON 88017 x MON 810 growers and submit a report on the program to EPA.

Compliance Assurance Program: Monsanto will develop a program to assess and promote grower compliance with refuge requirements for MON 88017 x MON 810 and submit reports to EPA.

Monitoring: Monsanto will create and implement a resistance monitoring program to track (statistically significant and biologically relevant) changes in target pest susceptibility to both the Cry3Bb1 and Cry1Ab proteins. Reports will be made to EPA.

Mitigation: A remedial action plan for cases of pest resistance to MON 88017 x MON 810 will be created and implemented.

Reports to EPA: Monsanto will submit reports on MON 88017 x MON 810 to EPA covering sales, grower agreements, compliance assurance program activities, and grower education.

II. BPPD REVIEW OF PROPOSED IRM PLAN

Monsanto has proposed essentially the same IRM plan for MON 88017 x MON 810 that was approved for Yieldgard Plus (MON 863 x MON 810) corn, though the specific details of that plan were not provided. The adequacy of the Yieldgard Plus plan for MON 88017 x MON 810 is dependent on two issues: 1) the characteristics of the expressed Cry3Bb1 and Cry1Ab proteins (i.e. are they functionally the same as the Cry3Bb1 in MON 863 and Cry1Ab in MON 810, does they target the same pests, etc.), and 2) the expression (i.e. dose) of the two toxins in MON 88017 x MON 810. Monsanto has submitted data addressing both points, showing that both the Cry3Bb1 and Cry1Ab proteins are functionally the same in Yieldgard Plus (consisting of MON 863 and MON 810) and MON 88017 x MON 810 and that the dose expression is also similar for both toxins.

While the submitted information clearly demonstrated the toxins are functionally equivalent, neither the field efficacy or expression assays utilized Yieldgard Plus (MON 863 x MON

810) as a treatment group. Rather, MON 810 (Cry1Ab) and MON 88017 (Cry3Bb1) were used for comparative purposes. The overall conclusions remain valid, nonetheless, it would have been interesting to include Yieldgard Plus for direct comparisons since Monsanto is planning to use the same IRM plan for both Yieldgard Plus and MON 88017 x MON 810.

Data generated independently by Monsanto for MON 88017 showed that the Cry3Bb1 protein in MON 88017 differed from the Cry3Bb1 in MON 863 by only one amino acid out of 653 total (99.8% homology). This one amino acid difference did not significantly impact efficacy, as both MON 88017 and MON 863 had identical root damage ratings in side-by-side comparisons (these data are contained in MRID# 461817-01 and were reviewed separately). Since MON 810 was inserted by conventional breeding, the performance of the Cry1Ab toxin in MON 88017 x MON 810 should be very similar, if not identical, to MON 810, which has been well characterized. The field efficacy data submitted here confirmed this assumption, as MON 88017 x MON 810 prevented target pest damage as well or better than MON 88017 or MON 810 alone. It is noted that no laboratory assays (i.e. LC_{50} determinations for target pests) were conducted specifically with MON 88017 x MON 810 corn. However, laboratory susceptibility has been performed separately for MON 88017 corn (see MRID# 461817-01) and, through annual resistance monitoring, for MON 810 corn. The diet bioassays for MON 88017 showed that Cry3Bb1 derived from MON 88017 and MON 863 produced similar LC_{50} susceptibility results in the tested target insects. Expression data for MON 88017 x MON 810 also demonstrated that the level of Cry1Ab and Cry3Bb1 proteins in various plant tissues were similar to those found in both MON 810 and MON 88017. Based on these data, it can be assumed that the dose expression of Cry1Ab and Cry3Bb1 is the same in MON 88017 x MON 810 as it is MON 810 (Cry1Ab) and MON 863 (Cry3Bb1). MON 810 is known to express a "high" dose for ECB (see EPA 2001 for a detailed discussion of dose). Previous testing for the YieldGard Rootworm registration revealed that the dose expressed by MON 863 is not a "high" dose for the CRW target pests (the actual dose has been characterized as a "low to moderate" dose). Since there are essentially no qualitative or quantitative differences between the Cry1Ab and Cry3Bb1 proteins in MON 88017 x MON 810 and MON 88017/MON 863 and MON 810, it is acceptable to apply the IRM plan developed for Yieldgard Plus (MON 863 x MON 810) to MON 88017 x MON 810. However, BPPD is recommending one modification to the plan (in-field refuge strip width) based on CRW larval movement data. This change is discussed in detail at the end of the BPPD Review section. Several other changes that have been proposed for the Yieldgard Plus IRM plan are also noted (in bold) in the description of the IRM plan below. Any other changes that are subsequently made to the Yieldgard Plus IRM plan should be made for the MON 88017 x MON 810 plan as well.

Monsanto's submission for MON 88017 x MON 810 described only the cursory elements of the existing Yieldgard Plus IRM plan. It is recommended that all aspects of the Yieldgard Plus IRM plan (i.e. the terms and conditions of the registration) be adapted and applied to the MON 88017 x MON 810 registration. The specific terms and conditions pertaining to IRM for Yieldgard Plus are detailed below (taken from EPA fact sheet for Yieldgard Plus corn, http://www.epa.gov/pesticides/biopesticides/ingredients/factsheets/factsheet_006430-006484.htm):

"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 6, and preferably 12 consecutive rows wide. If strips within the YieldGard Plus field are implemented, then at least 6, and preferably 12 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. [**Note: Recommended modifications to the minimum in-field strip width are discussed at the end of the BPPD Review section.**]

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 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 6, and preferably 12 consecutive rows wide. If strips within the YieldGard Plus field are implemented, then at least 6, and preferably 12 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. [**Note: Recommended modifications to the minimum in-field strip width are discussed at the end of the BPPD Review section.**]

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 Growers Association and state extension programs.

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

3] Beginning January 31, 2004 and annually thereafter, the registrants must provide a report to EPA summarizing the activities carried out under the education program for the prior year and the plans for their education program during the current year. The registrant must either submit a separate report or contribute to the report from the industry working group (ABSTC). [**Note: BPPD has proposed to change this term to require the reporting of only any substantive changes to the grower education program.**]

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. 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 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 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. **[Note: BPPD has proposed altering this term to require that the survey 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 preliminary summary of their findings by November 15 and a final written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA by January 31 of each year. The registrant shall confer with EPA on the design and content of the survey prior to its implementation. **[Note: BPPD has proposed to eliminate the requirement to submit a preliminary summary.]**

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 Yieldgard Plus 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. **[Note: BPPD has proposed to require an on-farm assessment program with 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 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, 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, 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 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.
4) A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by April 30th 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) must be treated with insecticides targeted at CRW adults as well as larvae."

Many of the requirements to submit protocols, strategies or additional information to the Agency for issues such as compliance, resistance monitoring, and remedial action have already been addressed by Monsanto for Yieldgard Plus, MON 863, and/or MON 810. In addition, the submission dates for required reports will have to be adjusted as appropriate. Any changes or modifications resulting from those submissions should be applicable to MON 88017 x MON 810 as well.

The Yieldgard Plus registration also required a number of reports to be submitted to the Agency on an annual basis. These reporting requirements should also apply to the MON 88017 x MON 810 registration, though it may be possible to combine reports that are

specific to the Cry3Bb1 or Cry1Ab toxins (e.g. monitoring). Reports regarding compliance may also be able to be combined with Yieldgard Plus where activities overlap. Also, the existing CAP and resistance monitoring strategy for Yieldgard Plus may be adapted to include MON 88017 x MON 810. 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: education program completed previous year and plan for next year, January 31st each year; **[Note proposed revision described above to require reports for substantive changes only.]**
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; preliminary survey report November 15th and full report January 31st each year; **[Note proposed revision to eliminate preliminary report requirement described above.]**
6) Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, April 30th each year.

While the IRM plan in place for Yieldgard Plus is acceptable for MON 88017 x MON 810, BPPD recommends modification to the minimum row width for in-field strip CRW refuges. Currently, the IRM plan for Yieldgard Plus requires 6 or more rows for in-field strips with CRW refuges. However, to provide consistency among all refuge options and all Bt corn product targeting CRW, BPPD recommends that the minimum in-field strip width for CRW refuges in the MON 88017 x MON 810 IRM plan be adjusted to 4 or more rows. A similar adjustment has been proposed for the MON 863, MON 88017 and Yieldgard Plus IRM plans as well.

Larval movement data recently reviewed by BPPD suggest that 4 row or greater strips are scientifically justifiable for CRW in-field refuges. The rationale and data supporting this argument were summarized in BPPD's review of the Herculex Rootworm IRM plan (BPPD 2005), a portion of which is excerpted below. Herculex Rootworm expresses the Cry34Ab1 and Cry35Ab1 toxins and was registered with a ≥4 row requirement for in-field strip refuges.

"Recent larval movement data published by Hibbard et al. (2003), showed that between 0.75% and 6% of larvae moved across rows. This represents a relatively high-end estimate of the number of larvae that could cross rows. This means that much narrower in-field strips should be sufficient to provide adequate protection from sub-lethal selection caused by CRW larval movement across rows and maintain low functional recessiveness. Any increase in sublethal selection would be offset by a greater probability that potentially resistant adults emerging from the Bt corn rows would mate with susceptible adults from the refuge row. Simulations by Storer (2003b) incorporated the Hibbard et al. larval movement data to compare how strip width can affect the durability. These simulations predicted that narrower in-field strips, between 2 and 10 rows, did not affect trait durability. Single-row strips could be too narrow and allow too much larval movement across rows to sufficiently maintain low functional

recessiveness." (taken from BPPD 2005)

In addition, the current IRM plan for Yieldgard Plus allows for treatment of CRW adults in the refuge, provided the Bt field is treated in a similar manner. Should Monsanto wish to amend this refuge treatment option to allow independent treatment of the refuge for pests other than corn rootworms (e.g. corn borers, spider mites), it is recommended that data be submitted regarding the impact of independent treatment of the refuge on CRW resistance management.

III. REFERENCES

BPPD, 2005. EPA Review of Dose, Adult Feeding Effects, and Insect Resistance Management (Trait Durability) Simulations and Plans for Bt Cry34/35Ab1 Construct PHP17662 (Event DAS-59122-7) Corn. S. Matten/A. Reynolds/T. Milofsky memorandum to M. Mendelsohn, July 13, 2005.

EPA, 2001. Bt plant-incorporated protectants October 15, 2001 biopesticides registration action document. Available at http://www.epa.gov/pesticides/biopesticides.

TABLE 1. Cry3Bb1 and Cry1Ab protein levels in MON 88017 x MON 810 tissues.

Tissue type	Growth stage	Cry3Bb1 Protein Levels (µg/g dwt)		Cry1Ab Protein Levels (µg/g dwt)	
		MON 88107 x MON 810 Mean (SD) [Range], n=9	MON 88017 Mean (SD) [Range], n=9	MON 88017 x MON 810 Mean (SD) [Range], n=9	MON 810 Mean (SD) [Range], n=9
Young leaf	V2-V3	670 (130) [550-920]	570 (170) [230-820]	110 (17) [85-140]	100 (12) [89-130]
Young root	V2-V3	350 (150) [88-560]	370(80) [240-510]	ND	ND
Pollen	R1	27 (5.7) [NA-34]	25 (4.2) [17-32]	NA	NA
Forage	R4-R6 (early dent)	100 (23) [71-150]	95 (19) [75-130]	14 (2.1) [11-17]	14(3.4) [8.4-19]
Forage root	R4-R6 (early dent)	140 (29) [89-180]	130 (29) [98-170]	ND	ND
Grain	R6	9.3 (3.4) [3.9-13]	15 (3.6) [10-22]	0.39 (0.13) [0.16-0.63]	0.43 (0.091) [0.27-0.54]

ND=not determined; NA=not applicable, as levels were below the level of detection.
Data from pg. 14. MRID #461850-01

TABLE 2. Efficacy of MON 88017 x MON 810 against European corn borer (ECB) and western corn rootworm (WCRW) in field trials.

Treatment Hybrid	Type	n	LDR	SEM	HSD
ECB Efficacy					
MON 88107 x MON 810	Test	80	0.8	0.08	B
Mon 810 x NK603	Control	80	0.9	0.10	B
MON 88017	Control	72	2.7	0.13	A
NK603	Non-*B.t. control*	80	2.7	0.14	A
WCRW Efficacy			**RDR**		
MON 88107 x MON 810	Test	133	0.1	0.004	B
Mon 810 x NK603	Control	108	1.24	0.07	A
MON 88017	Control	117	0.1	0.004	B
NK603	Non-*B.t.* control	112	1.35	0.08	A

LDR = leaf damage rating
RDR = root damage rating
SEM = standard error of the mean
HSD = Tukey-Kramer Honestly Significant Difference
Data from pg. 17, MRID 461850-01

DATA EVALUATION RECORD

EPA Secondary Reviewer: Alan Reynolds, Entomologist

STUDY TYPE:	Benefits
MRID NO:	461817-01
TEST MATERIAL:	Transgenic corn events MON 88017
PROJECT STUDY NO:	MSL-18835
SPONSOR:	Monsanto Company
TESTING FACILITY:	Monsanto Company 800 North Lindbergh Boulevard St. Louis, MO 63167
TITLE OF REPORT:	Human Health and Environmental Assessment of the Plant-Incorporated Protectant *Bacillus thuringiensis* Cry3Bb1 Protein Produced in Corn MON 88017
AUTHORS:	Ravinder S. Sidhu
STUDY COMPLETED:	January 22, 2004
CONCLUSION:	MON 88017 x MON 810 corn will likely provide comparable benefits as the previously registered Yieldgard Plus variety which expresses the same toxins and targets both corn rootworm and lepidopteran pests. Benefits will include efficacy against the target pests, reduced use of conventional insecticides, environmental benefits (reduced exposure of non-target insects), economic benefits (e.g. reduced costs, increased yields), and mycotoxin reduction. Additional benefits may be derived from Roundup (glyphosate) tolerance, although these potential advantages were not quantified by Monsanto.
CLASSIFICATION:	Acceptable
GOOD LABORATORY PRACTICE:	Not GLP compliant

I. SUMMARY OF PROPOSED BENEFITS

To address the potential benefits for MON 88017 x MON 810 corn, Monsanto has cited existing benefits documents for MON 863 corn and MON 810 corn. MON 863 is functionally equivalent to MON 88017 corn, as both express the Cry3Bb1 toxin for control of corn rootworm (CRW) larvae. MON 810 expresses the Cry1Ab toxin for control of lepidopteran stalk-boring insects. MON 88017 x MON 810 corn was created using conventional breeding between the MON 88017 and MON 810 lines.

Monsanto has submitted protein structure analysis (Cry3Bb1), protein expression, and efficacy data to support the conclusions that MON 88017 x MON 810 is equivalent in performance to

the single gene isolines. Structural data showed that the Cry3Bb1 protein in MON 88017 differs from the protein expressed in MON 863 by one amino acid out of 653 total (99.8% homology). Expression data showed that MON 863 and MON 88017 express Cry3Bb1 at comparable levels in all plant tissues (contained in MRID# 461817-01). Additional expression data have shown that MON 88017 x MON 810 (stacked product) and MON 88017 (single gene product) also express Cry3Bb1 at similar to identical levels in corn plant tissues. These data also showed that the stacked product and MON 810 (single gene product) have equivalent levels of Cry1Ab expression in all plant tissues. Submitted efficacy experiments demonstrated that MON 88017 x MON 810 provides the same level of protection/control against target pests (western corn rootworm and European corn borer) as MON 88017/MON 863 (CRW targeted) and MON 810 (lepidopteran targeted) corn.

In addition to the established benefits for MON 88017/MON 863 and MON 810, Monsanto cites the potential advantages of glyphosate tolerance offered by MON 88017 x MON 810. Glyphosate (marketed as Roundup) is an herbicide commonly used for weed control on agricultural crops such as corn. Monsanto notes that glyphosate has a "favorable environmental and safety profile" and offers control for a wide variety of weeds, has compatibility with IPM programs, and is cost effective. However, the potential benefits of Roundup tolerance were not quantified in this submission.

II. BPPD REVIEW OF PROPOSED BENEFITS

[It is noted that this review focuses only on the benefits information provided by Monsanto in their submission for MON 88017 x MON 810 corn. A public interest document (PID) was not submitted, therefore, a public interest determination (as is required for conditional FIFRA section 3c7 registrations) is not made here.]

BPPD agrees with Monsanto that the proposed MON 88017 x MON 810 product is functionally the equivalent of MON 88017 (and MON 863) for CRW control and MON 810 for lepidopteran control. The submitted analysis of amino acid homology, protein expression levels, and target pest activity (laboratory and field efficacy) have been reviewed in detail elsewhere for this product (see DERs for Insect Resistance Management and product chemistry).

CRW Benefits

For CRW control (i.e. MON 88017/MON 863 benefits), BPPD previously reviewed the benefits for MON 863 in detail when the product was registered (BPPD 2003). Based on the review, MON 863 was found to be in the public interest to support a FIFRA 3(c)(7)(C) registration. The benefits identified by BPPD's review for MON 863 are as follows:

- Efficacy: In separate comparative efficacy studies with registered insecticides, MON 863 prevented root damage from rootworm feeding as well or better than commonly used corn rootworm soil insecticides including Force 3G (tefluthrin), Counter CR (terbufos), and Lorsban 15G (chlorpyrifos). Root damage ratings for MON 863 were typically between 1.2 and 2.0, a high level of control relative to untreated control hybrids (RDR 3.3 to 3.9). The root damage ratings for the soil insecticides were typically between 1.9 and 2.4.

- Infested acreage/reduced pesticide treatments: Conventional insecticides are applied to 14 million acres of corn for control of CRW, which accounts for 1 out of every 7 applications of an insecticide on any agricultural crop. MON 863 use will greatly reduce or eliminate the pesticide applications on infested acreage.
- Yield benefits: Submitted data indicated that MON 863 corn hybrids have a yield benefit of 1.5 to 4.5% relative to control with a soil insecticide. Without MON 863 or conventional insecticides, CRW reduced corn yields by 9 to 28%.
- Practical benefits: Practical benefits of MON 863 for the grower include planting flexibility (can be planted early for long growing seasons), ease of use (no need for CRW insecticide applications, seed treatments can be used), and cost savings (insecticides, fuel, labor, equipment, storage and disposal).
- Human health: The crystalline toxins produced by *Bacillus thuringiensis* bacteria (including Cry3Bb1 expressed by MON 863) have a 50 year record of safe use and are considered nontoxic to humans. On the other hand, of the commonly used insecticides that MON 863 will replace (including numerous organophosphates), about one third are labeled as "danger," the highest category for acute toxicity. MON 863 is considered less risky than all of the major insecticides currently used to control CRW damage.
- Environmental risks: The Cry3Bb1 protein has no toxic effects on non-target organisms based on results in all appropriate tests. In addition, Cry3Bb1 is degraded rapidly in the soil (reducing non-target exposure). The Cry3Bb1 protein is expressed by the corn plant; thus, reducing the exposure to non-target organisms. In addition, Cry3Bb1 has a narrow target range. The protein is effective at killing only beetles of the family Chrysomelidae, specifically CRW and Colorado potato beetle (*Leptinotarsa decemlineata (Say)*). The family Chrysomelidae contains no known endangered species. As labeled, MON 863 corn poses less risk to the environment than the alternatives.
- Grower (economic) benefits: At full commercial maturity when MON 863 is available for all infested acreage, annual grower benefits are predicted to be $110 million per year. Grower benefits are defined as the difference between the value of MON 863 and it's cost. The value is based on expected yield improvements, reduced costs for insecticides, and practical benefits related to a more flexible and safer product for growers to use than the alternatives. Average grower benefits are estimated to be $6.56/acre. A reasonable estimate for net return per acre for corn (not including land charges) is about $60 per acre in recent years so MON 863 has the potential to increase average profits by 10% on average.

Since MON 88017 is the functional equivalent of MON 863, the benefits identified above are applicable to the CRW control aspects of the pending MON 88017 x MON 863 registration.

Lepidopteran Benefits

For lepidopteran control (primarily European corn borer, ECB, corn earworm, CEW, and southwestern corn borer, SWCB), the benefits of MON 810 were assessed and quantified as part of BPPD's 2001 reassessment of Bt crops (EPA 2001). The identified benefits are as follows:

- Efficacy: MON 810 provides season long control of stalk boring lepidoptera, which are typically difficult to control with conventional insecticides since they are often sheltered within the stalk. Though a relatively small portion of corn acreage is treated with conventional insecticides for lepidoptera, MON 810 has the potential to further reduce insecticide use and improve yields (even in acreage that would not normally be treated).
- Potential to replace conventional insecticides: Because of the efficacy benefits noted above, MON 810 has the potential to reduce conventional insecticide use in field corn. BPPD's 2001 Bt crops reassessment determined that a reduction of 3.9 million acres of field corn treated with insecticides occurred from 1995 to 2000, the time in which Bt corn was commercially introduced (EPA 2001). A large part of this reduction is likely due to the adoption of Bt corn by growers who has previously applied insecticides.
- Economic benefits to growers: Financial benefits for farmers from adoption of Bt corn have been variable, due in part to fluctuating corn commodity prices and inconsistent pest pressure. In BPPD's 2001 Bt crops reassessment, per acre benefits were determined to be between $2.11 and $12.21.
- Mycotoxin reduction: Mycotoxins, toxic or carcinogenic chemicals produced by *Fusarium* fungi, can infest corn tissue in areas damaged by ECB feeding. These toxins have human and livestock health implications and can cause significant economic losses to growers. MON 810 can reduce mycotoxin occurrence by as much as 90% by reducing ECB populations and feeding damage.

Since MON 88017 x MON 810 was created with conventional breeding using MON 810, the benefits identified above are applicable to the new product.

Stacked Product Benefits

MON 88017 x MON 810 will offer additional benefits above those identified individually for CRW and lepidopteran control above in that the product allows growers to control both pests simultaneously. Growers with acreage infested by both CRW and ECB that plant single trait varieties (i.e. MON 863 or MON 810 alone) may have to rely on insecticide treatments to address the non-targeted pest. A stacked product targeting both CRW and ECB can help to simply a grower's operation and maximize the human health, environmental, and economic benefits identified above.

A stacked product, Yieldgard Plus, which was created by conventional breeding of MON 863 and MON 810 has already been registered. The stacked product benefits for MON 88017 x MON 810 will likely be the same as those for Yieldgard Plus.

Herbicide Resistance Benefits

MON 88017 x MON 810 was engineered to be tolerant to application of Roundup (glyphosate) herbicide. This herbicide tolerance is the primary difference between MON 88017 x MON 810 and the previously registered Yieldgard Plus stacked product (both target the same pests and are functionally equivalent). Monsanto's submission provided a qualitative assessment of potential benefits from Roundup tolerance, but did not attempt to provide a quantitative analysis of any

economic or environmental benefits. A separate submission for MON 88017 corn (EPA Reg. No. 524-LLR) provided an estimate of a $10 per acre benefit from a potential 1 lb. per acre reduction in overall herbicide use, although supporting documentation was not provided.

The herbicide tolerance of MON 88017 x MON 810 will likely provide some additional benefits to growers, but given the lack of detail in Monsanto's submission, it is not possible to definitively determine these advantages. The potential benefits of Roundup use (as described by Monsanto) include efficacy (controls a wide range of weeds), crop safety, low environmental impact, flexibility, compatibility with integrated pest management (IPM), and cost. None of these claims could be verified, however, with the information supplied.

Overall Conclusions

The benefits resulting from use of MON 88017 x MON 810 will likely be the same as those for Yieldgard Plus, the previously registered stacked product that also expresses Cry3Bb1 and Cry1Ab. The primary benefits are associated with the control of corn rootworm and lepidopteran pests and the potential reduction in conventional insecticide use to control those pests. Additional benefits may be derived from tolerance to the herbicide Roundup, though these could not be quantitatively determined from the submitted information.

III. REFERENCES

BPPD, 2003. Benefits review for MON 863 corn. E. Brandt, S. Matten, and A. Reynolds memo to M. Mendelsohn, 2/24/03.

EPA, 2001. Bt plant-incorporated protectants October 15, 2001 biopesticides registration action document. Available at http://www.epa.gov/pesticides/biopesticides.

13544

R116587

Chemical:	**Bacillus thuringiensis Cry3Bb1 protein and the genetic material necessary (vector ZMIR39) for its production in corn Bacillus thuringiensis CryIA(b) delta-endotoxin and the genetic material necessary for its production (plasmid vector pZ01502) in corn, when used as a plant pesticide in all raw agricultural commodities of field corn, sweet corn *and popcorn.***
	PC Code: 006498 006461
HED File Code:	**41400 BPPD IRM**
Memo Date:	**10/13/2005**
File ID:	***DPD302513***
Accession #:	**412-06-0013**

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