US Environmental Protection Agency
Office of Pesticide Programs

June 8, 2010

BIOPESTICIDE FACTSHEET

Plant-Incorporated Protectant(s)

- *Bacillus thuringiensis* Cry 1A.l05 protein
- *Bacillus thuringiensis* Cry2Ab2 protein

United States
Environmental Protection
Agency

Office of Chemical Safety
and Pollution Prevention,
(7511P)

Pesticide
Fact Sheet

Name of Plant-Incorporated Protectant(s):

Bacillus thuringiensis Cry 1A.l05 protein and the genetic material necessary (vector PV-ZMIR245) for its production in corn event MON 89034

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary (vector PV-ZMIR245) for its production in corn event MON 89034

OECD Unique Identifier: MON-89Ø34-3; and MON-89Ø34-3 x MON-88Ø17-3

Reason for Issuance: Registration and Amendment

On June 10, 2008, conditional registrations were issued for MON 89034 and MON 89034 x MON 88017 products.

On December 15, 2008, the registrations were amended for MON 89034 and MON 89034 x MON 88017, to allow for a 5% structured refuge in the corn-belt (non-cotton growing regions) for corn borers.

Date Fact Sheet Issued: June 8, 2010

I. Description of the Plant-Incorporated Protectant

- **Pesticide Name:** MON 89034; and MON 89034 x MON 88017
- **Date Registered:** June 10, 2008
- **Registration Numbers:** 524-575 and 524-576
- **Trade and Other Names:** MON 89034 and MON 89034 x MON 88017

- **OPP Chemical Codes: 006515, 006514**

- **Basic Manufacturers:** Monsanto Company
  800 North Lindbergh Blvd
  St. Louis, MO 63167

- **Type of Pesticide: Plant-Incorporated Protectant (PIP)**

- **Uses: Field Corn and Sweet Corn**

  Target Pest(s): European corn borer (*Ostrinia nubilalis*), Southwestern corn borer (*Diatraea grandiosella*), Southern cornstalk borer (*Diatraea crambidoides*), Corn earworm (*Helicoverpa zea*), Fall armyworm (*Spodoptera frugiperda*), Corn stalk borer (*Papaipema nebris)*, and Sugarcane borer (*Diatreae saccharalis)*

II. Summary

EPA has conditionally registered a plant-incorporated protectant product containing two new active ingredients *Bacillus thuringiensis* Cry1A.105, and Cry2Ab2 insecticidal protein and the genetic material necessary for their production in event MON 89034 corn. The Agency has determined that the use of these pesticides is in the public interest and will not cause any unreasonable adverse effects on the environment during the time of conditional registration. EPA is also conditionally registering another product, MON 89034 x MON 88017, which contains a previously registered *Bacillus thuringiensis* Cry3Bb1 protein in addition to the two above mentioned new active ingredients. The registrant for both products is Monsanto Company.

The new plant-incorporated protectant product Event MON 89034 produces its own insecticide within the corn plant derived from *Bacillus thuringiensis* (Bt), a naturally occurring soil bacterium. The Bt proteins in this product, called Cry1A.105, and Cry2Ab2, control highly destructive lepidopteran corn pests including European corn borer (ECB), corn earworm (CEW), southwestern corn borer (SWCB), fall armyworm (FAW), and sugarcane borer (SCB). These pests feed on the base of seedlings and on the stalk, leaf, and ear tissue of corn plants, thereby destroying the entire plant, weakening the stalk, and/or damaging the ear. In areas where one or more of these pests is prevalent (*e.g.* corn belt), significant financial losses are realized from decreased corn yields and increased expenditures on chemical pest control agents, including organophosphate, carbamate and pyrethroid insecticides.

Results of efficacy trials conducted in 2003 - 2004 seasons in Puerto Rico and the United States indicate that MON 89034 corn provides effective control against European corn borer, corn earworm, southwestern corn borer, fall armyworm, and sugarcane borer.

On June 10, 2008, when the conditional time-limited registration of MON 89034, and MON 89034x MON 88017 was issued the non-Bt corn borer refuge was required to be at least 20% of the corn acreage in the corn-belt. On December 15, 2008, an amendment was issued for these products allowing a 5% structured refuge in the corn-belt (non cotton-growing regions) for corn-borers.

The additional data that are required as a condition of registration, after these amendments to the registrations were issued are listed in Section IV entitled "Regulatory Position for Cry1A.105, and Cry2Ab2."

Product Characterization

MON 89034 was developed by *Agrobacterium*-mediated transformation of corn using the 2T-DNA plasmid vector PV-ZMIR245 and produces two *Bacillus thuringiensis* proteins, Cry1A.105 and Cry2Ab2. Cry1A.105 is a chimeric protein composed of portions of Cry1Ab, Cry1Ac, and Cry1F proteins. Protein characterization data show that the plant-produced Cry1A.105 and Cry2Ab2 proteins have biochemical and functional activities that are similar to those of the E. coli- produced proteins that were used in several of the toxicity studies.

Mammalian Toxicity and Allergenicity Assessment

Monsanto has submitted acute oral toxicity data demonstrating the lack of mammalian toxicity at high levels of exposure to the pure Cry1A.105 and Cry2Ab2 protein. These data demonstrate the safety of the product at a level well above maximum possible exposure levels that are reasonably anticipated in the crop using submitted Cry1A.105 and Cry2Ab2 expression values. Basing this conclusion on acute oral toxicity data without requiring further toxicity testing and residue data is similar to the Agency position regarding toxicity testing and the requirement of residue data for the microbial *Bacillus thuringiensis* products from which this plant-incorporated protectant was derived (See 40 CFR Sec. 158.2130). For microbial products, further toxicity testing and residue data are triggered by significant adverse acute effects in studies such as the mouse oral toxicity study, to verify the observed adverse effects and clarify the source of these effects (Tiers II & III).

An acute oral toxicity study in mice (MRID 46694603) indicated that Cry1A.105 is non-toxic to humans. The oral LD_{50} for mice was greater than 2072 mg/kg bodyweight. This dose level is above 2000 mg/kg which is above the limit dose, the highest dose used in acute toxicity testing.

An acute oral toxicity study in mice (MRID 46951406) indicated that Cry2Ab2 is non-toxic to humans. Ten male and 10 female mice received *E. coli*-produced Cry2Ab2 protein at a dose of 2198 mg/kg by oral gavage in two doses (test protein group). Two negative control groups were also included in the study: bovine serum albumin protein control, and a vehicle control (2 mM carbonate-bicarbonate, 2mM reduced glutathione check). All animals were euthanized and necropsied on day 14. All mice survived the study. There were no significant differences in body weight or body weight change among the three groups during the study. The oral LD_{50} for males, females, and combined mice was greater than 2198 mg/kg. therefore, the Cry2Ab2 protein does not appear to cause any significant adverse effects at an exposure level of up to 2198 mg/kg bodyweight. The acute oral toxicity of the Cry2Ab2 protein was assessed in CD-1 mice. This places Cry2Ab2 protein in TOXICITY CATEGORY III because of dose amounts only; no signs of toxicity were observed.

When proteins are toxic, they are known to act via acute mechanisms and at very low dose levels. Therefore, since no acute effects were shown to be caused by Cry1A.105 or Cry2Ab2, even at relatively high dose levels, the Cry1A.105 protein and Cry2Ab2 are not considered toxic. Further, amino acid sequence comparisons between the Cry1A.105 and Cry2Ab2 and known toxic proteins in protein databases showed no similarities that would raise a safety concern. In addition, the Cry1A.105 and Cry2Ab2 proteins were shown to be substantially degraded by heat when examined by immunoassay. This instability to heat would also lessen the potential dietary exposure to intact Cry1A.105 and Cry2Ab2 proteins in cooked or processed foods. These biochemical features along with the lack of adverse results in the acute oral toxicity test indicate a reasonable certainty no harm from toxicity will result from dietary exposure to Cry1A.105 and Cry2Ab2 containing crops.

Since Cry1A.105 and Cry2Ab2 are proteins, allergenic potential was also considered. Currently, no definitive tests for determining the allergenic potential of novel proteins exist. Therefore, EPA uses a weight-of- evidence approach where the following factors are considered: source of the trait; amino acid sequence comparison with known allergens; and biochemical properties of the protein, including in vitro digestibility in simulated gastric fluid (SGF) and glycosylation. This approach is consistent with the approach outlined in the Annex to the Codex Alimentarius "Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants." The allergenicity assessment for Cry1A.105 and Cry2Ab2 follows:

1. Source of the traits. *Bacillus thuringiensis* is not considered to be a source of allergenic proteins.
2. Amino acid sequence. A comparison of the amino acid sequence of Cry1A.105 and Cry2Ab2 with known allergens showed no overall sequence similarity or identity at the level of eight contiguous amino acid residues, indicating a lack of potential linear epitopes found in known food allergens.
3. Digestibility. The Cry1A.105 and Cry2Ab2 protein were digested rapidly in simulated gastric fluid containing pepsin. The rapid degradation of Cry1A.105 in the gastric environment suggests little possible exposure to intact protein in the intestinal lumen where sensitization to food allergens occurs.
4. Glycosylation. Cry1A.105 and Cry2Ab2 expressed in corn was shown not to be glycosylated.
5. Conclusion. Considering all of the available information, EPA has concluded that the potential for Cry1A.105 to be a food allergen is minimal.

The information on the safety of pure Cry1A.105 protein provides adequate justification to address possible exposures in all corn crops.
Although Cry1A.105 and Cry2Ab2 were only shown not to be glycosylated in corn, both proteins are unlikely to be glycosylated in any other crops because in order for a protein to be glycoslyated, it needs to contain specific recognition sites for the enzymes involved in glycosylation, and the mechanisms of protein glycosylation are similar in different plants (Lerouge, P. Cabanes-Macheteau, M., Rayon, C., Fichette-Lainé, A-C., Gomord, V., and Faye,

L., "N-Glycoprotein biosynthesis in plants: recent developments and future trends," *Plant Molecular Biology* 38: 31-48, 1998).

Environmental Hazard Assessment

Maximum hazard dose toxicity testing on representative beneficial organisms from several taxa was performed in support of this Section 3 FIFRA registration. The toxicity of the Cry1A.105 and Cry2Ab2 proteins has been evaluated on several species of invertebrates including the lady beetle, minute pirate bug, parasitic hymenoptera, collembolan, daphnia, honey bee, and earthworm. Developmental observations were also made in the lady beetle, minute pirate bug and honeybee studies. Observations of possible reproductive effects were also made in the collembola studies. In addition, earthworm studies were voluntarily submitted to the Agency to ascertain the potential effects of the Cry1A.105 and Cry2Ab2 proteins on beneficial decomposer species. Avian dietary studies and soil fate data were also submitted.

Test substances used for studies submitted in support of the MON 89034 registration included bacterially-produced purified Cry1A.105 and Cry2Ab2 proteins and MON 89034 cornleaf tissue, pollen, and grain. The October 2000 SAP recommended that while actual plant material is the preferred test material, bacterially-derived protein is also a valid test substance, particularly in scenarios where test animals do not normally consume corn plant tissue and where large amounts of Cry protein (Cry protein concentrations that exceed levels present in plant tissue) are needed for maximum hazard dose testing. An insect feeding study, which compared the relative potency of plant produced Cry1A.105 and Cry2Ab2 proteins to the microbe produced proteins, indicated that plant produced protein was similar in toxicity to the microbe produced protein (Edelstein Memo, November 7, 2007).

Potential interaction between the Cry1A.105 and Cry2Ab2 proteins was addressed in a memorandum for the MON 89034 Experimental Use Permit accompanying the Agency's review of "Evaluation of the Potential for Interactions Between the *Bacillus thuringiensis* Proteins Cry1A.105 and Cry2Ab2" (Hunter, M. July 6, 2006). The purpose of this study was to characterize the potential for interaction between the lepidopteran-active proteins Cry1A.105 and Cry2Ab2. The study provides evidence that the proteins do not interact in an antagonistic or synergistic manner and that there will not be any unexpected interaction with regard to target and non-target insects. New data on the potential interaction between combined Cry1A.105, Cry2Ab2 with the Cry3Bb1 protein was submitted. The results from the study demonstrated that combined Cry1A.105 and Cry2Ab2 activity was not affected by the Cry3Bb1 protein and that Cry3Bb1 activity was not affected by combined Cry1A.105 and Cry2Ab2 activity (MRID 469513-05 & 469513-06).

Insect Resistance Management

Monsanto has demonstrated that the Cry1A.105 and Cry2Ab2 toxins have different modes of action and, consequently, a low likelihood of cross-resistance. Therefore, Cry1A.105 and Cry2Ab2 are suitable partners in a pyramided product. Monsanto has also shown that there is a low likelihood of cross-resistance between Cry1A.105 and Cry1Ab and between Cry2Ab2 and Cry1Ac. Both Cry1Ab and Cry1Ac are expressed in other registered Bt corn and Bt cotton PIPs. However, Monsanto did not address the likelihood of cross-resistance between Cry1A.105 and Cry1Ac, and Cry1Fa (Bt proteins already in existing Bt corn and Bt cotton products), and what impact such cross-resistance would have on the durability of MON 89034. As a result, Monsanto was required to provide additional information on cross-resistance of Cry1A.105 and Cry1Fa and Cry1Ac (including binding site models and use of resistant colonies) for the target pests and determine how such cross-resistance could impact the durability of MON 89034.

I. EXECUTIVE SUMMERY

Monsanto had originally proposed a 5% structured refuge, rather than the 20% structured refuge required for other Bt corn registrations, for field corn uses of MON 89034 in the U.S. Corn Belt. However, data and simulation modeling in Monsanto's original submission did not support the 5% proposed refuge for MON 89034 in the Corn Belt. There were uncertainties regarding the dose determination for susceptible and heterozygote (i.e. partially resistant) insects (i.e. ECB, SWCB, CEW, and FAW), the cross-resistance potential of Cry1A.105, Cry1Ac, and Cry1Fa and any impacts on the durability of MON 89034, and limitations in the simulation modeling. At the time of registration, the 20% structured refuge requirement in place for other Bt corn registrations was also required for field corn uses of MON 89034 in the Corn Belt until such time as Monsanto could address these uncertainties. The data for MON 89034 do support the use of a 20% refuge in cotton-growing regions in the southeastern U.S. where a 50% refuge has been required for other Bt corn registrations.

Subsequent to registration, Monsanto submitted additional data and an analysis of potential resistance risks to support an amendment to reduce the required non-Bt corn refuge for MON 89034 corn from 20% to 5% in the U.S. Corn Belt. After reviewing these data, EPA determined that a 5% refuge in the U.S. Corn belt should not significantly increase the risk of resistance for ECB, CEW, and SWCB. Monsanto sufficiently addressed the requirement to analyze potential cross resistance in existing Bt corn and Bt cotton products for Cry1A.105 and Cry1Fa, but additional analysis and information is still needed to fully assess cross resistance potential for Cry1Ac and Cry1A.105. The amendment to reduce refuge was approved on December 15, 2008.

III. Current Tolerance Exemptions In 40 CFR Part 174 Applicable To MON 89034 And MON 89034 X MON 88017 Products.

On July 16, 2008 (73 FR No. 137) the Agency established permanent exemptions from the requirement of a tolerance for residues of the *Bacillus thuringiensis* Cry1A.105 protein in or on the food and feed commodities: field corn, sweet corn, and popcorn when used as plant–incorporated protectant in all food commodities in accordance with good agricultural practices. On July 2, 2008 (73 FR No. 128) the existing permanent exemption from the requirement of a tolerance for residues of the *Bacillus thuringiensis* Cry2Ab2 protein under 174.519 was amended to include corn or cotton when used as a plant-incorporated protectant in the food and feed commodities: field corn, sweet corn, popcorn, cotton seed, cotton oil, cotton meal, cotton hay, cotton hulls, cotton forage, and cotton gin byproducts in accordance with good agricultural practices.

Listed below are the current tolerance exemptions in 40 CFR Part 174 applicable to MON 89034 and MON 89034 x MON 88017 products

§ 174.502 Bacillus thuringiensis Cry1A.105 protein; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry1A.105 protein in or on the food and feed commodities of corn; corn, field, flour; corn, field, forage; corn, field, grain; corn, field, grits; corn, field, meal; corn, field, refined oil; corn, field, stover; corn, sweet, forage; corn, sweet, kernel plus cob with husk removed; corn, sweet, stover; corn, pop, grain and corn, pop, stover are exempt from the requirement of a tolerance when the *Bacillus thuringiensis* Cry1A.105 protein is used as a plant-incorporated protectant in these food and feed corn commodities.

§ 174.518 Bacillus thuringiensis Cry3Bb1 protein in corn; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry3Bb1 protein in corn are exempt from the requirement of a tolerance when used as plant-incorporated protectants in the food and feed commodities of corn; corn, field; corn, sweet; and corn, pop.

§ 174.519 Bacillus thuringiensis Cry2Ab2 protein in corn and cotton; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry2Ab2 protein in or on corn or cotton are exempt from the requirement of a tolerance when used as a plant–incorporated protectant in the food and feed commodities of corn; corn, field; corn, sweet; corn, pop; and cotton seed, cotton oil, cotton meal, cotton hay, cotton hulls, cotton forage, and cotton gin byproducts.

§ 174.523 CP4 Enolpyruvylshikimate-3-phosphate (CP4 EPSPS) synthase in all plants; exemption from the requirement of a tolerance.

Residues of the CP4 Enolpyruvylshikimate-3-phosphate (CP4 EPSPS) synthase enzyme in all plants are exempt from the requirement of a tolerance when used as plant-incorporated protectant inert ingredients in all food commodities.

IV. Terms And Conditions Of Registration

A. Terms and Conditions for MON 89034 as Amended on December 15, 2008:

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

2) The subject registration will be limited to MON 89034 in field or sweet corn. Further, MON 89034 sweet corn may only be sold directly to processors or through commercial dealers to large growers. MON 89034 sweet corn must not be sold to small roadside or home growers.

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) This plant-incorporated protectant may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

5) Submit the following data in the time frames listed:

OPPTS Guideline/ Study Type	Required Data	Due Date
Residue Analytical Method – Plants (OPPTS 860.1340)	For event MON 89034 corn, an independent lab validation of the analytical method for the detection of Cry2Ab2 and/or Cry1A.105. You must also agree to provide to the EPA laboratory (Ft. Meade, MD) methodology and/or reagents necessary for validation of such analytical method within 6 months from the date that the Agency requests them.	4/1/2009
Aquatic Invertebrate Acute Toxicity Testing, Freshwater *Daphnids* (OPPTS 885.4240)	A 7-14 day *Daphnia* study as per the 885 Series OPPTS Guidelines needs to be performed. Alternatively, a dietary study of the effects on an aquatic invertebrate, representing the functional group of a leaf shredder in headwater streams, can be performed and submitted in lieu of the *Daphnia* study.	9/1/2009*
Insect Resistance Management – Resistance Monitoring	Monsanto must provide additional information on cross-resistance of Cry1A.105 and Cry1Ac (preferably including binding site models and use of resistant colonies) for the target pests and determine how such cross-resistance may impact the durability of MON 89034, including any impacts in the southern cotton-growing areas. The Cry1A.105 protein is a chimeric protein consisting of Domains I and II and the C-terminus of Cry1Ac. It is important to address not only the likelihood of cross-resistance potential of Cry1A.105 and Cry1Ab and, similarly, Cry1A.105 and Cry2Ab2 (which was done by Monsanto) but also that of Cry1A.105 and Cry1Ac.	7/1/2009*
Insect Resistance Management – Resistance Monitoring	Baseline susceptibility studies and/or a discriminating concentration assay are required for the Cry1A.105 protein against European corn borer (ECB), Southwestern corn borer (SWCB), and corn earworm (CEW) and for the Cry2Ab2 protein against SWCB and CEW.	7/1/2009* for ECB and CEW 8/31/2010* for SWCB

OPPTS Guideline/ Study Type	Required Data	Due Date
Insect Resistance Management – Resistance Monitoring	To support sweet corn uses, baseline susceptibility studies must be conducted on fall armyworm (FAW) populations collected from sweet corn growing areas. Monitoring studies will be conducted on FAW populations collected from sweet corn distribution areas in states in which Monsanto MON 89034 and/or MON 89034 x MON 88017 sweet corn plantings exceed 5,000 acres. The collected populations of FAW will be monitored for changes in susceptibility to the Cry1A.105 and Cry2Ab2 proteins.	4/1/2010

* Extensions were granted as listed in the above table.

6) The Insect Resistance Management (IRM) terms and conditions for this product are as follows.

The required IRM program for MON 89034 must have the following elements:

- Requirements relating to creation of a non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuge in conjunction with the planting of any acreage of MON 89034 field corn;
- Requirements for Monsanto to prepare and require MON 89034 users to sign "grower agreements," which impose binding contractual obligations on the grower to comply with the refuge requirements;
- Requirements regarding programs to educate growers about IRM requirements;
- Requirements regarding programs to evaluate and promote growers' compliance with IRM requirements;
- Requirements regarding programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to Cry1A.105 and Cry2Ab2 proteins in the target insects;
- Requirements regarding a "remedial action plan," which contains measures Monsanto would take in the event that any field relevant insect resistance was detected as well as to report on activity under the plan to EPA;
- Submit annual reports on units sold by state (units sold by county level will be made available to the Agency upon request), IRM grower agreement results, and the compliance assurance program including the education program on or before January 31st

each year, beginning in 2010.

a) Refuge Requirements for MON 89034 Field Corn

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year. Furthermore, these refuge requirements do not apply to commercial hybrid sweet corn.

1) Corn-Belt Refuge Requirements

For MON 89034 field corn grown outside cotton-growing areas (e.g., the Corn Belt), 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 5% non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn that may be treated with insecticides, as detailed below, to control lepidopteran stalk-boring and other pests.

- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips, and strips across the field.

- External refuges must be planted within ½ mile.

- When planting the refuge as strips across the field or as perimeter strips, refuges must be at least 4 consecutive rows wide.

- Insecticide treatments for control of ECB, CEW, SWCB, and other lepidopteran target pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.

2) Cotton-Growing Area Refuge Requirements

For MON 89034 field corn grown in cotton-growing areas, grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/ product use guide.

- Specifically, growers in these areas must plant a structured refuge of at least 20% non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn that may be treated with insecticides, as detailed below, to control lepidopteran stalk-boring and other pests.

- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips, and strips across the field.

- External refuges must be planted within ½ mile.

- When planting the refuge as strips across the field or as perimeter strips, refuges must be at least 4 consecutive rows wide.

- Insecticide treatments for control of ECB, CEW, SWCB, and other lepidopteran target pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.

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

b) Post-Harvest Requirements for MON 89034 Sweet Corn

Sweet corn is harvested long before field corn. Therefore, if the sweet corn stalks remaining in the field and any insects remaining in the stalks are destroyed shortly after harvest, a refuge is not needed as a part of the IRM program for sweet corn. Growers must adhere to the following types of crop destruction requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

- Crop destruction must occur no later than 30 days following harvest, but preferably within 14 days.

- The allowed crop destruction methods are: rotary mowing, discing, or plow-down. Crop destruction methods should destroy any surviving resistant insects.

c) Grower Agreements for MON 89034

1) Persons purchasing MON 89034 must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.

2) The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.

3) Monsanto must integrate this registration into the current system used for their other *Bt* corn PIPS, which is reasonably likely to assure that persons purchasing MON 89034 will affirm annually that they are contractually bound to comply with the requirements of the IRM program.

4) Monsanto must continue to use their current 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, Monsanto must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of the amendment.

5) Monsanto must integrate this registration into a current system, which is reasonably likely to assure that persons purchasing MON 89034 sign grower agreement(s).

6) Monsanto shall maintain records of all MON 89034 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, 2010 and annually thereafter, Monsanto shall provide EPA with a report showing the number of units of MON 89034 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. Note: The first report shall contain the specified information from the time frame starting with the date of registration and ending July 31, 2009.

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8) Monsanto must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

d) IRM Education and Compliance Monitoring Programs for MON 89034

1) Monsanto must design and implement a comprehensive, ongoing IRM education program designed to convey to MON 89034 users the importance of complying with the IRM program. The program shall include information encouraging MON 89034 users to pursue optional elements of the IRM program relating to refuge configuration and proximity to MON 89034 fields. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials. Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each MON 89034 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, Monsanto shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraphs 6a or 6b and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

3) On January 31, 2010, Monsanto must provide a report to EPA summarizing the activities carried out under the education program for the prior year. Annually thereafter, Monsanto must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. Monsanto must either submit a separate report or contribute to the report from the industry working group, Agricultural Biotechnology Stewardship Technical Committee (ABSTC).

4) Monsanto must design and implement an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing MON 89034 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 MON 89034. Monsanto shall coordinate with other *Bt* corn registrants in designing and implementing its compliance assurance program and integrate this

registration into the current compliance assurance program used for their other *Bt* corn PIPS. Other required features of the program are described in paragraphs 5 – 15 below.

5) Monsanto must establish and publicize a "phased compliance approach," i.e., a guidance document that indicates how they 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. While recognizing that for reasons of difference in business practices there are needs for flexibility between different companies, Monsanto must use a consistent set of standards for responding to non-compliance. The options shall include withdrawal of the right to purchase Monsanto corn PIP products 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 Monsanto corn PIP products the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell Monsanto corn PIP products.

6a) MON 89034 Field Corn: The IRM compliance assurance program shall include an annual survey, conducted by an independent third party, of a statistically representative sample of growers of MON 89034 field corn who plant the vast majority of all corn in the United States and in areas in which the selection intensity is greatest. The survey shall consider only those growers who plant 200 or more acres of corn in the Corn-Belt and who plant 100 or more acres of corn in corn-cotton areas. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from independent marketing research firms and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the United States.

6b) MON 89034 Sweet Corn: The IRM compliance assurance program shall include an annual survey of all MON 89034 sweet corn customers who purchase 5 or more bags of MON 89034 sweet corn. The survey shall measure the degree of compliance with the IRM program, identify the response rate (e.g., the percent of MON 89034 sweet corn acres covered by the responses), and consider the potential impact of non-response. An independent third party will participate in the design and implementation of the survey. Data and information derived from the annual survey will be audited by an independent third party.

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.

9a) MON 89034 Field Corn: Monsanto shall provide a final written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA by January 31st of each year, beginning in 2010. Monsanto shall confer with other registrants and EPA on the design and content of the survey prior to its implementation.

9b) MON 89034 Sweet Corn: Monsanto shall provide a written summary of the results of the prior year's survey (together with a description of the methodology used and the supporting data) to EPA by January 31st of each year, beginning in 2010. Monsanto shall confer with EPA on changes to the design and content of the survey prior to its implementation.

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

11) Monsanto shall conduct an annual on-farm assessment program. Monsanto shall train its representatives who make on-farm visits with growers of MON 89034 to perform assessments of compliance with IRM requirements. There is no minimum corn acreage size for this program. Therefore, growers will be selected for this program from across all farm sizes. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, Monsanto shall take appropriate action, consistent with its "phased compliance approach," to promote compliance.

12) Monsanto shall carry out a program for investigating legitimate "tips and complaints" that its growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, Monsanto shall take appropriate action, consistent with its "phased compliance approach."

13) If a grower, who purchases MON 89034 for planting, was specifically identified as not being in compliance during the previous year, Monsanto shall visit with the grower and evaluate whether the grower is in compliance with the IRM program for the current year.

14) Beginning January 31, 2010 and annually thereafter, Monsanto shall provide a report to EPA summarizing the activities carried out under their compliance assurance program for

15) 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. Monsanto may elect to coordinate information with other registrants and report collectively the results of compliance assurance programs.

16) Monsanto and the seed corn dealers for Monsanto must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license number of the growers will be protected.

e) Insect Resistance Monitoring and Remedial Action Plan for MON 89034

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

Monsanto will monitor for resistance to Cry1A.105 and Cry2Ab2 expressed in MON 89034.

The monitoring program shall consist of two approaches: (1) focused population sampling and laboratory testing and (2) investigation of reports of less-than expected control of labeled insects. Should field relevant resistance be confirmed, an appropriate resistance management action plan will be implemented.

(1) Focused Population Sampling

Monsanto will develop and ensure the implementation of a plan for resistance monitoring for *Spodoptera frugiperda* (fall armyworm or FAW) in counties in which MON 89034 and/or MON 89034 x MON 88017 sweet corn acreage exceeds 5,000 acres and the pest is capable of overwintering in that county. Monsanto should consult with academic and United States Department of Agriculture (USDA) experts in developing the monitoring plan and will provide EPA with a copy of its proposed resistance monitoring plan for EPA's approval prior to implementation. This proposed FAW monitoring plan must be submitted to EPA by January 31st of the year following that in which MON 89034 and/or MON 89034 x MON 88017 sweet corn acreage exceeds the trigger specified in this requirement (i.e., greater than 5,000 acres in any county in which FAW overwinters). The proposed plan must be implemented the season following the acreage trigger being met. The proposed plan will remain in place until an EPA approved plan can be implemented.

Monsanto shall annually sample and bioassay populations of the key target pests: *Ostrinia nubilalis* (European corn borer; ECB), *Diatraea grandiosella* (Southwestern corn borer; SWCB),

and *Helicoverpa zea* (corn earworm; CEW). Sampling for the target pests will be focused in areas identified as those with the highest risk of resistance development (e.g., where lepidopteran-active *Bt* hybrids are planted on a high proportion of the corn acres, and where the

insect species are regarded as key pests of corn). Bioassay methods must be appropriate for the goal of detecting field-relevant shifts in population response to MON 89034 and/or changes in resistance-allele frequency in response to the use of MON 89034 and, as far as possible, should be consistent across sampling years to enable comparisons with historical data. Each protein in MON 89034 must be tested separately, rather than a mixture of the two proteins, because resistance to one protein could be masked by the activity of the other.

The number of populations to be collected shall reflect the regional importance of the insect species as a pest, and specific collection regions will be identified for each pest. For ECB, a minimum of 12 populations across the sampling region will be targeted for collection at each annual sampling. For SWCB, the target will be a minimum of six populations. For CEW, the target will be a minimum of 10 populations. Pest populations should be collected from multiple corn-growing states reflective of different geographies and agronomic conditions. To obtain sufficient sensitivity to detect resistance alleles before they become common enough to cause measurable field damage, each population collection shall attempt to target 400 insect genomes (egg masses, larvae, mated females, and/or mixed-sex adults), but a successful population collection will contain a minimum of 100 genomes. It is recognized that it may not be possible to collect the target number of insect populations or genomes due to factors such as natural fluctuations in pest density, environmental conditions, and area-wide pest suppression.

The sampling program and geographic range of collections may be modified as appropriate based on changes in pest importance and for the adoption levels of MON 89034. The Agency shall be consulted prior to the implementation of such modifications.

The registrant will report to the Agency by August 31st of each year, beginning in 2010, the results of the population sampling and bioassay monitoring program.

Any incidence of unusually low sensitivity to the Cry1A.105 and Cry2Ab2 proteins in bioassays shall be investigated as soon as possible to understand any field relevance of such a finding.

Such investigations shall proceed in a stepwise manner until the field relevance can be either confirmed or refuted, and results of these shall be reported to the Agency annually before August 31st, beginning in 2010. The investigative steps will include:

1. Re-test progeny of the collected population to determine whether the unusual bioassay response is reproducible and heritable. If it is not reproducible and heritable, no further action is required.

2. If the unusual response is reproducible and heritable, progeny of insects that survive the diagnostic concentration will be tested using methods that are representative of exposure to MON 89034 under field conditions. If progeny do not survive to adulthood, any suspected resistance is not field relevant and no further action is required.

3. If insects survive steps 1 and 2, resistance is confirmed, and further steps will be taken to taken to evaluate the resistance. These steps may include:

- determining the nature of the resistance (i.e., recessive or dominant, and the level of functional dominance);
- estimating the resistance-allele frequency in the original population;
- determining whether the resistance-allele frequency is increasing by analyzing field collections in subsequent years sampled from the same site where the resistance allele(s) was originally collected;
- determining the geographic distribution of the resistance allele by analyzing field collections in subsequent years from sites surrounding the site where the resistance allele(s) was originally collected.

Should field relevant resistance be confirmed, and the resistance appears to be increasing or spreading, Monsanto will consult with the Agency to develop and implement a case-specific resistance management action plan.

(2) Investigation of Reports of Unexpected Levels of Damage by the Target Pests:

Monsanto will follow up on grower, extension specialist or consultant reports of unexpected levels of damage by the lepidopteran pests listed on the pesticide label. Monsanto will instruct its customers to contact them if such incidents occur. Monsanto will investigate all legitimate reports submitted to the company or the company's representatives.

If reports of unexpected levels of damage lead to the suspicion of resistance in any of the key target pests (ECB, SWCB, CEW, and FAW), Monsanto will implement the actions described below, based on the following definitions of *suspected resistance* and *confirmed resistance.*

Suspected resistance

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

- the corn in question has been confirmed to be lepidopteran-active *Bt* corn;
- the seed used had the proper percentage of corn expressing *Bt* protein;
- the relevant plant tissues are expressing the expected level of *Bt* protein; and
- it has been ruled out that species not susceptible to the protein could be responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and that there could be no other reasonable causes for the damage.

The Agency does not interpret *suspected resistance* to mean grower reports of possible control failures or suspicious results from annual insect monitoring assays, nor does the Agency intend that extensive field studies and testing be undertaken to confirm scientifically the presence of insects resistant to MON 89034 in commercial production fields before responsive measures are undertaken.

If resistance is *suspected,* Monsanto will instruct growers to do the following:

- Use alternative control measures in MON 89034 fields in the affected region to control the target pest during the immediate growing season.
- Destroy MON 89034 crop residues in the affected region within one month after harvest with a technique appropriate for local production practices to minimize the possibility of resistant insects over-wintering and contributing to the next season's target pest population.

Additionally, if possible, and prior to the application of alternative control measures or destruction of crop residue, Monsanto will collect samples of the insect population in the affected fields for laboratory rearing and testing. Such rearing and testing shall be conducted as expeditiously as practical.

Confirmed resistance

EPA defines *confirmed resistance* to mean, in the case of field reports of unexpected levels of damage from the key target pests, that all the following criteria are met:

- There is >30% insect survival and commensurate insect feeding in a bioassay, initiated with neonate larvae, that uses methods that are representative of exposure to *Bt* corn hybrids under field conditions (ECB and SWCB only).

- In standardized laboratory bioassays using diagnostic concentrations of the *Bt* protein suited to the target pest in question, the pest exhibits resistance that has a genetic basis and the level of survivorship indicates that there may be a resistance-allele frequency of $\geq$ 0.1 in the sampled population.

- In standardized laboratory bioassays, the LC_{50} exceeds the upper limit of the 95% confidence interval of the LC_{50} for susceptible populations surveyed both in the original baselines developed for this pest species and in previous years of field monitoring.

(3) Response to Confirmed Resistance in a Key Target Pest as the Cause of Unexpected Levels of Damage in the Field

When field resistance is *confirmed* (as defined above), the following steps will be taken by Monsanto:

- EPA will receive notification within 30 days of resistance confirmation;

- Affected customers and extension agents will be notified about confirmed resistance within 30 days;

- Monitoring will be increased in the affected area and local target pest populations will be sampled annually to determine the extent and impact of resistance;

- If appropriate (depending on the resistant pest species, the extent of resistance, the timing of resistance, and the nature of resistance, and the availability of suitable alternative control measures), alternative control measures will be employed to reduce or control target pest populations in the affected area. Alternative control measures may include advising customers and extension agents in the affected area to incorporate crop residues into the soil following harvest to minimize the possibility of over-wintering insects, and/or applications of chemical insecticides;

- Unless otherwise agreed with EPA, stop sale and distribution of the relevant lepidopteran-active *Bt* corn hybrids in the affected area immediately until an effective local mitigation plan approved by EPA has been implemented;

- Monsanto will develop a case-specific resistance management action plan within 90 days according to the characteristics of the resistance event and local agronomic needs. Monsanto will consult with appropriate stakeholders in the development of the action plan, and the details of such a plan shall be approved by EPA prior to implementation;

- Notify affected parties (e.g., growers, consultants, extension agents, seed distributors, university cooperators and state/federal authorities as appropriate) in the region of the resistance situation and approved action plan; and

- In subsequent growing seasons, maintain sales suspension and alternative resistance management strategies in the affected region(s) for the *Bt* corn hybrids that are affected by the resistant population until an EPA-approved local resistance management plan is in place to mitigate the resistance.

A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by August 31st each year, beginning in 2010, for the duration of the conditional registration.

f) Annual Reporting Requirements for MON 89034

1) Annual Sales: reported and summed by state (county level data available by request), January 31st each year, beginning in 2010;

2) Grower Agreement: number of units of MON 89034 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, beginning in 2010;

3) Grower Education: substantive changes to education program completed previous year, January 31st each year, beginning in 2010;

4) Compliance Assurance Plan: Compliance Assurance Program activities and results, January 31st each year, beginning in 2010;

5) Compliance Survey Results: to include annual survey results and plans for the next year; full report January 31st each year, beginning in 2010;

6) Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, August 31st each year, beginning in 2010.

B. Data Required to Support MON 89034 x MON 88017 as Amended on December 15, 2008:

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

2) The subject registration will be limited to MON 89034 x MON 88017 in field or sweet corn. Further, MON 89034 x MON 88017 sweet corn may only be sold directly to processors or through commercial dealers to large growers. MON 89034 x MON 88017 sweet corn must not be sold to small roadside or home growers.

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 the following data in the time frames listed:

OPPTS Guideline/ Study Type	Required Data	Due Date
Residue Analytical Method – Plants (OPPTS 860.1340)	For event MON 89034 x MON 88017 corn, an independent lab validation of the analytical method for the detection of Cry2Ab2 and/or Cry1A.105. You must also agree to provide to the EPA laboratory (Ft. Meade, MD) methodology and/or reagents necessary for validation of such analytical method within 6 months from the date that the Agency requests them.	4/1/2009
Aquatic Invertebrate Acute Toxicity Testing, Freshwater *Daphnids* (OPPTS 885.4240)	A 7-14 day *Daphnia* study as per the 885 Series OPPTS Guidelines needs to be performed. Alternatively, a dietary study of the effects on an aquatic invertebrate, representing the functional group of a leaf shredder in headwater streams, can be performed and submitted in lieu of the *Daphnia* study.	9/1/2009*
Insect Resistance Management – Resistance Monitoring	Monsanto must provide additional information on cross-resistance of Cry1A.105 and Cry1Ac (preferably including binding site models and use of resistant colonies) for the target pests and determine how such cross-resistance may impact the durability of MON 89034, including any impacts in the southern cotton-growing areas. The Cry1A.105 protein is a chimeric protein consisting of Domains I and II and the C-terminus of Cry1Ac. It is important to address not only the likelihood of cross-resistance potential of Cry1A.105 and Cry1Ab and, similarly, Cry1A.105 and Cry2Ab2 (which was done by Monsanto) but also that of Cry1A.105 and Cry1Ac.	7/1/2009*
Insect Resistance Management – Resistance Monitoring	Baseline susceptibility studies and/or a discriminating concentration assay are required for the Cry1A.105 protein against European corn borer (ECB), Southwestern corn borer (SWCB), and corn earworm (CEW) and for the Cry2Ab2 protein against SWCB and CEW.	7/1/2009* For ECB and CEW 8/31/2010* For SCWB
Insect Resistance Management – Resistance	To support sweet corn uses, baseline susceptibility studies must be conducted on fall armyworm (FAW) populations collected from sweet corn growing areas. Monitoring studies	4/1/2010

OPPTS Guideline/ Study Type	Required Data	Due Date
Monitoring	will be conducted on FAW populations collected from sweet corn distribution areas in states in which Monsanto MON 89034 and/or MON 89034 x MON 88017 sweet corn plantings exceed 5,000 acres. The collected populations of FAW will be monitored for changes in susceptibility to the Cry1A.105 and Cry2Ab2 proteins.	

* Extensions were granted as listed in the table above.

5) Submit or cite all data required to support the individual plant-incorporated protectant in Event MON 863 (YieldGard Rootworm), EPA Reg. No. 524-528. In the event that the Agency concludes Event 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.

6) The Insect Resistance Management (IRM) terms and conditions for this product are as follows.

The required IRM program for MON 89034 x MON 88017 must have the following elements:

- Requirements relating to creation of a non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuge in conjunction with the planting of any acreage of MON 89034 x MON 88017 field corn;

- Requirements for Monsanto to prepare and require MON 89034 x MON 88017 users to sign "grower agreements," which impose binding contractual obligations on the grower to comply with the refuge requirements;

- Requirements regarding programs to educate growers about IRM requirements;

- Requirements regarding programs to evaluate and promote growers' compliance with IRM requirements;

- Requirements regarding programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to Cry1A.105, Cry2Ab2, and Cry3Bb1 proteins in the target insects;

- Requirements regarding a "remedial action plan," which contains measures Monsanto would take in the event that any field relevant insect resistance was detected as well as to report on activity under the plan to EPA;

- Submit annual reports on units sold by state (units sold by county level will be made available to the Agency upon request), IRM grower agreement results, and the compliance assurance program including the education program on or before January 31st each year, beginning in 2010.

a) Refuge Requirements for MON 89034 x MON 88017 Field Corn

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year. Furthermore, these refuge requirements do not apply to commercial hybrid sweet corn.

1) Corn-Belt Refuge Requirements

For MON 89034 x MON 88017 field corn grown outside cotton-growing areas (e.g., the Corn Belt), 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. Two options for the 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 89034 x MON 88017 acres and refuge acres). It must be planted as a block adjacent to the MON 89034 x MON 88017 field, perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. 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 (determined using methods recommended by local or regional professionals); however, if rootworm adults are present at the time of foliar applications, then the MON 89034 x MON 88017 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 5% of the grower's corn acres (i.e. sum of MON 89034 x MON 88017 acres and corn borer refuge acres), and must be planted within ½ mile of the MON 89034 x MON 88017 field.

Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. 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 (determined using methods recommended by local or regional professionals). 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 89034 x MON 88017 acres and corn rootworm refuge acres) and must be planted as an adjacent block, perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. 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 89034 x MON 88017 field must be treated in a similar manner.

Growers who fail to comply with the IRM requirements risk losing access to Monsanto corn PIP Products.

2) Cotton-Growing Area Refuge Requirements

For MON 89034 x MON 88017 field corn grown in cotton-growing areas, grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

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

Two options for the 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 89034 x MON 88017 acres and refuge acres). It must be planted as a block adjacent to the MON 89034 x MON 88017 field, perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. 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 (determined using methods recommended by local or regional professionals); however, if rootworm adults are present at the time of foliar applications, then the MON 89034 x MON 88017 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 89034 x MON 88017 acres and corn borer refuge acres), and must be planted within ½ mile of the MON 89034 x MON 88017 field.

Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. 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

(determined using methods recommended by local or regional professionals). 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 89034 x MON 88017 acres and corn rootworm refuge acres) and must be planted as an adjacent block, perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. 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 89034 x MON 88017 field must be treated in a similar manner.

Growers who fail to comply with the IRM requirements risk losing access to Monsanto corn PIP products.

b) Post-Harvest Requirements for MON 89034 x MON 88017 Sweet Corn

Sweet corn is harvested long before field corn. Therefore, if the sweet corn stalks remaining in the field and any insects remaining in the stalks are destroyed shortly after harvest, a refuge is not needed as a part of the IRM program for sweet corn. Growers must adhere to the following types of crop destruction requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

- Crop destruction must occur no later than 30 days following harvest, but preferably within 14 days.

- The allowed crop destruction methods are: rotary mowing, discing, or plow down. Crop destruction methods should destroy any surviving resistant insects.

c) Grower Agreements for MON 89034 x MON 88017

1) Persons purchasing MON 89034 x MON 88017 must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.

2) The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.

3) Monsanto must integrate this registration into the current system used for their other *Bt* corn PIPS, which is reasonably likely to assure that persons purchasing MON 89034 x MON 88017 will affirm annually that they are contractually bound to comply with the requirements of the IRM program.

4) Monsanto must continue to use their current 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, Monsanto must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of the amendment.

5) Monsanto must integrate this registration into a current system, which is reasonably likely to assure that persons purchasing MON 89034 x MON 88017 sign grower agreement(s).

6) Monsanto shall maintain records of all MON 89034 x MON 88017 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, 2010 and annually thereafter, Monsanto shall provide EPA with a report showing the number of units of MON 89034 x 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. Note: The first report shall contain the specified information from the time frame starting with the date of registration and ending July 31, 2009.

8) Monsanto must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

d) IRM Education and Compliance Monitoring Programs for MON 89034 x MON 88017

1) Monsanto must design and implement a comprehensive, ongoing IRM education program designed to convey to MON 89034 x MON 88017 users the importance of complying with the IRM program. The program shall include information encouraging MON 89034 x MON 88017 users to pursue optional elements of the IRM program relating to refuge configuration and proximity to MON 89034 x MON 88017 fields. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, EPA- reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials. Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each MON 89034 x MON 88017 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, Monsanto shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraphs 6a or 6b and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

3) On January 31, 2010, Monsanto must provide a report to EPA summarizing the activities carried out under the education program for the prior year. Annually thereafter, Monsanto must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. Monsanto must either submit a separate report or contribute to the report from the industry working group, Agricultural Biotechnology Stewardship Technical Committee (ABSTC).

4) Monsanto must design and implement an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing MON 89034 x MON 88017 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 MON 89034 x MON 88017. Monsanto shall coordinate with other *Bt* corn registrants in designing and implementing its compliance assurance program and integrate this registration into the current compliance assurance program used for their other *Bt* corn PIPS. Other required features of the program are described in paragraphs 5 – 15 below.

5) Monsanto must establish and publicize a "phased compliance approach," i.e., a guidance document that indicates how they 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. While recognizing that for reasons of difference in business practices there are needs for flexibility between different companies, Monsanto must use a consistent set of standards for responding to non-compliance. The options shall include withdrawal of the right to purchase Monsanto corn PIP products 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 Monsanto corn PIP products the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell Monsanto corn PIP products.

6a) MON 89034 x MON 88017 Field Corn: The IRM compliance assurance program shall include an annual survey, conducted by an independent third party, of a statistically representative sample of growers of MON 89034 x MON 88017 field corn who plant the vast majority of all corn in the United States and in areas in which the selection intensity is greatest. The survey shall consider only those growers who plant 200 or more acres of corn in the Corn-Belt and who plant 100 or more acres of corn in corn-cotton areas. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from independent marketing research firms and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the United States.

6b) MON 89034 x MON 88017 Sweet Corn: The IRM compliance assurance program shall include an annual survey of all MON 89034 x MON 88017 sweet corn customers who purchase 5 or more bags of MON 89034 x MON 88017 sweet corn. The survey shall measure the degree of compliance with the IRM program, identify the response rate (e.g., the percent of MON 89034 x MON 88017 sweet corn acres covered by the responses), and consider the potential impact of non-response. An independent third party will participate in the design and implementation of the survey. Data and information derived from the annual survey will be audited by an independent third party.

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.

9a) MON 89034 x MON 88017 Field Corn: Monsanto shall provide a final written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA by January 31st of each year, beginning in 2010. Monsanto shall confer with other registrants and EPA on the design and content of the survey prior to its implementation.

9b) MON 89034 x MON 88017 Sweet Corn: Monsanto shall provide a written summary of the results of the prior year's survey (together with a description of the methodology used and the supporting data) to EPA by January 31st of each year, beginning in 2010. Monsanto shall confer with EPA on changes to the design and content of the survey prior to its implementation.

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

11) Monsanto shall conduct an annual on-farm assessment program. Monsanto shall train its representatives who make on-farm visits with growers of MON89034 x MON 88017 to perform assessments of compliance with IRM requirements. There is no minimum corn acreage size for this program. Therefore, growers will be selected for this program from across all farm sizes. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, Monsanto shall take appropriate action, consistent with its "phased compliance approach," to promote compliance.

12) Monsanto shall carry out a program for investigating legitimate "tips and complaints" that its growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, Monsanto shall take appropriate action, consistent with its "phased compliance approach."

13) If a grower, who purchases MON 89034 x MON 88017 for planting, was specifically identified as not being in compliance during the previous year, Monsanto shall visit with the grower and evaluate whether the grower is in compliance with the IRM program for the current year.

14) Beginning January 31, 2010 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. Monsanto may elect to coordinate information with other registrants and report collectively the results of compliance assurance programs.

15) Monsanto and the seed corn dealers for Monsanto must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license number of the growers will be protected.

e) Insect Resistance Monitoring and Remedial Action Plans for MON 89034 x MON 88017

(1) The Agency is imposing the following conditions for the Cry1A.105 and Cry2Ab2 toxins expressed in MON 89034:

Monsanto will monitor for resistance to Cry1A.105 and Cry2Ab2 expressed in MON 89034 x MON 88017. The monitoring program shall consist of two approaches: (1) focused population sampling and laboratory testing and (2) investigation of reports of less-than expected control of labeled insects. Should field relevant resistance be confirmed, an appropriate resistance management action plan will be implemented.

(a) Focused Population Sampling

Monsanto will develop and ensure the implementation of a plan for resistance monitoring for *Spodoptera frugiperda* (fall armyworm or FAW) in counties in which MON 89034 and/or MON 89034 x MON 88017 sweet corn acreage exceeds 5,000 acres and the pest is capable of overwintering in that county. Monsanto should consult with academic and United States Department of Agriculture (USDA) experts in developing the monitoring plan and will provide EPA with a copy of its proposed resistance monitoring plan for EPA's approval prior to implementation. This proposed FAW monitoring plan must be submitted to EPA by January 31st of the year following that in which MON 89034 and/or MON 89034 x MON 88017 sweet corn acreage exceeds the trigger specified in this requirement (i.e., greater than 5,000 acres in any county in which FAW overwinters). The proposed plan must be implemented the season

following the acreage trigger being met. The proposed plan will remain in place until an EPA approved plan can be implemented.

Monsanto shall annually sample and bioassay populations of the key target pests: *Ostrinia nubilalis* (European corn borer; ECB), *Diatraea grandiosella* (Southwestern corn borer; SWCB), and *Helicoverpa zea* (corn earworm; CEW). Sampling for the target pests will be focused in areas identified as those with the highest risk of resistance development (e.g., where lepidopteran-active *Bt* hybrids are planted on a high proportion of the corn acres, and where the insect species are regarded as key pests of corn). Bioassay methods must be appropriate for the goal of detecting field-relevant shifts in population response to MON 89034 x MON 88017 and/or changes in resistance-allele frequency in response to the use of MON 89034 x MON 88017 and, as far as possible, should be consistent across sampling years to enable comparisons with historical data. Each protein in MON 89034 must be tested separately, rather than a mixture of the two proteins, because resistance to one protein could be masked by the activity of the other.

The number of populations to be collected shall reflect the regional importance of the insect species as a pest, and specific collection regions will be identified for each pest. For ECB, a minimum of 12 populations across the sampling region will be targeted for collection at each annual sampling. For SWCB, the target will be a minimum of six populations. For CEW, the target will be a minimum of 10 populations. Pest populations should be collected from multiple corn-growing states reflective of different geographies and agronomic conditions. To obtain sufficient sensitivity to detect resistance alleles before they become common enough to cause measurable field damage, each population collection shall attempt to target 400 insect genomes (egg masses, larvae, mated females, and/or mixed-sex adults), but a successful population collection will contain a minimum of 100 genomes. It is recognized that it may not be possible to collect the target number of insect populations or genomes due to factors such as natural fluctuations in pest density, environmental conditions, and area-wide pest suppression.

The sampling program and geographic range of collections may be modified as appropriate based on changes in pest importance and for the adoption levels of MON 89034 x MON 88017. The Agency shall be consulted prior to the implementation of such modifications.

The registrant will report to the Agency by August 31st of each year, beginning in 2010, the results of the population sampling and bioassay monitoring program.

Any incidence of unusually low sensitivity to the Cry1A.105 and Cry2Ab2 proteins in bioassay shall be investigated as soon as possible to understand any field relevance of such a finding. Such investigations shall proceed in a stepwise manner until the field relevance can be either confirmed or refuted, and results of these shall be reported to the Agency annually before August 31st, beginning in 2010. The investigative steps will include:

1. Re-test progeny of the collected population to determine whether the unusual bioassay response is reproducible and heritable. If it is not reproducible and heritable, no further action is required.

2. If the unusual response is reproducible and heritable, progeny of insects that survive the diagnostic concentration will be tested using methods that are representative of exposure to MON 89034 x MON 88017 under field conditions. If progeny do not survive to adulthood, any suspected resistance is not field relevant and no further action is required.

3. If insects survive steps 1 and 2, resistance is confirmed, and further steps will be taken to taken to evaluate the resistance. These steps may include:

   - determining the nature of the resistance (i.e., recessive or dominant, and the level of functional dominance);

   - estimating the resistance-allele frequency in the original population;

   - determining whether the resistance-allele frequency is increasing by analyzing field collections in subsequent years sampled from the same site where the resistance allele(s) was originally collected;

   - determining the geographic distribution of the resistance allele by analyzing field collections in subsequent years from sites surrounding the site where the resistance allele(s) was originally collected.

Should field relevant resistance be confirmed, and the resistance appears to be increasing or spreading, Monsanto will consult with the Agency to develop and implement a case-specific resistance management action plan.

(b) Investigation of Reports of Unexpected Levels of Damage by the Target Pests:

Monsanto will follow up on grower, extension specialist or consultant reports of unexpected levels of damage by the lepidopteran pests listed on the pesticide label. Monsanto will instruct its customers to contact them if such incidents occur. Monsanto will investigate all legitimate reports submitted to the company or the company's representatives.

If reports of unexpected levels of damage lead to the suspicion of resistance in any of the key target pests (ECB, SWCB, CEW, and FAW), Monsanto will implement the actions described below, based on the following definitions of *suspected resistance* and *confirmed resistance.*

Suspected resistance

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

- the corn in question has been confirmed to be lepidopteran-active *Bt* corn;
- the seed used had the proper percentage of corn expressing *Bt* protein;
- the relevant plant tissues are expressing the expected level of *Bt* protein; and
- it has been ruled out that species not susceptible to the protein could be responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and that there could be no other reasonable causes for the damage.

The Agency does not interpret *suspected resistance* to mean grower reports of possible control failures or suspicious results from annual insect monitoring assays, nor does the Agency intend that extensive field studies and testing be undertaken to confirm scientifically the presence of insects resistant to MON 89034 x MON 88017 in commercial production fields before responsive measures are undertaken.

If resistance is *suspected,* Monsanto will instruct growers to do the following:

- Use alternative control measures in MON 89034 x MON 88017 fields in the affected region to control the target pest during the immediate growing season.
- Destroy MON 89034 x MON 88017 crop residues in the affected region within one month after harvest with a technique appropriate for local production practices to minimize the possibility of resistant insects over-wintering and contributing to the next season's target pest population.

Additionally, if possible, and prior to the application of alternative control measures or destruction of crop residue, Monsanto will collect samples of the insect population in the affected fields for laboratory rearing and testing. Such rearing and testing shall be conducted as expeditiously as practical.

Confirmed resistance

EPA defines *confirmed resistance* to mean, in the case of field reports of unexpected levels of damage from the key target pests, that all the following criteria are met:

- There is >30% insect survival and commensurate insect feeding in a bioassay, initiated with neonate larvae, that uses methods that are representative of exposure to *Bt* corn hybrids under field conditions (ECB and SWCB only) .

- In standardized laboratory bioassays using diagnostic concentrations of the *Bt* protein suited to the target pest in question, the pest exhibits resistance that has a genetic basis and the level of survivorship indicates that there may be a resistance-allele frequency of ≥ 0.1 in the sampled population.

- In standardized laboratory bioassays, the LC_{50} exceeds the upper limit of the 95% confidence interval of the LC_{50} for susceptible populations surveyed both in the original baselines developed for this pest species and in previous years of field monitoring.

(c) Response to Confirmed Resistance in a Key Target Pest as the Cause of Unexpected Levels of Damage in the Field

When field resistance is *confirmed* (as defined above), the following steps will be taken by Monsanto:

- EPA will receive notification within 30 days of resistance confirmation;

- Affected customers and extension agents will be notified about confirmed resistance within 30 days;

- Monitoring will be increased in the affected area and local target pest populations will be sampled annually to determine the extent and impact of resistance;

- If appropriate (depending on the resistant pest species, the extent of resistance, the timing of resistance, and the nature of resistance, and the availability of suitable alternative control measures), alternative control measures will be employed to reduce or control target pest populations in the affected area. Alternative control measures may include advising customers and extension agents in the affected area to incorporate crop residues into the soil following harvest to minimize the possibility of over-wintering insects, and/or applications of chemical insecticides;

- Unless otherwise agreed with EPA, stop sale and distribution of the relevant lepidopteran-active *Bt* corn hybrids in the affected area immediately until an effective local mitigation plan approved by EPA has been implemented;

- Monsanto will develop a case-specific resistance management action plan within 90 days according to the characteristics of the resistance event and local agronomic needs. Monsanto will consult with appropriate stakeholders in the development of the action plan, and the details of such a plan shall be approved by EPA prior to implementation;

- Notify affected parties (e.g., growers, consultants, extension agents, seed distributors, university cooperators and state/federal authorities as appropriate) in the region of the resistance situation and approved action plan; and

- In subsequent growing seasons, maintain sales suspension and alternative resistance management strategies in the affected region(s) for the *Bt* corn hybrids that are affected by the resistant population until an EPA-approved local resistance management plan is in place to mitigate the resistance.

A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by August 31st each year, beginning in 2010, for the duration of the conditional registration.

(2) The Agency is imposing the following conditions for the Cry3Bb1 toxin expressed in MON 88017:

i) Monsanto must monitor for Cry3Bb1 resistance and/or trends in increased tolerance for corn rootworm utilizing the current corn rootworm resistance monitoring plan for MON 89034 x MON 88017. Sampling should be focused in those areas in which there is the highest risk of resistance development.

ii) Monsanto must develop and validate an appropriate discriminating or diagnostic dose assay by January 31, 2010.

iii) Monsanto must finalize rootworm damage guidelines and submit these to EPA by January 31, 2010.

iv) Monsanto must follow-up on grower, extension specialist or consultant reports of unexpected damage or control failures for corn rootworm.

v) Monsanto must provide EPA with an annual resistance monitoring report by August 31st each year, beginning with 2010, reporting on populations collected the previous year.

vi) The current remedial action plan approved for MON 863 must be used for corn rootworm suspected and confirmed resistance in MON 89034 x MON 88017. If corn rootworm resistance is confirmed, all acres of MON 89034 x MON 88017 and refuges must be treated with insecticides targeted at corn rootworm adults as well as larvae.

f) Annual Reporting Requirements for Mon 89034 x MON 88017

1) Annual Sales: reported and summed by state (county level data available by request), January 31st each year, beginning in 2010;

2) Grower Agreement: number of units of MON 89034 x MON 88017 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, beginning in 2010;

3) Grower Education: substantive changes to education program completed previous year, January 31st each year, beginning in 2010;

4) Compliance Assurance Plan: Compliance Assurance Program activities and results, January 31st each year, beginning in 2010;

5) Compliance Survey Results: to include annual survey results and plans for the next year; full report January 31st each year, beginning in 2010;

6) Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, August 31st each year, beginning in 2010.

V. Regulatory Position For Cry1A.105, And Cry2Ab2

Pursuant to FIFRA section 3(c)(7)(C), EPA may conditionally register a new pesticide active ingredient for a period of time reasonably sufficient for the generation and submission of required data that are lacking because insufficient time has elapsed since the imposition of the data requirement for those data to be developed. EPA may grant such conditional registration only if EPA determines that (1) the use of the pesticide product during the period of the conditional registration will not cause any unreasonable adverse effect on the environment, and (2) the registration and use of the pesticide during the conditional registration is in the public interest. EPA determines that all of these criteria have been fulfilled.

The first criterion under FIFRA Section 3(c)(7)(C) mentioned above has been met because insufficient time has elapsed since the imposition of the data requirements for:

1) an independent lab validation of the analytical method for the detection of Cry2Ab2 and/or Cry1A.105 to satisfy residue analytical method in plants requirements for event MON 89034 corn and event MON 89034 x MON 88017 corn,

2) a 7 to 14 day *Daphnia* study as per the 885 Series OPPTS Guidelines or alternatively, a dietary study of the effects on an aquatic invertebrate, representing the functional group of a leaf shredder in headwater streams..

3) additional information on cross-resistance of Cry1A.105 and Cry1Fa and Cry1Ac (preferably including binding site models and use of resistant colonies) for the target pests and determine how such cross-resistance may impact the durability of MON 89034

4) baseline susceptibility studies and/or a discriminating concentration assay that are required for the Cry1A.105 protein against ECB, SWCB, and CEW and for the Cry2Ab2 protein against SWCB, CEW.

5) baseline susceptibility studies to support sweet corn uses that must be conducted on FAW populations collected from sweet corn growing areas; Monitoring studies that will be conducted on FAW populations collected from sweet corn distribution areas in states in which Monsanto MON 89034 and/or MON 89034 x MON 88017 sweet corn plantings exceed 1000 acres; and monitoring of the collected populations of FAW for changes in susceptibility to the Cry1A.105 and Cry2Ab2 proteins.

The applicants submitted or cited data sufficient for EPA to determine that conditional registration of *Bacillus thuringiensis* Cry2Ab2 and Cry 1A.105 proteins and the genetic material necessary for their production in event MON 89034 field corn and sweet corn under FIFRA 3(c)(7)(C) will not result in unreasonable adverse effects to the environment, as discussed above. The applicants submitted and/or cited satisfactory data pertaining to the proposed use. The human health effects data and nontarget organism effects data are considered sufficient for the

period of the conditional registration. These data demonstrate that no foreseeable human health hazards or ecological effects are likely to arise from the use of the product and that the risk of resistance developing to Cry2Ab2 and Cry 1A.105 proteins, during the conditional registrations are not expected to be significant.

Registration of *Bacillus thuringiensis* Cry2Ab2 and Cry 1A.105 proteins and the genetic material necessary for their production in event MON 89034 field corn and sweet corn is in the public interest because:

(1) Registration of MON 89034 is expected to result in the reduction of the use of higher risk, and often less effective and more expensive, conventional pesticides. A reduction in use of conventional pesticides equates to less potential for adverse effects to human health and the environment.

(2) Additionally, MON 89034 provide a wider spectrum of protection against primary and secondary corn pests, which should facilitate greater grain quality, a reduction of mycotoxin contamination, increased yield and ultimately have positive implications for human health.

In view of these minimal risks and the clear benefits related to *Bacillus thuringiensis* Cry2Ab2 and Cry 1A.105 proteins and the genetic material necessary for their production in event MON 89034 field corn and sweet corn , EPA believes that the use of the product during the limited period of the conditional registration will not cause any unreasonable adverse effects.

Although the data with respect to this particular new active ingredient are satisfactory, they are not sufficient to support an unconditional registration under FIFRA 3(c)(5). Additional data are necessary to evaluate the risk posed by the continued use of this product. Consequently, EPA is imposing the data requirements specified earlier in Section III.

EPA has determined, as explained in section II.F., that the third criterion for a FIFRA 3(c)(7)(C) conditional registration has been fulfilled because the use of *Bacillus thuringiensis* Cry2Ab2 and Cry 1A.105 proteins and the genetic material necessary for their production in event MON 89034 field corn and sweet corn under this registration is in the public interest.

The submitted data in support of this registration under section 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) have been reviewed and determined to be adequate. Studies mentioned above are included in the terms, conditions, and limitations of these registrations. This registration will not cause unreasonable adverse effects to man or the environment and is in the public interest.

The expiration date of the registrations has been set to September 30, 2010.

VI. Contact Person at EPA

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

Office location and telephone number:

8th Floor
One Potomac Yard
2777 S, Crystal Drive
Arlington, VA 22202
(703) 308-8077 Email: cerrelli.susanne@epa.gov

DISCLAIMER: The information in this Pesticide Fact Sheet is a summary only and is not to be used to satisfy data requirements for pesticide registration. Contact the Senior Regulatory Specialist listed above for further information.