

OCT 15 2001

Dr. Russell P. Schneider
Director, Regulatory Affairs
Monsanto Company
600 13th Street, N.W.
Suite 660
Washington, D.C. 20005

Dear Dr. Schneider:

Subject: Amendment Request Dated October 12, 2001 Regarding Monsanto's
Registration for Cry1Ab Protein Expressed in Corn
EPA Registration No. 524-489

The amendment referred to above, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the following comments.

Expiration Date:

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

Data :

You must submit the following data in the time frames specified.

1. The Agency is requiring Monsanto to submit an analytical method for the detection of Cry1Ab protein in corn grain and a thorough characterization of the antisera used in the method(s). The method must be validated by an independent laboratory validation. Both the method and the validation must be submitted to EPA by June 1, 2002.

2. Amino acid sequence data submitted indicate that there are no similarities between Cry1Ab protein and any known toxins or allergens. However, since the initial registration, the value of comparing the amino acid sequence to known toxins and allergens has been highlighted and therefore a stepwise & amino acid analysis of the subject protein against newly available known allergen sequence databases is required. In addition, a processing and/or heat stability study.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

must also be conducted. These additional data are required to augment the health effects database for Cry1Ab corn by March 15, 2003.

3. The Agency is requiring protein expression data in terms of dry weight, as the amount of protein present in the given tissue. Tissues for which expression data must be provided include: leaf, root, pollen, seed, and whole plant. In addition, data for each of these tissues should be provided for young plants in rapid growth, during flowering, and mature plants before harvest when that part of the plant is present. Data are due on or before March 15, 2003.

4. The Agency is requiring testing of Cry1Ab protein in soil under a range of conditions typical of *Bt* corn cultivation. EPA requires Monsanto or Monsanto in cooperation with other registrants to submit test protocols before the studies are actually conducted. In general, the Agency anticipates that soils would be sampled from fields where *Bt* corn has been grown continuously for at least 3 years compared with fields where no *Bt* crop has been grown. These paired fields would include several locations throughout the corn growing area of the US representing different soil and climatic variations. The Agency anticipates that samples would need to be taken 2 or 3 times during the growing season. Monsanto is required to submit a protocol on or before March 15, 2002. An interim report is due 12 months after the protocol is approved and a final report is due 24 months after the final protocol is approved.

5. EPA is requiring confirmatory field data for possible impacts on non-target insects. Either existing studies must be submitted or the registrants must submit a protocol for field survey studies on or before March 15, 2002 with an interim report submitted 12 months after approval of the protocol and a final report submitted 36 months after approval of the protocol.

6. Based upon research recently published in the Proceedings of the National Academy of Sciences and upon the response of the Agricultural Biotechnology Stewardship Technical Committee to the December 1999 *Bt* corn Data Call-in Notice, EPA has concluded that the weight of scientific data indicate that *Bt* corn poses no unreasonable adverse impact on monarch butterfly populations. However, it has been identified in one of these papers, (Stanley-Horne, et al, 2001) that the published data only cover acute exposure and longer term exposure to *Bt* corn pollen should be considered. EPA is aware that studies are underway to assess the potential for longer-term exposure to *Bt* corn pollen to adversely impact monarch populations. Monsanto must report the results of these studies to EPA as soon as the results are available publicly or Monsanto must provide valid scientific studies to address this issue by January 31, 2003. The report must be able to be made available to the public at the time it is submitted to EPA.

7. Submitted avian toxicity data on Cry1Ab *Bt* corn was scientifically sound and no treatment mortality or behavior change was observed between the dosed and control replicates. However, data from repeated exposure(s) to higher doses of *Bt* corn are needed to make a hazard assessment. A supplemental study is required. The study must be of appropriate duration to represent the start and growing periods of the test species such as six weeks in meat-type chickens. Balanced diets should be formulated according to the National Research Council

guidelines ("Nutrient Requirements of Poultry," Ninth Revised Edition, 1994) with the energy requirements of the test species being met by the inclusion of corn in the diet to assess hazards from chronic exposure of wild or domesticated fowl. A protocol for poultry studies must be submitted on or before March 15, 2002 with a final report submitted 18 months after approval of the protocol.

8. Studies are required to evaluate the impacts of north-south movement of *Helicoverpa zea* from corn-growing regions to cotton-growing regions on the resistance management of corn earworm, including field studies, as needed, to determine the adequacy of the current resistance management program. Either existing studies must be submitted or a protocol for field studies must be submitted on or before March 15, 2002 with an interim report submitted 12 months after approval of the protocol and a final report submitted 24 months after approval of the protocol.

9. Research on the impacts of insecticidal sprays on the effectiveness of the refuge are required. Monsanto must submit either a copy of the NC-205 protocol or a protocol of its own to the Agency by March 15, 2002. An interim report is due in 12 months after submitting the NC-205 protocol or approval of the registrant's protocol and a final report is due 24 months after submitting the NC-205 protocol or approval of the registrant's protocol.

Insect Resistance Management:

The required IRM program for *Bt* corn must have the following elements:

- 1] Requirements relating to creation of a non-*Bt* corn refuge in conjunction with the planting of any acreage of *Bt* corn;
- 2] Requirements for the registrants to prepare and require *Bt* corn users to sign "grower agreements" which impose binding contractual obligations on the grower to comply with the refuge requirements;
- 3] Requirements for the registrants to develop, implement, and report to EPA on programs to educate growers about IRM requirements;
- 4] Requirements for the registrants to develop, implement, and report to EPA on programs to evaluate and promote growers' compliance with IRM requirements;
- 5] Requirements for the registrants to develop, implement, and report to EPA on programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to Cry1Ab protein in the target insects;
- 6] Requirements for the registrants to develop, and if triggered, to implement a "remedial action plan" which would contain measures the registrants would take in the event that any insect resistance was detected as well as to report on activity under the plan to EPA;

7] Submit annual reports on sales, IRM grower agreements results, compliance, and educational program on or before January 31st each year.

a. Refuge Requirements

1) Corn-Belt Refuge Requirements

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 20% non-*Bt* corn that may be treated with insecticides as needed to control lepidopteran stalk-boring and other pests.
- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field.
- External refuges must be planted within ½ mile (1/4 mile or closer preferred).
- When planting the refuge in strips across the field, refuges must be at least 4 rows wide, preferably 6 rows wide.
- Insecticide treatments for control of ECB, CEW and Southwestern corn borer (SWCB) 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, crop consultants). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to non-*Bt* corn refuges.

2) Cotton-Growing Area Refuge Requirements for *Bt* Corn

For *Bt* 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 50% non-*Bt* corn that may be treated with insecticides as needed to control lepidopteran stalk-boring and other pests.
- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field.

- External refuges must be planted within ½ mile (1/4 mile or closer preferred).
- When planting the refuge in strips across the field, refuges must be at least 4 rows wide, preferably 6 rows wide.
- Insecticide treatments for control of ECB, CEW and Southwestern corn borer (SWCB) 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, crop consultants). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to non-*Bt* corn refuges.
- For the 2002 growing season, cotton-growing areas include the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Bryan, Caddo, Canadian, Garvin, and Grady), Tennessee (only the counties of Carroll, Chester, Crockett, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Henderson, Lake, Lauderdale, Lawrence, Lincoln, McNairy, 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 Greensville, Isle of Wight, Northampton, Southampton, Suffolk and Sussex) and Missouri (only the counties of Butler, Dunklin, Mississippi, New Madrid, Pemiscot, Scott and Stoddard).
- For the 2003 growing season and thereafter unless modified by an approved amendment, 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, Stoddard).

b. Grower Agreements

- 1] Persons purchasing the *Bt* corn product must sign a grower agreement. The term “grower agreement” refers to any grower purchase contract, license agreement, or similar legal document.
- 2] The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower

agreement, a grower must be contractually bound to comply with the requirements of the IRM program.

3] The registrant must establish by the 2003 growing season, a system which is reasonably likely to assure that persons purchasing the *Bt* corn product will affirm annually that they are contractually bound to comply with the requirements of the IRM program. The proposed system will be submitted to EPA on or before March 15, 2002.

4] The registrant must continue to use their current grower agreement and submit to EPA by November 1, 2001 a copy of that agreement and any specific stewardship documents referenced in the grower agreement. If Monsanto wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty days prior to implementing a proposed change, the registrant must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of the amendment.

5] The registrant must establish a system which is reasonably likely to assure that persons purchasing the *Bt* corn sign grower agreement(s), and must provide by January 31, 2002 a written description of that system.

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

7] Beginning on January 31, 2003 and annually thereafter, the registrant shall provide EPA with a report showing the number of units of its *Bt* 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 for the time frame starting with the date of registration and ending July 31, 2002.

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

c. IRM Education and IRM Compliance Monitoring Programs

1] Monsanto must design and implement a comprehensive, ongoing IRM education program designed to convey to *Bt* corn users the importance of complying with the IRM program. The program shall include information encouraging *Bt* corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to *Bt* corn fields. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written

materials, EPA reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials. Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each *Bt* corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Monsanto shall coordinate its education programs with educational efforts of other registrants and other organizations, such as the National Corn Grower Association and state extension programs.

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

3] Beginning January 31, 2002 and annually thereafter, the registrants must provide a report to EPA summarizing the activities carried out under the education program for the prior year and the plans for their education program during the current year. The registrant must either submit a separate report or contribute to the report from the industry working group (ABSTC).

4] The registrant must design and implement an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing its *Bt* corn product are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to the *Bt* corn product. The registrant shall coordinate with other registrants in designing and implementing its compliance assurance program. The registrant must prepare and submit by January 31, 2002 a written description of their compliance assurance program including a summary of the program implemented in the 2001 growing season. Other required features of the program are described in paragraphs 5] - 15] below.

5] The registrant must establish and publicize a "phased compliance approach," i.e., a guidance document that indicates how the registrant will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers. While recognizing that for reasons of difference in business practices there are needs for flexibility between different companies, all *Bt* corn registrants must use a consistent set of standards for responding to non-compliance. The options shall include withdrawal of the right to purchase *Bt* corn for an individual grower or for all growers in a specific region. An individual grower found to be significantly out of compliance two years in a row would be denied sales of the product the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell *Bt* corn.

6] The IRM compliance assurance program shall include an annual survey of a statistically representative sample of *Bt* corn growers conducted by an independent third party. The survey shall measure the degree of compliance with the IRM program by growers in different regions of

the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from the independent marketing research firm and academic scientists, to allow analysis of compliance behavior within the four ABSTC regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the U.S.

7] The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.

8] The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.

9] The registrant shall provide a preliminary summary of their findings by November 15 and a final written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA by January 31 of each year. The registrant shall confer with other registrants and EPA on the design and content of the survey prior to its implementation.

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

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

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

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

14] Beginning January 31, 2003 and annually thereafter, each registrant 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. The registrants may elect to coordinate information and report collectively the results of their compliance assurance programs.

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

d. Insect Resistance Monitoring

The Agency is imposing the following conditions for this product:

1) The registrants will monitor for resistance and/or trends in increased tolerance for *Ostrinia nubilalis* (European corn borer), *Diatraea grandiosella* (Southwestern corn borer), and/or *Helicoverpa zea* (corn earworm). Sampling should be focused in those areas in which there is the highest risk of resistance development. The ABSTC has identified four regions for its compliance and monitoring programs. Sampling target for each insect pest will be at least 200 insects in any region where adoption of *Bt* corn exceeds 50% and the insect is a pest species in that region. Sampling target for each insect pest will be at least 100 insects in all other regions where the insect is a pest species in that region.

2) The ABSTC will convene an advisory panel of academic experts from NC-205, USDA, and EPA to examine the current monitoring program and methodology and to consider enhancements to the current monitoring program for implementation in 2002. Consensus changes recommended by the joint panel will be implemented as soon as possible, beginning in 2002, including modification in the number of insects collected per site, number of sites, number of regions sampled, and/or modifications in methodology, such as field screening or F₂ screening.

3) The registrant shall provide to EPA a description of its resistance monitoring plan by January 31, 2003. The description shall include: sampling (number of locations and samples per locations), sampling methodology, bioassay methodology, standardization procedures, detection technique and sensitivity, and the statistical analysis of the probability of detecting resistance.

4) The registrant must follow up on grower, extension specialist or consultant reports of less than expected results or control failures for the target lepidopteran pests *Ostrinia nubilalis* (ECB), *Diatraea grandiosella* (SWCB), and *Helicoverpa zea* (CEW/CBW). The registrant will instruct its customers (growers and seed distributors) to contact them (e.g., via a toll-free customer service number) if incidents of unexpected levels of damage occurs from these target pests. The registrant will investigate all damage reports submitted to the company or the company's representatives. See Remedial Action Plans section below.

5) A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by April 30th each year for the duration of the conditional registration.

e. Remedial Action Plans

A Remedial Action Plan covering both suspected and confirmed resistance for European corn borer, corn earworm, and southwestern corn borer is provided in Enclosure 1. If resistance involves any of these three target pests, the registrants collectively must implement the Remedial Action Plan contained in Enclosure 1. The registrant must obtain approval from EPA before modifying the Remedial Action Plan for Corn.

Annual Reports:

The registrant will provide annual reports to EPA on its Cry1Ab PIP expressed in corn based on the following table.

Report	Description	Due Date
Annual Sales	Reported by county and state summed by state	January 31 st each year
Grower Agreement	Number of units of <i>Bt</i> corn seeds shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements	January 31 st each year beginning in 2003
Grower Education	Education program completed previous year and plan for next year	January 31 st each year
Proposed Compliance Plan	Written description of Compliance Assurance Program	January 31, 2002
Compliance Assurance Plan	Compliance Assurance Program Results	January 31 st each year starting in 2003
Compliance	To include annual survey results and plans for the next year	Preliminary survey report November 15 th each year and full report January 31 st each year thereafter

11/17

Insect Resistance Monitoring	Description of the program including sampling (number of locations and samples per locations), sampling methodology, bioassay methodology, standardization procedures, detection technique and sensitivity, and the statistical analysis of the probability of detecting resistance.	January 31, 2003
------------------------------	--	------------------


Additional reports are due as described in the following table:

IRM Grower Agreements	Proposed system to assure growers sign grower agreements	January 31, 2002
IRM Affirmation Plan	System to assure annual affirmation by growers of their IRM obligations	March 15, 2002
Changes to Grower Agreement and/or IRM documents	Current grower agreement(s) and any specific stewardship documents	November 1, 2001 and at least 30 days before any changes related to IRM are expected to be imposed.
Insect Resistance Monitoring Results	Results of monitoring and investigations of damage reports	April 30 th each year

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of MON810 corn and your letter of October 15, 2001 constitute acceptance of these conditions.

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

Sincerely,


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

Enclosure

Enclosure

Remedial Action Plan for Responding to Resistance in European Corn Borer
Corn Earworm and/or Southwestern Corn Borer
(October 15, 2001)

I. Definitions

Suspected resistance

EPA defines "suspected" resistance to mean, in the case of reported product failure, that:

- the corn in question has been confirmed to be *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 other reasonable causes for the observed product failure have been ruled out.

The Agency does not interpret "suspected resistance" to mean grower reports of possible control failures, nor does the Agency intend that extensive field studies and testing to confirm scientifically insect resistance be completed before responsive measures are undertaken.

If resistance is "suspected," the registrant must instruct growers to do the following:

- Use alternate control measures to control the pest suspected of resistance to *Bt* corn in the affected region.
- Destroy crop residues in the affected region immediately after harvest (i.e. within one month) with a technique appropriate for local production practices to minimize the possibility of resistant insects overwintering and contributing to the next season's pest population.

Confirmed Resistance

The registrant assumes responsibility for the implementation of resistance mitigation actions undertaken in response to the occurrence of resistance during the growing season. When resistance has been confirmed, the registrant must immediately stop sale and distribution of *Bt* corn in the remedial action zone (may be less than a single county, single county, or multiple counties) where the resistance has been shown until an effective local mitigation plan approved by EPA has been implemented.

A resistance event becomes confirmed if the progeny of the sampled ECB, CEW, or SWCB population would exhibit all of the following characteristics in bioassays initiated with neonates:

1. If there is > 30% survival and > 25% leaf area damaged in a 5-day bioassay using Cry1Ab-positive leaf tissue under controlled laboratory conditions.

2. If standardized laboratory bioassays using diagnostic doses for ECB (Marçon et al. 2000), SWCB (Trisyono and Chippendale 1999), or CEW/CBW (USDA/ARS/SIMRU, unpublished) demonstrate resistance has a genetic basis and survivorship in excess of 1% (gene frequency of population ≥ 0.1).
3. If an LC_{50} in a standard Cry1Ab diet bioassay exceeds the upper limit of the 95% confidence interval of the standard unselected laboratory population LC_{50} for susceptible ECB, SWCB, or CEW populations, as established by the ongoing baseline monitoring program.

II. Remedial Action

The registrant assumes responsibility for the implementation of resistance mitigation actions undertaken in response to the occurrence of resistance during the growing season. In cases of "confirmed" resistance, the following strategy for Cry1Ab *Bt* corn hybrids:

The registrant will report all instances of confirmed pest resistance, as defined above, to the Agency within 30 days. Upon identification of a confirmed instance of resistance, registrants will take the following immediate mitigation measures:

1. Notify customers and extension agents in the affected area,
2. Require to customers and extension agents in the affected area the use of alternative control measures to reduce or control the local target pest population,
3. Where appropriate, require to customers and extension agents in the affected area that crop residues be incorporated into the soil following harvest, to minimize the possibility of overwintering insects.
4. Immediately stop sale and distribution of *Bt* corn in the remedial action zone (may be a single or multiple counties) where the resistance has been shown until an effective local mitigation plan approved by EPA has been implemented.

Within 90 days of a confirmed instance of pest resistance, as defined above, registrants will:

1. Notify the Agency of the immediate mitigation measures that were implemented,
2. Submit to the Agency a proposed long-term resistance management action plan for the affected area,
3. Work closely with the Agency in assuring that an appropriate long-term resistance management action plan for the affected area is implemented, and

4. Implement an action plan that is approved by EPA and that consists of some or all the following elements, as warranted:

- a. Informing customers and extension agents in the affected area of pest resistance,
- b. Increasing monitoring in the affected area, and ensuring that local target pest populations are sampled on an annual basis,
- c. Recommending alternative measures to reduce or control target pest populations in the affected area,
- d. Implementing intensified local IRM measures in the affected area based on the latest research results. The implementation of such measures will be coordinated by the Agency with other registrants; and
- e. The implementation of the remedial action strategy will be coordinated by the Agency with other registrants and stakeholders.

For mitigation of resistance in the growing season(s) following a confirmed resistance incident(s), use of the following procedures:

- 1. Maintenance of the sales suspension of all *Bt* corn hybrids (with the same protein or similar *Bt* proteins as the *Bt* corn hybrids with the resistant population) in the affected region would remain in place until an EPA-approved local resistance management plan is in place to mitigate resistance in the affected region(s).
- 2. The development and recommendation of alternative resistance management strategies for controlling the resistant pest(s) on corn in the affected region.
- 3. Notification of all relevant personnel (e.g., growers, consultants, extension agents, seed distributors, processors, university cooperators, and state/federal authorities) in the affected region of the resistance situation.

15/17

YieldGard® Insect Protected Corn

Product Label

***Bacillus thuringiensis* CryIA(b) delta-endotoxin and the genetic material necessary for its production in corn**

Pure form of the Plant Pesticide, *Bacillus thuringiensis* subsp. *kurstaki* control protein as expressed by the *cryIA(b)* gene in corn cells.

Active Ingredient:

Bacillus thuringiensis CryIA(b) delta endotoxin and the genetic material necessary for its production in corn 0.023 - 0.029%*

*Percentage of total protein on a dry weight basis.

Keep Out of Reach of Children

CAUTION

EPA REGISTRATION NUMBER 524-489

EPA ESTABLISHMENT NUMBER 524-MO-002

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198

ACCEPTED
with COMMENTS
In EPA Letter Dated
OCT 15 2001
Under the Federal Insecticide,
Fungicide, and Rodenticide Act
recommended for the pesticide
registered under EPA Reg. No.
524-489

Directions for Use:

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

The following information regarding commercial production must be included in the Grower Guide for Cotton and Non-Cotton Growing Areas.

a) Corn-Belt/Non-Cotton Growing Areas

For Cry1Ab field corn grown outside cotton-growing areas (e.g., the Corn Belt), grower guides must specify that growers must adhere to the following refuge requirements.

Growers must plant a structured refuge of at least 20% non-Bt corn which may be treated with insecticides as needed to control lepidopteran stalk-boring and other pests.

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

External refuges must be planted within ½ mile (1/4 mile or closer preferred).

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

Insecticide treatments for control of ECB, CEW, and Southwestern corn borer (SWCB) 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, crop consultants). Instructions to growers will specify that microbial Bt insecticides must not be applied to non-Bt corn refuges.

b) Cotton-Growing Area Refuge Requirements for Bt corn

For the 2002 growing season, cotton-growing areas include the following states: Alabama, Arkansas, Florida, Georgia, Louisiana, North Carolina, Mississippi, South Carolina, Virginia (only the counties of Greensville, Isle of Wight, Northhampton, Southhampton, Sussex, and Suffolk), Missouri (only the counties of Butler, Dunklin, Mississippi, New Madrid, Pemiscot, Scott, and Stoddard), Oklahoma (only the counties of Bryan, Caddo, Canadian, Garvin, and Grady), Tennessee (only the counties of Carroll, Chester, Crockett, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Henderson, Lake, Lauderdale, Lawrence, Lincoln, McNairy, Madison, Obion, Rutherford, Shelby, and Tipton) and Texas (with exception of the counties of Dallam, Sherman, Hansford, Ochiltree, Lipscomb, Hartley, Moore, Hutchinson, Roberts, and Carson).

For 2003 and beyond growing seasons, cotton-growing areas include the following states: Alabama, Arkansas, Florida, Georgia, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman) Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northhampton, Southhampton, Suffolk City, Surrey, and Sussex), and Missouri (only the counties of Dunkin, New Madrid, Pemiscot, Scott, and Stoddard)

For Bt field corn grown in cotton-growing areas, grower guides must specify that growers must adhere to the following refuge requirements.

Growers must plant a structured refuge of at least 50% non-Bt corn which may be treated with insecticides as needed to control lepidopteran stalk-boring and other pests.

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

External refuges must be planted within 1/2 mile (1/4 mile or closer preferred).

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

Insecticide treatments for control of ECB, CEW, and Southwestern corn borer (SWCB) 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, crop consultants). Instructions to growers will specify that microbial Bt insecticides must not be applied to non-Bt corn refuges.

Corn has been transformed to express the CryIA(b) form of the *Bacillus thuringiensis* subsp. *kurstaki* (*B.t.k.*) delta endotoxin protein for the control or suppression of the following lepidopteran corn insect pests:

European corn borer	<i>Ostrinia nubilalis</i>
Southwestern corn borer	<i>Diatraea grandiosella</i>
Southern cornstalk borer	<i>Diatraea crambidoides</i>
Corn earworm	<i>Helicoverpa zea</i>
Fall armyworm	<i>Spodoptera frugiperda</i>
Stalk borer	<i>Papaipema nebris</i>

Sales of corn hybrids that contain Monsanto's *B.t.* corn plant pesticide must be accompanied by a Grower Guide which includes information on planting, production and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the *B.t.* delta-endotoxin protein are planted.