

 <p>U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Biopesticides and Pollution Prevention Division (7511C) 1200 Pennsylvania Ave., NW Washington, D.C. 20460</p> <p>NOTICE OF PESTICIDE: <input checked="" type="checkbox"/> Registration <input type="checkbox"/> Reregistration</p> <p>(under FIFRA, as amended)</p>	EPA Reg. Number: 68467-4	Date of Issuance: 5/27/05
	Term of Issuance: Conditional	
	Name of Pesticide Product: Mycogen Brand B.T. Cry1F Event DAS-06275-8 (moCry1F corn)	
Name and Address of Registrant (include ZIP Code): Penny L. Hunst, Ph.D. Global Trait Regulatory Leader-corn Mycogen Seeds c/o Dow AgroSciences LLC 9330 Zionsville Road Indianapolis, IN 46268-1054		
<p>Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.</p> <p>On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.</p> <p>The registration application referred to above, submitted in connection with registration under § 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you do the following terms and conditions.</p> <ol style="list-style-type: none"> 1) The subject registration will automatically expire on midnight October 15, 2008. 2) The subject registration will be limited to the use of <i>Bacillus thuringiensis</i> var. <i>aizawai</i> strain PS811 Cry1F insecticidal crystal protein and the genetic material necessary for its production (plasmid insert PHP12537) in Cry1F Event DAS-06275-8 corn. 3) Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires registrants of similar products to submit such data. <p>Continued...</p>		
Signature of Approving Official: <i>JSH see next pages</i>		Date: 5/27/05

- 4) Submit production information for this product to Mr. Owen Beeder of Office of Pesticide Programs, Registration Division (mail code 7505C) for the fiscal year in which this product is conditionally registered, in accordance with FIFRA § 29. The fiscal year begins October 1 and ends September 30. Production information will be submitted to the Agency no later than December 15, following the end of the preceding fiscal year.
- 5) The protocol for the Independent Lab Validation of analytical method GRM02.13 "Determination of Cry1F Insecticidal Crystal Protein in corn grain by Enzyme Linked Immunosorbant Assay" does not include a transgenic moCry1F treatment to substantiate the lack of interference posed by transgenic plant expression of Cry1F. Modify the protocol and submit to the EPA appropriate documentation to demonstrate that this method works to quantify Cry1F expressed in transgenic moCry1F corn on or before November 15, 2005.
- 6) Submit to the EPA laboratory (Ft. Meade, MD) methodology and/or reagents necessary for validation of a moCry1F analytical method within 6 months of the date of registration (under OPPTS Guidelines 860.1340). The extraction and detection method and independent third party laboratory validations as described for moCry1F protein appear to be adequate for analysis of moCry1F protein in corn grain. However, this method must be validated by both an independent laboratory and the EPA Biological and Economic Analysis Division laboratory before it can be considered a valid method.
- 7) Submit confirmatory testing of moCry1F protein levels in soil under a range of conditions typical of *Bt* corn cultivation. EPA requires Mycogen Seeds c/o Dow AgroSciences LLC 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. A protocol was approved for poCry1F in 2002. Submit a final report to the Agency for moCry1F by March 15, 2008.
- 8) Submit confirmatory field data for possible impacts of moCry1F on non-target insects. Preliminary data for poCry1F corn were provided to the Agency on March 14, 2002 and found to be acceptable. Submit a final report for moCry1F to the Agency by March 15, 2008.

The following registration requirements and conditions shall not require any action by Mycogen Seeds c/o Dow AgroSciences LLC unless and until Mycogen Seeds c/o Dow AgroSciences LLC commercializes moCry1F corn in the United States. **The term "commercialization" shall mean the sale of moCry1F corn seed to one or more growers for purposes of growing a commercial grain corn crop in the United States.**

You must commit to do the following Insect Resistance Management Program upon commercialization:

1] Requirements relating to creation of a non-*Bt* corn or non-lepidopteran resistant *Bt* corn refuge in conjunction with the planting of any acreage of *Bt* corn;

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

4] Requirements for the registrant to develop, implement, and report to EPA on programs to evaluate and promote growers' compliance with IRM requirements;

5] Requirements for the registrant 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 Cry1F protein in the target insects;

6] Requirements for the registrant to develop, and if triggered, to implement a "remedial action plan" which would contain measures the registrant 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 after commercialization.

a. Refuge Requirements

1) Corn-Belt Refuge Requirements

For lepidopteran resistant *Bt* 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 or non-lepidopteran resistant *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.

- 2/5
- 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, Southwestern corn borer (SWCB), fall armyworm (FAW), black cutworm (BCW), and western bean cutworm (WBCW) 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 or non-lepidopteran resistant *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, Southwestern corn borer (SWCB), fall armyworm (FAW), black cutworm (BCW), and western bean cutworm (WBCW) 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 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, Stoddard). The correct list of counties must be in the first grower guide.

b. Grower Agreements

1] Persons purchasing the moCry1F *Bt* corn products 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] Mycogen Seeds c/o Dow AgroSciences LLC must establish by the year of commercialization, 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.

4] At least 30 days prior to commercialization, Mycogen Seeds c/o Dow AgroSciences LLC must submit to EPA a copy of its grower agreement and any specific IRM documents referenced in the grower agreement. If Mycogen Seeds c/o Dow AgroSciences LLC 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 31st, of the first year after the commercialization of moCry1F corn a written description of that system.

6] The registrant shall maintain records of all *Bt* moCry1F corn grower agreements for a period of three years from December 31st of the year in which the agreement was signed.

7] Beginning on January 31st after the first year of commercialization 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: if the first year of commercialization is 2006, the first report shall contain the specified information for the time

frame starting with the date of registration and ending July 31, 2007.

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] Mycogen Seeds c/o Dow AgroSciences LLC 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. Mycogen Seeds c/o Dow AgroSciences LLC 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 after commercialization, 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 31st, of the first year after commercialization of moCry1F corn and annually thereafter, the registrant must provide EPA any changes to its grower education activities as part of the overall IRM compliance assurance program report. No separate grower education report is needed if the registrant submits a report in connection with other *Bt* registrants. The required features of the compliance assurance program are described in paragraphs 4]-15] below.

4] The registrant must design and implement an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing its *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 31st, of the first year after commercialization, a written description of their compliance assurance. 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] Prior to commercialization, the registrant shall provide a preliminary summary of its findings by November 15th of each year beginning with the year of commercialization 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 following commercialization. The registrant shall confer with other registrants and EPA on the design and content of the survey prior to its implementation.

10] Annually after commercialization, 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] Prior to commercialization, 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] Prior to commercialization, the registrant shall establish 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 31st, and annually thereafter, registrant shall provide a report to EPA summarizing the activities carried out under their compliance assurance program for the prior year including changes to the grower education program, 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 upon commercialization:

1) After commercialization, Mycogen Seeds c/o Dow AgroSciences LLC 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 registrant shall provide to EPA a description of its resistance monitoring plan by January 31st, of the first year after commercialization. The description shall include: sampling (number of locations and samples per locations), sampling methodology, bioassay methodology, standardization procedures, detection technique and sensitivity, and the statistical analysis of the probability of detecting resistance.

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

4) A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by April 30th each year after the commercialization 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 the Enclosure. If resistance involves any of these three target pests, the registrant must implement this Remedial Action Plan. The registrant must obtain approval from EPA before modifying the Remedial Action Plan for Lepidopteran-Protected Corn.

Annual Reports:

Beginning in the first year after commercialization, the registrant will provide annual reports to EPA on its moCry1F 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
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
Proposed Compliance Plan	Written description of Compliance Assurance Program	January 31 st

Compliance Assurance Plan	Compliance Assurance Program Results	January 31 st
Compliance	To include annual survey results, changes to the education program, and plans for the next year	Preliminary survey report November 15 th of the year of the survey and the full report the following January 31 st
Insect Resistance Monitoring	Results of monitoring and investigations of damage reports	April 30 th

Prior to commercialization of moCry1F corn, the following additional reports are required as described in the following table:

IRM Grower Agreements	Proposed system to assure growers sign grower agreements
IRM Affirmation Plan	System to assure annual affirmation by growers of their IRM obligations
Changes to Grower Agreement and/or IRM documents	Grower agreement(s) and any specific stewardship documents. These are also required at least 30 days before any changes related to IRM are expected to be imposed.
Insect Resistance Monitoring Results	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.

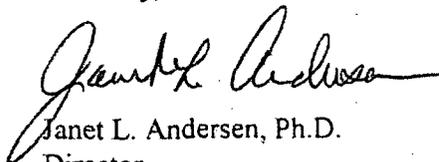
11/17

Submit five (5) copies of the revised final printed labeling before you release the product for shipment.

If these conditions are not complied with, then the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

Should you have any questions regarding submission of the data, please contact Dr. Sharlene Matten at telephone at 703-605-0514 or by e-mail at matten.sharlene@epa.gov.

Sincerely,



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

Enc.

Remedial Action Plan for Responding to Resistance in European Corn Borer
Corn Earworm and/or Southwestern Corn Borer

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 or Cry1F-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 LC₅₀ in a standard Cry1Ab or Cry1F diet bioassay exceeds the upper limit of the 95% confidence interval of the standard unselected laboratory population LC₅₀ 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 and/or Cry1F *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,

14
5/15

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

Mycogen Brand B.t. moCry1F Insect Resistant Corn Seed

This package contains insect resistant corn seed expressing a *B.t.* moCry1F insecticidal crystal protein derived from *Bacillus thuringiensis* var. *aizawai* strain PS811.

Active Ingredient:

Bacillus thuringiensis var. *aizawai* strain PS811 Cry1F insecticidal crystal protein and the genetic material necessary for its production (plasmid insert PHP12537) in Event DAS-06275-8 corn 0.000195 - 0.000957%*

Inert Ingredient:

A substance produced by a marker gene and the genetic material necessary for its production in corn 0.0001 - 0.01080%*

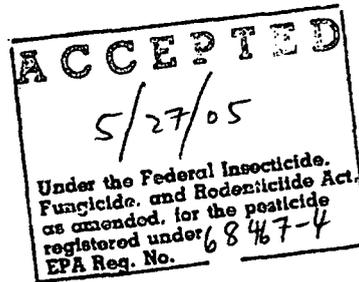
*% total protein on a dry weight basis in plant cells (whole plant).

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

EPA REG. NUMBER: 68467-

EPA ESTABLISHMENT NUMBER: 029964-IA-001.

Mycogen Seeds
c/o Dow AgroSciences LLC
9330 Zionsville Road
Indianapolis IN 46268



16
17**DIRECTIONS FOR USE**

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

Subject registration automatically expires at midnight on October 15, 2008.

The moCry1F insect resistant corn seed should be used as specified in the terms and conditions of the registration.

Corn has been transformed to express *Bacillus thuringiensis* var. *aizawai* strain PS811 moCry1F insecticidal crystal protein (ICP) for control of European corn borer and other lepidopteran pests.

Routine applications of insecticides to control European corn borer are unnecessary when corn expressing the *B.t.a.* moCry1F ICP is planted.

Growers are instructed to read information on insect resistance management. The following information regarding commercial production must be included in the grower guides for cotton and non-cotton growing areas:

Corn-Belt/Non-Cotton Growing Areas:

For Cry1F field corn grown outside cotton-growing areas (e.g., the Corn Belt), growers must adhere to the following refuge requirements.

- Growers must plant a structured refuge of at least 20% non-*Bt* corn and/or non-lepidopteran resistant *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, Southwestern corn borer (SWCB), fall armyworm (FAW), black cutworm (BCW), and western bean cutworm (WBCW) 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). Microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.

Cotton-Growing Area Refuge Requirements for *Bt* Corn

For *Bt* field corn grown in cotton-growing areas:

- Growers must plant a structured refuge of at least 50% non-*Bt* corn and/or non-lepidopteran resistant *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 fields.
- 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, Southwestern corn borer (SWCB), fall armyworm (FAW), black cutworm (BCW), and western bean cutworm (WBCW) 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

17
17

professionals (e.g., Extension Service Agents, crop consultants). 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).

USE PATTERN

CROP	PESTS
Field corn	Black cutworm Corn earworm European corn borer Fall armyworm Southwestern corn borer Western bean cutworm

EPA Accepted: / /

