

***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.(006491) Fact sheet**

I. Description of the Plant-Incorporated Protectant

- **Pesticide 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.

- **EPA Registration Number:** 68467-4

- **Date Registered:** May 27, 2005

- **Trade and Other Names:** Mycogen Brand B.t.Cry1F Event DAS-06275-8 Corn

- **OPP Chemical Code:** 006491

- **Basic Manufacturer:**

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

- **Type of Pesticide:** Plant-Incorporated Protectant Plant-Incorporated Protectant

- **Uses:** Field Corn

- **Target Pest(s):** European corn borer, southwestern corn borer, corn earworm, fall armyworm, black cutworm, western bean cutworm

II. Background

Mycogen Seeds (a Dow Agrosiences company) registered the genetically engineered *Bacillus thuringiensis* (B.t.) Cry1F Event DAS-06275-8 plant-incorporated protectant expressed in corn. The Cry1F Event DAS-06275-8 protein, like the Cry1F Event TC1507 (DAS-01507-1) protein, protects the corn from certain lepidopteran insect larvae: European corn borer (ECB), *Ostrinia nubilalis* (Huebner); southwestern corn borer (SWCB), *Diatraea grandiosella* (Dyar); fall armyworm (FAW), *Spodoptera frugiperda* (J.E. Smith); black cutworm (BCW), *Agrotis ipsilon* (Hufnagel); western bean cutworm (WBCW), *Richia albicosta* (Smith), and corn earworm (CEW), *Helicoverpa zea* (Boddie). The pesticide active ingredient is known as *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. An exemption from the requirement of a tolerance for *Bacillus thuringiensis* Cry1F protein and the genetic material necessary for its production in corn (non-Event specific) was granted on June 6, 2001 and is found at 40 CFR 180.1217.

III. Science Assessment

Product Characterization

The cry1F gene in event DAS-06275-8 codes for the identical truncated Cry1F protein as that expressed by 1507 maize plants. Codon changes were made to the gene to improve expression in 6275 maize plants, but these codon changes do not alter the amino acid sequence of the protein as compared to that expressed in 1507 maize plants. The first 605 amino acids of Cry1F Event DAS-06275-8 protein and Cry1F Event DAS-01507-1 protein are identical with the exception of an altered residue at position 604 (F604L). Because DAS-06275-8 and TC1507 (DAS-01507-1) proteins share an identical amino acid sequence, the protein equivalency, the insect-pest spectrum for TC1507 also support the DAS-06275-8 registration. The analytical method is the same for both 1507 corn and 6275 corn.

Specific DAS-06275-8 product characterization data indicate that plant-produced Cry1F protein is biologically, biochemically, and immunologically similar to that expressed in the source bacterium *B. thuringiensis* after trypsin digest. Southern blot data of restriction enzyme digests suggests that the insert in B.t. Cry1F corn line 6275 occurred as a simple integration of a partial copy of the T-DNA region (truncated at the 5' end) from plasmid PHP12537. One intact of the plant selectable marker gene for phosphinothricin acetyltransferase was confirmed. Southern blot analyses also revealed that tetracycline and spectinomycin resistance genes were not integrated into corn line 6275. Southern hybridization was used to assess the genetic stability of the insert in multiple generations of corn line 6275. Based on the segregation analyses, corn line 6275 exhibited stable Mendelian inheritance of the insert across the generations examined.

Human Health Assessment

Because the Cry1F protein in Event DAS-06275-8 and TC1507 share the same amino acid sequence, the toxicity of the Cry1F protein expressed in and 6275 and 1507 plants is expected to be similar. The toxicity and allergenicity data submitted in support of the TC1507 registration (EPA Reg. No. 029964-3; EPA, 2001) are also adequate to support the registration of 6275 corn.

An LD50 was estimated at >5050 mg / kg body weight of this microbially produced test material. The actual dose administered contained 576 mg Cry1F protein / kg body weight (Toxicity category III based on dose given with no observable effect). At this dose, an LD50 could not be calculated because there was no mortality throughout the 14 day study. Cry1F (maize-optimized) maize seeds contain approximately 0.0011 mg of Cry1F/g of maize kernel tissue. Cry1F (plant-optimized) maize seeds contain approximately 0.0017 to 0.0034 mg of Cry1F/gram of maize kernel tissue.

Data has been submitted which demonstrates that the Cry1F protein is rapidly degraded by gastric fluid in vitro and is non-glycosylated. In a solution of Cry1F:pepsin at a molar ratio of 1:100, complete degradation of Cry1F to amino acids and small peptides occurred in 5 minutes. A heat lability study demonstrated the loss of bioactivity of Cry1F protein to neonate tobacco budworm larvae after 30 minutes at 75°C. Additionally, a comparison of amino acid sequences of known allergens uncovered no evidence of any homology with Cry1F, even at the level of 8 contiguous amino acids residues. There was no identity of 35% or greater over 80 amino acid residues between the Cry1F and any known allergens. A match was identified between the Cry1F protein of Herculex I (poCry1F) corn and the Der p7 protein, an allergenic protein of the dust mite, *D. pteronyssinus* using a 6 contiguous amino acid bioinformatics search. No cross-reactivity between Cry1F protein in Herculex I maize and dust mite Der p7 protein was observed when tested with human sera positive for Der p7-IgE. Dust mite allergic individuals would not be expected to experience an allergic reaction from ingesting Cry1F. In addition, Cry1 proteins have not been implicated in toxic and/or allergenic reactions in humans or animals. Based on the weight-of-the evidence, the potential for the Cry1F protein to be a food allergen is minimal. Given the lack of findings suggesting potential allergenicity and the absence of adverse effects in the acute oral toxicity test, there is no evidence to suggest neither an adverse immune response nor a potential for mammalian toxicity from the Cry1F protein. Based on review of the data, there is a reasonable certainty of no harm to humans and animals posed by the aggregate exposure to residues of this protein.

Environmental Assessment

The 6275 corn environmental risk assessment is based primarily on the bridging of data submitted to the Agency for 1507 corn (EPA Reg. No. 029964-3; EPA, 2001). The cry1F gene encodes for the identical truncated Cry1F protein as expressed by 1507 maize plants. Codon changes were made to the gene to modify expression in 6275 maize plants, but these changes did not alter the amino acid sequence of the protein as compared to that expressed in 1507 maize plants. Therefore, the specificity (i.e., toxicity toward target pests) of the Cry1F protein expressed in 6275 and 1507 plants should be similar.

The environment hazard assessment includes outcrossing and potential for weeds to develop if pollen from (6275 or 1507) Cry1F corn was to fertilize other plants, horizontal gene transfer, expression of (6275 and 1507) Cry1F protein in plant tissues, ecological effects including effects on monarch butterflies, fate of Bt proteins in the environment and effects on endangered species, particularly Lepidoptera. Studies have been submitted which demonstrate no effects under test conditions to representative species of birds (Bobwhite quail), non-target soil organisms (Collembola and Earthworm), honey bees, ladybird beetle, green lacewing, parasitic wasp, the monarch butterfly, aquatic invertebrates (*Daphnia magna*) and non-target insects in corn fields.

Testing with bacterially prepared Cry1F protein at levels greatly exceeding those found in maize optimized plants resulted in no effect with several beneficial species including the monarch butterfly. Although, the expression data reveal that 6275 plants express somewhat lower concentrations of Cry1F protein in pollen and grain and higher levels of Cry1F protein in stalks, leaves, and roots than the 1507 plants, these expression differences are not expected to significantly change the exposure to lepidopteran non-target organisms. The increased expression of Cry1F protein in stalks in moCry1F hybrids could potentially decrease the risk of resistance development by corn borers whilst the decreased expression in pollen and grain should decrease the non-target exposure to Cry1F expressed in corn. In addition, it has been shown that conventional processes used in the commercial preparation of fish food inactivate any Cry1F protein present in corn grain. Cry1F protein in soil has been shown to degrade rapidly to very low levels. Field monitoring for effects of poCry1F corn on non-target insects confirmed the absence of adverse effects to non-target organisms. The EPA has determined that Cry1F protein expressed in corn is not likely to adversely affect listed species.

The EPA has reviewed the potential for gene capture and expression of Cry1F protein by wild or weedy relatives of corn in the United States, its possessions or territories and has found that there is no significant risk in the United States, its possessions or territories (EPA 2001).

Insect Resistance Management

Cry1F corn (event TC1507) was shown to provide a high dose (using two methods, numbers 4 and 5, recommended by the 1998 Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel) against ECB (EPA 2001). A high dose for Cry1F (event DAS-06275-8) was measured using a single approach (SAP method #4). 6275 corn caused greater than 99.99% mortality of ECB in the field. If evaluated independently of other available information, the high dose study would be considered supplemental (upgradeable to acceptable upon submission of verification of high dose by a second EPA approved method). However, the following data provide additional lines of evidence to sufficiently support Cry1F (TC6275) as producing a high dose of protein to control ECB as defined by the SAP: 1) Field efficacy data for Cry1F (TC6275) in comparison to Cry1F (TC1507) show that the performance of Cry1F DAS-06275-8 is statistically equivalent to that of Cry1F TC1507 and that both events are able to resist infestation of multiple lepidopteran pest species. Furthermore, TC1507 was

shown to provide a high dose using two SAP methods (#s 4 &5) against ECB (EPA 2001b). Because TC1507 has been determined to provide a high dose for ECB and DAS-06275-8 has been shown to have field efficacy equivalent to that of TC1507, it is reasonable to assume that DAS-06275-8 also provides a high dose for at least ECB. 2) An analysis of the comparative expression of Cry1F protein in 6275 and 1507 corn at different plant growth stages shows an increased amount (approx. two-fold) of Cry1F protein in 6275 corn stalks at the R1 stage as well as increased Cry1F in leaves, whole plants, and forage in 6275 corn compared to TC1507 corn. Because 6275 corn has greater expression of Cry1F in the lepidopteran target tissues than 1507 and 1507 has been shown to provide high dose for ECB; it should follow that 6275 corn also provides a high dose for ECB. The IRM requirements that were mandated by EPA for TC1507 corn (EPA 2001) are also applicable to 6275 corn (see Section IV. "Terms and Conditions of the Registration").

Benefits

EPA has reviewed the public interest document for 6275 corn and 1507 corn (EPA, 2001). 6275 Cry1F-protected corn will solidify and extend the benefits of insecticide use reduction that have been previously described for plant-optimized Cry1F-protected corn. Just as for 1507 Cry1F-protected corn, 6275 Cry1F-protected corn is comparatively less risky to health or the environment than currently registered pesticides and the expected benefits (including economic benefits) from the use of the new active ingredient are greater than those of alternative registered pesticides and other available non-chemical techniques.

References

U.S. Environmental Protection Agency (EPA) 2001b. Biopesticides Registration Action Document: *Bacillus thuringiensis* (Bt) Plant-incorporated Protectants (October 15, 2001).

IV. Terms and Conditions of the Registration

EPA Registration Number 68467-4

1. The subject registration will automatically expire on midnight October 15, 2008.
2. The subject registration will be limited to the use of *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.

3. Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires registrants of similar products to submit such data.
4. Submit production information for this product to Mr. Owen Beeder of Office of Pesticide Programs, Registration Division (mail code 7505C) for the fiscal year in which this product is conditionally registered, in accordance with FIFRA § 29. The fiscal year begins October 1 and ends September 30. Production information will be submitted to the Agency no later than December 15, following the end of the preceding fiscal year.
5. The protocol for the Independent Lab Validation of analytical method GRM?02.13 "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 Harmonized Test 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:

9. 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;
10. 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;
11. Requirements for the registrant to develop, implement, and report to EPA on programs to educate growers about IRM requirements;
12. Requirements for the registrant to develop, implement, and report to EPA on programs to evaluate and promote growers' compliance with IRM requirements;
13. 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;
14. 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;
15. 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.

- 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 Atips 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 31st

Grower Agreement Number of units of Bt corn seeds shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements January 31st

Proposed Compliance Plan Written description of Compliance Assurance Program January 31s

Compliance Assurance Plan Compliance Assurance Program Results January 31st

Compliance To include annual survey results, changes to the education program, and plans for the next year Preliminary survey report

November 15th of the year of the survey and the full report the following January 31st Insect Resistance Monitoring Results of monitoring and investigations of damage reports April 30th

Prior to commercialization of moCry1F corn, 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.

V. Additional Contact Information

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