

# Complacency on the Farm

Significant Noncompliance with  
EPA's Refuge Requirements  
Threatens the Future Effectiveness of  
Genetically Engineered Pest-protected Corn



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# Contents

Executive Summary .....	iv
Introduction .....	1
Background on EPA’s Regulation of Bt Corn .....	2
Data on Grower Compliance with .....	4
IRM Refuge Obligations from Registrants’ Reports to EPA	
Corn Borer-Protected Bt Corn Compliance .....	5
Corn Rootworm-Protected .....	6
Bt Corn Compliance	
Stacked Bt Corn Compliance .....	7
“Significant Deviations” from .....	8
Compliance from On-Farm Assessments	
Analysis and Conclusions.....	9
Recommendations .....	13
Appendix: Explanation of Calculation .....	18
of Total Non-compliant Bt Corn Acreage in 2005 and 2008	

## Executive Summary

Last year, millions of acres of genetically engineered corn were planted in the U.S. The farmers who planted those corn varieties were required to comply with government-imposed conditions put in place to protect the longevity of the technology and prevent adverse impacts on the environment.

The Center for Science in the Public Interest obtained through a Freedom of Information Request the annual Compliance Assurance Program reports (CAP Report) that are submitted to the Environmental Protection Agency (EPA) by the registrants of the various *Bt* corn products. Those reports provide data on compliance with the IRM refuge requirements by *Bt* corn farmers and can be used to analyze trends in compliance over time. Those reports found farmer compliance above 90% from 2003 to 2005. Starting in 2006, however, compliance rates declined demonstrably so that by 2008 (the last year for reported data), approximately 25% of *Bt* corn farmers did not comply with their IRM obligations. Instead of more farmers meeting the requirements over time, the data finds significant decreases in compliance to unacceptable levels.

In addition, using the compliance data and information about *Bt* corn adoption from USDA, it was determined that the total corn acreage out of compliance climbed from 2.29 million acres (3% of both biotech and conventional corn acres) to 13.23 million acres (almost 15% of all corn acres). This six-fold increase is due to the increase in farmer noncompliance and the increase in adoption of *Bt* varieties by farmers (from 35% in 2005 to 57% in 2008). Whereas non-compliant *Bt* farmers could rely in the past on their non-*Bt* neighbors' fields to supply pests without resistance to mate with any resistant pests that survived the *Bt* corn, that situation may not exist now or in the future for some areas of our country.

If EPA believes that protecting insect susceptibility to *Bt* is a "public good" and that all farmers must comply with refuge requirements to delay resistance to *Bt*, then the CAP Report data should be a wake-up call to EPA that the regulatory system is not working. EPA must change the obligations it imposes on the registrants to ensure greater compliance. In particular, EPA should not re-register existing *Bt* corn varieties until the registrants demonstrate higher compliance levels. In addition, if EPA does re-register *Bt* corn products, it should require the registrants to provide farmer incentives to meet their obligations and penalties for farmers found to be noncompliant. EPA should require the registrants to obtain annual certification from farmers and pay for independent third-party assessments of compliance. In addition, EPA must make registrants accountable for farmer noncompliance; if noncompliance is high, then EPA should impose monetary penalties and/or restrict seed sales by the registrant and its' wholly owned subsidiaries. Finally, EPA should promulgate a rule requiring labels on *Bt* seed bags specifying the IRM requirements.

## Introduction

In 1996, the Environmental Protection Agency (EPA) approved the first corn seed variety engineered with a gene from a *Bacillus thuringiensis* (*Bt*) bacterium as a safe pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Then from 1996 to 2008, EPA registered as pesticides approximately a dozen different corn varieties with *Bt* genes that provide corn-borer protection, corn-rootworm protection or both (called “stacked” gene varieties). All of those product registrations expire on September 30, 2010.

In its approval process, EPA imposed several conditions on growing *Bt* corn, including insect resistance management (IRM) requirements that would delay the development of resistance in the target pests. Those IRM requirements require that farmers plant non-*Bt* varieties in certain locations on their farms that would act as a “refuge” to increase the likelihood that any resistant pests that survive the *Bt* corn’s engineered pesticide would mate with susceptible pests. EPA also required that the registrants of the *Bt* corn varieties (a) establish grower agreements requiring compliance with the IRM obligations, (b) educate farmers about those obligations, and (c) report to EPA their compliance activities in annual Compliance Assurance Program (CAP) reports. Delaying resistance is important because it protects the benefits of *Bt* corn for future biotech farmers as well as farmers who use microbial insecticides with *Bt* bacterium.

As new *Bt* corn products have been developed, American (and many other) farmers have embraced them and the percentage of corn with *Bt* traits has increased tremendously. For example, in 2002, 24% of corn acreage was planted with a variety that contained a *Bt* gene. In 2008, the percentage was 57%, which translates into approximately 49 million acres of corn with at least one *Bt* gene that year.

This report uses data from the Industry CAP Reports from 2005 to 2008 to determine the rates at which *Bt* corn farmers are complying with their IRM obligations.<sup>1</sup> That data and its analysis should be important to policymakers who are entrusted to safeguard the environment and agricultural interests. Those policymakers will determine if those *Bt* corn products should remain on the market after the 2010 growing season. It is also critical information for EPA as it decides whether to register new stacked *Bt* corn varieties with different IRM requirements and compliance programs.

1. CSPI issued two previous reports on *Bt* corn farmer compliance with IRM obligations in 2003 based on data from the National Agricultural Statistics Service. Those reports can be found at [www.cspinet.org/biotech/reports.html](http://www.cspinet.org/biotech/reports.html).

## Background on EPA's Regulation of *Bt* Corn

On October 15, 2001, EPA re-registered four *Bt* corn varieties containing the Cry1Ab or Cry1F genes. Those corn varieties are engineered to protect the corn from corn-borer pests. Between 2003 and 2008, EPA registered five *Bt* corn varieties containing Cry3Bb1, Cry34Ab1/Cry35Ab1, or Cry 3A genes to protect the corn from rootworm

pests. In addition, EPA registered five “stacked” *Bt* corn varieties that contain one or more of the approved *Bt* genes, protecting the corn from both corn-borer and corn-rootworm pests. The registrations of all of the *Bt* corn varieties registered between 2001 and 2008 are set to expire on September 30, 2010.

In registering each engineered corn with one or more *Bt* genes, EPA determined that those products would not “significantly increase the risk of unreasonable adverse effects on the environment” nor “pose risks to human health or to non-target species.” EPA did conclude, however, that *Bt* corn raised “concerns with respect to insect resistance management” and specifically restricted

the manner in which those products could be grown to “adequately mitigate” insect resistance.<sup>2</sup>

IRM is used to describe practices that reduce the potential for insect pests to become resistant to a pesticide. According to EPA, “sound IRM will prolong the life of *Bt* pesticides and adherence to the plans is to the advantage of growers, producers, researchers and the American public.” (EPA Registration Action Document, Oct. 15, 2001, p. IID2). EPA’s rationale for its IRM requirements for *Bt* corn is summarized as follows:

*Bt* IRM is of great importance because of the threat insect resistance poses to the future use of *Bt* plant-pesticides and *Bt* technology as a whole. **EPA considers protection of insect (pest) susceptibility of *Bt* to be in the “public good.”** EPA has determined that development of resistant insects would constitute an adverse environmental effect. In order to delay the development of insect resistance of *Bt*

2. There are important environmental and human health reasons for delaying insect resistance. First, *Bt* crops act as alternatives to broad-spectrum insecticides or to prevent yield loss. Those broad spectrum insecticides can harm both the environment and farm workers. Thus, if *Bt* corn becomes ineffective against corn pests, some farmers may need to turn back to more harmful insecticides or risk a yield loss. Second, microbial *Bt* insecticides are currently used by farmers throughout the US, including organic producers. Resistance to *Bt* corn might also result in resistance to those microbial sprays, limiting their effectiveness as a relatively environmentally benign insecticide that controls crop pests.



Healthy European Corn Borer

field corn by maintaining insect susceptibility, growers “**must choose at least one of [the] structured refuge** (a portion of the total acreage using non-*Bt* seed) options . . .” (Emphasis added). (EPA Registration Action Document, Oct. 15, 2001, p. VI2).

To ensure insect susceptibility and to protect the environment, EPA determined that farmers growing *Bt* corn-borer protected varieties needed to: (a) plant a 20% non-*Bt* corn refuge in the Corn-Belt states,<sup>3</sup> and (b) plant their refuge in a block within the *Bt* field or external to the field but within one-half mile of the *Bt* corn. EPA found that those requirements are “scientifically-sound, protective, feasible, sustainable, and practical to growers.” (EPA Registration Document, Oct. 15, 2002, p. VI5).

For engineered varieties of corn rootworm-protected *Bt* corn, EPA determined that farmers needed to: (a) plant a 20% non-*Bt* corn refuge; and (b) plant their refuge as a block or strips adjacent or within the *Bt* corn field. For stacked varieties containing corn-rootworm and corn-borer products, the IRM requirements are a 20% refuge (50% in cotton-growing regions) that is either adjacent to or within the field if the refuge is for both products or within a half mile if the refuge is only for the corn borer product. For all the *Bt* corn products, if any one condition is not adhered to, the farmer is considered noncompliant.

To implement EPA’s IRM refuge requirements, the registrants enter into a contractual agreement with every farmer who buys *Bt* corn that obligates the farmer to plant the appropriate refuge.

EPA also requires the registrants, among other things, to educate growers about their IRM refuge obligations, to survey growers to determine rates of compliance with refuge requirements, and to establish a compliance assurance program (CAP) to identify and address noncompliant farmers. EPA requires that some farmers who significantly violate the IRM refuge requirements two years in a row not be allowed to purchase *Bt* seeds the following year.

Recently, EPA has approved new *Bt* corn products with reduced refuge requirements. On July 29, 2009, EPA registered a stacked *Bt* product called SmartStax from Monsanto and Mycogen Seeds containing two *Bt* toxins active against corn-rootworm pests and three *Bt* toxins to control different corn-borer pests. EPA approved SmartStax,



Corn Rootworm Larva

3. EPA’s requirements included a 50% refuge for corn-borer protected varieties grown in areas where *Bt* cotton is also grown, as well as for stacked *Bt* corn varieties with a *Bt* gene that impacts corn borers.

with complex IRM requirements allowing for either a 20% or 5% refuge, depending on the geographic location and the target pest's significance in that geographic location. EPA also acknowledged in that registration document that IRM compliance is "an area of ongoing concern" as data shows falling compliance rates in recent years. With the reduced refuge acreage, it will be critical that farmer comply completely with their IRM obligations.<sup>4</sup>

## **Data on Grower Compliance with IRM Refuge Obligations from Registrants' Reports to EPA**

As part of the EPA registration, the registrants are required to submit data on the compliance rates of farmers with refuge requirements and actions taken to bring noncompliant farmers back into compliance. The registrants—Dow AgroSciences, LLC, Monsanto Company, Pioneer Hi-Bred International, Inc., and Syngenta Seeds, Inc.—together submit one report annually entitled "Insect Resistance Management Compliance Assurance Program Report for Corn Borer-Protected *Bt* corn, Corn Rootworm-Protected *Bt* corn and Corn Borer/Corn Rootworm-Protected Stacked *Bt* Corn" (hereinafter referred to as the "Industry CAP Report"). Those annual reports for 2005–2008 were obtained from EPA through a request under the Freedom of Information Act. The compliance rate data set forth in this report were all obtained from those four reports.<sup>5</sup>

The Industry CAP Reports provide two types of data assessing farmers' compliance with refuge requirements. First, since 2000, the registrants have commissioned third-party, anonymous grower surveys. Those surveys have assessed *Bt* corn-borer compliance since 2000 and for compliance by growers of corn-rootworm and corn-borer/corn-rootworm stacked *Bt* corn since 2006. The compliance data was collected using a telephone survey from 2000 through 2006,<sup>6</sup> but in 2007, "due to the increasing complexity of growers' *Bt* corn planting practices and a need to standardize the grower survey across insect-protected traits," the industry utilized an Internet-based survey approach. Additional, but limited, information on the industry's third-party grower

4. EPA is also deciding whether it will register a stacked *Bt* gene product from Pioneer Hi-Bred International, where the company has proposed a seed mix refuge of greater than or equal to 2% of the seeds in the bag. An EPA Science Advisory Panel concluded in May, 2009 that such an IRM plan was not scientifically justified but did support a 20% "seed in a bag" refuge (which eliminates the need for a separately planted refuge within or near the *Bt* corn field – the distance requirement of the IRM obligation).

5. Some Industry CAP Reports summarize compliance data from previous years. Therefore, the data for years 2003 and 2004 is not from the Industry CAP Reports for those years but from information in the Industry CAP Reports for 2005 and/or 2006.

6. There are numerous problems with the accuracy of telephone surveys. As stated by EPA and EPA's Science Advisory Panel, there may be numerous "false positives" in a telephone survey where farmers may be encouraged to misrepresent their actions or "cheat" in their responses. (EPA Reassessment Report at IID 10-11). Thus, the telephone surveys may exaggerate compliance rates. However, this methodology was accepted by EPA as the method to estimate farmer compliance nationwide. Therefore, it is appropriate to use the results for this analysis of farmer compliance with IRM requirements. In any case, we assume that levels of farmers' understanding of the requirements and honesty are constant.

survey methodology can be found in each Industry CAP report.<sup>7</sup>

The second method used by the registrants for assessing farmer compliance with refuge requirements is through on-farm IRM assessments conducted by their agents (employees of the registrants, seed dealers who sell their seed, etc.). To obtain this compliance data, growers are selected from individual company customer lists and company representatives visit those farms to assess compliance. The criteria used by the companies to decide which farms to assess (the sampling size and scheme) are not made public. The representatives of the different companies receive similar training on how to conduct such assessments and use similar forms and questions to assess compliance. Additional information (although limited) about the on-farm IRM assessment methodology can be found in each Industry CAP Report.<sup>8</sup>

### Corn Borer-Protected *Bt* Corn Compliance

Farmers have been growing corn borer-protected *Bt* corn since the late 1990s and should be quite familiar with their IRM refuge obligations. The 2005 Industry CAP Report found through its telephone survey of 552 *Bt* Corn growers that 92% of them adhered to the refuge size requirements and 96% adhered to the distance requirement. Those results were similar to the telephone survey results in 2003 (92% for size, 93% for distance) and 2004 (91% for size and 96% for distance). In the 2006 telephone survey of 555 growers, the 2006 Industry CAP Report found 89% compliance with the size requirement and 96% compliance with the distance requirement.

To assess compliance in 2007 and 2008, the industry used an Internet-based survey and reported to EPA the following data:

- In 2007, 467 growers completed the Internet-based survey and only 80% of those growers met the size requirement. For the distance requirement, only 447 of the 467 growers surveyed recalled the layout of their corn-borer protected fields and of those 447 growers, 88% met the distance requirement.
- For 2008, 317 growers completed the Internet-based survey, of which 78% met the size requirement. Only 298 of the 317 growers recalled the layout of their corn-borer protected *Bt* corn field and 88% met the distance requirement.

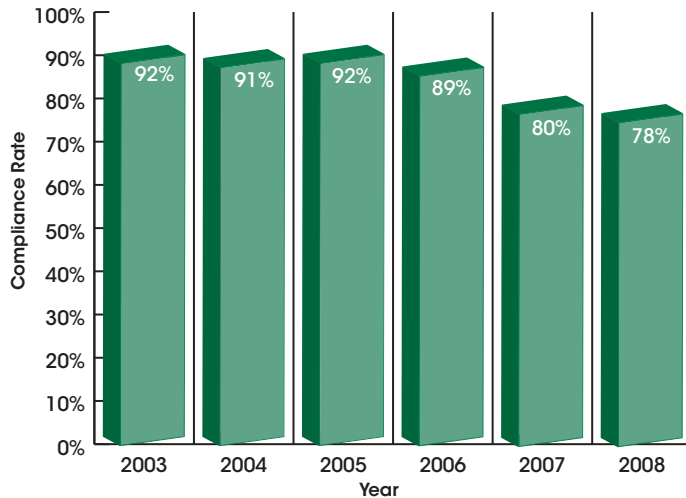
7. The telephone/Internet survey results arguably overstate compliance rates because they separate the size and distance obligations. Other surveys have found that in many instances noncompliant *Bt* growers fail to comply with either of the requirements, but not both. (Goldberger, Merrill and Hurley, 2005). As a violation of either requirement makes a farmer noncompliant, using the compliance rates with the size or distance requirements independently provides a conservative estimate of noncompliance.

8. This method of assessing compliance also has some inherent problems. In this case, representatives of the registrants are assessing compliance of their customers. They do not wish to lose their customers and will probably give them any benefit of the doubt when assessing compliance. CSPI has in the past and continues to argue in this report that only on-farm assessments conducted by independent third-party can truly measure compliance with IRM requirements. Also, while the telephone/Internet survey is meant to be a representative sample of *Bt* farmers nationwide, the on-farm assessments are not done by the companies in a manner that is random, representative, or statistically significant.

## Complacency on the Farm

Figures 1 and 2 illustrate farmers' compliance rates from 2003 to 2008.

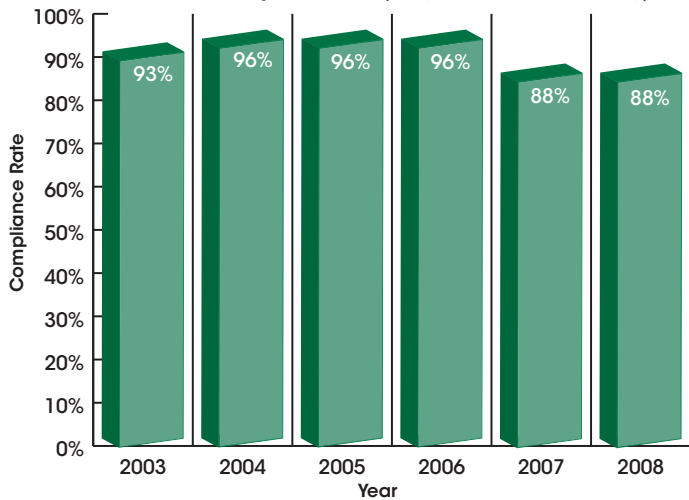
**Figure 1: Corn Borer-Protected *Bt* Corn Farmer Compliance with Size Requirement** (Telephone/Internet Survey)



The registrants also conducted **on-farm assessment** of compliance by farmers for corn borer-protected *Bt* (see Figure 3).

- In 2004, the registrants conducted 2,130 on-farm assessments and found 95% compliance (farmers who met both the size and distance requirements).
- In 2005, the registrants conducted 2,215 assessments, finding 94% compliance.
- In 2006, 2,020 assessments found 96% compliance.
- In 2007, 2,083 assessments found 91% compliance.
- In 2008, 1,312 assessments found 86% compliance.

**Figure 2: Corn Borer-Protected *Bt* Corn Farmer Compliance with Distance Requirement** (Telephone/Internet Survey)

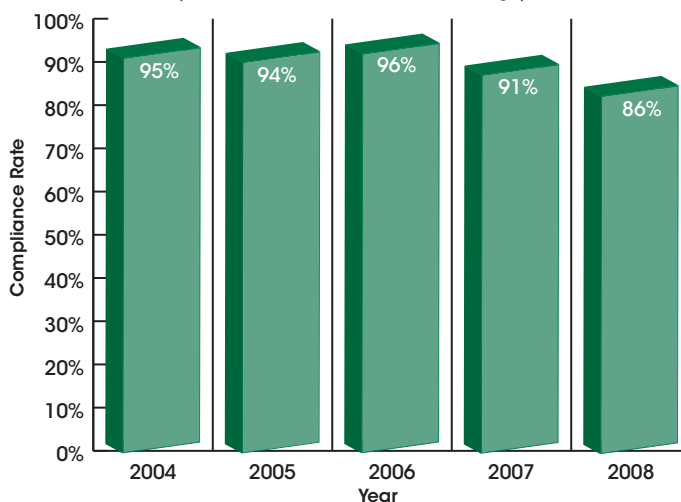


## Corn Rootworm-Protected *Bt* Corn Compliance

The registrants' first report on compliance for corn rootworm-protected *Bt* corn was for the 2006 growing season. That report was based on a **telephone** survey; the next two reports were **Internet based**.

- In 2006, the survey of 300 growers of corn rootworm-protected *Bt* corn found that 89% met the size requirement and 82% met the distance requirement.
- In 2007, 132 growers completed the Internet survey, and 80% met the size requirement and 79% met the distance requirement.<sup>9</sup>
- In 2008, 103 growers completed the Internet survey, and 74% met the size requirement and 63% met the distance requirement.

**Figure 3: Corn Borer-Protected *Bt* Corn, Grower Compliance** (On-Farm Assessment Methodology)



9. The sample sizes for the internet based survey for corn rootworm-protected *Bt* corn are small in 2007 and 2008. The Industry CAP reports do not explain why there is such a small sample size nor whether that impacts the compliance rate data they are submitting to EPA. There is no discussion in the Industry CAP reports that such a small sample size makes the data unreliable. Thus, it is included in this report.

The survey results from the 2006-2008 Industry CAP Reports can be found in Figure 4 and Figure 5.

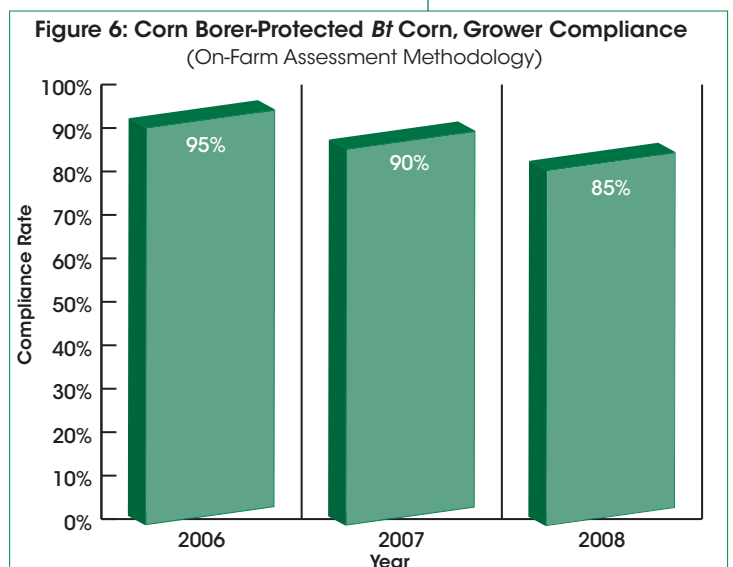
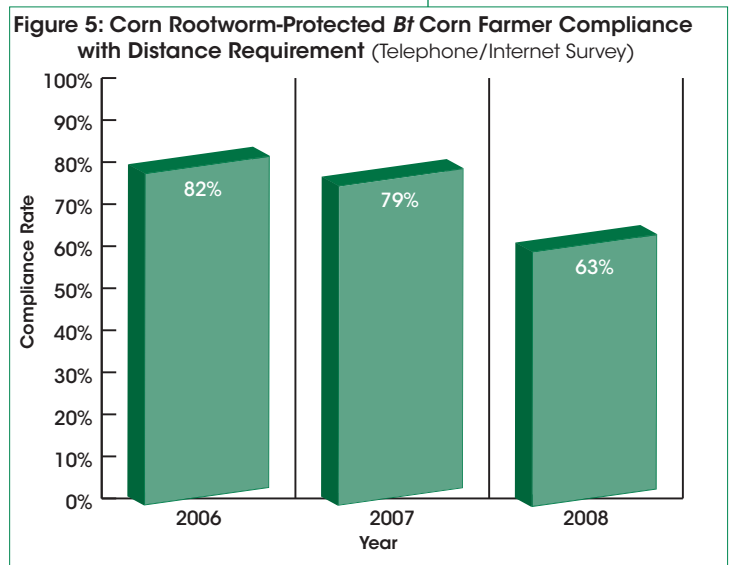
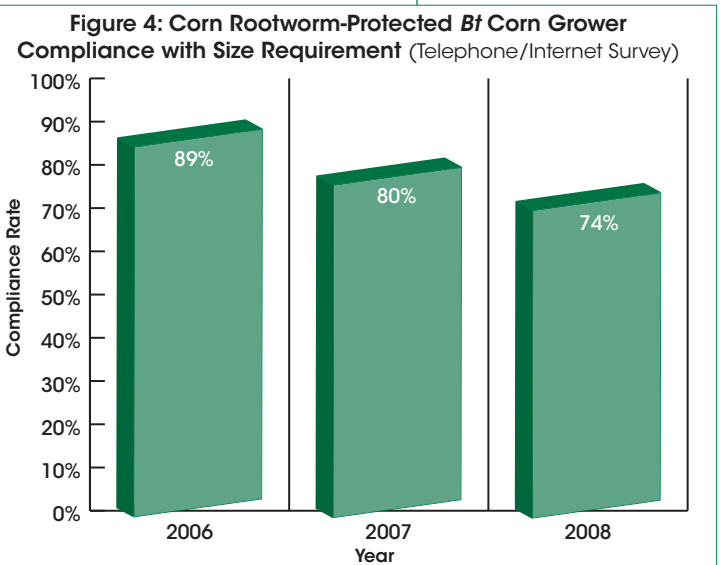
Similar to the on-farm assessments for corn borer-protected *Bt* corn, the on-farm assessment for corn rootworm-protected *Bt* corn farmers found higher compliance rates than reported in the telephone/Internet survey (see Figure 6).

- For 2006, on-farm assessment of 395 growers found 95% compliance.
- In 2007, on farm assessment of 247 growers found 90% compliance.
- In 2008, on-farm assessment of 134 growers found 85% compliance.

### Stacked *Bt* Corn Compliance

The Industry CAP Reports from 2006 through 2008 report compliance rates for farmers who grew *Bt* corn that was protected from both corn borers and corn rootworm (see Figures 7 and 8). The initial survey was **telephone** based; the subsequent surveys were **Internet** based.

- In 2006, the industry telephone survey of 301 farmers found 78% compliance with the size requirement and 92% compliance with the distance requirement.
- In 2007, the industry Internet survey of 456 growers found 70% met the size requirement and 66% of those who remembered the layout of their fields (449/456) met the distance requirement.
- In 2008, the industry Internet survey of 556 growers found that 72% met the size requirement and of the growers who recalled the layout of their fields (543/556), 66% adhered to the distance requirement.



## Complacency on the Farm

The Industry CAP Reports also assessed stacked *Bt* corn farmers using **on-farm** assess-

ments. In 2006, the industry assessed 600 farmers in this category and found 90% compliance. In 2007, they assessed 1069 farmers and again found 90% compliance. Finally, in 2008, they assessed 1546 farmers and found 86% compliance. The results are presented in Figure 9.

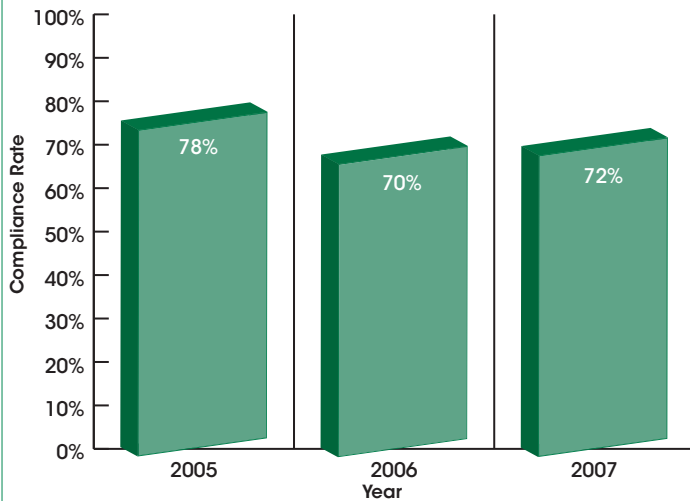
### “Significant Deviations” from Compliance from On-Farm Assessments

When conducting on-farm assessments to determine IRM compliance, company representatives characterize whether the noncompliant farm’s deviation is “significant.” While the definition of what is “significant” has not been made public,<sup>10</sup> those deviations clearly are not minor and trigger specific follow up actions from the companies, including revocation of access to *Bt* seed if compliance is not restored the next year.

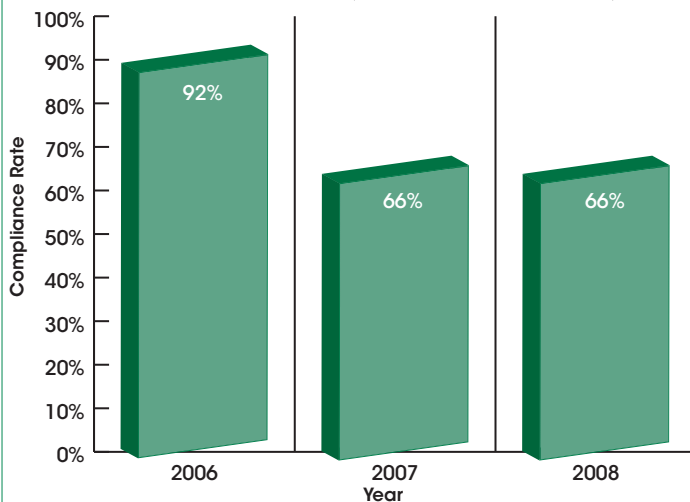
In the Industry CAP Reports, the on-farm assessments from 2003 to 2008 identify both the number of noncompliant farms and whether those farms’ noncompliance is “significant.” Table 1 shows the number of noncompliant growers for 2003 to 2008 and the percentages that are significant deviations, which range from 40% to 74% of total noncompliant farmers in a given year. The data from 2003 through 2005 is only for corn-borer protected *Bt* corn, while the data for 2006 through 2008 is separated into the three product categories: corn borer-protected *Bt* corn; corn rootworm-protected *Bt* corn, and stacked *Bt* corn.

The registrants are also required to conduct follow-up compliance visits for all farms found in non-compliance the previous year. The results of those on-farm assessments are set forth in the Industry CAP Reports, as well as information about whether any registrant revoked *Bt* seed-purchasing privileges

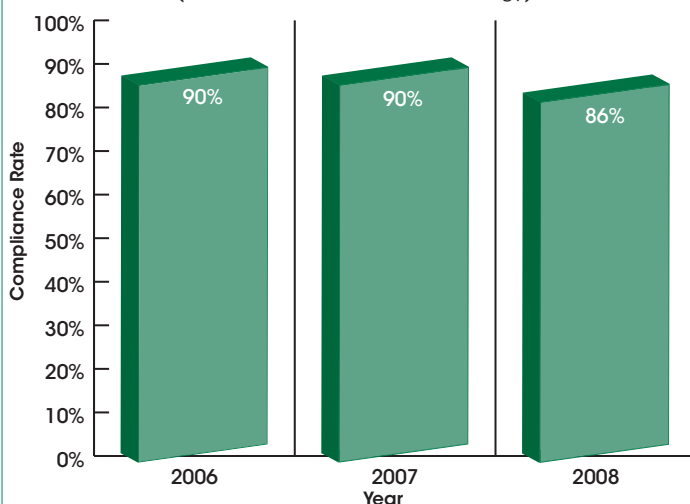
**Figure 7: Stacked *Bt* Corn, Grower Compliance with Size Requirement** (Telephone/Internet Survey)



**Figure 8: Stacked *Bt* Corn, Grower Compliance with Distance Requirement** (Telephone/Internet Survey)



**Figure 9: Stacked *Bt* Corn, (On-Farm Assessment Methodology)**



10. The industry claims that the definition needs to remain confidential so noncompliant farmers do not violate the IRM requirements but not enough to trigger the actions that follow if the violation is “significant.”

Year	<i>Bt</i> Corn Variety	Number of Noncompliant Growers	Number with "Significant Deviations"	Percent with Significant Deviations
2003	Corn Borer	172	104	60%
2004	Corn Borer	98	39	40%
2005	Corn Borer	126	75	60%
2006	Corn Borer	90	45	50%
2006	Corn Rootworm	21	11	52%
2006	Stacked	61	45	74%
2007	Corn Borer	188	129	69%
2007	Corn Rootworm	24	16	67%
2007	Stacked	110	77	70%
2008	Corn Borer	180	134	74%
2008	Corn Rootworm	19	12	63%
2008	Stacked	253	185	73%
Totals		1342	872	65%

Table 1: Data on "Significant Deviations" from On-Farm Assessments, 2003- 2008<sup>11</sup>

from any farmer with "significant" deviations two years in a row. In the Industry CAP Reports from 2003 to 2007, there were 541 significant violations and only three revocations reported in 2006. The registrants reported that all other first-time significant deviators corrected their deviations the following year.

## Analysis and Conclusions

Based on the data provided by the registrants (rather than assessments by independent third parties) in their Industry CAP Reports, the following analysis and conclusions can be made about *Bt* corn farmer compliance with EPA's refuge requirements.

1. Based on the industry telephone/Internet survey, grower compliance with EPA refuge requirements has dropped significantly in the past four years, from acceptable compliance levels (above 90%) to unacceptable levels ranging from 66% to 78%. in 2008. Thus, approximately one out of every four *Bt* corn farmers was out of compliance with at least one major IRM requirement.

Farmers began growing *Bt* corn in the 1990s and by 2003, the data from the registrants suggested that farmers understood the IRM requirements and were complying with those obligations. From 2003 to 2005, farmer compliance with the size requirement averaged approximately 92% and compliance with the distance requirement

11. The number of significant deviations for the stacked *Bt* varieties in the 2008 Industry CAP Report was reported incorrectly. Nick Storer, the Chairman of the Agricultural Biotechnology Stewardship Technical Committee provided the correct number in a telephone call in August, 2009.

averaged approximately 95%. During those years, the industry survey covered only *Bt* corn varieties designed to address corn borer pests.

Beginning in 2006, *Bt* corn varieties with corn-rootworm protection and stacked varieties were included in the industry survey on *Bt* corn farmer compliance with IRM requirements and **compliance rates on all *Bt* varieties decreased**. For farmers growing rootworm-protected *Bt* corn, in 2006 compliance rates on the size requirement were 89% but then dropped to 74% in 2008. Similarly, the compliance rates for the refuge distance requirement were found to be 82% in 2006 but dropped to 63% in 2008.

The surveying results for farmers growing the stacked *Bt* product, with its complicated refuge requirements, also found decreasing compliance rates. For the size requirements, the initial survey in 2006 found compliance at 78% which then dropped in 2008 to 72%. For the distance requirement, while the survey reported a 92% compliance rate in 2006, the next two years had rates of only 66%. Finally, even the corn borer-protected *Bt* corn, which had high compliance rates in 2004-2006 (90+ %), also had its compliance rates drop from 92% in 2005 to 79% in 2008 for the size requirement and from 96% in 2005 to 88% in 2008 for the distance requirement. Therefore, compliance with both size and distance requirements decreased significantly in 2006-2008 for every category reported (the three different types of *Bt* products and the two IRM requirements). By 2008, for the three different *Bt* corn varieties, **approximately 25% of *Bt* corn growers were out of compliance with at least one requirement**, clearly an unacceptable number.

The lower rates in 2007 and 2008 correspond with the survey methodology changing from a telephone survey to an Internet survey. In the Industry CAP Report of 2007, the industry addressed whether the methodology change accounted for the decrease in compliance. The registrants found the Internet survey to be “an accurate and reliable tool to measure adherence with the refuge requirements.” They found that “results observed from those growers who only planted corn-borer protected *Bt* corn suggests that the Internet survey does not add significant bias to the data, however, it cannot be ruled out that changes in the survey methodology have accounted for some of the differences in the 2007 results as compared to past years.” Therefore, the registrants don’t attribute the majority of the decrease in compliance to the methodology change to an Internet survey and EPA accepted the survey results and the registrants’ explanation. Thus, the trends documented by the survey are a reflection of compliance, not caused by the survey methodology.

The Industry CAP Reports for 2007 and 2008 do acknowledge the decline in adherence to refuge requirements. Those reports do not identify a specific reason for the decline but state that many factors may be at work. The 2007 report identifies as one possible reason that farmers might have made last-minute planting decisions that

caused them to miss by a small amount planting the proper refuge.<sup>12</sup> It also acknowledges that overall compliance levels “appear to be related to the use of corn rootworm traits, and especially stacked *Bt* corn,” which have different distance requirements and can cause confusion. Finally, it suggests that farms planting multiple *Bt* corn products may be counted as two noncompliant farms when they may actually meet the requirements for at least one of the products. None of those explanations, however, negates the fact that compliance has decreased significantly and that the EPA requirements set minimum standards that must be met by all farmers for each *Bt* product being grown.

**2. The on-farm assessments, which have consistently shown higher levels of compliance than the telephone/Internet surveys, illustrate the same compliance trend — significant compliance decreases between 2005 and 2008.**

The on-farm assessments show significantly higher levels of compliance than the telephone/Internet survey results, and the industry report makes no attempt to explain the different results. However, the compliance rate trends are almost identical: Compliance rates reached a plateau in the years 2004 through 2006 with compliance at 90% or better and dropped from 2006 to 2008 (in some cases by as much as 10%) to hover around 85% for the three different products. **Therefore, even the on-farm assessments, with a larger but not random sample of farms, shows the same downward trend in compliance rates.** The current rate of 85% compliance should not be acceptable to EPA, the public, and industry. As noncompliance increases the likelihood that resistant pests will emerge also increases.

**3. Approximately one-seventh (15%, or 13 million acres) of the total corn (both biotech and conventional) crop in the United States was non-compliant with EPA’s IRM requirements in 2008. That was an almost six-fold increase in total non-compliant corn acreage in just four years.**

Using the industry telephone/Internet survey data and data from the National Agricultural Statistics Service (NASS), one can calculate an estimate of the number total number of noncompliant acres in the United States and determine how that acreage number has changed between 2005 and 2008. Those calculations, set forth in Appendix A, find that there were 2.29 million acres of noncompliant corn in 2005 and 13.23 million acres in 2008, a **six-fold increase** in just four years. Therefore, in 2008 **approximately one in every seven acres of corn (both biotech and conventional) was in violation of EPA’s requirements.**<sup>13</sup> 13 million acres of noncompliant corn is

12. This explanation is not supported by the results of the on-farm assessments by the registrants. For the farms found to be noncompliant, between 50-70% of them are “significant” deviations. Those deviations involve more than missing the refuge by a small amount.

13. While the on-farm assessments do not paint as bad a compliance picture as the Internet survey, that data still shows a significant decrease in compliance for each *Bt* category from 90–95% to 85%. If the calculations were done with these numbers, one would still see a many-fold increase in noncompliant acres.

equivalent to the whole corn crop of Iowa, which grew more corn in 2008 than any other State, 13.3 million acres.

There are two primary reasons for this huge increase in non-compliance corn acreage: (1) the significant decrease in compliance over the past four years (a 19 % decrease from 92% to 73%) so that more than 25% of all *Bt* corn farms are now in noncompliance, and (2) the great increase in the planting of *Bt* corn by farmers (from 35% of all corn acres in 2005 to 57% of all corn acres in 2008).

While the trend toward increasing adoption of *Bt* varieties proves that farmers find those products beneficial, it also impacts how effective EPA's IRM strategy may be at delaying the onset of resistant pests. When adoption of *Bt* varieties was 35% in 2005, the majority of corn farmers grew non-*Bt* corn and their farms provided a natural refuge for neighbors growing *Bt* corn. In 2008, however, 57% of all corn acres were *Bt* corn with some states reaching levels as high as 69% (Iowa). In addition, some local areas have reached levels where 80% of the fields are *Bt* corn. Under those circumstances, the number of non-*Bt* farmers whose fields can act as "natural refuge" for neighbors who are non-compliant *Bt* farmers is significantly less and approaching zero.<sup>14</sup> Therefore, it is the combination of lower compliance rates and increasing adoption rates that makes the current compliance levels unacceptable. If both those trends continue, then as much as one-third of all corn acreage could be noncompliant in a few years, increasing the likelihood that resistance could evolve and spread rapidly.

#### **4. The compliance rates for the two requirements – size and distance – are similar from 2005 to 2008.**

Although it might be expected that compliance rates for the two different IRM obligations – the 20% size and the location of the refuge – might differ, the industry data does not support a conclusion that one obligation is more difficult to achieve than the other. In 2005 and 2006, compliance rates were higher for both obligations and then decreased significantly in 2007 and 2008.

- The size requirements results for 2006 were 89% for corn-borer *Bt* corn, 89% for corn-rootworm *Bt* corn, and 78% for stacked *Bt* corn. In 2008, the results were 78% for corn-borer *Bt* corn, 74% for corn-rootworm *Bt* corn, and 72% for stacked *Bt* corn.
- The distance requirement results for 2006 were 96% for corn-borer *Bt* corn, 82% for corn-rootworm *Bt* corn, and 92% stacked *Bt* corn. In 2008, they dropped to 88% for corn-borer *Bt* corn, 63% for corn-rootworm *Bt* corn, and 66% stacked *Bt* corn.

14. If 80% of all fields are *Bt* corn, then the area has reached a saturation point where there are no non-*Bt* farmers.

The only discernible trend is that compliance with both IRM requirements has decreased in the past several years.

- 5. The majority of the violations found during on-farm assessments fall within the definition of “significant deviations.” This trend has been consistent over time.**

Other than one year (2004) for one product (corn borer-protected *Bt* corn) when “significant deviations” accounted for only 40% of all on-farm assessments of noncompliance, all other data presented by the industry showed rates of significant deviations of between 50% and 74% for different *Bt* products in the years 2005-2008. Thus, a clear majority of deviations (that is, noncompliance on farms with IRM obligations) found in on-farm assessments fall within the industry’s definition of “significant.” That reinforces the view that if a farm is not in compliance, it is not likely due to a technicality or minor infraction but instead the farmer has seriously missed achieving compliance. **There is no trend in the percentage of significant deviations increasing or decreasing within that time period.**<sup>15</sup>

- 6. The levels of noncompliance will increase the likelihood of developing resistant strains of pests.**

EPA found in 2001 that if refuge options were deployed correctly, “there is a limited chance of insect resistance evolving over the next seven years of the registration of these products.” (EPA Registration Action Document, Oct. 15, 2001, p. V16). The data from the Industry CAP Reports, however, report noncompliance rates that now have reached 25% of all *Bt* corn farmers. Clearly that level of noncompliance cannot be what EPA anticipated and could speed the likelihood of evolving resistant pests.

## Recommendations

Thousands of farmers are planting corn varieties engineered with *Bt* toxin genes on millions of acres, and the acreage will only increase with the addition of new super-stacked varieties. In the next few years, local and regional adoption could reach 80%, where virtually every farmer in an area is planting a *Bt* variety.

The *Bt* technology will not be sustainable if the registrants and farmers fail to prevent resistant pests from evolving in the pest population. To do this, EPA has established IRM requirements that balance the best science on corn pests and the practical aspects of farming to reduce the likelihood of establishing a resistant pest population. The Industry CAP Report data, however, clearly shows that: (1) there is significant non-

15. It should be noted that for some data points (on-farm assessment noncompliance for corn rootworm-protected *Bt* corn and stacked corn) the number of violating farms is small, making the percentage numbers less reliable and making trends difficult to establish.

compliance for all *Bt* varieties, with as many as 25% of *Bt* corn farmers not in compliance with the requirements, and (2) compliance has decreased greatly over the last three years, corresponding to the extensive planting of *Bt* corn rootworm and stacked products. Those later products have slightly different IRM requirements and complicate farmers' planting decisions and compliance options.

Unless EPA and the registrants significantly lower levels of noncompliance, the public may lose the current benefits of using the existing *Bt* corn, the current benefits of *Bt* microbial sprays, and the anticipated benefits of other *Bt* corn varieties engineered in the future. If the government cannot ensure that IRM restrictions are complied with, it is questionable whether the regulatory system can adequately oversee the safe growing of those engineered crops. Therefore, CSPI makes the following recommendations to safeguard *Bt* technology for current and future generations:

**1. EPA should not re-register any of the current *Bt* corn varieties whose registration expires on September 30, 2010, unless the registrants demonstrably improve farmer compliance with IRM requirements.** If compliance does improve and EPA decides to re-register the current *Bt* corn varieties in 2010, it should impose the following additional requirements on the registrants and farmers to ensure better grower compliance with the IRM refuge requirements:

■ **Require farmers to annually certify to the registrants their actual compliance with IRM obligations and document how they complied.** EPA should require that every farmer planting *Bt* corn certify each June that he or she has planted the proper size refuge and provide as evidence of compliance (1) a map identifying the *Bt* and non-*Bt* fields on the farm and (2) seed purchase records to show that non-*Bt* seed corn was purchased. Such an obligation would continually remind farmers about their IRM requirements and reduce noncompliance (as most farmers would comply rather than lie on an official certification). The certification would also perform two additional compliance monitoring functions: (1) it would be an inexpensive method to obtain individual compliance information; and (2) it could be a screening mechanism to determine which growers might need field investigation for possible noncompliance. Data from the certifications should be summarized by the companies and provided to EPA in the annual CAP Report.

■ **Require that future on-farm assessments be conducted by independent third parties with no financial relationship to the registrants or farmers.** Those assessments would provide EPA and the registrants with independent and unbiased data on actual compliance rates and deter farmers from avoiding their legal obligations. Two separate on-farm assessments should be required. First, a random, statistically significant sample of *Bt* corn farms should be assessed to provide the registrants and EPA with data on national and regional compliance with IRM obligations. Second, as is the current practice,

on-farm assessment should be conducted to determine the compliance status of selected *Bt* corn farmers and deter their noncompliance. Targets for those on-farm assessments should be selected based on results from grower surveys, tips received by the registrants about noncompliance, review of certifications and field maps, and past history of noncompliance (i.e., any grower found in noncompliance should be inspected for at least the next two years). For both types of on-farm assessments (random and targeted), the independent assessor should use all information and records to determine compliance, including seed purchase records, site maps, and farmer interviews.

- **Require the registrants to reward farmers who meet their IRM obligations.** Providing a financial reward could be an extremely effective method of achieving greater compliance. For example, the registrants could give corn farmers a coupon with every bag of *Bt* corn seed that would allow the farmer to purchase non-*Bt* corn seed for their refuge at a discount. That would provide an economic incentive for farmers and reward those who plant the required refuge. EPA might also require the registrants to explore mechanisms to rebate a part of the seed purchase price to a farmer after they demonstrate that they have met their IRM obligations.
- **Require the registrants to penalize farmers who do not comply with IRM obligations.** The current penalty of not selling *Bt* seed to any farmer who “significantly” violates the IRM requirements two years in a row is not severe enough. The registrants should deny *Bt* seed to any farmer the year following a “significant deviation” and prevent that farmer from ever growing *Bt* corn if they violate IRM obligations in any two years in a five-year time period. Farmers who do not comply with refuge requirements jeopardize the continued use of *Bt* corn for responsible farmers. To date, the registrants have restricted *Bt* seed sales to a handful of noncompliant farmers, but that has not deterred the widespread noncompliance found in the industry surveys.
- **Require the registrants to improve their IRM education strategy and link it to performance objectives, such as better compliance.** Farmers have been planting *Bt* corn for a dozen years, yet the industry survey data indicate that the current education effort is not working. While every *Bt* corn farmer should be aware of IRM requirements, the industry survey found that almost a quarter of them could not correctly identify the size and distance requirements on an unaided basis. Compliance will never reach needed levels if that many farmers are unaware of their specific obligations.
- **Require the registrants to break down the compliance data they report from the Internet survey and the on-farm assessments by geographic regions.** As adoption has increased, some regions of the country are reaching the point where 80% of all corn fields are *Bt* corn. It is important to have re-

gional compliance data to identify whether regional differences in compliance might increase the likelihood of developing resistant pests.

2. **EPA should include in its *Bt* product registrations specific penalties it will impose on the registrants if compliance rates do not meet specified targets (such as 90%).** If the registrant does not meet the specified compliance targets, EPA could impose a significant monetary penalty or limit the number of *Bt* seeds a registrant and its fully-owned subsidiaries could sell the following year. Those penalties could be imposed in a sliding scale, where the penalty increases as the compliance rate decreases. While there is no acceptable level of noncompliance, by setting targets for IRM compliance and identifying specific consequences to the registrant if those targets are not met, there will be much stronger incentives to improve compliance.<sup>16</sup>
3. **EPA should explore with farmers the reasons they have not complied with the IRM requirements and determine if additional information or incentives are needed to improve compliance.** Are farmers confused by the different IRM requirements for different *Bt* products? Do farmers not understand their obligations? Do the refuge requirements not work on farms due to the way farms operate (e.g., farm layout issues)? Do farmers have difficulty finding suitable refuge hybrids? Do farmers get sufficient compliance information from seed dealers? With answers to those and other questions, EPA and the registrants might be better able to address some of the difficulties with farmer compliance.
4. On April 4, 2007, EPA published an Advanced Notice of Proposed Rulemaking addressing revisions to the current production regulations for plant incorporated protectants (72 FR 16312). In that notice, EPA identified that it was reviewing whether to revise its current labeling requirements, which only apply to environmental use permits and seed increase registrations. Given the current state of compliance with IRM obligations by farmers growing *Bt* corn products, **EPA should revise its labeling requirements so that the seed bags sold to farmers are labeled with information about the proper use of the regulated article, including the IRM obligations.** Putting a label on the seed bag identifying the IRM obligations would increase compliance and reinforce the messages given to farmers from seed dealers and developers. Each bag could identify what are the planting restrictions, similar to how a chemical pesticide label identifies how to properly use the product.
5. **For the SmartStax variety containing five *Bt* toxins (two for corn rootworm and three for corn borer pests) registered on July 29, 2009, EPA needs to**

16. Implementing this recommendation will require EPA to rethink its decision years ago to allow the registrants to provide compliance data together, instead of by company. It is important that individual registrants be held accountable for the compliance rate of its growers. Industry-wide data may be helpful to determine compliance trends and target educational efforts but the *Bt* product registration is individual to the particular company and product. Thus, individual compliance rates for individual products are necessary to ensure that the particular registrant is complying with its individual obligations. Industry members obviously prefer industry-wide compliance monitoring activities so that they can avoid individual responsibility for their product complying with the IRM conditions in their registration.

review closely the revised compliance assurance program (CAP) it required to be submitted by Monsanto and Mycogen Seeds by October 20, 2009. EPA should not accept any revised CAP unless it sets a combination of education, rewards, and penalties that have a strong likelihood of resulting in high levels of compliance (greater than 90%). EPA should provide the public and expert scientists with a copy of the proposed revised CAP and allow for comments so that EPA can get input from different stakeholders on how best to achieve as high a level of compliance as possible.

- 6. EPA should not re-register the SmartStax variety in November, 2011, unless the registrants are able to obtain extremely high level of compliance with IRM compliance by farmers (95% or better).** SmartStax is the first of what could be numerous new stacked *Bt* corn varieties with a small 5% refuge requirements. Some modeling suggests that planting a small but noncompliant refuge might accelerate resistance even more than planting no refuge at all. If farmers cannot achieve high levels of compliance for current products and new products such as SmartStax, then EPA may need to modify the IRM requirements for new *Bt* products to make them similar to older products, in order to slow the likelihood of resistance and increase farmer compliance.

## Appendix: Explanation of Calculation of Total Non-compliant *Bt* Corn Acreage in 2005 and 2008

### 2005 Calculation

#### Step 1 – Determine a conservative annual rate of noncompliance.

In 2005, the industry telephone survey found 92% compliance with the *Bt* corn (corn-borer protected) refuge size requirement and 96% compliance with the distance requirement. Thus, at least 8% of all *Bt* corn farmers were noncompliant, since a violation of either requirement puts a farm in noncompliance with the EPA IRM obligations.

#### Step 2 – Determine number of acres of *Bt* corn in noncompliance.

In 2005, according to the National Agricultural Statistics Service (NASS) at USDA, 81.76 million acres of corn were planted for all purposes. In addition, the NASS estimated that 26% of all corn planted was a variety with *Bt* insect resistance and 9% of all corn planted was a stacked variety involving *Bt* insect resistance and herbicide tolerance. Thus, 35% of all corn planted was *Bt* corn, or approximately 28.62 million acres (81.76 million times .35). If 8% of all *Bt* farms were noncompliant for at least one IRM obligations, then approximately 2.29 million acres (28.62 million times .08) of corn were noncompliant, which was almost 3% (2.29 million divided by 81.76 million) of all corn grown.

### 2008 Calculation

#### Step 1 – Determine a conservative annual rate of noncompliance

An annual compliance rate can be calculated from the data in the 2008 Industry Cap Report, which does not provide one annual noncompliance rate but instead six annual compliance rates (one for the size requirement and one for the distance requirement for the three different types of *Bt* corn grown by farmers). To determine an average compliance rate for all *Bt* corn farmers, one first determines the number of compliant farmers in each category (by multiplying the number of farmers completing the survey in that category by the compliance percentage).

#### Corn-borer

(317 growers) x (.78 in compliance with size) = 247 farmers in compliance

(298 growers) x (.88 in compliance with distance) = 262 farmers in compliance

Corn-rootworm

$(103 \text{ growers}) \times (.74 \text{ in compliance with size}) = 76 \text{ farmers in compliance}$

$(103 \text{ growers}) \times (.63 \text{ in compliance with distance}) = 65 \text{ farmers in compliance}$

Stacked

$(556 \text{ growers}) \times (.72 \text{ in compliance with size}) = 400 \text{ growers in compliance}$

$(543 \text{ growers}) \times (.66 \text{ in compliance with distance}) = 358 \text{ growers in compliance}$

Then one can determine the total number of compliant farmers for the size and distance requirements and divide that by the total number of responses to the survey for all three categories to get a compliance rate.

Size compliance rate

Total number of farmers in survey for size –  $317+103+556 = 976$  farmers

Total number of compliant farms for size –  $247+76+400= 723$  farmers

Percentage of compliance with size requirement –  $723$  divided by  $976 = 74\%$

Distance compliance rate

Total number of farmer in survey for distance –  $298+103+543=944$

Total number of compliant farmer for distance –  $262+63+358=683$

Percentage of compliance with distance requirement –  $683$  divided by  $944=73\%$

Thus, farmer compliance was only 74% for the size requirement and 73% for the distance requirement.

**Step 2 – Determine number of acres of *Bt* corn in noncompliance**

According to NASS, in 2008 85.98 million acres of corn were planted. In addition, NASS estimated that 17% of all corn planted in 2008 was a variety with *Bt* insect resistance and 40% was a stacked variety with both *Bt* insect resistance and herbicide tolerance. Thus, 57% of all corn planted in 2008 was *Bt* corn, or approximately 49 million acres (85.98 million times .57). Therefore, if 27% of the *Bt* corn farms were noncompliant, then approximately 13.23 million acres of corn (49 million times .27) violated EPA's IRM requirements in 2008.