



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

DEC 20 2006

ASSISTANT ADMINISTRATOR
FOR ENFORCEMENT AND
COMPLIANCE ASSURANCE

MEMORANDUM

SUBJECT: Consent Agreement and Proposed Final Order for
In the Matter of Syngenta Seeds, Inc., FIFRA HQ-2007-5007

FROM: Granta Y. Nakayama *Granta Y. Nakayama*
Assistant Administrator

TO: Environmental Appeals Board

Attached for your approval is a Consent Agreement and proposed Final Order (CAFO) to settle the civil penalty action against Syngenta Seeds, Inc. (Respondent) referenced above.

This memorandum is being provided in accordance with your January 5, 1993 Consent Order Review procedures. I have reviewed the CAFO and have determined that it is consistent with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and with Environmental Protection Agency (EPA) policies. This enforcement settlement uses the Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations, 65 Fed. Reg. 19618 (April 11, 2000) (Audit Policy).

1. This action is being settled pursuant to 40 C.F.R. § 22.13(b) and §§ 22.18(b)(2) and (3), before the filing of a Complaint using the CAFO to simultaneously initiate and conclude the matter.

2. Consistency with the FIFRA Penalty Policy

A. Background and Statement of Facts

EPA's enforcement action against Syngenta arises from the distribution and sale of an unregistered plant incorporated protectant (PIP) contained in corn seed. EPA has alleged 1,053 violations in the settlement agreement. The unadjusted gravity-based penalty for these violations is the statutory maximum of \$6,071,500. EPA has evaluated this matter under the Audit Policy and determined that Syngenta qualifies for a 75% reduction of the gravity-based penalty. Thus, the penalty in the CAFO is \$1,517,875.

i. Registration of Plant Incorporated Protectants

i. Registration of Plant Incorporated Protectants

EPA promulgated regulations on July 19, 2001, to establish the regulatory framework governing PIPs. 66 Fed. Reg. 37814 (2001) codified at 40 C.F.R. § 174. In this regulation, EPA defined the term “plant incorporated protectant” as “[a] pesticidal substance that is intended to be produced and used in a living plant, or in the produce thereof, and the genetic material necessary for production of such a pesticidal substance. [The term] also includes any inert ingredient contained in the plant, or produce thereof”. 40 C.F.R. 174.3. Because a PIP is genetic material introduced into a plant with the intent of producing a pesticidal effect, it clearly meets the FIFRA section 2 definition of a pesticide.

Each time genetic material is inserted into a different location of a gene sequence a new “event” is created. Because each event has the potential to create different pesticidal and other effects, the Agency requires each separate event to be separately assessed and registered as a separate PIP prior to any distribution or sale.

ii. The PIP at Issue - Bt10

Syngenta is the registrant of Bt11, a PIP used in corn. The pesticidal protein for Bt11 was derived from the Cry1Ab gene, isolated from *Bacillus thuringiensis* (Bt). While developing Bt11, Syngenta¹ also developed another event from the same Cry1Ab gene, known as Bt10. During commercial evaluation Syngenta did not consider Bt10 suitable for commercial purposes and thus discontinued development of and did not seek a pesticide registration for Bt10. During this early development of its PIP corn lines, it appears that Syngenta mislabeled some seeds containing the Bt10 events as Bt11 events. Thus, for several years while Syngenta thought it was developing solely Bt11 corn lines for distribution and sale, it was also developing some Bt10 lines created from the mislabeled Bt11 seeds. This unregistered event was distributed and sold for over four years, in violation of FIFRA.

Immediately upon notification of the possible violations, EPA conducted a safety assessment of the proteins expressed in Bt10. That assessment included determining whether there were EPA-approved tolerances or tolerance exemptions for those proteins. Tolerances and tolerance exemptions for proteins are based on the specific protein. EPA determined that the proteins expressed in Bt10 were covered by tolerance exemptions which EPA had issued previously for other PIPs. Accordingly, EPA determined that the presence of Bt10 in the food supply did not present an unreasonable risk of harm to human health or the environment.

iii. Statement of Facts

1

Some of the past actions discussed here were taken by Syngenta's corporate predecessors. However, the violations alleged in this matter all occurred with Syngenta in its present corporate form.

On December 15, 2004, Syngenta notified EPA by letter of a possible distribution of an unregistered PIP planted on less than 12 acres. Respondent stated in the letter that it would launch an investigation and inform EPA of the scope of any violations on a continuous basis, as information was made available. On January 7, 2005, Respondent notified EPA that at least two breeding lines of field corn contained the unregistered PIP. Respondent identified this unregistered event as Bt10. Respondent stated that it had been distributing and selling seed corn with the unregistered PIP Bt10, assuming the seed corn contained the registered PIP Bt11, EPA Reg. No. 67979-1, since approximately 2001. On February 22, 2005, Respondent notified EPA that it identified five breeding lines of seed corn that have always contained Bt10. Respondent identified that only two of the breeding lines were used to create commercial hybrids which were distributed to farmers.

Respondent submitted documents containing the records tracking movement and disposition of seed containing Bt10 to dealers in 21 states and two foreign countries and tracking movement of imports and exports of seeds containing Bt10 between 2002 and 2005.

B. Penalty Calculations under FIFRA Enforcement Response Policy (ERP)

In determining an administrative civil penalty, Section 14(a)(4) of FIFRA requires the Administrator to take into account the: (1) size of the business of the person charged, (2) effect on the person's ability to continue in business, and (3) gravity of the violation. These factors are incorporated in the *FIFRA ERP*. The unadjusted gravity-based penalty based on the *FIFRA ERP* is \$6,071,500. In accordance with the Audit Policy, EPA reduced the gravity-based penalty by 75% percent (\$4,553,625). Respondent did not gain a significant economic benefit from its violations. Therefore, the penalty for settlement purposes is \$1,517,875.

The FIFRA ERP provides a five-step process to determine a penalty:

- i. Determination of the gravity of the violation: Appendix A of the FIFRA ERP denotes each violation charged as a level 2 violation.
- ii. Determination of the size of business category: Respondent has gross revenues in excess of \$1,000,000, which is a category I size of business designation under the ERP.
- iii. Determination of the dollar amount per violation: The FIFRA ERP provides a matrix which utilizes the values determined in steps 1 and 2 above to identify a per violation penalty figure. Using this matrix, EPA determined that level 2 violations by a business with a business category I designation are assessed at \$5,500 per violation, which is increased to \$6,500 for violations occurring after March 15, 2004.
 - a. Distribution of Unregistered Pesticide: On 1044 occasions, Respondent violated Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), which makes it unlawful for any person in any State

to distribute or sell to any person any pesticide that is not registered. Specifically, on 1044 occasions Respondent distributed the unregistered plant incorporated pesticide Bt10.

Of the total distributions, 1037 originated within the United States. Of these, 762 occurred prior to or on March 15, 2004 and 275 occurred on or after March 15, 2004. Violations occurring prior to or on March 15, 2004, are assessed a maximum penalty of \$5,500 and those occurring after March 15, 2004 are assessed a maximum penalty of \$6,500 per count. Thus, \$5,500 multiplied by 762, and \$6,500 multiplied by 275, totals \$5,978,500.

On seven occasions, Respondent imported an unregistered pesticide into the United States. Five of these occurred prior to March 15, 2004 and two occurred on or after that date. Thus, \$5,500 multiplied by five, and \$6,500 multiplied by two, totals \$40,500.

The total unadjusted gravity-based penalty for 1044 violations of distributing or selling an unregistered pesticide is \$6,019,000.

- b. Import/Export Notification Violations: On nine occasions, Respondent failed to file required reports in violation of Section 12(a)(1)(N) of FIFRA, 7 U.S.C. § 136j(a)(1)(N).

On two occasions, Respondent failed to file required export reports. One of these occurred prior to March 15, 2004 and one occurred on or after that date. Thus \$5,500 and \$6,500 totals \$12,000.

On seven occasions Respondent failed to file a Notice of Arrival (EPA Form 3540-1). Five of these occurred prior to March 15, 2004 and two occurred on or after that date. Thus, \$5,500 multiplied by 5, and \$6,500 multiplied by 2, totals \$40,500.

The total unadjusted gravity-based penalty for nine violations for failing to submit Import/Export Notifications is \$52,500.

Thus the total unadjusted gravity-based penalty for the 1053 violations is \$6,071,500.

- iv. Gravity adjustments: The penalty determined in step 3, above, is subject to further adjustments based on criteria provided in the FIFRA ERP Appendix B. Gravity adjustment values are assigned for different categories of harm, culpability, and compliance history. The sum of the

gravity values is then used to determine whether the penalty per violation should increase, decrease, or remain the same, according to Table 3 of the FIFRA ERP.

Gravity of Harm - Pesticide: Gravity value = 1
Complainant assigned a Gravity value of 1 because the PIP, if registered, would not have been a toxicity category I pesticide.

Gravity of Harm - Harm to Human Health: Gravity value = 1
Complainant assigned a Gravity value of 1 because the violations did not pose any additional risks to the safety of the food supply.

Gravity of Harm - Environmental Harm: Gravity value = 1
Complainant assigned a Gravity value of 1 because the violations did not pose any additional environmental risk.

Gravity of Misconduct - Compliance History: Gravity value = 4
Complainant assigned a Gravity value of 4 because Respondent had several prior level 2 violations.

Gravity of Misconduct - Culpability: Gravity value = 2
Complainant assigned a Gravity value of 2 because the violation resulted from negligence and there is no evidence that the violation was either knowing or willful.

The total gravity value was 9, which results in a penalty assessment at the penalty matrix value. FIFRA ERP at 22 (TABLE 3).

- v. Consideration of ability to continue in business: Complainant does not believe that the proposed penalty would affect Respondent's ability to stay in business.

Based on the foregoing, Complainant assessed an unadjusted civil monetary penalty of \$6,071,500.

C. Self-Reporting Under the Audit Policy

Under the Audit Policy, the gravity-based penalty may be reduced by 100% if all nine of the conditions described in the policy are met. If the respondent does not meet the first condition of the Audit Policy (a requirement that the violation(s) was identified through systematic discovery) the Respondent is not entitled to the full 100% penalty mitigation. However, if the Respondent meets conditions two through nine, it may still receive a 75% reduction in penalty. The other eight conditions are: 2) the violations were voluntarily disclosed, 3) the disclosures

were promptly reported, 4) that the discovery and disclosure of the violations were independent of a government or third-party plaintiff, 5) the violations were corrected, 6) the recurrence of the violations were prevented, 7) there were no similar prior violations, 8) the violations were not otherwise excluded, and 9) the party cooperated with EPA during its investigation of the violations.

As explained below, after a full review of Syngenta's eligibility for the audit policy, EPA concluded that Syngenta did not qualify for 100% penalty mitigation, because the violations were not discovered through an environmental audit or compliance management system. EPA defines systematic discovery as "the detection of a *potential violation* through an environmental audit or a compliance management system that reflects the entity's due diligence in preventing, detecting and correcting violations." 65 Fed. Reg. 19629 (2000). Syngenta learned of possible violations of FIFRA through a seed company, Garst, Inc., which was in the process of being purchased by Syngenta. Garst first discovered the violation while testing corn seed thought to contain Bt11, which was purchased from Syngenta prior to the buyout of Garst. Garst reported to Syngenta that results from genetic testing showed that the seed it purchased did not contain the registered PIP Bt11. This initial discovery by Garst led to the discovery of the violations eventually disclosed to EPA by Syngenta. EPA determined that this did not demonstrate a periodic or objective review of Syngenta's seed operations and practices designed to comply with FIFRA requirements. Therefore, Syngenta did not satisfy the first condition of the Audit Policy and was not entitled to 100% mitigation of the gravity-based penalty.

However, EPA determined that Respondent met the other eight mandatory conditions in the Audit Policy. The initial submission disclosing possible violations of FIFRA was by letter to EPA, dated December 15, 2004. Until the receipt of that letter, EPA was unaware of the violations in this settlement agreement. Furthermore, based on information submitted by the Respondent and additional information gained through EPA's own investigation and interviews, it appears that the violations were disclosed within 21 days after a reasonable discovery period of December 15, 2004. Thus, Respondent met conditions two and three of the Audit Policy. During its investigation, EPA did not discover any information that would indicate that the Respondent made its disclosures because of a government intervention or third party suit. Therefore, Respondent met condition four of the Audit Policy.

In a process developed in cooperation with EPA and USDA, Syngenta identified all its affected breeding lines and the distribution of affected seed to locate current plantings and seed. As agreed with EPA and USDA, Syngenta destroyed all affected plants and quarantined all affected seed. Under USDA's oversight, Syngenta destroyed all the affected seed. Syngenta documented each of these actions and submitted the documentation to EPA for review and verification. To avoid similar violations in the future, Syngenta developed a detailed set of QA/QC procedures and trained its staff to assure that personnel understand and correctly implement the FIFRA requirements for PIPs. Syngenta also developed an audit and audit procedures to ensure that its PIPs were in compliance with FIFRA. Each of these documents was submitted to EPA for review. Therefore, EPA concluded that Respondent met conditions five and six of the Audit Policy.

A search of the National Compliance Database did not reveal similar violations for the Respondent within the past three years or the same violations for Respondent's parent company within the past five years. Therefore, Respondent has met condition seven of the Audit Policy.

Syngenta's violations did not fall into any of the categories described in condition eight of the Audit Policy, therefore, Syngenta met that condition. Respondent cooperated with EPA, which was demonstrated by the numerous submissions by the Respondent to EPA described above, as well as the Respondent's responses to EPA's requests for information while conducting the investigation. Therefore, Respondent has met condition nine of the Audit Policy.

In conclusion, based upon the above discussion, the Respondent met the eight mandatory Audit Policy conditions and EPA reduced the gravity-based penalty by 75% (\$4,553,625). Therefore, the penalty agreed upon by the Parties for settlement purposes is \$1,517,875.

3. Human Health and Environmental Concerns

The distribution and sale of unregistered pesticides deprives EPA of being able to assess potential risks from the pesticide and impairs EPA's ability to take those actions necessary to ensure that potential risks to human health or the environment are evaluated prior to the sale and distribution of the pesticide. All unregistered pesticides have the potential to pose an unreasonable risk of harm to human health and the environment. Respondent's unregistered pesticide posed a risk to human health and the environment because EPA was prevented from determining whether Bt10 met the standard of registration in FIFRA Section 3(c)(5) prior to distribution in commerce or whether the food grown from Bt10 was safe to eat. Fortunately, EPA reviewed data submitted by Syngenta and concluded that the proteins expressed in Bt10 are covered by existing food tolerance exemptions and do not pose any additional risks to the safety of the food supply.

4. Disposition of the Pesticide

All Bt10 seed stocks, except for archival samples, were destroyed under USDA supervision.

5. Past or Pending Actions

Syngenta has no past or pending FIFRA actions arising from these facts.

For the foregoing reasons, I recommend that the EAB approve the Consent Agreement and sign the Proposed Final Order.

Please address any questions concerning this memorandum or the attached CAFO to Ginny Phillips at 564-6139 or Carl Eichenwald at 564-4036.

Attachments

cc: Ginny Phillips
Carl J. Eichenwald
Counsel for Complainant

Warren U. Lehrenbaum
Counsel for Respondent