

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
REGION 8

2011 SEP 30 AM 10:28

Docket No. FIFRA-08-2011-0015

FILED
EPA REGION VIII
SEP 30 2011

In the Matter of:

AgBio Development, Inc.
9915 Raleigh Street
Westminster, CO 80031

Respondent.

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**PENALTY COMPLAINT AND NOTICE OF
OPPORTUNITY FOR HEARING**

JURISDICTION

1. This civil administrative enforcement action is authorized by Congress in section 14(a) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. § 136l(a). The rules for this proceeding are the "Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, Issuance of Compliance or Corrective Action Orders and the Revocation, Termination or Suspension of Permits ("Rules of Practice")," 40 C.F.R. part 22, a copy of which is enclosed.

2. The undersigned EPA officials have been properly delegated the authority to issue this action.

3. EPA alleges that Respondent has violated FIFRA by importing a pesticide without an approved Notice of Arrival (NOA) and distributing an adulterated pesticide. For these violations, EPA proposes the assessment of a civil penalty as more fully explained below.

NOTICE OF OPPORTUNITY FOR A HEARING

4. Respondent has the right to a public hearing before an administrative law judge (ALJ) to disagree with (1) any fact alleged by EPA in the complaint, or (2) the appropriateness of the proposed penalty.

5. To disagree with the complaint, and assert your right to a hearing, Respondent must file a written answer (and one copy) with the Regional Hearing Clerk, 1595 Wynkoop Street (8RC), Denver, Colorado 80202, within thirty (30) days of receiving this Complaint. The answer must clearly admit, deny or explain the factual allegations of the complaint, the grounds for any defense, the facts you may dispute, and your specific request for a public hearing. Please see section 22.15 of the Rules of Practice for a complete description of what must be in your answer.

FAILURE TO FILE AN ANSWER AND REQUEST FOR HEARING WITHIN THIRTY (30) DAYS MAY WAIVE RESPONDENT'S RIGHT TO DISAGREE WITH THE ALLEGATIONS OR PROPOSED PENALTY, AND RESULT IN A DEFAULT JUDGMENT AND ASSESSMENT OF THE PENALTY PROPOSED IN THE COMPLAINT.

QUICK RESOLUTION

6. Respondent may resolve this proceeding at any time by paying the specific penalty (\$5,720) proposed in this Complaint. Such payment need not contain any response to, or admission of, the allegations in the complaint. Such payment constitutes a waiver of Respondent's right to contest the allegations and to appeal the final order. See section 22.18 of the Rules of Practice for a full explanation of the quick resolution process. If Respondent chooses to resolve this proceeding by paying the specific penalty proposed in this Complaint, payment must be made, within thirty (30) calendar days of receipt of this Complaint, by sending a certified or cashier's check, including the name and docket number of this case, payable to "Treasurer, United States of America," in care of:

US Environmental Protection Agency
Fines and Penalties
Cincinnati Finance Center
P. O. Box 979077
St. Louis, MO 63197-9000

A copy of the check must be mailed simultaneously to the attorney listed below.

SETTLEMENT NEGOTIATIONS

7. EPA encourages discussing whether cases can be settled through informal settlement conferences. If you want to pursue the possibility of settling this matter, or have any other questions, contact Brenda L. Morris at (303) 312-6891 or the address below. **Please note that calling or requesting a settlement conference does NOT delay the running of the thirty (30) day period for filing an answer and requesting a hearing.**

STATUTORY AND REGULATORY BACKGROUND

8. The importation of pesticides into the United States is governed by Section 17(c) and (e) of FIFRA, 7 U.S.C. §§ 136o(c) and 136o(e), and the regulations promulgated thereunder by the Secretary of the Treasury in consultation with the Administrator of the U.S. EPA (the Administrator). These regulations are located at 19 C.F.R. Part 12.

9. 19 C.F.R. § 12.111 states, in pertinent part, that all imported pesticides are required to be registered under the provisions of Section 3 of FIFRA, 7 U.S.C. § 136a, and under the regulations (40 C.F.R. Part 156.10) promulgated thereunder by the Administrator before being permitted entry into the United States.

10. 19 C.F.R. § 12.112 states, in pertinent part, that an importer desiring to import pesticides into the United States shall submit to the Administrator a Notice of Arrival of Pesticides or Devices (NOA) (EPA form 3540-1), prior to the arrival of the shipment in the United States. *See also* Section 17(c) of FIFRA, 7 U.S.C. § 136o(c).

11. Section 2(s) of FIFRA defines a "person" as "any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not." 7 U.S.C. § 136(s).

12. Section 2(w) of FIFRA defines "producer" as "the person who manufactures, prepares, compounds, propagates, or processes any pesticide or device or active ingredient used in producing a pesticide."

13. Section 2(u) of FIFRA defines the term "pesticide," in pertinent part, as "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest." 7 U.S.C. § 136(u).

14. Section 2(gg) of FIFRA defines the term "to distribute or sell" to mean "to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver." 7 U.S.C. § 136(gg).

15. Section 2(q) defines a "misbranded" pesticide as one which has labeling that "bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular." 7 U.S.C. § 136(q).

16. Pursuant to Section 12(a)(1)(E) of FIFRA "it shall be unlawful for any person in any State to distribute or sell to any person any pesticide which is adulterated or misbranded." 7 U.S.C. § 136j(a)(1)(E).

17. Pursuant to Section 12(a)(2)(N) of FIFRA, "it shall be unlawful for any person who is a registrant, wholesaler, dealer, retailer, or other distributor to fail to file reports required" by FIFRA. 7 U.S.C. § 136j(a)(2)(N).

FACTUAL ALLEGATIONS AND ALLEGED VIOLATIONS

18. The Respondent, AgBio Development, Inc., is a Colorado corporation and, therefore, is a "person" as defined in Section 2(s) of FIFRA, 7 U.S.C. § 136(s).

19. Respondent is located at 9915 Raleigh Street, Westminster, CO 80031.

20. Respondent is a "producer," as defined in Section 2(w) of FIFRA, 7 U.S.C. §136(w), who "distributes" or "sells," as defined in Section 2(gg) of FIFRA, 7 U.S.C. §136(gg), a "pesticide," as defined in Section 2(u) of FIFRA, 7 U.S.C. §136(u).

21. Respondent has imported and distributed the pesticides Mycostop Biofungicide, EPA registration number 64137-5, and Mycostop Mix, EPA registration number 64137-9.

22. The pesticides, Mycostop Biofungicide, EPA registration number 64137-5, and Mycostop Mix, EPA registration number 64137-9, made formal entry into the United States at Denver International Airport on or about June 10, 2011. Respondent received the shipment on or about June 10, 2011.

23. On or about June 10, 2011, Respondent submitted an NOA to the U.S. EPA for the import shipment of the pesticide products, Mycostop Biofungicide, EPA registration number 64137-5, and Mycostop Mix, EPA registration number 64137-9. The NOA stated the entry date for the pesticides as June 13, 2011.

24. On June 10, 2011 at 2:36 P.M., Ms. Margaret Collins, an Environmental Protection Specialist with U.S. EPA Region 8, emailed Respondent telling him that EPA may decide to inspect the shipment of pesticides that is due to arrive on June 13, 2011, with shipment number 6838964156. Ms. Collins stated she would know whether EPA would conduct an inspection on the shipment the morning of June 13, 2011 and would email Respondent then.

25. On June 10, 2011 at 2:47 PM, Respondent emailed Ms. Collins to inform her that the shipment of pesticides arrived before Respondent expected and was delivered to Respondent by DHL due to the refrigeration requirement. Respondent stated that the boxes had not yet been opened.

26. On June 13, 2011, an investigator employed by the U.S. EPA and duly authorized to conduct inspections under FIFRA, conducted an inspection of the shipment imported by Respondent on June 10, 2011, in order to determine compliance with Section 17 of FIFRA, 7 U.S.C. § 136o.

27. The Mycostop Mix in the shipment matched the information on record with the U.S. EPA.

28. Respondent repackages the Mycostop Biofungicide at its facility. The product ships in a small labeled envelope and Respondent repackages the small envelope into a larger labeled envelope.

29. The EPA approved label states the active ingredient in Mycostop Biofungicide is 35% dried spores and mycelium of ray fungus.

30. The shipment imported on or about June 10, 2011 contained 35% dried spores and mycelium of ray fungus and the label on the smaller envelopes the pesticide product was shipped in stated the active ingredient as 35% dried spores and mycelium of ray fungus.

31. Respondent repackaged the pesticide product into a larger envelope with labels stating the active ingredient was 30% dried spores and mycelium of ray fungus.

32. The NOA and label submitted with the NOA listed the active ingredient as the 30% dried spores and mycelium of ray fungus.

33. On or about June 16, 2011, Respondent resubmitted the NOA with the active ingredient listed as the correct 35% dried spores and mycelium of ray fungus and the U.S. EPA approved the NOA the same day.

SPECIFIC ALLEGATIONS

COUNT 1

34. Paragraphs 1 through 33 are incorporated by reference as though set forth here in full.

35. On or about June 10, 2011, Respondent failed to file and obtain EPA approval for a NOA for the pesticides Mycostop Biofungicide, EPA registration number 64137-5, and Mycostop Mix, EPA registration number 64137-9, prior to the arrival of the pesticides in the United States, as is required by Section 17(c) of FIFRA, 7 U.S.C. § 136o(c), and 19 C.F.R. § 12.112, and in violation of Section 12(a)(2)(N) of FIFRA, 7 U.S.C. § 136j(a)(2)(N).

36. Respondent's violation of Section 12(a)(2)(N) of FIFRA, 7 U.S.C. § 136j(a)(2)(N), subjects Respondent to the issuance of an Administrative Complaint assessing a civil penalty under Section 14(a) of FIFRA, 7 U.S.C. § 136l(a).

COUNT 2

37. Paragraphs 1 through 33 are incorporated by reference as though set forth here in full.

38. Respondent repackaged the pesticide Mycostop Biofungicide, EPA registration number 64137-5, at AgBio Development, Inc., a pesticide producing establishment with EPA establishment number 68253-CO-1.

39. Repackaging with the incorrect label is a violation of Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

40. Respondent's violation of Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), subjects Respondent to the issuance of an Administrative Complaint assessing a civil penalty under Section 14(a) of FIFRA, 7 U.S.C. § 136l(a).

PROPOSED CIVIL PENALTY

41. FIFRA, 7 U.S.C. § 136l(a)(1), authorizes the assessment of a civil penalty of up to \$7,150.00 per violation. In arriving at the penalty proposed below, EPA, as required by the statute, 7 U.S.C. § 136l(a)(4), has taken into consideration, to the extent known, the size of Respondent's business; Respondent's ability to continue in business in light of the proposed penalty; and the nature, circumstances, extent and gravity of the alleged violation.

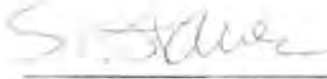
42. EPA's approach to calculating appropriate penalties is outlined in its Enforcement Response Policy for the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), December, 2009 (enclosed), which provides a rational, consistent, and equitable method for applying these statutory factors to the facts and circumstances of specific cases. Using the policies to apply the statutory factors to the facts of this case, **EPA proposes that a total penalty of \$5,720 be assessed against Respondent for the violations alleged above.** EPA's penalty calculation/narrative is enclosed and incorporated as Complainant's Exhibit 1 to this Complaint. Additionally, Complainant has enclosed a copy of "Information for Small Businesses."

43. The ALJ is not bound by EPA's penalty policy or the penalty proposed by Complainant, and may assess a penalty above the proposed amount, up to the maximum amount authorized in the statute.

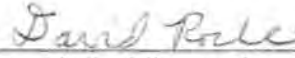
To discuss settlement or ask any questions you may have about this process, please contact the attorney indicated below.

United States Environmental Protection Agency
Region 8, Office of Enforcement,
Compliance and Environmental Justice,
Complainant


Date: 7/29/11

By: 
Sandra Stavnes, Director
Technical Enforcement Program

Date: 9/29/11

By: 
David Rochlin, Acting Chief
Regulatory Enforcement Program

Date: 9/30/11

By: 
Brenda Morris, Senior Enforcement Attorney
USEPA Region 8
1595 Wynkoop Street
Denver, CO 80202
(303) 312-6891

In the Matter of: AgBio Development, Inc.
Docket No.:

CERTIFICATE OF SERVICE

The undersigned hereby certifies that the original and one copy of the PENALTY COMPLAINT, AND NOTICE OF OPPORTUNITY FOR HEARING with Exhibits and enclosures were hand-carried to the Regional Hearing Clerk, EPA Region 8, 1595 Wynkoop Street; Denver, Colorado 80202-1129, and that a true copy of the same was sent via Certified Mail to the registered agent for AgBio Development, Inc. to the following address:

Jan Craig Meneley
Registered Agent for
AgBio Development, Inc.
9915 Raleigh Street
Westminster, CO 80031

9/30/2011
Date

Jan C Meneley
Signature

Name and Title

§ 21.13

approve or disapprove the State issued statement, in accordance with the requirements of § 21.5.

(2) The Regional Administrator will periodically review State program performance. In the event of State program deficiencies the Regional Administrator will notify the State of such deficiencies.

(3) During that period that any State's program is classified as deficient, statements issued by a State shall also be sent to the Regional Administrator for review. The Regional Administrator shall notify the State, the applicant, and the SBA of any determination subsequently made, in accordance with § 21.5, on any such statement.

(i) If within 60 days after notice of such deficiencies has been provided, the State has not taken corrective efforts, and if the deficiencies significantly affect the conduct of the program, the Regional Administrator, after sufficient notice has been provided to the Regional Director of SBA, shall withdraw the approval of the State program.

(ii) Any State whose program is withdrawn and whose deficiencies have been corrected may later reapply as provided in § 21.12(a).

(g) Funds appropriated under section 106 of the Act may be utilized by a State agency authorized to receive such funds in conducting this program.

§ 21.13 Effect of certification upon authority to enforce applicable standards.

The certification by EPA or a State for SBA Loan purposes in no way constitutes a determination by EPA or the State that the facilities certified (a) will be constructed within the time specified by an applicable standard or (b) will be constructed and installed in accordance with the plans and specifications submitted in the application, will be operated and maintained properly, or will be applied to process wastes which are the same as described in the application. The certification in no way constitutes a waiver by EPA or a State of its authority to take appropriate enforcement action against the owner or operator of such facilities for violations of an applicable standard.

PART 22—CONSOLIDATED RULES OF PRACTICE GOVERNING THE ADMINISTRATIVE ASSESSMENT OF CIVIL PENALTIES AND THE REVOCATION/TERMINATION OR SUSPENSION OF PERMITS

Subpart A—General

Sec.

- 22.1 Scope of this part.
- 22.2 Use of number and gender.
- 22.3 Definitions.
- 22.4 Powers and duties of the Environmental Appeals Board, Regional Judicial Officer and Presiding Officer; disqualification, withdrawal, and reassignment.
- 22.5 Filing, service, and form of all filed documents; business confidentiality claims.
- 22.6 Filing and service of rulings, orders and decisions.
- 22.7 Computation and extension of time.
- 22.8 *Ex parte* discussion of proceeding.
- 22.9 Examination of documents filed.

Subpart B—Parties and Appearances

- 22.10 Appearances.
- 22.11 Intervention and non-party briefs.
- 22.12 Consolidation and severance.

Subpart C—Prehearing Procedures

- 22.13 Commencement of a proceeding.
- 22.14 Complaint.
- 22.15 Answer to the complaint.
- 22.16 Motions.
- 22.17 Default.
- 22.18 Quick resolution; settlement; alternative dispute resolution.
- 22.19 Prehearing information exchange; prehearing conference; other discovery.
- 22.20 Accelerated decision; decision to dismiss.

Subpart D—Hearing Procedures

- 22.21 Assignment of Presiding Officer; scheduling the hearing.
- 22.22 Evidence.
- 22.23 Objections and offers of proof.
- 22.24 Burden of presentation; burden of persuasion; preponderance of the evidence standard.
- 22.25 Filing the transcript.
- 22.26 Proposed findings, conclusions, and order.

Subpart E—Initial Decision and Motion to Reopen a Hearing

- 22.27 Initial decision.
- 22.28 Motion to reopen a hearing.

1st Page only

FIFRA ENFORCEMENT RESPONSE POLICY
FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

Waste and Chemical Enforcement Division
Office of Civil Enforcement
Office of Enforcement and Compliance Assurance
United States Environmental Protection Agency

December 2009