# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION VII 901 NORTH 5<sup>th</sup> STREET KANSAS CITY, KANSAS 66101

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ENVIRONHENTAL PROTECTION AGENCY-REGION VII REGIONAL HEARING CLERK

## BEFORE THE ADMINISTRATOR

) Docket No. FIFRA-07-2006-0252
)
) COMPLAINT AND NOTICE OF
) OPPORTUNITY FOR HEARING
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# **COMPLAINT**

### Section I

## Jurisdiction

- 1. This is an administrative action for the assessment of civil penalties instituted pursuant to Section 14 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 1361.
- 2. This Complaint serves as notice that the United States Environmental Protection Agency (EPA) has reason to believe that Respondents have violated Section 12 of FIFRA, 7 U.S.C. § 136j.

## Section II

### **Parties**

- 3. The Complainant, by delegation from the Administrator of the EPA and the Regional Administrator, EPA, Region VII, is the Director of the Water, Wetlands, and Pesticides Division, EPA, Region VII.
- 4. The Respondents are: BAP, L.L.C. (formerly known as Baltzell Agri-Products, Inc.), a pesticide producer, located at 6930 F Street, Omaha, Nebraska 68117, and Wellmark International, a pesticide registrant, located at 1501 E. Woodfield Road, Suite 200 West, Schaumburg, Illinois 60173. Respondents are and were at all times referred to in this Complaint, "persons" as defined by Section 2(s) of FIFRA, 7 U.S.C. § 136(s). BAP, L.L.C., is a corporation qualified to do business in the state of Nebraska.

## Section III

# Violations

# **General Allegations**

- 5. The Complainant hereby states and alleges that Respondents have violated FIFRA as follows:
- 6. Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), states that it is unlawful for any person to distribute or sell any pesticide which is adulterated or misbranded.
- 7. Section 2(gg) of FIFRA, § 136(gg), 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.
- 8. Registrants may distribute or sell their registered product under another person's name and address instead of, or in addition to, their own, as allowed by regulation at 40 C.F.R. § 152.132. Such distribution and sale is termed "supplemental distribution" and the product is referred to as a "distributor product." The distributor is considered an agent of the registrant for all intents and purposes under FIFRA, and both the registrant and the distributor may be held liable for violations pertaining to the distributor product. Supplemental distribution is permitted upon notification to EPA if specific conditions, stated at 40 C.F.R. § 152.132(a) through (e), are met. As a requirement of supplemental distribution, the label of the distributor product must be the same as that of the registered product, with exceptions stated at 40 C.F.R. § 151.132(d)(1) through (5).
- 9. Wellmark International is the registrant for EPA Registration Number (EPA Reg. No.) 2724-372, Zoecon Granular IGR Cattle Supplement. EPA's records indicate the most current label for Zoecon Granular IGR Cattle Supplement, EPA Reg. No. 2724-372, was accepted by EPA on January 29, 2001.
- 10. Wellmark International is the registrant for EPA Reg. No. 2724-494, RF9904 Granules. EPA's records indicate the most current label for RF9904 Granules, EPA Reg. No. 2724-494, was accepted by EPA on March 29, 2002.
- 11. EPA's records indicate that BAP, L.L.C. requested, and EPA assigned company number 74534 to BAP, L.L.C. EPA also assigned EPA Establishment Number 74534-NE-001 to BAP, L.L.C. on December 3, 2001.
- 12. EPA's records indicate that on June 6, 2002, EPA was informed of Wellmark International's intent to supplementally distribute their product, EPA Reg. No. 2724-372, Zoecon Granular IGR Cattle Supplement, through BAP, L.L.C., using the product name, Altosid Range Mineral-2, and the distributor product number EPA Reg. No. 2724-372-74534.
- 13. EPA's records indicate that on June 6, 2002, EPA was informed of Wellmark International's intent to supplementally distribute their product, EPA Reg. No. 2724-494, RF9904 Granules, through BAP, L.L.C., using the product name, Altosid Range Mineral-4, and the distributor product number EPA Reg. No. 2724-494-74534.

14. On April 7, 2004, a representative of the Nebraska Department of Agriculture (NDA) inspected Baltzell Agri-Products, Inc. (now BAP, L.L.C.). Corporate information obtained by EPA regarding Baltzell Agri-Products, Inc., indicated the firm's name changed in January 2006, (the physical address did not change) and it is now known as BAP, L.L.C. The NDA representative collected photographs and copies of labels for the facility's distributor products, Altosid Range Mineral-2 and Altosid Range Mineral-4. On the date of the inspection, BAP, L.L.C.'s Vice President, Beau W. Baltzell, signed a Voluntary Statement and a Notice of Inspection and a Receipt for Samples presented to Respondent by the NDA representative. The statement signed by Mr. Baltzell indicated the firm has an agreement with Wellmark International "to formulate Altosid Range Mineral-2, EPA Reg. No. 2724-372 and Altosid Range Mineral-4, EPA Reg. No. 2724-494."

# Count 1

- 15. The facts stated in paragraphs 6 through 14 are realleged and incorporated as if fully stated herein.
- 16. On April 7, 2004, the NDA representative requested a copy of BAP, L.L.C.'s sales records for Altosid Range Mineral-2, a distributor product. BAP, L.L.C., mailed to EPA under separate cover, a copy of a BAP, L.L.C. sales record documenting the sale on June 20, 2003, of Altosid Range Mineral-2.
- 17. On April 7, 2004, the representative collected a copy of BAP, L.L.C.'s label for the distributor product, Altosid Range Mineral-2.
- 18. The distributor product, Altosid Range Mineral-2, was misbranded as the copy of BAP, L.L.C.'s distributor product label for the distributed pesticide stated, in pertinent part:

# "ALTOSID RANGE MINERAL - 2

\* \* \*

## **ACTIVE INGREDIENT:**

S-Methroprene (CAS #65733-16-6)......0.02% OTHER INGREDIENTS:.....98.98%

\* \* \*'

whereas Wellmark International's accepted label of January 29, 2001, for EPA Reg. No. 2724-372, stated the actual percentage of the Other Ingredients to be 99.98%.

- 19. BAP, L.L.C.'s label bearing the product name of Altosid Range Mineral-2 was further misbranded as the label failed to bear the following statements that appeared on Wellmark International's label accepted by EPA on January 29, 2001, for EPA Reg. No. 2724-372:
  - a) Precautionary Statements for Hazards to Humans and Domestic Animals;
  - b) correct Environmental Hazards Statement;
  - c) correct Storage and Disposal Statement;
  - d) correct Feeding and Management Instructions; and,
  - e) a correct Ingredients heading.

- 20. BAP, L.L.C.'s distributor product label for Altosid Range Mineral-2 was also misbranded as the label bore the following statements:
  - 1) "WARNING: This product, which contains added copper, should not be fed to sheep or related species that have a low tolerance level to copper."
  - 2) "Notice: This product contains no prohibited animal by-products in accordance with FDA Regulation 21 CFR 589.2000. This manufacturing facility does not handle, store or use any prohibited animal by-products."

These statements did not appear on Wellmark International's label for EPA Reg. No. 2724-372 accepted by EPA on January 29, 2001.

- 21. BAP, L.L.C.'s distributor product label for Altosid Range Mineral-2 collected by the NDA representative was further misbranded as the EPA registration number for the registered product was not followed by a dash and the distributor's company number, as required by 40 C.F.R. § 152.132.
- 22. Respondents violated Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), by distributing or selling a misbranded pesticide.
- 23. Pursuant to Section 14 of FIFRA, 7 U.S.C. § 136*l*, and based on the facts stated in paragraphs 15 through 22, it is proposed that a civil penalty of \$5,500 be assessed against Respondents.

## Count 2

- 24. The facts stated in paragraphs 6 through 14 are realleged and incorporated as if fully stated herein.
- 25. On April 7, 2004, the NDA representative requested a copy of BAP, L.L.C.'s sales records for Altosid Range Mineral-4, a distributor product. BAP, L.L.C., mailed to EPA under separate cover, a copy of a BAP, L.L.C. sales record dated March 20, 2003, documenting the sale of the distributor product, Altosid Range Mineral-4.
- 26. On April 7, 2004, the NDA representative collected a copy of the distributor product label for BAP, L.L.C.'s distributor product, Altosid Range Mineral-4.
- 27. The distributor product label, Altosid Range Mineral-4, was misbranded as the copy of BAP, L.L.C.'s distributor product label for the distributed pesticide stated, in pertinent part:

# "ALTOSID RANGE MINERAL - 4

\* \* \*

## ACTIVE INGREDIENT:

S-Methroprene (CAS #65733-16-6)......0.01% OTHER INGREDIENTS:.....98.99%

\* \* \*"

whereas Wellmark International's accepted label dated March 29, 2002, for EPA Reg. No. 2724-494, stated the actual percentage of the Other Ingredients to be 99.99%.

- 28. BAP, L.L.C.'s product label collected by the NDA representative bearing the distributor product name, Altosid Range Mineral-4, failed to bear the following statements that appeared on Wellmark International's label for EPA Reg. No. 2724-494 accepted by EPA on March 29, 2002:
  - a) correct Signal Word;
  - b) correct placement of the Signal Word;
  - c) Precautionary Statements for Hazards to Humans and Domestic Animals;
  - d) correct Environmental Hazards Statement;
  - e) correct Storage and Disposal Statement;
  - f) correct Feeding and Management Instructions;
  - g) and, a correct Ingredients heading.
- 29. BAP, L.L.C.'s distributor product label for Altosid Range Mineral-4 collected by the NDA representative was further misbranded as the label bore the following statements:
  - 1) "WARNING: This product, which contains added copper, should not be fed to sheep or related species that have a low tolerance level to copper."
  - 2) "Notice: This product contains no prohibited animal by-products in accordance with FDA Regulation 21 CFR 589.2000. This manufacturing facility does not handle, store or use any prohibited animal by-products."

These statements did not appear on Wellmark International's label for EPA Reg. No. 2724-494 accepted by EPA on March 29, 2002.

- 30. BAP, L.L.C.'s distributor product label for Altosid Range Mineral-4 collected by the NDA representative was further misbranded as the EPA registration number for the registered product was not followed by a dash and the distributor's company number, as required by 40 C.F.R. § 152.132.
- 31. Respondents violated Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), by distributing or selling a misbranded pesticide.
- 32. Pursuant to Section 14 of FIFRA, 7 U.S.C. § 136*l*, and based on the facts stated in paragraphs 23 through 31, it is proposed that a civil penalty of \$5,500 be assessed against Respondents.

## Section IV

# Total Proposed Penalty

33. Section 14 of FIFRA, 7 U.S.C. § 136*l*, and the Debt Collection Improvement Act of 1996, as implemented by the Civil Monetary Penalties Inflation Adjustment Rule, 40 C.F.R. Part 19, authorize the issuance of this Complaint for the assessment of a civil penalty of up to Five Thousand Five Hundred Dollars (\$5,500) for each violation occurring prior to March 15, 2004. The EPA proposes to assess a total civil penalty of Eleven Thousand Dollars (\$11,000) against Respondents for the above-described violations.

# Appropriateness of Proposed Penalty

- 34. The penalty proposed above has been calculated after consideration of the statutory factors set forth in Section 14 of FIFRA, 7 U.S.C. § 1361. Specifically, EPA considered the size of the business of Respondents, the effect of the proposed penalty on Respondents' ability to continue in business and the gravity of the alleged violations. In its calculation of the proposed penalty, EPA has taken into account the particular facts and circumstances of the alleged violations, with specific reference to EPA guidance for the calculation of proposed penalties under FIFRA (See Enclosure, July 2, 1990, Enforcement Response Policy for the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)).
- 35. For purposes of calculating the proposed penalty, EPA obtained financial information indicating that each of the Respondent's total business revenues were in excess of \$1,000,000 per year. This information placed each of the Respondents in Category I size of business, as set forth in the FIFRA Civil Penalty Calculation Worksheet attached hereto and incorporated herein by reference (See Enclosure). If EPA's estimate of each of the Respondent's total business revenues is incorrect, each of the Respondents may submit reliable financial documentation indicating another category is appropriate.
- 36. Respondents have the right, upon submittal of certified financial information, to consideration of Respondents' financial condition in mitigation of the proposed penalty insofar as is necessary to permit Respondents to continue in business.
- 37. The proposed penalty constitutes a demand *only if* Respondents fail to raise *bona fide* issues of ability to pay, or other *bona fide* affirmative defenses relevant to the determination of any final penalty.
- 38. Said issues of ability to pay or other affirmative defenses relevant to a final penalty may and should be brought to the attention of Complainant at the earliest opportunity in this proceeding.
- 39. Payment of the total penalty \$11,000 may be made by certified or cashier's check payable to the "Treasurer, United States of America," and remitted to:

Mellon Bank EPA – Region 7 P.O. Box 371099M Pittsburgh, Pennsylvania 15251 40. If Respondents do not contest the findings and assessments set forth above, payment of the penalty assessed herein may be remitted as described in the preceding paragraph, including a reference to the name and docket number of the Complaint. In addition, a copy of the check should be sent to:

Regional Hearing Clerk EPA - Region 7 901 North 5<sup>th</sup> Street Kansas City, Kansas 66101

and a copy to:

Mr. Rupert G. Thomas Assistant Regional Counsel EPA - Region 7 901 North 5<sup>th</sup> Street Kansas City, Kansas 66101

# NOTICE OF OPPORTUNITY FOR HEARING

#### Section V

# Answer and Request for Hearing

41. Pursuant to Section 14(a) of FIFRA, 7 U.S.C. § 136(a), Respondents have the right to request a hearing to contest any material fact contained in this Complaint or to contest the appropriateness of the penalty proposed herein. If Respondents wish to avoid being found in default, Respondents must file a written answer and request for hearing with:

Regional Hearing Clerk EPA - Region 7 901 North 5<sup>th</sup> Street Kansas City, Kansas 66101

within thirty (30) days of service of this Complaint and Notice of Opportunity for Hearing. Said answer shall clearly and directly admit, deny, or explain each of the factual allegations contained in the Complaint with respect to which Respondents have any knowledge, or shall clearly state that Respondents have no knowledge as to particular factual allegations in the Complaint. The answer shall also state:

- A. The circumstances or arguments that are alleged to constitute the grounds of defense;
- B. The facts that Respondents intend to place at issue; and
- C. Whether a hearing is requested.

Failure to deny any of the factual allegations in the Complaint constitutes an admission of the undenied allegations.

Administrator, and the civil penalties proposed therein shall become due and payable without further proceedings.

44. Respondents are advised that, after the Complaint is issued, the Consolidated Rules of Practice prohibit any <u>ex parte</u> (unilateral) discussion of the merits of any action with the EPA Regional Administrator, members of the Environmental Appeals Board, the Regional Judicial Officer, Administrative Law Judge, or any person likely to advise these officials in the decision of the case.

#### Section VI

## Settlement Conference

45. Whether or not a hearing is requested, an informal settlement conference may be arranged at Respondents' request. Respondents may confer with the EPA concerning: (1) whether or not the alleged violation occurred; or (2) the appropriateness of the proposed penalty in relation to the size of Respondents' business, the gravity of the violations, and the effect of the proposed penalty on Respondents' ability to continue in business. Additionally, the proposed penalty may be adjusted if Respondents establish a bona fide issue of ability to pay. To explore the possibility of settlement in this matter, contact:

Mr. Rupert G. Thomas Assistant Regional Counsel EPA Region 7 901 North 5<sup>th</sup> Street Kansas City, Kansas 66101 Telephone: (913) 551-7282

- 46. A request for an informal settlement conference does not extend the thirty (30) day period during which a written answer and request for a hearing must be submitted. The informal conference procedure may be pursued as an alternative to and simultaneously with the adjudicatory hearing procedure.
- 47. EPA encourages all parties against whom a civil penalty is proposed to pursue the possibility of settlement. However, no penalty reduction will be made simply because an informal settlement conference is held. If settlement is reached, the parties will enter into a

written Consent Agreement, and a Final Order will be issued. The issuance of such a Consent Agreement and Final Order shall constitute a waiver of Respondents' right to request a hearing on any matter stipulated to therein.

Date

William A.

Director

Water, Wetlands and Pesticides Division

Mr. Rupert G. Thomas
Assistant Regional Counsel
Office of Regional Counsel

## **Enclosures:**

- 1. FIFRA Civil Penalty Calculation Worksheet
- 2. Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, Issuance of Compliance Action Orders, and the Revocation, Termination or Suspension of Permits, 40 C.F.R. Part 22
- 3. July 2, 1990, Enforcement Response Policy for the Federal Insecticide, Fungicide, and Rodenticide Act
- 4. SBREFA Fact Sheet
- 5. Notice of Securities and Exchange Commission Registrants Duty to Disclose Environmental Legal Proceedings

# **CERTIFICATE OF SERVICE**

I certify that on the date noted below I hand delivered the original and one copy of this Complaint and Notice of Opportunity for Hearing to the Regional Hearing Clerk, EPA, 901 North 5<sup>th</sup> Street, Kansas City, Kansas 66101.

I further certify that on the date noted below I sent by certified mail, return receipt requested, a copy of the signed original Complaint and Notice of Opportunity for Hearing; a copy of 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, 40 C.F.R. Part 22; a copy of the July 2, 1990, Enforcement Response Policy for the Federal Insecticide, Fungicide, and Rodenticide Act; a copy of the FIFRA Civil Penalty Calculation Worksheet; the SBREFA Fact Sheet; and the Notice of Securities and Exchange Commission Registrants' Duty to Disclose Environmental Legal Proceedings, to the following:

Mr. Joseph L. Leahy, Jr. Registered Agent for: BAP, L.L.C. 2120 So. 72<sup>nd</sup> Street Omaha, Nebraska 68124

and

CT Corporation System
Registered Agent for:
Wellmark International
208 S. LaSalle St., Suite 814
Chicago, Illinois 60604-1101

8-14-06

Date

Linda Koska

# FIFRA CIVIL PENALTY CALCULATION WORKSHEET ENFORCEMENT RESPONSE POLICY for FIFRA - Reference

RESPONDENTS: BAP, L.L.C. (Formerly: Baltzell Agri-Products, Inc.) Prepared By: Barbara Shepard

Omaha, NE

Date:

August 10, 2006

AND: Wellmark International, Schaumburg, IL

	Count I	Count 2
Appendix A		
1. Statutory Violation	12(a)(1)(E)	12(a)(1)(E)
2. FTTS Code	1EA	IEA
3. Violation Level	2	2
Appendix C - Table 2 - Size of Business Category		
4. Violator Category * § 14(a)(1) or § 14(a)(2)	14(a)(1)	14(a)(1)
5. Size of Business Category	1	1
Appendix C - Table 1 - FIFRA Civil Penalty Matrix		
6. BASE PENALTY.	\$ 5,500	\$ 5,500
Appendix B - Gravity Adjustments		
7a. Pesticide Toxicity	1	1
7b. Human Harm	3	3
7c. Environmental Harm	3	3
7d. Compliance History	2	2
7e. Culpability	. 0	0
7f. Total Gravity Adjustment Value (add items 7a - 7e)	9	9
Appendix C - Table 3 - Adjustments		
7g. Percent Adjustment	-0-	-0-
7h. Dollar Adjustment	-0-	-0-
8. Final Penalty** (item 7h from item 6)	\$ 5,500	\$ 5,500
Combined Total Penalty (total of all columns for line 8, above)	\$11,000	

<sup>\*</sup> Section 14(a)(1) of FIFRA - Any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who violates any provision of this subchapter may be assessed a civil penalty by the Administrator of not more than \$5,000 for each offense.

Section 14(a)(2) of FIFRA - Any private applicator or other person not included in paragraph (1) who violates any provision of this subchapter subsequent to receiving a written warning from the Administrator or following a citation for a prior violation, may be assessed a civil penalty by the Administrator of not more than \$1,000 for each offense, except that any applicator not included under paragraph (1) of this subsection who holds or applies registered pesticides, or use dilutions of registered pesticides, only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served, and who violates any provision of this subchapter may be assessed a civil penalty by the Administrator of not more than \$500 for the first offense nor more than \$1,000 for each subsequent offense.

<sup>\*\*</sup>The final penalty in each column of line 8 cannot exceed the statutory maximum.