UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION VII 901 NORTH 5th STREET KANSAS CITY, KANSAS 66101 ENVIRONMENTAL PROTECTION ENVIRONMENTAL PROTECTION ENVIRONMENTAL PROTECTION

ENVIRON IEILAL PROTECTION AGENCY-REGION VII REGIONAL HEARING CLERK

BEFORE THE ADMINISTRATOR

IN THE MATTER OF

Harvest Brands, Inc. 1057 S. 69 Highway Pittsburg, Kansas 66762) Docket No. FIFRA-07-2006-0256

) COMPLAINT AND NOTICE OF) OPPORTUNITY FOR HEARING

Respondent

<u>COMPLAINT</u>

)))

)

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 Respondent has violated Section 12 of FIFRA, 7 U.S.C. § 136j.

Section Π

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 Respondent is Harvest Brands, Inc., a pesticide producer, located at 1057 S. 69 Highway, Pittsburg, Kansas 66762. The Respondent is and was at all times referred to in this Complaint, a "person" as defined by Section 2(s) of FIFRA, 7 U.S.C. § 136(s), and a company doing business in the state of Kansas.

Section III

Violations

General Allegations

5. The Complainant hereby states and alleges that Respondent has 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 registered pesticide which is adulterated or misbranded.

7. Section 2(q)(1)(F) of FIFRA, 7 U.S.C. § 136(q)(1)(F), states that a pesticide is misbranded if the label does not contain directions for use which are necessary and if complied with, are adequate to protect health and the environment.

8. Section 2(q)(1)(G) of FIFRA, 7 U.S.C. § 136(q)(1)(G), states that a pesticide is misbranded if the label fails to bear warning or caution statements which are necessary and, if complied with, are adequate to protect health and the environment.

9. Section 2(gg) of FIFRA, 7 U.S.C. § 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.

10. At all times relevant to this Complaint, Respondent operated a pesticide producing facility in Pittsburg, Kansas. Respondent requested, and EPA assigned EPA Establishment No. 07627-KS-01 to Respondent's producing facility. Respondent is the registrant, producer, and distributor of the pesticides:

- 1) Stockade Fly Control For Horses Block with Rabon Oral Larvicide, EPA Registration Number (EPA Reg. No.) 7627-26,
- 2) Stockade Fly Control Mineral Mix with Rabon Oral Larvicide, EPA Reg. No. 7627-21, and
- 3) Stockade Fly Control Block with Rabon Oral Larvicide, EPA Reg. No. 7627-22.

11. By letter dated August 31, 1999, Registration Division of EPA reregistered Respondent's product and accepted, with comments, Respondent's label for Stockade Fly Control For Horses Block with Rabon Oral Larvicide, EPA Reg. No. 7627-26. EPA required Respondent to make specified labeling changes and provide to EPA two (2) copies of the final printed label prior to releasing the product for shipment.

12. By letter dated January 6, 2000, Registration Division of EPA reregistered Respondent's product and accepted, with comments, Respondent's label for Stockade Fly Control Mineral Mix with Rabon Oral Larvicide, EPA Reg. No. 7627-21. EPA required Respondent to make specified labeling changes and provide to EPA two (2) copies of the final printed label prior to releasing the product for shipment.

13. By letter dated January 5, 2000, Registration Division of EPA reregistered Respondent's product and accepted, with comments, Respondent's label for Stockade Fly Control Block with Rabon Oral Larvicide, EPA Reg. No. 7627-22. EPA required Respondent to make specified labeling changes and provide to EPA two (2) copies of the final printed label prior to releasing the product for shipment.

14. On November 4, 2003, a representative of the Kansas Department of Agriculture (KDA) conducted an inspection at Harvest Brands, Inc., and obtained copies of Respondent's production records, sales records, and a bill of lading. The KDA representative was provided copies of labels and collected physical samples of all pesticide products produced by Respondent which were packaged, labeled, released, and held for sale and shipment on the date of the inspection.

Count 1

15. The facts stated in paragraphs 6 through 14 are realleged and incorporated as if fully stated herein.

16. During the inspection on November 4, 2003, Respondent provided the KDA representative a copy of Respondent's label for Stockade Fly Control Block with Rabon Oral Larvicide, EPA Reg. No. 7627-22. Respondent's representative signed a label certification statement certifying the copy of the label provided to the KDA representative is identical to labels placed on inventory of EPA Reg. No. 7627-22 that Respondent held for distribution or sale on November 4, 2003.

17. The label of the product referred to in paragraph 16 was misbranded in that it failed to bear a heading titled "Environmental Hazards" and the caution statement under this heading, "This pesticide is toxic to fish." This heading and caution did appear on the label accepted by EPA in connection with the product's reregistration under Section 3 of FIFRA, 7 U.S.C. § 136a, on January 5, 2000, under EPA Reg. No. 7627-22.

18. Respondent violated Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), by holding for sale or distribution the misbranded Stockade Fly Control Block with Rabon Oral Larvicide, EPA Reg. No. 7627-22.

19. Pursuant to Section 14 of FIFRA, 7 U.S.C. § 136*l*, and based upon the facts stated in paragraphs 14 through 18, it is proposed that a civil penalty of \$5,500 be assessed against Respondent.

Count 2

20. The facts stated in paragraphs 6 through 14 are realleged and incorporated as if fully stated herein.

21. During the inspection on November 4, 2003, Respondent provided the KDA representative a copy of Respondent's label for Stockade Fly Control for Horses Block with Rabon Oral Larvicide, EPA Reg. No. 7627-26. Respondent's representative signed a label certification statement certifying the copy of the label provided to the KDA representative is identical to labels placed on inventory of EPA Reg. No. 7627-26 that Respondent held for distribution or sale on November 4, 2003.

22. The label of the product referred to in paragraph 21 did not bear caution statements as required under reregistration of the product under the First Aid Statement, Note to Physicians and Veterinarians, Hazards to Humans, and User Safety Recommendations. These caution statements were required by EPA to be inserted on the label in connection with the product's reregistration under Section 3 of FIFRA, 7 U.S.C. § 136a, on August 31, 1999, under EPA Reg. No. 7627-26. Respondent also failed to provide to EPA two (2) copies of a final printed label as required as terms of the reregistration.

23. The label of the product referred to in paragraph 21 bore the following statement under the Directions for Use section: "This product is not to be used on horses destined for slaughter." This statement did not appear on the label accepted by EPA in connection with the product's reregistration under Section 3 of FIFRA, 7 U.S.C. § 136a, on August 31, 1999, under EPA Reg. No. 7627-26.

24. The label of the product referred to in paragraph 21 bore the following statement under the Hazards to Humans section: "This product may cause skin sensitization in certain individuals." This statement did not appear on the label accepted by EPA in connection with the product's reregistration under Section 3 of FIFRA, 7 U.S.C. § 136a, on August 31, 1999, under EPA Reg. No. 7627-26.

25. Respondent violated Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), by holding for sale or distribution the misbranded Stockade Fly Control for Horses Block with Rabon Oral Larvicide, EPA Reg. No. 7627-26.

26. Pursuant to Section 14 of FIFRA, 7 U.S.C. § 136*l*, and based upon the facts stated in paragraphs 20 through 25, it is proposed that a civil penalty of \$5,500 be assessed against Respondent.

Count 3

27. The facts stated in paragraphs 6 through 14 are realleged and incorporated as if fully stated herein.

28. During the inspection on November 4, 2003, Respondent provided the KDA representative a copy of Respondent's label for Stockade Fly Control Mineral Mix with Rabon Oral Larvicide, EPA Reg. No. 7627-21. Respondent's representative signed a label certification statement certifying the copy of the label provided to the KDA representative is identical to labels placed on inventory of EPA Reg. No. 7627-21 that Respondent held for distribution or sale on November 4, 2003.

29. The label of the product referred to in paragraph 28 bore the following statements under the Directions for Use section:

"Allow free choice to cattle. Cattle should consume an average of 0.8 ounces of the Fly Block per 100 pounds of body weight per day, which is equivalent to 8 ounces for a 1000 lb. animal daily. This will supply the recommended average daily intake of 70 mgs. Rabon Oral Larvicide per hundred pounds of body weight. Animals should not be starved for minerals before initiation of the Stockade Fly Block with Rabon program but omit all salt from other feed after the program is started. Do not feed other free choice sources of salt or mineral containing salt in any form. Allow one block for each 10 head of cattle and place near watering and loafing areas. Put out no more than two weeks supply at a time.

If consumption of Stockade Fly Control Block with Rabon is above 0.8 ounce per 100 lbs. of body weight per day, reduce the number of feed locations or relocate. If consumption is below 0.8 ounces per 100 lbs. of body weight per day, increase the number of feed locations. Start feeding Stockade Fly Control Block with Rabon early in the spring before flies begin to appear, and continue feeding throughout the summer and into the fall.

Stockade Fly Control with Rabon may be fed up to slaughter and to lactating dairy cows. Stockade Fly Control Block with Rabon prevents . . .

In order to achieve optimum fly control, Stockade Fly Control Block with Rabon ..."

The foregoing statements did not appear on the label accepted by EPA for EPA Reg. No. 7627-21, on January 6, 2000, in connection with reregistration under Section 3 of FIFRA, 7 U.S.C. § 136a. Respondent has not submitted to EPA a subsequent label amendment to request a modification of the above statements.

30. The label of the product referred to in paragraph 28 did not bear an Environmental Hazards heading or the caution, "This product is toxic to fish." The Environmental Hazards heading and caution did appear on the label accepted by EPA on January 6, 2000, in connection with reregistration of EPA Reg. No. 7627-21 under Section 3 of FIFRA, 7 U.S.C. § 136a. Respondent failed to provide to EPA two (2) copies of the final printed label for the reregistered EPA Reg. No. 7627-21.

31. Respondent violated Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), by holding for sale or distribution misbranded Stockade Fly Control Mineral Mix with Rabon Oral Larvicide, EPA Reg. No. 7627-21.

32. Pursuant to Section 14 of FIFRA, 7 U.S.C. § 136*l*, and based upon the facts stated in paragraphs 27 through 31, it is proposed that a civil penalty of \$5,500 be assessed against Respondent.

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 Sixteen Thousand Five Hundred Dollars (\$16,500) against Respondent 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 Respondent, the effect of the proposed penalty on Respondent's 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 Respondent's total business revenues were over one million dollars per year. This information placed Respondent 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 Respondent's total business revenues is incorrect, Respondent may submit reliable financial documentation indicating another category is appropriate.

36. Respondent has the right, upon submittal of certified financial information, to consideration of Respondent's financial condition in mitigation of the proposed penalty insofar as is necessary to permit Respondent to continue in business.

37. The proposed penalty constitutes a demand *only if* Respondent fails to raise *bona fide* issues of ability to pay, or other *bona fide* affirmative defenses relevant to the determination of any final penalty.

38. <u>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.</u>

39. Payment of the total penalty - \$16,500 - may be made by certified or cashier's check payable to "Treasurer, United States of America," and remitted to:

Mellon Bank EPA – Region 7 P.O. Box 371099M Pittsburgh, Pennsylvania 15251

40. If Respondent does 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 5th Street Kansas City, Kansas 66101

and a copy to:

Mr. Rupert Thomas Assistant Regional Counsel EPA - Region 7 901 North 5th 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), Respondent has 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 Respondent wishes to avoid being found in default, Respondent must file a written answer and request for hearing with:

Regional Hearing Clerk EPA - Region 7 901 North 5th 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 Respondent has any knowledge, or shall clearly state that Respondent has 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 Respondent intends 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.

42. Any hearing that is requested shall be held and conducted in accordance with 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 (copy enclosed).

43. If Respondent fails to file a written answer and request for hearing within thirty (30) days of service of this Complaint and Notice of Opportunity for Hearing, such failure will constitute a binding admission of all of the allegations in this Complaint, and a waiver of Respondent's right to a hearing under FIFRA. A Default Order may thereafter be issued by the Regional Administrator, and the civil penalties proposed therein shall become due and payable without further proceedings.

44. Respondent is 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 Respondent's request. Respondent 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 Respondent's business, the gravity of the violation, and the effect of the proposed penalty on Respondent's ability to continue in business. Additionally, the proposed penalty may be adjusted if Respondent establishes a bona fide issue of ability to pay. To explore the possibility of settlement in this matter, contact:

Mr. Rupert Thomas Assistant Regional Counsel EPA Region 7 901 North 5th 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 Respondent's right to request a hearing on any matter stipulated to therein.

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Director Water, Wetlands and Pesticides Division

Mr. Ruplet 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 5th 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:

> The Prentice-Hall Corporation System, Kansas, Inc. Registered Agent for: Harvest Brands, Inc. 200 S.W. 30th Street Topeka, Kansas 66611

8/15/06 Date

Julia A. Cacho

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

RESPONDENT: Harvest Brands, Inc. ADDRESS: 1057 S. 69 Highway Pittsburg, Kansas 66762

Prepared By: Barbara Shepard

Date: 8/01/06

	Count 1	Count 2	Count 3
Appendix A			
1. Statutory Violation	Sec. 12(a)(1)(E)	Sec. 12(a)(1)(E)	Sec. 12(a)(1)(E)
2. FTTS Code	1EG	1EF and 1EG	1EF and 1EG
3. Violation Level	2	2	2
<u>Appendix C - Table 2</u> - Size of Business Category			
4. Violator Category * § 14(a)(1) or § 14(a)(2)	§ 14(A)(1)	§ 14(a)(1)	§ 14(a)(1)
5. Size of Business Category	I		
Appendix C - Table 1 - FIFRA Civil Penalty Matrix			
6. BASE PENALTY	\$5,500	\$5,500	\$5,500
Appendix B - Gravity Adjustments			
7a. Pesticide Toxicity	1	1	1
7b. Human Harm	3	3	3
7c. Environmental Harm	3	3	3
7d. Compliance History	0	0	0
7e. Culpability	2	2	2
7f. Total Gravity Adjustment Value (add items 7a - 7e)	9	9	9
Appendix C - Table 3 - Adjustments			
7g. Percent Adjustment	-0-	-0-	-0-
7h. Dollar Adjustment	-0-	-0-	-0-
8. Final Penalty** (item 7h from item 6)	\$5,500	\$5,500	\$5,500
Combined Total Penalty (total of all columns for line 8, above)	\$16,500		

* 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.

**The final penalty in each column of line 8 cannot exceed the statutory maximum.