



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Region 1
5 Post Office Square - Suite 100
Boston, MA 02109-3912

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SEP 26 2012

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Office of Regional Hearing Clerk

BY HAND

September 26, 2012

Wanda I. Santiago
Regional Hearing Clerk
U.S. Environmental Protection Agency – Region 1
5 Post Office Square - Suite 100 (ORA 18-1)
Boston, MA 02109-3912

Re: In the Matter of Exergen Corporation, Docket No. FIFRA-01-2012-0066

Dear Ms. Santiago:

Enclosed for filing in the referenced action, please find the original and one copy of a Complaint and Notice of Opportunity for Hearing, which seeks penalties for alleged violations of Section 12(a)(1)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act.

Thank you for your attention to this matter.

Sincerely,

A handwritten signature in blue ink, appearing to read "Hugh W. Martinez".

Hugh W. Martinez, Senior Enforcement Counsel
Counsel for Complainant

Enclosures

cc: James G. Votaw, Esquire, Counsel for Exergen
Kan S. Tham, EPA Region 1

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 1

RECEIVED

SEP 26 2012

EPA ORC *WS*
Office of Regional Hearing Clerk

In the Matter of:)

Exergen Corporation)
400 Pleasant Street)
Watertown, MA 02472,)

Respondent.)

Proceedings under Section)
14(a) of the Federal)
Insecticide, Fungicide, and)
Rodenticide Act, as amended,)
7 U.S.C. Section 136l(a).)
_____)

Docket No. FIFRA-01-2012-0066

**COMPLAINT and NOTICE OF
OPPORTUNITY FOR HEARING**

COMPLAINT

1. This Complaint and Notice of Opportunity for Hearing (“Complaint”) is being issued under Section 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”), as amended, 7 U.S.C. § 136l(a). This Complaint alleges that the Respondent, Exergen Corporation, has violated Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), and regulations promulgated pursuant to FIFRA at 40 C.F.R. Parts 150 -189 *et seq.* The Complaint also provides written notice that the United States Environmental Protection Agency proposes to assess civil administrative penalties. The Complainant is, by lawful delegation, the Legal Enforcement Manager in the Office of Environmental Stewardship, United States Environmental Protection Agency, Region 1 (“EPA”).

GENERAL ALLEGATIONS

2. The Respondent is Exergen Corporation, a company that produces, distributes, and sells heat detection products, including “Temporal Scanner” infrared thermometers, for use by general consumers and professionals. Respondent is incorporated and does business in Massachusetts.

Respondent's principal place of business is located at 400 Pleasant Street in Watertown, Massachusetts (the "Exergen Facility" or "Exergen Establishment").

3. Respondent is a "person" as defined by Section 2(s) of FIFRA, 7 U.S.C. § 136(s), and is subject to FIFRA and the regulations promulgated thereunder. Respondent is also a "producer" as defined by Section 2(w) of FIFRA, 7 U.S.C. § 136(w), and "distributor" within the meaning of Section 14(a)(1) of FIFRA, 7 U.S.C. § 136l(a)(1).

4. From on or about September 22, 2008 until on or about September 21, 2010, Respondent "distributed" or "sold," within the meaning of Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), the following temporal scanner thermometers:

- a. Exergen Temporal Scanner, TAT-2000C Home Model, with Silver Ion Antimicrobial Head and bearing one or more of the claims referenced in Paragraph 6 of this Complaint (the "TAT-2000C");
- b. Exergen Temporal Scanner, TAT-5000 Professional Model, with Silver Ion Antimicrobial Head and bearing one or more of the claims referenced in Paragraph 6 of this Complaint (the "TAT-5000"); and,
- c. Exergen Temporal Scanner, TAT-2000 Series Professional Model, with Silver Ion Antimicrobial Head and bearing one or more of the claims referenced in Paragraph 6 of this Complaint (the "TAT-2000").

5. Each of the TAT-2000C, TAT-5000, and TAT-2000 products (collectively referred to as "the Products") consists of a temporal scanner thermometer for consumer use (TAT-2000C) or professional use (TAT-5000 and TAT2000). Each of the Products incorporates a head (or "probe") that is treated with an antimicrobial compound designed to destroy bacteria and other microbes on the Products.

6. From on or about September 22, 2008 until on or about September 21, 2010, Exergen distributed or sold the Products with labels and/or labeling, including Internet advertising, brochures, product inserts, and/or other materials, making one or more of the following statements or claims:

- a. "Silver Ion Antimicrobial Head; ... and Germ Busting; Imbedded silver destroys bacteria, mold, mildew and fungi; ...antimicrobial head that destroys harmful bacteria, mold mildew and fungi;"
- b. "A Silver Bullet in the War Against Microbes; the material that the head is made from has been laboratory tested to reduce levels of Methicillin-Resistant Staphylococcus aureus (MRSA)... Eschericia coli (E. coli) ... by over 90% ... becoming the only thermometer with a head capable of self-disinfecting;"
- c. "...thermometer head is manufactured from a material that is fully impregnated with silver ions that are continually released at the surface to destroy the microbes; Imbedded silver destroys bacteria (including E. coli), mold, mildew, and fungi...;"
- d. "...thermometer features the added protection of a silver ion antimicrobial head that destroys harmful bacteria, mold, mildew and fungi. The material is fully impregnated with silver ions that are continually released...the antimicrobial head is expected to be effective for approximately 10,000 readings;"
- e. "Silver Ion Antimicrobial Probe Head;...provides continuous antimicrobial protection for more than five years. The antimicrobial compound of the silver ion probehead works proactively against a broad spectrum of bacteria, fungi and other microbes;"
- f. "Effective against microbes – Laboratory tests demonstrate the controlled release of silver ions from the sensor head provides continuous antimicrobial protection for more than five years; the antimicrobial compound works proactively against a broad spectrum of bacteria, fungi and other microbes;" and/or
- g. "Kills even the most resistant bacteria strains – Laboratory tests show that Methicillin-resistant Staphylococcus aureus (MRSA) and Vancomycin-resistant Enterococci (VRE) are reduced by over 20% in ten minutes..."

7. Section 2(t) of FIFRA, 7 U.S.C. § 136(t), defines the term "pest" to mean, in pertinent part, "any insect, rodent, nematode, fungus, weed" or "any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism..." declared by EPA to be a pest under Section 25(c)(1) of FIFRA, 7 U.S.C § 136w(c)(1).

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

9. Based on Respondent’s claims made in or as part of the sale or distribution of each of the TAT-2000C, TAT-5000, and TAT-2000 products, each was intended to prevent, destroy, repel or mitigate a pest and each was, therefore, a pesticide as defined by FIFRA and not otherwise exempt from regulation under FIFRA.

10. Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), and 40 C.F.R. § 152.15 state, in pertinent part, that it shall be unlawful for any person in any State to distribute or sell to any person any pesticide that is not registered under Section 3 of FIFRA, with certain exemptions. The FIFRA regulations at 40 C.F.R. Part 152 set forth procedures, requirements, and criteria concerning the registration of pesticides under FIFRA Section 3.

11. On September 21, 2010, pursuant to Sections 8 and 9 of FIFRA, 7 U.S.C. §§ 136f and 136g, duly-authorized EPA inspectors (the “Inspectors”) conducted an inspection at the Exergen Establishment in Watertown, MA.

12. During the September 21, 2010 inspection at the Exergen Establishment (the “Inspection”), the Inspectors collected physical samples and/or documentary samples (e.g., photographs or photocopies) of each of the Products.

13. Each of the Products sampled and/or documented during the Inspection were packaged, labeled, and released for shipment.

14. During or as a result of the Inspection, the Inspectors collected copies of sales records that were created and compiled by Exergen for each of the TAT-2000C, TAT-5000, and TAT-2000 products. The sales records showed that Exergen distributed or sold, or offered for distribution or sale, each of the Products during all or part of 2008, 2009, and 2010, inclusive.

15. With respect to Respondent's distribution or sale of the Products, the sales records collected by the Inspectors identify, for each distribution or sale, the name of the product involved, the quantity distributed or sold, and the specific date of each such transaction. Exergen has asserted a claim of confidentiality with respect to information contained in the sales records.

16. Upon information and belief, at all times relevant to the allegation of violation in this Complaint, Respondent had neither sought nor obtained registration of any of the Products pursuant to Section 3 of FIFRA.

17. On April 11, 2012, under a cover letter to Exergen dated April 13, 2012, EPA issued a "Stop Sale, Use, or Removal Order" to Exergen, pursuant to Section 13 of FIFRA, 7 U.S.C. § 136k, alleging FIFRA violations regarding the distribution or sale of the Products and pertaining to all quantities and sizes of the Products, wherever located, within the ownership, control, or custody of Respondent.

COUNT I -
Unregistered Pesticides: TAT-2000C

18. Paragraphs 1 through 17 are realleged and incorporated by reference.

19. During or as a result of the Exergen Inspection, the Inspectors documented that Respondent distributed or sold the TAT-2000C product without having first registered the TAT-2000C as a pesticide, as required under Section 3 of FIFRA.

20. As a result of the Exergen Inspection, a review of records provided by Respondent, and further investigation, EPA determined that Respondent distributed or sold the TAT-2000C product on numerous occasions¹ during 2008, 2009, and 2010.

21. Therefore, on numerous occasions Respondent violated Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), and regulations promulgated pursuant to FIFRA, including 40 C.F.R. Part 152.

COUNT II -
Unregistered Pesticides: TAT-5000

22. Paragraphs 1 through 21 are realleged and incorporated by reference.

23. During or as a result of the Exergen Inspection, the Inspectors documented that Respondent distributed or sold the TAT-5000 product without having first registered the TAT-5000 as a pesticide, as required under Section 3 of FIFRA.

24. As a result of the Exergen Inspection, a review of records provided by Respondent, and further investigation, EPA determined that Respondent distributed or sold the TAT-5000 product on numerous occasions² during 2008, 2009, and 2010.

¹ Respondent has claimed that the information it has provided concerning sales is confidential business information. EPA has not yet evaluated this claim, but for now will only reference the specific number of transactions at issue in communications with Respondent.

² See footnote 1.

25. Therefore, on numerous occasions Respondent violated Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), and regulations promulgated pursuant to FIFRA, including 40 C.F.R. Part 152.

COUNT III -
Unregistered Pesticides: TAT-2000

26. Paragraphs 1 through 25 are realleged and incorporated by reference.

27. During or as a result of the Exergen Inspection, the Inspectors documented that Respondent distributed or sold the TAT-2000 product without having first registered the TAT-2000 as a pesticide, as required under Section 3 of FIFRA.

28. As a result of the Exergen Inspection, a review of records provided by Respondent, and further investigation, EPA determined that Respondent distributed or sold the TAT-2000 product on numerous occasions³ during 2008, 2009, and 2010.

29. Therefore, on numerous occasions Respondent violated Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), and regulations promulgated pursuant to FIFRA, including 40 C.F.R. Part 152.

CIVIL PENALTY

30. Section 14(a) of FIFRA, 7 U.S.C. § 136l(a), authorizes EPA to assess a civil penalty of up to \$5,000 for each violation of FIFRA and the regulations promulgated pursuant thereto. Pursuant to the Debt Collection Improvement Act of 1996 (“DCIA”), Pub. L. No. 104-134, 110 Stat. 1321 (1996), and EPA’s Civil Monetary Penalty Inflation Adjustment Rule, promulgated

³ See footnote 1.

thereunder and codified at 40 C.F.R. Part 19, this amount was increased to \$6,500 for violations occurring after March 15, 2004 and to \$7,500 for violations occurring after January 12, 2009.

31. Based on the forgoing findings of violations of FIFRA, EPA seeks to assess a civil penalty of not more than \$6,500 per violation for each separate violation alleged in Counts I, II, and III, above, that occurred on or before January 12, 2009 and a civil penalty of not more than \$7,500 per violation for each separate violation alleged in Counts I, II, and III, above, that occurred after January 12, 2009. As explained in footnotes 1, 2, and 3 above, the particular number of violations is not provided at this time due to a confidentiality claim asserted by Respondent but not yet assessed by EPA. EPA will provide the number of violations in discussions with Respondent about this Complaint, and prior to any hearing on this case.

32. The assessment of a penalty for each of the violations is warranted because the Products were sold or distributed without first being registered as a pesticide under FIFRA Section 3, 7 U.S.C. § 136a. The FIFRA Section 3 registration requirement lies at the core of FIFRA's regulatory scheme and serves a fundamental purpose of ensuring that no pesticide or device is distributed, sold, or used in a manner that may pose an unreasonable risk to human health or the environment. This registration requirement under FIFRA Section 3 is also important because it helps ensure that pesticide end users and members of the public have accurate, up-to-date, and compliant information about any pesticides in the marketplace.

33. In determining the amount of the penalty to be assessed under Section 14(a) of FIFRA, EPA will take into account the statutory factors listed in Section 14(a)(4) of FIFRA, 7 U.S.C. § 136l(a)(4), which include the appropriateness of the penalty to the size of the business of the

person charged, the effect of the penalty on the person's ability to continue in business, and the gravity of the violation. EPA will also take into account the "FIFRA Enforcement Response Policy" issued by the Waste and Chemical Enforcement Division, Office of Civil Enforcement, Office of Enforcement and Compliance Assurance, dated December 2009, a copy of which is enclosed with this Complaint.

34. Prior to any hearing on this case, EPA will file a document specifying the number of Respondent's violative distribution or sales transactions, a proposed penalty for the FIFRA violations, and an explanation of how the proposed penalty was calculated, as required by the Consolidated Rules of Practice, at 40 C.F.R. Part 22 (enclosed).

35. Neither assessment nor payment of any administrative penalty shall affect Respondent's continuing obligation to comply with FIFRA and its implementing regulations.

NOTICE OF OPPORTUNITY TO REQUEST A HEARING

36. As provided in Section 14(a)(3) of FIFRA, 7 U.S.C. § 136l(a)(3), and in accordance with 5 U.S.C. § 554 and 40 C.F.R. § 22.14, Respondent has the right to request a formal hearing to contest any material fact set forth in this Complaint or to contest the appropriateness of the proposed penalty. To avoid being found in default and having a penalty assessed without further proceedings, Respondent must file a written Answer **within thirty (30) days** of receipt of this Complaint. In accordance with 40 C.F.R. § 22.15, the Answer should (1) clearly and directly admit, deny, or explain each of the factual allegations contained in the Complaint, (2) briefly state all facts and circumstances, if any, which constitute grounds for a defense, and (3) specifically request an administrative hearing (if desired). The denial of any material fact or

raising any affirmative defense(s) shall be construed as a request for a hearing. Failure to deny any of the factual allegations in this Complaint will constitute an admission of the undenied allegations. The original and one copy of the Answer, as well as a copy of all other documents that Respondent files in this action, must be sent to:

Wanda I. Santiago
Regional Hearing Clerk
U.S. Environmental Protection Agency – Region 1
5 Post Office Square, Suite 100 (ORA 18-1)
Boston, Massachusetts 02109-3912

37. Respondent should also send a copy of the Answer, as well as a copy of all other documents that Respondent files in this action to Hugh W. Martinez, the attorney assigned to represent EPA and designated to receive service on behalf of Complainant in this matter at:

Hugh W. Martinez, Senior Enforcement Counsel
U.S. Environmental Protection Agency – Region 1
5 Post Office Square, Suite 100 (OES 04-3)
Boston, MA 02109-3912
Phone: (617) 918-1867
Fax: (617) 918-0867

38. The hearing that will be held upon Respondent's request will be conducted in accordance with the Administrative Procedure Act (5 U.S.C. §§ 551 *et seq.*) and the Consolidated Rules.

39. If Respondent fails to file a written Answer within thirty (30) days of the service of this Complaint, pursuant to 40 C.F.R. § 22.17(a), Respondent may be found in default which constitutes an admission of all the facts alleged in this Complaint, a waiver of the right to a hearing, and assessment of the above-cited penalties without further proceedings.

INFORMAL SETTLEMENT CONFERENCE

40. Whether or not Respondent requests a hearing, Respondent may confer informally with EPA to discuss the facts of this case, or the proposed penalties, and/or the possibility of settlement. EPA has the authority to modify the amount of the proposed penalty, where appropriate, to reflect any settlement reached with Respondent in an informal conference. The terms of such an agreement would be embodied in a Consent Agreement and Final Order. A Consent Agreement and Final Order, signed by Complainant and Respondent, would be binding as to all terms and conditions specified therein. Any requests for an informal conference, and any other questions that Respondent may have regarding this Complaint, should be directed to EPA legal counsel, Hugh W. Martinez, using the contact information provided herein.

41. A request for an informal settlement conference does not extend any deadline in this proceeding, including the thirty (30) day period for the submission of a written Answer to this Complaint.

42. If Respondent has any questions concerning the settlement process, or wishes to arrange for an informal conference, Respondent should contact Hugh W. Martinez at (617) 918-1867.



Joanna B. Jerison, Legal Enforcement Manager
Office of Environmental Stewardship

Date: 9/25/12

CERTIFICATE OF SERVICE

I hereby certify that the foregoing Complaint and Notice of Opportunity for Hearing was delivered in the following manner to the addresses listed below:

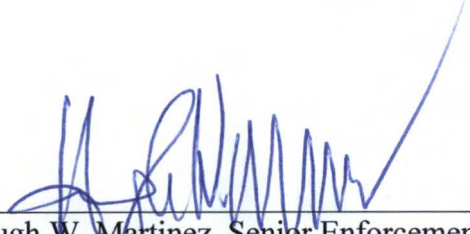
Original and One Copy by
Hand Delivery to:

Wanda I. Santiago
Regional Hearing Clerk
Environmental Protection Agency
5 Post Office Square, Suite 100 (ORA 18-1)
Boston, MA 02109-3912

One Copy by Certified Mail,
Return Receipt Requested, to:

James G. Votaw, Esquire
Manatt, Phelps & Phillips, LLP
Counsel for Exergen Corporation
700 12th Street, N.W., Suite 1100
Washington, D.C. 20005

Signed:



Hugh W. Martinez, Senior Enforcement Counsel
Office of Environmental Stewardship
U.S. Environmental Protection Agency – Region 1
5 Post Office Square, Suite 100 (OES 04-3)
Boston, MA 02109-3912
Phone: (617) 918-1867
Fax: (617) 918-0867
martinez.hugh@epa.gov

Date :

9-26-12