



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION I – New England
5 Post Office Square - Suite 100
Boston, Massachusetts 02109-3912

BY HAND

June 28, 2012

Wanda I. Santiago, Regional Hearing Clerk
U.S. Environment Protection Agency, Region I
5 Post Office Square, Suite 100 (ORA18-1)
Boston, MA 02109-3912

RECEIVED

JUN 28 2012

EPA ORC
Office of Regional Hearing Clerk

Re: BioSensory, Inc., Docket No. FIFRA-01-2012-0043

Dear Ms. Santiago:

Enclosed for filing in the above-referenced matter are the original and one copy of a Complaint and Notice of Opportunity for Hearing.

Thank you for your assistance in this matter.

Sincerely,

Peter DeCambre
Senior Enforcement Counsel

Enclosures

cc: James Silva, President, BioSensory, Inc.
Michael Boucher, McKenna Long & Aldridge LLP

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 1

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JUN 28 2012

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Office of Regional Hearing Clerk

In the Matter of:)
BioSensory, Inc.)
107 Providence Street)
Putnam, CT 06260)
) Docket No. FIFRA-01-2012-0043
)
Respondent.)
Proceedings under Section)
14(a) of the Federal)
Insecticide, Fungicide, and)
Rodenticide Act, as amended)
7 U.S.C. Section 136l(a).)
)

COMPLAINT

This Complaint and Notice of Opportunity for Hearing (the "Complaint") is being issued under Section 14(a)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), as amended, 7 U.S.C. §136l(a)(1), and the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits, 40 C.F.R. Part 22 ("Part 22" or the "Consolidated Rules"). This Complaint alleges that the Respondent, BioSensory, Inc. ("BioSensory" or the "Respondent"), has violated Sections 12(a)(2)(L), 12(a)(2)(N), 12(a)(1)(F), and 12(a)(1)(B) of FIFRA, 7 U.S.C. §§ 136j(a)(2)(L), 136j(a)(2)(N), 136j(a)(1)(F), and 136j(a)(1)(B), and the regulations promulgated pursuant to FIFRA at 40 C.F.R. Part 152 *et seq.* and 19 C.F.R. §§ 12.110 – 12.117. This Complaint provides written notice of the United States Environmental Protection Agency's ("EPA") proposal to

In the Matter of: BioSensory, Inc., Docket No. FIFRA-01-2012-0043
Complaint and Notice of Opportunity for Hearing

assess administrative penalties for the violations alleged herein. This Complaint also provides notice of Respondent's opportunity to request a hearing on the proposed penalty. The Complainant is, by lawful delegation, the Legal Enforcement Manager in the Office of Environmental Stewardship, EPA Region 1.

STATUTORY AND REGULATORY BACKGROUND

1. The Respondent is BioSensory, Inc., a company that imports into the United States, produces, distributes and sells insect management products and devices, among other things. Respondent also imported, distributed and sold the "NightWatch Bedbug Monitor" and "Dragonfly II Mosquito Trap" devices. Respondent is a business incorporated under the laws of the Delaware, doing business at all relevant times in Connecticut. Respondent's principal place of business is located at 107 Providence Street, Putnam, Connecticut 06260.

2. 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.

3. Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), defines "to distribute or sell" as "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."

4. Respondent operates a facility at 107 Providence Street in Putnam, Connecticut (the "BioSensory Facility"). Pursuant to Section 7(a) and (b) of FIFRA, 7 U.S.C. § 136e(a) and (b), and 40 C.F.R. § 167.20, on or about June 1, 1998, BioSensory registered the BioSensory

In the Matter of: BioSensory, Inc., Docket No. FIFRA-01-2012-0043
Complaint and Notice of Opportunity for Hearing

Facility as a pesticide-producing establishment. EPA's national office in Washington, D.C. ("EPA Headquarters") assigned the Office of Pesticide Program company number 70909 to BioSensory. Subsequently, EPA Region 1 assigned the EPA Establishment Number 70909-CT-001 to the Facility.

5. Section 2(dd) of FIFRA, 7 U.S.C. § 136(dd), defines the term "establishment" as "any place where a pesticide or device or active ingredient used in producing a pesticide is produced, or held, for distribution or sale." Accordingly, the BioSensory Facility is an "establishment," as defined under Section 2(dd) of FIFRA.

6. Respondent is a "producer" as that term is defined in Section 2(w) of FIFRA, 7 U.S.C. § 136(w), and 40 C.F.R. § 167.3. At all times relevant to the violations alleged in this Compliant, Respondent produced pesticides and/or devices at the BioSensory Facility.

7. Panint Electronic Ltd. ("Panint") operates a facility that is located in Hong Kong, China at the following address: Panint Electronic Ltd, Flat2-4, 7/F, Seapower Centre, 73 Lei Muk Road, Kwai Chung, N.T. (the "Panint Facility"). At all times relevant to the violations alleged in this Compliant, the Panint Facility produced and exported the Dragonfly II Mosquito Trap (hereinafter, "Dragonfly Device") and the NightWatch Bedbug Monitor (hereinafter, "NightWatch Device") to BioSensory as devices for sale and distribution.

8. The Panint Facility is an "establishment," as defined under Section 2(dd) of FIFRA. At all times relevant to the violations alleged in this Compliant, the Panint Facility was not registered as a pesticide-producing establishment under Section 7(a) of FIFRA and 40 C.F.R. § 167.20.

In the Matter of: BioSensory, Inc., Docket No. FIFRA-01-2012-0043
Complaint and Notice of Opportunity for Hearing

9. Section 7(c)(1) of FIFRA, 7 U.S.C. § 136e(c)(1), and the regulations codified at 40 C.F.R. § 167, Subpart E, require any producer operating a registered establishment to report to EPA the types and amounts of each pesticide product that it is currently producing, which it produced during the past year, and which it sold or distributed during the past year.

10. Under 40 C.F.R. § 167.85(d), a producer is responsible for obtaining, completing, and reporting this information each year, even if it has not produced any pesticidal product for the reporting year. This information must be submitted to EPA on a form supplied by EPA on or before March 1 of the year following the calendar year which is the subject of the report.

11. On or about December 5, 2008, EPA issued a Notice of Warning (NOW) [EPA Reference No. FIFRA-NOW-2008-013] to Respondent, pursuant to Section 12(a)(2)(L) of FIFRA, 7 U.S.C. § 136j(a)(2)(L), for failure to file its annual pesticide production report for calendar year 2007, as required by Section 7 of FIFRA, on or before the March 1, 2008 due date. BioSensory received the NOW on or about December 12, 2008.

12. 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-organisms” declared by EPA to be a pest under Section 25(c)(1) of FIFRA, 7 U.S.C. § 136w(c)(1).

13. Section 2(u)(1) of FIFRA, 7 U.S.C. § 136(u)(1), defines the term “pesticide” to mean, in pertinent part, “any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.”

14. Section 2(h) of FIFRA, 7 U.S.C. § 136(h), defines the term “device” as “any

instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animals life (other than man and other bacteria, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides when sold separately therefrom.”

15. EPA regulations at 40 C.F.R Part 152, Subpart Z enumerate the provisions of FIFRA and FIFRA regulations that are applicable to devices. *See* 40 C.F.R § 152.500. Such applicable provisions include, among others, the following:

- a. Labeling requirements under Section 2(q)(1) of FIFRA, 7 U.S.C. §136(q)(1), and 40 C.F.R. Part 156;
- b. Establishment registration and reporting requirements under FIFRA Section 7, 7 U.S.C. § 136e, and 40 C.F.R. Part 167;
- c. Requirements relating to books and records and establishment inspections under Sections 8 and 9 of FIFRA, 7 U.S.C. §§ 136f and 136g, and 40 C.F.R. Part 169;
- d. Importation requirements under FIFRA Section 17, 7 U.S.C. § 136o;
- e. Child-resistant packaging requirements under Section 25(c)(3) of FIFRA, 7 U.S.C. § 136w(c)(3); and,
- f. Requirements relating to FIFRA violations, enforcement, and penalties under Sections 12, 13, and 14 of FIFRA, 7 U.S.C. §§ 136j, 136k, and 136l. *See* 41 Fed. Reg. 51065 (November 19, 1976).

GENERAL ALIGATIONS

16. BioSensory is or was, at times relevant to the violations alleged in this Complaint, a “registrant” as defined under Section 2(y) of FIFRA, 7 U.S.C. §136(y), in that it sought and obtained registration from EPA Headquarters for the following pesticide under Section 3 of FIFRA, 7 U.S.C. § 136a, identified by the EPA registration number assigned thereto:

- a. Dragonfly Octenol Lure, EPA Reg. No. 70909-3 (the “Octenol Lure”).

17. The Octenol Lure contains the active ingredient 1-Octen-3-ol at 24.5%.

In the Matter of: BioSensory, Inc., Docket No. FIFRA-01-2012-0043
Complaint and Notice of Opportunity for Hearing

18. At all times relevant to the violations alleged in this Compliant, BioSensory offered for sale at least two devices for distribution or sale on its website. The first device is the Dragonfly Device (identified by BioSensory part number 503) which is produced in the Panint Facility and imported by BioSensory for distribution or sale in the United States and is used and packaged with the Octenol Lure. The second device is the NightWatch Device (identified by BioSensory part number 506) which is produced in the Panint Facility and imported by BioSensory for distribution or sale in the United States and is used and packaged with the Octenol Lure.

19. At all times relevant to the violations alleged in this Compliant, when sold for use in the Dragonfly Device, the Octenol Lure was packaged with three cartridges in a bag bearing an EPA approved label. The combined Dragonfly Device was packaged with the Octenol Lure three-pack is sold under BioSensory's product number 565.

20. At all times relevant to the violations alleged in this Compliant, when sold for use in the NightWatch Device, the Octenol Lure was packaged with four cartridges in a bag without an EPA approved label. The combined NightWatch Device was packaged with the Octenol Lure four-pack is sold under BioSensory's product number 568.

21. At all times relevant to the violations alleged in this Complaint, by importing, distributing, selling, offering for sale, shipping, and/or delivering for shipment the Dragonfly Device and the NightWatch Device, Respondent engaged in actions that fall within the scope of the term "to distribute or sell" as defined in Section 2(gg) of FIFRA. Accordingly, Respondent is a distributor for purposes of Section 12(a)(2)(N) of FIFRA, 7 U.S.C. § 136j(a)(2)(N).

In the Matter of: BioSensory, Inc., Docket No. FIFRA-01-2012-0043
Complaint and Notice of Opportunity for Hearing

22. Pursuant to Section 12(a)(2)(N) of FIFRA, 7 U.S.C. § 136j(a)(2)(N), it is unlawful for “for any person … who is a registrant, wholesaler, dealer, retailer, or other distributor to fail to file reports required by this subchapter.”
23. The import of pesticides and devices into the United States is governed by Sections 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 EPA.
24. FIFRA Section 17(c), 7 U.S.C. § 136o(c), requires the Secretary of the Treasury to notify the EPA Administrator of the arrival of pesticides and devices in the United States.
25. FIFRA Section 17(e), 7 U.S.C. § 136o(e), requires the Secretary of the Treasury, in consultation with the Administrator, to prescribe regulations for the enforcement of FIFRA Section 17(c).
26. Pursuant to FIFRA Section 17(e), the Secretary of the Treasury, acting through the United States Custom Service, prescribed regulations for the enforcement of Section 17(c) of FIFRA at 19 C.F.R. §§ 12.110 – 12.117 (the “Pesticide/Device Import Regulations”).
27. The Pesticide/Device Import Regulations at 19 C.F.R. § 12.112(a) state, in pertinent part, that “an importer desiring to import pesticides or devices into the United States shall submit to the Administrator a Notice of Arrival of Pesticides and Devices (Environmental Protection Agency Form 3540-1), hereinafter referred to as a Notice of Arrival, prior to the arrival of the shipment in the United States.”
28. Through the Notice of Arrival (“NOA”), the importer reports vital information to

In the Matter of: BioSensory, Inc., Docket No. FIFRA-01-2012-0043
Complaint and Notice of Opportunity for Hearing

EPA regarding the pesticides or devices such as the major active ingredients, quantity, country of origin, producing establishment number, carrier, port of entry, and points of contact. This information allows EPA to make informed decisions, before pesticides and devices arrive in the United States, as to whether such importation will pose unreasonable adverse risks to public health and the environment. The NOA also provides contact information in the event of an emergency related to the movement of potentially toxic pesticide materials.

29. An NOA constitutes a report under Section 12(a)(2)(N) of FIFRA, 7 U.S.C. § 136j(a)(2)(N), that must be filed with the EPA Administrator prior to the arrival of each shipment of pesticides or devices in the United States.

30. On September 28, 2010, a duly authorized EPA inspector (the “Inspector”) conducted a FIFRA inspection at the BioSensory Facility pursuant to Sections 8 and 9 of FIFRA, 7 U.S.C. §§ 136f and 136g, to investigate compliance with FIFRA based on the suspected import, selling and distribution of violative pesticide products or devices into the United States by Respondent (the “September 2010 Inspection”).

31. A device is “misbranded” pursuant to Section 2(q)(1)(D) of FIFRA, 7 U.S.C. § 136(q)(1)(D), in pertinent part, if “its label does not bear the registration number assigned under section 136e of this title [FIFRA Section 7] to each establishment in which it was produced.” See 40 C.F.R. §§ 156.10(a)(1)(v) and 156.10(a)(5).

32. Based upon the September 2010 Inspection, a review of Respondent’s records, and additional documents submitted by Respondent to EPA on or about October 21, 2011, EPA determined that Respondent imported and introduced into the stream of commerce for

In the Matter of: BioSensory, Inc., Docket No. FIFRA-01-2012-0043
Complaint and Notice of Opportunity for Hearing

distribution or sale in the United States the NightWatch and Dragonfly Devices from between September 2009 and October 2010.

33. Section 2(p) of FIFRA, 7 U.S.C. § 136(p), defines the term “labeling” to mean, in pertinent part, “all labels and other written, printed, or graphic matter” either “accompanying the pesticide or device at any time” or “to which reference is made on the label or in literature accompanying the pesticide or device....”

34. Pursuant to Section 12(a)(1)(B) of FIFRA, 7 U.S.C. § 136j(a)(1)(B), it is unlawful “for any person in any State to distribute or sell to any person ... any registered pesticide if any claims made for it as part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration” under Section 3 of FIFRA, 7 U.S.C. § 136a. The prohibition against making substantially differing claims under Section 12(a)(1)(B) extends to advertisements in any advertising medium to which the general public has access and includes, among other things, recommending the use of a registered product for an unregistered use. *See* 40 C.F.R. § 168.22.

35. BioSensory distributes or sells the Dragonfly Device and the NightWatch Device, each of which is produced in the Panint Facility and imported by BioSensory for distribution or sale in the United States. BioSensory distributes or sells both the Dragonfly Device and the NightWatch Device for use with the Octenol Lure.

36. The pesticide registration for the Octenol Lure authorizes the use of the Octenol Lure in the Dragonfly Device. At all times relevant to the violations alleged in this Complaint, the pesticide registration for the Octenol Lure does not authorize the use of the Octenol Lure in

In the Matter of: BioSensory, Inc., Docket No. FIFRA-01-2012-0043
Complaint and Notice of Opportunity for Hearing

the NightWatch Device.

37. BioSensory distributes or sells the NightWatch Device with the Octenol Lure, together as a unit. BioSensory also distributes or sells the Dragonfly Device with the Octenol Lure, together as a unit.

VIOLATIONS

COUNT 1 – Failure to Submit Annual Reports (Reporting Years 2007 – 2010)

38. Paragraphs 1 through 37 are realleged and incorporated by reference.

39. Pursuant to Section 7(c)(1) of FIFRA, 7 U.S.C. § 136e(c)(1), and 40 C.F.R. Part 167, Subpart E, any producer operating an establishment registered as a pesticide-producing establishment under FIFRA Section 7 must initially report to EPA, within 30 days of the establishment registration, the types and amounts of each pesticide product that is currently producing, that is produced during the past year, and that it sold or distributed during the past year. In addition, FIFRA Section 7(c)(1) requires any producer operating a registered establishment to report such information to EPA annually, by March 1, for the preceding calendar year.

40. Notwithstanding the March 1 due date, the Respondent did not submit its pesticide production report for the 2007, 2008, 2009, and 2010 reporting years.

41. Respondent's failure to submit the required information for each of the 2007, 2008, 2009, and 2010 reporting years on or before March 1 of 2008, 2009, 2010, and 2011, respectively, constitutes four (4) separate violations of 7(c)(1) of FIFRA and 40 C.F.R. Part 167, Subpart E. Such failures are unlawful pursuant to Section 12(a)(2)(L) of FIFRA and each is a

violation for which penalties may be assessed pursuant to Section 14(a)(1) of FIFRA, 7 U.S.C. § 136l(a)(1).

COUNT 2 – Failure to File Reports of Pesticide/Device Import

42. Paragraphs 1 through 41 are realleged and incorporated by reference.
43. Based upon the September 2010 Inspection, a review of Respondent's records, and additional documents submitted by Respondent to EPA on or about October 21, 2011, including the U.S. Customs Border Control ("USCBP") Form 7501 and USCBP Form 3461, the EPA Inspector documented that Respondent imported for distribution or sale the Dragonfly Device and the NightWatch Device from the Panint Facility for a period of at least one year, from September 2009 to September 2010.
44. Based upon the September 2010 Inspection, a review of Respondent's records, additional documents submitted by Respondent to EPA on or about October 21, 2011, and further EPA investigation, Respondent imported on six separate occasions the NightWatch Device and/or the Dragonfly Device into the United States for distribution or sale without filing the required NOAs with EPA, as required by Section 17 of FIFRA, 7 U.S.C. § 136o, and 19 C.F.R. § 12.112(a). The date of the six shipments and number of units included in each were September 30, 2009 (216 pieces), March 31, 2010 (108 pieces), May 26, 2010 (216 pieces), June 05, 2010 (88 pieces), June 29, 2010 (107 pieces), and August 23, 2010 (154 pieces).
45. Between September 30, 2009 and August 23, 2010, Respondent imported the Dragonfly and/or NightWatch Devices into the United States for distribution or sale through at least six separate shipments without filing the required NOA with EPA, as required by Section

17 of FIFRA, 7 U.S.C. § 136o, and 19 C.F.R. § 12.112(a).

46. Accordingly, on at least six (6) separate occasions Respondent violated Section 12(a)(2)(N) of FIFRA, 7 U.S.C. § 136j(a)(2)(N), and the regulations promulgated pursuant to FIFRA at 19 C.F.R. §§ 12.110 – 12.117, each of which is a violation for which penalties may be assessed pursuant to Section 14(a)(1) of FIFRA.

COUNT 3 –Distribution or Sale of Misbranded Devices

47. Paragraphs 1 through 46 are realleged and incorporated by reference.

48. At all times relevant to the violations alleged in this Compliant, Respondent imported and introduced into the stream of commerce for distribution or sale in the United States the NightWatch Device on at least sixty-eight (68) separate occasions, from on or about September 2009 to on or about October 2010.

49. At all times relevant to the violations alleged in this Compliant, Respondent imported and introduced into the stream of commerce for distribution or sale in the United States the Dragonfly Device on at least eighteen (18) separate occasions, from on or about September 2009 to on or about October 2010.

50. On information and belief, for each separate instance of importation and introduction into the stream of commerce for distribution or sale referenced in the preceding Paragraphs 48 and 49, Respondent distributed or sold such devices without the labels bearing a valid registration number assigned under FIFRA Section 7 to the establishment in which the devices were produced, as required under Section 7(a) of FIFRA, 7 U.S.C. § 136e(a), and 40 C.F.R. § 156.10(f).

In the Matter of: BioSensory, Inc., Docket No. FIFRA-01-2012-0043
Complaint and Notice of Opportunity for Hearing

51. Based upon the September 2010 Inspection, a review of Respondent's records, and additional documents submitted by Respondent to EPA on or about October 21, 2011, EPA determined that each distribution or sale referenced in Paragraphs 48 and 49, above, represents the distribution or sale of a misbranded pesticide under Section 2(q)(1)(D), 7 U.S.C. § 136(q)(1)(D).

52. Accordingly, on at least eighty-six (86) separate occasions, Respondents violated Section 12(a)(1)(F) of FIFRA, 7 U.S.C. § 136j(a)(1)(F), and the FIFRA regulations at 40 C.F.R. § 156.10(f), each of which is a violation for which penalties may be assessed pursuant to Section 14(a)(1) of FIFRA.

COUNT 4 – Distribution or Sale of Registered Pesticide for Unregistered Use

53. Paragraphs 1 through 52 are realleged and incorporated by reference.

54. The pesticide registration for the Octenol Lure (EPA Reg. No. 70909-3) authorizes use of the Octenol Lure in BioSensory's Dragonfly Device but not in BioSensory's NightWatch Device.

55. BioSensory distributes or sells the NightWatch Device with the Octenol Lure, together as a unit.

56. Based upon the September 2010 Inspection, a review of Respondent's records, and additional documents submitted by Respondent to EPA on or about October 21, 2011, EPA determined that Respondent distributed or sold the Dragonfly Lure, packaged with the NightWatch Device, together as a unit, on at least twenty-nine (29) separate occasions between September 2009 to October 2010.

In the Matter of: BioSensory, Inc., Docket No. FIFRA-01-2012-0043
Complaint and Notice of Opportunity for Hearing

57. Based upon the September 2010 Inspection, a review of Respondent's records, and additional documents submitted by Respondent to EPA on or about October 21, 2011, EPA determined that Respondent distributed or sold the Dragonfly Lure for an unregistered use on at least twenty-nine (29) separate occasions between September 2009 to October 2010.

58. Accordingly, on at least twenty-nine (29) separate occasions, Respondent violated Section 12(a)(1)(B) of FIFRA, 7 U.S.C. § 136j(a)(1)(B), and the regulations promulgated pursuant to FIFRA at 40 C.F.R. Part 152 *et seq.*, each of which is a violation for which penalties may be assessed pursuant to Section 14(a)(1) of FIFRA.

PROPOSED CIVIL PENALTY

59. 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 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 thereunder and codified at 40 C.F.R. Part 19, this amount was increased to \$6,500 for violations occurring after March 15, 2004, *see* 69 Fed. Reg. 7121 (February 13, 2004), and to \$7,500 for violations occurring after January 12, 2009. *See* 73 Fed. Reg. 75340-46 (December 11, 2008).

60. Based on the foregoing findings of violations of FIFRA, EPA seeks to assess a civil penalty of up to \$7,500 per violation for each of the violations alleged in Counts 1-4 above. The assessment of a penalty for the violations is warranted because the violations are serious and

In the Matter of: BioSensory, Inc., Docket No. FIFRA-01-2012-0043
Complaint and Notice of Opportunity for Hearing

involve: 1) failure to file annual reports of the type and amount of each pesticide product produced, sold, or distributed; 2) importing pesticides or devices into the United States without submitting the required reports (i.e., NOAs) with EPA; 3) distribution or sale of misbranded pesticide devices not displaying a valid EPA establishment registration number; and 4) distribution or sale of a registered pesticide for an unregistered use.

61. The FIFRA requirement that a producer operating a registered establishment report to EPA the type and amounts of each pesticide product that it is currently producing, that is produced during the past year, and that it sold or distributed during the past year is important because these annual reports are generally the only mechanism available for obtaining information on the type and quantity of pesticidal products produced in registered domestic and foreign establishments. This information is important to Agency efforts to protect human health and the environment and maintain the integrity of the pesticide program. EPA uses this information to effectively prioritize and target inspections and for a variety of risk assessment and risk reduction activities.

62. The FIFRA requirement to submit NOA reports to EPA prior to importing a pesticide or device into the United States protects against unreasonable risks to human health or the environment by providing EPA with vital information regarding the pesticide or device before its arrival into the United States for distribution or sale. NOAs provide important information regarding any pesticide or device entering the United States —including active ingredients, quantities, countries of origin, identity of producing establishments, carriers, and ports of entry— and enable EPA to make informed decisions about whether importation will

In the Matter of: BioSensory, Inc., Docket No. FIFRA-01-2012-0043
Complaint and Notice of Opportunity for Hearing

pose unreasonable adverse risks to public health or the environment. NOAs also provide critical contact information in the event of an emergency related to the movement of potentially toxic pesticide materials.

63. The FIFRA requirement to display a valid EPA registration number for pesticide products is important because it helps maintain the integrity of the federal pesticide program implemented by EPA. A primary purpose of that program is to ensure that no pesticide or device is produced, imported, distributed, sold, or used in a manner that may pose an unreasonable risk to human health or the environment. Properly registering and displaying EPA registration number for pesticide products helps EPA carry out compliance, risk assessment, and risk reduction functions under FIFRA that are important for protecting human health and the environment. Without displaying an EPA registration number on a pesticide product, EPA has no way of determining what pesticides are being produced, sold, and distributed.

64. The FIFRA prohibition against the distribution or sale of misbranded pesticides or devices and the prohibition against distribution or sale of registered pesticides/devices for an unregistered use are each important because each helps ensure that pesticide end users and members of the public have fully compliant, accurate, and up-to-date information regarding pesticides or devices in the marketplace and the establishments in which the pesticides or devices are produced.

65. In determining the amount of the penalty to be assessed under Section 14(a) of FIFRA, 7 U.S.C. § 136l(a), 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

In the Matter of: BioSensory, Inc., Docket No. FIFRA-01-2012-0043
Complaint and Notice of Opportunity for Hearing

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 (the "Penalty Policy"), and the May 2010 "Enforcement Response Policy for FIFRA Section 7(c) Pesticide Producing Establishment Reporting Requirement" (the "Penalty Policy"), copies of which accompany this Complaint.

66. Prior to any hearing on this case, EPA will file a document specifying a proposed penalty for Respondent's FIFRA violations and explaining how the proposed penalty was calculated, as required by the Consolidated Rules (enclosed).

67. 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

68. 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. 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

In the Matter of: BioSensory, Inc., Docket No. FIFRA-01-2012-0043
Complaint and Notice of Opportunity for Hearing

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 (Mail Code: DRA 18-1)
U.S. Environmental Protection Agency
Region 1
5 Post Office Square, Suite 100
Boston, Massachusetts 02109-3912

69. 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 Peter DeCambre, the attorney assigned to represent EPA and designated to receive service on behalf of Complainant in this matter at:

Peter DeCambre
Enforcement Counsel
U.S. Environmental Protection Agency
Office of Environmental Stewardship (OES04-1)
5 Post Office Square, Suite 100
Boston, MA 02109-3912
(617) 918-1890
(617) 918-1809 (paper fax)
(617) 918-0890 (electronic fax)

70. 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.

71. 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 and a waiver of the right to a hearing, and the above cited penalties may be assessed without further proceedings.

INFORMAL SETTLEMENT CONFERENCE

72. 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 the above-referenced EPA attorney, Peter DeCambre.

73. 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.

74. If Respondent has any questions concerning the settlement process, or wishes to arrange for an informal conference, Respondent should contact Peter DeCambre at (617) 918-1890.



Audrey Zucker, Acting Legal Enforcement Manager
Office of Environmental Stewardship

Date: 6/27/12

In the Matter of: BioSensory, Inc., Docket No. FIFRA-01-2012-0043
Complaint and Notice of Opportunity for Hearing

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 (DRA 18-1)
Boston, MA 02109-3912

One Copy by Certified Mail
Return Receipt Requested to:

Michael Boucher
McKenna Long & Aldridge LLP
1900 K Street NW
Washington, DC 20006

Date : 6/28/12

Signed:


Peter DeCambre

Senior Enforcement Counsel
Office of Environmental Stewardship (OES04-1)
U.S. Environmental Protection Agency
5 Post Office Square, Suite 100
Boston, MA 02109-3912