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**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION IX
75 HAWTHORNE STREET
SAN FRANCISCO, CALIFORNIA 94105**

_____)	
In the Matter of:)	Docket No. FIFRA- 09-2023-0069
)	
HIRO Systems Hawaii LLC)	COMPLAINT AND NOTICE OF
)	OPPORTUNITY FOR HEARING
)	
<u>Respondent.</u>)	

I. PRELIMINARY STATEMENT

This is a civil administrative action brought pursuant to section 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (“FIFRA”), 7 U.S.C. § 136l(a), for the assessment of a civil administrative penalty against HIRO Systems Hawaii LLC for violations of section 12 of FIFRA, 7 U.S.C. § 136j.

Complainant is the Manager of the Toxics Section in the Enforcement and Compliance Assurance Division, U.S. Environmental Protection Agency, Region IX, who has been duly delegated to issue this Complaint and Notice of Opportunity for Hearing (“Complaint”) pursuant to EPA Region 9 Delegation R9-5-14 (Feb. 11, 2013) and EPA Administrator Delegation 5-14 (May 11, 1994-updated Feb. 4, 2016).

Respondent is HIRO Systems Hawaii LLC (“Respondent”), a limited liability company registered to conduct business in the State of Hawaii with headquarters in Honolulu, Hawaii.

II. STATUTORY AND REGULATORY BACKGROUND

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

2. Section 2(h) of FIFRA, 7 U.S.C. § 136(h), defines “device,” in part, as “any instrument or contrivance . . . which is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life . . .”

3. Section 2(t) of FIFRA, 7 U.S.C. § 136(t), defines “pest,” in part, as any “form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other living animals) which the Administrator declares to be a pest under section 25(c)(1).”

4. 40 C.F.R. § 152.5 provides that pursuant to the authority in section 25(c)(1) of FIFRA, 7 U.S.C. § 136w(c)(1), the Administrator declared that a pest is “[a]ny fungus, bacterium, virus, prion, or other microorganism, except for those on or in living man or other living animals and those on or in processed food or processed animal feed, beverages, drugs . . . and cosmetics. . . .”

5. Section 2(u) of FIFRA, 7 U.S.C. § 136(u), defines a “pesticide” in part, as any “substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.”

6. 40 C.F.R. § 152.15 provides that “a pesticide is any substance (or mixture of substances) intended for a pesticidal purpose” and that a substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration, if:

a) The person who distributes or sells the substance claims, states, or implies (by labeling or otherwise) that:

(1) the substance (either by itself or in combination with any other substance) can or should be used as a pesticide; or

(2) the substance consists of or contains an active ingredient and that it can be used to manufacture a pesticide; or

b) The substance consists of or contains one or more active ingredients and has no significant commercially valuable use as distributed or sold other than

(1) use for pesticidal purpose (by itself or in combination with any other

substance),

(2) use for manufacture of a pesticide; or

- c) The person who distributes or sells the substance has actual or constructive knowledge that the substance will be used, or is intended to be used, for a pesticidal purpose.

7. Section 2(mm) of FIFRA, 7 U.S.C. § 136(mm), provides “antimicrobial pesticides” are pesticides intended to “disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms; or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime.”

8. Sections 2(p)(1) and (2) of FIFRA, 7 U.S.C. §§ 136(p)(1) and (2), define “label” as “the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers” and “labeling” in part, as “all labels and all other written, printed, or graphic matter –

A) accompanying the pesticide or device at any time; or

B) to which reference is made on the label or in literature accompanying the pesticide...”

9. Section 2(q)(1) of FIFRA, 7 U.S.C. § 136(q)(1), states: “[a] pesticide is misbranded if–

A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;

...

D) its label does not bear the registration number assigned under section 7 to each establishment in which it was produced;

E) any word, statement, or other information required by or under the authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared to other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with,

together with any requirements imposed under section 3(d) of this Act, are adequate to protect health and the environment; [or]

G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 3(d) of this Act, is adequate to protect health and the environment.”

10. 40 C.F.R. § 156.10(a)(1) provides every pesticide product shall bear a label, the contents of which must show clearly and prominently the following:

- (i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;
- (ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;
- (iii) The net contents as prescribed in paragraph (d) of this section;
- (iv) The product registration number as prescribed in paragraph (e) of this section;
- (v) The producing establishment number as prescribed in paragraph (f) of this section;
- (vi) An ingredient statement as prescribed in paragraph (g) of this section;
- ...
- (vii) The directions for use as prescribed in paragraph (i) of this section...

11. 40 C.F.R. § 156.10(a)(5) provides “[p]ursuant to section 2(q)(1)(A) of the Act, a pesticide or a device . . . is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

- ...
- (ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;
- ...
- (iv) A false or misleading comparison with other pesticides or devices;
- (v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;
- ...
- (ix) Claims as to the safety of the pesticide or its ingredients, including statements such as ‘safe,’ ‘nonpoisonous,’ ‘noninjurious,’ ‘harmless or ‘nontoxic to humans and

pets' with or without such a qualifying phrase as 'when used as directed;' and
(x) Non-numerical and/or comparative statements on the safety of the product,
including but not limited to:

- (A) 'Contains all natural ingredients'
- (B) 'Among the least toxic chemicals known' or
- (C) 'Pollution approved.'"

12. 40 C.F.R. § 156.10(f) requires the producing establishment registration number appear in any suitable location on the label or immediate container and preceded by the phrase "EPA Est.", of the final establishment at which the product was produced.

13. 40 C.F.R. 152.3 defines "pesticide product" as a pesticide in the particular form (including composition, packaging, and labeling) in which the pesticide is, or is intended to be, distributed or sold. The term includes any physical apparatus used to deliver or apply the pesticide if distributed or sold with the pesticide.

14. Section 2(w) of FIFRA, 7 U.S.C. § 136(w), defines "produce" as "to manufacture, prepare, compound, propagate, or process any pesticide or device or active ingredient used in producing a pesticide."

15. 40 C.F.R. § 167.3 provides "[p]roduce means to manufacture, prepare, propagate, compound, or process any pesticide . . . or to package, repack, label, relabel, or otherwise change the container of any pesticide or device."

16. Section 2(w) of FIFRA, 7 U.S.C. § 136(w), defines "producer" to mean "the person who manufactures, prepares, compounds, propagates, or processes any pesticide or device or active ingredient used in producing a pesticide."

17. 40 C.F.R. § 167.3 defines "producer" as "any person, as defined by the Act, who produces any pesticide, active ingredient, or device (including packaging, repackaging, labeling and relabeling)."

18. Section 2(dd) of FIFRA, 7 U.S.C. § 136(dd), defines "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."

19. Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), defines "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.” *See also* 40 C.F.R. § 152.3, definition of “distribute or sell.”

20. Section 3(a) of FIFRA, 7 U.S.C. § 136a(a), provides that no person in any State may distribute or sell to any person any pesticide that is not registered under this Act. *See also* 40 C.F.R. § 152.15.

21. Section 7(a) of FIFRA, 7 U.S.C. § 136e(a), provides that no person shall produce any pesticide subject to this subchapter in any State unless the establishment in which it is produced is registered with the Administrator.

22. Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), provides 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.

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

24. Section 12(a)(1)(F) of FIFRA, 7 U.S.C. § 136j(a)(1)(F), provides it shall be unlawful for any person in any State to distribute or sell to any person any device which is misbranded.

25. Section 12(a)(2)(L) of FIFRA, 7 U.S.C. § 136j(a)(2)(L), provides it shall be unlawful for any person who is a producer to violate any provisions of section 136e of this title.

III. ALLEGATIONS

26. Paragraphs 1 through 25 above are hereby alleged and incorporated by reference.

27. At all times relevant to this Complaint, Respondent was a limited liability company organized under the laws of the State of Hawaii.

28. Therefore, at all times relevant to this Complaint, Respondent was a “person” as defined by section 2(s) of FIFRA, 7 U.S.C. § 136(s).

29. At all times relevant to this Complaint, Respondent was the owner and/or operator of the business located at 1450 Ala Moana Blvd., Ste. 1235 in Honolulu, Hawaii (“Facility”).

30. At times relevant to this Complaint, Respondent sold at the Facility the following products: ***HIRO Proprietary Blend Raw TEG, HOCL Hypo-Chlorus Acid Eco-Friendly Sanitization Solution by Hiro, HIROCL Hypochlorus Acid Sanitization Solution, Clean Republic Disinfectant + Sanitizer, and Side-Kik HOCL Generator.***

HIRO Proprietary Blend Raw TEG

31. At times relevant to the Complaint, the labeling for the product, ***HIRO Proprietary Blend Raw TEG***, bore the following claims:

- a) “We provide non-toxic sanitizer services for every building...”
- b) “TEG (triethylene glycol) solution ...creates a NAS (Nano Atmospheric Sanitization) DRY Cloud that is deemed NON-TOXIC by the FDA and EPA, created total aerial and surface sanitization up to 40,000 square feet in minutes.”
- c) “Teg [sic] Glycol is the best sanitizer for home & commercial places...”
- d) “This powerful solution has been tested and proven by the FAA as a powerful viricidal agent while at the same time non-toxic to humans... making TEG the perfect solution for disinfecting airplane cabins...”
- e) “HIRO Systems Hawaii is your one-stop shop for the best commercial non-toxic sanitizer solution.”

32. Based on the claims made in its labeling as described in paragraph 31, the product, ***HIRO Proprietary Blend Raw TEG***, was intended to be used as a sanitizer, viricide, and disinfectant.

33. “Viruses” are a “pest,” as that term is defined in section 2(t) of FIFRA, 7 U.S.C § 136(t).

34. Based on the claims made in its labeling as described in paragraph 31, the product, ***HIRO Proprietary Blend Raw TEG***, was a “pesticide,” as that term is defined in section 2(u) of FIFRA, 7 U.S.C. § 136(u), and 40 C.F.R. § 152.15, and specifically, an “antimicrobial pesticide” pursuant to section 2(mm)(1)(A)(i) of FIFRA, 7 U.S.C. § 136(mm)(1)(A)(i).

HOCL Hypo-chlorus Acid Eco-Friendly Sanitization Solution by Hiro

35. At times relevant to the Complaint, the labeling for the product, ***HOCL Hypo-chlorus Acid Eco-Friendly Sanitization Solution by Hiro*** bore the following claims:

- a) “HOCL IS LISTED BY THE EPA AS AN APPROVED CHEMICAL AGAINST THE SARS/COV2 VIRUS.”
- b) “NON-TOXIC YET TESTED UP TO 80x MORE EFFECTIVE THAN BLEACH AT NEUTRALIZING PATHOGENS.”

36. Based on its name, the product, ***HOCL Hypo-chlorus Acid Eco-Friendly Sanitization Solution by Hiro***, was intended to be used as a sanitizer.

37. “SARS/COV2 VIRUS” is a “pest,” as that term is defined in section 2(t) of FIFRA, 7 U.S.C. § 136(t).

38. Based on its name and the claims made in its labeling as described in paragraph 35, the product, ***HOCL Hypo-chlorus Acid Eco-Friendly Sanitization Solution by Hiro***, was a “pesticide,” as that term is defined in section 2(u) of FIFRA, 7 U.S.C. § 136(u), and 40 C.F.R. § 152.15, and specifically, an “antimicrobial pesticide” pursuant to section 2(mm)(1)(A)(i) of FIFRA, 7 U.S.C. § 136(mm)(1)(A)(i).

HIROCL Hypochlorus Acid Sanitization Solution

39. At times relevant to the Complaint, the labeling for the product, ***HIROCL Hypochlorus Acid Sanitization Solution***, bore the following claims:

- a) “Our 100ppm HirOCL (Hypochlorous Acid) is the perfect natural and non-toxic sanitizer...”
- b) “...for effective everyday sanitization.”
- c) “The family set [which includes HIROCL Hypochlorus Acid Sanitization Solution] is the perfect option for ensuring that your family is safe not only from pathogens such as the coronavirus...”

40. Based on its name and the claims made in its labeling as described in paragraph 39, the product, ***HIROCL Hypochlorus Acid Sanitization***, was intended to be used as a sanitizer.

41. “Pathogens such as the coronavirus” are “pests,” as that term is defined in section 2(t) of FIFRA, 7 U.S.C. § 136(t).

42. Based on its name and the claims made in its labeling as described in paragraph 39, the product, ***HIROCL Hypochlorus Acid Sanitization Solution***, was a “pesticide,” as that term is defined in section 2(u) of FIFRA, 7 U.S.C. § 136(u), and 40 C.F.R. § 152.15, and specifically, an “antimicrobial pesticide” pursuant to section 2(mm)(1)(A)(i) of FIFRA, 7 U.S.C. § 136(mm)(1)(A)(i).

Clean Republic Disinfectant + Sanitizer

43. ***Clean Republic Disinfectant + Sanitizer*** is a “pesticide” assigned EPA Reg. No: 85134-1-97177, as defined in section 2(u) of FIFRA, 7 U.S.C. § 136(u), and 40 C.F.R. § 152.15.

Side-Kik HOCL Generator

44. At times relevant to this Complaint, the labeling for the product, ***Side-Kik HOCL Generator*** bore the following claims:

- a) “[Side-Kik HOCL Generator] empowers you to create your very own HOCL (Hypochlorous Acid) and EPA-approved disinfectant for COVID-19”

- b) “Food disinfection”
- c) “Household disinfection”

45. Based on the claims made in its labeling as described in paragraph 44, the product, ***Side-kik HOCL Generator***, was intended to be used for disinfection.

46. The virus that causes “COVID-19” is a “pest,” as that term is defined in section 2(t) of FIFRA, 7 U.S.C. § 136(t).

47. The product, ***Side-Kik HOCL Generator***, was an instrument or contrivance “intended for trapping, destroying, repelling, or mitigating a pest . . .”.

48. Therefore, based on the claims made in its labeling as described in paragraph 44, the product, ***Side-Kik HOCL Generator***, was a “device,” as that term is defined in section 2(h) of FIFRA, 7 U.S.C. § 136(h).

COUNT 1: Distribution or Sale of an Unregistered Pesticide

HIRO Proprietary Blend Raw TEG

49. Paragraphs 1 through 48 are hereby realleged and incorporated by reference.

50. On or about May 19, 2022, Respondent offered for sale the product, ***HIRO Proprietary Blend Raw TEG***, at its Facility.

51. Therefore, on or about May 19, 2022, Respondent “distributed or sold” ***HIRO Proprietary Blend Raw TEG***, as that term is defined in section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), and 40 C.F.R. § 152.3.

52. At all times relevant to this Complaint, ***HIRO Proprietary Blend Raw TEG*** was not registered with EPA pursuant to section 3 of FIFRA, 7 U.S.C. § 136a.

53. Therefore, Respondent’s distribution or sale of the pesticide, ***HIRO Proprietary Blend Raw TEG***, on or about May 19, 2022, constitutes one (1) violation of section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), which states that it is 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, 7 U.S.C. § 136a.

COUNT 2: Distribution or Sale of a Misbranded Pesticide

HIRO Proprietary Blend Raw TEG

54. Paragraphs 1 through 53 are hereby realleged and incorporated by reference.

55. On or about May 19, 2022, the labeling for the product, ***HIRO Proprietary Blend Raw TEG***, included the following claims:

- a) "...creates a NAS (Nano Atmospheric Sanitization) DRY Cloud that is deemed NON-TOXIC by the FDA and EPA.."
- b) "This powerful solution has been tested and proven by the FAA as a powerful viricidal agent while at the same time non-toxic to humans..."
- c) "... the best commercial non-toxic sanitizer solution."

56. The claims in the labeling described in paragraph 55 constitute "false and misleading statements" pursuant to 40 C.F.R. §§ 156.10(a)(5)(v) and (ix), and was therefore "misbranded," as that term is defined in section 2(q)(1) of FIFRA, 7 U.S.C. § 136(q)(1), and 40 C.F.R. § 156.10(a)(5).

57. On or about May 19, 2022, the label for the product, ***HIRO Proprietary Blend Raw TEG***, did not include directions for use, net contents, or ingredient statement.

58. The contents of the label described in paragraph 57 did not include information required under 40 C.F.R. § 156.10(a)(1), and was therefore "misbranded," as that term is defined in section 2(q)(1)(F) of FIFRA, 7 U.S.C. § 136(q)(1)(F).

59. Consequently, Respondent's distribution or sale of the pesticide, ***HIRO Proprietary Blend Raw TEG***, on or about May 19, 2022, constitute one (1) violation of section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), which states that it is unlawful for any person in any state to distribute or sell to any person any pesticide which is misbranded.

COUNT 3: Production in an Unregistered Establishment

HIRO Proprietary Blend Raw TEG

60. Paragraphs 1 through 59 are hereby realleged and incorporated by reference.

61. After June 2, 2021, but prior to May 19, 2022, Respondent transferred the contents of raw TEG solution from one container into separate containers at its Facility.

62. After June 2, 2021, but prior to May 19, 2022, Respondent branded the containers of the repackaged raw TEG solution described in paragraph 61 with a HIRO label identifying it as ***HIRO Proprietary Blend Raw TEG*** at its Facility.

63. Therefore, Respondent "produced" ***HIRO Proprietary Blend Raw TEG***, 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 its Facility, and Respondent was 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.

64. At all times relevant to this Complaint, Respondent's Facility was an "establishment,"

as that term is defined in section 2(dd) of FIFRA, 7 U.S.C. § 136(dd).

65. At all times relevant to this Complaint, Respondent's Facility was not registered with the Administrator as an "establishment," as required pursuant to section 7(a) of FIFRA, 7 U.S.C. § 136e(a).

66. Therefore, Respondent's production of the pesticide, ***HIRO Proprietary Blend Raw TEG*** at its Facility constitutes one (1) violation of section 12(a)(2)(L) of FIFRA, 7 U.S.C. § 136j(a)(2)(L), which states it shall be unlawful for any person who is a producer to violate any provisions of section 7 of FIFRA.

COUNT 4: Distribution or Sale of an Unregistered Pesticide

HOCL Hypo-Chlorus Acid Eco-Friendly Sanitization Solution by Hiro

67. Paragraphs 1 through 48 are hereby realleged and incorporated by reference.

68. On or about May 19, 2022, Respondent offered for sale the product, ***HOCL Hypo-Chlorus Acid Eco-Friendly Sanitization Solution by Hiro***, at its Facility.

69. Therefore, on or about May 19, 2022, Respondent "distributed or sold" ***HOCL Hypo-Chlorus Acid Eco-Friendly Sanitization Solution by Hiro***, as that term is defined in section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), and 40 C.F.R. § 152.3.

70. At all times relevant to this Complaint, ***HOCL Hypo-Chlorus Acid Eco-Friendly Sanitization Solution by Hiro*** was not registered with EPA pursuant to section 3 of FIFRA, 7 U.S.C. § 136a.

71. Therefore, Respondent's distribution or sale of the pesticide, ***HOCL Hypo-Chlorus Acid Eco-Friendly Sanitization Solution by Hiro***, on or about May 19, 2022, constitutes one (1) violation of section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), which states that it is 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, 7 U.S.C. § 136a.

COUNT 5: Distribution or Sale of a Misbranded Pesticide

HOCL Hypo-Chlorus Acid Eco-Friendly Sanitization Solution by Hiro

72. Paragraphs 1 through 48 and 68 through 71 are hereby realleged and incorporated by reference.

73. On or about May 19, 2022, the labeling for the product, ***HOCL Hypo-Chlorus Acid Eco-Friendly Sanitization Solution by Hiro***, included the following claims:

- a) "HOCL IS LISTED BY THE EPA AS AN APPROVED CHEMICAL AGAINST

THE SARS/COV2 VIRUS.”

- b) “NON-TOXIC YET TESTED UP TO 80x MORE EFFECTIVE THAN BLEACH AT NEUTRALIZING PATHOGENS.”

74. The claims in the labeling described in paragraph 73 constitute “false and misleading statements” pursuant to 40 C.F.R. §§ 156.10(a)(5)(iv), (v) and (ix), and was therefore “misbranded,” as that term is defined in section 2(q)(1) of FIFRA, 7 U.S.C. § 136(q)(1), and 40 C.F.R. § 156.10(a)(5).

75. On or about May 19, 2022, the label for the product, ***HOCL Hypo-Chlorus Acid Eco-Friendly Sanitization Solution by Hiro***, did not include directions for use, net contents, or ingredient statement.

76. The contents of the label described in paragraph 75 did not include information required under 40 C.F.R. § 156.10(a)(1), and was therefore “misbranded” as that term is defined in section 2(q)(1)(F) of FIFRA, 7 U.S.C. § 136(q)(1)(F).

77. Consequently, Respondent’s distribution or sale of the pesticide, ***HOCL Hypo-Chlorus Acid Eco-Friendly Sanitization Solution by Hiro***, on or about May 19, 2022, constitutes one (1) violation of section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), which states that it is unlawful for any person in any state to distribute or sell to any person any pesticide which is misbranded.

COUNT 6: Production in an Unregistered Establishment

HOCL Hypo-Chlorus Acid Eco-Friendly Sanitization Solution by Hiro

78. Paragraphs 1 through 48, 68 through 71, and 73 through 77, are hereby realleged and incorporated by reference.

79. After June 2, 2021, but prior to May 19, 2022, Respondent transferred sodium hypochlorite solution from one container into separate containers at its Facility.

80. After June 2, 2021, but prior to May 19, 2022, Respondent branded the repackaged containers of sodium hypochlorite described in paragraph 79 with a HIRO label identifying it as ***HOCL Hypo-Chlorus Acid Eco-Friendly Sanitization Solution by Hiro*** at its Facility.

81. At times relevant to this Complaint, Respondent “produced” ***HOCL Hypo-Chlorus Acid Eco-Friendly Sanitization Solution by Hiro***, 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 its Facility, and Respondent was 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.

82. At all times relevant to this Complaint, Respondent's Facility was an "establishment," as that term is defined in section 2(dd) of FIFRA, 7 U.S.C. § 136(dd).

83. At all times relevant to this Complaint, Respondent's Facility was not registered with the Administrator as an "establishment," as required pursuant to section 7(a) of FIFRA, 7 U.S.C. § 136e(a).

84. Therefore, Respondent's production of the pesticide, ***HOCL Hypo-Chlorus Acid Eco-Friendly Sanitization Solution by Hiro***, at the facility constitutes one (1) violation of section 12(a)(2)(L) of FIFRA, 7 U.S.C. § 136j(a)(2)(L), which states it shall be unlawful for any person who is a producer to violate any provisions of section 7 of FIFRA.

COUNT 7: Distribution or Sale of an Unregistered Pesticide

HIROCL Hypochlorus Acid Sanitization Solution

85. Paragraphs 1 through 48 are hereby realleged and incorporated by reference.

86. On or about May 19, 2022, Respondent offered for sale the product, ***HIROCL Hypochlorus Acid Sanitization Solution***, at its Facility.

87. Therefore, on or about May 19, 2022, Respondent "distributed or sold" ***HIROCL Hypochlorus Acid Sanitization Solution***, as that term is defined in section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), and 40 C.F.R. § 152.3.

88. At all times relevant to this Complaint, ***HIROCL Hypochlorus Acid Sanitization Solution*** was not registered with EPA pursuant to section 3 of FIFRA, 7 U.S.C. § 136a.

89. Therefore, Respondent's distribution or sale of the pesticide, ***HIROCL Hypochlorus Acid Sanitization Solution***, on or about May 19, 2022, constitutes one (1) violation of section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), which states that it is 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, 7 U.S.C. § 136a.

COUNT 8: Distribution or Sale of a Misbranded Pesticide

HIROCL Hypochlorus Acid Sanitization Solution

90. Paragraphs 1 through 48 and 86 through 89 are hereby realleged and incorporated by reference.

91. On or about May 19, 2022, the labeling for ***HIROCL Hypochlorus Acid Sanitization Solution*** included the following claim:

a) "... the perfect natural and non-toxic sanitizer..."

92. The claim in the labeling described in paragraph 91 constitutes a "false and misleading statement" pursuant to 40 C.F.R. § 156.10(a)(5) (ix), and was therefore "misbranded," as that term is defined in section 2(q)(1) of FIFRA, 7 U.S.C. § 136(q)(1), and 40 C.F.R. § 156.10(a)(5).

93. On or about May 19, 2022, the label for the product, ***HIROCL Hypochlorus Acid Sanitization Solution***, did not include directions for use, net contents, or ingredient statement.

94. The contents of the label described in paragraph 93 did not include information required under 40 C.F.R. § 156.10(a)(1), and was therefore "misbranded" as that term is defined in section 2(q)(1)(F) of FIFRA, 7 U.S.C. § 136(q)(1)(F).

95. Consequently, Respondent's distribution or sale of the pesticide, ***HIROCL Hypochlorus Acid Sanitization Solution***, on or about May 19, 2022, constitutes one (1) violation of section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), which states that it is unlawful for any person in any state to distribute or sell to any person any pesticide which is misbranded.

COUNT 9: Production in an Unregistered Establishment

HIROCL Hypochlorus Acid Sanitization Solution

96. Paragraphs 1 through 48, 86 through 89, and 91 through 95 are hereby realleged and incorporated by reference.

97. After June 2, 2021, but prior to May 19, 2022, Respondent transferred sodium hypochlorite solution from one container into separate containers at its Facility.

98. After June 2, 2021, but prior to May 19, 2022, Respondent branded the repackaged containers of sodium hypochlorite described in paragraph 97 with a HIRO label identifying it as ***HIROCL Hypochlorus Acid Sanitization Solution*** at its Facility.

99. At times relevant to this Complaint, Respondent "produced" ***HIROCL Hypochlorus Acid Sanitization Solution***, 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 Respondent's Facility and Respondent was 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.

100. At all times relevant to this Complaint, Respondent's Facility was an "establishment," as that term is defined in section 2(dd) of FIFRA, 7 U.S.C. § 136(dd).

101. At all times relevant to this Complaint, Respondent's Facility was not registered

with the Administrator as an “establishment,” as required pursuant to section 7(a) of FIFRA, 7 U.S.C. § 136e(a).

102. Therefore, Respondent’s production of the pesticide, ***HIROCL Hypochlorus Acid Sanitization Solution***, at the Facility constitutes one (1) violation of section 12(a)(2)(L) of FIFRA, 7 U.S.C. § 136j(a)(2)(L), which states it shall be unlawful for any person who is a producer to violate any provisions of section 7 of FIFRA

COUNTS 10-11: Distribution or Sale of a Misbranded Device

Side-Kik HOCL Generator

103. Paragraphs 1 through 48 are hereby realleged and incorporated by reference.

104. On or about June 2, 2021, Respondent offered for sale the product, ***Side-Kik HOCL Generator***, at its Facility.

105. On or about May 19, 2022, Respondent offered for sale the product, ***Side-Kik HOCL Generator***, at its Facility.

106. Therefore, on or about June 2, 2021, and May 19, 2022, Respondent “distributed or sold” the product, ***Side-Kik HOCL Generator***, as that term is defined in section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), and 40 C.F.R. § 152.3.

107. At times relevant to this Complaint, the labeling for the ***Side-Kik HOCL Generator*** included the following claims:

- a) “[Side-Kik HOCL Generator] empowers you to create your very own HOCL (Hypochlorous Acid) and [sic] EPA-approved disinfectant for COVID-19”

108. The claim in the labeling described in paragraph 107 constitutes a “false and misleading statement” pursuant to 40 C.F.R. § 156.10(a)(5)(v), and was therefore “misbranded,” as that term is defined in section 2(q)(1) of FIFRA, 7 U.S.C. § 136(q)(1), and 40 C.F.R. § 156.10(a)(5).

109. At times relevant to this Complaint, the label for the product, ***Side-Kik HOCL Generator***, did not include directions for use nor did it bear an EPA registration number assigned under section 7 to the establishment in which it was produced.

110. The lack of directions for use and EPA establishment registration number on the labeling for the ***Side-Kik HOCL Generator*** constitutes “misbranding,” as that term is defined in sections 2(q)(1)(D) and (F) of FIFRA, 7 U.S.C. §§ 136(q)(1)(D) and (F).

111. Consequently, Respondent’s distributions or sales of the pesticide device, ***Side-***

Kik HOCL Generator, on or about June 2, 2021, and May 19, 2022, constitute two (2) violations of section 12(a)(1)(F) of FIFRA, 7 U.S.C. § 136j(a)(1)(F), which states that it is unlawful for any person in any state to distribute or sell to any person any device which is misbranded.

COUNTS 12-13: Distribution or Sale of a Misbranded Pesticide

Clean Republic Disinfectant + Sanitizer Pesticide

112. Paragraphs 1 through 48 are hereby realleged and incorporated by reference.

113. On or about June 2, 2021, Respondent offered for sale ***Clean Republic Disinfectant + Sanitizer*** at the Facility.

114. On or about May 19, 2022, Respondent offered for sale ***Clean Republic Disinfectant + Sanitizer*** at the Facility.

115. Therefore, on or about June 2, 2021, and May 19, 2022, Respondent “distributed or sold” ***Clean Republic Disinfectant + Sanitizer***, as that term is defined in section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), and 40 C.F.R. § 152.3.

116. On or about June 2, 2021, and May 19, 2022, the ***Clean Republic Disinfectant + Sanitizer*** label did not bear the EPA registration number assigned under section 7 to the establishment in which it was produced.

117. At times relevant to this Complaint, ***Clean Republic Disinfectant + Sanitizer*** was “misbranded,” as that term is defined in section 2(q)(1)(D) of FIFRA, 7 U.S.C. § 136(q)(1)(D).

118. Consequently, Respondent’s distributions or sales of the pesticide, ***Clean Republic Disinfectant + Sanitizer***, on or about June 2, 2021, and May 19, 2022, constitute two (2) violations of section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), which states that it is unlawful for any person in any state to distribute or sell to any person any pesticide which is misbranded.

IV. PROPOSED CIVIL PENALTY

Section 14(a)(1) of FIFRA, 7 U.S.C. § 136l(a)(1), and the Civil Monetary Penalty Inflation Adjustment Rule at 40 C.F.R. Part 19, provide that any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who violates any provision of FIFRA may be assessed a civil penalty of not more than \$23,494 for each offense that occurred after November 2, 2015, and is assessed on or after January 6, 2023. When determining an appropriate civil penalty, section 14(a)(4) of FIFRA, 7 U.S.C. § 136l(a)(4), requires EPA to consider the appropriateness of such penalty to the size of the business of the person charged, the effect on the

person's ability to continue in business, and the gravity of the violation. To determine the appropriate penalty to be assessed in this matter, Complainant considered the facts of this matter against those statutory factors by applying the EPA's December 2009 FIFRA Enforcement Response Policy and the memorandum dated January 12, 2022, entitled *Amendments to EPA's Civil Penalty Policies to Account for Inflation (effective January 15, 2022) and Transmittal of the 2022 Civil Monetary Penalty Inflation Adjustment Rule*. The Policy provides a rational, consistent, and equitable methodology for applying the statutory penalty factors to a particular case. A copy of the Policy and relevant inflation amendment are enclosed with this Complaint. Based on the violations alleged in this Complaint, and after consideration of the statutory factors enumerated above, EPA proposes to assess the following civil penalty:

Count	Alleged Violation	Penalty
1	12(a)(1)(A)	\$5,438
2	12(a)(1)(E)	\$9,148
3	12(a)(2)(L)	\$5,438
4	12(a)(1)(A)	\$5,438
5	12(a)(1)(E)	\$9,148
6	12(a)(2)(L)	\$5,438
7	12(a)(1)(A)	\$5,438
8	12(a)(1)(E)	\$9,148
9	12(a)(2)(L)	\$5,438
10	12(a)(1)(F)	\$9,148
11	12(a)(1)(F)	\$9,148
12	12(a)(1)(E)	\$1,817
13	12(a)(1)(E)	\$1,817
		\$82,002

V. NOTICE OF OPPORTUNITY TO REQUEST A HEARING

You have 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. Any hearing requested will be conducted in accordance with the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.*, and the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation or Suspension of Permits ("Consolidated Rules of Practice"), 40 C.F.R. Part 22. A copy of the Consolidated Rules of Practice is enclosed with this Complaint.

You must file a written Answer within thirty (30) days of receiving this Complaint to avoid being found in default, which constitutes an admission of all facts alleged in the

Complaint and a waiver of the right to a hearing, and to avoid having the above penalty assessed without further proceedings. If you choose to file an Answer, you are required by the Consolidated Rules of Practice to clearly and directly admit, deny, or explain each of the factual allegations contained in this Complaint to which you have any knowledge. If you have no knowledge of a particular fact and so state, the allegation is considered denied. Failure to deny any of the allegations in this Complaint will constitute an admission of the undenied allegation.

The Answer shall also state the circumstances and arguments, if any, which are alleged to constitute the grounds of defense, and shall specifically request an administrative hearing, if desired. If you deny any material fact or raise any affirmative defense, you will be considered to have requested a hearing. The Answer must be filed with:

Regional Hearing Clerk (ORC-1)
U.S. Environmental Protection Agency, Region IX
75 Hawthorne Street
San Francisco, CA 94105

In addition, please send a copy of the Answer and all other documents that you file in this action to:

Nathaniel N. Moore
Office of Regional Counsel (ORC-2)
U.S. Environmental Protection Agency, Region IX
75 Hawthorne Street
San Francisco, CA 94105
Moore.Nathaniel@epa.gov

Nathaniel N. Moore is the attorney assigned to represent EPA in this matter and can be contacted at Moore.Nathaniel@epa.gov or (415) 972-3899.

You are further informed that the Consolidated Rules of Practice prohibit any *ex parte* (unilateral) discussion of the merits of any action with the Regional Administrator, Regional Judicial Officer, Administrative Law Judge, or any person likely to advise these officials in the decision of the case, after the Complaint is issued.

VI. INFORMAL SETTLEMENT CONFERENCE

EPA encourages all parties against whom a civil penalty is proposed to pursue the possibility of settlement through informal conferences. Therefore, regardless of whether you request a hearing or not, you may confer informally with EPA through Mr. Moore, the EPA attorney assigned to this case, regarding the facts of this case, the amount of the proposed

penalty, and the possibility of settlement. An informal settlement conference does not, however, affect your obligation to file an Answer to this Complaint.

VII. ALTERNATIVE DISPUTE RESOLUTION

The parties also may engage in any process within the scope of the Alternative Dispute Resolution Act, 5 U.S.C. § 581 *et seq.*, which may facilitate voluntary settlement efforts. Dispute resolution using alternative means of dispute resolution does not divest the Presiding Officer of jurisdiction nor does it automatically stay the proceeding.

VIII. QUICK RESOLUTION

Instead of requesting an informal settlement conference or filing an Answer requesting a hearing, you may choose to resolve the proceeding by paying the specific penalty proposed in the Complaint and filing a copy of the check or other instrument of payment with the Regional Hearing Clerk within thirty (30) days after receiving the Complaint. If you wish to resolve the proceeding in this manner instead of filing an answer but need additional time to pay the penalty, you may file a written statement stating that you agree to pay the proposed penalty in accordance with 40 C.F.R § 22.18(a)(1) with the Regional Hearing Clerk within 30 days after receiving the Complaint. The written statement need not contain any response to, or admission of, the allegations in the Complaint. Within sixty (60) days after receiving the Complaint, the full amount of the proposed penalty must be paid. Failure to make such payment within this sixty-day period may subject you to default. Upon receipt of payment in full, the Regional Judicial Officer will issue a Final Order. Payment by a respondent shall constitute a waiver of the respondent's rights to contest the allegations and to appeal the Final Order. In addition, full payment of the proposed penalty shall only resolve Respondent's liability for Federal civil penalties for violations and facts alleged in the Complaint and does not affect the right of EPA or the United States to pursue appropriate injunctive or other equitable relief or criminal sanctions for any violations of law.

IX. CONSENT AGREEMENT AND FINAL ORDER

EPA has the authority, where appropriate, to modify the amount of the proposed penalty to reflect any settlement reached with you in an informal conference or through alternative dispute resolution. The terms of such an agreement would be embodied in a Consent Agreement and Final Order. A Consent Agreement signed by both parties would be binding as to all terms and conditions specified therein when the Regional Judicial Officer signs the Final Order.

Dated on this 5th day of July 2023.

MATTHEW SALAZAR Digitally signed by MATTHEW
SALAZAR
Date: 2023.07.05 16:14:29 -07'00'

Matt Salazar, PE
Manager, Toxics Section
Enforcement & Compliance Assurance Division
U.S. Environmental Protection Agency, Region IX

CERTIFICATE OF SERVICE

In the Matter of HiRO Systems Hawaii, LLC

EPA Docket No. FIFRA-09-2023-0069

I certify that the foregoing Complaint and Notice of Opportunity for Hearing, was filed via email with the Regional Hearing Clerk, United States Environmental Protection Agency, Region 9 at R9HearingClerk@epa.gov and that a true and correct copy of (1) the Complaint and Notice of Opportunity for Hearing; (2) the Consolidated Rules of Practice at 40 C.F.R. Part 22; (3) the FIFRA Enforcement Response Policy; and (4) the Amendments to EPA's Civil Penalty Policies to Account for Inflation (effective January 15, 2022) and Transmittal of the 2022 Civil Monetary Penalty Inflation Adjustment Rule was sent via Certified Mail, with verification of delivery requested, to:

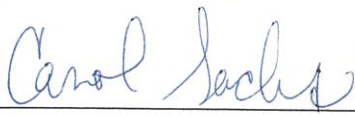
POM Enterprises LLC

Registered Agent on behalf of HIRO Systems Hawaii LLC

Attention: David Yonamine, President, and Dustin Hara, Managing Member of HIRO Systems Hawaii, LLC

250 Kawaihae Street Unit 16A
Honolulu, Hawaii 96825

Certified Mail No. 7019 0700 0001 7652 6410

 7/6/2023

Carol Sachs

Enforcement and Compliance Assurance Division, ECAD

US EPA, Region 9

75 Hawthorne Street

San Francisco, CA 94105