UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5
77 WEST JACKSON BOULEVARD
CHICAGO, IL 60604-3590
May 12, 2020

VIA EMAIL

Dr. Herb Estreicher
Partner
Keller and Heckman LLP
1001 G Street, Northwest
Suite 500 West
Washington, D.C. 20001

estreicher@khlaw.com

Re: Consent Agreement and Final Order In the Matter of Bio-Cat, Inc. and Bio-Cat Microbials, LLC Docket Number FIFRA-05-2020-0038

Dr. Estreicher:

Enclosed please find a copy of a fully executed Consent Agreement and Final Order in resolution of the above case. This document was filed on May 12, 2020 with the Regional Hearing Clerk.

The civil penalty in the amount of $300,000 is to be paid in the manner described in paragraphs 113-114. Please be certain that the company's name and the docket number of this case are written on both the transmittal letter and the check, or in the comments field if you are paying by electronic funds transfer. Due within 30 calendar days of the filing date is $75,000, $76,125 within 120 days of the filing date, $76,000 within 240 days of the filing date, and $75,500 within 360 days of the filing date.

Thank you for your cooperation in resolving this matter.

Sincerely,

ABIGAIL WESLEY

Digitally signed by ABIGAIL WESLEY
Date: 2020.04.30 15:15:17 -05'00'

Abigail Wesley
Pesticides and Toxics Compliance Section

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

In the Matter of:	)	**Docket No.** FIFRA-05-2020-0038
	)	
Bio-Cat, Inc.	)	
Troy, Virginia	)	
	)	**Proceeding to Assess a Civil Penalty**
and	)	**Under Section 14(a) of the Federal**
	)	**Insecticide, Fungicide, and Rodenticide**
Bio-Cat Microbials, LLC	)	**Act, 7 U.S.C. § 136*l*(a)**
Shakopee, Minnesota	)	
	)	
Respondents.	)	
	)	

Consent Agreement and Final Order

Preliminary Statement

1. This is an administrative action commenced and concluded under Section 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136*l*(a), and Sections 22.13(b) and 22.18(b)(2) and (3) of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits (Consolidated Rules) as codified at 40 C.F.R. Part 22.

2. The Complainant is the Director of the Enforcement and Compliance Assurance Division, United States Environmental Protection Agency (EPA), Region 5.

3. The Respondents are Bio-Cat, Inc. and Bio-Cat Microbials, LLC ("Bio-Cat"), a corporation and limited liability company, respectively, doing business in the States of Virginia and Minnesota.

4. Where the parties agree to settle one or more causes of action before the filing of a complaint, the administrative action may be commenced and concluded simultaneously by the

issuance of a consent agreement and final order (CAFO). 40 C.F.R. § 22.13(b).

5. The parties agree that settling this action without the filing of a complaint or the adjudication of any issue of fact or law is in their interest and in the public interest.

6. Respondents consent to the assessment of the civil penalty specified in this CAFO, and to the terms of this CAFO.

Jurisdiction and Waiver of Right to Hearing

7. Respondents admit the jurisdictional allegations in this CAFO and neither admit nor deny the factual allegations in this CAFO.

8. Respondents waive their right to request a hearing as provided at 40 C.F.R. § 22.15(c), any right to contest the allegations in this CAFO and its right to appeal this CAFO.

9. Respondents certify, to the best of their knowledge, that they are complying with FIFRA, 7 U.S.C. §§ 136-136y.

Statutory and Regulatory Background

10. Section 2(s) of FIFRA, 7 U.S.C. § 136(s), defines the term "person" as "any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not."

11. Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), defines the term "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." Also see 40 C.F.R. §152.3.

12. Section 2(t) of FIFRA, 7 U.S.C. § 136(t), defines the term "pest" as " (1) any insect, rodent, nematode, fungus, weed, or (2) any other 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 [of the EPA] declares to be a pest" under Section 25(c)(1) of FIFRA, 7 U.S.C. § 136w(c)(1). Also see 40 C.F.R. § 152.5.

13. Section 2(u) of FIFRA, 7 U.S.C. § 136(u), defines the term "pesticide" as, among other things, "(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant." Also see 40 C.F.R. §152.3.

14. Section 2(v) of FIFRA, 7 U.S.C. § 136(v), defines the term ''plant regulator,'' as, among other things, "any substance or mixture of substances intended, through physiological action, for accelerating or retarding the rate of growth or rate of maturation, or for otherwise altering the behavior of plants or the produce thereof."

15. Section 2(w) of FIFRA, 7 U.S.C. § 136(w), defines the term "produce" in part as "to manufacture, prepare, compound, propagate, or process any pesticide or device or active ingredient used in producing a pesticide." Also see 40 C.F.R. § 167.3.

16. Section 2(p)(1) of FIFRA, 7 U.S.C. § 136(p)(1), defines a "label" as "written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers."

17. Section 2(p)(2) of FIFRA, 7 U.S.C. § 136(p)(2) defines "labeling" as "all labels and other written, printed, or graphic matter—(A) accompanying the pesticide at any time; or (B) to which reference is made on the label or in literature accompanying the pesticide. . . ."

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

20. 40 C.F.R. § 152.15 states in part that no person may distribute or sell any pesticide product that is not registered under FIFRA. It further states that a substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration, if the person who distributes or sells the substance claims, states, or implies (by labeling or otherwise) that the substance can or should be used as a pesticide.

21. 40 C.F.R. § 152.15(c) states in part that no person may distribute or sell any pesticide product that is not registered under FIFRA. It further states that a substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration, if 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.

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

23. Under 40 C.F.R. § 168.22(a), EPA interprets Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), as extending to advertisements in any advertising medium to which pesticide users or the general public have access.

24. 40 C.F.R. § 168.70(b) provides, in pertinent part, that each unregistered export pesticide product must bear labeling that (1) complies with all of the prominence and legibility requirements of 40 C.F.R. § 156.10(a)(2); (2) complies with all the language requirements in 40 C.F.R. §§ 168.69(c) and 156.10(a)(3); and (3) contains the following information:

(i) The name and address of the producer, in accordance with the requirements of 40 C.F.R. § 156.10(c);

(ii) The net weight or measure of contents, in accordance with the requirements of 40 C.F.R. § 156.10(d);

(iii) The pesticide producing establishment number, in accordance with the requirements of 40 C.F.R. § 156.10(f);

(iv) An ingredients statement, in accordance with the requirements of 40 C.F.R. § 156.10(g) of this chapter.

(v) Human hazard and precautionary statements in accordance with the requirements of 40 C.F.R. Part 156, Subpart D. The statements must be true and accurate translations of the English statements.

(vi) The statement "Not Registered for Use in the United States of America," which may be amplified by additional statements accurately describing the reason(s) why the export pesticide product is not registered in the United States, or is not registered for particular uses in the United States.

25. Section 2(q)(1)(D) of FIFRA, 7 U.S.C. § 136(q)(1)(D), defines a pesticide as "misbranded" if its label does not bear the registration number assigned under Section 7 of FIFRA, 7 U.S.C. § 136e, to each establishment in which it was produced.

26. Section 2(q)(1)(G) of FIFRA, 7 U.S.C. § 136(q)(1)(G), defines a pesticide as "misbranded" if its label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirement imposed under Section 3(d) of FFIFRA, 7 U.S.C. § 136a(d), is adequate to protect health and the environment.

27. Section 2(q)(1)(H) of FIFRA, 7 U.S.C. § 136(q)(1)(H), defines a pesticide as "misbranded" in the case of a pesticide not registered in accordance with Section 3 of FIFRA, 7 U.S.C. § 136a, and intended for export, if the label does not contain, in words prominently

placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) as to render it likely to be noted by the ordinary individual under customary conditions of purchase and use, the following: ‘‘Not Registered for Use in the United States of America.”

28. Section 2(q)(2)(A) of FIFRA, 7 U.S.C. § 136(q)(2)(A), defines a pesticide as “misbranded,” if the label does not bear an ingredient statement.

29. Section 2(q)(2)(C)(iii) of FIFRA, 7 U.S.C. § 136(q)(2)(C)(iii), in pertinent part, defines a pesticide as “misbranded,” if there is not affixed to its container, and to the outside container or wrapper of the retail package, if there be one, through which the required information on the immediate container cannot be clearly read, a label bearing the net weight or measure of the content.

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

31. Section 7(a) of FIFRA, 7 U.S.C. § 136e(a), provides that no person may produce any pesticide subject to FIFRA or active ingredient used in producing a pesticide subject to FIFRA unless the establishment in which it is produced is registered with EPA.

32. Section 12(a)(2)(L) of FIFRA, 7 U.S.C. § 136j(a)(2)(L), states that it is unlawful for any person who is a producer to violate any provision of Section 7 of FIFRA, 7 U.S.C. § 136e.

33. The Administrator of EPA may assess a civil penalty against any distributor who violates any provision of FIFRA of up to $20,288 for each offense that occurred after November 2, 2015 pursuant to Section 14(a)(1) of FIFRA, 7 U.S.C. § 136*l*(a)(1), and 40 C.F.R. Part 19.

Factual Allegations and Alleged Violations

34. Respondents are a "person" as defined at Section 2(s) of FIFRA, 7 U.S.C. § 136(s).

35. At all times relevant to this CAFO, Respondents owned or operated a business at 689 Canterbury Road, Shakopee, Minnesota 55379 ("Respondents' facility").

36. At all times relevant to this CAFO, Respondents' facility was an "establishment" as defined at Section 2(dd) of FIFRA 7 U.S.C. § 136(dd).

37. At all times relevant to this CAFO, Respondents' facility was not registered with EPA as a pesticide producing establishment under Section 7(a) of FIFRA, 7 U.S.C. § 136e(a).

38. On or about February 23, 2017, an inspector employed by the Minnesota Department of Agriculture (MDA) and authorized to conduct inspections under FIFRA conducted an inspection at Respondents' facility ("Inspection").

39. During the inspection, the inspector collected labeling, to include advertising and marketing materials, production, and distribution records for BIOSTART, BIOSTART ST, BIOSTART LT, BIOSTART LT Organic, BIOSTART OG, BIOSTART DFT, BIOSTART Defensor, BIOSTART 1X, BIOSTART Dry 10X, BIOSTART Concentrate Liquid, and BIOSTART Concentrate Dry ("BIOSTART et al.").

40. During the inspection, the inspector collected labeling, production, and distribution records for Link and Reprieve.

41. During the inspection, a bin label and shipping record statement was signed by a representative of Bio-Cat, indicating that the labels collected during the inspection were a true and accurate representation of the labeling on the containers of BIOSTART et al., Link, and Reprieve, for shipments occuring during calendar years 2016 and 2017.

BIOSTART et al. Claims

42. During the inspection, the inspector collected advertising and marketing materials from Respondents for BIOSTART et al.

43. The BIOSTART et al. advertising and marketing materials stated, among other things:

a. *"BIOSTART interacts on or close to the root surface of the plant to produce beneficial enzymes and growth-promoting substances.";*

b. *"Enhances root, shoot and plant growth";*

c. *"BENEFITS: Enhanced root mass; bigger, stronger plants.";*

d. *"They interact symbiotically on, or close to, the root surface where they produce beneficial enzymes and growth promoting substances while working against pathogenic microorganisms.";*

e. *"Enhanced root mass";*

f. *"Bacillus bacteria are known to produce a wide variety of extra-cellular enzymes including proteases, amylases, cellulases, lipases, β-1 ,3 glucanase and chitinases, which in addition to breaking down organic matter in the soil can protect the plant against phytopathogenic microorganisms by hydrolyzing or modifying the pathogens cell wall structure.";*

g. *"Literature references indicate Bacillus can produce phytohormones including indole acetic acid (IAA) which is directly related to an increase in root length and plant growth.*";

h. *"Microorganisms like Bacillus inhabit the rhizosphere, growing on and close to the root, beneficially influencing the growth of roots and plants. Bacillus*

are part of the plant growth-promoting rhizobacteria (PGPR).";

i. *"PGPR synthesize plant hormones that help seed germination and regulate plant growth. Examples are indole acetic acid, gibberellic acid, and cytokinins, thought to directly and beneficially affect plant growth, resulting in higher yields.";*

j. *"They also produce metabolites called siderophores that provide anti-fungal and anti-microbial activity. These molecules chelate iron required for pathogen growth.";*

k. "*Colonization of the rhizosphere by BIOSTART® spores increases root mass and aids the growth and overall health and robustness of the plants.";*

l. *"Bacillus inhibit growth of potentially detrimental bacteria by a process known as competitive inhibition.";*

m. *"BIOSTART® is a unique blend of four proprietary Bacillus strains designed to promote enhanced root development leading to stronger plants and higher yields.";*

n. *"Bigger roots lead to stronger, healthier, more robust plants which lead to increased yields.";*

o. *"Enhance root, shoot and plant growth through production of small molecules (phytohormones).";*

p. *"Phytohormones: Production of powerful plant root, shoot and plant growth stimulant – Indole Acetic Acid (IAA)";*

q. *"Plants more resistant to biological and physical stress"; and*

r. *"Aid plants in combating biological and physical stress through competitive*

and direct inhibition of pathogenic fungi and stimulating the plants natural defense mechanisms."

44. During the inspection, the inspector collected bin labeling from Respondents for BIOSTART DFT, BIOSTART ST, BIOSTART LT and BIOSTART LT Organic.

45. The labeling for BIOSTART DFT, BIOSTART ST, BIOSTART LT and BIOSTART LT Organic stated, among other things:

a. *"Enhances root, shoot and plant growth"; and*

b. *"Aids plants in combating biological and physical stress."*

46. On or about August 7, 2019, an EPA representative viewed www.bcmicrobials.com, an online website owned and/or operated by Respondents ("Respondents' website").

47. On or about August 7, 2019, Respondents' website stated, among other things:

"Why Bacillus?

• Production of fungicides, insecticides and other microbial compounds

• Production of phytohormones – produces compounds that enhance plant growth

• Endophytic – grow within plants without causing harm to protect plants from fungi, insects, etc."

48. During the August 7, 2019 review of Respondents' website, the product page for BIOSTART Defensor stated, among other things:

"BIOSTART Defensor is a proprietary microbial soil inoculant that enhances biodiversity and discourages the growth of undesirable microorganisms in the soil ecosystem."

49. At all times relevant to the CAFO, BIOSTART et al. were "pesticides" as defined at Section 2(u) of FIFRA, 7 U.S.C. § 136(u).

50. At all times relevant to the CAFO, BIOSTART et al. were not registered under Section 3 of FIFRA, 7 U.S.C. § 136(a).

BIOSTART et al. Misbranding (Exports)

BIOSTART Concentrate Liquid (55 and 275-Gallon Containers)

51. During the inspection, the inspector collected labeling from Respondents for 55 and 275-gallon containers of BIOSTART Concentrate Liquid, for export shipments occuring during calendar year 2016, to customers outside of the United States.

52. Labeling for BIOSTART Concentrate Liquid, that was affixed to quantities of BIOSTART Concentrate Liquid exported for distribution or sale during calendar year 2016 to customers outside of the United States, failed to identify the EPA Establishment Number in which it was produced and did not contain an ingredient statement and the statement, "Not Registered for Use in the United States of America," as required by 40 CFR § 168.70 and Section 2(q) of FIFRA, 7 U.S.C. § 136(q).

53. The labels for BIOSTART Concentrate Liquid, collected during the inspection, at all times relevant to this CAFO, were misbranded, as they did not identify the EPA Establishment Number in which the product was produced and did not contain an ingredient statement and the statement, "Not Registered for Use in the United States of America."

BIOSTART Concentrate Liquid (1-Liter and 25-Kilogram Containers)

54. During the inspection, the inspector collected labeling from Respondents for 1-liter and 25-kilogram containers of BIOSTART Concentrate Liquid, for export shipments occuring during calendar year 2016, to customers outside of the United States.

55. Labeling for BIOSTART Concentrate Liquid, that was affixed to quantities of BIOSTART Concentrate Liquid exported for distribution or sale during calendar year 2016 to customers outside of the United States, failed to identify the EPA Establishment Number in which it was produced and did not contain the net weight or measure of content, human hazard, precautionary, and ingredient statements, and the statement, "Not Registered for Use in the United States of America," as required by 40 CFR § 168.70 and Section 2(q) of FIFRA, 7 U.S.C. § 136(q).

56. The labels for BIOSTART Concentrate Liquid, collected during the inspection, at all times relevant to this CAFO, were misbranded, as they did not identify the EPA Establishment Number in which the product was produced and did not contain the net weight or measure of content, human hazard, precautionary, and ingredient statements, and the statement, "Not Registered for Use in the United States of America."

BIOSTART 1X

57. During the inspection, the inspector collected production and distribution records from Respondents for 15-gallon containers of BIOSTART 1X, for export shipments occuring during calendar year 2016, to customers outside of the United States.

58. Quantities of BIOSTART 1X, that were exported for distribution or sale during calendar year 2016 for customers outside of the United States, failed to contain a label identifying certain criteria as required by 40 CFR § 168.70.

59. Quantities of BIOSTART 1X, for export shipments, and at all times relevant to this CAFO, were misbranded, as they did not contain a label.

BIOSTART Concentrate Dry

60. During inspection, the inspector collected labeling from Respondents for 1-kilogram containers of BIOSTART Concentrate Dry, for export shipments occuring during calendar year 2016, to customers outside of the United States.

61. Labeling for BIOSTART Concentrate Dry, that was affixed to quantities of BIOSTART Concentrate Dry exported for distribution or sale during calendar year 2016 to customers outside of the United States, failed to identify the EPA Establishment Number in which it was produced and did not contain the net weight or measure of content, human hazard, precautionary, and ingredient statements, and the statement, "Not Registered for Use in the United States of America," as required by 40 CFR § 168.70 and Section 2(q) of FIFRA, 7 U.S.C. § 136(q).

62. The labels for BIOSTART Concentrate Dry, collected during the inspection, at all times relevant to this CAFO, were misbranded, as they did not identify the EPA Establishment Number in which the product was produced and did not contain the net weight or measure of content, human hazard, precautionary, and ingredient statements, and the statement, "Not Registered for Use in the United States of America."

BIOSTART ST

63. During the inspection, the inspector collected labeling from Respondents for 500-milliliter and 0.5-kilogram containers of BIOSTART ST, for export shipments occuring during calendar year 2016, to customers outside of the United States.

64. Labeling for BIOSTART ST, that was affixed to quantities of BIOSTART ST exported for distribution or sale during calendar year 2016 to customers outside of the United

States, failed to identify the EPA Establishment Number in which it was produced and did not contain the net weight or measure of content, human hazard, precautionary, and ingredient statements, and the statement, "Not Registered for Use in the United States of America," as required by 40 CFR § 168.70 and Section 2(q) of FIFRA, 7 U.S.C. § 136(q).

65. The labels for BIOSTART ST, collected during the inspection, at all times relevant to this CAFO, were misbranded, as they did not identify the EPA Establishment Number in which the product was produced and did not contain the net weight or measure of content, human hazard, precautionary, and ingredient statements, and the statement, "Not Registered for Use in the United States of America."

BIOSTART LT

66. During the inspection, the inspector collected labeling from Respondents for 1-gallon containers of BIOSTART LT, for export shipments occuring during calendar year 2016, to customers outside of the United States.

67. Labeling for BIOSTART LT, that was affixed to quantities of BIOSTART LT exported for distribution or sale during calendar year 2016 to customers outside of the United States, failed to identify the EPA Establishment Number in which it was produced and did not contain the net weight or measure of content, human hazard, precautionary, and ingredient statements, and the statement, "Not Registered for Use in the United States of America," as required by 40 CFR § 168.70 and Section 2(q) of FIFRA, 7 U.S.C. § 136(q).

68. The labels for BIOSTART LT, collected during the inspection, at all times relevant to this CAFO, were misbranded, as they did not identify the EPA Establishment Number in which the product was produced and did not contain the net weight or measure of content,

human hazard, precautionary, and ingredient statements, and the statement, "Not Registered for Use in the United States of America."

BIOSTART DFT

69. During the inspection, the inspector collected labeling from Respondents for 1-gallon containers of BIOSTART DFT, for export shipments occuring during calendar year 2016, to customers outside of the United States.

70. Labeling for BIOSTART DFT, that was affixed to quantities of BIOSTART DFT exported for distribution or sale during calendar year 2016 to customers outside of the United States, failed to identify the EPA Establishment Number in which it was produced and did not contain human hazard, precautionary, and ingredient statements, and the statement, "Not Registered for Use in the United States of America," as required by 40 CFR § 168.70 and Section 2(q) of FIFRA, 7 U.S.C. § 136(q).

71. The labels for BIOSTART DFT, collected during the inspection, at all times relevant to this CAFO, were misbranded, as they did not identify the EPA Establishment Number in which the product was produced and did not contain human hazard, precautionary, and ingredient statements, and the statement, "Not Registered for Use in the United States of America."

BIOSTART Dry 10X

72. During inspection, the inspector collected labeling from Respondents for 25-kilogram containers of BIOSTART Dry 10X, for export shipments occuring during calendar year 2016, to customers outside of the United States.

73. Labeling for BIOSTART Dry 10X, that was affixed to quantities of BIOSTART Dry 10X exported for distribution or sale during calendar year 2016 to customers outside of the

United States, failed to identify the EPA Establishment Number in which it was produced and did not contain human hazard, precautionary, and ingredient statements, and the statement, "Not Registered for Use in the United States of America," as required by 40 CFR § 168.70 and Section 2(q) of FIFRA, 7 U.S.C. § 136(q).

74. The labels for BIOSTART Dry 10X, collected during the inspection, at all times relevant to this CAFO, were misbranded, as they did not identify the EPA Establishment Number in which the product was produced and did not contain human hazard, precautionary, and ingredient statements, and the statement, "Not Registered for Use in the United States of America."

Link Claims

75. During the inspection, the inspector collected labeling from Respondents for Link.

76. The labeling for Link stated, among other things:

a. *"A powerful bio-fertiliser [sic] for the promotion of plant growth and health on all crops."; and*

b. "PGPR (Plant Growth Promoting Rhizobacteria)."

77. At all times relevant to the CAFO, Link was a "pesticide" as defined at Section 2(u) of FIFRA, 7 U.S.C. § 136(u).

78. At all times relevant to the CAFO, Link was not registered under Section 3 of FIFRA, 7 U.S.C. § 136(a).

Link Misbranding (Export)

Link (2016)

79. During the inspection, the inspector collected labeling from Respondents for 1 and 2.5-gallon containers of Link, for export shipments occuring during calendar year 2016, to customers outside of the United States.

80. Labeling for Link, that was affixed to quantities of Link exported for distribution or sale during calendar year 2016 to customers outside of the United States, failed to identify the EPA Establishment Number in which it was produced, human hazard and precautionary, and ingredient statements, and the statement "Not Registered for Use in the United States of America" as required by 40 CFR § 168.70 and Section 2(q) of FIFRA, 7 U.S.C. § 136(q).

81. The labels for Link, collected during the inspection, at all times relevant to this CAFO, were misbranded, as they failed to identify the EPA Establishment Number in which it was produced, human hazard and precautionary, and ingredient statements, and the statements, "Not Registered for Use in the United States of America."

Link (2017)

82. During the inspection, the inspector collected labeling from Respondents for 2.5-gallon containers of Link, for export shipments occuring during calendar year 2017, for customers outside of the United States.

83. Labeling for Link, that was affixed to quantities of Link exported for distribution or sale during calendar year 2017 to customers outside of the United States, failed to identify the EPA Establishment Number in which it was produced, an ingredient statement, and the statement, "Not Registered for Use in the United States of America," as required by 40 CFR § 168.70 and Section 2(q) of FIFRA, 7 U.S.C. § 136(q).

84. The labels for Link, collected during the inspection, at all times relevant to this CAFO, were misbranded, as they failed to identify the EPA Establishment Number in which it was produced, an ingredient statement, and the statement, "Not Registered for Use in the United States of America."

Reprieve Claims

85. During the inspection, the inspector collected labeling from Respondents for Reprieve.

86. The labeling for Reprieve stated, among other things:

a. *"A powerful bio-fertiliser [sic] for the promotion of plant growth on lands or crops where there is a threat or history of disease infestations.";*

b. "PGPR (Plant Growth Promoting Rhizobacteria)"; and

c. *"For use on all crops and all soil types where plant diseases are prevalent."*

87. At all times relevant to the CAFO, Reprieve was a "pesticide" as defined at Section 2(u) of FIFRA, 7 U.S.C. § 136(u).

88. At all times relevant to the CAFO, Reprieve was not registered under Section 3 of FIFRA, 7 U.S.C. § 136(a).

Reprieve Misbranding (Export)

Reprieve (2016)

89. During the inspection, the inspector collected labeling from Respondents for 1 and 2.5-gallon containers of Reprieve, for export shipments occuring during calendar year 2016, to customers outside of the United States.

90. Labeling for Reprieve, that was affixed to quantities of Reprieve exported for distribution or sale during calendar year 2016 for customers outside of the United States, failed

to identify the EPA Establishment Number in which it was produced, human hazard and precautionary, and ingredient statements, and the statement, "Not Registered for Use in the United States of America" as required by 40 CFR § 168.70 and Section 2(q) of FIFRA, 7 U.S.C. § 136(q).

91. The labels for Reprieve, collected during the inspection, at all times relevant to this CAFO, were misbranded, as they failed to identify the EPA Establishment Number in which it was produced, human hazard and precautionary, and ingredient statements, and the statements, "Not Registered for Use in the United States of America."

Reprieve (2017)

92. During the inspection, the inspector collected labeling from Respondents for 2.5-gallon containers of Reprieve, for export shipments occuring during calendar year 2017, for customers outside of the United States.

93. Labeling for Reprieve, that was affixed to quantities of Reprieve exported for distribution or sale during calendar year 2017 to customers outside of the United States, failed to identify the EPA Establishment Number in which it was produced, an ingredient statement, and the statement, "Not Registered for Use in the United States of America," as required by 40 CFR § 168.70 and Section 2(q) of FIFRA, 7 U.S.C. § 136(q).

94. The labels for Reprieve, collected during the inspection, at all times relevant to this CAFO, were misbranded, as they failed to identify the EPA Establishment Number in which it was produced, an ingredient statement, and the statement, "Not Registered for Use in the United States of America."

Counts 1-29
BIOSTART et al. Distributions (Domestic)

95. Complainant incorporates paragraphs 1 through 94 of this CAFO as if set forth in

this paragraph.

96. During calendar years 2016 and 2017, Respondents distributed or sold the unregistered pesticides, BIOSTART et al., on at least 29 separate occasions, to customers within the United States.

97. Each of Respondents' distributions or sales set forth in the prior paragraph constitutes an unlawful act pursuant to Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A).

Counts 30-41
BIOSTART et al. Distributions (Export)

98. Complainant incorporates paragraphs 1 through 94 of this CAFO as if set forth in this paragraph.

99. During calendar year 2016, Respondents distributed or sold the misbranded pesticides, BIOSTART et al., on at least 12 separate occasions, to customers outside the United States.

100. Each of Respondents' distributions or sales set forth in the prior paragraph constitutes an unlawful act pursuant to Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

Counts 42-44
Link Distributions (Export)

101. Complainant incorporates paragraphs 1 through 94 of this CAFO as if set forth in this paragraph.

102. During calendar years 2016 and 2017, Respondents distributed or sold the misbranded pesticide, Link, on at least three separate occasions, to customers outside the United States.

103. Each of Respondents' distributions or sales set forth in the prior paragraph constitutes an unlawful act pursuant to Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

Counts 45-47
Reprieve Distributions (Export)

104. Complainant incorporates paragraphs 1 through 94 of this CAFO as if set forth in this paragraph.

105. During calendar years 2016 and 2017, Respondents distributed or sold the misbranded pesticide, Reprieve, on at least three separate occasions, to customers outside the United States.

106. Each of Respondents' distributions or sales set forth in the prior paragraph constitutes an unlawful act pursuant to Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

Count 48
Pesticide Production in an Unregistered Establishment

107. Complainant incorporates paragraphs 1 through 94 of this CAFO as if set forth in this paragraph.

108. At all times relevant to the CAFO, Respondents manufactured, prepared, compounded, propagated, or processed BIOSTART et al., Link, and Reprieve at Respondents' facility.

109. At all times relevant to the CAFO, Respondents packaged, repackaged, labeled, relabeled, or otherwise changed the container of BIOSTART et al., Link, and Reprieve at Respondents' facility.

110. At all times relevant to this CAFO, Respondents produced BIOSTART et al., Link, and Reprieve at Respondents' facility, as production is defined at Section 2(w) of FIFRA, 7 U.S.C. § 136(w), and 40 C.F.R. § 167.3.

111. At all times relevant to this CAFO, Respondents' production of pesticide products in a facility that was not registered with EPA as a pesticide producing establishment constitutes

an unlawful act pursuant to 12(a)(2)(L) of FIFRA, 7 U.S.C. § 136j(a)(2)(L).

Civil Penalty

112. Pursuant to Section 14(a)(4) of FIFRA, 7 U.S.C. § 136*l*(a)(4), Complainant determined that an appropriate civil penalty to settle this action is $300,000. In determining the penalty amount, Complainant considered the appropriateness of the penalty to the size of Respondents' business, the effect on Respondents' ability to continue in business, and the gravity of the violation. Complainant also considered EPA's FIFRA Enforcement Response Policy, dated December 2009.

113. Respondents must pay a $300,000 civil penalty in four installments with interest as follows:

Installment	Due By	Payment	Principal	Interest
Payment #1	Within 30 days of effective date of CAFO	$75,000	$75,000	$0
Payment #2	Within 120 days of effective date of CAFO	$76,125	$75,000	$1,125
Payment #3	Within 240 days of effective date of CAFO	$76,000	$75,000	$1,000
Payment #4	Within 360 days of effective date of CAFO	$75,500	$75,000	$500

Respondents must pay the installments by electronic funds transfer, payable to "Treasurer, United States of America," and sent to:

Federal Reserve Bank of New York
ABA No. 021030004
Account No. 68010727
33 Liberty Street
New York, New York 10045
Field Tag 4200 of the Fedwire message should read:
"D 68010727 Environmental Protection Agency"

In the comment or description field of the electronic funds transfer, state Bio-Cat, Inc. and Bio-Cat Microbials, LLC and the docket number of this CAFO.

114. Respondents must send a notice of payment that states Respondents' name and the case docket number to EPA at the following email addresses when it makes each installment payment of the penalty:

Regional Hearing Clerk (E-19J)
whitehead.ladawn@epa.gov

Abigail Wesley
wesley.abigail@epa.gov

Robert H. Smith
smith.roberth@epa.gov

115. This civil penalty is not deductible for federal tax purposes.

116. If Respondents do not pay any installment payment as set forth in paragraph 113, above, the entire balance of the civil penalty, shall become due and owing upon written notice by EPA to Respondents of the delinquency. EPA may refer the delinquency to the Attorney General to recover any unpaid penalty with interest by action in the appropriate United States district court under Section 14(a)(5) of FIFRA, 7 U.S.C. § 136*l*(a)(5). The validity, amount and appropriateness of the civil penalty are not reviewable in a collection action.

117. Pursuant to 31 C.F.R. § 901.9, Respondents must pay the following on any amount overdue under this CAFO. Interest will accrue on any amount overdue from the date payment was due at a rate established by the Secretary of the Treasury. Respondents must pay a $15 handling charge each month that any portion of the penalty is more than 30 days past due. In addition, Respondents must pay a 6 percent per year penalty on any principal amount 90 days past due.

General Provisions

118. The parties consent to service of this CAFO by e-mail at the following valid e-mail addresses: smith.roberth@epa.gov (for Complainant), and estreicher@khlaw.com (for Respondent).

119. This CAFO resolves only Respondents' liability for federal civil penalties for the violations alleged in the CAFO.

120. This CAFO does not affect the rights of EPA or the United States to pursue appropriate injunctive or other equitable relief or criminal sanctions for any violations of law.

121. This CAFO does not affect Respondents' responsibility to comply with FIFRA and other applicable federal, state and local laws.

122. This CAFO is a "final order" for purposes of EPA's FIFRA Enforcement Response Policy.

123. The terms of this CAFO bind Respondents, its successors and assigns.

124. Each person signing this agreement certifies that he or she has the authority to sign for the party whom he or she represents and to bind that party to its terms.

125. Each party agrees to bear its own costs and attorneys fees, in this action.

126. This CAFO constitutes the entire agreement between the parties.

Bio-Cat, Inc. and Bio-Cat Microbials, LLC, Respondent

4/30/20
Date

Chris Schuler
President
Bio-Cat, Inc.
and
Managing Member
Bio-Cat Microbials, LLC

United States Environmental Protection Agency, Complainant

05/12/2020
Date

MICHAEL HARRIS
Digitally signed by MICHAEL HARRIS
Date: 2020.05.12 07:49:33 -05'00'

Michael D. Harris
Director
Enforcement and Compliance Assurance Division

In the Matter of:
Bio-Cat, Inc. and Bio-Cat Microbials, LLC
Docket No. FIFRA-05-2020-0038

Final Order

This Consent Agreement and Final Order, as agreed to by the parties, shall become effective immediately upon filing with the Regional Hearing Clerk. This Final Order concludes this proceeding pursuant to 40 C.F.R. §§ 22.18 and 22.31. IT IS SO ORDERED.

05/12/2020
Date

ANN COYLE Digitally signed by ANN COYLE Date: 2020.05.12 11:45:26 -05'00'

Ann L. Coyle
Regional Judicial Officer
United States Environmental Protection Agency
Region 5

Consent Agreement and Final Order
In the Matter of: Bio-Cat, Inc. and Bio-Cat Microbials, LLC
Docket Number: FIFRA-05-2020-0038

CERTIFICATE OF SERVICE

I certify that I served a true and correct copy of the foregoing **Consent Agreement and Final Order**, docket number FIFRA-05-2020-0038, which was filed on May 12, 2020, in the following manner to the following addressees:

Copy by E-mail to Respondent:	Dr. Herb Estreicher estreicher@khlaw.com
Copy by E-mail to Attorney for Complainant:	Robert H. Smith smith.roberth@epa.gov
Copy by E-mail to Regional Judicial Officer:	Ann Coyle coyle.ann@epa.gov

Dated: May 12, 2020

LADAWN WHITEHEAD Digitally signed by LADAWN WHITEHEAD Date: 2020.05.12 12:34:43 -05'00'

LaDawn Whitehead
Regional Hearing Clerk
U.S. Environmental Protection Agency, Region 5