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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 6

1201 Elm Street, Suite 500
Dallas, Texas 75270

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REGIONAL HEARING CLERK
EPA REGION VI

In the Matter of

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§

Allied BioScience, Inc.,

Docket No. FIFRA-06-2022-0401

Respondent.

CONSENT AGREEMENT AND FINAL ORDER

Preliminary Statement

The U.S. Environmental Protection Agency, Region 6 (“EPA” or “Complainant”), and Allied BioScience, Inc., (“Respondent”) have agreed to a settlement of this action before the filing of a complaint, and thus this action is simultaneously commenced and concluded pursuant to Rules 22.13(b) and 22.18(b)(2) of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits, 40 C.F.R. §§ 22.13(b) and 22.18(b)(2).

Jurisdiction

1. This proceeding is an administrative action for the assessment of civil penalties instituted pursuant to Section 14 of the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”), 7 U.S.C. § 136l.

2. This Consent Agreement and Final Order serves as notice that the EPA has reason to believe that Respondent has violated Section 12 of FIFRA, 7 U.S.C. § 136j.

Parties

3. Complainant is the Director of Enforcement and Compliance Assurance Division of the EPA, Region 6, as duly delegated by the Administrator of the EPA and the Regional Administrator, EPA, Region 6.

4. Respondent is Allied BioScience, Inc., a company formed in the state of Delaware and conducting business in the state of Texas.

Statutory and Regulatory Background

5. Congress enacted FIFRA, 7 U.S.C. 136 et. seq., in 1947 and amended it in 1972 and in 1996. The general purpose of FIFRA is to provide the basis for regulation, sale, distribution and use of pesticides in the United States.

6. Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), states that it shall be unlawful for any person to distribute or sell any pesticide that is not registered under Section 3 of FIFRA, 7 U.S.C. § 136a, or whose registration has been cancelled or suspended.

7. Pursuant to the regulation at 40 C.F.R. § 152.15, in relevant part, no person may distribute or sell any pesticide product that is not registered under the Act, except as provided in 40 C.F.R. §§ 152.20, 152.25, and 152.30.

8. Section 18 of FIFRA, 7 U.S.C. 136p, provides that the Administrator may, at the Administrator's discretion, exempt any Federal or State agency from any provision of this Act if the Administrator determines that emergency conditions exist which require such exemption.

9. Pursuant to the regulation at 40 C.F.R. § 152.30(e), an unregistered pesticide may be distributed or sold in accordance with the terms of an emergency exemption under FIFRA Section 18, 7 U.S.C. § 136p, if the product is labeled in accordance with part 156 of this chapter.

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

11. Section 2(q)(1)(A) of FIFRA, 7 U.S.C. § 136(q)(1)(A), states, *inter alia*, that a pesticide is misbranded if its labeling bears any statement, design or graphic representation relative thereto or to its ingredients which is false or misleading in any particular.

12. Pursuant to the regulation at 40 C.F.R. § 156.10(a)(5), false and misleading statements that can cause a pesticide to be misbranded include, *inter alia*:

- a. A false or misleading statement concerning the effectiveness of the pesticide or device (40 C.F.R. § 156.10(a)(5)(ii));
- b. A false or misleading comparison with other pesticides or devices (40 C.F.R. § 156.10(a)(5)(iv));
- c. Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the federal government (40 C.F.R. § 156.10(a)(5)(v)); or
- d. 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” (40 C.F.R. § 156.10(a)(5)(ix)).

13. Section 14(a)(1) of FIFRA, 7 U.S.C. § 136l(a)(1), authorizes a civil penalty of not more than \$5,000 for each offense. The Debt Collection Improvement Act of 1996, 31 U.S.C. § 3701, as amended, and the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, 28 U.S.C. § 2461, and implementing regulations at 40 C.F.R. Part 19, increased these

statutory maximum penalties to \$20,528 for violations that occur after November 2, 2015, and for which penalties are assessed on or after December 23, 2020.

Definitions

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

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

16. The regulations found at 40 C.F.R. § 152.15(a)(1) and (b) further defines the term “pesticide” as any substance intended for a pesticidal purpose, and thus 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; or the substance consists of or contains one or more active ingredients and has no significant commercially valuable use as distributed or sold other than use for pesticidal purpose.

17. Section 2(t) of FIFRA, 7 U.S.C. § 136(t), defines “pest” to mean (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-organism on or in living man or other living animals) which the Administrator declares to be a pest under Section 25(c)(1).

18. Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), defines “to distribute or sell” to mean to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship,

deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver.

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

20. Section 2(p)(2) of FIFRA, 7 U.S.C. § 136(p)(2), defines “labeling” 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.

EPA Findings of Fact and Conclusions of Law

21. Respondent is, and at all times referred to herein was, a “person” as defined by Section 2(s) of FIFRA, 7 U.S.C. § 136(s).

22. On January 25, 2021, the EPA requested, and Respondent provided documentation and information concerning Respondent’s compliance with FIFRA and the federal regulations promulgated thereunder.

23. Respondent leased an EPA registered facility at: 7800 Dallas Parkway, Suite 650 Plano, Texas 75024(the “Facility”).

24. Pursuant to Section 9 of FIFRA, 7 U.S.C. § 136g, the EPA conducted an inspection of the Facility on July 9, 2021, to further investigate Respondent’s compliance with FIFRA and the federal regulations promulgated thereunder (the “Inspection”).

25. Respondent produced and distributed a product called “SurfaceWise 2” (“the Product”).

26. Labeling for the Product stated that the Product “kills 99.9% of viruses including COVID-19, influenza, the common cold, RSV, MRSA and more.”

27. Labeling for the Product also stated that the Product “Provides the first-ever, long-lasting, always-on protection against viruses and bacteria – including SARS-CoV-2.”

28. Viruses and bacteria are “pests” as that term is defined by Section 2(t) of FIFRA, 7 U.S.C. § 136(t).

29. The Product was a “pesticide” as that term is defined by Section 2(u) of FIFRA, 7 U.S.C. § 136(u), because it is a substance intended for preventing, destroying, repelling, or mitigating pests.

30. The Product was a “pesticide” as that term is further defined by 40 C.F.R. § 152.15(a)(1), which requires registration pursuant to Section 3 of FIFRA, 7 U.S.C. § 136a, because it is a substance intended for pesticidal purposes for which Respondent stated by labeling when distributing the Product that the Product can or should be used as a pesticide.

31. The Product consisted of or contains the active ingredient 1-Octadecanaminium,N,N-dimethyl-N-[3-(trihydroxysilyl)propyl],chloride.

32. The Product was a “pesticide” as that term is further defined by 40 C.F.R. § 152.15(b), which requires registration pursuant to Section 3 of FIFRA, 7 U.S.C. § 136a, because the Product consisted of or contained of one or more active ingredients, 1-Octadecanaminium,N,N-dimethyl-N-[3-(trihydroxysilyl)propyl],chloride, and has no significant commercially valuable use distributed or sold other than use for pesticidal purposes.

33. At the time the Product was distributed or sold by Respondent, the Product was not registered pursuant to Section 3 of FIFRA, 7 U.S.C. § 136a.

34. Pursuant to Section 18 of FIFRA, and 40 C.F.R. § 152.30(e), an unregistered pesticide may be distributed or sold in accordance with the terms of an emergency exemption under FIFRA Section 18, if the product is labeled in accordance with Part 156 of this chapter.

35. On August 24, 2020, the EPA issued two public health exemptions pursuant to Section 18 of FIFRA, 7 U.S.C. § 136p, to the Texas Department of Agriculture for the Product.

36. On January 19, 2021, the EPA issued two amended public health exemptions pursuant to Section 18 of FIFRA, 7 U.S.C. § 136p, to the Texas Department of Agriculture, revising conditions set forth in the original public health exemptions issued on August 24, 2020.

37. On January 19, 2021, the EPA issued public health exemptions pursuant to Section 18 of FIFRA, 7 U.S.C. § 136p, to the Arkansas Department of Agriculture and Oklahoma Department of Agriculture for the Product.

38. The August 24, 2020 public health exemptions and January 19, 2021 public health exemptions are herein collectively referred to as the “Public Health Exemptions.”

39. The conditions set forth in the Public Health Exemptions limited distribution of the Product to the following facilities:

- a. Twenty-Seven (27) American Airlines aircraft and airport facilities in Texas;
- b. Two (2) Total Orthopedics Sport and Spine facilities in Texas;
- c. Four (4) American Airlines aircraft and airport facilities in Arkansas; and
- d. Five (5) American Airlines aircraft and airport facilities in Oklahoma.

Hereinafter the “Authorized Facilities”.

EPA Findings of Violation

40. The facts stated in the EPA Findings of Fact and Conclusions of law above are herein incorporated.

41. Complainant hereby states and alleges that Respondent has violated FIFRA and the federal regulations promulgated thereunder as follows:

Counts 1 – 122

Unlawful Distribution of an Unregistered Pesticide

42. Pursuant to Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), it is unlawful for any person to distribute or sell any pesticide that is not registered under Section 3 of FIFRA, 7 U.S.C. § 136a, or whose registration has been cancelled or suspended.

43. Pursuant to Section 18 of FIFRA, 7 U.S.C. § 136p, and 40 C.F.R. § 152.30(e), an unregistered pesticide may not be distributed or sold unless in accordance with the terms set forth in the emergency exemption issued pursuant to Section 18.

44. Beginning on or about March 24, 2020, through on or about July 2021, Respondent distributed the Product not in accordance with the terms set forth in the Public Health Exemptions when distributing the Product on multiple occasions to persons not included in the Authorized Facilities.

45. Each distribution of the Product not in accordance with the terms set forth in the Public Health Exemptions is a violation of Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A).

Counts 123-144

Unlawful Distribution or Sale of a Misbranded Pesticide

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

47. The labeling for the Product bared the following false or misleading statements:

- a. "SurfaceWise®2 shows a greater than 3 log reduction in surface time lab tests on both Staph aureus and Pseudomonas aeruginosa."
- b. Two bar charts listing pathogens other than SARS-CoV-2, "S. aureus" and "P. aeruginosa", with the captions ">5 log reduction in a suspension test" and ">3.5 log reduction in a sanitizer spray test"
- c. "SurfaceWise®2 has strong bactericidal (kill) activity under multiple test conditions against both gram+ and gram- micro organisms."
- d. A bar chart referring to pathogens other than SARS-CoV-2, "S. aureus" and "P. aeruginosa", with the caption ">3.5 log reduction in a surface sanitizer test after stainless steel surface wearing"
- e. "General antimicrobial activity."
- f. "Proven, statistically significant clinical and microbiological results in high risk study units."
- g. "Up to 55% reduction in sites positive for pathogens, e.g., MRSA, Strep, E. coli and fungi"
- h. "99% BACTERIAL REDUCTION"
- i. "80% LOWER C.DIFF RATES*"
- j. Re: Acute Oral Toxicity: "No clinical signs of toxicity observed"
- k. Re: Acute Inhalation Toxicity: "No clinical signs of toxicity observed"
- l. Re: Acute Eye Irritation: "Practically non-toxic and not an irritant"
- m. Re: Acute Skin Toxicity: "No clinical signs of toxicity or dermal irritation observed"
- n. Re: Acute Skin Irritation: "Practically non-toxic and not an irritant"
- o. Re: Skin Sensitization: "Not considered a sensitizer"
- p. "SurfaceWise™ coatings are non-toxic non sensitizers with category IV safety characterization based on EPA categorization."
- q. "Enhanced durability on surfaces, indicating over 90-day durability."

- r. “Unique proprietary analytical tools to confirm coverage and durability over 90 days.”
- s. “SurfaceWise®2 coating has 90% remaining after 15 abrasion cycles and 85% remaining after 50 cycles. Based on SurfaceWise 1 field data, this extrapolates to at least 90 days in the field.”
- t. “[L]ow toxicity profile, safe to use on the most common surface types and materials in professional and public places.”

Hereinafter the “Statements.”

48. The Product was misbranded when bearing the Statements.

49. The misbranded Product was distributed or sold on one hundred twenty-two (122) occasions from March 24, 2020, through on or about July 2021.

50. Each distribution or sale of the misbranded Product is a violation of Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

CONSENT AGREEMENT

51. For the purpose of this proceeding, as required by 40 C.F.R. § 22.18(b)(2),

Respondent:

- a. admits the jurisdictional allegations set forth herein;
- b. neither admits nor denies the specific factual allegations stated herein;
- c. consents to the assessment of a civil penalty, as stated herein;
- d. consents to the issuance of any specified compliance or corrective action order;
- e. consents to any conditions specified herein;
- f. consents to any stated Permit Action;
- g. waives any right to contest the allegations set forth herein; and

h. waives its right to appeal the Final Order accompanying this Consent Agreement.

52. Respondent consents to the issuance of this Consent Agreement and Final Order and consents for the purposes of settlement to the payment of the civil penalty specified herein.

53. Respondent and EPA agree to conciliate this matter without the necessity of a formal hearing and to bear their respective costs and attorneys' fees.

Penalty Payment

54. Pursuant to the authority granted in Section 14(a) of FIFRA, and upon consideration of the entire record, including consideration of: (1) the effect upon Respondent's ability to continue in business; (2) the gravity of the alleged violation; (3) Respondent's ability to pay the proposed civil penalty; and (4) EPA's "Enforcement Response Policy for the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)" dated July 2, 1990, it is **ORDERED** that the Respondent be assessed a civil penalty of two hundred and fifty-three thousand, and thirty-two dollars (\$253,032.00), as set forth below.

55. Respondent shall pay the penalty within thirty (30) days of receiving notice of the effective date of the Final Order. Such payment shall identify Respondent by name and docket number and shall be by certified or cashier's check made payable to the "United States Treasury" and sent to:

U.S. Environmental Protection Agency
Fines and Penalties
Cincinnati Finance Center
PO Box 979077
St. Louis, Missouri 63197-9000

or by alternate payment method described at <http://www.epa.gov/financial/makepayment>.

56. A copy of the check or other information confirming payment shall simultaneously be sent to the following:

Lorena S. Vaughn
Regional Hearing Clerk
U.S. Environmental Protection Agency, Region 6
vaughn.lorena@epa.gov; and

Blake Sieminski
Enforcement and Compliance Assurance Division
Waste Enforcement Branch
U.S. Environmental Protection Agency, Region 6
sieminski.blake@epa.gov

57. Respondent understands that its failure to timely pay any portion of the civil penalty may result in the commencement of a civil action in Federal District Court to recover the full remaining balance, along with penalties and accumulated interest. In such case, interest shall begin to accrue on a civil or stipulated penalty from the date of delinquency until such civil or stipulated penalty and any accrued interest are paid in full. 31 C.F.R. § 901.9(b)(1). Interest will be assessed at a rate of the United States Treasury Tax and loan rates in accordance with 31 U.S.C. § 3717. Additionally, a charge will be assessed to cover the costs of debt collection including processing and handling costs, and a non-payment penalty charge of six percent (6%) per year compounded annually will be assessed on any portion of the debt which remains delinquent more than ninety (90) days after payment is due. 31 U.S.C. § 3717(e)(2).

Effect of Settlement and Reservation of Rights

58. Full payment of the penalty proposed in this Consent Agreement shall only resolve Respondent's liability for federal civil penalties for the violations alleged herein. Complainant reserves the right to take any enforcement action with respect to any other violations of the FIFRA or any other applicable law.

59. The effect of settlement described in the immediately preceding paragraph is conditioned upon the accuracy of Respondent's representations to the EPA, as memorialized in the paragraph directly below.

60. Respondent certifies by the signing of this Consent Agreement that it is presently in compliance with all requirements of FIFRA and its implementing regulations based on Respondent's best knowledge.

61. Full payment of the penalty proposed in this Consent Agreement shall not in any case affect the right of the Agency or the United States to pursue appropriate injunctive or other equitable relief or criminal sanctions for any violations of law. This Consent Agreement and Final Order does not waive, extinguish or otherwise affect Respondent's obligation to comply with all applicable provisions of the FIFRA and regulations promulgated thereunder.

62. Complainant reserves the right to enforce the terms and conditions of this Consent Agreement and Final Order.

General Provisions

63. By signing this Consent Agreement, the undersigned representative of Respondent certifies that he or she is fully authorized to execute and enter into the terms and conditions of this Consent Agreement and has the legal capacity to bind the party it represents to this Consent Agreement.

64. This Consent Agreement shall not dispose of the proceeding without a final order from the Regional Judicial Officer or Regional Administrator ratifying the terms of this Consent Agreement. This Consent Agreement and Final Order shall be effective upon the filing of the Final Order by the Regional Hearing Clerk for EPA, Region 6. Unless otherwise stated, all time periods stated herein shall be calculated in calendar days from such date.

65. The penalty specified herein shall represent civil penalties assessed by EPA and shall not be deductible for purposes of Federal, State and local taxes.

66. This Consent Agreement and Final Order shall apply to and be binding upon Respondent and Respondent's agents, successors and/or assigns. Respondent shall ensure that all contractors, employees, consultants, firms, or other persons or entities acting for Respondent with respect to matters included herein comply with the terms of this Consent Agreement and Final Order.

67. The EPA and Respondent agree to the use of electronic signatures for this matter pursuant to 40 C.F.R. § 22.6. The EPA and Respondent further agree to electronic service of this Consent Agreement and Final Order by email to the following:

To EPA: *pittman.lawrence@epa.gov*

To Respondent: *jkeefe@alliedbioscience.com*; and *swilson@kslaw.com*

RESPONDENT:
ALLIED BIOSCIENCE, INC.

Date: 2/25/2022 | 11:18:33 AM PST

DocuSigned by:


14658122BDA9419

Signature

Bob Godfroid
Name

President & Chief Scientific Officer
Title

COMPLAINANT:
U.S. ENVIRONMENTAL PROTECTION AGENCY



Digitally signed by Seager, Cheryl
DN: cn=Seager, Cheryl,
email=Seager.Cheryl@epa.gov
Date: 2022.03.03 12:00:53 -06'00'
Cheryl T. Seager
Director
Enforcement
and Compliance Assurance Division
U.S. EPA, Region 6

FINAL ORDER

Pursuant to Section 14(a) of FIFRA, 7 U.S.C. § 136l(a), 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, the foregoing Consent Agreement resolving this matter is hereby ratified and incorporated by reference into this Final Order.

Respondent is ORDERED to comply with all of the terms of the Consent Agreement. In accordance with 40 C.F.R. § 22.31(b), the effective date of the foregoing Consent Agreement and this Final Order is the date on which this Final Order is filed with the Regional Hearing Clerk.

This Final Order shall resolve only those causes of action alleged in the Consent Agreement. Nothing in this Final Order shall be construed to waive, extinguish, or otherwise affect Respondents' (or its officers, agents, servants, employees, successors, or assigns) obligation to comply with all applicable federal, state, and local statutes and regulations, including the regulations that were the subject of this action.

IT IS SO ORDERED.

**THOMAS
RUCKI**

Digitally signed by THOMAS RUCKI
DN: cn=US, o=U.S. Government,
ou=Environmental Protection Agency,
ou=THOMAS RUCKI,
0.9.2342.19200300.100.1.1+68001003655804
Date: 2022.03.03 12:47:02 -0600

Thomas Rucki
Regional Judicial Officer

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing Consent Agreement and Final Order was electronically delivered to the Regional Hearing Clerk, U.S. EPA, Region 6, 1201 Elm Street, Dallas, Texas 75270-2102, and that a true and correct copy was sent this day in the following manner to the addressees:

Copy via Email to Complainant:

pittman.lawrence@epa.gov

Copy via Email to Respondent:

Jennifer Keefe
Allied BioScience, Inc.
jkeefe@alliedbioscience.com; and

Suzanne Wilson
King & Spalding, LLP.
swilson@kslaw.com

**LAWRENCE
PITTMAN**

Digitally signed by LAWRENCE PITTMAN
DN: c=US, o=U.S. Government,
ou=Environmental Protection Agency,
cn=LAWRENCE PITTMAN,
0.9.2342.19200300.100.1.1=680010031302
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Date: 2022.03.03 13:54:18 -06'00'

Signed
Office of Regional Counsel
U.S. EPA, Region 6