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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ENVIRONMENTAL APPEALS BOARD
WASHINGTON, D.C. ENVIR. APPEALS BOARD

IN THE MATTER OF:

OmniLytics, Inc.

Respondent.

Docket No. FIFRA-HQ-2013-5003

CONSENT AGREEMENT AND FINAL ORDER

CONSENT AGREEMENT

Complainant, United States Environmental Protection Agency ("EPA") and Respondent, OmniLytics, Inc. ("OmniLytics"), agree to this action and consent to the entry of this Consent Agreement and Final Order ("CAFO") before taking testimony and without any adjudication of any issues of law or fact herein.

I. NATURE OF ACTION

1. This is a civil administrative action commenced under section 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA" or the "Act"), as amended, 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 ("Consolidated Rules"), 40 C.F.R. part 22. This action imposes civil penalties pursuant to section 14(a) of FIFRA.
2. Complainant and Respondent have conferred for the purpose of settlement pursuant to 40 C.F.R. § 22.18, and desire to settle this action. Accordingly, before any testimony has been taken and without any admission of violation, or adjudication of any issue of fact or law, and in accordance with 40 C.F.R. § 22.13(b), Complainant and Respondent have agreed to the execution of this CAFO. Respondent hereby agrees to comply with the terms of this CAFO.

II. THE PARTIES

3. Rosemarie A. Kelley, Director, Waste and Chemical Enforcement Division, Office of Civil Enforcement, Office of Enforcement and Compliance Assurance, is authorized by lawful delegation to institute and settle civil administrative actions brought pursuant to section 14(a) of FIFRA.

4. Respondent, OmniLytics, is a corporation doing business in Salt Lake City, Utah, with revenues in excess of \$4,000,000 in calendar year 2012.

III. PRELIMINARY STATEMENT

5. Respondent stipulates that Complainant has jurisdiction over the subject matter of this Consent Agreement.
6. Respondent waives any defenses it might have as to venue and jurisdiction.
7. Pursuant to 40 C.F.R. § 22.18(b)(2), Respondent waives its right to contest the allegations herein, its right to appeal the Final Order, and its right to request a judicial or administrative hearing on any issue of law or fact set forth in, and resolved by, this Consent Agreement.
8. Respondent neither admits nor denies the allegations and determinations set forth in Section V of this Consent Agreement.

IV. STATUTORY AND REGULATORY BACKGROUND

9. It shall be unlawful for any person to refuse to maintain or submit any records required by or under FIFRA. 7 U.S.C. §§ 136f and 136j(a)(2)(B).
10. The Administrator may prescribe regulations requiring producers, registrants, and applicants for registration to maintain such records ... as the Administrator determines to be necessary for the effective enforcement of this Act....” 7 U.S.C. § 136f(a).
11. 40 C.F.R. § 169.2(k) requires that producers of pesticide products retain records containing research data relating to registered pesticides, including all underlying raw data, as long as the registration is valid and the producer is in business.
12. The Administrator is authorized to assess a civil penalty against any registrant, commercial applicator, wholesaler, dealer, retailer or other distributor who violates any provision of FIFRA. The maximum statutory civil penalty is \$6,500 for each offense that occurred after March 15, 2004 through January 12, 2009, and \$7,500 for each offense occurring after January 12, 2009. 7 U.S.C. § 136l(a)(1).
13. The term “person” means “any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not.” 7 U.S.C. § 136(s).
14. The term “to distribute or sell” means “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.” 7 U.S.C. § 136(gg).

15. The term “producer” means “the person who manufactures, prepares, compounds, propagates, or processes any pesticide or device or active ingredient, used in producing a pesticide.” 7 U.S.C. § 136(w).
16. The term “sponsor” means “(1) A person who initiates and supports, by provision of financial or other resources, a study; (2) A person who submits a study to the EPA in support of an application for a research or marketing permit; or (3) A testing facility, if it both initiates and actually conducts the study.” 40 C.F.R. § 160.3.
17. The term “study” means “any experiment at one or more test sites, in which a test substance is studied in a test system under laboratory conditions or in the environment to determine or help predict its effects, metabolism, product performance (efficacy studies only as required by 40 C.F.R. §§ 158.400 or 161.640 as applicable), environmental and chemical fate, persistence and residue, or other characteristics in humans, other living organisms, or media.” 40 C.F.R. § 160.3.
18. The term “registrant” means “a person who has registered any pesticide pursuant to the provisions of [FIFRA].” 7 U.S.C. § 136(y).
19. The term “pesticide” means, in part: “any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.” 7 U.S.C. § 136(u).

V. EPA ALLEGATIONS AND DETERMINATIONS

20. Respondent is a “person” as that term is defined by FIFRA. 7 U.S.C. § 136(s).
21. Respondent is a “registrant” as that term is defined by FIFRA. 7 U.S.C. § 136(y).
22. Respondent is a “sponsor” as that term is defined by 40 C.F.R. § 160.3, of the following studies: EPA MRID No. 463614-01C, EPA MRID No. 470088-01C, EPA MRID No. 465754-01C, and EPA MRID No. 468873-01C.
23. Respondent is the registrant of the following pesticides: Agriphage, EPA Reg. No. 67986-1, and Agriphage-CMM, EPA Reg. No. 67986-6.
24. Respondent is a “producer” of Agriphage, EPA Reg. No. 67986-1 and Agriphage-CMM, EPA Reg. No. 67986-6 as that term is defined by FIFRA. 7 U.S.C. § 136(w).
25. Agriphage, EPA Reg. No. 67986-1, and Agriphage-CMM, EPA Reg. No. 67986-6, are intended to destroy, repel, or mitigate pests.
26. Therefore, Agriphage, EPA Reg. No. 67986-1, and Agriphage-CMM, EPA Reg. No. 67986-6 are “pesticides” as defined by FIFRA. 7 U.S.C. § 136(u).
27. On or about September 13, 2004, Respondent submitted the study entitled: “Product Chemistry: Agriphage Comprehensive Resubmission,” MRID No. 463614-01C

(conducted by Respondent), to EPA in support of the registration of Agriphage, EPA Reg. No. 67986-1.

28. On or about May 18, 2005, Respondent submitted the study entitled: "Product Chemistry: Agriphage Amendment of MRID 460938-01 and 461970-01," MRID No. 465754-01C (conducted by Respondent), to EPA in support of the registration of Agriphage, EPA Reg. No. 67986-1.
29. On or about July 13, 2006, Respondent submitted the study entitled: "Product Chemistry: Agriphage Amendment #2 of MRID 46093801 and Amendment #1 of MRID 46575401" MRID No. 468873-01C (conducted by Respondent), to EPA in support of the registration of Agriphage, EPA Reg. No. 67986-1.
30. On or about December 18, 2006, Respondent submitted the study entitled: "Product Chemistry: Agriphage-CMM," MRID No. 470088-01C (conducted by Respondent), to EPA in support of the registration of Agriphage-CMM, EPA Reg. No. 67986-6.
31. On or about May 21, 2010, Respondent submitted the study entitled: "Product Chemistry: Bacteriophage for Xanthomonas campestris pv. vesicatoria and Pseudomonas syringae pv. tomato," MRID No. 48106001 (conducted by Respondent), to EPA in support of the registration of Agriphage, EPA Reg. No. 67986-1.
32. On or about August 19, 2008, and January 18, 2012, a duly authorized representative of the EPA conducted an inspection of Respondent's laboratory facility located at 5450 W. Wiley Post Way, Salt Lake City, Utah, 84116. The inspections were conducted to determine the facility's compliance with the FIFRA Good Laboratory Practice Standards regulations at 40 C.F.R. part 160 and the Books and Records of Pesticide Production and Distribution regulations at 40 C.F.R. part 169.
33. The inspections conducted on or about August 19, 2008, and January 18, 2012, of Respondent's laboratory facility located at 5450 W. Wiley Post Way, Salt Lake City, Utah, 84116, revealed that no raw data was available from the laboratory facility, the registrant, or the producer of Agriphage, EPA Reg. No. 67986-1 and Agriphage-CMM, EPA Reg. No. 67986-6, to support the conclusions of the final report for the studies listed in Paragraphs 27-31 above.
34. Therefore, Respondent's conduct described in Paragraph 33 above reveals that each failure to maintain records as required under FIFRA, 7 U.S.C. § 136f is a separate violation under FIFRA, 7 U.S.C. § 136j(a)(2)(B), as detailed in the chart below.

Count	Study	Violation
1	MRID No. 463614-01C	7 U.S.C. § 136j(a)(2)(B)
2	MRID No. 465754-01C	7 U.S.C. § 136j(a)(2)(B)
3	MRID No. 468873-01C	7 U.S.C. § 136j(a)(2)(B)
4	MRID No. 470088-01C	7 U.S.C. § 136j(a)(2)(B)
5	MRID No. 481060-01	7 U.S.C. § 136j(a)(2)(B)

VI. TERMS OF SETTLEMENT

35. Respondent consents to issuance of this Consent Agreement and to its terms, and consents, for the purposes of settlement, to the payment of the civil penalty set forth in Section VII.
36. Respondent's compliance with the terms of this CAFO shall fully settle all civil claims or civil causes of action alleged in Section V.
37. Compliance with this CAFO shall not be a defense to any subsequent action EPA may commence pursuant to federal law or regulation for violations occurring after the date of this Consent Agreement, or any violations of FIFRA not alleged in this Consent Agreement that may have occurred prior to the date that this Consent Agreement is fully executed by both Parties.
38. Nothing in this CAFO is intended to, nor shall be construed to operate in any way to, resolve any criminal liability of Respondent.

VII. CIVIL PENALTY

39. Complainant has calculated a penalty pursuant to the statutory penalty factors listed in section 14(a)(3) of FIFRA, 7 U.S.C. §136/(a)(3), the Enforcement Response Policy for the Federal Insecticide, Fungicide, and Rodenticide Act (December 2009) and the Enforcement Response Policy for FIFRA Good Laboratory Practice Regulations (September 1991), Appendix G of the FIFRA ERP.
40. Based upon the information in Complainant's inspections of August 19, 2008, and January 18, 2012, referenced in Section V, and in accordance with the penalty adjustments allowed under the FIFRA ERP, Complainant has derived a penalty of \$22,680.
41. The penalty agreed upon by the Parties for settlement purposes is \$22,680.
42. Not more than sixty (60) calendar days following execution of the Final Order by the Environmental Appeals Board, Respondent shall either:
 - a) Dispatch a cashier's or certified check payable to the order of the "Treasurer of the United States of America" in the amount of \$22,680 and bearing the notation, "OmniLytics, Inc., Civil Penalty Docket No. FIFRA HQ-2013-5003" to the following address:

U.S. Environmental Protection Agency
Fines and Penalties
Docket No. FIFRA-HQ-2013-5003

Cincinnati Finance Center
PO Box 979077
St. Louis, MO 63197-9000

or

- b) Make an electronic payment by wire transfer in the amount of \$22,680 with the notation, "OmniLytics, Inc., Civil Penalty Docket No. FIFRA HQ-2013-5003," by using the following instructions:

Federal Reserve Bank of New York
ABA = 021030004
Account = 68010727
SWIFT address = FRNYUS33
33 Liberty Street
New York, NY 10045
Field Tag 4200 of the Fedwire message should read:
"D 68010727 Environmental Protection Agency."

43. To ensure a record of compliance with this Consent Agreement, Respondent shall forward a copy of the check or wire transfer to EPA to the attention of:

Brian Dyer
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W. (Mail Code 2249A)
Washington, DC 20460-0001

and

Headquarters Hearing Clerk
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W. (Mail Code 1900C)
Washington, DC 20460-0001

44. If Respondent fails to pay the civil penalty of \$22,680 within sixty (60) calendar days of the execution of the Final Order, then Respondent shall pay an additional stipulated penalty of \$5,000 per calendar day, plus interest, at the statutory judgment rate provided for in 31 U.S.C. § 3717, as in effect on the date of execution of the Final Order, unless Complainant in writing excuses or mitigates the stipulated penalty. Complainant may excuse or mitigate the stipulated penalty if Complainant determines in its sole discretion, that failure to comply occurred despite Respondent's exercise of good faith and due diligence. If additional stipulated penalties are due, Complainant will dispatch to Respondent a demand letter via certified mail, return receipt requested, which specifies the total amount due and owed by Respondent, including any interest allowed by law. Within fourteen (14) calendar days following Respondent's receipt of such demand letter, Respondent shall pay the stipulated penalty in the manner specified in this Section.

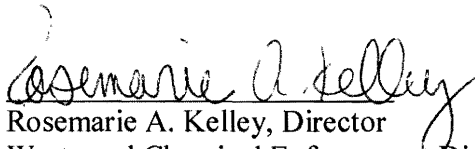
45. Failure to remit the civil penalty, or any stipulated penalty plus interest provided herein, may result in this matter being forwarded to the United States Department of Justice to recover such amount by action in federal court under section 14(a)(5) of FIFRA. 7 U.S.C. § 1361(a)(5). The validity, amount and appropriateness of the civil penalty are not reviewable in a collection action.
46. This civil penalty is not deductible for federal tax purposes.

VIII. OTHER MATTERS

47. Nothing in this CAFO shall relieve Respondent of the duty to comply with all applicable provisions of FIFRA and with other federal, state, tribal, and local laws and regulations.
48. This CAFO shall bind both Parties. This includes each Party's officers, directors, employees, successors, and assigns. The undersigned representative of each Party to this CAFO certifies that he or she is duly authorized to represent and bind the Party whom he or she claims to represent.
49. This CAFO shall bind the Parties in full effect upon execution of the Final Order by EPA's Environmental Appeals Board.
50. Respondent's obligations under this CAFO shall terminate when Respondent has paid the civil penalty, and any applicable interest or late charges, as specified in Section VII of the Consent Agreement in accordance with the Final Order.
51. Each Party agrees to bear its own costs and attorney fees in this matter.

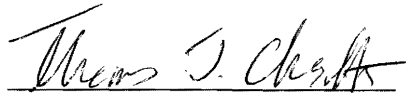
WE AGREE TO THIS:

FOR COMPLAINANT:



Rosemarie A. Kelley, Director
Waste and Chemical Enforcement Division
Office of Civil Enforcement
Office of Enforcement and Compliance Assurance
United States Environmental Protection Agency

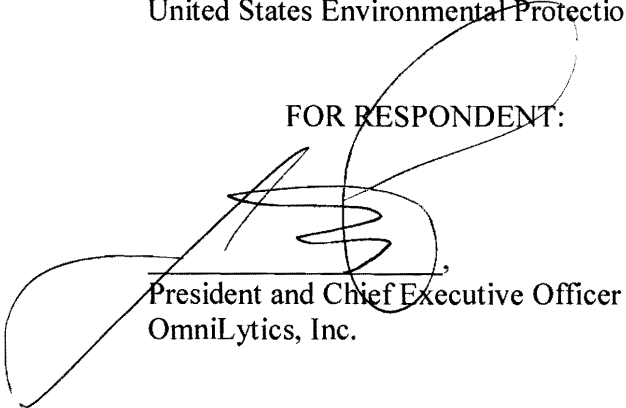
5/21/13
Date:



Thomas Charlton, Attorney
Waste and Chemical Enforcement Division
Office of Civil Enforcement
Office of Enforcement and Compliance Assurance
United States Environmental Protection Agency

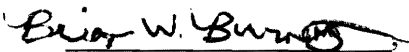
5/14/13
Date:

FOR RESPONDENT:



President and Chief Executive Officer
OmniLytics, Inc.

5/6/13
Date:



Brian W. Burnett
Counsel for OmniLytics, Inc.

5/7/13
Date: