

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

)	
IN THE MATTER OF:)	
)	
Sumitomo Chemical Company, Ltd.,)	Docket No. FIFRA-HQ-2016-5020
)	
Respondent.)	
)	

CONSENT AGREEMENT AND FINAL ORDER

CONSENT AGREEMENT

Complainant, United States Environmental Protection Agency (“EPA”) and Respondent, Sumitomo Chemical Company, Ltd. (“Sumitomo”), 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 THE ACTION

1. This is a civil administrative action instituted 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. Gregory A. Sullivan, Acting 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 is a public corporation doing business in Japan and throughout the world principally in five business segments, including Health and Crop Sciences. Respondent's consolidated gross revenues in fiscal year 2015 were in excess of \$18,652,503 (Thousands).

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 or 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. Pursuant to FIFRA section 12(a)(2)(B)(i), 7 U.S.C. § 136j(a)(2)(B)(i), it shall be unlawful for any person to refuse to prepare, maintain, or submit any records required by or under FIFRA Section 8, 7 U.S.C. § 136f.
10. FIFRA section 8 provides that the Administrator "may prescribe regulations requiring producers, registrants, and applicants for registration to maintain such records with respect to . . . the pesticides and devices produced as the Administrator determines are necessary for the effective enforcement of this subchapter . . ." 7 U.S.C. § 136f(a).
11. 40 C.F.R. § 169.2(k) requires producers of pesticides to maintain "records containing research data relating to registered pesticides, including all test reports submitted to the Agency in support of registration or in support of a tolerance petition, all underlying raw data, and interpretations and evaluations thereof, whether in the possession of the producer or in the possession of the independent testing facility or laboratory (if any)

which performed such tests on behalf of the producer... 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 \$7,500 for each offense occurring after January 12, 2009 and on or before November 2, 2015. 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 “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).
15. The term “registrant” means “a person who has registered any pesticide pursuant to the provisions of [FIFRA].” 7 U.S.C. § 136(y).
16. 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

17. Respondent is a “person” as that term is defined by FIFRA, 7 U.S.C. § 136(s).
18. Respondent is a “producer,” as that term is defined by FIFRA, 7 U.S.C. § 136(w), of S-1563 Flying and Crawling Insect Killer Spray.
19. Respondent is the “registrant,” as that term is defined by FIFRA, 7 U.S.C. § 136(y), of S-1563 Flying and Crawling Insect Killer Spray, a pesticide currently registered under EPA Registration Number 10308-36.
20. S-1563 Flying and Crawling Insect Killer Spray is intended to destroy, repel, or mitigate pests, and is a “pesticide” as defined by FIFRA, 7 U.S.C. § 136(u).
21. Respondent sponsored the study entitled, “S-1563 Evaluation of a Spray Containing S-1563 (Water Based Aerosol) for Knockdown and Kill of Caged Flies and Mosquitoes,” MRID No. 49020247 (“STUDY 1”).

22. Respondent sponsored the study entitled, "S-1563 Evaluation of a Spray Containing S-1563 (Water Based Aerosol) for Knockdown and Kill of Crawling Venomous Arthropods (Scorpions, Spiders and Centipedes)," MRID No. 49020248 ("STUDY 2"). Study 1 and 2 will hereinafter be referred to collectively as the "Studies."
23. The Studies were conducted by i2L Research USA laboratory, located at 1330 Dillon Heights Ave., Baltimore MD 21228 ("Laboratory") and coordinated by Niketas Spero of the Laboratory.
24. On or about January 10, 2013, Respondent submitted the Studies to EPA in support of the registration of S-1563 Flying and Crawling Insect Killer Spray as a pesticide. The reports for the Studies (on page 3 of each report) included the following signed Good Laboratory Practice Standards ("GLPS") compliance statement: "The study described in this document was conducted according to its protocol and using sound scientific principles. The study does not comply with the Good Laboratory Practice Standards issued by the EPA in 40 CFR 160, dated August 17, 1989, because, amongst other missing elements, a Quality Assurance Unit did not audit the study protocol, critical phases, raw data or the Final Study Report. However, all original raw data and facility records supporting the Final Study Report are documented and maintained and will be available for inspection/audit by the U.S. EPA."
25. On May 7, 2015, EPA's Office of Enforcement and Compliance Assurance sent a letter to Respondent and the Laboratory informing them that EPA representatives would be conducting an inspection of the Laboratory in order to determine compliance with the FIFRA GLPS, set forth at 40 C.F.R. part 160, and the Books and Records of Pesticide Production and Distribution regulations, set forth at 40 C.F.R. part 169, and to audit the data for the Studies presented to EPA in support of the registration of S-1563 Flying and Crawling Insect Killer Spray ("the Inspection").
26. On or about May 18, 2015 to May 20, 2015, a representative from EPA's Office of Compliance conducted the Inspection of the Laboratory.
27. The Inspector's report of May 20, 2015 observed, in part, that "[r]ecords are missing for accountability of test substance;" "[r]ecords for colonies of test system are missing (rearing of test system) for study MRID 49020247;" "[r]ecords were missing for calibration of spraying (application);" "[r]ecords for calibration of application of CO₂ are lacking (MRID 49020247)."

28. In a letter dated June 9, 2015, Ms. Kristine Styer, Head of Efficacy at the Laboratory at the time of the Inspection, responded to the Inspector's observations and submitted records, including records for the calibration of spraying (application).
29. Respondent's failure to maintain the research data identified in paragraph 27 relating to S-1563 Flying and Crawling Insect Killer Spray is a violation of law under FIFRA Section 12(a)(2)(B)(i), 7 U.S.C. § 136j(a)(2)(B)(i), for which Respondent may be assessed a civil penalty pursuant to FIFRA Section 14(a)(1), 7 U.S.C. § 136l(a)(1).

VI. TERMS OF SETTLEMENT

30. 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.
31. Full payment of the penalty proposed in this CAFO shall only resolve Respondent's liability for Federal civil penalties for the violations alleged in Section V of this CAFO.
32. 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.
33. Nothing in this CAFO is intended to, nor shall be construed to operate in any way to, resolve any criminal liability of Respondent.

*Revised
9/29/2016
JDC jr.*

VII. CIVIL PENALTY

34. Complainant has calculated a penalty pursuant to the statutory penalty factors listed in Section 14(a)(4) of FIFRA, 7 U.S.C. §136l(a)(3), the Enforcement Response Policy for the Federal Insecticide, Fungicide, and Rodenticide Act Good Laboratory Practice Regulations ("GLP ERP") (September 1991), and the Enforcement Response Policy for the Federal Insecticide, Fungicide, and Rodenticide Act (December 2009) ("FIFRA ERP").
35. In accordance with the penalty adjustments allowed under the FIFRA ERP, Complainant has derived a penalty of \$7,150.00.
36. The penalty agreed upon by the Parties for settlement purposes is \$7,150.00.

37. Within 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 \$7,150.00 and bearing the notation, "Sumitomo Chemical Company, Ltd., Civil Penalty Docket No. FIFRA HQ-2016-5020" to the following address:

U.S. Environmental Protection Agency
Fines and Penalties
Docket No. FIFRA-HQ-2015-5020
Cincinnati Finance Center
P.O. Box 979077
St. Louis, MO 63197-9000

or

- b) Make an electronic payment by wire transfer in the amount of \$7,150.00 with the notation, "Sumitomo Chemical Company, Ltd., Civil Penalty Docket No. FIFRA HQ-2016-5020," 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."

38. 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:

Joseph Varco
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W. (Mail Code 2843)
Washington, DC 20460-0001

and

Headquarters Hearing Clerk
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mail Code 1900R
Washington, DC 20460

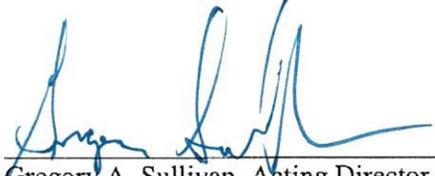
39. If Respondent fails to pay the civil penalty of \$7,150.00 within sixty (60) calendar days of the execution of the Final Order, then Respondent shall pay an additional stipulated penalty of \$5,000 per calendar day, plus interest, at the statutory judgment rate provided for in 31 U.S.C. § 3717, as 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.
40. 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.
41. This civil penalty is not deductible for federal tax purposes.

VIII. OTHER MATTERS

42. 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.
43. 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.
44. This CAFO shall bind the Parties in full effect upon execution of the Final Order by EPA's Environmental Appeals Board.
45. 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.
46. Each Party agrees to bear its own costs and attorney fees in this matter.

WE AGREE TO THIS:

FOR COMPLAINANT:



Gregory A. Sullivan, Acting Director
Waste and Chemical Enforcement Division
Office of Civil Enforcement
Office of Enforcement and Compliance Assurance
United States Environmental Protection Agency

9/6/16

Date:



Christina E. Cobb, Attorney
Waste and Chemical Enforcement Division
Office of Civil Enforcement
Office of Enforcement and Compliance Assurance
United States Environmental Protection Agency

8/30/2016

Date:

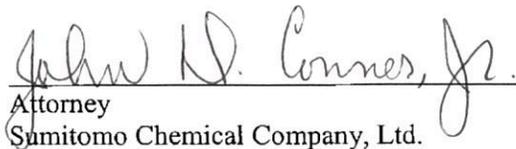
FOR RESPONDENT:



Kazuyuki Nuki
Executive Officer
AgroSolutions Division Japan
Environmental Health Division
Health and Crop Science Sector
Sumitomo Chemical Company, Ltd.

25/8/2016

Date:



John D. Conner, Jr.
Attorney
Sumitomo Chemical Company, Ltd.

8/29/2016

Date: