



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

FEB 03 2017

REPLY TO THE ATTENTION OF
LC-8J

VIA EMAIL

Sandra O'Kelley
Associate Manager, Regulatory Affairs
Merial, Incorporated
3239 Satellite Boulevard
Duluth, Georgia 30096

Sandra.O'Kelley@Merial.com

Re: Consent Agreement and Final Order In the Matter of Merial Limited
Docket Number **FIFRA-05-2017-0007**

Ms. O'Kelley,

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 2/3/2017 with the Regional Hearing Clerk.

The civil penalty in the amount of \$8,251 is to be paid in the manner described in paragraphs 43-44. Please be certain that the docket number is written on both the transmittal letter and on the check. Payment is due within 30 calendar days of the filing date.

Thank you for your cooperation in resolving this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Abigail Wesley".

Abigail Wesley
Pesticides and Toxics Compliance Section

Enclosure

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

In the Matter of:

Merial, Incorporated
Duluth, Georgia



Respondent.

Docket No. FIFRA-05-2017-0007

Proceeding to Assess a Civil Penalty
Under Section 14(a) of the Federal
Insecticide, Fungicide, and Rodenticide
Act, 7 U.S.C. § 136l(a)

Consent Agreement and Final Order
Commencing and Concluding a Proceeding

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. § 136l(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 Land and Chemicals Division, United States Environmental Protection Agency (EPA), Region 5.
3. Respondent is Merial, Incorporated (Merial), doing business in Duluth, Georgia.
4. 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.
5. Respondent consents to the assessment of the civil penalty specified in this Consent Agreement and Final Order (CAFO), and to the terms of this CAFO.

Jurisdiction and Waiver of Right to Hearing

6. Respondent admits the jurisdictional allegations in this CAFO and neither admits nor denies the factual allegations in this CAFO.

7. Respondent waives its rights 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 rights to appeal this CAFO.

Statutory and Regulatory Background

8. The importation of pesticides into the United States is governed by Section 17(c) and (e) of FIFRA, 7 U.S.C. §§ 136o(c) and 136o(e), and the regulations promulgated thereunder by the Secretary of the Treasury in consultation with the Administrator of the EPA (the Administrator). These regulations are found at 19 C.F.R. Part 12.

10. 19 C.F.R. § 12.111 states, in pertinent part, that all imported pesticides are required to be registered under the provisions of Section 3 of FIFRA, 7 U.S.C. § 136a, and under the regulations promulgated thereunder by the Administrator before being permitted entry into the United States. These regulations are found at 40 C.F.R. Parts 152 and 156.

11. 19 C.F.R. § 12.112 states, in pertinent part, that an importer desiring to import pesticides into the United States shall submit to the Administrator a Notice of Arrival of Pesticides or Devices (EPA Form 3540-1), prior to the arrival of the shipment to the United States. See also Section 17(c) of FIFRA, 7 U.S.C. § 136o(c).

12. 40 C.F.R. § 156.10(a) states, that every pesticide product shall bear a label containing the information specified by FIFRA and the regulations in this part.

13. Section 2(q)(1)(A) of FIFRA, 7 U.S.C. § 136(q)(a)(A), defines a pesticide as “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.

14. 40 C.F.R. § 156.10(a)(5) provides, that examples of statements or representations in the labeling which constitute misbranding include... (v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government, and (vii) A true statement used in such a way as to give a false or misleading impression to the purchaser.

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

16. Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), defines the term “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.

17. 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.

18. 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 accompanying the pesticide or device at any time or to which reference is made on the label or in literature accompanying the pesticide or device.

19. Section 2(t) of FIFRA, 7 U.S.C. § 136(t), defines a “pest” as any insect, rodent, nematode, fungus, weed, or any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other microorganism (except viruses, bacteria, or other living microorganisms on or in living man or other living animals) which the Administrator declares to be a pest under Section 25(c)(1) of FIFRA, 7 U.S.C. § 136 w(c)(1).

20. Section 2(u) of FIFRA, 7 U.S.C. § 136(u), defines a “pesticide” as any substance or

mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.

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

22. Section 17(e) of FIFRA, 7 U.S.C. § 136o(e), and 19 C.F.R § 12.1(b) provide that the regulations for the importation of pesticides and devices are joint regulations and enforceable by the cooperating agencies.

23. Section 14(a)(1) of FIFRA, 7 U.S.C. § 136l(a)(1), provides that any registrant, commercial applicator, wholesaler, dealer, retailer or other distributor who violates any provision of FIFRA may be assessed a civil penalty by EPA of not more than \$5,000 for each offense. The Federal Civil Penalties Inflation Adjustment Act of 1990, as amended through 2015, 28 U.S.C. § 2461 note, and its implementing regulations at 40 C.F.R. Part 19, increased this amount to \$18,750 for each offense occurring after November 2, 2015.

Factual Allegations and Alleged Violation

24. Respondent is, and was at all times relevant to this Complaint, a corporation, and therefore, a “person” as that term is defined at Section 2(s) of FIFRA, 7 U.S.C. § 136(s).

25. On or about October 18, 2016, Expeditors International (Expeditors), located at 300 Tradeport Drive, Suite 300, Atlanta, Georgia 30354, was a broker/agent for Respondent.

26. On or about October 18, 2016, Respondent submitted a Notice of Arrival of Pesticides or Devices to EPA, Region 5, for the import shipment, identified by Entry Number 231-2096336-3, which arrived from France by air transport into the Port of Cincinnati.

27. The import shipment, identified by Entry Number 231-2096336-3, consisted of 8 50-kilogram drums of the pesticide "Fipronil," EPA Registration Number (EPA Reg. No.) 7969-243.

28. The Notice of Arrival identified Merial as the importer of record for the shipment of "Fipronil," EPA Reg. No. 7969-243.

29. On or about October 18, 2016, Respondent "distributed or sold" the pesticide product "Fipronil," EPA Reg. No. 7969-243, as that term is defined in 2(gg) of FIFRA, 7 U.S.C. § 136(gg).

30. Respondent was a distributor of the pesticide product "Fipronil," EPA Reg. No. 7969-243.

31. Respondent, as importer of "Fipronil," EPA Reg. No. 7969-243 and by doing business in the United States, is subject to the requirements of FIFRA and the regulations promulgated thereunder.

32. "Fipronil," EPA Reg. No. 7969-243 is a registered pesticide, as defined in Section 2(u) of FIFRA, 7 U.S.C. § 136(u).

33. On or about October 22, 2014, the EPA, Office of Chemical Safety and Pollution Prevention (OSCPP), accepted the amended label for "Fipronil," EPA Reg. No. 7969-243 to update and reformat the labeling. OSCPP provided Respondent with a stamp that documented its acceptance of the amended label.

34. Labels affixed to the 8 50-kilogram drums of "Fipronil," EPA Reg. No. 7969-243, that were distributed or sold on or about October 18, 2016, contained, among other things, the stamp that read:

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 7969-243.”

35. 40 C.F.R. § 156.10(a) requires container labeling statements to be placed on the label or container as applicable.

36. 40 C.F.R. § 156.10(a)(5) provides, in pertinent part, that a pesticide is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims.

37. Section 2(q)(1)(A) of FIFRA, 7 U.S.C. § 136(q)(a)(A), defines a pesticide as “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.

38. Labels affixed to the 8 50-kilogram drums of “Fipronil,” EPA Reg. No. 7969-243, that entered into the United States on or about October 18, 2016, were false or misleading as noted at 40 C.F.R. § 156.10(a)(5)(vii), as they contained a true statement used in such a way that could give a false or misleading impression to the purchaser.

39. On or about October 18, 2016, Respondent distributed or sold the misbranded pesticide “Fipronil,” EPA Reg. No. 7969-243, under entry number 231-2096336-3 with a label bearing a statement, design, or graphic representation relative thereto or to its or to its ingredients which was false or misleading, which constitutes an unlawful act in violation of Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

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

41. Respondent's violation of Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E) subjects Respondent to the issuance of an Administrative Complaint assessing a civil penalty under Section 14(a) of FIFRA, 7 U.S.C § 136l(a).

Civil Penalty

42. Pursuant to Section 14(a)(4) of FIFRA, 7 U.S.C. § 136l(a)(4), Complainant determined that an appropriate civil penalty to settle this action is \$8,251. In determining the penalty amount, Complainant considered the appropriateness of the penalty to the size of Respondent's business, the effect on Respondent's ability to continue in business, and the gravity of the violation. Complainant also considered EPA's Enforcement Response Policy for the Federal Insecticide, Fungicide, and Rodenticide Act, dated December 2009.

43. Within 30 days of the effective date of this CAFO, Respondent must pay an \$8,251 civil penalty for the FIFRA violation. Respondent must pay the penalty by an on-line payment. To pay on-line, go to www.pay.gov. Use the Search Public Forms option on the tool bar and enter SFO 1.1 in the search field. Open the form and complete the required fields.

44. A transmittal letter stating Respondent's name, complete address, the case title and the case docket number must accompany the payment. Respondent must send a copy of the transmittal letter and proof of payment to:

Regional Hearing Clerk (E-19J)
U.S. EPA, Region 5
77 West Jackson Blvd.
Chicago, IL 60604

Abigail Wesley (LC-8J)
Pesticides and Toxics Compliance Section
U.S. EPA, Region 5
77 West Jackson Blvd.
Chicago, IL 60604

Jose DeLeon (C-14J)
Office of Regional Counsel
U.S. EPA, Region 5
77 West Jackson Blvd.
Chicago, IL 60604

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

46. If Respondent does not pay the civil penalty timely, EPA may refer the matter to the Attorney General who will recover such amount by action in the appropriate United States district court under Section 14(a)(5) of FIFRA, 7 U.S.C. § 136l(a)(5). The validity, amount and appropriateness of the civil penalty are not reviewable in a collection action.

47. Pursuant to 31 C.F.R. § 901.9, Respondent 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. Respondent must pay a \$15 handling charge each month that any portion of the penalty is more than 30 days past due. In addition, Respondent must pay a 6 percent per year penalty on any principal amount 90 days past due.

48. Respondent certifies that it is complying with FIFRA, 7 U.S.C. §§ 136-136y.

General Provisions

49. Consistent with the “Standing Order Authorizing E-Mail Service of Order and Other Documents Issued by the Regional Administrator or Regional Judicial Officer Under the Consolidated Rules,” dated March 27, 2015, the parties consent to service of this CAFO by e-mail at the following valid e-mail addresses: deleon.jose@epa.gov (for Complainant), and Sandra.O'Kelley@Merial.com (for Respondent). The parties waive their right to service by the methods specified in 40 C.F.R. § 22.6.

50. This CAFO resolves only Respondent’s liability for federal civil penalties for the

violations and facts alleged in the CAFO.

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

52. This CAFO does not affect Respondent's responsibilities to comply with FIFRA and other applicable federal, state, and local laws.

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

54. The terms of this CAFO bind Respondent, its successors, and assigns.

55. 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.

56. Each party agrees to bear its own costs and attorney fees in this action.

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

**In the Matter of:
Merial, Incorporated**

Merial, Incorporated

17-Jan-2017
Date

John Lee
John Lee
Supply Planner
Merial, Incorporated

MERIAL LEGAL
11 Jan 2017

**In the Matter of:
Merial, Incorporated**

United States Environmental Protection Agency, Complainant

1/26/2017

Date




Margaret M. Guerriero
Director
Land and Chemicals Division

In the Matter of:
Merial, Incorporated
Docket No. FIFRA-05-2017-0007

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.

February 2, 2017
Date


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

In the matter of: Merial, Incorporated
Docket Number: FIFRA-05-2017-0007

CERTIFICATE OF SERVICE

I certify that I served a true and correct copy of the foregoing *Consent Agreement and Final Order*, which was filed on February 3, 2017, in the following manner to the addressees:

Copy by Email to
Respondent:

Sandra O'Kelley
Sandra.O'Kelley@Merial.com

Copy by E-mail to
Attorney for Complainant:

Jose DeLeon
deleon.jose@epa.gov

Copy by E-mail to
Regional Judicial Officer:

Ann Coyle
coyle.ann@epa.gov

Dated:

February 3, 2017



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