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

IN THE MATTER OF:

é

Bayer CropScience LP,

Docket No. FIFRA-HQ-2016-5021

Respondent.

# **CONSENT AGREEMENT AND FINAL ORDER**

#### **CONSENT AGREEMENT**

Complainant, United States Environmental Protection Agency ("EPA") and Respondent, Bayer Environmental Science, a division of Bayer CropScience LP ("Bayer"), 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

- 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. § 136/(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 corporation doing business in Research Triangle Park, North Carolina with revenues in excess of \$10,000,000 in calendar year 2014.

### **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.

1

- 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 BACKGROUND**

- 9. Pursuant to FIFRA Section 12(a)(2)(Q), 7 U.S.C. § 136j(a)(2)(Q), it shall be unlawful for any person to falsify all or part of any information relating to the testing of any pesticide (or any ingredient, metabolite, or degradation product thereof), including the nature of any protocol, procedure, substance, organism, or equipment used, observations made, or conclusions or opinion formed, submitted to the Administrator, or that the person knows will be furnished to the Administrator or will become a part of any records required to be maintained by FIFRA.
- 10. 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. § 136*l*(a)(1).
- 11. 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).
- 12. The term "registrant" means "a person who has registered any pesticide pursuant to the provisions of [FIFRA]." 7 U.S.C. § 136(y).
- 13. 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

14. Respondent is a "person" as that term is defined by FIFRA, 7 U.S.C. § 136(s).

8

 Respondent is the "registrant," as that term is defined by FIFRA, 7 U.S.C. § 136(y), of BES0570 Insecticide, EPA Reg. No. 432-1526, alternate name, Harmonix Insect Spray ("Harmonix").

,\*

- 16. Harmonix is intended to destroy, repel, or mitigate pests, and therefore is a "pesticide" as defined by FIFRA, 7 U.S.C. § 136(u).
- 17. On or about March 2, 2012, Respondent submitted the study entitled "Evaluation of knockdown and kill efficacy of BES0570 against the black carpenter ant (*Camponotus pennsylvanicus*) in a laboratory study," MRID No. 486005-28 ("STUDY 1"), to EPA in support of the registration of Harmonix.
- 18. On or about March 2, 2012, Respondent submitted the study entitled "Laboratory evaluation of residual efficacy of BES0570 on porous and non-porous surfaces against American, Oriental, brown-banded and German cockroaches," MRID No. 486005-29 ("STUDY 2"), to EPA in support of the registration of Harmonix.
- STUDY 1 and STUDY 2 were conducted by Bayer Environmental Science at Clayton Development and Training Center located at 981 NC 42 East, Clayton, North Carolina 27527 ("Clayton Facility").
- 20. On or about June 18, 2014, a duly authorized representative of EPA conducted an inspection of the Clayton Facility to determine compliance with FIFRA regulations ("the Inspection").
- 21. The Inspection revealed that some of the data in the final report submitted to EPA with STUDY 1 in support of the registration of Harmonix were not consistent with the raw data for STUDY 1 that was available at the Clayton Facility.
- 22. The Inspection revealed that a data table in the final report submitted to EPA with STUDY 2 in support of the registration of Harmonix could not be recalculated from the raw data for STUDY 2 that was available at the Clayton Facility.
- 23. By submitting information in the final report for STUDY 1 that was inconsistent with the testing data for STUDY 1, Respondent falsified part of the information relating to the testing of a pesticide submitted to EPA in violation of FIFRA Section 12(a)(2)(Q), 7 U.S.C. § 136j(a)(2)(Q).<sup>1</sup>
- 24. By submitting information in the final report for STUDY 2 that could not be recalculated from the raw data for STUDY 2, Respondent falsified part of the information relating to

<sup>&</sup>lt;sup>1</sup> FIFRA Section 12(a)(2)(Q) violations require only a showing that the information submitted was false, not that the submitter knowingly falsified testing information or submitted information that it knew to be false. *See* EPA's September 1991 "Enforcement Response Policy for the [FIFRA] Good Laboratory Practice (GLP) Regulations" at 6-7 (contrasting 12(a)(2)(Q) violations with "knowing" violations at 12(a)(2)(M) and (R)).

the testing of a pesticide submitted to EPA in violation of FIFRA Section 12(a)(2)(Q), 7 U.S.C. § 136j(a)(2)(Q).<sup>2</sup>

25. Respondent may be assessed a civil penalty pursuant to FIFRA Section 14(a)(1), 7 U.S.C. § 136*l*(a)(1), for each violation of FIFRA Section 12(a)(2)(Q), 7 U.S.C. § 136*j*(a)(2)(Q).

### VI. TERMS OF SETTLEMENT

- 26. Respondent consents to issuance of this Consent Agreement and to its terms, and consents, for the purposes of settlement, to pay the civil penalty set forth in Section VII.
- 27. In accordance with 40 C.F.R. § 22.18(c), Respondent's full compliance with this Consent Agreement shall only resolve Respondent's liability for federal civil penalties alleged in Section V of this CAFO.
- 28. 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.
- 29. 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

- 30. 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)(4), the Enforcement Response Policy for the Federal Insecticide, Fungicide, and Rodenticide Act (December 2009) ("FIFRA ERP"), and the Enforcement Response Policy for the [FIFRA] Good Laboratory Practice (GLP) Regulations (September 1991) ("GLPS ERP").
- 31. Based upon the information collected pursuant to Complainant's Inspection, and in accordance with the GLPS ERP and the FIFRA ERP, Complainant has calculated an appropriate penalty of \$15,000.
- 32. The penalty agreed upon by the Parties for settlement purposes is \$15,000.
- 33. 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 \$15,000 and bearing the notation,

2

<sup>&</sup>lt;sup>2</sup> See n.1.

"Bayer CropScience LP Civil Penalty Docket No. FIFRA HQ-2016-5021" to the following address:

For standard mail delivery:

U.S. Environmental Protection Agency Fines and Penalties Docket No. FIFRA-HQ-2016-5021 Cincinnati Finance Center P.O. Box 979077 St. Louis, MO 63197-9000

For FedEx, DHL, UPS, USPS certified or registered, etc.:

U.S. Environmental Protection Agency Fines and Penalties Docket No. FIFRA-HQ-2016-5021 Cincinnati Finance Center Box 979077 SL-MO-C2-GL St. Louis, MO 63101

or

b) Make an electronic payment by wire transfer (Fedwire) in the amount of \$15,000 with the notation, "Bayer CropScience LP Civil Penalty Docket No. FIFRA HQ-2016-5021," through the Federal Reserve Bank of New York by using the following information:

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

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

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

1

Clerk of the Board U.S. Environmental Protection Agency Environmental Appeals Board 1200 Pennsylvania Avenue, N.W. Mail Code 1103M Washington, DC 20460-0001

- 35. If Respondent fails to pay the civil penalty of \$15,000 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.
- 36. 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. § 136*l*(a)(5). The validity, amount and appropriateness of the civil penalty are not reviewable in a collection action.
- 37. This civil penalty is not deductible for federal tax purposes.

#### **VIII. OTHER MATTERS**

- 38. 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.
- 39. 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.
- 40. This CAFO shall bind the Parties in full effect upon execution of the Final Order by EPA's Environmental Appeals Board.
- 41. 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.

42. Each Party agrees to bear its own costs and attorney fees in this matter.

1

b,

# WE AGREE TO THIS:

FOR COMPLAINANT:

1

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

E Calibr

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

Advience Trivedi 10-25-2016

FOR RESPONDENT:

<u>10/24/2016</u> Date

Gilles Galliou, Vice President Environmental Science North America Bayer CropScience LP 2 T.W. Alexander Drive Research Triangle Park, NC 27709