

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

IN THE MATTER OF:)	
The Procter & Gamble Company,)	Docket No. FIFRA-HQ-2016-5018
Respondent.)	

CONSENT AGREEMENT AND FINAL ORDER

CONSENT AGREEMENT

Complainant, United States Environmental Protection Agency ("EPA") and Respondent, The Procter & Gamble Company ("P&G"), 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 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 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 P&G is a corporation doing business in Cincinnati, Ohio, with revenues in excess of \$76 billion.

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. 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. § 136j(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 that performed such tests on behalf of the producer, as long as the registration is valid and the producer is in business.
12. 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.

13. 40 C.F.R. part 160 prescribes FIFRA Good Laboratory Practice Standards ("GLPS") for use in conducting studies that support or are intended to support applications for research or marketing permits for pesticide products regulated by EPA.
14. 40 C.F.R. § 160.12 states that any person who submits to EPA an application for a research or marketing permit and who, in connection with the application, submits data from a study to which this part applies shall include in the application a true and correct statement, signed by the applicant, the sponsor, and the study director, of one of the following types: (a) a statement that the study was conducted in accordance with part 160 (GLPS); or (b) a statement describing in detail all differences between the practices used in the study and those required by part 160; or (c) a statement that the person was not a sponsor of the study, did not conduct the study, and does not know whether the study was conducted in accordance with part 160.
15. 40 C.F.R. § 160.17(b) states that submission of a statement required by 40 C.F.R. § 160.12 that is false may form the basis for imposition of civil penalties under FIFRA Section 14.
16. 40 C.F.R. § 160.35(a) states that for any given study conducted in accordance with GLPS, the study's quality assurance unit shall be entirely independent and separate from the personnel engaged in the direction and conduct of that study.
17. 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. 7 U.S.C. § 136f(a)(1).
18. 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).
19. 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.
20. 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.
21. The term "registrant" means "a person who has registered any pesticide pursuant to the provisions of [FIFRA]." 7 U.S.C. § 136(y).

22. 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

23. Respondent is a "person" as that term is defined by FIFRA, 7 U.S.C. § 136(s).
24. Respondent is the "registrant," as that term is defined by FIFRA, 7 U.S.C. § 136(y), of Speedo, a pesticide currently registered under EPA Registration Number 3573-98 ("Speedo").
25. Speedo is intended to destroy, repel, or mitigate pests, and is a "pesticide" as defined by FIFRA, 7 U.S.C. § 136(u).
26. Respondent is the "sponsor," as that term is defined by 40 C.F.R. § 160.3, of a study entitled: "Ocular irritation assay for certain antimicrobial products making cleaning claims using the bovine corneal opacity and permeability assay with optional histology," MRID No. 49081609 ("the Study").
27. On or about May 13, 2013, Respondent submitted the Study to EPA in support of Speedo's registration as a pesticide.
28. With its application for registration of Speedo, Respondent submitted to EPA a signed statement stating that the Study "was conducted in compliance with the U.S. EPA GLP Standards 40 CFR 160 in all material aspects" with two exceptions. The two exceptions Respondent acknowledged in the compliance statement were: (1) "the identity, strength, purity and composition or other characteristics to define the test substance has not been determined by the testing facility," and (2) "the stability of the substance under the storage conditions has not been determined by the testing facility and is not included in the final report."
29. On or about June 29, 2015 to July 1, 2015, an authorized representative of EPA conducted an inspection of the Institute for In Vitro Sciences, Inc., located at 30 W. Watkins Mill Road, Gaithersburg, MD 20878 (the "Facility") in order to determine compliance with the EPA FIFRA GLP regulations, 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 ("the Inspection").
30. The Inspection revealed that at the time Respondent's Study was conducted, there was a lack of separation between the Quality Assurance Unit from personnel engaged in the direction and conduct of the study, specifically, that the manager of information systems/lead electronic archivist reported to the head of Quality Assurance, and that Quality Assurance personnel were responsible for the control of standard operating procedures for the Study.

31. The Inspection revealed that there was no documentation explaining why four bovine eye corneas were not treated with the test substance and/or discarded and no documentation for the disposal method of the total number of bovine eye corneas used in the Study as required by 40 C.F.R. § 169.2(k).
32. The Inspection revealed that the Facility's testing practices did not conform to the GLPS set forth at 40 C.F.R. § 160.35(a).
33. Respondent's signed compliance statement submitted to EPA with the Study in support of its application for registration of Speedo did not describe the differences between the practices used in the Study and those required by the GLPS.
34. Respondent's submission of a false compliance statement is a violation of FIFRA Section 12(a)(2)(Q), 7 U.S.C. § 136j(a)(2)(Q), and therefore, also pursuant to 40 C.F.R. § 160.17(b), may form the basis for the imposition of a civil penalty under FIFRA Section 14(a)(1), 7 U.S.C. § 136l(a)(1).¹
35. Respondent's failure to maintain all required research data relating to Speedo 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

36. 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.
37. Respondent's compliance with the terms of this CAFO shall fully settle all civil claims or civil causes of action alleged in Section V.
38. 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.
39. Nothing in this CAFO is intended to, nor shall be construed to operate in any way to, resolve any criminal liability of Respondent.

¹ Pursuant to FIFRA Section 12(a)(2)(Q), the submission of a GLPS compliance statement which incorrectly describes the differences between the practices used in the study and those required by GLPS is considered a "false" statement. See EPA's December 2009 *Enforcement Response Policy for the Federal Insecticide, Fungicide, and Rodenticide Act* ("FIFRA ERP").

VII. CIVIL PENALTY

40. 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 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").
41. Based upon the information gathered as a result of Complainant's Inspection referenced in Section V, and in accordance with the penalty adjustments allowed under the FIFRA ERP, Complainant has derived a penalty of \$14,300.
42. The penalty agreed upon by the Parties for settlement purposes is \$14,300.
43. 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 \$14,300 and bearing the notation, "The Procter & Gamble Company, Civil Penalty Docket No. FIFRA HQ-2016-5018" to the following address:

U.S. Environmental Protection Agency
Fines and Penalties
Docket No. FIFRA-HQ-2016-5018
Cincinnati Finance Center
PO Box 979077
St. Louis, MO 63197-9000

or

- b) Make an electronic payment by wire transfer in the amount of \$14,300 with the notation, "The Procter & Gamble Company, Civil Penalty Docket No. FIFRA HQ-2016-5018," 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."

44. 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 20460-0001

45. If Respondent fails to pay the civil penalty of \$14,300 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.
46. 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. § 136J(a)(5). The validity, amount and appropriateness of the civil penalty are not reviewable in a collection action.
47. This civil penalty is not deductible for federal tax purposes.

VIII. OTHER MATTERS


48. 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.
49. 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.

50. This CAFO shall bind the Parties in full effect upon execution of the Final Order by EPA's Environmental Appeals Board.
51. 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.
52. Each Party agrees to bear its own costs and attorney fees in this matter.

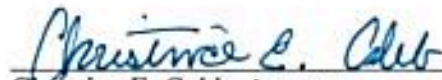
WE AGREE TO THIS:

FOR COMPLAINANT:



Gregory Sullman, Director (Acting)
Waste and Chemical Enforcement Division
Office of Civil Enforcement
Office of Enforcement and Compliance Assurance
United States Environmental Protection Agency


8/23/16
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

August 17, 2016
Date:

FOR RESPONDENT:



Ken Patel,
Vice President and General Counsel-Global
Brand Legal and Global Beauty
The Procter & Gamble Company

August 1, 2016
Date:



Attorney
Counsel for The Procter & Gamble Company

August 1, 2016
Date: