

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

In re:	) ) ) D	Oocket No. FIFRA-HQ-2020-5012
Danaher Corporation, New Owner of Pall Corporation	) )	
Respondent.	)	

#### FINAL ORDER

Pursuant to 40 C.F.R. § 22.18(b)-(c) of EPA's Consolidated Rules of Practice, the attached Consent Agreement resolving this matter is incorporated by reference into this Final Order and is hereby ratified.

The Respondent is ORDERED to comply with all terms of the Consent Agreement, effective immediately.

So ordered.<sup>1</sup>

ENVIRONMENTAL APPEALS BOARD

Dated: November 5, 2020

Mary Kay Lynch Environmental Appeals Judge

<sup>&</sup>lt;sup>1</sup> The three-member panel ratifying this matter is composed of Environmental Appeals Judges Mary Kay Lynch, Aaron P. Avila, and Kathie A. Stein.

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

In the Matter of:	)	
	)	Docket No. FIFRA-HQ-2020-5012
Danaher Corporation,	)	
New Owner of Pall Corporation	)	
Washington, D.C.	)	
Respondent.	)	
	)	
	)	

#### **CONSENT AGREEMENT AND FINAL ORDER**

#### **CONSENT AGREEMENT**

Complainant the United States Environmental Protection Agency (EPA) and Respondent Danaher Corporation (collectively, "the Parties"), 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 and Authorities

- 1. The Parties have entered into this Agreement to settle voluntarily disclosed violations of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or "the Act"), as amended, 7 U.S.C. §§ 136-136y and its implementing regulations that Respondent discovered during due diligence activities at Pall Corporation ("Pall") facilities following Danaher's acquisition of Pall; the disclosed violations are described in more detail below.
- 2. This civil administrative proceeding for the assessment of penalties is authorized pursuant to Section 14(a) of FIFRA, 7 U.S.C. § 136*l*(a).
- 3. This matter is governed by the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, Issuance of Compliance or Corrective Action Orders, and the Revocation, Termination or Suspension of Permits, ("Consolidated Rules"), 40 C.F.R. Part 22, a copy of which has been provided to Respondent.
- 4. The Parties have entered into this Agreement for the purpose of simultaneously commencing and concluding this matter, as authorized by 40 C.F.R. §§ 22.13(b) and 22.18(b)(2) and (3). This Agreement contains all terms of the settlement agreed to by the Parties.
- 5. As required by 40 C.F.R. § 22.18(b)(2), for purposes of this proceeding only, Respondent:

- a. admits that the EPA has jurisdiction over the subject matter which is the basis of this Agreement;
- b. neither admits nor denies the specific factual allegations contained in this Agreement;
- c. consents to the assessment of the civil penalty provided in this Agreement;
- d. waives any right to contest the alleged violations of law set forth in this Agreement; and
- e. waives its rights to appeal the proposed Final Order accompanying this Agreement.

#### II. The Parties

- 6. Complainant is Diana J. Saenz, Acting Director of the Waste and Chemical Enforcement Division, Office of Civil Enforcement, Office of Enforcement and Compliance Assurance, EPA, and is authorized by lawful delegation to institute and settle civil administrative actions brought under Section 14(a) of FIFRA.<sup>1</sup>
- 7. Respondent is Danaher Corporation incorporated under the laws of the State of Delaware with its main office located at 2200 Pennsylvania Avenue, NW, Suite 800W, Washington, D.C. 20037.

#### III. Factual Background

- 8. Respondent is a globally diversified conglomerate comprised of more than 20 operating companies in the fields of diagnostics, life sciences, and environmental and applied solutions.
- 9. Pall manufactures and distributes filtration, separation, and purification products in biopharmaceutical, food and beverage, medical, aerospace, microelectronics and general industrial areas.
- 10. On August 31, 2015, Pall was acquired by Respondent through a merger transaction resulting in Pall becoming an indirect and wholly owned subsidiary of Respondent.
- 11. After the August 2015 acquisition, Respondent and Pall retained third-party outside counsel to oversee an audit of Pall's facilities and evaluate whether certain filtration products manufactured and produced by Pall qualified as pesticide devices subject to FIFRA and, if so, to evaluate their compliance with FIFRA's requirements for pesticide devices (the "Initial Audit").
- 12. By letter dated May 23, 2016, Respondent (along with Pall) notified the EPA of the results of the Initial Audit which included potential noncompliance with FIFRA by Pall within the audited Pall facilities (the "Self-Disclosure"). Specifically, the Self-Disclosure noted

EPA Administrator Delegation 5-14 (May 11, 1994) Administrative Update Feb. 4, 2016; OECA Redelegation 5-14 (September 2015); OCE Redelegation 5-14 (September 2015).

that certain filter products and product families manufactured, imported, and/or sold by certain Pall facilities potentially qualified as pesticide devices under FIFRA and potentially failed to comply with certain FIFRA requirements for pesticide devices. Respondent (along with Pall) self-disclosed these violations and requested penalty mitigation under the EPA's policies, *Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations* ("Audit Policy"), 65 Fed. Reg. 19,618 (Apr. 11, 2000) and *Interim Approach to Applying the Audit Policy to New Owners* ("Interim Approach"), 73 Fed. Reg. 44,991 (Aug. 1, 2008). The Interim Approach modifies certain conditions of the Audit Policy for owners of newly acquired facilities.

- 13. By letter dated May 26, 2016, Respondent (along with Pall) proposed to expand the scope of the Initial Audit into additional Pall products and product families for FIFRA compliance and on June 24, 2016, as requested by the EPA, provided a list of products and product families to be audited (the "Expanded Audit"). The EPA accepted the proposed expansion and entered into an audit agreement on June 10, 2016 which covered disclosures in both the Initial Audit and the Expanded Audit.
- 14. As agreed upon by the Parties and pursuant to the June 10, 2016 audit agreement, Respondent (along with Pall) provided periodic status updates on the audit of Pall. On December 4, 2018, a final report ("Final Report") was submitted to the EPA identifying certain Pall devices that were not compliant with the following FIFRA requirements applicable to pesticide devices pursuant to 40 C.F.R. § 152.500:
  - a. Labeling requirements under Section 2(q)(1) of FIFRA, 7 U.S.C. § 136(q)(1) and 40 C.F.R. Part 156;
  - b. Establishment registration and reporting requirements under Section 7 of FIFRA, 7 U.S.C. § 136e and 40 C.F.R. Part 167;
  - c. Requirements relating to books and records under Section 8 of FIFRA, 7 U.S.C. § 136f, and 40 C.F.R. Part 169; and
  - d. Requirements for the importation of devices under Section 17 of FIFRA, 7 U.S.C. § 1360 and 19 C.F.R. §§ 12.110-12.117.
- 15. The pesticide devices identified in the Final Report, as stated in paragraph 14, resulted in the following specific violations of FIFRA:
  - a. Distribution and sale of misbranded pesticide devices in violation of Section 12(a)(1)(F) of FIFRA, 7 U.S.C. § 136j(a)(1)(F);
  - b. Production of pesticide devices at establishments not registered with the EPA in violation of Section 12(a)(2)(L) of FIFRA, 7 U.S.C. § 136j(a)(2)(L);
  - c. Failure to submit required device production reports in violation of Section 12(a)(2)(L) of FIFRA, 7 U.S.C. § 136(a)(2)(L);
  - d. Failure to maintain required records in violation of Section 12(a)(2)(B)(i) of FIFRA, 7 U.S.C. § 136j(a)(2)(B)(i); and

- e. Failure to file Notices of Arrival for each shipment of pesticide devices imported into the United States in violation of Section 12(a)(2)(N) of FIFRA, 7 U.S.C. § 136j(a)(2)(N).
- 16. The Final Report, together with the accompanying answers on behalf of Respondent and Pall to EPA's questionnaire, summarized the implementation of corrective measures and steps taken by Respondent and Pall to prevent recurrence of the violations that had been disclosed, including implementation of a comprehensive and multilayered corporate-wide program within Pall to ensure future FIFRA compliance.
- 17. The final list of Pall products and product families subject to this Agreement are identified in Attachment A and the final list of establishments subject to this Agreement and disclosed violations to be settled in this Agreement are identified in Attachment B, both attachments are hereby incorporated by reference.

## Respondent's Certifications

- 18. Pursuant to the EPA's Audit Policy and the Interim Approach, with regard to the Pall products, product families and disclosures listed in Attachments A and B, Respondent (along with Pall) certifies and warrants as true the following facts upon which this Agreement is based:
  - a. The violations were discovered through an audit or through a compliance management system reflecting due diligence;
  - b. The violations were discovered voluntarily;
  - c. The violations were promptly disclosed to the EPA in writing;
  - d. The violations were disclosed prior to commencement of an agency inspection or investigation, notice of citizen suit, filing of a complaint by a third party, reporting of the violations by a "whistleblower" employee, or imminent discovery by a regulatory agency;
  - e. The violations have been corrected;
  - f. Appropriate steps have been taken to prevent a recurrence of the violations;
  - g. The specific violations (or closely related violations), identified in Attachments A and B, have not occurred within three years of the date of disclosures identified in Section III at the same Pall facilities that are the subject of this Agreement and have not occurred within five years of the date of disclosure identified in Section III as part of a pattern at multiple facilities owned or operated by Pall. For the purposes of Subparagraph G, a violation is:

- i. Any violation of federal, state, or local environmental law identified in a judicial or administrative order, consent agreement or order, complaint, or notice of violation, conviction or plea agreement; or
- ii. Any act or omission for which the regulated entity has previously received penalty mitigation from EPA or a state or local agency.
- h. The violations have not resulted in serious actual harm nor presented an imminent and substantial endangerment to human health or the environment, and they did not violate the specific terms of any judicial or administrative Final Order or Agreement; and
- i. Respondent has cooperated as requested by the EPA.

#### IV. Civil Penalty

- 19. The EPA agrees, based upon the facts and information submitted by and on behalf of Respondent and Pall and upon Respondent's certification herein to the veracity of this information, that Respondent has satisfied all of the conditions set forth in the Audit Policy and the Interim Approach for the violations described in Attachment B, and thereby qualifies for 100% reduction of the gravity component of the civil penalty for violations that otherwise would apply.
- 20. Under the Audit Policy and the Interim Approach, the EPA assesses a penalty equal to the economic benefit a new owner gained as a result of avoided operation and maintenances costs from the date a facility is acquired until corrections are complete. Based on information provided by and on behalf of Respondent and use of the EPA's Economic Benefit (BEN) computer model, for the violations described in Attachment B, specifically, failing to file Notices of Arrival for pesticide devices imported into the United States, the EPA has determined that Respondent obtained an economic benefit of \$48,215 in avoided costs.
- 21. Accordingly, the civil penalty agreed upon up by the Parties is \$48,215.

#### V. Terms of Settlement

- 22. Respondent consents to and agrees to pay a civil administrative penalty of FORTY-EIGHT THOUSAND TWO HUNDRED AND FIFTEEN DOLLARS (\$48,215) for the violations alleged herein within thirty (30) days after the effective date of the Final Order.
- 23. For payment of the civil penalty, Respondent shall either:
  - a. Dispatch a cashier's or certified check in the amount of FORTY-EIGHT THOUSAND TWO HUNDRED AND FIFTEEN DOLLARS (\$48,215) made payable to the order of the "Treasurer of the United States of America", and bearing the case docket number: "FIFRA-HQ-2020-5012" to the following address:

U.S. Environmental Protection Agency Fines and Penalties Docket No. FIFRA-HQ-2020-5012 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 \$48,215 with the notation, "Danaher Corporation, New Owner of Pall Corporation, Civil Penalty Docket No. FIFRA-HQ-2020-5012" 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"

24. To ensure a record of compliance with this Agreement, Respondent agrees to forward a copy of the check, wire transfers, and/or internet-based payments to the EPA, to the following two addresses:

Joseph Varco, Life Scientist
U.S. Environmental Protection Agency
Waste and Chemical Enforcement Division (2249A)
Office of Civil Enforcement, OECA
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, D.C. 20460
E-mail: varco.joseph@epa.gov.

Clerk, Environmental Appeals Board U.S. Environmental Protection Agency MC 1103M EPA East Building 1200 Pennsylvania Avenue, N.W. Washington, D.C. 20460 E-Mail: clerk EAB@epa.gov

- 25. By written notice to Respondent, the EPA may change the address and/or person listed above.
- 26. Pursuant to 31 U.S.C. § 3717, the EPA is entitled to assess interest and penalties on debts owed to the United States and a charge to cover the cost of processing and handling a delinquent claim. Interest will therefore begin to accrue on the civil penalty from the date of entry of the Final Order, if the penalty is not paid by the date required. Interest will be assessed at the rate of the United States Treasury tax and loan rate in accordance with 40 C.F.R. § 13.11. A charge will be assessed to cover the costs of debt collection, including processing and handling costs and attorney fees. In addition, a penalty charge of six percent (6%) per year compounded annually will be assessed on any portion of the debt that remains delinquent more than ninety (90) days after payment is due.
- 27. Respondent's obligations under this Agreement shall end when it has paid the civil penalty as required by this Agreement and the Final Order and complied with its obligations under this section of this Agreement.
- 28. For the purpose of state and Federal income taxation, Respondent or its affiliates shall not be entitled, and agree not to attempt, to claim a deduction for any civil penalty payment made pursuant to the Final Order. Any attempt by Respondent or its affiliates to deduct any such payments shall constitute a violation of this Agreement.

### VI. Severability

- 29. As part of this Agreement, and in satisfaction of the requirements of the Audit Policy and the Interim Approach, Respondent (along with Pall) has certified to certain facts, as set forth in Section III. Paragraph 18 of this Agreement. The Parties agree that, if and to the extent that the EPA determines that the facts in the Self-Disclosure or the certification provided by or on behalf of Respondent or Pall are materially false or inaccurate, the portion of this Agreement pertaining to the affected products and facilities, including mitigation of the proposed penalty, may be voided or this entire Agreement may be declared null and void at the EPA's election, and the EPA may proceed with an enforcement action.
- 30. The Parties agree that Respondent and its affiliates reserve all of their rights should this Agreement be voided in whole or in part. The Parties further agree that Respondent's obligations under this Agreement shall cease should this Agreement be rejected by the EAB; provided, however, that in the event that the EAB expresses any objections to, or its intent to reject, this Agreement, the Parties agree that they shall exercise their mutual best efforts to address and resolve the EAB's objections.

#### VII. Reservation of Rights

31. In accordance with 40 C.F.R. § 22.18(c), Respondent's full compliance with this Agreement shall only resolve Respondent's liability for federal civil penalties for the violations and facts alleged in Section III of this Agreement.

- 32. Nothing in this Agreement and the Final Order shall be construed to limit the authority of the EPA and/or the United States to undertake any action against Respondent, in response to any condition which the EPA or the United States determines may present an imminent and substantial endangerment to the public health, welfare, or the environment. Furthermore, full payment of the penalty shall not in any case 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.
- 33. Compliance with this Agreement shall not be a defense to any subsequent action the EPA may commence pursuant to Federal law or regulation for violations occurring after the date of this Agreement, or any violations of FIFRA not alleged in this Agreement that may have occurred prior to the date that this Agreement is fully executed by both Parties.

#### VIII. Other Matters

- 34. This Agreement shall be binding upon the Parties and their respective officers, directors, employees, successors and assigns. Any change in ownership or corporate status of the Respondent including, but not limited to, any transfer of assets or real or personal property shall not alter Respondent's responsibilities under this Agreement, including the obligation to pay the civil penalty referred to in Section V.
- 35. This Agreement shall take full effect upon the signing and filing of the Final Order by the EAB.
- 36. Nothing in this Agreement shall relieve Respondent of the duty to comply with all applicable provisions of FIFRA or other Federal, state, or local laws or regulations, nor shall it restrict the EPA's authority to seek compliance with any applicable laws, nor shall it be construed to be a ruling on, or a determination of, any issue related to any federal, state, or local permit.
- 37. Each party shall bear its own attorneys' fees, costs, and disbursements incurred in this proceeding.
- 38. In executing this Agreement, Respondent certifies that it is in full compliance with respect to the violations alleged in this Agreement.
- 39. The undersigned representative of each Party certifies that he or she is duly authorized by his or her respective Party to enter into this binding Agreement.

#### **WE AGREE TO THIS:**

#### FOR COMPLAINANT:

# DIANA SAENZ Digitally signed by DIANA SAENZ Date: 2020.09.14 21:49:31 -04'00'

Diana J. Saenz, Acting Director Waste and Chemical Enforcement Division Office of Civil Enforcement Office of Enforcement and Compliance Assurance United States Environmental Protection Agency

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

Date: 9/09/2020

# FOR RESPONDENT:

Brian W. Ellis
Senior Vice President and General Counsel
Danaher Corporation

#### **CERTIFICATE OF SERVICE**

I certify that copies of the foregoing "Consent Agreement" and "Final Order," in the matter of *Danaher Corporation, New Owner of Pall Corporation*, Docket No. FIFRA-HQ-2020-5012, were sent to the following persons in the manner indicated:

# By E-mail:

Susan V. Harris, Esq.
Sidley Austin, LLP
One South Dearborn
Chicago, IL 60603
Email: svharris@sidley.com

Christina Cobb
Office of Civil Enforcement
Office of Enforcement and Compliance Assurance
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Mail Code 2249A
Washington, DC 20460
E-mail: cobb.christina@epa.gov

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Dated: November 5, 2020

Eurika Durr Clerk of the Board