

STATE OF MAINE
PENOBSCOT, ss.

SUPERIOR COURT
CIVIL ACTION
Docket No. _____

MAINE DEPARTMENT OF)
ENVIRONMENTAL PROTECTION,)

Plaintiff,)

v.)

MALLINCKRODT US LLC,)

Defendant.)

**COMPLAINT FOR CIVIL PENALTIES
AND INJUNCTIVE RELIEF**

INTRODUCTION

1. This is an action seeking injunctive relief and civil monetary penalties for Mallinckrodt's ongoing failure to comply with binding orders, issued by the Maine Department of Environmental Protection, that govern the cleanup of what is believed to be the most contaminated site in Maine, the former HoltraChem site on the Penobscot River in Orrington. Mallinckrodt has stopped meaningful work at the site despite the Department orders, complaining of the difficulties and the high costs of cleaning up their toxic site because of the sheer extent of the contamination that it has encountered during remediation. But this is no excuse for Mallinckrodt's ongoing failure to adhere to the cleanup standards and other requirements of the orders, which were fully adjudicated and affirmed by the Law Court over ten years ago and are now final and binding. The Department brings this action to ensure that Mallinckrodt completes the important work that it is required to do by law.

PARTIES AND LOCATION OF VIOLATIONS

2. Plaintiff Maine Department of Environmental Protection (“Department” or “DEP”) brings this action by and through the Maine Attorney General, pursuant to powers vested in him by the common law and by 5 M.R.S. § 191 (2026) as the State’s chief law enforcement officer.

3. The Department is an agency of the State of Maine with its principal offices in Augusta, Kennebec County. Pursuant to 38 M.R.S. §§ 341-A, 342, 347-A (2026), the Department is responsible for administering and enforcing Maine’s environmental laws within title 38.

4. The Department comprises a Commissioner of the Department, four bureaus that administer the Department’s environmental programs, and the Board of Environmental Protection, a seven-member citizen board that, among other responsibilities, makes decisions on appeals of Commissioner licensing and enforcement actions.

5. The Department is seeking injunctive relief pursuant to 38 M.R.S. §§ 347-A(2) and 348(1) (2026), and civil monetary penalties pursuant to 38 M.R.S. § 349 (2026).

6. Defendant Mallinckrodt US LLC (“Mallinckrodt”) is a Delaware corporation and a subsidiary of Medtronic plc (“Medtronic”), a corporation incorporated in Ireland with its operational headquarters in Minnesota.

7. At all times relevant to this Complaint, Mallinckrodt was the owner and operator of the Site at issue in this action and further described below at ¶ 15.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction over this action pursuant to 4 M.R.S. § 105 (2026), 38 M.R.S. §§ 347-A, 348, 349, and 14 M.R.S. § 6051(13) (2026).

9. This Court has personal jurisdiction over Defendant pursuant to 14 M.R.S. § 704-A(2) (2026).

10. Venue is proper in Penobscot County pursuant to 14 M.R.S. § 501 (2026) because the violations giving rise to this action occurred and are occurring in Penobscot County.

STATUTORY AND REGULATORY FRAMEWORK

11. The Department was established to “prevent, abate and control the pollution of the air, water and land and preserve, improve and prevent diminution of the natural environment of the State.” 38 M.R.S. § 341-A(1).

12. All orders of the Department may be enforced by the Attorney General or the Department, 38 M.R.S. § 347-A(5), and the Attorney General is expressly authorized to institute a civil action “[i]n the event of a violation of any provision of the laws administered by the [D]epartment or of any order, regulation, license, permit, [or] approval,” *id.* § 348(1).

13. Any person who violates “the terms or conditions of a[] [Department] order” is “subject to a civil penalty, payable to the State, of not less than \$100 and not more than \$10,000 for each day of that violation.” 38 M.R.S. § 349(2). If the violation relates to hazardous waste, the violator is subject to a maximum penalty of not more than \$25,000 for each day of the violation. *Id.*

14. For purposes of statutes administered by the Department, “person” is defined to include a legal entity, 38 M.R.S. § 361-A(4) (2026), which would include a limited liability company, *see* 31 M.R.S. § 1502(14) (2026).

FACTS

The Orrington Site and Initial Remediation Efforts

15. Mallinckrodt owns the former HoltraChem chloralkali manufacturing facility on an approximately 235-acre parcel adjacent to the Penobscot River in Orrington, Maine, and identified

on the town of Orrington tax map at 005, lot 068 (“the Site”).¹ Approximately 77 acres of the parcel were affected by Mallinckrodt’s operations; approximately 50 acres of the parcel are developed and include the manufacturing facility, five landfills, a surface impoundment, and waste piles. The Plant Area—the contiguous section within the Site upon which the former Cell Building facility was built—is approximately 12 acres.

16. Among other substances, the Site discharged to the environment tons of mercury (Hg) and thousands of tons of mercury-contaminated brine-sludge, substances that are defined as hazardous wastes pursuant to 06-096 C.M.R. ch. 850, § 3.²

17. Pursuant to the federal Resource Conservation and Recovery Act (“RCRA”), 42 U.S.C. §§ 6901-6992k, the U.S. Environmental Protection Agency (“EPA”), with Department assistance, pursued corrective action at the Site starting in the mid-1980s. These efforts resulted in various Site Investigation Reports and Corrective Measures Studies that assessed the extent of contamination at the Site and the need for remediation.

¹ The complicated ownership history of the Site from plant construction in 1967 until operations ended in 2000 is detailed in *Maine People’s Alliance et al. v. Holtrachem Manufacturing Co. and Mallinckrodt Inc.*, 211 F. Supp. 2d 237, 241 (D. Me. 2002). Mallinckrodt is the current Site owner and was the Site owner during the relevant period of contamination; it is therefore the responsible party for purposes of the Department orders underlying this suit. See 38 M.R.S. § 1362(2) (2026); *Me. People’s All. et al. v. Holtrachem Mfg. Co., LLC, and Mallinckrodt US LLC*, 1:00-cv-00069-JAW, 2022 WL 3102401, at *1 (D. Me. Aug. 4, 2022).

² In addition to mercury, the following hazardous substances, as defined in 38 M.R.S. § 1362(1), were found in environmental media on the Site: cresol, 1,1 dichloroethane, 1,1 dichloroethene, acetone, bromoform, carbon disulfide, carbon tetrachloride, chlorobenzene, chloroform, chloromethane, hexachlorethane, methylene chloride; pentachloroethane, polychlorinated biphenyl, tetrachloroethane, arsenic, barium, lead, cadmium, chromium, and manganese. Other contaminants of concern on the Site include bromodichloromethane, dibromochloromethane, and chloropicrin. Bromodichloromethane and dibromochloromethane have been classified by the U.S. Environmental Protection Agency as probable or possible human carcinogens. Chloropicrin is a poison that can cause lacrimation, vomiting, bronchitis, pulmonary edema, irritation to gastrointestinal and respiratory tracts, and lethal lung injury when introduced through ingestion, intravenous, and intraperitoneal routes.

18. In 2000, the Maine People’s Alliance and the Natural Resources Defense Council filed a RCRA citizen suit against Mallinckrodt alleging that Mallinckrodt had, over a period of years, discharged mercury from the Site into the Penobscot River and that these discharges resulted in an imminent and substantial danger to public health and the environment. After a trial, the United States District Court for the District of Maine found that Mallinckrodt had contributed to the mercury-bearing releases from the Site to the Penobscot River and ordered Mallinckrodt to fund and participate with the plaintiffs in a study to determine the extent of harm to the river and the need for a remediation plan. *Me. People’s All. et al. v. Holtrachem Mfg. Co. and Mallinckrodt Inc.*, 211 F. Supp. 2d 237, 251-52, 255-56 (D. Me. 2002). The District Court’s decision and follow-up orders were affirmed on appeal. *See Me. People’s All. v. Mallinckrodt Inc.*, 471 F.3d 277 (1st Cir. 2006).

19. After 20 years of further litigation, a Consent Decree was approved by the District Court in the RCRA citizen suit. The Consent Decree requires, among other things, that Mallinckrodt contribute at least \$187 million, and up to \$267 million, to cleanup of the Penobscot River. *See Me. People’s All. et al. v. Holtrachem Mfg. Co., LLC, and Mallinckrodt US LLC*, 1:00-cv-00069-JAW, 2022 WL 3102401, at *1 (D. Me. Aug. 4, 2022). The Consent Decree does not address contamination at the Site, which remains unremediated and is the subject of this action.

20. In 2002, the Department and EPA engaged with Mallinckrodt in a rigorous and iterative process, including opportunities for public comment, to develop cleanup standards for various contaminants at the Site, known as Media Protection Standards (“MPSs”), that would be protective of public health and the environment. Through this process, the Department and EPA approved, among other things, an MPS for mercury in soils and other solid media (“mercury MPS”) of 2.2 parts per million (“ppm”). Mallinckrodt included this approved MPS in its

Corrective Measures Studies and Corrective Measures Study Workplan for the Site, which were submitted to the Department.

21. In 2004, Mallinckrodt's revised Corrective Measures Study was the subject of public review and comment, including a public hearing. Most of the commenters were opposed to Mallinckrodt's proposed corrective actions and specifically requested that corrective measures be taken to remove all mercury-contaminated soil from the Site so that future generations would not have to deal with these wastes. The Department subsequently requested additional information from Mallinckrodt, including the detailed evaluation of two alternatives to remove all solid media exceeding the MPSs from the Site. In its 2005 response, Mallinckrodt rejected the Department's suggested approach of removing all solid media exceeding the MPSs from the Site.

The Department's Issuance of a Site Remediation Order (2008)

22. The disagreement between Mallinckrodt and the Department over the cleanup approach resulted in the Department issuing a unilateral cleanup order. The Uncontrolled Hazardous Substance Sites Law, 38 M.R.S. §§ 1361-1371 (2026) ("Uncontrolled Sites Law"), authorizes the Commissioner to order remediation of "a location at which hazardous substances are or were handled [and] may create a danger to the public health, to the safety of any person[,] or to the environment," *id.* § 1365(1). In enacting the law, the Legislature declared "that it is in the public interest of the State and its citizens to provide the capacity of prompt and effective planning and implementation of plans to abate, clean up[,] or mitigate threats posed or potentially posed by uncontrolled sites" and that "[t]his paramount state interest outweighs any burden, economic or otherwise, imposed by this chapter." 38 M.R.S. § 1361 (emphasis added).

23. On November 24, 2008, pursuant to the Uncontrolled Sites Law, the Department Commissioner issued a Designation of Uncontrolled Hazardous Substance Site and Order

(“Commissioner’s Order”), which required Mallinckrodt to remediate the Site, including by removing all solid media exceeding the MPSs for the specified hazardous wastes such as mercury and chloropicrin.

24. The Commissioner’s Order noted that documents from the RCRA consultation process demonstrated that “soils on the Site are contaminated with the hazardous substance, mercury, and other contaminants which negatively affect the groundwater quality, surface water quality, sediment quality, air quality, and biological life on and adjacent to the Site.” Commissioner’s Order, Ex. A, at 22.

25. The Commissioner’s Order contains further findings that state:

As part of the Site Investigation process overseen by EPA and [the Department], [MPSs] designed to protect the public health and safety were developed as the cleanup levels for soils, ground water, surface water and sediment. Hazardous substances remain onsite that . . . exceed the [MPSs] and therefore pose a danger to the public health, safety and the environment.

Id.

26. Based on these and the Commissioner’s other findings, the Commissioner’s Order concluded that remediation was necessary to protect public health and the environment, including a requirement that Mallinckrodt “[e]xcavate all solid media exceeding the [MPSs] . . . includ[ing] all Plant Area Soils” and “[d]ispose of all excavated media exceeding the [MPSs] in licensed offsite disposal units.” *Id.* at 27-28.

27. The Commissioner’s Order required that “Mallinckrodt shall by January 31, 2009[,] provide a Corrective Measures Implementation Plan [CMIP] for the Department’s review and approval that will at a minimum provide for . . . [e]xcavation of all solid media exceeding the [MPSs] . . . includ[ing] all Plant Area Soils” and “[d]isposal of all excavated media exceeding the [MPSs] in licensed offsite disposal units.” *Id.* at 32.

28. The Commissioner's Order required that the CMIP must provide for "[r]emoval of the industrial sewer," which continued to be a pathway for contaminants to the Penobscot River. *Id.* at 25-26, 32.

29. The Commissioner's Order also required that "Mallinckrodt shall, by December 31, 2008, establish a trust fund to provide financial assurance, the terms and amount of which are acceptable to the Department, and shall fund such trust fund, for activities included in this Order," and the ongoing operation of systems implemented during the RCRA consultation process, including "the operation of the wastewater treatment plant, groundwater collection system, groundwater monitoring, and maintenance of the Ferry Road filtration systems." *Id.* at 35. The trust fund must comply with State and Federal law, including the Maine Hazardous Waste Management Rules.

Mallinckrodt's Appeals of the Department's Orders (2008-2014)

30. On December 19, 2008, Mallinckrodt filed an administrative appeal of the Commissioner's Order with the Board of Environmental Protection ("BEP").

31. On August 19, 2010, the BEP issued its Order on Appeal ("BEP Order"), which affirmed and incorporated the Commissioner's Order, with certain modifications set forth in the BEP Order. Except for a limited exception regarding certain landfill areas on the Site that is not applicable here, the BEP Order affirmed the requirement in the Commissioner's Order that Mallinckrodt remove "the plant area soils . . . as well as any other area on-site of soils in excess of the [MPSs]" and noted that "*this requirement is necessary to address a danger or likelihood of danger to public health and safety and the environment.*" BEP Order, Ex. B, §§ 6(D)(4) (at pp. 15-16) and 12(E) (at p. 47) (emphasis added). The BEP Order noted the importance of

Mallinckrodt implementing excavation and removal work as expeditiously as possible to reduce the risks to human health and the environment posed by the Site.

32. Before the BEP, Mallinckrodt objected to the removal of all soils and other solid media sitewide above the applicable MPSs, but the BEP upheld this requirement over Mallinckrodt's objection.

33. On September 17, 2010, Mallinckrodt filed a judicial appeal of the Commissioner's Order, as affirmed with modifications by the BEP Order (henceforth, collectively, "DEP Orders"), along with raising an independent claim pursuant to 42 U.S.C. § 1983, in Penobscot County Superior Court. The suit was subsequently transferred to the Maine Business and Consumer Docket ("BCD"). In the BCD, Mallinckrodt did not contest the requirement that it remove all soils and other solid media sitewide above the applicable MPSs.

34. In decisions dated October 31, 2012, and January 25, 2013, the BCD affirmed the DEP Orders and dismissed Mallinckrodt's section 1983 claim.

35. On February 15, 2013, Mallinckrodt filed a notice of appeal of the DEP Orders to the Maine Supreme Judicial Court sitting as the Law Court.

36. On April 3, 2014, the Law Court issued a decision, *Mallinckrodt US LLC v. DEP*, 2014 ME 52, 90 A.3d 428, affirming the DEP Orders.

37. The DEP Orders, including their incorporated MPS for mercury, have thus been final since 2014 and have governed all of Mallinckrodt's remediation work at the Site since that time.

***Mallinckrodt's Post-Litigation Site Remediation Work
Pursuant to the DEP Orders (2014-2023)***

38. The DEP Orders require Mallinckrodt to submit CMIPs, or work plans, in prioritized phases and delegates to the Department the authority to determine the priority of remediation tasks.

39. Mallinckrodt began remediation work at the Site pursuant to the DEP Orders in 2014. Removal of soil above applicable MPSs followed a process by which the area to be excavated would be identified and sub-divided into “cells” based on the results of prior soil investigation that determined the necessary depth of excavation. After excavation, confirmation sampling would be used to document that all soil above the applicable MPS had been removed. This process of identification and confirmation was generally followed for all excavation work on the Site from 2014 through 2023.

40. On June 19, 2018, after completion of work on the Landfill 1 area of the Site, Mallinckrodt petitioned the Commissioner for relief from further compliance with the requirements of the DEP Orders. The Commissioner denied that petition on August 7, 2018.

41. Mallinckrodt subsequently submitted to the Department a CMIP to remediate the Cell Building area, within the larger Plant Area, following the process described in ¶ 39, *supra*. The Department approved the CMIP, and Mallinckrodt began remediating the Cell Building area in August 2019.

42. In 2021, Mallinckrodt proposed acquiring financial assurance in compliance with the DEP Orders in the form of a surety bond for near-term remediation and a trust fund assured by a surety bond for long-term operations. The Department conditioned its approval of the proposed terms of financial assurance upon Mallinckrodt's compliance with all applicable RCRA and state standards for financial assurance. Mallinckrodt, however, subsequently submitted proposed surety

bond and trust fund documents that were facially non-compliant with the terms of the DEP Orders because they did not comply with the State’s Hazardous Waste Rules and with RCRA regulations. *See* 06-096 C.M.R. ch. 854, § 6(C)(17); 40 C.F.R. § 264.151.

43. On March 13, 2023, the Department informed Mallinckrodt in a progress meeting that, pursuant to the DEP Orders, the Department’s highest remaining priority at the Site was the still unremediated portion of the Plant Area. The Department therefore requested a work plan from Mallinckrodt to complete Plant Area remediation as the next prioritized remediation phase for the Site.

44. On June 2, 2023, the Department notified Mallinckrodt by letter that its existing work plans did not address the Department’s identified highest remediation priority for the Site—the remainder of the Plant Area. The Department requested that a work plan meeting be held and that Mallinckrodt submit to the Department, within 45 days of receipt of the June 2 letter, a work plan to remediate the remainder of the Plant Area (except the Maintenance Building) consistent with the applicable MPSs, including the removal of all soils and other solid media with mercury concentrations above the MPS of 2.2 ppm.

***Mallinckrodt’s Failure to Submit a Plant Area
Remediation Plan in Compliance with the DEP Orders***

45. By letter dated July 20, 2023, Mallinckrodt acknowledged receipt of the Department’s June 2, 2023, letter and acknowledged that the terms of the DEP Orders, “read literally,” provide that Mallinckrodt “must remove all soils with mercury above the MPS of 2.2 ppm.” Mallinckrodt, however, did not provide the requested work plan and instead asked for a discussion with the Department to see if there was a “reasonable way” to address this “requirement” of the DEP Orders and obtain some “flexibility.”

46. The Department responded in a July 31, 2023, letter, emphasizing that although meeting the 2.2 ppm mercury MPS for soil remediation at the Site may present some challenging technical issues for Mallinckrodt, that MPS was a long-established cleanup requirement of the DEP Orders and therefore the Department would not agree to allow Mallinckrodt to vary from that requirement.

47. After several additional meetings and calls with the Department, Mallinckrodt submitted by letter dated November 2, 2023, its *Plant Area CMI Plan, Concrete and Utility Removal, Addendum 4* (“Plant Area CMIP”). Mallinckrodt’s submission came 108 days after the 45-day deadline provided in the Department’s June 2, 2023, letter.

48. Mallinckrodt’s Plant Area CMIP did not propose to remediate all soils exceeding the mercury MPS in the Plant Area, as required by the DEP Orders. Rather, Mallinckrodt proposed arbitrarily limiting excavation work and materially departing from the processes that had previously guided excavation work at the Site.

49. By letter dated January 4, 2024, the Department notified Mallinckrodt that its proposed Plant Area CMIP was unacceptable because it did not comply with the DEP Orders, which require the removal of all soils and other solid media from the Site exceeding the applicable MPSs and authorize the Department to set the priority of tasks under CMIPs. For example, the Department’s January 4, 2024, letter stated, “[n]either Mallinckrodt nor the Department have the flexibility or authority to pre-determine the maximum depth of any excavation of this [S]ite. The [DEP Orders are] clear that all soils above the MPS must be removed.” Mindful of the ongoing delays at the Site, however, and rather than outright rejecting the Plant Area CMIP as non-compliant with the DEP Orders, the Department approved Mallinckrodt’s Plant Area CMIP but with modifications necessary to meet the requirements of the DEP Orders, including the removal

of all soils and other solid media exceeding the MPSs. Pursuant to the DEP Orders, Mallinckrodt was then required to incorporate the Department's modifications of the non-compliant Plant Area CMIP into a new work plan within 30 days of receipt of the January 4, 2024, Department letter.³

50. Mallinckrodt responded by letter dated February 5, 2024, but failed to incorporate any of the Department's modifications of the non-compliant Plant Area CMIP into a work plan as required by the DEP Orders and the Department's January 4, 2024, letter. Mallinckrodt's letter requested another meeting with the Department to present a new work plan. On March 6, 2024, during this requested meeting, Mallinckrodt presented a work plan for the Plant Area that still did not incorporate the Department's modifications to the Plant Area CMIP as required by the Department Orders and the Department's January 4, 2024, letter.

51. On numerous occasions, the Department informed Mallinckrodt that, to be approved, any CMIP or work plan for the Plant Area must comply with the requirements of the DEP Orders, including the removal of all soils and other solid media exceeding the mercury MPS of 2.2 ppm to protect public health, safety, and the environment.⁴ Despite the express language of the DEP Orders and the Department's repeated reminders, Mallinckrodt repeatedly refused to comply with the clear and longstanding requirement that it remove all soils and other solid media at the Site exceeding the MPSs to protect public health, safety, and the environment.

³ See Commissioner's Order, Ex. A, § 14 (at p. 36): "For every approval [of a CMIP] with modification, DEP will specify the nature of the required modification. DEP's modification shall be deemed incorporated into and enforceable under this Order, and Mallinckrodt shall incorporate such modification into the relevant work plan, proposal or report within thirty (30) days of receipt of such approval with modification unless DEP agrees in writing to an extended period."

⁴ The Department reiterated this point to Mallinckrodt in writing on June 29, 2019; July 23, 2023; October 2, 2023; and January 4, 2024, and verbally at meetings with Mallinckrodt held on September 26, 2023, and March 6, 2024.

52. On December 20, 2024, after failing to comply with the DEP Orders since no later than February 5, 2024, when it was required to submit a compliant Plant Area CMIP, Mallinckrodt again petitioned the Department to be relieved of its responsibilities under the DEP Orders, including the requirement to remove soils and other solid media exceeding the MPSs, which the Department declined to do.

53. On March 19, 2025, DEP issued a Notice of Violation (“NOV”) alleging ongoing violations of Sections 3(a), 3(c), and 3(r) of the Commissioner’s Order (Ex. A at pp. 32-33) and Sections 6(D)(4), 12(E), and 14 of the BEP Order (Ex. B at pp. 15-16, 47, 49-50). *See* NOV, Ex. C, at 6. These violations are incorporated below.

***Mallinckrodt’s Declaration of its Intention to
No Longer Comply with the DEP Orders***

54. On April 8, 2025, Mallinckrodt requested a meeting with Department staff to discuss the NOV, which occurred remotely on July 14, 2025. During this meeting, Department staff provided a revised deadline of August 18, 2025, for Mallinckrodt to submit for the Department’s review and approval a detailed work plan to remove all soils and other solid media above the Site MPSs from the unremediated portions of the Plant Area.

55. At the July 14, 2025, meeting, Ashley Pinnock, Senior Legal Director and Managing Environmental Health and Safety Counsel for Medtronic, expressly stated that the plan that Mallinckrodt would submit by August 18, 2025, would outline the final extent of Mallinckrodt’s remediation efforts—not only for the Plant Area but for the entire Site.

56. On August 18, 2025, Mallinckrodt submitted its response to the NOV, including a workplan in the form of an addendum to the Plant Area CMIP it previously submitted in November 2023—*Plant Area CMI Plan, Concrete and Utility Removal, Addendum 5* (“Addendum 5”).

57. Mallinckrodt's Addendum 5 once again did not incorporate the Department's January 4, 2024, modifications to the Plant Area CMIP or otherwise propose to remove all soils and other solid media at the Site exceeding the applicable MPSs. Rather, Addendum 5 proposed that Mallinckrodt would only excavate "surface soils" to a depth of four feet in six specific areas on the Site unilaterally chosen by Mallinckrodt. Like Mallinckrodt's prior submissions, Addendum 5 did not comply with the DEP Orders and the requirements of the Department's January 4, 2024, letter.

58. On October 20, 2025, the Department issued an Amended NOV ("ANOV") re-alleging violations of Sections 3(a), 3(c), and 3(r) of the Commissioner's Order and Sections 6(D)(4), 12(E), and 14 of the BEP Order. *See* ANOV, Ex. D, at 7. The ANOV alleged that Mallinckrodt was in ongoing violation of the DEP Orders by failing to complete the process for establishing a trust fund to provide financial assurance for ongoing Site remediation and management. The Department also requested that Mallinckrodt clarify whether it intended to comply with the DEP Orders by (i) removing all industrial sewer line from the Site and (ii) excavating, removing, and disposing of soils and other solid media exceeding the MPSs on, under, or surrounding Temporary Soil Stockpile Area No. 1 ("TSSA 1") (a paved area that has not yet been fully assessed for contamination). *Id.* at 8.

59. On November 19, 2025, Mallinckrodt responded to the Department's ANOV with *Plant Area CMI Plan, Concrete and Utility Removal, Addendum 5-Amended* ("Amended Addendum 5"), which again proposed to leave in place soils with mercury concentrations above the MPS and confirmed Mallinckrodt's intention to abandon in place large portions of the industrial sewer. Mallinckrodt further stated, "[w]hile [we] anticipate[] certain restoration work in TSSA 1, the area has been designed to safely contain soil prior to offsite shipment and does not

pose a threat to human health or the environment.” Regarding its obligations under the DEP Orders to obtain financial assurance, Mallinckrodt responded that it did not need to comply at that time because the Department had not responded to its previous non-compliant proposal and because Mallinckrodt “has assured [the Department] on multiple occasions that it anticipated no future funding issues, and Mallinckrodt has never declined to perform Site work based on funding deficiencies.” Like Mallinckrodt’s prior submissions, Amended Addendum 5 did not comply with the DEP Orders and the requirements of the Department’s January 4, 2024, letter.

60. By letter dated March 26, 2026, the Department replied to Mallinckrodt’s November 19, 2025, Amended Addendum 5, reiterating that (i) “until Mallinckrodt presents the Department with a CMIP for the excavation, removal, and disposal of all contaminated soils in the Plant Area consistent with the applicable MPSs, Mallinckrodt is and will continue to be in violation of the DEP Orders, as detailed in the ANOV”; and (ii) “the [DEP Orders] require the removal of *all* industrial sewer line from the Site,” not just removal of industrial sewer line to a depth of 4 feet below ground surface. Regarding TSSA 1, the Department requested that Mallinckrodt “submit to the Department, within 30 days of this letter, a plan to characterize and appropriately remediate [TSSA 1] once remediation work on other areas of the Site is completed.” Regarding financial assurance, the Department provided Mallinckrodt until April 27, 2026, “to submit financial assurance documents that comply with the required language in” the RCRA regulations.⁵

61. On April 24, 2026, Mallinckrodt responded with a reiteration of its position that it would not (i) submit a CMIP to remove all contaminated soils and other solid media from the Plant Area consistent with the applicable MPSs; (ii) remove all industrial sewer line from the Site; (iii)

⁵ The Department provided Mallinckrodt with 30 days despite the financial assurance requirement being in place since 2014, and despite Mallinckrodt submitting inadequate proposed financial assurance documents in 2021.

submit a plan to characterize contamination and remediate TSSA 1; or (iv) obtain financial assurance for remediation of the Site.

Mallinckrodt Continues to Violate the DEP Orders on an Ongoing, Daily Basis

62. As of the date of this Complaint, Mallinckrodt has not submitted to the Department a CMIP that incorporates the Department's January 4, 2024, modifications or otherwise addresses the excavation and removal from the Plant Area of all soils and other solid media exceeding applicable MPSs, including all soils and other solid media with mercury levels above the 2.2 ppm mercury MPS, as required by the DEP Orders.

63. As of the date of this Complaint, Mallinckrodt has failed to excavate and remove all soils and other solid media exceeding applicable MPSs in the Plant Area, including all soils and other solid media with mercury levels above the 2.2 ppm mercury MPS, as required by the Commissioner's Order, §§ 3(a), (r) (Ex. A at pp. 32-33), and as upheld by the BEP Order, §§ 6(D)(4) (at pp. 15-16) and 12(E) (Ex. B at p. 47).

64. Mallinckrodt's failure to submit a plan to excavate and remove all soils and other solid media exceeding applicable MPSs in the Plant Area, including all soils and other solid media with mercury levels above the 2.2 ppm mercury MPS, as required by the DEP Orders, and its failure to remove all such soils and other solid media as required by the DEP Orders, has resulted in ongoing, daily violations since no later than February 5, 2024 (the date by which Mallinckrodt was required to submit a compliant CMIP).

65. As of the date of this Complaint, Mallinckrodt has not submitted a CMIP, or other relevant work plan, to the Department that satisfies the requirement in the DEP Orders to remove all industrial sewer line from the Site.

66. Mallinckrodt's failure to submit a plan to remove all industrial sewer line from the Site, as required by the DEP Orders, and its failure to remove all industrial sewer line from the Site, has resulted in ongoing, daily violations since no later than November 19, 2025 (the date Mallinckrodt stated its intention to not satisfy this requirement in the DEP Orders).

67. As of the date of this Complaint, Mallinckrodt has not submitted a CMIP, or other relevant work plan, to the Department that satisfies DEP's request for submission of a plan to characterize and remediate TSSA 1, a request that implements the requirements of the DEP Orders.

68. Mallinckrodt's failure to submit a plan to characterize and remediate TSSA 1 has resulted in ongoing, daily violations since no later than April 27, 2026 (the deadline provided by the Department for Mallinckrodt to submit such a plan).

69. As of the date of this Complaint, Mallinckrodt has not obtained RCRA-compliant financial assurance, as required by the DEP Orders and the Department's March 26, 2026, letter.

70. Mallinckrodt's failure to obtain required financial assurance has resulted in ongoing, daily violations since no later than April 27, 2026 (the latest deadline provided by the Department for Mallinckrodt to obtain such financial assurance).

71. Soils in the unremediated portion of the Plant Area have been observed to contain visible elemental mercury. Soils containing mercury at concentrations above the MPS also remain in place at multiple locations across the Plant Area where excavations had not been previously completed, with the understanding they would be completed when the Plant Area was addressed. Furthermore, the TSSA 1 area, which includes the leach fields associated with the facility laboratory, has not been characterized or fully assessed for the nature and extent of contamination.⁶

⁶ During the cleanup to date, outgoing contaminated soil has been measured in tons; total tons of mercury-contaminated soils disposed offsite via rail car exceeds 500,000 tons. In its August 18, 2025, *Plant Area CMI Plan, Concrete and Utility Removal, Addendum 5*, Mallinckrodt claimed to

COUNT I (Violation of DEP Orders; Failure to Remove Soils Above MPSs)

72. The Department realleges and incorporates herein by reference paragraphs 1 through 71 of this Complaint.

73. By failing to excavate, remove, and dispose of all soils and other solid media in the Plant Area consistent with the applicable MPSs, including the 2.2 ppm MPS for mercury, Mallinckrodt is in violation of the DEP Orders on an ongoing, daily basis since no later than February 5, 2024. Commissioner's Order §§ 3(a), 3(c), and 3(r) (Ex. A at pp. 32-33) and BEP Order §§ 6(D)(4) and 12(E) (Ex. B at pp. 15-16, 47).

74. To remedy this ongoing violation, the Department seeks injunctive relief pursuant to 38 M.R.S. §§ 347-A(1) and 348(1).

75. For this ongoing violation, the Department seeks penalties of up to \$25,000 for each day of the violation pursuant to 38 M.R.S. § 349(2).

COUNT II (Violation of DEP Orders; Failure to Submit Compliant CMIP)

76. The Department realleges and incorporates herein by reference paragraphs 1 through 75 of this Complaint.

77. By failing to submit a CMIP for the excavation, removal, and disposal of all contaminated soils and other solid media in the Plant Area consistent with all applicable MPSs, Mallinckrodt is in violation of the DEP Orders on an ongoing, daily basis since no later than February 5, 2024. Commissioner's Order § 3(a) (Ex. A at pp. 32-33) and BEP Order §§ 6(D)(4) and 12(E) (Ex. B at pp. 15-16, 47).

have removed 27,500 pounds of mercury from the Site. The Department cannot independently verify that number. Regardless, it is evident that mercury-contaminated soils above the MPS still remain on this highly contaminated Site.

78. To remedy this ongoing violation, the Department seeks injunctive relief pursuant to 38 M.R.S. §§ 347-A(1) and 348(1).

79. For this ongoing violation, the Department seeks penalties of up to \$25,000 for each day of the violation pursuant to 38 M.R.S. § 349(2).

COUNT III (Violation of DEP Orders; Failure to Incorporate DEP Modifications to CMIP)

80. The Department realleges and incorporates herein by reference paragraphs 1 through 79 of this Complaint.

81. Section 14 of the Commissioner’s Order (Ex. A at p. 36) states and requires: “For every approval with modification [of a CMIP], DEP will specify the nature of the modification. DEP’s modification shall be deemed incorporated into and enforceable under this Order, and Mallinckrodt shall incorporate such modification into the relevant work plan, proposal or report within thirty (30) days of receipt of such approval with modifications unless DEP agrees in writing to an extended period.”

82. By failing to incorporate the modifications to the Plant Area CMIP specified by the Department on January 4, 2024, Mallinckrodt is in violation of the Commissioner’s Order on an ongoing, daily basis since no later than February 5, 2024.

83. To remedy this ongoing violation, the Department seeks injunctive relief pursuant to 38 M.R.S. §§ 347-A(1) and 348(1).

84. For this ongoing violation, the Department seeks penalties of up to \$25,000 for each day of the violation pursuant to 38 M.R.S. § 349(2).

COUNT IV (Violation of DEP Orders; Failure to Establish Financial Assurance)

85. The Department realleges and incorporates herein by reference paragraphs 1 through 84 of this Complaint.

86. By failing to establish a trust fund to provide financial assurance, Mallinckrodt is in violation of the DEP Orders on an ongoing, daily basis since no later than April 27, 2026. Commissioner's Order § 9 (Ex. A at p. 35) and BEP Order § 14(A) (Ex. B at pp. 49-50).

87. To remedy this ongoing violation, the Department seeks injunctive relief pursuant to 38 M.R.S. §§ 347-A(1) and 348(1).

88. For this ongoing violation, the Department seeks penalties of up to \$25,000 for each day of the violation pursuant to 38 M.R.S. § 349(2).

COUNT V (Violation of DEP Orders; Failure to Submit Plan to Remove Industrial Sewer)

89. The Department realleges and incorporates herein by reference paragraphs 1 through 88 of this Complaint.

90. By refusing to submit a CMIP or workplan to remove all industrial sewer line at the Site, as required by the DEP Orders, Mallinckrodt is in violation of the DEP Orders on an ongoing, daily basis since no later than April 27, 2026. Commissioner's Order § 3(d) (Ex. A at p. 32) and BEP Order § 12(F) (Ex. B at pp. 47-48).

91. To remedy this ongoing violation, the Department seeks injunctive relief pursuant to 38 M.R.S. §§ 347-A(1) and 348(1).

92. For this violation, the Department seeks penalties of up to \$25,000 for each day of this ongoing violation pursuant to 38 M.R.S. § 349(2).

COUNT VI (Violation of DEP Orders; Failure to Submit Plan for TSSA 1)

93. The Department realleges and incorporates herein by reference paragraphs 1 through 92 of this Complaint.

94. By refusing to submit a CMIP or workplan to characterize contaminants in and remediate TSSA 1, as required by the DEP Orders, Mallinckrodt is in violation of the DEP Orders

on an ongoing, daily basis since no later than April 27, 2026. Commissioner's Order §§ 3(a), 3(c), and 3(r) (Ex. A at pp. 32-33) and BEP Order §§ 6(D)(4) and 12(E) (Ex. B at pp. 15-16, 47).

95. To remedy this ongoing violation, the Department seeks injunctive relief pursuant to 38 M.R.S. §§ 347-A(1) and 348(1).

96. For this violation, the Department seeks penalties of up to \$25,000 for each day of this ongoing violation pursuant to 38 M.R.S. § 349(2).

RELIEF REQUESTED

WHEREFORE, the Department respectfully asks this Court to grant the following relief:

- A. Enter judgment against Mallinckrodt on the Department's claims set forth in Counts I-VI;
- B. Order Mallinckrodt to, within 30 days from the date of the entry of judgment, submit to the Department for its review and approval:
 - 1. A CMIP(s) or workplan(s) to: (a) remove all soils and other solid media above the applicable MPSs in the DEP Orders from the Plant Area; (b) characterize contaminants in and remediate TSSA 1; and (c) remove all industrial sewer line from the Site; and
 - 2. Documentation of the establishment of financial assurance consistent with the DEP Orders, the NOV, and the ANOV;
- C. Order Mallinckrodt to pay a civil penalty of not less than \$100 and no more than \$25,000 for each day of each of its ongoing violations of laws administered by the Department and orders of the Commissioner and the BEP pursuant to 38 M.R.S. §§ 349(2), (5);

- D. Order Mallinckrodt to pay the costs of this litigation, including, but not limited to, court costs and attorney's fees, pursuant to 14 M.R.S. § 1522 (2026);
- E. Issue a permanent injunction, pursuant to 38 M.R.S. § 348(1), requiring Mallinckrodt to comply with all requirements in the DEP Orders, the NOV, and the ANOV, and to comply with all further requirements and schedules established by the Department in response to the submissions in paragraph B and any further submissions pursuant to the DEP Orders, the NOV, and the ANOV; and
- F. Grant such additional relief as the Court deems just and proper.

Dated: August 25, 2026

Respectfully submitted,

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