Mallinckrodt US LLC

June 19, 2018

VIA ELECTRONIC & U.S. MAIL

Paul Mercer, Commissioner
Maine Department of Environmental Protection
17 State House Station
28 Tyson Drive
Augusta, Maine 04333-0017

Re: Petition for Modification of BEP April 14, 2014 Order

Dear Commissioner Mercer:

Pursuant to Chapter 2, Section 26(B) of the Department's rules, Mallinckrodt US LLC ("Mallinckrodt") respectfully petitions the Commissioner to initiate proceedings before the Board of Environmental Protection (the "Board" or "BEP") to modify its order "concerning a chlor-alkali manufacturing facility in Orrington, Penobscot County, Maine," dated August 19, 2010 (the "BEP Order") to allow use of the same leachability tests to determine the depth of excavation in the Plant Area as used for Landfill 1 and 2.

Mallinckrodt also requests modification of the BEP Order to make clear that certain portions of the industrial sewer can be cleaned and remain in place to prevent unacceptable risks to worker safety.

Modification to Address Plant Area Volume and Depth of Materials

Chapter 2 specifies that the Department may take action to modify a requirement based on a number of criteria, including "a change in any condition or circumstance that requires . . . temporary or permanent modification." 06-096 C.M.R. c. 2 § 27(F). New Site data (over 2,000 soil samples) indicate that volumes of Plant Area at-depth material exceeding applicable standards are deeper and significantly greater than stated in the BEP Order (or the predecessor Department Order.) This new information makes the depth of excavation as important in the Plant Area as it was in Landfills 1 and 2. Since the Board Order allows the use of leachability studies to determine the appropriate depth of excavation based on leachability to groundwater for Landfills 1 and 2, this approach also should be allowed in the Plant Area.

The express language of the BEP Order grants the Commissioner flexibility to address changed circumstances as they arise in the course of the remediation and to impose reasonable terms and conditions to complete the remediation in a safe and responsible manner. The BEP Order requires "excavation of solid media exceeding the Media Protection Standards [("MPS")]" of 2.2 ppm total mercury at the former chlor-alkali plant site in Orrington, Maine (the "Site"). BEP Order at 53, ¶ 3(a); *see also* BEP Order at 15 (D). The BEP Order, however, permits

material exceeding the MPS to remain in place in some instances. For example, material located in Landfills 1 and 2 exceeding the MPS may remain on-site if the results of a study of the distribution of contaminants and desorption supports leaving those materials in place. BEP Order at 39(D). In other words, depth of excavation of soils beneath Landfills 1 and 2 is determined based on an assessment of the potential for contaminants of concern adsorbed to soils beneath the landfills to desorb at concentrations that would cause groundwater to exceed the MPS. *See* BEP Order at 34. Further, as the Board explained in its order:

> [A]s remediation proceeds, circumstances will undoubtedly arise as more information is obtained about the nature and extent of contamination at the Site which will need to be addressed.

BEP Order at 49.

> [T]he Commissioner's authority under the Uncontrolled Sites Law includes not only the authority to order necessary remediation, but also the implied authority to impose reasonable terms and conditions to ensure that the required remediation is completed safely, responsibly, and in a manner that does not jeopardize public resources.

BEP Order at 51.

For this reason, Mallinckrodt does not believe that modification of the BEP Order is necessary in order to come to a decision and implement a new approach with respect to the at-depth material in the Plant Area. Notwithstanding this, for the sake of clarifying any ambiguity Mallinckrodt submits this Petition for Modification of the BEP Order under Chapter 2, Section 27(f) of the Department's Rules.

While performing remediation work at the Site, Mallinckrodt has obtained new, previously unavailable data regarding the volume and depth of material in the Plant Area. This new data indicates that there is a significantly greater volume of material that exceeds the MPS in the Plant Area than the DEP or Mallinckrodt realized at the time the BEP Order was entered. The attached Technical Memorandum, prepared by Kathryn Zeigler, the Mallinckrodt Project Manager for the Site and Geosyntec Consultants, the Site Engineers, provides the detailed technical basis for this conclusion. Pursuing removal of the totality of this material would thwart much of the BEP's remedy selection analysis and rationale. It would also result in significant remediation schedule delays, increase risk to worker safety, and appreciably increase cost without any measurable benefits to human health or the environment. Further, addressing the Plant Area excavation depth in a manner similar to Landfills 1 and 2 is consistent with the Board's findings and would facilitate remediation of the Site in a timely manner without jeopardizing human health or the environment.

This Petition sets forth relevant background information, a procedural history, the criteria under which modification is proposed, the factual basis for the modification, and the proposed modified language.

I. Background & Procedural History

Mallinckrodt is in the process of remediating the Site. This work involves excavation and removal of a large quantity of environmental media that has been contaminated by various waste materials, including mercury and other contaminants of concern. Facility dismantling and demolition activities began in 2010 and continued as required by the BEP Order. All buildings and infrastructure not being used for the current remedial work have now been removed from the Site. As outlined in the BEP Order, Mallinckrodt has submitted, and the Department has approved remedial designs (Corrective Measures Implementation Plans or "CMIPs") for seven distinct areas at the Site, six of which are currently complete. The Department also approved Phase 1 work within the Plant Area, which is currently underway. Further, the Landfill 1 CMIP was recently approved by the Department, and work will begin under this plan before the end of May. Since 2015, Mallinckrodt has excavated over 175,500 tons of non-hazardous soils and 31,500 tons of soils containing listed waste from the Site. These soils have been stockpiled, sampled, segregated, loaded into 2,100 railcars, and shipped without incident and disposed at offsite licensed disposal facilities. Due to health and safety concerns associated with chloropicrin, in situ treatment of chloropicrin impacted soils using injections and soil vapor extraction methods is also in progress. A new groundwater treatment plant was also constructed and began full-scale operation in 2012. As required in the BEP Order, a groundwater model has been developed for the Site and was approved by the Department in September of 2017. Groundwater extraction wells have continued to operate at the Site, and the design for the Final Groundwater Extraction System was approved by the Maine DEP in January 2018.

This remediation work is being carried out pursuant to the Board's Order dated August 19, 2010, which modified the Department's November 24, 2008 Order (the "DEP Order") in several material respects. The DEP Order required "[e]xcavation of all solid media exceeding the [MPS]. This includes all Plant Area Soils, Cell Building Soils, Retort and Old Retort Building Soils, Sediments, Landfill Ridge Soils, and sludge and other mercury-contaminated material from all five landfills." Order at 32, ¶ 3(a). The BEP Order modified the DEP Order, in pertinent part, by not requiring removal of Landfills 3, 4, and 5,[1] and allowing material exceeding the MPS in Landfills 1 and 2 to remain on-site in certain circumstances. The BEP Order prescribes the following:

> Excavation of solid media exceeding the Media Protection Standards. This includes all Plant Area Soils, Cell Building Soils, Retort and Old Retort Building Soils, Sediments, Landfill Ridge Soils, and sludges and other mercury contaminated material from Landfill Area 1 and Landfill 2, except that the depth to which contaminated soil under Landfills 1 and 2 will be removed shall be determined as specified in Finding of Fact 10(D) of this Decision.

BEP Order at 53, ¶ 3(a). Finding of Fact 10(D) of the BEP Order specifies that:

[1] The materials in Landfills 3, 4, and 5 include wastes that contain mercury at levels greater than the MPS for mercury.

> . . . Mallinckrodt must conduct a study, propose to and approved by the Department, to determine the approximate distribution of concentrations of mercury [and other materials] in the soils (both saturated and unsaturated) under Landfills [sic] 1 and mercury and carbon tetrachloride under Landfill 2. Mallinckrodt shall conduct column leaching tests such that the adsorption/desorption or other degradation processes of the residual soil contamination beneath the landfills can be quantified, and on this basis the Department shall determine the area and depth of soil excavation beneath the landfills. This determination must be based on modeling natural desorption/degradation processes and other considerations such as the type of final cover to be placed over the area of the landfills after they are excavated.

BEP Order at 39.

This language depicts an acknowledgement by BEP of certain risks when working at depth.

II. Changed Conditions or Circumstances Require Modification

Modification of the BEP Order is appropriate due to "a change in any condition or circumstance that requires . . . a temporary or permanent modification of the terms of the license."[2] 06-096 C.M.R. c. 2, § 27(F); *see also* 06-096 C.M.R. c. 2, § 26(B). As described in the attached Technical Report, Mallinckrodt has engaged in significant additional sampling at the Site in connection with carrying out the remedial activities prescribed by the BEP Order. At the time of the BEP Order, 116 borings had been undertaken in the Plant Area however only 42 of these were deeper than 2 feet. Since then, an additional 197 borings have been completed in this area resulting in over 300 soil borings and over 2,700 samples from this area having been characterized and analyzed to date. This has allowed Mallinckrodt and the Department to obtain a better understanding of Site conditions than what was available when the BEP Order was entered.

Analysis of the new samples indicates that the Plant Area volume of material exceeding the MPS for mercury was significantly underestimated at the time of the BEP proceeding. If this information had been available during the BEP proceedings, Mallinckrodt would have pursued a different approach to management of the Plant Area material.

A. Pre-BEP Order Plant Area Volumes Were Underestimated and Would Have Impacted the BEP's Analysis.

The estimated volume of material for removal from the Plant Area at the time of the BEP hearing was 59,920 CY, based on data collected by DEP and Mallinckrodt prior to issuance of the DEP order. Data that is now available indicates that the actual volume of material exceeding the MPS in the Plant Area is 164,000 CY, nearly three times greater. This new estimate is based in part on the 197 additional Plant Area borings and over 2000 additional samples completed since the BEP Order was finalized. Material exceeding the MPS was

[2] "License" is defined to include approvals or "similar forms of permissions issued by the Department that is required by law, and represents the State's exercise of regulatory or police powers." 06-096 C.M.R. c. 2, § 1(L).

observed deeper than 12 feet, with the deepest concentration of material exceeding the MPS observed at 26 feet below ground surface ("bgs"). The groundwater in this area ranges from 3 feet to 13 feet below ground surface (bgs) with an average elevation of 9 feet bgs. As noted above, the attached Technical Memorandum provides additional details concerning this new data.

Greater Plant Area volumes exceeding the MPS represent a changed condition or circumstance that requires modification of the BEP Order for several reasons. First, greater Plant Area volumes will result in a significantly extended remediation schedule. Aside from cost implications, this delay will require re-analysis under RCRA guidance. For instance, the RCRA 2020 Program sets forth the goal of implementing final remedies at 95 percent of facilities requiring corrective action by the year 2020. If Mallinckrodt is required to remove the additional at-depth material exceeding the MPS in the Plant Area, the construction schedule will extend into 2020 and potentially beyond.

Re-analysis is also required under the following RCRA corrective action threshold/balancing criteria:

- Implementability: Issues associated with greater-than-anticipated Plant Area excavations include impacts on materials, construction methods, personnel, and capacity at offsite disposal facilities.[3]

- Short-Term Effectiveness: Increased Plant Area volumes for removal may cause a greater quantity of mercury to become re-mobilized during excavation than initially anticipated. Increased volumes also mean that a greater quantity of material will require off-site removal with associated truck/rail traffic. There will be greater noise, dust, volatilization, and exposure potential over what was initially anticipated. A greater potential for mercury vaporization or colloidal transport exists because more hazardous material will be handled.

- Cost: The total cost of the remediation will increase significantly.

Further, the volume of material itself factored into the BEP's remedy selection decision. The total volume for removal required under the DEP's initially proposed remedy (240,220 CY) was much greater than the volume to be removed under Mallinckrodt's proposed remedy (131,320 CY). The BEP concluded that the lower volume for removal made the Mallinckrodt proposal more favorable:

[3] Mr. Karl Kasper testified on behalf of Mallinckrodt at the BEP hearing that Stablex, the contaminated soil disposal facility located in Canada, would not be able to process the volume of material to be removed per the Commissioner's Order. BEP Order at 27-28. This was based on estimates of 240,000 tons of hazardous waste for removal from the Site. While Lavalle testified on behalf of the Commissioner that Stablex can accept 300 metric tons per day and has historically added treatment capacity and made significant capital investments to meet the needs of large multi-year projects, it is unknown whether Stablex could process a significantly greater volume of material from the Plant Area.

> There are significant cost, logistical and implementation time differences between proposals which argue in favor of Mallinckrodt's proposed alternative.

BEP Order at 24.

B. Mallinckrodt Would Have Challenged Depth of Plant Area Excavation at the BEP Hearing If the Current Volume Estimate Had Been Available.

During the BEP proceedings, Mallinckrodt objected to the requirement that it remove all soils exceeding the MPS from the Site. *See* BEP Order at 16, n. 13. Where the depth of excavation significantly impacted the amount of material to be removed, as was the case with respect to Landfill 1, Mallinckrodt challenged the depth of excavation.[4] Because the Plant Area volumes were small in comparison, the landfills were the primary focus.

As noted above, at the time of the BEP hearing it was anticipated that only 59,920 CY of material would be removed from the entire Plant Area at the Site to a depth of approximately 12 feet. The additional data Mallinckrodt has collected in connection with performing work at the Site, however, indicates that the maximum depth of soils with concentrations above the MPS is now approximately 26 feet below grade, well below the groundwater table and 2 to 3 times deeper than originally expected. This increased depth results in 164,000 CY of material which exceeds the MPS in the Plant Area, a nearly three-fold increase. If that fact had been known at the time of the BEP hearing, Mallinckrodt would have challenged the depth of the excavation in the Plant Area the same way it challenged the depth of excavation in other areas at the Site (*e.g.*, Landfill 1). Moreover, the Board's decision regarding the depth of excavation in Landfill 1 strongly suggests that the Board would have ruled in Mallinckrodt's favor on the issue of the Plant Area soils, consistent with its treatment of Landfill 1 as similar concerns are implicated.

[4] For instance, Mallinckrodt agreed that Landfill 1 should be removed, but the Commissioner and Mallinckrodt disagreed on the depth to which contaminated media beneath the landfill should be removed. BEP Order at 31. The Commissioner's witness, Dr. John Beane, argued that removal of contaminated soil should proceed through the water table to glacial till in order to remove the source of contamination. Mallinckrodt's witness, Mr. Guy Vaillancourt, testified that Mallinckrodt would remove waste in Landfill 1 and address remaining soil contamination through a new groundwater extraction and treatment system. Mr. Vaillancourt explained that excavation to the till layer would be problematic given the groundwater flow through overburden and the location of the landfill with respect to the river. The concern was that the excavation could become filled with water due to the steep groundwater table. The Board found that Mr. Vaillancourt's testimony regarding limitations on depth of excavation was persuasive given the proximity of the landfill to the river, the thickness of the sand and gravel layer, and the steepness of the water table in this portion of the Site. It required Mallinckrodt to conduct tests to determine the concentration of contaminants in soils beneath the waste in Landfill 1 and the ability of the contaminants of concern to desorb from the soils. This information would be used by the Commissioner to determine the necessary depth of soils excavation under Landfill 1. BEP Order at 31-32.

C. The Risk Associated with Leaving Material-At-Depth Exceeding the MPS is Low.

The MPS of 2.2 ppm for total mercury is considerably more protective than the Maine DEP's Remedial Action Guidelines for Sites Contaminated with Hazardous Substances (Effective Date: February 5, 2016) ("RAGs") for soils:

EXPOSURE PATHWAY	GUIDELINE EXPOSURE CONCENTRATION
Groundwater Exposure Residential (elemental mercury)	None applicable, as the guideline for this exposure scenario is based upon the Maine Bureau of Heath Maximum Exposure Guidelines ("MEGs") and there is no MEG set for elemental mercury.
Groundwater Exposure Construction Worker (elemental mercury)	1,500 ppb
Soil Residential (inorganic mercury compounds and mercuric chloride)	51 mg/kg
Soil Commercial Worker (inorganic mercury compounds and mercuric chloride)	510 mg/kg
Soil Construction Worker (inorganic mercury compounds and mercuric chloride)	930 mg/kg

In formulating the RAGs, MEDEP guidelines "were derived using conservative default exposure factors." RAGs at 26.[5] The lowest Guideline exposure concentration for mercury, associated with the soil Residential exposure pathway, is 51 mg/kg (ppm), more than an order of magnitude higher than the MPS of 2.2 ppm. Therefore, the risk associated with leaving materials exceeding 2.2 ppm in place is low. The Technical Memorandum also provides a more detailed risk discussion, supporting this conclusion.

III. Proposed Modification

Mallinckrodt proposes to modify the BEP Order language as follows highlighted in red:

> Excavation of solid media exceeding the Media Protection Standards. This includes all Plant Area Soils, Cell Building Soils, Retort and Old Retort Building Soils, Sediments, Landfill Ridge Soils, and sludges and other mercury contaminated material from Landfill 1 and Landfill 2, except the depth to which contaminated soil under **the Plant Area and** Landfills 1 and 2 will be removed shall be determined as specified in Finding of Fact 10(D) of this Decision.

BEP Order at 53 ¶ 3(a).

[5] The guidelines established in the RAGs are considered to be "conservative" because "the guidelines were derived using conservative default exposure factors because all potential pathways were not considered." RAGs at 26. The RAGs indicate that less conservative exposure assumptions may be employed where a site is adequately characterized and a full risk assessment is conducted. *Id.*

> …Mallinckrodt must conduct a study, proposed to and approved by the Department, to determine the approximate distribution of concentrations of mercury [and other materials] in the soils (both saturated and unsaturated) under Landfills[sic] 1, and mercury and carbon tetrachloride under Landfill 2, **and mercury in the soils (both saturated and unsaturated) in the Plant Area**. Mallinckrodt shall conduct column leaching tests such that the adsorption/desorption or other degradation processes of the residual soil contamination ~~beneath the landfills~~ can be quantified, and on this basis the Department shall determine the areas and depth of soil excavation ~~beneath the landfills~~. This determination must be based on modeling natural desorption/degradation processes and other considerations such as the type of final cover to be placed over the area of the landfills after they are excavated.

BEP Order at 39 ¶ 10(D).

Modification to Address Removal of Certain Sections of Industrial Sewer due to Safety Concerns

Chapter 2 specifies that the Department may take action to modify a requirement based on a number of criteria, including "[t]he licensed discharge or activity poses a threat to human health or the environment" and "[t]he license fails to include any standard or limitation legally required on the date of issuance." 06-096 C.M.R. c. 2 §§ 27(C) and (D).

Section 3(d) of the Order requires the "[r]emoval of the industrial sewer."_At the time the Order was issued, the Chloropicrin Area was defined based on 13 borings with samples collected at depths ranging from 8 to 18 feet deep. Since the Industrial Sewer is located at depths up to 20 feet below the surface in this area, it was not anticipated this piping was present in chloropicrin impacted soils. Since that time however, nearly 20 additional borings were completed up to 35 feet deep, resulting in an understanding of chloropicrin impacted soil at much greater depths, including deeper than the elevation of the Industrial Sewer. Excavation of these chloropicrin impacted soils, and the sewer piping within this area, would pose a danger to workers, which is why the Department has approved in situ treatment of these soils to achieve the MPS instead of excavation. Since the concentrations of mercury in soil within the Chloropicrin Area are already below 2.2 mg/kg, when the in situ chloropicrin remediation is complete the soils in this area will be in compliance with the MPS. Furthermore, the concern about the sewer piping being a preferential pathway will be eliminated because by the time the chloropicrin is reduced to the MPS, impacted soils upgradient of this area will also have been remediated, thus eliminating the concern about a future preferential pathway if this piping is abandoned in place. Removal of this section of the Industrial Sewer, below the surface in soils which meet the MPS will create unnecessary health and safety risks associated with construction at depth with no additional environmental benefit.

Furthermore, a formal modification of the Order should not be required to allow the Department to permit Mallinckrodt to address health and safety concerns by leaving a limited segment of the Industrial Sewer in place due to safety issues associated with both chloropicrin

and working at depth, since the Department already has the ability to modify the CMIP as incorporated in the Order per Paragraphs 4 and 32.[6]

Nevertheless, Mallinckrodt has included a request that the Commissioner formally request a modification to the Order to allow the industrial sewer to remain in place in the chloropicrin area where removal would pose an unacceptable risk to worker safety and human health.

The specific areas of piping are discussed in detail in the Attached Technical Memorandum Figures.

Mallinckrodt requests modification of the Order as follows:

"3.d. Removal of the industrial sewer unless health & safety concerns are present in which case the sewer line must be cleaned and abandoned in place."

IV. Conclusion

Mallinckrodt respectfully requests that the Commissioner initiate a modification of the Orders before the BEP to allow plant area soils to be treated similarly to Landfills 1 and 2 because newly obtained data requires such a modification. Mallinckrodt also requests modification of the Order to make clear that certain portions of the industrial sewer can be cleaned and remain in place to prevent unacceptable risks to worker safety.

Thank you for your consideration of this matter. Please contact me at 314-797-7197 or 314-753-0413(cell) should you require additional information.

Very Truly Yours,

Patricia Duft
Vice President, Mallinckrodt US LLC

Attachment: Technical Memorandum by Geosyntec Consultants dated June 19, 2018

[6] The Order also requires Mallinckrodt to "conduct all activities under this Order in compliance with …other applicable Federal, State, and local laws." See order at 33 ¶ 4. Moreover, all work undertaken must also specifically comply with "all Occupational Safety and Health Act" ("OSHA") regulations. *Id.* at 39 ¶ 32.