



STATE OF MAINE
DEPARTMENT OF ENVIRONMENTAL PROTECTION



PAUL R. LEPAGE
GOVERNOR

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COMMISSIONER

August 7, 2018

Patricia Duft, Vice President
Mallinckrodt US, LLC
7777 Bonhomme Ave. Suite 1800
St. Louis, MO 63105

Re: **Petition for Modification of April 14, 2014 Board of Environmental Protection Order**

Dear Ms. Duft:

This letter constitutes my decision on the Petition for Modification of the April 14, 2014 Order of the Board of Environmental Protection that was issued to United States Surgical Corporation and Mallinckrodt, LLC.

The Department received and has considered your Petition dated June 19, 2018, which requests a modification of the April 14, 2014 Board Order (Board Order) on the basis that a change in condition or circumstances requires a modification of the Board Order. The Petition also invokes the criteria which allow a modification if the activity “poses a threat to human health or the environment” or the order “fails to include any standard or limitation legally required on the date of issuance.”

Pursuant to 38 § 341-D(3), at the request of the Commissioner, after notice and opportunity for a hearing, the Board may modify in whole or in part any license. In the context of a petition for modification, the term “license” includes an “order.” 06-096 CMR ch. 2 § 27.

The Board may modify an order when it finds that any of the criteria in 38 M.R.S. § 342(11-B) or Chapter 2 § 27 have been met. These criteria include a situation in which the activity poses a threat to human health or the environment, the order fails to include a legally required standard or condition, or there has been a change in any condition or circumstance that requires modification of an order.

38 M.R.S. § 342(11-B)(C), (D) & (F); 06-096 CMR ch. 2 § 27(C), (D) & (F).

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The Department notified parties that were intervenors in the underlying Board proceeding of the Petition and allowed them to file responses until July 23, 2018. Chapter 2 § 26(B) provides that after the period for responses from the intervenors, within 21 days the Commissioner must either dismiss the Petition or recommend to the Board that it initiate proceedings to modify the order. A decision by the Commissioner to dismiss a petition, or a decision by the Board not to initiate modification proceedings or to take no action at the close of such proceedings, is within the Commissioner's or the Board's sole discretion and is not subject to judicial review. 06-096 CMR ch. 2 § 26(H). For the reasons set forth below, I have concluded that the Petition did not demonstrate a sufficient factual or legal basis for me to recommend modification of the Order and therefore the Petition is dismissed.

In support of your argument that a change in a condition or circumstance requires modification of the Board Order, you state that new site data indicate that volumes of Plant Area at-depth material exceeding applicable standards are deeper and significantly greater than stated in the Board Order. You request that the Board Order be modified to allow native soils with mercury contamination above the Media Protection Standards (MPS) to be left in place in the Plant Area, stating that the groundwater extraction system would be an environmentally protective remedy for any such mercury that had the potential to leach into groundwater. You request that leachability tests, which were permitted to be used for Landfill 1 and Landfill 2, be allowed for the Plant Area to determine the necessary depth of excavation.

DEP staff's review of the evidence found that the Board Order allowed for leaving material above the MPS in Landfill 1 and Landfill 2 because of the specific technical challenges present at those two sites. Landfill 1 is proximate to the river, has steep topographical and groundwater slopes, and has soil made up of coarse-grained materials at or below the high tide level of the river. At Landfill 2, the site specific challenges were the location of the landfill in a topographical depression and the contact of the landfill with Southerly Stream. None of these conditions exist at the Plant Area, which is relatively flat, and has no river or stream contact. Moreover, Mallinckrodt and Department staff were aware that the Plant Area sat on top of a deep bedrock valley and it could be anticipated that contamination may have migrated down through the upper soil layers. Further, the cell building/Plant Area was expected to be the area with the potential for the largest volume of elemental mercury. Thus, the Department does not consider the extent of the contamination to be a change in condition or circumstance that warrants a modification of the Order.

The contention in the Petition that pursuing the removal of all solid media exceeding the MPS at the Plant Area site would result in remediation schedule delays also does not warrant a modification of the Order. The Department does not agree that the removal required in the Board Order would extend the length of time to complete corrective action measures. In fact, reliance on removal by the groundwater extraction system as proposed in the Petition would entail a greater length of time to achieve compliance with MPS than the removal currently required.

With regard to the worker safety concerns the petition mentions with the excavation required, based on Mallinckrodt's characterization, cell PA4-2 and PA4-2A, an area 60 feet by 60 feet, requires excavation to 26 feet below grade. A second area, cell PA4-8 and PA4-8A, a 50 feet by 50 feet area, requires a 16-foot excavation. Most of the rest of the Plant Area requires less than 10 feet depth of excavation. Mallinckrodt has successfully and safely excavated to 22 feet below grade in Landfill 2, which is a more challenging location. The Department does not agree that the proposed depths required for removal are technically impracticable or unsafe.

The Petition's second request is that the Board Order be modified to allow the industrial sewer to remain in place in a section of the site contaminated with chloropicrin because removal would pose a threat to human health or the environment and the Board Order failed to include a standard or limitation legally required on the date of issuance. The Petition argues that removing certain segments of the industrial sewer would create a safety issue due to encountering chloropicrin and working at depth, and that soil borings in the area of the industrial sewer indicate that mercury is below the MPS. Therefore, the Petition argues that abandonment in place should be allowed.

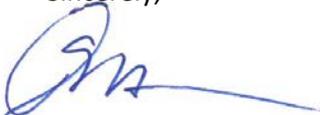
Mallinckrodt submitted, and the Department approved, a corrective action plan to remediate chloropicrin to the site's MPS by chemical oxidation and soil vapor extraction. On July 17, 2018, Mallinckrodt provided an update on the status of its chloropicrin remediation, demonstrating that the remediation is effective, and Mallinckrodt stated that it saw no obstacles that would prevent the approved plan from meeting the MPS for chloropicrin. It is the Department's understanding that Mallinckrodt plans to implement Phase 2 of that remediation plan in October of 2018. The completion of the chloropicrin remediation should address that issue raised in the Petition regarding excavation of

the industrial sewer. The Department does not agree that chloropicrin presents an obstacle to the removal of the industrial sewer.

At the time of the Board hearing preceding the issuance of the Order, Department staff expressed concerns that the industrial sewer and surrounding soils were potential conduits for contaminated groundwater. Those concerns have been found to be valid, as this year the Department has seen mercury contamination above the MPS associated with piping as follows: 1) in April at Plant Area (Phase 1) cell PA1-2 and PA1-3, where additional excavation was required after bottom samples failed to meet MPS three times; 2) in May, when corroded flanges on the industrial sewer appeared to have leaked; 3) in June, at Landfill 1 where a cracked fiberglass pipe released significant visible mercury; and 4) in July, when catch basin #4 in the Plant Area had a failed bottom sample due to leaks in the system. Additionally, based on work on the site done to date, DEP staff expects that during excavation of the Plant Area unmapped piping or utilities will be found that may contain or may have leaked mercury or brine sludge. Given that the industrial sewer carried large volumes of listed waste (brine sludge), that sections of the industrial sewer could not be videotaped because of obstructions or collapse, that the sewer and backfill may act as a conduit for contamination, and that chloropicrin is not a legitimate barrier to removal of the sewer, the Department concludes that the Petition's arguments do not warrant a change in the Board Order to allow the abandonment in place of any sections of the industrial sewer.

In conclusion, the Petition for Modification did not include a sufficient factual basis for a recommendation that the Board initiate modification proceedings and therefore, based on the analysis, factual findings, and conclusions set forth above, the Petition for Modification is dismissed.

Sincerely,

A handwritten signature in blue ink, appearing to read 'PM', with a long horizontal flourish extending to the right.

Paul Mercer, Commissioner
Maine Department of Environmental Protection

Cc: Jerry Reid, Me Asst Attorney General
Peggy Bensinger, Me Asst. Attorney General
David Burns Director BRWM
Chris Swain, DEP

