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FOR PLACEMENT IN THE ADMINISTRATIVE RECORD

September 17, 2012

BY ELECTRONIC MAIL AND FEDERAL EXPRESS

Ms. Anna Krasko
On-Scene Coordinator, Region 1 EPA
5 Post Office Square
Mail Code: OSRR07-1
Boston, MA 02109-3912

Re: Centredale Manor Restoration Project Superfund Site: Comments of Emhart Industries, Inc. on U.S. EPA's Proposed Plan Amendment (July 2012) and EPA's Technical Memorandum – Impact of Dioxin Reassessment (May 31, 2012)

Dear Anna:

Please find enclosed the comments of Emhart Industries, Inc. ("Emhart") on the Proposed Plan Amendment (July 2012) and Technical Memorandum – Impact of Dioxin Reassessment (May 31, 2012) issued by the United States Environmental Protection Agency ("EPA") concerning the Centredale Manor Restoration Project Superfund Site ("Site").

For your ease of review, you will receive with your paper copy of the comments three CDs that include cited sources. Some of these sources have been provided to you previously; however, due to timing of the submission, they were not included on the Administrative Record in the latest October 2011 version. Please place a set of the comments and the documents on the provided CDs in the Administrative Record for the Site.

If you have any questions or would like to discuss Emhart's comments, please contact either of the undersigned.

Sincerely,



Jerome C. Muys, Jr.
Jeffrey M. Karp
Direct line: 202 370 3920
jmuys@sandw.com

Enclosures (with paper copy)
Eve Stolov Vaudo, Esq. (w/o enclosures)



FOR PLACEMENT IN THE ADMINISTRATIVE RECORD

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Ms. Anna Krasko
On-Scene Coordinator, Region 1 EPA
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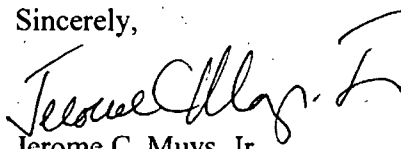
Re: Centredale Manor Restoration Project Superfund Site

Dear Anna:

Please be advised that Black & Decker, Inc. hereby adopts, as if filed on its own behalf, the following documents and all attachments thereto recently submitted by Emhart Industries, Inc. ("Emhart") for inclusion in the Administrative Record for the Centredale Manor Restoration Project Superfund Site: (1) Emhart's Comments on U.S. EPA's Proposed Remedial Action Plan (October 2011), Addendum to the Interim Final Feasibility Study Report (September 2011), and Interim Final Feasibility Study Report (April 30, 2010), submitted to U.S. EPA on March 2, 2012; and (2) Emhart's Comments on U.S. EPA's Proposed Plan Amendment (July 2012) and Technical Memorandum – Impact of Dioxin Reassessment (May 31, 2012), submitted to U.S. EPA on September 17, 2012.

If you have any questions, please contact either of the undersigned.

Sincerely,



Jerome C. Muys, Jr.

Jeffrey M. Karp

Direct line: 202 370 3920

jmuys@sandw.com

cc: Eve Stolov Vaudo, Esq.

FOR PLACEMENT IN THE
ADMINISTRATIVE RECORD

Centredale Manor Restoration Project
Superfund Site

Comments of Emhart Industries, Inc. on
U.S. EPA's Proposed Plan Amendment
(July 2012) and EPA's Technical
Memorandum – Impact of Dioxin
Reassessment (May 31, 2012)

Submitted by Sullivan & Worcester LLP
1666 K Street, N.W., Suite 700
Washington, D.C. 20006

September 17, 2012

**CENTREDALE MANOR RESTORATION PROJECT SUPERFUND SITE –
COMMENTS OF EMHART INDUSTRIES, INC. ON EPA’S PROPOSED PLAN
AMENDMENT (JULY 2012) AND EPA’S TECHNICAL MEMORANDUM – IMPACT
OF DIOXIN REASSESSMENT (MAY 31, 2012)**

I. EXECUTIVE SUMMARY

Emhart Industries, Inc. (“Emhart”) respectfully submits these Comments on the Proposed Plan Amendment (July 2012) and Technical Memorandum – Impact of Dioxin Reassessment (May 31, 2012) issued by the United States Environmental Protection Agency (“EPA” or the “Agency”) for the Centredale Manor Restoration Project Superfund Site in North Providence, Rhode Island (the “Site”). Emhart requests that these Comments be included in the Administrative Record for the Site.

In October of 2011, EPA issued for public comment its Proposed Remedial Action Plan (“PRAP”) for the Site. In February of 2012, as part of its on-going “dioxin reassessment,” EPA established a non-cancer toxicity value for 2,3,7,8-tetrachlorodibenzo-p-dioxin (“2,3,7,8-TCDD”). Because EPA alleges that the risks at the Site are due, in part, to the presence of 2,3,7,8-TCDD, in May of 2012 it revised its human health risk assessments and recalculated dioxin cleanup values for the Site, taking into account the new toxicity value for 2,3,7,8-TCDD. EPA now proposes to revise the October 2011 PRAP to reflect the revised risk assessments and impose more stringent dioxin cleanup values, and has issued a Proposed Plan Amendment (the “Amendment”) encompassing these changes. The Amendment would incorporate consideration of the newly-calculated non-cancer human health hazards from dioxin exposure and would lower the residential cleanup value of 1,000 parts per trillion for dioxin in soil to a cleanup level of 50 parts per trillion.

If adopted, the Amendment would create significant additional uncertainty regarding the lateral and vertical extent of contamination at the Site, because in many instances the newly-

proposed cleanup values are below the analytical detection limit utilized by EPA during the Site investigation. This in turn would introduce additional uncertainty regarding the actual costs that would be incurred to remediate the Site to the more stringent standards.

These failings are compounded by the fact that EPA simply ignored the obvious implications of its decision to revise its risk assessments and propose significantly more stringent cleanup values, and as a consequence compromised the entire remedy selection process. EPA never took the obvious, and legally-required, next step of re-evaluating the remedial alternatives under consideration in light of the changed circumstances. Thus, while the proposed Amendment undoubtedly will alter both the volume of materials requiring cleanup, and the cost thereof, EPA never took those changed circumstances into consideration when it issued the latest iteration of its proposed cleanup plan.

II. BACKGROUND

The federal regulations implementing EPA's obligations under the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA") are set forth in the National Contingency Plan ("NCP"). The NCP sets forth the organizational structure and required procedures governing EPA's preparation for and response to discharges of oil and releases of hazardous substances, pollutants, and contaminants.¹ Among other things, the NCP established the necessary requirements for the conduct of a "Remedial Investigation" and a "Feasibility Study" (collectively, the "RI/FS"), the key components of EPA's remedy selection process under CERCLA.²

¹ 40 CFR § 300.1.

² 40 CFR § 300.430(d) & (e).

In the RI/FS, EPA must document (1) its investigation of the nature and extent of contamination at the site at issue, and (2) develop and evaluate remedial alternatives for the site.³ Essential elements of EPA's site investigation as required by the NCP and documented in the RI are site-specific baseline human health and ecological risk assessments.

The NCP requires EPA to "conduct a site-specific baseline risk assessment to characterize the current and potential future threats to human health and the environment that may be posed by contaminants migrating to groundwater or surface water, releasing to air, leaching through soil, remaining in the soil, and bio-accumulating in the food chain."⁴ EPA is to apply the results of the baseline risk assessment to help establish acceptable exposure levels for use in developing remedial alternatives in the FS.⁵

The NCP also requires EPA to "characterize the nature of and threat posed by the hazardous substances and hazardous materials and gather data necessary to assess the extent to which the release poses a threat to human health or the environment or to support the analysis and design of potential response actions."⁶ Where necessary, EPA must conduct field investigations to assess the actual and potential exposure pathways through environmental media and the actual and potential exposure routes.

In connection with its remedial investigation at Centredale, EPA prepared several baseline risk assessment documents.⁷ However, EPA's risk assessments were not Site-specific

³ U.S. EPA, *Guidance for Conducting Remedial Investigations and Feasibility Studies under CERCLA*, EPA/540/G-89/004, OSWER Dir. 9355.3-01 (Oct. 1998).

⁴ 40 CFR § 300.430(d)(4).

⁵ *Ibid.*

⁶ 40 CFR § 300.430(d)(2).

⁷ See, MACTEC, U.S. Army Corps of Engineers, *Interim-Final Baseline Human Health Risk Assessment, Centredale Manor Restoration Project Superfund Site* (Aug. 6, 2004); MACTEC, U.S. Army Corps of Engineers, *Interim-Final Baseline Ecological Risk Assessment, Centredale Manor Restoration Project Superfund Site* (Sep. 30, 2004); MACTEC, U.S. Army Corps of Engineers, *Addendum to the Interim-Final Baseline Risk Assessment, Part I-Human Health, Part II-Ecological, Centredale Manor Restoration Project Superfund Site* (Aug. 1, 2006);

as required by the NCP.⁸ EPA's failure to perform Site-specific risk assessments resulted in a grossly-deficient RI, a flawed FS, and ultimately a legally-unsupportable proposed cleanup plan.⁹ (See Appendix A for further discussion.)

III. COMMENTS ON EPA'S PROPOSED PLAN AMENDMENT

A. EPA'S PROPOSED PLAN AMENDMENT IS NOT SUPPORTED BY ITS OWN DATA

As a result of the Agency's on-going "dioxin reassessment," EPA proposes to revise its human health risk assessment for the Site and to establish more stringent dioxin cleanup values. It is undisputed that this would result in an expansion of the areas of the Site requiring cleanup. However, the extent to which additional cleanup would be required, and the costs thereof, are highly uncertain and cannot be determined based on the current record. The lateral and vertical extent of contamination present at levels exceeding EPA's proposed, more rigorous cleanup values is simply unknown.

EPA is unable to determine the extent of cleanup required under the newly-proposed, more rigorous cleanup values because it lacks data of sufficient analytical precision. The vast preponderance of the samples collected by EPA during the RI were analyzed using laboratory detection limits well above the numerical values to which EPA now proposes for cleanup. Thus, the combination of EPA's decision to forego analytical rigor in Site investigation, coupled with its new proposal to require cleanup of dioxin compounds to infinitesimally minute concentrations

MACTEC, U.S. Army Corps of Engineers, *Supplemental Baseline Human Health and Ecological Risk Assessment: Oxbow Area Floodplain Soil and Sediment, Centredale Manor Restoration Project Superfund Site* (Jun. 1, 2011).

⁸ 40 CFR § 300.430(d)(4); 55 Fed. Reg. 8709.

⁹ See, Letter from J. Muys, Bingham McCutchen to A. Krasko, EPA (Oct. 19, 2006) (regarding Emhart's Comments on the Interim-Final Baseline Risk Assessments and Remedial Investigation (RI) and the Interim-Final Preliminary Remediation Goals Report (PRG)); Letter from J. Muys, Bingham McCutchen to A. Krasko, EPA (Jan. 25, 2007) (regarding Emhart's Comments on the Addendum to the Interim-Final Baseline Human Health and Risk Assessment (BHHRA) and Interim-Final Baseline Ecological Risk Assessment (BERA): Oxbow Area); Letter from J. Muys, Sullivan & Worcester LLP to E. Vaudo and A. Krasko, EPA (Oct. 21, 2011) (regarding Emhart's Comments on the Interim-Final Supplemental Baseline Human Health and Ecological Risk Assessments: Oxbow Area Floodplain Soil and Sediment); Integral Consulting, Inc., *Field Sampling and Data Report: 2010 Supplemental Investigation of the Lyman Mill Reach Sediment and Flood Plain Soils* (Jul. 2011).

has resulted in a data gap of such a magnitude that EPA simply cannot justify its most recent cleanup proposal. Short of completely re-performing the RI for the Site, EPA has no choice but to evaluate remedial options that would not entail excavation of dioxin-impacted media to the levels currently proposed by EPA.

B. EPA'S PROPOSED DELINEATION OF ADDITIONAL CLEANUP AREAS DOES NOT SATISFY NCP REQUIREMENTS

Under its new proposal, EPA has included within its delineation of additional cleanup areas at the Site a wide swath of residential use floodplain soils that were never characterized during EPA's RI and never evaluated for potential remediation under EPA's FS. Indeed, it appears that in the absence of adequate data EPA has proposed to expand the areas of the Site requiring remediation to include virtually all soils within the 100-year floodplain. In a number of these proposed expansion areas there is no indication whatsoever that cleanup would actually be required, even under the proposed new cleanup values. EPA's failure to investigate the extent, if any, of dioxin-impacted media in this area, or to include this area in its evaluation of remedial alternatives in the FS, renders EPA's current proposal to expand the Site remedy to include this area both technically infeasible and contrary to the requirements of CERCLA, the NCP, and EPA's own guidance documents.¹⁰

EPA's RI contains virtually no data whatsoever to which the Agency could reasonably cite in support of its proposal to extend the areal limits of the cleanup to include these floodplain soils. Indeed, it does not appear that EPA has concluded with any reasonable degree of certainty

¹⁰ See, e.g., U.S. EPA, *Human Health: Exposure Assessment*, http://www.epa.gov/oswer/riskassessment/human_health_exposure.htm (last visited on Sep. 14, 2012); U.S. EPA, *Human Health Toxicity Values in Superfund Risk Assessments*, OWSWER Dir. 9285.7-53 (Dec. 5, 2003); U.S. EPA, *EPA Non-Cancer Toxicity Value for Dioxin and CERCLA/RCRA Cleanups*, <http://epa.gov/superfund/health/contaminants/dioxin/dioxinsoil.html> (last visited on Sep. 14, 2012); U.S. EPA, *Role of Baseline Risk Assessment in Superfund Remedy Selection*, EPA 542/R-93/003, OWSWER Dir. 9355.0-30 (Apr. 22, 1991).

that dioxin-impacted media at concentrations in excess of the EPA proposed cleanup values are even present in this area.

In the absence of actual data supporting its new proposal, EPA appears to have fallen back on sheer speculation, stating, for example, that “the proposed cleanup areas or remedial footprints as conveyed in the FS are conceptual,” and that “more precise cleanup areas will be developed during the remedial design.” Similarly, EPA states that “the vertical extent is assumed to be one foot based on limited sub-surface data, but will be confirmed during remedial design.” Finally, EPA itself concedes in the Technical Memorandum that the limited number of adequate Site samples is not sufficient to allow use of the EPA-developed and widely-recognized statistical software ProUCL to calculate a reasonable estimation of the volume of materials that would have to be excavated at the Site under the proposal.

The arbitrariness of EPA’s volume estimates is further illustrated when one considers that EPA proposes to reduce the applicable cleanup value by a factor of 20 (from 1,000 ppt to 50 ppt), but assumes that the volume of material that would have to be excavated under the new value would increase by less than 1 percent in most areas (430 cy out of 63,000 cy). This is contrary not only to common sense, but to EPA’s actual experience in the field.

Finally, in a graphic illustration of the potential consequences of EPA’s failure to comply with NCP requirements that it consider a range of alternatives, and the costs thereof, before proposing a plan for cleanup, we note that EPA’s latest proposal wholly fails to consider whether acquisition of residential properties might be required under the proposal and, if it were, how that might affect the technical feasibility and cost effectiveness of the proposal. The NCP requires EPA to evaluate these types of contingencies before a remedy has been proposed.

C. EPA MAY NOT UTILIZE A POSTULATED CHEMICAL FINGERPRINT AS A SURROGATE FOR SITE DELINEATION

EPA's Technical Memorandum presents the concept of a Site-related dioxin/furan "signature" for floodplain soils at the Site. However, EPA's definition of this alleged Site-related signature is not supported by the Administrative Record for the Site. For example, in defining the Site-related signature, EPA asserts that the concentration of 2,3,7,8-TCDD at the Site is greater than the maximum concentration of 2,3,7,8-TCDD detected in upgradient floodplain soil samples from Greystone Mill Pond. However, a review of the Administrative Record reveals that EPA has never sampled Greystone Mill Pond floodplain soils. Rather, the non-aqueous, abiotic samples collected by EPA from Greystone Mill Pond were sediment samples. All of the upstream floodplain soil samples that EPA contends constitute "background" actually were collected by EPA below Greystone Mill Dam, along the Woonasquatucket River. Consequently, EPA's definition of the chemical fingerprint as presented in the Technical Memorandum is baseless, arbitrary, and capricious.

D. EPA FAILED TO CONDUCT A SITE-SPECIFIC RISK ASSESSMENT IN SUPPORT OF ITS PROPOSAL CONTRARY TO THE REQUIREMENTS OF THE NCP AND EPA'S OWN GUIDANCE

EPA's 2012 proposed update to its human health risk assessments for the Site does not conform either to NCP requirements or EPA guidance. Among other things, EPA (1) failed to comply with the NCP and its own guidance governing the use of toxicity data, specifically toxicity data for 2,3,7,8-TCDD; and (2) developed 2,3,7,8-TCDD proposed cleanup values for the Site based, in part, on a flawed human health risk assessment which failed to include baseline risk assessments for certain of the proposed additional cleanup areas. Accordingly, the human health risks presented by EPA in its latest proposal with respect to 2,3,7,8-TCDD at Centredale, and the cleanup values derived therefrom, do not meet legal requirements.

Rather than include in its proposal Site-specific, baseline risk assessments for residential floodplain soils and other additional areas covered by the proposal as required by the NCP and

EPA guidance,¹¹ EPA proposes to rely on non-Site-specific and unrealistically high exposure parameters in these areas. This resulted in assessments of exposure that were far in excess of the “reasonable maximum exposure scenario,” defined by EPA to be an exposure that uses a combination of upper-bound and midrange exposure factors such that it represents an exposure scenario that is both protective and reasonable, not the worst possible case.¹² Thus, EPA’s proposal to use non-Site-specific exposure factors results in an overestimation of potential human health risks. Moreover, since cleanup values are defined, in part, through the risk assessment process, the cleanup values proposed in the PRAP Amendment¹³ also are not Site-specific and consequently unduly stringent.

Finally, the manner in which EPA applied target cancer risk goals in its proposed screening analyses and in its proposed development of target cleanup goals is internally inconsistent and thus arbitrary and capricious. EPA’s proposed update to its human health risk assessments screens the exposure point concentrations for certain areas of the Site at a 10^{-5} incremental cancer risk level. Inexplicably, when EPA computes cancer risk estimates associated with other Site locations or media, and when it develops target cleanup levels for Allendale and Lyman Mill sediments and Allendale and Lyman Mill Reach soils (including the Oxbow Area), EPA applies a ten-fold more stringent 10^{-6} target cancer risk level. (See Appendix B for further discussion). Furthermore, in calculating these hypothetical cancer risks and target cleanup levels EPA errs in its use of a Tier 3 cancer slope factor instead of a Tier 1 reference

¹¹ 40 CFR § 300.430 (d)(4); 55 Fed. Reg. 8710.

¹² U.S. EPA, *Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual Supplemental Guidance*, “Standard Default Exposure Factors,” Interim Final, OSWER Dir. 9285.3-03 (Mar. 25, 1991).

¹³ U.S. EPA, *Proposed Plan Amendment, Centredale Manor Restoration Project Site, North Providence, Rhode Island* (Jul. 2012).

dose, contrary to the NCP and EPA's own guidance.¹⁴ This issue is discussed in further detail below.

E. EPA'S DEVELOPMENT OF REVISED CLEANUP VALUES FOR 2,3,7,8-TCDD AND DIOXIN AT THE SITE IS CONTRARY TO ITS OWN GUIDANCE AND WITHOUT FOUNDATION IN LAW

In implementing its risk assessment protocols, EPA has considered the availability and scientific quality of relevant toxicity values and developed a hierarchy of toxicity values and guidance governing the sources of toxicity information to be used by EPA in performing human health risk assessments at Superfund sites, such as the Centredale Site. The hierarchy used by EPA is a three tiered system, with "Tier 1" values being the preferred values, and "Tier 3" values being the least preferred.¹⁵

The toxicity values used in EPA's risk analyses are defined in the NCP as "To Be Considered" ("TBC") values. TBC toxicity values are those "with a high degree of credibility."¹⁶ In February of 2012, EPA published a non-cancer reference dose ("RfD") for 2,3,7,8-TCDD which, based on EPA's hierarchy, is a Tier 1 toxicity value. According to EPA, this RfD is now the recommended TBC value for use in developing site-specific dioxin cleanup levels under CERCLA and the NCP.¹⁷ Despite EPA's claims that it needed to update its human health risk assessments in light of the new RfD for dioxin, in reality, EPA is continuing to rely on the less-reliable Tier 3 toxicity value for selecting remedial areas and determining target cleanup levels for that compound.¹⁸ EPA's error in continuing to apply the Tier 3 value while

¹⁴ U.S. EPA, *Human Health Toxicity Values in Superfund Risk Assessments*, OSWER Dir. 9285.7-53 (Dec. 5, 2003); U.S. EPA, *EPA Non-Cancer Toxicity Value for Dioxin and CERCLA/RCRA Cleanups*, <http://epa.gov/superfund/health/contaminants/dioxin/dioxinsoil.html> (last visited on Sep. 14, 2012).

¹⁵ U.S. EPA, *Human Health Toxicity Values in Superfund Risk Assessments*, OSWER Dir. 9285.7-53 (Dec. 5, 2003).

¹⁶ 53 Fed. Reg. 51436.

¹⁷ U.S. EPA, *EPA Non-Cancer Toxicity Value for Dioxin and CERCLA/RCRA Cleanups*, <http://epa.gov/superfund/health/contaminants/dioxin/dioxinsoil.html> (last visited on Sep. 14, 2012).

¹⁸ U.S. EPA and U.S. Army Corps of Engineers, AMEC, *Technical Memorandum – Impact of Dioxin Reassessment, Centredale Manor Restoration Project Superfund Site* (May 2012).

using the availability of the new Tier 1 value as the rationale for updating its Centredale risk assessments is contrary to EPA practice at other sites and unsupportable in light of both NCP requirements and EPA practice.

It must be mentioned that although EPA has identified the Integrated Risk Information System ("IRIS") value as the recommended TBC value, there is no legal reason for EPA to change the cleanup values proposed in the October 2011 PRAP. The posting of an IRIS value does not constitute rule making, and neither does it make the value legally binding for the purposes of Superfund risk assessments.¹⁹

IV. CONCLUSION

EPA's proposed plan Amendment is arbitrary and capricious and otherwise not in accordance with law for the reasons set forth herein including, but not limited to: (1) it failed to obtain the data necessary to delineate the extent of contamination at the Site and to evaluate remedial alternatives in accordance with NCP requirements; (2) EPA's risk assessments and cleanup value determinations for the Site are severely flawed and are not in accord with the NCP or otherwise in compliance with the law and guidance; and (3) EPA applied target risk thresholds inconsistently in determining cleanup levels for residential and non-residential receptors. Therefore, EPA's proposed plan Amendment must be rejected and the matter remanded to EPA for further deliberations in accordance with applicable requirements.

¹⁹ U.S. EPA, *Use of IRIS Values in Superfund Risk Assessment*, OSWER Dir. 9285.7-16 (Dec. 21, 1993).

**APPENDIX A: EPA FAILED TO PERFORM SITE-SPECIFIC RISK ASSESSMENT,
RESULTING IN A LEGALLY-UNSUPPORTABLE PROPOSED CLEANUP PLAN**

Section 2.2 of the EPA Technical Memorandum presents a “Risk Evaluation of Residential Floodplain Soil Eastern Shore of Allendale Pond and Lyman Mill Pond.”²⁰ The risk evaluation presented in the Technical Memorandum employs what is described as a “streamlined risk assessment approach.”²¹ However, EPA’s Risk Assessment Guidance for Superfund (“RAGS”) makes no mention of the conduct of a “risk evaluation,” nor does it make provision for a “streamlined risk assessment approach.” In fact, the Technical Memorandum clearly differentiates between the baseline human health risk assessment provided for in the RAGS guidance and the risk evaluation conducted by EPA for certain residential soil areas at the Site.

The “streamlined approach” presented in the Technical Memorandum²² lacks the essential elements of a baseline risk assessment (*e.g.*, hazard identification, exposure assessment, toxicity assessment, risk characterization, consideration of uncertainties) as required by the NCP²³ and corresponding EPA guidance on risk assessment. Furthermore, as described below, the “streamlined approach” used by EPA in the Amendment is so overly conservative that it fails to meet the NCP requirement that the assessment of risk be conducted utilizing the reasonable maximum exposure scenario (“RME”).

In its “streamlined approach,” EPA erroneously equates the maximum detected concentration of a contaminant of concern on each property with the exposure point concentration for that parcel. EPA justified this approach based on a paucity of data collected in the area of the residential floodplain. Thus, EPA concedes its failure to collect sufficient data in

²⁰ U.S. EPA and U.S. Army Corps of Engineers, AMEC, *Technical Memorandum – Impact of Dioxin Reassessment, Centredale Manor Restoration Project Superfund Site* (May 2012).

²¹ *Ibid.*

²² *Ibid.*

²³ 55 Fed. Reg. 8709.

the area of the residential floodplain to derive appropriate exposure point concentrations for use in the baseline human health risk assessment, which is contrary to the NCP requirements that the lateral and vertical extent of contamination at Superfund sites be fully characterized before further work is undertaken.

Additionally, in the Technical Memorandum EPA relied on exposure parameters that EPA termed “site-specific.” However, the exposure parameters used in its “streamlined approach” are in some cases not even remotely plausible for this region of the country. For example, contrary to EPA guidance²⁴ and EPA regional precedent, in the Technical Memorandum EPA fails to consider seasonal changes to certain exposure parameters, such as soil ingestion rates or exposed dermal surface areas. Rather, in EPA’s “risk evaluation” children and adolescents are assumed to be present outside year-round for 12 straight years without shoes and wearing only a short-sleeved shirt and shorts, even though the average day-time temperature for this area of the country is below 60 degrees Fahrenheit for eight months out of the year and measurable snowfalls are expected during six months of the year. Adults are similarly assumed to be under-attired year-round, wearing only shoes, short-sleeved shirt, and shorts. These assumptions unrealistically inflate the potential for dermal exposure to soil and thus render the assessment wholly unreliable.

Moreover, contrary to its own guidance, published literature and EPA’s evaluation of published literature, the Technical Memorandum wrongly assumed that the dioxin present in soil is 100% bioavailable. EPA recognizes the importance of making appropriate site-specific adjustments to a risk assessment when the medium of exposure in an exposure assessment is

²⁴ U.S. EPA, *Risk Assessment Guidance for Superfund (RAGS), Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment) Interim*, OSWER Dir. 9285.7-02EP (Jul. 2004).

different from the medium of exposure assumed by the toxicity value.²⁵ Such an adjustment is made by applying a site-specific bioavailability factor.²⁶ EPA guidance on the relative bioavailability of dioxins in soil²⁷ states that “an adjustment would be considered appropriate if evidence were sufficient to indicate that the relative bioavailability (RBA) of the PCDD/F mixture in soils was less than 100%.” EPA provides additional guidance by stating the following:²⁸

During the remedial investigation/feasibility study (RI/FS), PRGs are generally modified based on site-specific data (*e.g.*, exposure duration, frequency of exposure, etc. - see Risk Assessment Guidance for Superfund (RAGS) Part B, see as well The Role of Baseline Risk Assessments in Remedy Selection Decision). Bioavailability is a factor to be considered during this process.

In the case of contaminated soil associated with the Site, the Technical Memorandum concludes that PCDD/Fs, principally 2,3,7,8-TCDD, contribute significantly to the overall potential risk to recreational and residential receptors via the incidental soil ingestion exposure pathway. Furthermore, in EPA’s so-called Site-specific baseline human health risk assessments for the source area soil and the Lyman Mill Reach Sediment and Flood Plain Soil (including the Oxbow Area), as well as in the Agency’s “risk evaluations” for the floodplain, the Technical Memorandum assumes that the 2,3,7,8-TCDD in incidentally ingested soil matrix is completely absorbed (*i.e.*, the RBA is 100%). This assumption is not Site-specific, and runs contrary to the EPA’s analysis of dioxin bioavailability data. EPA evaluated published data regarding dioxin bioavailability in soil and concluded that “...these results support the conclusion that the RBA

²⁵ U.S. EPA, *Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation (Part A), Interim Final*. EPA/540/1-89/002 (Dec. 1989); U.S. EPA, SRC, Inc., *Final Report Bioavailability of Dioxins and Dioxin-Like Compounds in Soil* (Dec. 20, 2010).

²⁶ U.S. EPA, *EPA Non-Cancer Toxicity Value for Dioxin and CERCLA/RCRA Cleanups*, <http://epa.gov/superfund/health/contaminants/dioxin/dioxinsoil.html> (last visited on Sep. 14, 2012).

²⁷ U.S. EPA, SRC, Inc., *Final Report Bioavailability of Dioxins and Dioxin-Like Compounds in Soil* (Dec. 20, 2010).

²⁸ U.S. EPA, *EPA Non-Cancer Toxicity Value for Dioxin and CERCLA/RCRA Cleanups*, <http://epa.gov/superfund/health/contaminants/dioxin/dioxinsoil.html> (last visited on Sep. 14, 2012).

for dioxin in soils evaluated in these studies is less and, and likely to be substantially less than 100%.²⁹ The conclusion reached by EPA regarding the RBA for dioxin in soil is more than sufficient evidence to indicate that the RBA of PCDD/F mixture in soil is less than 100%.

Furthermore, EPA found that bioavailability of dioxin appears to decrease with aging (*i.e.*, time contained within the soil matrix) and with increased organic carbon in soil.³⁰ Given that the dioxin at the Site has purportedly been in the environment for approximately 50-60 years and organic carbon content of the soil ranges from 0.5% to 23%,³¹ the Technical Memorandum also should have considered the affects of these abiotic factors and concluded that dioxin RBA is not 100%.

Even in light of the foregoing evidence and guidance, the Technical Memorandum failed to account for Site-specific bioavailability of dioxins in soil, which is inconsistent with EPA guidance. Ironically, EPA went the extra mile for a variety of biota (*e.g.*, earthworms, fish, and swallows) by conducting Site-specific evaluations of dioxin uptake from soil and sediment for those potential ecological receptors,³² but failed to make the appropriate Site-specific adjustments on RBA for human receptors.

The arbitrariness of the exposure assumptions used in the Technical Memorandum for residential receptors is further illustrated by the fact that EPA guidance expressly provides that consideration should be given to climate and that the default assumptions are designed for

²⁹ U.S. EPA, SRC, Inc., *Final Report Bioavailability of Dioxins and Dioxin-Like Compounds in Soil* (Dec. 20, 2010).

³⁰ *Ibid.*

³¹ U.S. EPA, *Interim-Final Remedial Investigation Centredale Manor Restoration Project Superfund Site, North Providence, Rhode Island* (Jun. 30, 2005); Integral Consulting, Inc., *Field Sampling and Data Report: 2010 Supplemental Investigation of the Lyman Mill Reach Sediment and Flood Plain Soils* (Jul. 2011).

³² MACTEC, U.S. Army Corps of Engineers, *Interim-Final Baseline Ecological Risk Assessment, Centredale Manor Restoration Project Superfund Site* (Sep. 30, 2004).

warmer climates and may even overestimate exposure in warmer climates.³³ In addition, at other sites within the region, EPA typically has used seasonal adjustments of exposure frequency that have the effect of limiting assumed soil ingestion and dermal exposure in human health risk assessments. For example, in the August 4, 1999 memorandum by EPA entitled “Protectiveness of Cleanup Levels for Removal Actions Outside the River – Protection of Human Health,” it evaluated potential future residential exposure to surface soils at the GE Housatonic River site in Pittsfield, Massachusetts. In that evaluation, EPA adopted a more realistic, yet conservative assumption that “residents are exposed to contaminated soil in their yard five days per week for seven months of the year (May through November) when the ground is not frozen or snow-covered.”³⁴ EPA made a similar assumption on exposure frequency for an assessment of risk to soil in Merino Park, Providence, Rhode Island. In the Merino Park assessment, EPA assumed that the exposure to site surface soil only occurs during the “warmer months of the year (May-October).”³⁵ EPA’s selective use of climate and seasonality considerations for the Site renders its conduct arbitrary and capricious.

EPA’s use of far upper-end exposure parameters, maximum detected soil concentrations, and an unrealistic maximum bioavailability for dioxin in soil as its default value in the Site risk assessment also is contrary to NCP requirements regarding use of an “RME scenario,” which is defined as an exposure scenario that reflects averages and 95th percentile exposure values.³⁶ EPA’s failure to conduct a proper Site-specific baseline human health risk assessment, including

³³ U.S. EPA, *Risk Assessment Guidance for Superfund (RAGS), Volume I: Human Health Evaluation Manual (Part I, Supplemental Guidance for Dermal Risk Assessment) Interim*, OSWER Dir. 9285.7-02EP (Jul. 2004).

³⁴ Memorandum from Anne-Maria Burke, U.S. EPA Region I to Richard Cavagnero, General Electric, Project Leader (Aug. 4, 1999).

³⁵ Memorandum from Chau Vu, U.S. EPA Region I Human Health Risk Assessor, Technical Support Section to Ted Bazenas, OSC, Emergency Response and Removal Group, U.S. EPA Region I (Nov. 23, 2010).

³⁶ 55 Fed. Reg. 8710.

EPA's failure to conduct a proper RME assessment for residential soils, is contrary to the NCP and EPA guidance documents.

**APPENDIX B: EPA APPLIED TARGET RISK CRITERIA INCONSISTENTLY
AND ARBITRARILY IN DETERMINING THE NEED FOR CLEANUP AND
SELECTING CLEANUP LEVELS**

In accordance with the NCP and EPA guidance, site-specific cleanup levels are customarily developed using target risk thresholds. In typical practice, an acceptable level of cancer or non-cancer risk is selected (*e.g.*, 10^{-5} cancer risk or hazard index of 1, respectively). The acceptable risk level becomes the target risk threshold, and it is used in the site-specific exposure equations to back-calculate cleanup levels.

EPA's 2012 proposed update to its human health risk assessments uses target risk thresholds for two primary purposes:

1. To define areas that EPA claims will require remediation; and
2. To set cleanup levels in those areas that EPA has selected for remediation.

EPA, however, arbitrarily and capriciously applies different target risk levels for different areas of the Site in determining whether remediation is required. For example, surface soil sampling data from the Lee Romano Field and vicinity are screened against a risk-based concentration of 280 ng/kg for 2,3,7,8-TCDD, based on a target cancer risk threshold of 10^{-5} . Because none of the samples from the Lee Romano Field and vicinity have concentrations of 2,3,7,8-TCDD exceeding the screening level, EPA concludes that "...the soils at and in the vicinity of the Lee Romano Field are not impacted by the site and need not be considered further."

Similarly, EPA uses a cancer target risk threshold of 10^{-5} to develop a cancer-based screening threshold for 2,3,7,8-TCDD in soil at Merino Park, and uses a non-cancer target risk hazard quotient of 2.0 to compute risk-based screening levels for soil at that site.³⁷ EPA states

³⁷ Memorandum from Chau Vu, U.S. EPA Region 1 Human Health Risk Assessor, Technical Support Section to Ted Bazenas, OSC, Emergency Response and Removal Group, U.S. EPA Region 1 (Nov. 23, 2010); Memorandum

that the risk-based concentrations based on a 10^{-5} target cancer risk threshold and a target hazard quotient of 2.0 are both protective.

Inexplicably, when EPA computes cleanup levels for the source area soil and the floodplain soil at the Site, it relies on target risk thresholds that are ten-fold more stringent by using a target cancer risk threshold of 10^{-6} and a non-cancer hazard quotient of 1.³⁸ EPA's selective application of varying target risk thresholds is both inconsistent and arbitrary. Hence, EPA's proposed update to its human health risk assessments results in an arbitrary and capricious determination of whether a remedy is necessary as well as an arbitrary and capricious cleanup value determination for those areas alleged to require remediation.

from Chau Vu, U.S. EPA Region 1 Human Health Risk Assessor, Technical Support Section to Ted Bzenas, OSC, Emergency Response and Removal Group, U.S. EPA Region 1 (Mar. 29, 2012).

³⁸ U.S. EPA and U.S. Army Corps of Engineers, AMEC, *Technical Memorandum – Impact of Dioxin Reassessment, Centredale Manor Restoration Project Superfund Site* (May 2012).

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