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Ms. Cheryl Chase, Director
Inland Water Resources Division
Bureau of Water Protection and Land Reuse
Connecticut Department of Energy and Environmental Protection
79 Elm Street, Hartford, CT 06106-5127

Dear Ms. Chase:

Re: Comments on the Final Report – "Evaluation of Risk-Based Decision Making Connecticut Department of Energy and Environmental Protection (CT DEEP)"

Conestoga-Rovers and Associates inc. (CRA) respectfully submits the following comments regarding the "Evaluation of Risk-Based Decision Making – Connecticut Department of Energy and Environmental Protection (CT DEEP)" report (the "Report"), prepared by CDM-Smith and Charter Oak Environmental Services, Inc., dated August 29, 2014. CRA's Risk Assessment Group has reviewed the Report and commends CT DEEP's initiative in developing regulatory guidelines regarding the conduct of human health and ecological risk assessments for contaminated sites in Connecticut.

The risk assessment regulatory process that has been used for several decades is not well understood by involved stakeholders and generally results in overly conservative and cost-ineffective remedial programs to obtain closure and re-use of contaminated sites. Despite lessons learned and recent scientific developments, very little, if anything, has changed in the risk assessment methodology. The development of new guidelines by CT DEEP provides a great opportunity for a paradigm shift toward more meaningful, efficient, and scientifically valid risk assessments.

The recommendations presented in the Report are a good start, especially with respect to conducting Human Health Risk Assessments (HHRAs). This section includes discussion and advice against hyper-conservative approaches such as the discussion regarding target cancer risk levels versus potentially affected populations presented on Pages 6-23 to 6-24 of the Report. It recognizes a critical fact - most all risk assessments for contaminated sites deal with small areas and small numbers of exposed people. Given the small number of people typically exposed, we agree with the Report's recommendation that 10^{-6} target cancer risk level is usually too conservative.

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However, this discussion might benefit from some additional text/clarification. A rationale should be given for the proposed double-criterion scale: a 10^{-5} target risk level for individual chemicals and a 10^{-4} target risk for all chemicals. Since risks at many contaminated sites are dominated by one or two primary chemicals of concern, the current advice effectively amounts to a target risk for all chemicals of about 10^{-5}. Secondly, it can be inferred from the previous discussion that these proposed criteria would be low default values. That is, less conservative risks could be used for very small populations whereas more conservative risk levels (less than 10^{-5}) would be discouraged. This default status should be made explicit. Thirdly, it can also be inferred that these target risk levels are to be applied to the Reasonable Maximal Exposure (RME) individual. Again, this probable intent should be made explicit. Fourthly, we recommend mandating the use of the central tendency exposure (CTE) individual, which is usually ignored (as discussed in the Report). Due to the combination of small populations exposed and hyper-conservative exposure assumptions, the RME population size is often most likely to be zero (i.e., no people fulfill all assumptions). RME scenarios for fish consumption and contaminated sediments, in our experience, tend to be especially unreasonable. To make risk assessments more realistic, understandable, and cost-effective, we suggest that default CTE risks be set at about ½ to ⅓ those for RME. Mandating use of CTE in risk assessment decisions would constrain exposure scenarios, and risk assessment decisions, to those that may actually occur with some frequency.

CRA welcomes the discussion in the Report regarding the hyper-conservatism of the published risk potency factors. Our concern is that the very high level of conservatism inherent in cancer slope factors, reference doses (RfDs), and exposure scenarios remain unclear to non-expert readers. That is, the current discussion in the Report does not go far enough in explaining just how conservative typical “risk assessments” truly are. The name itself is misleading since “risk assessment” also applies to much more realistic, technically based actuarial risk assessments (e.g., car safety, heart disease), while those for chemical risks include a myriad of overt and hidden safety factors, as wells as embedded policy decisions. For example, the typical cancer slope factor includes use of an upper confidence limit on the worst case bioassay data, and assumes that moderately high dose effects can be extrapolated to very, very low doses. Many scientists, including CRA’s Risk Assessment Group, believe that many regulated carcinogens are not, in fact, carcinogens at all at environmental exposure levels. Similarly, RME for some endpoints (e.g., fish consumption) are not, in fact, anything close to “reasonable.” It would be good public policy to mandate that risk assessments include some level of cumulative error analysis, in which all the hidden safety factors inherent in a risk estimate are specifically

addressed and estimated quantitatively. We recognize that this may be technically difficult. However, the uncritical, common-place usage of these ultra-conservative "risk assessment" methods confuses most stakeholders, even experts and regulators, into believing they are realistic assessments of risk. Another option could be utilizing Monte-Carlo risk assessments as default alternatives to the typical deterministic HHRA methods, since good probabilistic risk analyses identify and quantify the total safety factors.

The discussion of ecological risk assessment (ERA) in the Report includes some good elements; however, the implicit recommendation to have *de minimis* areas necessary to trigger an ERA is underemphasized. If ERAs are to be incorporated into the CT DEEP regulatory program, CRA strongly recommends that specific *de minimis* areas should be adopted.

Also, the Report refers to *de minimis* areas of undeveloped land, but a discussion of developed land is notably absent. The value of not considering developed land in ERAs would be to avoid spending money cleaning up what will be, after clean-up, marginal ecological habitat. This is a basic good common sense approach that is rarely considered in the ERA process. Furthermore, another option that should be considered is the opportunity to preserve some equivalent area of good habitat in lieu of costly clean-up of the marginal ecological habitat often found at contaminated sites. Making land acquisition and preservation a default alternative to clean-up would presumably provide more net ecological benefits per dollar spent, and also serve as a *de facto* cost-benefit analysis to constrain ERA-driven risk management decisions.

Fundamentally, CRA believes that the continued use of current methods of ERA is not consistent with good science, expensive, and often counter-productive. First, ecological risk pertains to populations and communities of animals; where losses of a small number of individuals of any population or small areas of habitat are ecologically insignificant. The underlying assumption of current ERA methods, as currently practiced across North America, is that very small areas of usually moderately low contaminant levels can cause ecological risk. This underlying assumption is contrary to the science of ecology. It may not be good public policy to protect most exposed and sensitive species (i.e., the shrews and/or mink) on small areas of usually not very good habitat. However, it seems wrong to continue the misconception that many contaminated sites, in fact, pose real ecological risk.

That ERAs, as currently practiced, almost never address real ecological risk has several implications. First, it is important to recognize that the ERA process diverts public and private resources, and public attention away from real environmental impacts: exotic species

protection, habitat destruction, and climate change. Remediation of contaminated sites is an inherently ineffective, expensive, and probably illusory method to protect ecological habitat and species of concern. Second, there is reduced rationale for conservatism since most all contaminated sites and areas of impact are too small to cause ecologically significant impacts. Similar to cancer risk evaluations alluded to in the Report; almost all contaminated sites are too small to require the currently used default of very conservative methods for ERAs. To be balanced, CRA recognizes that some sites may, in fact, cause societally-significant ecological effects. However, these are atypical sites that contain all of the following: 1) high concentrations of persistent chemicals; 2) dispersed over large areas; and 3) important biological habitats. CRA recommends that less conservative methods be the default for all contaminated sites except for those very large sites that contain societally-important ecological resources.

A second problem with continuing the current ERA methods is that they are expensive, inefficient, and, AT BEST, capricious and arbitrary. Consider the current state-of-the-practice for Screening Assessments, where the maximum observed concentration is compared to Ecological Screening Values (ESV) that are often too low to be either believable or useful. The net effect of this compounded conservatism is screening assessments that do not screen. Instead, many nuisance compounds are identified as compounds of potential ecological concern (COPECs) even though they have no potential at all to cause toxicity (especially at the small scales of the average contaminated site). Before more valuable time and resources are wasted addressing these spurious COPECs, CRA recommends that risk assessors rescreen using more reliable estimates of mean concentrations and developing more reliable ESVs.

Thus, CRA strongly recommends that more defensible screening methods be utilized as new default methods. Specifically, screening with 95% upper confidence limits (UCLs) **and** mean concentrations except for very small datasets (e.g., less than 10 samples) or when **un-biased** samples yield 95% UCLs greater than the maxima. This change should be very easy to justify since use of the maximum concentration for screening has so many aberrant qualities in addition to inefficiency. Notably, ecological risk pertains to mean exposure, and the maximum is not really relevant. The maximum concentration is also highly unstable across sampling intensity. Worse, maxima respond contrarily to additional sampling: use of the maximum penalizes more complete sampling since maxima go up with sampling intensity. Use of the maximum concentration is also very wasteful: the remainder of the dataset, collected at great expense, is just wasted. Moreover, the maximum concentration is generally the least believable value in any dataset; it is usually an outlier and often the result of biased sampling

(i.e., known source areas that provide limited ecological habitat). Consequently, of any value in the dataset, the maximum is often the worst estimator of mean conditions. Use of the maximum for screening was never technically justified.

Another serious problem with current ecological screening assessments is the proliferation and use of trivial, unscientific ESVs. Due to a number of conservative pseudo-scientific methods, many widely used ESVs occur in the range of background concentrations. This renders them suspect as toxicological values – it doesn't make any sense that widely occurring species could face frank toxicity from widely occurring concentrations. Occurrence in the range of background values also renders the ESVs not useful, at best, as screening values (especially when only maximum concentrations are considered). (Note that useless is the best outcome for some of the worst ESVs, such as the EcoSSLs for vanadium and antimony. That is, the best outcome is that screening result will simply be ignored. But screening values are widely misunderstood and used as valid toxicological values, so many of these very low ESVs actually impart negative information about potential risks. In these cases, these ESVs are worse than useless.)

CRA believes that ESVs should be explicitly limited to values that have some potential to be both toxicologically legitimate AND useful in screening assessments. For naturally occurring compounds, a base value of the 90th percentile concentrations, as in the Dutch soil and sediment Maximum Permissible Concentrations (MPC) ESV (Crommentuijn et al., 1997), would be defensible toxicologically and also much more useful than many currently-used ESVs. For anthropogenic compounds, ESVs should not be set below typical analytical detection levels or typical clean-up levels. For example, many available screening levels of polychlorinated biphenyl compounds (PCBs) and pesticides are at, and sometimes below, conventional detection levels. Use of these ultra-low ESVs triggers insensible behavior before (use of more expensive, more sensitive analytical methods) and after detection of these chemicals (incidental detection of PCBs and pesticides at low levels triggers extensive and expensive evaluation of these spurious COPECs). What is the value of ESVs that are well below likely risk levels and reasonable clean-up levels?

The Report simultaneously recommends a good science and so-called "effects-based" values. The "effects-based" sediment quality benchmarks (SQB) are not, in any way, consistent with scientific methods (Smith and Jones, 2011). They are not actually even "effects" based (Smith, 2008). These values are most probably the result of constrained random sampling of

background concentrations. This mechanism explains why TEC/ER-L/TEL/LEL[1] for metals closely resemble median background concentrations (r^2 for regressions of these lower tier SQBs with median background concentrations are > 98%); they are background concentrations (Smith and Jones, 2005 and 2007). Instead of good science, the co-occurrence values are pseudoscience (i.e., technical analyses that purport to be, or can be confused with, good science) (Smith and Jones, 2011), and because they are so poorly understood, they are best characterized as bad pseudoscience. They are also bad public policy since they typically produce ESVs that are essentially equal to median background concentrations, and because they are widely misused and almost always misunderstood. As an alternative, we suggest using the higher tier co-occurrence numbers (PEC/ER-M/PEL/SEL)[2]. Although these higher tier co-occurrence SQBs are similarly bereft of scientific validity, they are higher than lower tier numbers and much more efficient in terms of screening. Alternatively, the Dutch MPC sediment values are transparent, have some scientific underpinning, and are estimated to be above most background concentrations.

The Report's recommendation to employ British Columbia (BC) soil screening levels is problematic in three respects. First is that this recommendation represents an implicit but important policy decision: that the health of soil biota and plants, hereafter termed "worms and weeds", on private land are appropriate assessment endpoints for ERA. This is a critical policy issue that needs to be explicitly and clearly stated, so that readers can understand that this policy is being recommended. The second problem is that this implicit policy is not a good public policy. The guidance of United States Environmental Protection Agency (EPA) and other States indicates that appropriate endpoints for ecological risk should be societally important species and habitats; the worms and weeds on private lands are not of great societal concern. Thus, for example, landowners are usually free to develop their lands into non-habitat for native plants and soil biota – buildings, parking lots, lawns, and agricultural fields. Similarly, a trip to the local lawn and garden center provides the visitor a wide selection of over the counter products developed to kill worms, weeds, and other biological pests. Lastly, we have concerns about the validity of the BC soil screening numbers and grave concerns about other

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1 These acronyms pertain to the lower tier concentrations for various co-occurrence SQB: threshold effects concentration (TEC); environmental response-low (ER-L); threshold effects level (TEL); and lowest effects level (LEL).

2 These acronyms pertain to the higher tier concentrations for various co-occurrence SQB: probable effects concentration (PEC); environmental response-medium (ER-M); probable effects level (PEL); and severe effects level (SEL).

soil-screening levels based on protecting “worms and weeds”, such as EPA’s EcoSSLs. The latter ESVs are implicitly recommended for compounds lacking a BC criterion. The toxicological datasets for plants and soil invertebrates tend to be very limited; so many soil screening levels for these endpoints are more policy and default assumptions than science. For example, the vast majority of studies used to develop the EcoSSLs for terrestrial plants are based annual agricultural crops that have been artificially selected for rapid growth and high yield at the expense of the genetic diversity inherent in native species. Again, CRA recommends the Dutch MPC numbers, which have a high background concentration as a minimum screening level.

Again, CRA commends CT DEEP's initiative in developing regulatory guidelines regarding the conduct of human health and ecological risk assessment, and their preliminary attempts to make risk assessment more useful and transparent. CRA encourages the CT DEEP to take advantage of this opportunity to be the catalyst for a risk assessment paradigm shift toward more meaningful, efficient, and scientifically valid risk assessments.

Yours truly,

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