2005 Review of Canada-Wide Standards for Petroleum Hydrocarbons in Soil:

Report of the Toxicity Reference Value (TRV) Advisory Sub Group

February 2006

Acknowledgement

We would like to thank all the members of the Toxicity Reference Value Advisory Sub Group for their contribution to this effort, including participation in numerous conference calls and a face-to-face meeting, as well as countless hours spent reviewing documentation and meeting minutes in advance of the conference calls.

Mike Zemanek, CCME SQGTG
Warren Kindzierski, Chair

Executive Summary

The Toxicity Reference Value (TRV) Advisory Sub Group was formed to review information and develop recommendations and advice for the CCME Soil Quality Guidelines Task Group with respect to human health toxicity reference values for Petroleum Hydrocarbon contaminants in soil.

The TRV Sub Group conducted nine teleconference meetings and held a one day-long meeting in Calgary, AB between August 2005 and February 2006. These meetings resulted in a number of recommendations being put forward to the CCME Soil Quality Guidelines Task Group. These recommendations are presented below with further rationale provided in the body of this report:

For cumulative effects approach for hydrocarbon fractions used by Atlantic RBCA:

1 The CWS four hydrocarbon fraction-approach (F1 to F4) is similar in intent to the current Atlantic Partnership In RBCA Implementation (PIRI) approach at the Tier I level. The issue of whether equivalency exists between the CWS process and the current Atlantic PIRI process is best served through further interaction between CCME and Atlantic RBCA outside of this Sub Group.

For modification of F3 and F4 aliphatic oral exposure limits:

2 Modifying the F3 and F4 aliphatic TRVs in light of new toxicological information available from scientific literature theoretically would be technically correct, however, the impact on the TRVs is so small that change is a low priority at this time.

For direct soil exposure pathway and treatment of ingestion and skin contact:

3 The TRV Sub Group recommends that the CCME SQGTG combine the ingestion and skin contact pathways (consistent with CCME protocol) for the purpose of determining soil quality guidelines.

For vapour measurements of n-hexane and other C_6 to C_8 aliphatics at contaminated sites:

4 The TRV Sub Group initially identified a recommendation for the CCME SQGTG to undertake efforts to pull together field data on vapour measurements of n-hexane and other C_6 to C_8 aliphatics at contaminated sites. The purpose of this recommendation was to obtain a better understanding of the extent to which this hydrocarbon may be present in vapours relative to other C_6 to C_8 aliphatics at contaminated sites. However this recommendation was judged unnecessary after further discussion.

For Toxicity Reference Value (TRV) for n-hexane:

5 The TRV Sub Group recommends that the CCME SQGTG develop a separate Toxicity Reference Value and soil quality guideline for n-hexane. In accomplishing this, the

CCME SQGTG needs to consider relevant toxicology studies to determine a TRV to represent this hydrocarbon compound.

For Toxicity Reference Value (TRV) to represent the toxic potency of F1 C_6 to C_8 aliphatic hydrocarbons:

6 A recommendation was initially considered for the CCME SQGTG to continue using the current Toxicity Reference Value of 18.4 mg/m^3 for the F1 C_6 to C_8 aliphatic mixture with n-hexane. However this recommendation was not carried after further discussion because consensus could not be achieved among the Sub Group.

7 The TRV Sub Group recommends that the CCME SQGTG initiate a more complete analysis of irritancy data with respect to exposure to F1 C_6 to C_8 aliphatic hydrocarbons as proposed by Equilibrium Environmental Inc. (Equilibrium, 2006)

8 The TRV Sub Group recommends that the CCME SQGTG undertake efforts to pull together field data on vapour measurements of the following hydrocarbons that may possibly be associated with neurotoxicity: n-heptane, 3-methyl hexane, 3,4-dimethyl hexane, and n-nonane.

9 The TRV Sub Group recommends that the CCME SQGTG further investigate scientific evidence of neurotoxicity that may be associated with exposure to the following hydrocarbons: n-heptane, 3-methyl hexane, 3,4-dimethyl hexane, and n-nonane.

For Toxicity Reference Values (TRV's) for F2 to F4 aromatic and aliphatic fractions:

10 Modification of the F2 aromatic Toxicity Reference Value for inhalation is not warranted.

11 The TRV Sub Group recommends that CCME SQGTG should develop a Toxicity Reference Value for 1,2-diethylbenzene for the oral exposure route. Once an oral TRV is developed, the F2 soil quality guideline should be reassessed.

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1.0 Introduction

The Canadian Council of Ministers of the Environment (CCME) is the major intergovernmental forum in Canada for discussion and joint action on environmental issues of national concern. The 14 member governments work as partners in developing nationally consistent environmental standards and practices.

The Canada-Wide Standards (CWS) for Petroleum Hydrocarbons (PHC) in Soil ("the Standard") was established pursuant to the 1998 Canada-wide Accord on Environmental Harmonization of the Canadian Council of Ministers of the Environment (CCME) and its Canada-wide Environmental Standards Sub-Agreement. The PHC CWS is a remediation standard that specifies the environmental endpoints and assessment procedures necessary to address releases of PHC in the soil and subsurface environment. The Standard is based on an application of risk analysis that identifies acceptable concentrations of each PHC fraction in soil in consideration of exposure pathways and protection goals for receptors (humans, plants, animals) applicable for each land use.

The PHC CWS was endorsed by Ministers of Environment (with the exception of Quebec) in May 2001. A commitment was made to review additional scientific, technical and economic analysis to reduce information gaps and uncertainties and allow revisions in 2005. Since that time, a CCME Soil Quality Guidelines Working Group ("the Working Group") requested and reviewed information from stakeholders regarding concerns with the current CCME PHC CWS. The Working Group identified priorities and nominated those priorities to the CCME Soil Quality Guidelines Task Group. The SQGTG agreed on areas of revision of the PHC CWS. Toxicity Reference Values (TRV) was identified as an area to be considered for revisions.

Mandate of TRV Sub Group –The mandate of the Toxicity Reference Value Advisory Sub Group was to develop recommendations and to advise the CCME Soil Quality Guidelines Task Group with respect to human health toxicity reference values for Petroleum Hydrocarbon contaminants in soil.

Specific activities undertaken by the Sub Group included:

- Reviewing relevant information submitted to CCME with respect to human health toxicity reference values for the four hydrocarbon fractions and relevant sub-fractions that were used in the initial standard.
- Reviewing information submitted on the additive nature of direct soil exposure pathways (dermal exposure and soil ingestion) and development of recommendations consistent with appropriate policy and protocol decisions.
- Reviewing information submitted on the cumulative effects approach for hydrocarbon fractions used in the Atlantic RBCA model.
- Obtaining and reviewing additional information directly relevant to submissions that were made to CCME with respect to human health toxicity reference values.

- Developing terms of reference and directing research/review activities undertaken to complete the task.
- Examining relevant policy and protocol decisions developed since the original CCME PHC CWS derivation.
- Determining if there were relevant and significant technical or policy changes since the development of the CCME PHC CWS that may result in substantial changes to the current human health toxicity reference values.
- Developing updated recommendations and rationale for human health reference values consistent with relevant CCME policy framework and the current state of science.

The Sub Group reported to the CCME Soil Quality Guidelines Task Group about its activities and work progress by providing meeting minutes on a regular and timely basis. Membership of the Sub Group is provided in Appendix A.

2.0 Recommendations

2.1 Cumulative effects approach for hydrocarbon fractions used by Atlantic RBCA.

1 **Final Sub Group Position** – The CWS four hydrocarbon fraction-approach (F1 to F4) is similar in intent to the current Atlantic Partnership In RBCA Implementation (PIRI) approach at the Tier I level. The issue of whether equivalency exists between the CWS process and the current Atlantic PIRI process is best served through further interaction between CCME and Atlantic RBCA outside of this Sub Group.

Rationale – Information discussed by the TRV Sub Group support the premise that the CWS process and the current PIRI process give similar results at the Tier I level when applied at a contaminated site. Modelling assumptions and TRVs have, for the most part, been harmonized between the two methods; where modelling assumptions differ, the PIRI assumptions are generally slightly more conservative, resulting in predicted human exposures that are greater by a factor of about 2 (Mitchell *et al.*, 2006 [in press]). The CWS uses a soil allocation factor of 0.5, while the PIRI approach bases Tier 1 levels on a target hazard index of 1. This difference is to some extent offset by the PIRI Tier 1 levels being based on whole products, which generally encompass at least 2 fractions, as well as the modelling conservatism noted above.

NOTE – the TRV Sub Group only evaluated the equivalency of these approaches from a human health perspective; no attempt was made by this group to compare the different approaches for protecting ecological receptors.

2.2 Modification of F3 and F4 aliphatic oral exposure limits.

2 **Final Sub Group Position** – Modifying the F3 and F4 aliphatic TRVs in light of new toxicological information available from scientific literature theoretically would be technically correct, however, the impact on the TRVs is so small that change is a low priority at this time.

Rationale – Equilibrium (2005a) indicated that recent toxicity studies suggested the oral TDI for F3 aliphatics (2 mg/kg/day) could possibly be raised to 12 mg/kg/day. Another recent study could also be used to derive a TDI for F4 aliphatics of 12 mg/kg/day, less than the current value of 20 mg/kg/day, although it is noted that neither of the F4 aliphatic studies yielded a LOAEL dose and, therefore, this latter revision may not improve human health risk estimates (Equilibrium, 2005a). However, the Equilibrium (2005a) report was a preliminary analysis and greater documentation and analysis would be recommended prior to establishing a revised oral TDI.

In any event, incorporating these revised TDI values would not have a discernible effect on the Tier 1 soil ingestion or dermal contact values calculated for F3 and F4, since the toxicity of these fractions is dominated by the aromatic components. Furthermore, the ecological soil contact pathway governs the guidelines for these fractions. Since these modifications to the TRV values would have no effect on the Tier 1 guidelines, and since formally revising a regulatory TRV value can be a time-consuming process, it is not considered to be worthwhile to pursue these modifications at this time.

2.3 Direct soil exposure pathway and treatment of ingestion and skin contact.

3 **Final Sub Group Recommendation** – The TRV Sub Group recommends that the CCME SQGTG combine the ingestion and skin contact pathways (consistent with the CCME protocol) for the purpose of determining soil quality guidelines.

Rationale – Sample calculations undertaken by D. Williams and I. Mitchell (Meridian Environmental Inc., Calgary, AB) – members of the TRV Sub Group – indicate that the impact of combining the direct soil exposure pathway and treatment of ingestion and skin contact is small on resulting soil quality guidelines. The revised *CCME 2005 Draft Protocol for the Derivation of Environmental and Human Health Soil Quality Guidelines* already combines these pathways. Also, as separate TRVs are not derived for the dermal exposure route, it is considered appropriate to combine exposure for these routes. Combining ingestion and skin contact exposure pathways will not govern the Tier I PHC CWS value.

2.4 Field data on vapour measurements of n-hexane and other C_6 to C_8 aliphatics at contaminated sites.

4 **Final Sub Group Position** – The TRV Sub Group initially identified a recommendation for the CCME SQGTG to undertake efforts to pull together field data on vapour measurements of n-hexane and other C_6 to C_8 aliphatics at contaminated sites. The purpose of this recommendation was to obtain a better understanding of the extent to which this hydrocarbon may be present in vapours relative to other C_6 to C_8 aliphatics at contaminated sites. However this recommendation was judged unnecessary after further discussion.

Rationale – Concerns were expressed by some stakeholders about whether the current RfC for the C_6 to C_8 aliphatic subfraction was fully protective of the neurotoxic potential of n-hexane, which appears to have significantly greater toxicity than other chemicals in this subfraction (Equilibrium, 2005b). Based on the currently applied C_6 to C_8 aliphatics RfC of 18.4 mg/m^3 and the US EPA n-hexane RfC of 0.7 mg/m^3, if n-hexane comprises more than 3.8% of the C_6-C_8 aliphatic subfraction, it could potentially drive the toxicity of the subfraction (i.e., if the subfraction was present in air at a concentration equal to its RfC, the n-hexane concentration could potentially exceed the n-hexane RfC if present at 3.8% by volume). Originally, the Sub Group proposed the collection of vapour

measurements of n-hexane at contaminated sites to determine whether this 3.8% threshold could be exceeded. However, headspace analysis data, which subsequently became available and field measurement data reviewed by the Sub Group indicated that n-hexane could potentially exceed the 3.8% threshold in some cases (at least in relatively fresh gasoline and diesel vapours). Therefore, further efforts to collect field vapour measurements for this purpose were deemed unnecessary. Based on the available data, the development of a separate TRV and soil quality guideline for n-hexane appears to be warranted.

2.5 Toxicity Reference Value (TRV) for n-hexane.

5 **Final Sub Group Recommendation** – The TRV Sub Group recommends that the CCME SQGTG develop a separate Toxicity Reference Value and soil quality guideline for n-hexane. In accomplishing this, the CCME SQGTG needs to consider relevant toxicology studies to determine a TRV to represent this hydrocarbon compound.

Rationale – As noted above, product headspace and field measurement data reviewed by the TRV Sub Group indicate that n-hexane could exist in sufficient quantities in the F1 aliphatic hydrocarbon fraction to 'drive' the toxicity of this fraction, particularly in fresh gasoline and diesel vapours. The amount of n-hexane in vapours was variable, with field data on several sites ranging from non-detect to tens of mg/m^3 (Sevigny *et al*., 2003, supplemented by raw data presented by Ross Wilson). Adoption of the n-hexane RfC for the entire subfraction would have significant socioeconomic consequences, potentially leading to F1 guidelines below the analytical detection limit. In addition, given the unique toxicological characteristics of n-hexane, it was not considered to be scientifically defensible to assume that the entire subfraction is as potent as n-hexane. Due to the variability in vapour phase n-hexane concentrations, adjusting the subfraction RfC to an intermediate value based on n-hexane toxicity and content does not appear feasible at this time. Therefore, the Sub Group concluded that the derivation of a separate soil quality guideline for n-hexane would be the best approach to ensure that n-hexane concentrations at contaminated sites do not result in unacceptable health risks. In order to develop a soil quality guideline for n-hexane, a TRV for this substance needs to be developed by Health Canada, or adopted from another jurisdiction (i.e., likely the US EPA according to Health Canada's preferred hierarchical approach for identifying TRVs).

2.6 Toxicity Reference Value (TRV) to represent the toxic potency of F1 C_6 to C_8 aliphatic hydrocarbons.

6 **Final Sub Group Position** – The TRV Sub Group initially identified a recommendation for the CCME SQGTG to continue using the current Toxicity Reference Value of 18.4 mg/m^3 for the F1 C_6 to C_8 aliphatic mixture with n-hexane. However this recommendation was not carried after further discussion.

Rationale – Consensus was unable to be reached among the Sub Group.

7 **Final Sub Group Recommendation** – The TRV Sub Group recommends that the CCME SQGTG initiate a more complete analysis of irritancy data with respect to exposure to F1 C_6 to C_8 aliphatic hydrocarbons as proposed by Equilibrium (2006).

Rationale – During the course of discussions, the TRV Sub Group was aware that uncertainty exists in relation to using this TRV for protection against respiratory and/or mucosal membrane irritancy endpoints as a result of human exposure to F1 C_6 to C_8 aliphatic hydrocarbons. For example, an American Petroleum Institute two-year rat inhalation exposure study (API, 1995 as cited in MDEP, 2003) – which was not used in derivation of the current TRV of 18.4 mg/m^3 – indicated evidence of irritation and mucosal lining inflammation in rats. These end points occurred at a dose of ~3100 mg/m^3, which is less than the NOAEL used to derive the current TRV. In addition, the issue of potential respiratory and/or mucosal membrane irritation in sensitive sub groups was raised during discussions.

A review of published literature on aliphatic hydrocarbon vapour concentrations that have been associated with an absence, or occurrence, of respiratory and/or mucosal membrane irritation in humans was prepared for the TRV Sub Group (Equilibrium, 2006). This review included a comparison of aliphatic hydrocarbon vapour concentrations with the TRV of 18.4 mg/m^3, which is used to assess human health risks from inhalation exposures to F1 C_6 to C_8 aliphatic hydrocarbons at contaminated sites in Canada.

The vapour concentration data reviewed were derived primarily from studies with human volunteers exposed to individual aliphatic hydrocarbons as well as mixtures of petroleum hydrocarbon containing significant proportions of aliphatic hydrocarbons. The range of hydrocarbons (by carbon number) that were evaluated extended from C_4 to C_{10} range, and thus potential respiratory effects that may be associated with aliphatics outside of the C_6 to C_8 range were also evaluated. The focus of the review was on hydrocarbons within the C_6 to C_8 range.

The weight of evidence of literature reviewed by Equilibrium (2006) suggests that respiratory effects are not expected to occur with a high incidence at an exposure concentration comparable to the CCME TRV for C_6 to C_8 aliphatics (i.e., 18.4 mg/m^3). While uncertainties remain, the review did not find evidence that appreciable respiratory or mucosal membrane irritation would be present from human exposure to C_6 to C_8 aliphatics existing in indoor air at concentrations equal to the TRV of 18.4 mg/m^3.

8 **Final Sub Group Recommendation** – The TRV Sub Group recommends that the CCME SQGTG undertake efforts to pull together field data on vapour measurements of the following hydrocarbons that may possibly be associated with neurotoxicity: n-heptane, 3-methyl hexane, 3,4-dimethyl hexane, and n-nonane.

Rationale – Preliminary results of an EnviroTest (2006) laboratory study investigating the composition of specific naphthalene-like versus alkyl benzene-like compounds

indicated that the above-mentioned hydrocarbons were present in headspace above pure product gasoline and diesel samples. However, it is unknown whether any of these hydrocarbons are present in measurable quantities with respect to pure and weathered products at contaminated sites. Evidence of the presence of these individual hydrocarbons may necessitate further investigation by the CCME SQGTG into protection against neurotoxic health effects-related endpoints.

9 **Final Sub Group Recommendation** – The TRV Sub Group recommends that the CCME SQGTG further investigate scientific evidence of neurotoxicity that may be associated with exposure to the following hydrocarbons: n-heptane, 3-methyl hexane, 3,4-dimethyl hexane, and n-nonane.

Rationale – Preliminary results of the EnviroTest (2006) laboratory study investigating the composition of specific naphthalene-like versus alkyl benzene-like compounds indicated that aliphatic hydrocarbons were present in headspace above pure product gasoline and diesel samples. In addition, Equilibrium (2005b) indicated that n-heptane, 3-methyl hexane, 3,4-dimethyl hexane and n-nonane could potentially form neurotoxic metabolites. Limited available data for n-heptane, 3-methyl hexane and n-nonane suggest that these compounds have a significantly lower neurotoxic potential than n-hexane, but further investigation is recommended.

2.7 Toxicity Reference Value (TRV's) for F2 to F4 aromatic and aliphatic fractions.

10 **Final Sub Group Position** – Modification of the F2 aromatic Toxicity Reference Value for inhalation is not warranted at this time. However international developments regarding the carcinogenicity of naphthalene should be monitored.

Rationale – A report prepared for Health Canada by Equilibrium Environmental Inc. (Equilibrium, 2005b) identified that new inhalation toxicity studies and regulatory reference values have been developed for naphthalene and methylnaphthalenes since the release of the Canada Wide Standard for Petroleum Hydrocarbons in Soil. In addition, Equilibrium (2005b) identified that new inhalation toxicity studies and preliminary reference values have been developed for 1,2-diethylbenzene and 1,2,4-triethylbenzene since the release of the Canada Wide Standard for Petroleum Hydrocarbons in Soil.

The TRV Sub Group assessed the potential for these substances to be present in sufficient quantities to pose a risk to human health via indoor air exposure and drive the existing F2 TRV. In addition, the carcinogenic potential of naphthalene – by a genotoxic mechanism – was identified and acknowledged by the Sub Group to require further investigation.

The Sub Group examined several lines of evidence through a combination of predicted and empirical data. Soil vapour screening concentrations for the protection of indoor air were derived for each substance of concern by applying a conservative dilution factor to its inhalation reference concentration. These soil vapour screening concentrations were

then used as health protection limits to compare with concentrations of these substances expected to be in the soil vapour phase under worst-case conditions, i.e. in the presence of neat petroleum product.

The expected worst-case soil vapour phase concentrations for these substances of concern were estimated by three approaches. First, vapour phase concentrations were estimated by applying Raoult's Law to common petroleum product mixtures (Meridian, 2005). Second, maximum vapour phase concentrations were predicted by applying Henry's Law to published water-phase concentrations measured in a batch equilibrium experiment with diesel fuel (after Lee et al., 1992). Finally, concentrations of these substances were measured in the vapour phase in headspace above several pure product gasoline and diesel fuel samples at equilibrium in a closed system (EnviroTest, 2006).

The maximum estimated vapour phase concentrations of naphthalene, methylnaphthalenes, 1,2-diethylbenzene, and 1,2,4-triethylbenzene determined by each method was less than the corresponding screening concentration derived for protection of indoor air quality. These substances identified are therefore unlikely to pose a risk to indoor air quality at petroleum-contaminated sites.

Consequently, modification of the F2 aromatic Toxicity Reference Value for inhalation is not warranted on the basis of the information reviewed. However, as more data become available on both the composition of the aromatic sub-fractions in vapours at contaminated sites and on toxicity of the compounds and mixtures in this range, further re-evaluation may be required.

11 **Final Sub Group Recommendation** – The TRV Sub Group recommends that CCME SQGTG should develop a Toxicity Reference Value for 1,2-diethylbenzene for the oral exposure route. Once an oral TRV is developed, the F2 soil quality guideline should be reassessed.

Rationale – Preliminary results of the EnviroTest (2006) laboratory study investigating the composition of specific naphthalene-like versus alkyl benzene-like compounds indicated that 1,2-diethylbenzene is present at considerable concentrations in pure product gasoline and diesel samples. In addition, Equilibrium (2005a) reported that significant unique toxicity could be posed by this hydrocarbon through the oral exposure route. There are currently no regulatory TRVs available for this substance; Equilibrium (2005a) suggested that the current data could lead to a preliminary TDI on the order of 0.002 mg/kg/day to 0.004 mg/kg/day, or 10 to 20 times lower than the current TDI for the relevant subfraction. The Sub Group therefore recommends developing a formal oral TDI for 1,2-diethylbenzene. If, based on this TRV and the amount of the substance in petroleum products, the subfraction TDI is found to be unprotective of this substance, either the subfraction TDI should be adjusted or a separate guideline should be developed for 1,2-diethylbenzene.

3 References

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Appendix A – Toxicity Reference Value Advisory Sub Group Membership

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