5.0 HAZARD ASSESSMENT AND RISK CHARACTERIZATION

5.1 SELECTING A TOXICITY REFERENCE VALUE (TRV)

Appropriate Toxicity Reference Values (TRVs) are required to characterize the potency of the contaminants of concern and to facilitate calculation of numeric risk estimates. Under Canadian guidance (Health Canada 2004), PCBs and dioxins (TEQ concentrations) are not considered carcinogens, consequently a Threshold Daily Intake (TDI) was employed as the TRV.

Health Canada provides TDIs for 2,3,7,8-TCDD (for TEQ concentrations), and Total PCBs. In the model, TDIs were applied to assess the sum of the doses from all exposure pathways. The TRVs used are listed in Table 5.1.

5.2 MODELING RESULT

Once the TRV was entered into the model, a Hazard Quotient was automatically calculated. A hazard quotient is the ratio of the calculated Total Daily Dose to the TRV (in this case, a TDI), as follows:

$$Hazard\ Quotient\ (HQ) = \frac{Calculated\ Total\ Daily\ Dose}{Tolerable\ Daily\ Intake\ Dose\ (TDI)}$$

The calculated Hazard Quotients for the AHSL site are provided in Table 5.1. Health Canada guidance considers any concentration resulting in a HQ greater than 0.2 to warrant additional scrutiny as a potential risk to human health.

Based on the results of the model, there may be a potential but low concern for human health risk associated with workers and local residents being exposed to Total PCBs. Maximum hazard quotients were estimated as <0.45, marginally greater than the 0.2 threshold, but still below the TDI value. Note that uncertainty associated with the true value arises from the use of data affected by a non- detected outcome.

The estimated daily doses of Total PCB are only slightly larger than the TDI and the risk prediction is due to a high detection limit of fish. It is unlikely that there will be unacceptable risk, but additional fish tissue analysis of PCBs, using high resolution analysis, is desirable to confirm this. All other potential exposure pathways (accidental soil ingestion, particle inhalation and dermal contact) contributed negligible risk to the overall risk prediction. If the high resolution analysis of fish tissue indicates negligible (or acceptable) risk, due to eating fish, it is likely that human health risks due to all exposure routes combined are negligible (or acceptable).

Table 5.1 Results of Risk Characterization, AHSL site, Malaysia.

	Total PCBs			PCB + PCDD/F TEQs non-Carcinogen			PCB + PCDD/F TEQs Carcinogen		
	Employee	Local Resident - Adult	Local Resident - Child	Employee	Local Resident - Adult	Local Resident - Child	Employee	Local Resident - Adult	Local Resident - Child
Doses (mg/kg day)									
Dose $_{Soilingestion}$	$9.9x10^{-8}$	$1.1x10^{-7}$	$2.3x10^{-7}$	$4.3x10^{-12}$	$1.8x10^{-12}$	$3.9x10^{-13}$	$7.1x10^{-13}$	$3.0x10^{-14}$	$6.5x10^{-14}$
Dose $_{foodingestion}$	0.00026	0.00026	0.00046	---	---	---	---	---	---
Dose $_{Particleinhalation}$	$3.3x10^{-11}$	$3.5x10^{-11}$	$6.9x10^{-11}$	$1.4x10^{-15}$	$6.0x10^{-17}$	$1.1x10^{-16}$	$2.3x\ 10^{-16}$	$1.0x10^{-17}$	$2.0x10^{-17}$
Dose $_{Derma\ Contact}$	$5.5x10^{-8}$	$6.0x10^{-8}$	$6.5x10^{-8}$	$2.4x10^{-12}$	$1.0x10^{-13}$	$1.1x10^{-13}$	$4.0x10^{-13}$	$1.7x10^{-14}$	$1.8x10^{-14}$
Dose $_{Total}$	0.00026	0.00026	0.00046	$6.7x10^{-12}$	$2.8x10^{-13}$	$5.0x10^{-13}$	$1.1x10^{-12}$	$4.7x10^{-14}$	$8.3x10^{-14}$
TRV[1]	0.001 mg/kg day			$2.0x10^{-9}$ mg/kg day			130000 kg day/mg		
Hazard Quotient	**0.26**	**0.26**	**0.46**	0.0033	0.00014	0.00025			
ILCR							$1.4x10^{-7}$	$6.1x10^{-9}$	$1.1x10^{-8}$

TRVs used in the risk assessment model. Tolerable Daily Intake values (TDIs) for non carcinogens (Health Canada 2004), and Oral Slope Factor (SFo) for carcinogens (USEPA 2008A).

Bold Numbers = are above the 0.2 threshold and therefore indicate potential human health risk.

Exposures to PCDD/Fs + DL-PCB TEQs did not indicate potential human health risks. PCDD/Fs + DL-PCB TEQs had HQs below the 0.2 threshold. However, there were no fish tissue measurements for these chemicals. Fish tissue analysis using high resolution analysis (HR-GCMS) will be needed to confirm the absence of unacceptable human health risk.

5.3 RISK CHARACTERIZATION FOR CARCINOGENS

The exposure assessment, hazard assessment and risk characterization thus far has been conducted assuming that PCDD/Fs and PCBs are non-threshold contaminants. This is consistent with the Canadian perspective on this group of chemicals (Health Canada 2004). In contrast, the United States considers PCDD/F and dioxins to be carcinogens (USEPA 2008A). Following this perspective, a slightly different approach would be used to estimate human health risk.

The approaches differ in primarily two ways:

- In the exposure model, two additional variables have been added, life expectancy (LE) and years of exposure (D_{years}); and
- The toxicity reference value (TRV) selected in the hazard assessment is a cancer slope factor (SF), rather than a tolerable daily intake (TDI).

A cancer slope factor is multiplied with the calculated daily dose of each exposure pathway separately. For PCBs and PCDD/Fs, only a slope factor specific to oral exposures (SF_O) was available. Consistent with the Canadian and US approaches for carcinogenic substances, in the absence of SF values for the inhalation and dermal exposure pathways, the SF_O can be applied to these pathways.

The product of dose and SF is the incremental lifetime cancer risk, or ILCR. This is the additional probability (above background) that the exposed person will incur cancer from the exposure (typically based on experimental animal data or epidemiology). ILCRs for individual exposure pathways can be added together to determine the overall ILCR.

The dose for each exposure pathway is also calculated differently compared to non-carcinogens (threshold contaminants). Two additional variables are added to the calculation of exposure (daily dose). They are years of exposure and life expectancy. Years of exposure can be the number of years up to the writing of the risk assessment report, or the total anticipated number of years including years in the future. However, if future years of exposure are included in the calculation, this should be explicitly stated in the uncertainties section.

The results of the risk characterization for PCDD/Fs and PCB as carcinogens is provided (Table 5.1). The calculated ILCRs were all below the Health Canada threshold for acceptable cancer risk, $1x10^{-5}$. However, there were no fish tissue measurements of PCBs and PCDD/Fs enabling the calculation of a tissue ingestion TEQ dose. Fish tissue analysis using high resolution analysis (HR-GCMS) is desirable to confirm the absence of unacceptable human health risk.

5.4 DISCUSSION

Due to the conservative assumptions and uncertainty associated with a screening level risk assessment, it is possible that initial risk estimates may suggest apparent human health risks exist, simply due to overestimation. Generally, when a screening level risk assessment indicates potential risk, the risk assessor/manager has two options: to refine the risk assessment, by estimating more reasonable input variables (i.e., perform a detailed risk assessment), or to begin to implement risk management activities if the estimated risks are justified.

If the choice is to refine the risk assessment, it is helpful to look at the individual doses calculated for each of the exposure pathways. If one pathway contributes a much larger portion of the total dose than the other exposure pathways, it would be most appropriate to try to refine this component of the risk characterization model first. For example, ingestion of fish appears to be a significant contributor to daily total PCB dose, possible refinements to the calculation of daily dose could include improving estimates of:

- Fish tissue concentrations (C_{Food});
- Daily intake rate of fish (IR_{Food});

- Absorption factor for the gastrointestinal tract (AF_{GIT}); and
- Number of days in a year that fish from the site are consumed (D_{days}).

Of the POPs contaminants of potential concern (Total PCBs and PCDD/Fs +PCBs), only Total PCB concentrations suggested a potential human health concern (calculated hazard quotient 0.45 for children and 0.26 for adults). Following Health Canada guidance, any HQ greater than 0.2 warrants closer scrutiny for the potential to impact to human health, because of the possibility of additional exposure/risk from other exposure pathways.

For the fish sample PCB analysis, the limit of quantification (or "detection limit") was 5.0 mg/kg in tissue which is considered higher than normal); therefore, concentrations of individual PCB homologues were shown as <5.0 mg/kg. In the model it was assumed that the actual concentration in fish tissue was one half the stated detection limit. Although this is a reasonable approach it is likely still conservative and would have resulted in an over-estimation of hypothetical exposure via fish consumption.

The remaining exposure pathways (accidental ingestion of soil, dermal contact with contaminated soils and inhalation of particulates) contributed very little to the overall predicted PCB dose. The model indicates that the human health risk posed by these pathways combined is negligible and may be considered acceptable.

Because the concentration of total PCBs in fish tissue was not quantified and had a high detection limit, the potential health risk from fish consumption could not be fully resolved. Additional samples/analyses would be beneficial to confirm low concentrations. Therefore, re-sampling and re-analysis using HR-GCMS, is desirable before potential risks can be adequately assessed. In addition to PCBs, fish tissues should also be analyzed for dioxin/furans, and chlorinated pesticides. This analysis is recommended to determine if fish consumption should be halted.

This outcome highlights the importance of requesting chemical analysis with data quality objectives (i.e, detection limits) suitably low to meet the need of both screening chemical in the Problem Formulation, and for calculating risks. This type of outcome occurs from time-to-time in environmental risk assessment and the occurrence here should be regarded as an opportunity from which to draw experience and to avoid in the future.

The risk assessment was confined to POPs chemicals which had available TRVs. It is possible that other contaminants are present at the site, which may pose a health risk. These contaminants may include metals, metalloids, salts, hydrocarbons and POPs chemicals which did not have readily available TRVs.

The handling and ultimate disposal of treatment pond sludge should also be confirmed. Information available at the time of writing this report indicated that sludge was managed on site and that there were no off-site applications of

the material. Confirmation of the handling and disposal practices is necessary in order to discount the possibility of human exposure scenarios not assessed in this report.

5.5 GENERAL CONSIDERATIONS

The Exposure Assessment, Hazard Assessment and Risk Characterization conducted in this report are in support of a screening-level risk assessment (also called a Preliminary Quantitative Risk Assessment). Being a screening-level risk assessment, it is anticipated that there will be uncertainty in the estimates of risk. At the screening level, it is anticipated that estimates of individual variables will be approximate. However, where possible, uncertainty in individual variables should be addressed by making estimates more conservative (i.e., numbers which will make estimates more likely to err on the side of over estimating rather than under estimating risks).

5.6 UNCERTAINTY AND ASSUMPTIONS

In order to carry out a screening level risk assessment, most uncertainties will have to be addressed by making assumptions. Uncertainties and assumptions used in this risk assessment are summarized here:

- The assessment was limited to contaminants for which there were guidelines or criteria for screening. Some organochlorine pesticides were detected and quantified, but were not considered in the risk assessment due to a lack of guidelines.

- The estimate of exposure assessment concentrations was based on a small data set. The maximum concentration was used in the exposure assessment to provide a reasonable estimate of worst-case average exposure over time.

- In cases where country-specific values did not exist for the exposure assessment model variables, Canadian variables were chosen as a default. However, it is acknowledged that country-specific numbers would be preferable.

- Water concentrations of PCDD/Fs and PCBs were not considered in the risk assessment. Based on the low water solubility of POPs chemicals, it is anticipated that only very low concentrations would be found dissolved in water. Previous experience working with PCDD/Fs has indicated that exposure to water contributes a very small dose relative to other exposure pathways in a human health risk assessment.

- On-site soils were separated from off-site soils. The purpose of doing this was as follows: 1) for screening in the problem formulation (and selection of contaminants of potential concern for the risk assessment), it was important not to consider contaminant concentrations which may have

been attributable to other potential sources of contamination (i.e., other than the site being assessed); and, 2) for the exposure assessment, it was important to develop separate exposure scenarios. For the AHSL site, there were both on-site receptors (workers) and off-site receptors (local residents). Because the concentrations of contaminants that these two groups would be exposed to could be quite different, it was important to examine at on-site soils and off-site soils separately.

- The assessment of risk was made using existing conditions at the site. If conditions change in the future, the assessment may under-predict potential risks. However, future changes, if properly planned, should only further reduce future human health risks.

- For the cancer model, an estimate of total duration of exposure had to be made. In some cases, this estimate was difficult (i.e., for local residents). A conservative estimate was used to address this uncertainty.