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) value was employed as the TRV.

Health Canada provides a TDI for 2,3,7,8-TCDD of 2.0×10^{-9} mg TEQ/kg day. In the model, TDIs were applied to assess the sum of the doses from all exposure pathways.

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:

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

The calculated Hazard Quotients for the MEA facility are provided in Table 5.1. Health Canada guidance considers any concentration resulting in a HQ greater than 0.2 to pose a potential risk to human health that warrants closer scrutiny in case other exposure pathways unaccounted for may further contribute to exposure and risk.

Based on the results of the model, there may be a potential human health risk associated with workers and local residents being exposed to PCBs and TCDD/TCDFs. Hazard quotients were as high as 58.5, several fold higher than the 0.2 threshold.

Table 5.1 Results of Risk Characterization for Non-Carcinogens, MEA facility, Samut Prakan, Thailand.

	PCB + TCDD/F TEQs non-Carcinogen		
	MEA Employee	**Local Resident**	
	Adult	Adult	Child
Doses (pg/kg day)	**Storage Site**	**Home**	**Home**
Dose $_{SoilIngestion}$	0.022	0.039	0.082
Dose $_{FoodIngestion}$	67.84	67.84	116.9
Dose $_{ParticleInhalation}$	0.0011	0.0031	0.0047
Dose $_{DermaContact}$	0.028	0.024	0.028
Dose$_{Total}$	67.89	67.91	117.0
TRV[1]	2.0 pg/kg day		
Hazard Quotient	**33.9**	**34.0**	**58.5**

[1] Tolerable Daily Intake (TRVs) for non-carcinogens (Health Canada 2004), Oral Slope Factor (SFo) for carcinogens (USEPA 2008).

Bold Numbers = indicate potential human health risk. Risk assessment should be refined or risk management steps should be taken.

5.3 RISK CHARACTERIZATION FOR CARCINOGENS

The exposure assessment, hazard assessment and risk characterization thus far has been conducted assuming that PCDD/PCDFs and PCBs are threshold contaminants, and thus the risk assessment should adequately assess all long term chronic effects representative of a threshold response.

Treating PCBs and PCDD/PCDFs as threshold contaminants is consistent with the Canadian perspective on this group of chemicals. In contrast, the USA considers PCDD/PCDFs and dioxins to be carcinogens. 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_{year}); 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 DL-PCBs and dioxins/furans TEQs, 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 (ILCR). This is the additional probability (above background) that the representative exposed individual will incur cancer from the exposure (typically based on experimental animal data or epidemiollgy). ILCRs for individual exposure pathways can be added together to determine the overall ILCR.

The dose for each exposure pathway is also calculated differently relative to non-carcinogens (threshold contaminants). The goal is to compute the "lifetime-averaged daily dose", which is required for meaningful computations involving the cancer slope factor. This is achieved through use if two additional variables; (i) years of exposure and (ii) 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 being conducted assuming PCB and PCDDs/PCDFs are carcinogens are provided (Table 5.2). The highest calculated ILCR was 0.0036. This represents a one-in-278 probability above background that the MEA worker is going to die of cancer. This is 360 times greater than the Canadian upper limit of acceptable cancer risk (ILCR of 1 x 10^{-5} or a one-in-100,000 probability). Similar to the risk calculations for non-carcinogens (threshold contaminants), the greatest exposure, and greatest contributor to potential risk is the dietary exposure route.

Table 5.2 Results of Risk Characterization for Carcinogens, MEA facility, Samut Prakan, Thailand.

	PCB + TCDD/F TEQs Carcinogen		
	MEA Employee	**Local Resident**	
	Adult	Adult	Child
Doses (pg/kg day)	Storage Site	Home	Home
Dose $_{SoilIngestion}$	0.0064	0.0111	0.0193
Dose $_{FoodIngestion}$	19.38	19.38	27.54
Dose $_{ParticleInhalation}$	0.00034	0.00088	0.0017
Dose $_{DermaContact}$	0.0080	0.0007	0.0097
Dose$_{Total}$	19.4	19.4	27.6
TRV[1]	0.00013 kg day/pg		
ILCR	**0.0025**	**0.0025**	**0.0036**

[1] Tolerable Daily Intake (TRVs) for non-carcinogens (Health Canada 2004), Oral Slope Factor (SFo) for carcinogens (USEPA 2008).

Bold Numbers = indicate potential human health risk. Risk assessment should be refined or risk management steps should be taken

5.4 DISCUSSION

The results of a risk characterization model essentially complete computational aspects of the screening level risk assessment process; interpretation of results is then necessary to rationalize further actions. Due to the conservative assumptions and uncertainty associated with a screening level risk assessment, it is possible that there is no actual human health risk. The risk assessor/manager essentially has two options: to refine the risk assessment, by estimating more reasonable input variables (i.e., perform a detailed risk assessment), or to implement appropriate risk management activities.

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. In the case-study example, above, ingestion of fish and dermal contact with contaminated oil/soil appear to be the greatest contributor to daily dose. Consequently, 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}).

Based on the modeling results, DL-PCB & TCDD/F TEQ concentrations may pose a human health risk. Children of local residents had the highest calculated HQ (58.5) and highest ILCR (0.0036). Following the Health Canada guidance, any HQ greater than 0.2 or ILCR greater than 0.00001 warrants closer scrutiny for the potential to impact to human health, because of the possibility of additional exposure/risk from other exposure pathways.

The results indicate that the greatest daily exposure likely occurs via eating contaminated dietary items (e.g., fish and other aquatic organisms). Therefore, the results suggest that the best way to refine the risk assessment may be to improve the estimates of dietary contact.

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.

5.5 UNCERTAINTIES AND ASSUMPTIONS

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; this arises from incomplete/imperfect site information and variability in site conditions and human exposure parameters. This is a normal aspect of human health risk assessment for contaminated sites. 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 that will make estimates more likely to err on the side of over estimating rather than under estimating risks).

To better under stand the ramification of assumptions and uncertainties respecting the risk results, an evaluation of uncertainty is conducted. 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.

- Variables for the exposure assessment model. Where country-specific numbers did not exist, Canadian variables were chosen as a default. It is acknowledged that country-specific numbers would be better.

- For the Hazard Assessment, only TEQ concentrations of PCBs and PCDDs/PCDFs were considered. This limits the number of toxicity endpoints considered to AH-1 (Aryl hydrcarbonase-1) receptor mediated effects. There are other possible effects that the TEQ-based criterion does not address.

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

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

- Fish tissue concentrations selected in the exposure assessment were not based on maximum measured concentration. Instead, the fish concentration of a fish collected from a fish pond was selected over Chao Phraya River fish. Based on our knowledge of the site, people are much more likely to be consuming fish from this pond rather than the river. In addition, Chao Phraya River fish will be exposed to contaminants from multiple upstream sources and therefore chemical concentrations in tissues are not necessarily reflective of contaminants potentially released from the case-study site.