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:

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

The calculated Hazard Quotients for the SPL site 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, workers family members and local residents being exposed to PCBs and dioxins/furans. Hazard quotients were as high as 38.2, several fold higher than the 0.2 threshold.

Table 5.1 Results of Risk Characterization for Non-Carcinogens, SPL site, Lao PDR.

	PCB + TCDD/F TEQs non-Carcinogen								
	Workshop Employee				Employee Family		Local Resident		School Children
	Adult				Adult	Child	Adult	Child	Child
	Workshop	EDL outside	Home	Scenario total	Home	Home	Home	Home	School
Doses (mg/kg day)									
Dose $_{Soilingestion}$	$3.48x10^{-11}$	$1.35x10^{-12}$	$8.13x10^{-12}$	$4.43x10^{-11}$	$2.04x10^{-11}$	$3.72x10^{-11}$	$5.63x10^{-12}$	$1.03x10^{-11}$	$2.12x10^{-12}$
Dose $_{foodingestion}$	$8.8x10^{-10}$	-	-	$8.08x10^{-10}$	$8.08x10^{-10}$	$1.21x10^{-9}$	$8.08x10^{-10}$	$1.21x10^{-9}$	0
Dose $_{Particleinhalation}$	$5.64x10^{-12}$	$7.13x10^{-14}$	$7.90x10^{-13}$	$6.50x10^{-12}$	$1.08x10^{-12}$	$1.79x10^{-12}$	$2.98x10^{-13}$	$4.93x10^{-13}$	$1.02x10^{-13}$
Dose $_{Derma\ Contact}$	$4.43x10^{-11}$	$1.35x10^{-11}$	$8.47x10^{-12}$	$6.63x10^{-11}$	$8.47x10^{-12}$	$1.02x10^{-11}$	$2.34x10^{-12}$	$2.83x10^{-12}$	$1.56x1^{-12}$
Dose $_{Derma\ Contact\text{-}Oil}$ [2]	$5.42x10^{-8}$		$2.12x10^{-8}$	$7.54x10^{-8}$	$2.12x10^{-8}$				
Dose $_{Total}$	$5.51x10^{-8}$	$1.49x10^{-11}$	$2.12x10^{-8}$	$7.63x10^{-8}$	$2.20x10^{-8}$	$1.25x10^{-9}$	$8.16x10^{-10}$	$1.22x10^{-9}$	$3.78x10^{-12}$
TRV[1]	$2x10^{-9}$ mg/kg day				$2x10^{-9}$ mg/kg day		$2x10^{-9}$ mg/kg day		$2x10^{-9}$ mg/kg day
Hazard Quotient	**27.55**	0.01	**10.61**	**38.16**	**11.02**	**0.63**	**0.41**	**0.61**	0.002

[1] TRV is a Tolerable Daily Intake (TDIs) for non-carcinogens (Health Canada 2004).

[2] Dermal contact with contaminated oil was assumed to occur only for Employees working in the workshop, employees cooking at home and adults residing at the employee's home.

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 dioxins/furans and PCBs are non-threshold contaminants. This is consistent with the Canadian perspective on this group of chemicals (Health Canada 2004b). In contrast, the United States considers dioxins/furan 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_{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 PCBs and dioxins/furans, 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 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). The goal is to compute the "lifetime-averaged daily dose", which is required for calculations using 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 for PCB and dioxins/furans as carcinogens are provided (Table 5.2). Based on current assumptions and data, the calculated ILCRs were typically greater than the Canadian upper limit of acceptable cancer risk (ILCR of 1 x 10^{-5}). School children attending an adjacent school were the only group had calculated ILCRs lower than 1 x 10^{-5}.

An ILCR lower than 1 x 10^{-5} indicates negligible (or acceptable) incremental cancer risk. Similar to the risk calculations for non-carcinogens (threshold contaminants), the greatest exposure, and greatest contributor to potential risk, is dermal contact with contaminated oils, followed by the ingestion of fish.

Table 5.2 Results of Risk Characterization for Carcinogens, SPL site, Lao PDR.

	PCB + TCDD/F TEQs Carcinogen								
	Workshop Employee				Employee Family		Local Resident		School Children
	Adult				Adult	Child	Adult	Child	Child
	Workshop	EDL outside	Home	Scenario total	Home	Home	Home	Home	School
Doses (mg/kg day)									
Dose $_{Soilingestion}$	$7.55x10^{-12}$	$2.92x10^{-13}$	$1.76x10^{-12}$	$9.60x10^{-12}$	$4.42x10^{-12}$	$8.06x10^{-12}$	$1.22x10^{-12}$	$2.23x10^{-12}$	$4.58x10^{-13}$
Dose $_{foodingestion}$	$1.75x10^{-10}$			$1.75x10^{-10}$	$1.75x10^{-10}$	$2.61x10^{-10}$	$1.75x10^{-10}$	$2.61x10^{-10}$	0
Dose $_{Particleinhalation}$	$1.22x10^{-12}$	$1.54x10^{-14}$	$1.71x10^{-13}$	$1.41x10^{-12}$	$2.33x10^{-13}$	$3.87x10^{-13}$	$6.46x10^{-14}$	$1.07x10^{-13}$	$2.21x10^{-14}$
Dose $_{Derma\ Contact}$	$9.60x10^{-12}$	$2.91x10^{-12}$	$1.84x10^{-12}$	$1.44x10^{-11}$	$1.84x10^{-12}$	$2.22x10^{-12}$	$5.08x10^{-13}$	$6.14x10^{-13}$	$3.37x10^{-13}$
Dose $_{Derma\ Contact\text{-}Oil}$ [2]	$1.18x10^{-8}$		$4.59x10^{-9}$	$1.64x10^{-8}$	$4.59x10^{-9}$				
Dose $_{Total}$	$1.20x10^{-8}$	$3.22x10^{-12}$	$4.59x10^{-9}$	$1.66x10^{-8}$	$4.77x10^{-9}$	$2.72x10^{-10}$	$1.77x10^{-10}$	$2.64x10^{-10}$	$8.17x10^{-13}$
TRV[1]	130000 kg day/mg				130000 kg day/mg		130000 kg day/mg		130000 kg day/mg
ILCR	**$1.56x10^{-3}$**	$4.18x10^{-7}$	**$5.97x10^{-4}$**	**$2.16x10^{-3}$**	**$6.20x10^{-4}$**	**$3.53x10^{-5}$**	**$2.30x10^{-5}$**	**$3.43x10^{-5}$**	$1.06x10^{-7}$

[1] TRV is an Oral Slope Factor (SF_o) for carcinogens (USEPA 2008).

[2] Dermal contact with contaminated oil was assumed to occur only for Employees working in the workshop, employees cooking at home and adults residing at the employee's home.

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

5.4 BLOOD ANALYSIS

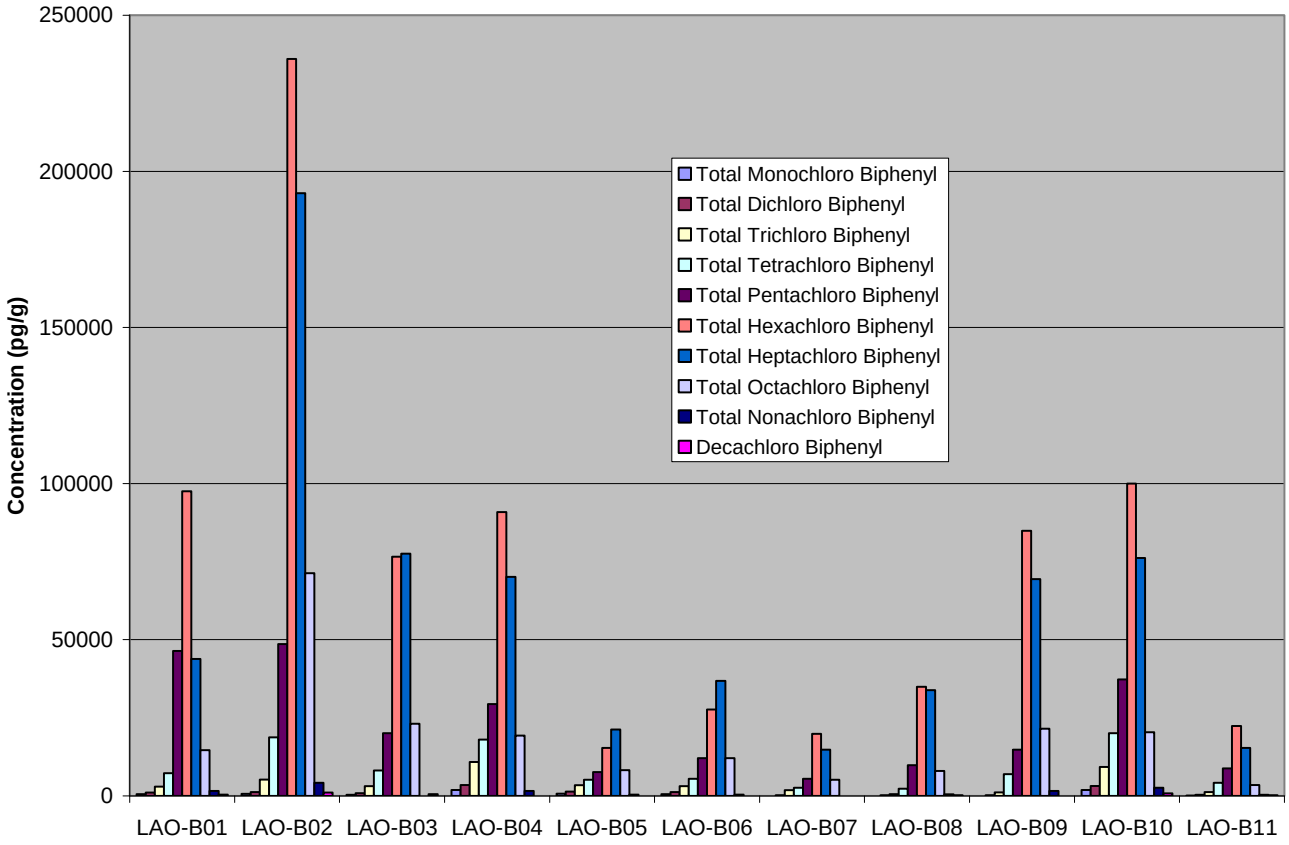
Blood analyses of the blood of workshop workers, other SPL employees, and their spouses provided a wide range of concentrations (Table 5.3, Figure 5.1). There also appears to be a clear linkage between the workshop and exposure to PCBs. The samples with the highest concentrations (i.e., 08LAO-B01 through B06 and B10) all correspond to workshop employees. The employee with the highest concentration (sample 08LAO-B02), had worked in the workshop the longest, confirming that PCBs accumulate in worker body tissues over time. These data, however, do not distinguish from other sources of PCB exposure (unrelated to the SPL site) that may be present in any individual's activities.

Table 5.3 Blood PCBs concentrations of EDL employees and family members (pg/g lipid), SPL case study, Vientiane, Laos PDR.

	PCB TEQs (WHO2005)		Total PCBs	Sex	Relations
	ND=0	ND=1/2 DL			
08LAO-B01	60.1	60.1	216,000	Male	Workshop tech staff
08LAO-B02	67.3	76.8	580,000	Male	Manager of workshop
08LAO-B03	34.6	38.8	210,000	Male	Assistant Manager
08LAO-B04	209	209	245,000	Male	Workshop tech staff
08LAO-B05	67.4	67.4	63,400	Male	Workshop tech staff
08LAO-B06	51.2	57.1	99,300	Male	Workshop tech staff
08LAO-B07	0.142	1.66	49,800	Female	Spouse of B01
08LAO-B08	0.302	2.18	90,200	Female	Spouse of B02
08LAO-B09	0.613	3.55	200,000	Female	Admin staff of EDL Center
08LAO-B10	176	176	272,000	Male	Workshop tech staff
08LAO-B11	0.213	0.87	56,100	Female	Former workshop tec staff

PCB TEQs were calculated by measuring the concentration of individual congeners, multiplying these by their respective WHO 2005 TEF and then taking the sum of calculated TEQs. In cases where individual congener concentrations were too low to be measured (i.e non-detectable or "ND") , TEQs for these congeners were calculated in two ways: 1) by assuming that their concentration is 0 and 2) by assuming that their concentration is equal to half the method detection limit (i.e., 1/2DL).

Figure 5.1 Blood PCBs concentrations (homologues) of EDL employees and family members (pg/g lipid), SPL case study, Vientiane, Laos PDR.



5.5 DISCUSSION

5.5.1 Modeled Exposures

Due to the conservative assumptions and uncertainty associated with a screening level risk assessment, screening level risk estimates are typically over estimates of the true risk. Where marginal risks are calculated, it is conceivable that more refinement of assumptions or improved site-specific data may indicate that risks are lower and perhaps acceptable (i.e., suggesting that there is no actual human health risk). When elevated risks are calculated, 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, dermal contact with contaminated oil appears to be the greatest contributor to daily dose. Consequently, possible refinements to the calculation of daily dose could include improving estimates of:

- Transformer oil concentrations (C_{Oil});
- Skin area exposed (S_{AH});
- Soil/Oil loading to exposed skin (SL_H);
- Absorption factor for the skin (AF_{Skin}); and
- Number of dermal exposures per day (EF).

PCB and TCDD/F TEQ concentrations appear to be sufficiently high to infer elevated human health risks. Workshop employees had the highest calculated HQ (38.2) and highest ILCR (0.0022). 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.

There is some uncertainty attached to the exposure to contaminated oils. Oils were not assessed for PCB or dioxin/furan concentrations, and were therefore estimated. In Appendix A4, the rationale for the concentration chosen is presented. Other estimated model variables for the oil exposure model scenario are discussed. In the model a dermal absorption factor (AF_{Skin}) of 0.5 was adopted. If the true absorption efficiency of PCBs and dioxins/furans is on the order of 0.8 (i.e., 80% absorption), then the predicted HQ and ILCR would be higher, 51.5 and 0.00352 respectively.

Without the contribution of contaminated oils to the dose, the highest dose (0.63), is still three times higher than the Health Canada threshold. This was the exposure for a child of an employee.

The results suggest that the greatest daily exposure likely occurs via exposure to contaminated oils, followed by eating contaminated dietary items (i.e. fish). Therefore, the results suggest that the best way to refine the risk assessment might be to improve the estimates of oil contact first, and food exposure secondly.

The risk assessment was confined to PCBs; 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.

5.5.2 Blood Analysis

The analysis of PCBs in blood serum confirmed that workshop workers have been exposed to elevated concentrations of PCBs, which is inferred to derive from the workshop activities. The analysis of the blood of workshop workers, other EDL employees, and workshop worker's wives indicate a clear linkage between the workshop and exposure to PCBs. Workshop employees had the highest blood concentrations of PCBs and on inspection there appeared to be a strong relationship between PCB blood concentrations and the number of years worked within the workshop (although other external sources of PCBs as an exposure factor in an individual's life cannot be ruled out). The person with the highest blood PCB concentration (sample 08LAO-B02) has worked in the workshop the longest. The next highest blood concentrations were from people who have each spent more than five years in the workshop (samples 8LAO-B03, -B04, -B09, and -B10).

A brief literature review indicates that the highest measured PCB blood concentrations of a workshop worker, in TEQs, is significantly (>25 times) higher than the average background concentrations of PCBs in blood of people living in Laos, as well as many western countries (Table 5.4).

Table 5.4 Background Blood PCB concentrations (pg TEQ/g lipid, WHO1998, ½ DL).

Location	Ref.	N	Concentration (pg TEQ/g lipid, WHO1998)
Sepone, Laos	1	5	1.90
Vientiane, Laos	1	50	3.23
Germany	1	13	8.00
Toronto, Canada	2	63	3.3 (75percentile = 6.0)

References: 1. Schecter et al. 2003.;
2. Longnecker 2000.

The health implications of the blood concentrations measured at the SPL case study site are unclear. Humans tend to be less sensitive to dioxin-like contaminants than many other animals and there is a large variability in the level of response by humans to dioxin-like contaminant exposure (WHO 1998). Potential effects of excessive exposure to dioxin-like contaminants include cancers, birth defects, endocrine disruption, immunotoxicity, reproductive effects and deformities in neurological development (WHO 1998; Imamura et al. 2007). Common acute symptoms (i.e., effects from very high short-term exposure) include general fatigue, headaches, numbness of extremities, coughs, diarrhea, acneform eruptions of the skin and anomalous skin pigmentation (Imamura et al. 2007).

Predicting effects based on measure blood concentrations is difficult due to uncertainty in the relationship between blood levels, duration of exposure and observed effects. There are no regulatory guidelines for blood concentrations. The only derived blood concentration guidelines apparently available were derived by the American Chemistry Council (ACC 2003). The ACC used available tolerable daily intake values (TDIs) from ATSDR (Agency for Toxic Substances and Disease Registry), WHO JECFA (Joint FAO/WHO Expert Committee on Food Additives), ECSCF (European Commission Scientific Committee on Food) and WHO1998, to derive an estimate of an acceptable blood concentration. The concentrations they derived ranged from 10 to 30 pg TEQ/g lipid in blood. These guidelines should be considered very rough estimates, as there were several conservative assumptions made in their derivation (ACC 2003).

5.6 UNCERTAINTY 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 which 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 PCBs, based on the activities of the SPL site. Some organochlorine pesticides were detected and quantified, but were not considered in the risk assessment due to limited site data of these other chemicals, and potential for such substances to derive from off-site sources.

- 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 preferable.

- Water concentrations of dioxins/furans 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. Compared to other exposure media and pathways, PCBs dissolved in water contributes a relatively small dose and consequent risk to human health.

- 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 SPL site, there were both on-site receptors (workers) and off-site receptors (families of workers, local residents and school children). Because the concentrations of contaminants that these 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 should be updated. 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.

- No measurements of PCBs or dioxins/furan were performed on transformer oils. Therefore professional judgment and literature values were used to estimate a reasonable concentration to be used in the risk model. In addition, there is little available information on the dermal uptake of PCBs or dioxins/furans from oils. These values were developed using literature values and in some cases adjusted based on best professional judgement.