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 SEDCW 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 warehouse workers, dormitory residents and local residents being exposed to PCBs and dioxins/furans. Hazard quotients were as high as 2.66, more than ten times higher than the 0.2 threshold.

Table 5.1 Results of Risk Characterization for Non-Carcinogens, SEDCW site, Cambodia.

	PCB + TCDD/F TEQs non-Carcinogen							
	Warehouse Employee			Resident of Dormitory		Local Resident	
	Adult			Adult	Child	Adult	Child
	Warehouse	SEDCW outside	Scenario total	Home	Home	Home	Home
Doses (mg/kg day)							
Dose $_{Soilingestion}$	$3.12x10^{-12}$	$6.79x10^{-13}$	$3.80x10^{-12}$	$2.28x10^{-11}$	$4.16x10^{-11}$	$1.27x10^{-12}$	$2.31x10^{-12}$
Dose $_{foodingestion}$	$3.51x10^{-9}$		$3.51x10^{-9}$	$3.51x10^{-9}$	$3.23x10^{-9}$	$3.51x10^{-9}$	$3.23x10^{-9}$
Dose $_{Particleinhalation}$	$1.55x10^{-13}$	$3.38x10^{-14}$	$1.89x10^{-13}$	$1.21x10^{-12}$	$2.19x10^{-12}$	$1.34x10^{-13}$	$1.22x10^{-13}$
Dose $_{Derma\ Contact}$	$8.90x10^{-12}$	$1.52x10^{-12}$	$1.04x10^{-11}$	$2.13x10^{-12}$	$1.94x10^{-12}$	$1.18x10^{-13}$	$1.07x10^{-13}$
Dose $_{Total}$	$3.52x10^{-9}$	$2.23x10^{-12}$	$3.52x10^{-9}$	$3.53x10^{-9}$	$5.28x10^{-9}$	$3.51x10^{-9}$	$5.24x10^{-9}$
TRV[1]	2.0×10^{-9} mg/kg day			2.0×10^{-9} mg/kg day		2.0×10^{-9} mg/kg day	
Hazard Quotient	**1.76**	0.001	**1.76**	**1.77**	**2.64**	**1.75**	**2.62**

[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.

"x10" in a number indicates "exponent", therefore as an example, 3.12x10-12 is the same as 0.00000000000312.

* The results were presented and used by the Cambodian participants and Hatfield Project Team for the Risk Assessment exercise during the POPs toolkit review in December 2009, and at the National Training Workshop in Siem Reap from 19-21 January 2009.

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 2008). 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 calculate the "lifetime-averaged daily dose", which is required for meaningful calculations involving the cancer slope factor (SF). This is achieved through the use of 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 all greater than the Canadian upper limit of acceptable cancer risk (an ILCR of 1.0×10^{-5}).

An ILCR lower than 1.0×10^{-5} indicates negligible (or acceptable) incremental risk of contracting cancer. Similar to the risk calculations for non-carcinogens (threshold contaminants), the greatest exposure, and greatest contributor to potential risk, is the ingestion of contaminated food (crabs) from the site.

Table 5.2 Results of Risk Characterization for Carcinogens*, SEDCW site, Cambodia.

	PCB + TCDD/F TEQs Carcinogen							
	Warehouse Employee			Resident of Dormitory		Local Resident	
	Adult			Adult	Child	Adult	Child
	Warehouse	SEDCW outside	Scenario total	Home	Home	Home	Home
Doses (mg/kg day)							
Dose $_{Soilingestion}$	1.70×10^{-12}	3.70×10^{-13}	2.07×10^{-12}	1.25×10^{-11}	2.27×10^{-11}	6.90×10^{-13}	1.26×10^{-12}
Dose $_{foodingestion}$	1.91×10^{-9}		1.91×10^{-9}	1.91×10^{-9}	2.86×10^{-9}	1.91×10^{-9}	2.86×10^{-9}
Dose $_{Particleinhalation}$	8.47×10^{-14}	1.84×10^{-14}	1.03×10^{-13}	6.57×10^{-13}	1.09×10^{-12}	3.65×10^{-13}	6.05×10^{-13}
Dose $_{Derma\ Contact}$	4.85×10^{-12}	8.30×10^{-13}	5.68×10^{-12}	1.16×10^{-12}	1.06×10^{-12}	6.40×10^{-14}	5.80×10^{-14}
Dose $_{Total}$	1.92×10^{-9}	1.22×10^{-12}	1.92×10^{-9}	1.93×10^{-9}	2.88×10^{-9}	1.91×10^{-9}	2.86×10^{-9}
TRV[1]	130000 kg day/mg			130000 kg day/mg		130000 kg day/mg	
ILCR	**0.000250**	1.58×10^{-7}	**0.000250**	**0.000251**	**0.000374**	**0.000249**	**0.000371**

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

"x10" in a number indicates "exponent", therefore as an example, 3.12x10-12 is the same as 0.00000000000312.

* The results were presented and used by the Cambodian participants and Hatfield Project Team for the Risk Assessment exercise during the POPs toolkit review in December 2009, and at the National Training Workshop in Siem Reap from 19-21 January 2009.

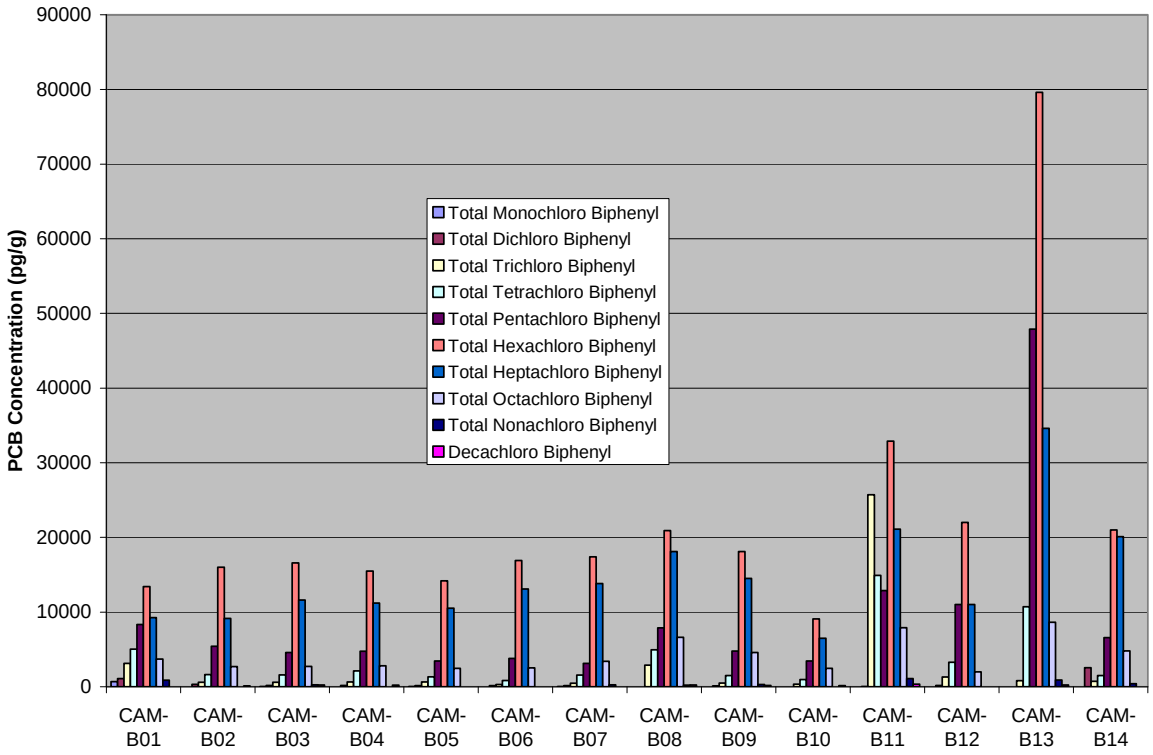
5.4 BLOOD ANALYSIS

The analysis of the blood of warehouse workers and other EDC Training Center employees generally indicates little variation in concentration (Table 5.3, Figure 5.1). Notable exceptions were samples 08CAM-B01, 08CAM-B11 and 08CAM-B13, which had higher concentrations than other samples. 08CAM-B01 exhibited dioxin/furan + PCB TEQ concentrations more than 10 times higher than other blood samples. Information on this individual indicates that he used to train other employees on how to re-condition old transformers; he also regularly brought transformer oils home for burning or to be used to lubricate a sewing machine. The other two samples (08CAM-B11 and -B13) exhibited total PCB concentrations 1.8 and three times greater than the next highest concentration, respectively. Samples 08CAM-B11 and -B13 corresponded to the senior warehouse manger and a janitor at the warehouse.

Table 5.3 Blood PCB concentrations of EDC employees and family members (pg/g lipid), SEDCW case study, Phnom Penh, Cambodia.

	PCB TEQs (WHO2005)		Total PCBs	Sex	Relations
	ND=0	ND=1/2 DL			
08CAM-B01	57.4	63.1	45600	Male	Nurse in training center
08CAM-B02	3.55	3.72	35900	Male	Guard of training center
08CAM-B03	2.32	2.56	38400	Male	Guard of training center
08CAM-B04	1.48	2.09	37400	Male	Guard of training center
08CAM-B05	3.59	3.93	32700	Male	Police of Warehouse
08CAM-B06	2.59	2.9	37700	Male	Police of Warehouse
08CAM-B07	1.95	2.3	40200	Male	Accountant of training center
08CAM-B08	0.214	1.37	61800	Male	Manager of warehouse II
08CAM-B09	0.139	0.884	44500	Male	worker of warehouse
08CAM-B10	1.75	1.93	23000	Female	Jsnitor of warehouse
08CAM-B11	6.29	6.66	117000	Male	Manager of warehouse I
08CAM-B12	5.46	6	50800	Male	Police of Warehouse
08CAM-B13	1.38	4.24	183000	Female	Janitor of Warehouse
08CAM-B14	0.205	2.08	57700	Male	Manager of Warehouse III

Figure 5.1 Blood PCB concentrations (homologues) of EDC employees and family members (pg/g lipid), SEDCW study site, Phnom Penh, Cambodia.



5.5 DISCUSSION

5.5.1 Modeled Exposures

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:

- Food concentrations (C_{Food});
- Daily intake rate of natural food (IR_{Food});

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

Based on the modeling results, DL-PCB & TCDD/F TEQ concentrations may pose a human health risk. Children living in the SEDCW dormitories with their parents had the highest calculated HQ (2.7) and highest ILCR (0.00038). 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., crabs 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.

5.5.2 Blood Analysis

The analysis of PCBs in blood serum generally indicated that blood concentrations of PCBs were low. This finding is not surprising, considering that the warehouse is relatively new (less than 10 years old) and employees generally did not have a history of working with or near electrical transformers.

A brief literature review indicates that the measured PCB blood concentrations of the sampled potentially exposed people are generally similar to the average background concentrations of PCB in blood of people living in other 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.

Sample 08CAM-B01 had a distinctly higher PCB TEQ concentration (more than 10 times) than the next highest concentration. The TEQ-based concentrations seem odd, considering that the total PCB concentration is similar to the other blood samples. A review of the data indicated that this sample had a disproportionally higher concentration of PCB 126 (3,3',4,4',5-PeCB). PCB 126 has much higher toxic potency than most other PCBs, and therefore has a very large influence on the calculated total TEQ concentration (Van den Berg 2006). PCB 126 was once used as a dielectric fluid (USDHHS 2006). It is possible that the individual corresponding to 08CAM-B01 had exposure to older transformers containing this PCB. Results of our interview with the individual indicated that he worked at the training center for eight years, and he visits the warehouse almost on a daily basis. He collects wastes from the warehouse, mostly oil soaked wooden frames for kitchen fires, and he takes home transformer oil to lubricate his sewing machine. He has also handled old transformers and transformer oil during training presentations.

Samples 08CAM-B11 and –B13 had slightly higher total PCB concentrations than the other samples (1.8 to 3 times higher), although the PCB TEQ concentrations were within the range of other samples. The individual corresponding to 08CAM-B11 was the senior warehouse manager. He is older (53 years old) than the others sampled, and has worked in the EDC warehouses since 1987, which may partly explain the greater concentration accumulated. The individual also had an office in the warehouse from which a dust sample was collected. The dust had a higher concentration of PCBs than most outdoor soil concentrations (08CAM-021, Table 3.1). Sample 08CAM-B13 corresponded to a janitor working at the SEDCW site. It is unclear why she might have higher total PCB concentrations; however, she may have had greater exposure to contaminated dust than other employees.

The health implications of the blood concentrations measured at the SEDCW 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). Common effects of exposure to dioxin-like contaminants include cancers, birth defects, endocrine disruption, immuno-toxicity, reproductive effects and deformities in neurological development (WHO 1998; Imamura et al. 2007). Common acute symptoms include general fatigue, headaches, numbness of extremities, coughs, diarrhea, acneform eruptions of the skin and skin pigmentation (Imamura et al. 2007).

Predicting effects based on measure blood concentrations is difficult. 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).

Based on our assessment, it would appear that only the individual corresponding to sample 08CAM-B01 may be at some human health risk. The remaining workers had similar blood concentrations to background concentrations and were below the rough guideline calculated by the American Chemistry Council (ACC 2003).

5.6 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 estimates of individual variables used in risk calculations are often approximate, and it is anticipated that there will be uncertainty in the estimates of risk. However, where possible, uncertainty in individual variables have been 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).

5.7 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.

- 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. Previous experience working with dioxins/furans 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 SEDCW site, there were both on-site receptors (workers) and off-site receptors (local residents). 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 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.