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Chapter 23

COMPARISON OF INTERNATIONAL RISK-BASED SCREENING LEVELS

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ABSTRACT

In response to a growing public concern over the potential environmental and human health-related effects associated with impacted sites, many countries have launched national frameworks for remediation of high priority sites. Some countries have developed Risk-Based Screening Levels (RBSLs) as part of a national framework. RBSLs are numerical media concentrations used to inform decision making about land contamination. Many countries have yet to develop their own RBSLs. Those countries often require that the regulated community to use RBSLs developed for other countries and, in some cases, to select and defend the most appropriate RBSLs for use.

Understanding the underlying assumptions used in developing internationally available RBSLs and their intended purpose is essential to making informed decisions regarding their use to manage contamination and mitigate risk. This paper evaluates some of the underlying assumptions used by a representative group of countries in developing RBSLs.

This analysis was, by necessity, done at the level of primary assumptions, methods and technical elements. Despite this fact, some general conclusions regarding use of internationally available RBSLs have been drawn in the paper.

Keywords: International, Risk-assessment, RBSL, Screening Level

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1. INTRODUCTION

Derivation methods for RBSLs differ from country to country, and consequently, the numerical values can vary significantly. Insight into the reasons for the differences will help the regulated community and regulatory agencies alike in making informed decisions about the most appropriate RBSLs in making decisions about management of land contamination in specific regions.

Differences in the regulatory contexts under which RBSLs are developed internationally has lead to diverse terms to describe them, such as screening values, guidance values, action levels or intervention values, maximum acceptable concentrations and maximum permissible risk levels, cut off values, trigger values, and environmental quality objectives. Some RBSLs are set at risk levels deemed to be negligible or insignificant. Other RBSLs are established as warning levels, while others still are set at levels that represent potentially unacceptable risk.

Understanding the underlying assumptions used in developing internationally available RBSLs and their intended purpose is essential to making informed decisions regarding their use to manage contamination and mitigate risk. This paper will evaluate some of the underlying assumptions within the RBSLs used by a representative group of countries. Specific objectives of the review include:

- Describing the state of the science of RBSL derivation methods and their application; and
- Assessing commonalities and differences amongst international methods and the resulting numerical values.

2. PRACTICES AND PRINCIPLES

The derivation of an RBSL has both political and scientific bases. A major political issue that arises during this process is the definition of "permissible" or "tolerable" risk. The underlying questions of how to set RBSLs for deciding between "acceptable" and "unacceptable" risk has been challenging risk assessors, regulators and the public in the U.S. and European countries for several decades now. It is important to recognize, however, that decisions about levels of risk that are considered "acceptable" or "unacceptable" can be made without ever identifying the hazard, measuring the actual hazard posed (risk assessment), or addressing how best to regulate it (risk management). In other words, decisions about the risk level at which RBSLs are set are "policy" decisions, not scientific ones.

The science of RBSL development entails risk estimation, which in turn, involves exposure and toxicity assessment. Actual exposure is largely dependent on site-specific conditions, (e.g. soil type and soil properties, depth of groundwater table, etc) and on the land-use (e.g. receptor characteristics, activity on the site, type of buildings at the particular site in question). Exposure assessment is generally considered a "soft science" as it depends on conjecture (sometimes called hypothesis), qualitative analysis of data and uncertain experimental results and sometimes, anecdotal information. Toxicity is an inherent property of the contaminants present at the site in question. The science of toxicology is considered a "hard science" as it relies on experimental, empirical, quantifiable data and is intended to be objective. However, toxicology data are often interpreted differently, even by knowledgeable scientists.

The policy and scientific issues that bear on RBSL development are discussed below.

3. STATE OF THE POLICY

The question of "How safe is safe enough?" has been at the forefront of environmental decision making in the U.S., Canada, Europe, Australia and New Zealand for several decades now. Despite the longstanding debate, the question of determining "context-specific" risk acceptance criteria below which no (further) control is warranted continues to challenge the environmental community and require global attention in the urban renewal and consolidation subject area. Part of the reason is that, in spite of efforts by regulatory entities that have "blazed the trail" for risk-based decision making to carefully define their procedures and assumptions in developing RBSLs, the message is often misinterpreted by referencing the risk level set by these initial agencies as the level of "acceptable risk", implying that any higher risk is "unacceptable." Frequently the misquoted risk level is one in a million risk (1×10^{-6})

The level of risk to which RBSLs are set usually depends on the intended application within the regulatory framework, although application is inconsistent. While there are no fixed rules, there are some common practices, which are briefly discussed below.

3.1 Negligible Risk

Derivation of RBSLs that correspond to negligible risk levels are intended to maintain soil concentrations at levels such that, even under the most sensitive land use scenarios, exposure will result in negligible or de minimis risk. RBSLs established at negligible risk levels are generally used in defining long term environmental objectives. Long term objectives for soil quality, for example, are usually based on what is considered to be a negligible risk level.

3.1.1 Unacceptable Risk

On the other hand, RBSLs set at potentially unacceptable or intolerable risk levels aim at preventing significant adverse effects from occurring. Action levels are often set at levels that correspond to a potentially unacceptable risk level.

3.1.1.1 Actions Required

While in the past, RBSLs were widely applied for forcing remediation works, RBSLs are now generally used as trigger values for some type of action, whose outcomes are then considered in relation to site-specific needs and objectives.

Actions can include remediation, but they may also take the form of:

- Restrictions in land use;
- Further investigations; and/or
- Conduct of site specific risk assessment.

4. STATE OF THE SCIENCE

4.1 Exposure Assessment

In developing RBSLs to protect human health, the intent is to ensure that exposure to contaminants at the guideline concentration will not result in adverse human health effects. Therefore, exposure assessment entails estimating daily intake. In the derivation of generic RBSLs, generic exposure scenarios are assumed that are often designed to be protective even in highly unrealistic worst-case circumstances (i.e. where highly unlikely conditions may lead to the highest possible exposure). For example, in setting residential standards for soil, it is typically assumed that the potentially exposed population has daily contact with soil via incidental ingestion, dermal contact, and inhalation over a lengthy period of time (i.e., 30 years for adults in the U.S.).

Use of overly conservative default scenarios represents "hyper vigilance" on the part of the regulators, because in setting RBSLs based on these exposure combinations, land use that is unlikely to occur is protected, in addition to land use that is likely to occur. This approach has the benefit of allowing the regulators to state categorically that contaminated land is not permitted to pose a health risk. This simplifies the complex question of "how safe is safe enough" for the regulators, but there is cause for concern with this over-simplified approach. If these generic RBSLs are broadly misapplied as remediation goals, the result can be high economic cost for very little, if any, reduction in "actual" risk to the end user.

4.2 Toxicity Assessment

During the toxicity assessment, estimates of the tolerable daily intake (TDI) of individual compounds are made. One of the key issues in toxicology data interpretation is making sure that the toxicological information is relevant to the specific problem under investigation, in this case the potential for human health effects. Because reasonable scientists sometimes disagree about the meaning of toxicity data, different regulatory entities have developed different sets of toxicity benchmarks. These toxicity benchmarks underpin the discipline of health and environmental risk assessment and are, along with the differences in the definition of "permissible" or "tolerable" risk, a primary contributor to differences amongst the RBSLs that have been developed internationally.

One major difference between the U.S. and other countries is in the way that carcinogens are evaluated and regulated. In countries such as the Canada, the United Kingdom (U.K.), and the Netherlands, chemical carcinogens are regulated using a case-by-case approach. Known or suspected chemical carcinogens are subjected to an individual review that considers both the mechanism of action and epidemiology data. This process usually involves the formation of expert advisory committees that make the decisions regarding exposure standards or regulations, rather than an agency. The advisory body commonly uses a "weight-of-the-evidence" approach, in which all of the available information and test data are used to formulate a scientific position for consideration as the basis for a regulatory decision. This approach has historically been poorly received in the U.S. due to pressure to establish public policy that errs on the side of safety. In the wake of unrelenting financial pressure from competing social needs, and the European experience, the weight-of-evidence approach has gained momentum within the U.S. Environmental Protection Agency (EPA) in recent years (http://www.fplc.edu/risk/vol6/fall/pausten.htm).

4.3 Country-Specific Risk-Based Screening Levels:

AECOM has developed a prototype International RBSL database. The prototype database has been generated to allow comparison of human health protective RBSLs for a variety of the most common compounds across the globe. For the comparisons to be meaningful, it was important to ensure that the environmental application of the values was similar. For this reason the database currently contains RBSLs for the residential soil scenario only. Residential RBSLs have been included for both a lower tier of "Permissible" or "Acceptable" levels and an upper tier of "Intervention" or "Action" levels. The dataset includes approximately fifty compounds representative of several different chemical classes.

Unfortunately, the methodology used in deriving the RBSLs is published for relatively few countries, and in some cases, background documentation is published but not accessible. Therefore, derivation methodology is often not transparent, which significantly hampered efforts to do a meaningful comparison amongst the various country-specific RBSLs. As a result, the reason for differences in RBSLs developed by different countries is not always evident.

For the purposes of this paper, comparisons have been made between lesser known RBSLs developed by Asian countries and those developed by several of the countries for which risk-based contaminated land management is well established and RBSLs are fairly well documented.

4.3.1 Australia and New Zealand

The approach to deriving Health-Based Investigation Levels (HILs) in Australia/New Zealand is based on the concept of tolerable daily intake (TDI), which is a dose that humans may be exposed to everyday without experiencing appreciable risk. The HILs are established for "toxic effects other than cancer" and "cancer toxic effects" as opposed to being based on mechanistic distinctions (threshold vs. non-threshold) like the other countries discussed in this paper. In developing the HILs, a portion of the TDI is allocated to each medium that may contribute to overall exposure for a particular COPC, although the proportion is not fixed. In addition, HILs are set so that total exposure (i.e., background + soil) does not to exceed the TDI. Therefore, the HILs address cumulative exposure (across all media) (NEPC, 1999a; NEPC, 1999b).

Australian Acceptable Daily Intakes (ADIs) for agricultural and veterinary chemicals (http://www.health.gov.au/internet/main/publishing.nsf/Content/ocs-adi-list.htm) have been developed and are the recommended as the primary source of toxicity information for use in establishing HILs (NEPC, 1999a), (NHMRC, 1999). For other chemicals, World Health Organization (WHO) ADIs are typically used. The target risk level at which the HILs are set is not clearly stated in the technical support documents. However, based on the fact that WHO ADIs are based on a 1 x 10^{-5} for carcinogens, and they are the primary source of toxicity values when Australian ADIs are not available, it is assumed that the Australian HILs also correspond to a cancer risk of 1 x 10^{-5}. HILs have been developed for about 40 COPCs and are defined as the concentration above which further appropriate investigation will be required (NEPC, 1999a).

4.3.2 Canada

Recommended Soil Quality Guidelines (SQGs) were published by the Canadian Council Ministers of the Environment (CCME) in 1997 (CCME, 2006). Health Canada has developed its own reference doses (TDIs for threshold substances and Risk Specific Doses or RSDs associated with risks of 10^{-4}, 10^{-5}, 10^{-6} and 10^{-7} for non-threshold substances) for a variety of contaminants and uses those in establishing SQGs.

The Canadian guidelines indicate that human health SQGs representative of both a 1×10^{-5} and a 1×10^{-6} incremental cancer risk have been developed (CCME, 2006). However, it appears from the lookup tables that the only COPC for which a SQG corresponding to a 1×10^{-5} risk level has been developed is benzene. Values for other COPCs appear to correspond to a 1×10^{-6} (one in a million) cancer risk goal. A distinguishing feature of the Canadian SQGs is the way in which background contamination is approached. Background is set at 80% of the SQG for all compounds, causing the SQG to be reduced to 20% of the original calculation.

The Canadian SQGs are defined as “numerical limits or narrative statements recommended to support and maintain designated uses of the soil environment” (CCME, 2006). SQGs have been developed for 65 COPCs.

4.3.3 China

The Chinese values are officially called Environmental Quality Standards (EQS). They were developed to the protect soil and groundwater, environment, and people who work at, visit, or live neighboring an industrial facility. They are referred to as maximum (permissible) values (PRC, 1999).

Chinese EQS values for have been developed for about 90 COPCs. Standards for Class A are defined as "target values" for soil that is suitable for all uses. Standards for Class B are intended as "action levels” above which remedial action should be taken to bring the concentrations back to Class A standards (PRC, 1999). The EQS values referenced in this paper are the Class A target values.

The EQSs designed to protect against cancer endpoints are based on an excess lifetime cancer risk of 1×10^{-5} (one in 100,000). Those established on the basis of non-cancer endpoints correspond to a hazard quotient of one (PRC, 1999). Anecdotal information suggests that the EQS values represent a translation of the U.S. values with exposure assumptions changed to better describe the Chinese population. Therefore, it is assumed that U.S. toxicity factors were used in their derivation, although this has not been confirmed.

4.3.4 Hong Kong

The Hong Kong Environmental Protection Department (EPD) recently published Risk-Based Remediation Goals (RBRGs) for Contaminated Land Management (EPD, 2007a). RBRGs are intended as site assessment criteria that are appropriate for most sites in Hong Kong, where humans are the only significant receptors that require protection.

The Hong Kong RBRGs were developed as threshold contaminant concentrations, below which exposure is considered minimal. However, despite the definition of the RBRGs as levels below which exposure is considered minimal, the Guidance Manual for the Use of Risk-Based Remediation Goals (RBRGs) for Contaminated Land Management (EPD, 2007a) states that when concentrations of soil or groundwater are detected above the RBRGs, "cleanup" is required.

The Guidance Manual indicates that relevant overseas methodologies, such as ASTM (1995 and 2000) and CCME (NEPC, 1999) were used in developing RBRGs with input of local data insofar as possible. Toxicity data used in deriving the RBRGs were derived from a number of sources, but primarily from the U.S. EPA's Integrated Risk Information System (IRIS) at http://www.epa.gov/iriswebp/iris/subst/index.html. RBRGs protective of cancer endpoints are based on an excess lifetime cancer risk of 1×10^{-6}. Those established on the basis of non-cancer endpoints correspond to a hazard quotient of one (EPD, 2007a; EDP, 2007b).

4.3.5 Netherlands

Human health based RBSLs developed by the Netherlands are called Dutch Intervention Values (DIVs). The DIVs are intended to be used in a defined policy framework (i.e., the Dutch Soil Protection Act) to identify areas that are "Seriously Contaminated" and are only intended for use in evaluating polluted properties. A distinguishing feature of the DIVs is that they are to be applied on a spatial scale. For there to be an instance of serious contamination, the average concentration of a minimum of 25 m^3 of soil must exceed a DIV. In instances where serious contamination is defined, it then needs to be determined whether action to deal with the contamination is urgently required. The factors which dictate urgency are the actual risks to which man and ecosystems are currently being subjected, and the risks of migration. These are highly dependent on land use (RIVM, 2000).

The source of human toxicity values is the Re-Evaluation of Human-Toxicological Maximum Permissible Risk Levels (RIVM, 2001). Dutch toxicity values are expressed as Maximum Permissible Risk (MPR) values, which quantify the human-toxicological risk limits (i.e., TDI, tolerable concentration in air (TCA), oral cancer risk and/or inhalation cancer risk) for approximately 50 chemicals. For compounds that exhibit threshold effects, the MPR has been defined as a TDI. For genotoxic carcinogens (using the non-threshold approach), the MPR is defined as the exposure level with an excess lifetime cancer risk of 1 x 10^{-4} (1 in 10,000) for the oral (CR_{oral}) or inhalation ($CR_{inhalation}$) pathways. DIVs have been developed for 130 COPCs.

4.3.6 Thailand

The Pollution Control Department of Thailand has published Soil Quality Standards (SQS) for a limited number of compounds (PCD, 2004). Thai SQSs have been developed for 36 COPCs.

The Thai standards for non-carcinogens correspond exactly to the U.S. EPA Region 9 Preliminary Remediation Goals (PRGs) from 2000. SQSs for carcinogens are a factor of 10 higher than the U.S. EPA Region 9 PRGs, which were set at a target cancer risk goal of 1 x 10^{-6}. Therefore, the SQSs for carcinogens correspond to a target cancer risk of 1 x 10^{-5}.

4.3.7 United Kingdom

The official values for England and Wales, are the Soil Guideline Values (SGVs) published by the Environment Agency (EA, 2010). The SGVs derived for non-threshold substances are derived on the basis of a hierarchy of authoritative sources developed specifically for soil contamination, and a target risk of 1 x 10^{-5} where methods as defined by the EA are applicable. Additionally the principal of “As Low As Reasonably Practicable” or ALARP is applied for genotoxic carcinogens (EA, 2009a; EA, 2009b). A total of eleven SGVs have been developed by the EA at this point following a recent review of underlying assumptions and four additional reports are in process. SGVs and associated guidance previous to 2008 were formally withdrawn as of August 2008 (EA, 2010).

4.3.8 United States

The U.S. EPA recently harmonized RBSLs formerly published by U.S. EPA Regions 3, 6, and 9 by publishing a single table of generic Regional Screening Levels (RSLs) at http://www.epa.gov/reg3hwmd/risk (U.S. EPA., 2010a).

The primary source for toxicity values used in deriving the U.S. RSLs is the Integrated Risk Information System (IRIS) (U.S. EPA., 2010b), an on-line computer database of toxicological information (http://www.epa.gov/iris/index.html), which contains toxicity values for hundreds of compounds. Constituents with known or potential noncarcinogenic effects are assumed to have a dose below which no adverse effect occurs. This dose is called the threshold dose. The Reference Concentration (RfC) is the corresponding inhalation toxicity benchmark for noncarcinogens. The underlying assumption made by U.S. EPA during regulatory risk characterization for constituents with known or assumed potential carcinogenic effects is that no threshold dose exists (i.e., some finite level of risk associated with each non- zero dose). This differs from other International agencies, which consider the possibility that some carcinogens act through a threshold mechanism. The U.S. EPA also differs from other International agencies in considering toxicological effects other than carcinogenicity (i.e., structural chromosome aberrations, DNA damage/repair, and in vitro transformation) as supportive evidence for a chemical's potential carcinogenicity in classifying compounds as carcinogens (U.S. EPA., 2003). Therefore, more COPCs are considered potential carcinogens under the U.S. risk assessment framework.

The RSLs correspond to either a 1 x 10^{-6} risk level for carcinogens or a hazard quotient of one for non-carcinogens. The EPA RSLs are defined as chemical-specific concentrations for individual contaminants in soil that may warrant further investigation or possibly, site cleanup. The technical support document for the RSLs emphasizes that RSLs should not be considered cleanup standards until other response options have been evaluated and considered (U.S. EPA., 2010a).

4.4 Comparison of Risk-Based Screening Levels

Table 1 shows a side-by-side comparison of country-specific RBSLs for a select group of COPCs. These compounds were selected because they tend to be some of the COPCs of most public concern and they often drive contaminated land management decisions. Values in bold represent the lowest COPC-specific RBSL across the represented countries. Italicized values represent the highest COPC-specific RBSL amongst all of the countries. Table 2 is a comparison of exposure assumptions implicit in the country-specific RBSLs.

4.4.1 Most Conservative RBSLs

As shown in Table 1, the Canadian SQGs (Soil Quality Guidelines) represented the lowest of the RBSLs for eight out of the 15 COPCs. The conservative nature of the Canadian SQGs is the result of several highly conservative assumptions made by the CCME in their derivation. Those assumptions (CCME, 2006) are:

- Guidelines developed considering all relevant pathways and media (only 20% of the tolerable daily intake allocated to soil);
- SQGs are calculated after considering the sum of the background soil exposure; and
- With the exception of benzene, all SQGs for carcinogens correspond to a 1 x 10^{-6} cancer risk.

4.4.2 Least Conservative RBSLs

The DIVs (Dutch Intervention Values) had the highest RBSL for six out of the 15 COPCs.

The liberal nature of the DIVs is due primarily to:

- DIVs for carcinogens correspond to a 1 x 10^{-4} cancer risk; and
- Carcinogenic potency is expressed as a MPR (Maximum Permissible Risk) level that recognizes that non-genotoxic carcinogens have a threshold below which carcinogenic effects do not occur (by contrast to the non-threshold approach assumed in the U.S.).

The DIVs for soil were developed for use in determining whether land that is "already contaminated" poses a serious threat to public health. In addition, the DIVs are intended to be applied on a spatial scale, not for comparing to individual sample results. For there to be an instance of "serious contamination", the average concentration of a minimum of 25 m^3 of soil or sediment, must be higher than the DIV for at least one substance. Dutch Target Values, which are intended to protect sustainable soil quality and have an ecological health basis, are intended for use in evaluating "uncontaminated" land (RIVM, 2000).

4.4.3 Sources of Variability

Some sources of variability in the RBSLs presented in this paper are illustrated in Table 2 and discussed below.

5. EXPOSURE PATHWAYS

The exposure pathways considered in deriving RBSLs are fairly consistent amongst the countries evaluated in this paper. However, several of the country-specific RBSLs (Australia, Netherlands, U.K.) appear to include the additional pathway of produce ingestion (JRC, 2007) (NEPC, 1999b) (RIVM, 2007) (EA, 2009a). However, it is not entirely clear whether the default RBSLs include produce ingestion for all COPCs or if the pathway is only included for those COPCs for which produce ingestion has the potential to be a risk driver. Again, the lack of clarity in many of the support documents makes such issues difficult to resolve.

Table 1. Comparison of Country-Specific Risk-Based Screening Levels

Country:	Australia New Zealand	Canada	China	Hong Kong		Netherlands	Thailand	United Kingdom	United States
				Urban	Rural				
Reference:	NEPC, 1999a	CCME, 2006	PRC, 1999	EPD, 2007a		RIVM, 2000	PCD, 2004	EA, 2010	U.S. EPA, 2010a
METALS									
Arsenic	*100*	12	20	22.1	21.8	55	3.9	32	**0.39**
Chromium VI	100	0.4	NA	221	218	*380*[1]	300	NA	**0.29**
Lead	300	**140**	**140**	248	255	*530*	NA	NA	400
PETROLEUM RELATED CONSTITUENTS									
Benzene	1.1	**0.0068**	0.2	0.704	0.279	1	*6.5*	0.33	1.1
Toluene	68	**0.08**	26	1440	704	130	520	610	*5000*
Ethyl-benzene	48	**0.018**	10	*709*	298	50	230	350	5.4
Xylenes	48	**2.4**	5	95	36.8	25	210	230[8]	*630*
MTBE[3]	NA	NA	NA	**6.88**	**2.8**	*100*[4]	NA	NA	43
PERSISTENT ORGANIC POLLUTANTS									
Total Dioxin/ Furans	NA	**0.000004**	NA	0.001	0.001	0.001[4]	NA	*0.008*[2]	0.0000045[5]
Aldrin	NA	NA	0.04	NA	NA	*4*[9]	NA	NA	**0.029**
DDT[6]	NA	**0.7**	1	NA	NA	4[9]	*17*	NA	1.7
Total PCBs[7]	*10*	1.3	**0.2**	0.236	0.226	1	2.2	NA	0.22
CHLORINATED SOLVENTS									
Trichloro-ethene	NA	**0.01**	12	0.523	0.211	*60*	28	NA	2.8
Tetrachloro-ethene	NA	0.2	4	**0.101**	**0.044**	4	*57*	NA	0.55
Vinyl Chloride	NA	NA	NA	NA	NA	0.1	*1.5*	NA	**0.06**

NA – Not available

Bolded values represent the lowest COPC-specific RBSL.

Italicized values represent the highest COPC-specific RBSL.

[1] Value for total chromium, not chromium VI.

[2] U.K. - Value should be compared to the sum of all dioxins, furans and dioxin-like PCBs.

[3] MTBE - Methyl-tert butyl ether

[4] Netherlands - No reliable value could be derived. Value given is called an "indicative level for serious soil contamination".

[5] USA - Value for 2,3,7,8-TCDD.

[6] DDT - p,p'-Dichlorodiphenyltrichloroethane

[7] PCBs - Polychlorinated biphenyls

[8] Value for p-Xylenes, as this is the most conservative of the three xylene values given.

[9] Netherlands – Values represent sum of aldrin, eldrin & dieldrin, and sum of DDT, DDE & DDD respectively.

Table 2. Comparison of Country-Specific Assumptions for Development of Residential Risk-Based Screening Level

Country:	Australia New Zealand	Canada	China	Hong Kong		Nether-lands	Thailand	United Kingdom	United States
				Urban	Rural				
Reference:	NEPC, 1999b	CCME, 2006	PRC, 1999	EPD, 2007b		RIVM, 2007	PCD, 2004	EA, 2009a	U.S. EPA, 2010a
EXPOSURE PATHWAYS									
Soil Ingestion	√	√	√	√	√	√	√	√	√
Dermal Contact w/Soil	√	√	√	√	√	√	√	√	√
Inhalation of Outdoor Air	√	√		√	√	√	√	√	√
Inhalation of Indoor Air	√	√		√	√	√	√	√	√
Consumption of Produce	√					√		√	
TARGET CANCER RISK									
$1 X 10^{-4}$						√			
$1 X 10^{-5}$	√		√				√	√	
$1 X 10^{-6}$		√		√	√				√
EXPOSURE ASSUMPTIONS (Adult/Child[1])									
Adult Body Weight Child (kg)	64 13.2	71 16.5	55.9	50 15	50 15	70 15	NS	71 5.6-20[4]	70 15
Adult Inhalation Rate Child (m^3/day)	22 15	15.8 9.3	NA	20-21[2] 10	20-21[2] 10	20 7.6	NS	12-16.4[4] 8.5-12.7[4]	20 20
Adult Soil Ingestion Rate Child (mg/day)	25 100	20 80	50	200 100	200 100	50 100	NS	50 100	100 200
Adult Skin Surface Area Child (m^2)	NA	2500 2600	2550	2300 1200	2950 1500	900-1700[3] 500-2800[3]	NS	1610-2200[4] 300-870[4]	5700 2800
Adult Exposure Duration Child (years)	70 Age	30 4	40	30 6	30 6	70 6	NS	70 6	30 6
Regulatory Action Required Upon Exceedance									
Intervention						√[5]			
Remediation		√		√[6]	√[6]				
Action (further investigation, risk assessment, restrict landuse)	√		√				√[7]		√
Not Specified								√[8]	

NS – Thai exposure assumptions "not specified".

[1]Exposure assumptions for the child are specific to children between the ages of birth to six years (or closest age group for specific regulatory agency).

[2]Different inhalation rates for indoor and outdoor air.

[3]Different exposed skin surface area assumed for indoor and outdoor.

[4]CLEA model divides a lifetime into eighteen age intervals (or age classes) to account for variations in exposure characteristics with age.

[5]For there to be an instance of serious contamination, the average concentration of a minimum of 25 m^3 of soil must exceed a Dutch Intervention Value. In instances where serious contamination is defined, it then needs to be determined whether action to deal with the contamination is "urgently" required. Factors which dictate urgency are the actual risks to which man and ecosystems are being subjected, and the risks of migration.

[6]Defined as levels below which exposure is considered minimal, but the guidance (EPD, 2007a) states that when concentrations of soil or groundwater are detected above the RBRGs, "cleanup" is required.

[7]Action required upon exceedance of Thai standards is not specified, but since they are based on U.S. EPA Region 9 Preliminary Remediation Goals (recently superseded by EPA Regional Screening Levels), it is assumed that they represent action levels, similar to the U.S. exposure assumptions.
[8]Soil Guideline Values (SGV) are described as an "acceptable" level of soil contamination, but U.K. guidance does not indicate that concentrations above the SGV are "unacceptable". Required action is not specified.

The Chinese EQSs (Environmental Quality Standards) do not appear to consider the inhalation pathway (PRC, 1999), which seems sets these RBSLs apart from the others.

In setting SQGs, the CCME (Canadian Council Ministers of the Environment) only allocates 20% of the residual acceptable daily intake (ADI) to soil because it is assumed that there are other media to which people are exposed (air, water, food, and consumer products) that must be taken into account in setting an RBSL (CCME, 2006). Australia takes a similar approach in developing its HILs (Health-Based Investigation Levels) except that the allocation is not fixed (generally, the HIL allocation has been higher than 20%) (NEPC, 1999a).

6. EXPOSURE ASSUMPTIONS

The soil ingestion rate is usually the most sensitive input parameter to the equations used to derive soil RBSLs for most COPCs. Exceptions to this general rule of thumb, however, include highly lipophilic or fat soluble COPCs (i.e., POPs), for which dermal uptake can sometimes represent a more significant exposure pathway than soil ingestion. There are a few highly volatile COPCs for which the inhalation pathway dominates the soil RBSL (e.g., trimethylbenzenes), but these are rare.

Interestingly, the soil ingestion rates assumed in developing the Canadian SQGs (lowest RBSLs for eight out of 15 COPCs) are amongst the least conservative (lowest) of all the featured countries. The exposed skin surface area assumed in development of the Canadian SQGs is in the range of that assumed by the other countries, although the area assumed for children, age five to 11 years, could be considered somewhat high relative to the other countries. Of the country-specific RBSLs compared in this paper, the U.S. exposure assumptions are generally the most conservative. U.S. RSLs represented the lowest of the RBSLs for four out of 15 COPCs.

There is variability in other exposure assumptions used by different countries as well. For example, the body weight assumed in developing the Chinese EQS and Hong Kong RBRGs are lower (50 – 55 kg) (PRC, 1999), (EPD, 2007b) than the body weight assumed by western countries (≈ 70 kg) (CCME, 2006), (U.S. EPA., 2010a), (RIVM, 2007), (EA, 2009a) and Australia/New Zealand (64 kg) (NEPC, 1999b).

7. TOXICITY BENCHMARKS

An underlying assumption made by U.S. EPA in developing toxicity benchmarks for constituents with known or assumed potential carcinogenic effects that differs from other International agencies is that, for carcinogens, no threshold dose exists (i.e., there is some finite level of risk associated with each non-zero dose) (U.S. EPA., 2003). International agencies in many other countries (Australia/New Zealand, Canada, U.K., Netherlands) (NEPC, 1999a), (CCME, 2006), (EA, 2009b) (RIVM, 2001) consider the possibility that some carcinogens act through a threshold mechanism, which is generally considered to be the scientifically accurate assumption.

The area of cancer assessment is one where different national strategies in environmental policies are often reflected. For example, Health Canada classifies benzene as carcinogenic to humans but does not derive an oral cancer risk value because it considers exposure by the oral route to be negligible (CCME, 2006). On the other hand, the Dutch National Institute of Public Health and the Environment (RIVM) and the U.S. EPA have both developed an oral cancer toxicity factor by doing a route extrapolation from inhalation unit risks based on leukemia incidence in occupationally-exposed humans (RIVM, 2001; U.S. EPA, 2003).

It is not possible to say definitively whether one agency or another is consistently more or less conservative than the others in deriving toxicity benchmarks, just that toxicity information is often interpreted differently from one country to the next and these interpretations influence the level at which RBSLs are set.

8. TARGET RISK GOALS

Target risk goals used in establishing country-specific RBSLs reflect policy decisions made by the individual international regulatory entities regarding what represents an "acceptable" or "tolerable" risk. All of the RBSLs described in this paper correspond to a non-cancer hazard quotient of 1, while the RBSLs for carcinogens correspond to a range of target cancer risk goals from 1×10^{-4} to 1×10^{-6}. The DIVs (Dutch Intervention Values) correspond to a cancer risk of 1×10^{-4} and the U.S. RSLs, Canadian SQGs (except for benzene), the Chinese EQS, and Hong Kong RBRGs correspond to a cancer risk of 1×10^{-6}. The remaining RBSLs (Australia/New Zealand, Thailand, U.K.) correspond to a target cancer risk goal of 1×10^{-5}. As the target risk goal represents the starting point from which RBSLs are calculated, the variances amongst different countries clearly influences the level at which RBSLs are set.

The ITER (International Toxicity Estimate for Risk) is a free Internet database of human health risk values and cancer classifications for over 600 chemicals of environmental concern from several organizations worldwide (TERA, 2008). The ITER database is available at http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?iter and presents risk data in a tabular format along with a synopsis explaining differences in data and a link to each organization for more information. This database represents an excellent source of information on the differences between toxicity factors used to set country-specific RBSLs. However, care must be taken to compare risk values that are expressed in the same terms. To do this, it is necessary to read the text below the summary tables in the database, as the tables express the health risk values in different units of measure.

9. CONCLUSIONS

The speed and ease of application are amongst the greatest benefits of applying generic default RBSLs and are the primary reason why the use of RBSLs has become so common. Their use can provide clarity, comparability and transparency to non-specialist stakeholders. However, their inappropriate use can, and often does, lead to misleading results and misallocation of funds.

Countries that have formally developed or adopted RBSLs have done so under different National regulatory frameworks and exceedance of RBSLs requires different response actions from one country to the next. Most countries use generic RBSLs as part of a broader approach that includes the option of conducting a site-specific risk assessment as one of several possible actions in circumstances where a RBSL has been exceeded. However, there are some exceptions, such as Hong Kong where an exceedance requires cleanup. Exceedance of Chinese Class B "action levels", which are not discussed in this paper, also requires remediation. However, a key aspect of all programs should be evaluation of the applicability of the generic RBSLs to individual contaminated sites. It is important to note, however, that RBSLs are developed for evaluating and setting priorities for impacted sites on a consistent risk basis. They are rarely intended to be considered as thresholds above which health effects are inevitable or to be used as "de facto" cleanup goals.

The significance of exceeding a RBSL, whether it corresponds to a maximum permissible concentration or an action level, should be judged in relation to the conservative assumptions adopted during development. The significance of a RBSL exceedance should also consider the target risk level at which the RBSL is set relative to the level of risk posed by other sources (e.g. risk of inhalation of contaminated air or risks from smoking).

Understanding the underlying assumptions used in developing internationally available RBSLs is essential to making informed decisions regarding their use to manage contamination and mitigate risk, even if they are used outside of the National regulatory framework under which they were developed. This paper has attempted to explain some of the apparent differences between a subset of the internationally available RBSLs. In some cases, differences can be attributed to different national strategies in environmental policies (e.g., whether background or cumulative exposure across multiple media is considered). Moreover, the RBSLs have been set at different target risk goals, which reflect differences in what is considered an "acceptable" risk from one country to the next. In other cases, the reasons for differences between internationally accepted RBSLs are not clearly understood due to poor documentation.

There are a number of important considerations in determining the appropriateness of using of the generic RBSLs discussed in this paper outside of the regulatory framework for which they were intended. For example, the Canadian SQGs were developed considering all other media (air, water, food, consumer products) and background concentrations. As a result, only 20% of the tolerable daily intake was allocated to soil in establishing the SQGs. This, may or may not be an appropriate allocation depending on the site and the regulatory framework in which these SQGs are used.

The Dutch Intervention Values (DIVs) were developed for use in determining whether land that is "already contaminated" poses a "serious" threat to public health. However, the DIVs are intended to be applied on a spatial scale, not for comparing to individual sample results. For there to be an instance of "serious contamination" under the regulatory framework for which the DIVs are intended, the average concentration of a minimum of 25 m^3 of soil must be higher than the DIV for at least one substance. However, even when a situation of "serious contamination" is properly identified based on exceedance of the DIV by the recommended volume of soil, a number of factors should still evaluated, such as the actual risks to which man and ecosystems are subjected and the potential for migration, in determining the urgency of intervention.

Thai SQS values appear to be based on U.S. EPA PRGs (preliminary remediation goals) from 2000. The EPA Region 9 website (http://www.epa.gov/region09/waste/sfund/prg/index.html) indicates that the Region 9 PRGs should no longer be used for contaminant screening of environmental media because they have been replaced with the more current U.S. EPA Regional Screening Levels (RSLs). The EPA Region 9 PRGs had not been updated in years and, therefore, for a number of COPCs, the PRGs are no longer based on up-to-date toxicity information. Therefore, the Thai standards are out of date.

The U.K. SGVs have been the subject of much confusion and controversy amongst both regulators and practitioners regarding the U.K. SGVs (Soil Guideline Values). The problem identified with the SGVs is that they essentially provide an "acceptable" level of soil contamination, but do not necessarily indicate whether concentrations at or just above the SGV are "unacceptable". This called into question whether the SGVs achieve their primary objective, which was to help identify contaminated land. The SGVs were formally withdrawn as of August 2008, however since early 2009 new risk assessment documentation has been published in the U.K. in an attempt to clear up some of the earlier confusion.

Finally, in deriving or choosing RBSLs for carcinogens, it is necessary to take a view about the acceptability of levels of additional risk. What is considered to be the acceptable level of risk can vary over orders of magnitude (usually between 1 x 10^{-4} and 1 x 10^{-6}) between different organizations. As shown in Table 2, out of the eight countries for which RBSLs have been evaluated in this paper, three have established RBSLs for carcinogens at a 1 x 10^{-6} cancer risk; four have established RBSLs at 1 x 10^{-5}, and one at 1 x 10^{-4}. Despite the differences in target cancer risk goals used by different authoritative organizations, there appears to be growing consensus for selecting a target risk of 1 x 10^{-5} as the upper-bound "acceptable" risk (JRC, 2007). The consensus may be moving toward selecting 1 x 10^{-5} as the upper-bound "acceptable" risk from one COPC and 1 x 10^{-4} as the upper-bound "acceptable" risk from any one source.

The following conclusions regarding the use of internationally available RBSLs discussed in this paper are provided:

- Canadian SQGs only allocate 20% of the tolerable daily intake to soil and are set at an "acceptable" risk goal of 1 x 10^{-6}, making them amongst the more conservative internationally available RBSLs;
- DIVs are amongst the least conservative of the RBSLs and are not generally appropriate for use in Tier 1 screening assessments where maximum soil concentrations are compared to "generic" RBSLs as they are intended for application to a minimum of 25 m^3 of "impacted" soil;
- Thai SQS values are out of date as they are based on U.S. EPA PRGs from 2000, and all PRGs have been replaced by U.S. RSLs;
- The U.K. SGVs have been fluctuating rapidly for several years, but some consensus has now been reached and SGVs are being published again.
- There appears to be growing consensus for selecting a target risk of 1 x 10^{-4} as the upper-bound "acceptable" risk from any one source and 1 x 10^{-5} as the upper-bound "acceptable" risk from any one COPC.

This analysis was, by necessity, done at the level of primary assumptions, methods and technical elements. A detailed comparison of algorithms and input values has not yet been undertaken. This is primarily because many of the RBSLs that have been developed are not well documented. A detailed analysis of this sort will likely require surveying the regulators in countries for which risk-based management of contaminated land is relatively new to gain better insight into the bases for the RBSLs that have been developed in those countries.

10. REFERENCES

ASTM, 1995. American Society for Testing and Materials. Standard Guide for Risk-Based Corrective Action Applied at Petroleum Release Sites.

ASTM, 2000. American Society for Testing and Materials. Standard Guide for Risk-Based Corrective Action.

CCME, 2006. Canadian Council of Ministers of the Environment. A Protocol for the Derivation of Environmental and Human Health Soil Quality Guidelines.

EA, 2009a. Environment Agency, U.K. Updated Technical Background Document to the CLEA Model. Science Report – SC050021/SR3. http://www.environment-agency.gov.uk/static/documents/Research/CLEA_Report_-_final.pdf

EA, 2009b. Environment Agency, U.K. Human Health Toxicological Assessment of Contaminants in Soil. Science Report – Final SC050021/SR2. January 2009. http://www.environment-agency.gov.uk/static/documents/Research/TOX_guidance_report_-_final.pdf

EA, 2010. Environment Agency, U.K. CLEA publications. http://www.environment-agency.gov.uk/research/planning/33722.aspx

EPD, 2007a. Environmental Protection Department, Government of Hong Kong. Guidance Manual for the Use of Risk-Based Remediation Goals for Contaminated Land Management. December.

EPD, 2007b. Environmental Protection Department, Government of Hong Kong. Background Document on Development of Risk-Based Remediation Goals for Contaminated Land Management. April.

JRC, 2007. Joint Research Commission, European Commission. Derivation Methods Of Soil Screening Values In Europe. A Review and Evaluation Of National Procedures Towards Harmonisation.

NEPC, 1999a. National Environmental Protection Council, Australia. Schedule B (7a). Guidelines on Health-Based Investigation Levels. Assessment of Site Contamination.

NEPC, 1999b. National Environmental Protection Council, Australia. Schedule B (7b). Guidelines on Exposure Scenarios and Exposure Settings. Assessment of Site Contamination.

NHMRC, 1999. Toxicity Assessment for Carcinogenic Soil Contaminants Canberra: National Health and Medical Research Council. (previously titled Draft Cancer Risk Assessment for Environmental Contaminants).

PRC, 1999. People's Republic of China. Environmental Quality Risk Assessment Criteria for Soil at Manufacturing Facilities. National Standards of The People's Republic of China. HJ/T 25-99. Approved by State Environmental Protection Administration. June 9th.

PCD, 2004. Pollution Control Department of Thailand. Notification of National Environmental Board No. 25. http://www.pcd.go.th/info_serv/en_reg_std_soil01.html#s1.

RIVM, 2000. Rijksinstituut Voor Volksgezondheid en Milieu (National Institute of Public Health and the Environment). ANNEX A: Target Values, Soil Remediation Intervention Values And Indicative Levels For Serious Contamination.

RIVM, 2001. Rijksinstituut Voor Volksgezondheid en Milieu (National Institute of Public Health and the Environment). Re-evaluation of human-toxicological maximum permissible risk levels. RIVM report 711701 025. March.

RIVM, 2007. Rijksinstituut Voor Volksgezondheid en Milieu (National Institute of Public Health and the Environment). CSOIL 2000: an exposure model for human risk assessment of soil contamination: A model description. RIVM report 711701054/2007.

TERA, 2008. Toxicology Excellence in Risk Assessment. The International Toxicity Estimate for Risk (ITER) database. http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?iter.

U.S. EPA, 2003. United States Environmental Protection Agency. Draft Final Guidelines for Carcinogen Risk Assessment. EPA/630/P-03/001A. NCEA-F-0644A. February, 2003. [URL: www.epa.gov/ncea/raf/cancer2003.htm].
U.S. EPA, 2010a. United States Environmental Protection Agency. Regional Screening Levels for Chemical Contaminants at Superfund Sites. http://www.epa.gov/reg3hwmd/risk.
U.S. EPA, 2010b. United States Environmental Protection Agency. Integrated Risk Information System (IRIS). On-line database. Updated monthly. http://www.epa.gov/iriswebp/iris/index.html.