Chapter 9

DETERMINATION OF 'ACCEPTABLE' AND 'SAFE' LEVELS OF CHEMICAL EXPOSURE

An important and yet controversial issue that comes up in attempts to establish 'safe' or 'tolerable' levels for human exposure to chemical constituents relates to the notion of an 'acceptable chemical exposure level' (ACEL). The ACEL may be considered as the concentration of a chemical in a particular medium or product that, when exceeded, presents significant risk of adverse impact to potential receptors. In fact, in a number of situations, the ACEL concept tends to drive the public health risk management decision made about several consumer products. However, the ACELs may not always result in 'safe' or 'tolerable' risk levels – in part due to the nature of the critical exposure scenarios, receptor-specific factors, and other conditions that are specific to the particular hazard situation. Under such circumstances, it becomes necessary to develop more stringent and health-protective levels that will meet the 'safe' or 'tolerable' risk level criteria.

This chapter presents discussions of how risk assessment may facilitate a determination of what constitutes a reasonably 'safe' or 'acceptable' concentration of chemicals appearing in a variety of consumer products and in the human environments. This also includes an elaboration of a number of analytical relationships that can be adapted or used to estimate such 'safe' levels that are necessary for public health risk management decisions.

9.1. Requirements and Criteria for Establishing Risk-Based Chemical Exposure Levels

Risk-based chemical exposure levels (RBCELs) may generally be derived for various chemical sources by manipulating the exposure and risk models previously presented in Chapters 6 and 8. This involves a 'back-calculation' process that yields a media concentration predicated on health-protective exposure parameters; as an example, the RBCEL generally results in a cumulative non-cancer hazard index of ≤ 1 and/or a cumulative carcinogenic risk $\leq 10^{-6}$. In general, since risk is a function of both the exposure to a chemical and the toxicity of that chemical, a complete understanding of the exposure scenarios together with an accurate determination of the constituent

toxicity is key to developing permissible exposure levels that will be protective of human health.

The target RBCELs are typically established for both the carcinogenic and non-carcinogenic effects of the constituents of concern – with the more stringent value usually being selected as a public health criterion (Figure 9.1); invariably, the carcinogenic limit tends to be more stringent in most situations where both values exist. Within the general procedural framework, the following criteria and general guidelines may additionally be used to facilitate the process of establishing media-specific RBCELs and/or public health goals:

- Assuming dose additivity, $\sum_{j=1}^{p} \sum_{i=1}^{n} \frac{CMAX_{ij}}{RBCEL_{ij}} < 1$

  where $CMAX_{ij}$ is the prevailing maximum concentration of constituent i in product or matrix j, and $RBCEL_{ij}$ is the risk-based chemical exposure level for constituent i in product or matrix j.
- In developing public health goals, it usually is necessary to establish a target level of risk for the constituents of concern; such standards are generally established within the risk range of 10^{-7} to 10^{-4} (with a lifetime excess cancer risk of 10^{-6} normally used as a point-of-departure) and a hazard index of 1.
- It is recommended that the cumulative risk posed by multiple chemical constituents not exceed a 10^{-4} cancer risk and/or a hazard index of unity.
- If sensitive populations (including vulnerable persons, such as children and the sick) are to be protected, then more stringent standards may be required.
- If nearby populations are exposed to hazardous constituents from other sources, lower target levels may generally be required than would ordinarily be necessary.
- If exposures to certain hazardous constituents occur through multiple routes, lower target levels should generally be prescribed.

Indeed, if/when these conditions are satisfied, then the RBCEL represents a maximum acceptable constituent level that will likely be sufficiently protective of public health. In general, exceeding the RBCEL will usually call for the development and implementation of a corrective action and/or public health risk management plan.

9.1.1. MISCELLANEOUS METHODS FOR ESTABLISHING ENVIRONMENTAL QUALITY GOALS

Several possibilities exist to use various analytical tools in the development of alternative and media-specific chemical exposure concentration limits and environmental quality goals. Some select general procedures commonly employed in establishing environmental quality goals are briefly annotated below. Broadly speaking, these approaches represent reasonably conservative ways of setting environmental quality goals. The use of such methods will generally ensure that risks are not underestimated – which tantamount to situations that result in the adequate protection of public health.

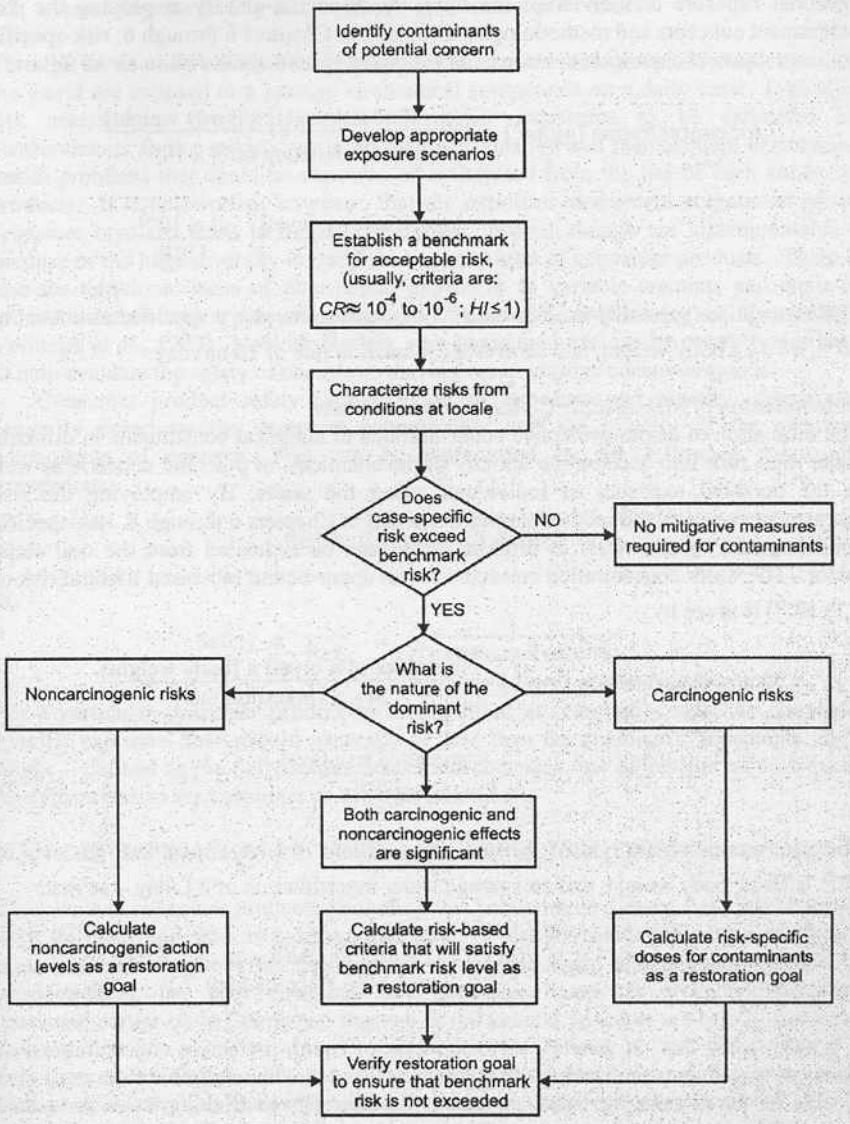

Figure 9.1. General protocol for developing risk-based chemical exposure levels and public health goals

Determination of Risk-specific Concentrations in Air

The estimation of health-protective concentrations of chemical constituents in air must take into account the toxicity of the chemicals of potential concern, as well as the potential exposure of individuals breathing the impacted air. By employing the risk assessment concepts and methodologies discussed in Chapters 6 through 8, risk-specific concentrations of chemicals in air may be estimated from the unit risk in air as follows:

$$\text{Air concentration } [\mu g/m^3] = \frac{[\text{specified risk level}] \times [\text{body weight}]}{SF_i \times [\text{inhalation rate}] \times 10^{-3}}$$

$$= \frac{[\text{specified risk level}]}{URF_i} = \frac{1 \times 10^{-6}}{URF_i} \qquad (9.1)$$

The assumptions generally used for such computations involve a specified risk level of 10^{-6}, a 70-kg body weight, and an average inhalation rate of 20 m^3/day.

Determination of Risk-specific Concentrations in Water

The estimation of health-protective concentrations of chemical constituents in drinking water must take into account the toxicity of the chemicals of potential concern, as well as the potential exposure of individuals using the water. By employing the risk assessment concepts and methodologies discussed in Chapters 6 through 8, risk-specific concentrations of chemicals in drinking water can be estimated from the oral slope factor. The water concentration corrected for an upper-bound increased lifetime risk of R (=10^{-6}) is given by:

$$\text{Water concentration [mg/L]} = \frac{[\text{specified risk level}] \times [\text{body weight}]}{SF_o \times [\text{ingestion rate}]}$$

or,

$$= \frac{\text{specified risk level}}{URF_o} \qquad (9.2)$$

The assumptions generally used for such computations involve a specified risk level of 10^{-6}, a 70-kg body weight, and an average water ingestion rate of 2 L/day – so that:

$$\text{Water concentration [mg/L]} = \frac{1 \times 10^{-6} \times 70 \text{ kg}}{SF_o \text{ (mg/kg/day)}^{-1} \times 2 \text{ L/day}} = \frac{3.5 \times 10^{-5}}{SF_o}$$

It is noteworthy that, in general, the estimation of health-protective concentrations of chemical constituents in drinking water that is associated with negligible risks must also account for the fact that tap water is typically used directly as drinking water, as well as for preparing foods and beverages. The water is also used for bathing/showering, in washing clothes and dishes, flushing of toilets, and in a variety of other household uses – some of which could result in potential dermal and inhalation exposures as well. To allow for these additional exposures, therefore, the assumed daily volume of water

consumed by an adult is typically increased from the default value of 2 L/day indicated above, to 3 L-equivalents/day (Leq/day).

9.2. Assessing the Safety of Chemicals in Consumer Products

Through the use of a variety of consumer products, numerous groups of peoples around the world are exposed to a barrage of chemical compounds on a daily basis. Typically, risk assessments (which allow the consumer exposures to be estimated by measurements and/or models) assist in the determination and management of potential health problems that could be expected or anticipated from the use of such consumer products. It is noteworthy, however, that the exposure assessment component of the processes involved tends to be particularly complicated, though not insurmountable – because of the huge diversity in usage and composition of consumer products. There is also the additional issue of intermittent exposures to variable amounts and types of products containing varying concentrations of chemical compounds (van Veen, 1996; Vermeire *et al.*, 1993). Notwithstanding, risk-based analyses can be carefully designed to help evaluate the safety of chemicals that appear in various consumer goods.

Consumer product safety is a function of exposure and toxicity, determined primarily based on the exposure patterns/rates and the toxicity of the chemical components of concern. This can be represented by the following conceptual expressions:

$$\text{Risk} = f(\text{Exposure,Toxicity}) \tag{9.3}$$

or,

$$\text{Safety} \;\alpha\; \frac{1}{\text{Risk}} = \frac{1}{f(\text{Exposure,Toxicity})} \tag{9.4}$$

For a particular consumer product to be classified as reasonably safe, the chemical-specific exposure dose should generally be less than the chemical's 'acceptable' daily intake – defined as the daily intake level for a chemical that represents no anticipated significant risk to the consumer or exposed individual.

9.2.1. DETERMINATION OF 'TOLERABLE' CHEMICAL CONCENTRATIONS

Chemicals in consumer products (including that occurring in dietary materials or foods) may be classified into two broad categories – carcinogenic and non-carcinogenic materials. The methods for deriving the 'acceptable' daily intakes and/or 'tolerable' concentrations for such chemicals are generally based on procedures/protocols presented earlier on in Chapters 6 through 8; the general concepts are briefly annotated below.

'Acceptable' Daily Intake and 'Tolerable' Concentration for Carcinogens

The 'acceptable' daily intake for carcinogenic materials appearing in a consumer product may be estimated by using the following approximate relationships:

$$\text{ADI}_{\text{carcinogen}} = \frac{[\text{TR x AT x 365 d/yr}]}{[\text{ED x EF x SF}]} \tag{9.5}$$

Thence, the 'tolerable' chemical concentration for carcinogens [$TC_{carcinogen}$] (mg/kg or mg/L) in the consumer product will be defined by,

$$TC_{carcinogen} = \frac{[ADI_{carcinogen} \times BW]}{[FR \times CR \times ABS]} \times CF \qquad (9.6)$$

where $ADI_{carcinogen}$ is the 'acceptable' daily intake for the carcinogenic materials (mg/kg-day); TR is the generally acceptable risk level (usually set at 10^{-6}); AT is the averaging time (years); ED is the exposure duration (yr); EF is the exposure frequency (d/yr); SF is the cancer potency or slope factor ($[mg/kg\text{-}d]^{-1}$); BW is the average body weight (kg); FR is the fraction of consumed material that is assumed to be contaminated; CR is the consumption rate (kg/d or L/d); ABS is the % absorption rate; and CF is a conversion factor to help maintain the dimensional tractability of the algorithm.

'Acceptable' Daily Intake and 'Tolerable' Concentration for Non-carcinogens

The 'acceptable' daily intake for non-carcinogenic materials appearing in a consumer product may be estimated by using the following approximate relationship:

$$ADI_{non\text{-}carcinogen} = \frac{[HQ \times AT \times 365\ d/yr \times RfD]}{[ED \times EF]} \qquad (9.7)$$

Thence, the 'tolerable' chemical concentration for non-carcinogens [$TC_{non\text{-}carcinogen}$] (mg/kg or mg/L) in the consumer product will be defined by,

$$TC_{non\text{-}carcinogen} = \frac{[ADI_{noncarcinogen} \times BW]}{[FR \times CR \times ABS]} \times CF \qquad (9.8)$$

where $ADI_{non\text{-}carcinogen}$ is the 'acceptable' daily intake for the non-carcinogenic materials (mg/kg-day); HQ is the generally acceptable hazard level (usually set at 1); AT is the averaging time (years); ED is the exposure duration (yr); EF is the exposure frequency (d/yr); RfD is the non-cancer reference dose or acceptable daily intake (mg/kg-d); BW is the average body weight (kg); FR is the fraction of consumed material that is assumed to be contaminated; CR is the consumption rate (kg/d or L/d); ABS is the % absorption rate; and CF is a conversion factor to help maintain the dimensional tractability of the algorithm.

9.3. Determination of Risk-Based Chemical Exposure Levels

After defining the critical exposure routes and exposure scenarios appropriate for a given a chemical exposure problem, it generally becomes possible to estimate a corresponding RBCEL that would not pose significant risks to an exposed population. To determine the RBCEL for a chemical compound, algebraic manipulations of the hazard index and/or carcinogenic risk equations together with the exposure estimation equations discussed in Chapters 6 through 8 can be used to arrive at the appropriate

analytical relationships. The step-wise computational efforts involved in this exercise consist of a 'back-calculation' process that yields a media concentration predicated on health-protective exposure parameters; as an example, the RBCEL generally results in a cumulative non-cancer hazard index of ≤ 1 and/or a cumulative carcinogenic risk $\leq 10^{-6}$. Indeed, for chemicals with carcinogenic effects, a target risk of (1×10^{-6}) is typically used in the 'back-calculation'; and a target hazard index of 1.0 is typically used for non-carcinogenic effects.

The processes involved in the determination of the RBCELs are summarized in the proceeding sections. For substances that are both carcinogenic and possess systemic toxicity properties, the lower of the carcinogenic or non-carcinogenic criterion should be used for the relevant public health risk management action or decision.

9.3.1. *RBCELs* FOR CARCINOGENIC CONSTITUENTS

As discussed in Chapters 6 through 8, the cancer risk (CR) for the significant human exposure routes (comprised of inhalation, ingestion, and dermal exposures) may be represented as follows:

$$CR = \{ \sum_{i=1}^{p} CDI_p \times SF_p \}$$

$$= [CDI_i \times SF_i]_{inhalation} + [CDI_o \times SF_o]_{ingestion} + [CDI_d \times SF_o]_{dermal\ contact}$$

additive risk

$$\equiv C_m\{[INHf \times SF_i] + [INGf \times SF_o] + [DEXf \times SF_o]\} \quad (9.9)$$

where the CDIs represent the chronic daily intakes, adjusted for absorption (mg/kg-day); INHf, INGf, and DEXf represent the inhalation, ingestion, and dermal contact 'intake factors', respectively (see Chapter 6); C_m is the chemical concentration in environmental/exposure matrix of concern; and the SFs are the route-specific cancer slope factors; and the subscripts *i, o* and *d* refer to the inhalation, oral ingestion, and dermal contact exposures, respectively.

The above model can be re-formulated to calculate the carcinogenic RBCEL (viz., $RBCEL_C$) for the environmental/exposure media of interest. This involves 'back-calculating' from the chemical intake equations presented in Chapter 6 for inhalation, ingestion, and dermal contact exposures. Hence,

$$RBCEL_C = C_m = \frac{CR}{\{[INHf \times SF_i] + [INGf \times SF_o] + [DEXf \times SF_o]\}} \quad (9.10)$$

For illustrative purposes, let us assume that there is only one chemical constituent present in soils at a hypothetical contaminated land, and that only exposures via the dermal and ingestion routes contribute to, or at least dominate the total target carcinogenic risk (of, say $CR = 10^{-6}$). Then,

$$CDI = \frac{CR}{SF_o} = RSD$$

or,

$$(CDI_{ing} + CDI_{der}) = \frac{CR}{SF_o}$$

i.e.,

$$\frac{(RBC_c \times SIR \times CF \times FI \times ABS_{si} \times EF \times ED)}{(BW \times AT \times 365)} + \frac{(RBC_c \times CF \times SA \times AF \times ABS_{sd} \times SM \times EF \times ED)}{(BW \times AT \times 365)} = \frac{CR}{SF_o}$$

Consequently,

$$RBCEL_c = \frac{(BW \times AT \times 365) \times (RSD)}{(CF \times EF \times ED)\{(SIR \times FI \times ABS_{si}) + (SA \times AF \times ABS_{sd} \times SM)\}}$$

where RSD represents the risk-specific dose, defined by the ratio of the target risk to the slope factor.

Indeed, the estimated RBCEL may serve as surrogate for a health-based acceptable chemical exposure level (ACEL) – albeit some case-specific adjustments will usually be required, in order to arrive at a true ACEL used in public health risk management decisions.

Health-Based ACELs for Carcinogenic Chemicals

As health-based criteria, ACELs for carcinogens may be determined in a similar manner to the so-called 'virtually safe dose' (VSD) of a carcinogenic chemical constituent. A VSD is the daily dose of a carcinogenic chemical that, over a lifetime, will result in an incidence of cancer at a specified risk level; usually, this is calculated based on the appropriate *de minimis* risk level.

The governing equation for calculating ACELs for carcinogenic constituents is shown in Box 9.1. This model – developed from algorithms and concepts presented earlier on in Chapters 6 through 8 – assumes that there is only one chemical constituent involved in the problem situation. In other situations where several chemicals may be of concern, it is assumed (for simplification purposes) that each carcinogen has a different mode of biological action and target organs. Each of the carcinogens is, therefore, assigned 100% of the 'acceptable' excess carcinogenic risk (typically equal to $[1 \times 10^{-6}]$) in calculating the health-based ACELs; in other words, the excess carcinogenic risk is not allocated among the carcinogens.

Example Calculations. Consider a hypothetical situation whereby some human receptors may be consuming water contaminated with methylene chloride. Then, the allowable human exposure due to ingestion of 2 liters of the water containing methylene chloride (with oral SF = 7.5×10^{-3} $[mg/kg/day]^{-1}$) by a 70-kg weight adult over a 70-year lifetime is given by:

$$ACEL = \frac{(R \times BW \times LT \times CF)}{(SF \times I \times A \times ED)}$$

i.e.,

$$ACEL_{methchl} = \frac{[10^{-6} \times 70 \times 70 \times 1]}{[0.0075 \times 2 \times 1 \times 70]} \approx 0.005 \text{ mg/L} = 5 \text{ µg/L}$$

Thus, the health-based ACEL for methylene chloride, based on an acceptable excess lifetime cancer risk of 10^{-6}, is estimated to be 5 µg/L.

Next, consider another situation of a contaminated land impacting a multipurpose surface water-body due to overland flow. This surface water body is used both as a culinary water supply source and for recreational purposes. Assuming – in addition to the water intake – an average daily consumption of aquatic organisms, DIA, of 6.5g/day, and a BCF of 0.91 L/kg for methylene chloride, then the health-based exposure levels for the ingestion of both water and fish is determined from the following modified equation:

$$ACEL_{methchl} = \frac{[R \times BW \times LT \times CF]}{[SF \times (I + (DIA \times BCF)) \times A \times ED]}$$

$$= \frac{[10^{-6} \times 70 \times 70 \times 1]}{[0.0075 \times (2 + (0.0065 \times 0.91)) \times 1 \times 70]} \approx 0.005 \text{ mg/L} = 5 \text{ µg/L}$$

Thus, in this particular case, the allowable exposure levels for drinking water and eating aquatic organisms contaminated with methylene chloride is also approximately 5 µg/L.

Box 9.1. General equation for calculating acceptable chemical exposure levels for carcinogenic constituents

$$ACEL_c = \frac{(R \times BW \times LT \times CF)}{(SF \times I \times A \times ED)}$$

where:

$ACEL_c$	= acceptable chemical exposure level (equivalent to the VSD) in medium of concern (e.g., mg/kg in food; mg/L in water)
R	= specified benchmark risk level, usually set at 10^{-6} (dimensionless)
BW	= body weight (kg)
LT	= assumed lifetime (years)
CF	= conversion factor (equals 10^6 for ingestion exposure from solid materials; 1.00 for ingestion of fluids)
SF	= cancer slope factor ($[mg/kg\text{-}day]^{-1}$)
I	= intake assumption (mg/day for solid material ingestion rate; L/day for fluid ingestion)
A	= absorption factor (dimensionless)
ED	= exposure duration (years)

9.3.2. *RBCELs* FOR NON-CARCINOGENIC EFFECTS OF CHEMICAL CONSTITUENTS

As discussed in Chapters 6 through 8, the hazard index (HI) for the significant human exposure routes (comprised of inhalation, ingestion and dermal exposures) is given by:

$$HI = \{ \sum_{i=1}^{p} \frac{CDI_p}{RfD_p} \}$$

$$= [\frac{CDI_i}{RfD_i}]_{inhalation} + [\frac{CDI_o}{RfD_o}]_{ingestion} + [\frac{CDI_d}{RfD_o}]_{dermal\ contact}$$

$$\equiv C_m\{[\frac{INHf}{RfD_i}] + [\frac{INGf}{RfD_o}] + [\frac{DEXf}{RfD_o}]\} \quad (9.11)$$

where the CDIs represent the chronic daily intakes, adjusted for absorption (mg/kg-day); INHf, INGf, and DEXf represent the inhalation, ingestion, and dermal contact 'intake factors', respectively (see Chapter 6); C_m is the chemical concentration in environmental/exposure matrix of concern; and the RfDs are the route-specific reference doses; the subscripts *i, o* and *d* refer to the inhalation, oral ingestion and dermal contact exposures, respectively.

The above model can be re-formulated to calculate the non-carcinogenic RBCEL (viz., $RBCEL_{nc}$) for the environmental/exposure media of interest. This is derived by 'back-calculating' from the chemical intake equations presented in Chapter 6 for inhalation, ingestion, and dermal contact exposures. Hence,

$$RBCEL_{nc} = C_m = \frac{1}{\{[\frac{INHf}{RfD_i}] + [\frac{INGf}{RfD_o}] + [\frac{DEXf}{RfD_o}]\}} \quad (9.12)$$

For illustrative purposes, assume that there is only one chemical constituent present in soils at a hypothetical contaminated land, and that only exposures via the dermal and ingestion routes contribute to, or at least dominate the total target hazard index (of HI = 1). Then,

$$CDI = RfD$$

or,

$$(CDI_{ing} + CDI_{der}) = RfD_o$$

i.e.,

$$\frac{(RBC_{nc} \times SIR \times CF \times FI \times ABS_{si} \times EF \times ED)}{(BW \times AT \times 365)} + \frac{(RBC_{nc} \times CF \times SA \times AF \times ABS_{sd} \times SM \times EF \times ED)}{(BW \times AT \times 365)} = RfD_o$$

Consequently,

$$RBCEL_{nc} = \frac{(BW \times AT \times 365) \times (RfD_O)}{(CF \times EF \times ED)\{(SIR \times FI \times ABS_{si}) + (SA \times AF \times ABS_{sd} \times SM)\}}$$

assuming a benchmark hazard index of unity.

Indeed, the estimated RBCEL may serve as surrogate for a health-based acceptable chemical exposure level (ACEL) – albeit some case-specific adjustments will usually be required, in order to arrive at a true ACEL used in public health risk management decisions.

Health-Based ACELs for Non-Carcinogenic Chemicals

As health-based criteria, ACELs for non-carcinogens may be determined in a similar manner to the so-called 'allowable daily intakes' (ADIs) of a non-carcinogenic chemical constituent. The ADI represents the threshold exposure limit below which no adverse effects are anticipated.

The governing equation for calculating ACELs for non-carcinogenic effects (i.e., the systemic toxicity) of chemical constituents is shown in Box 9.2. This model – derived from algorithms and concepts presented earlier on in Chapters 6 through 8 – assumes that there is only one chemical constituent involved. In situations where several chemicals may be of concern, it is assumed (for simplification purposes) that each chemical has a different organ-specific non-carcinogenic effect. Otherwise, the right hand side may be multiplied by a percentage factor to account for contribution to hazard index by each non-carcinogenic chemical subgroup.

Box 9.2. General equation for calculating acceptable chemical exposure levels for non-carcinogenic effects of systemic toxicants

$$ACEL_{nc} = \frac{(RfD \times BW \times CF)}{(I \times A)}$$

where:

$ACEL_{nc}$	= acceptable chemical exposure level in medium of concern (e.g., mg/kg in food; mg/L in water)
RfD	= reference dose (mg/kg-day)
BW	= body weight (kg)
CF	= conversion factor (equals 10^6 for ingestion exposure from solid materials; 1.00 for fluid ingestion)
I	= intake assumption (mg/day for solid material ingestion rate; L/day for fluid ingestion)
A	= absorption factor (dimensionless)

Example Calculations. Consider a hypothetical situation whereby some human receptors may be consuming water contaminated with ethylbenzene. Then, the allowable human exposure concentration associated with the ingestion of 2 liters of water containing ethylbenzene (with RfD of 0.1 mg/kg/day) by a 70-kg weight adult is given by:

$$ACEL = \frac{[\text{RfD x BW}]}{[\text{DW x A}]}$$

i.e.,

$$ACEL_{ebz} = \frac{[0.1 \text{ x } 70]}{[2 \text{ x } 1]} = 3{,}500 \text{ µg/L}$$

Next, consider another situation of a contaminated land impacting a multipurpose surface water-body due to overland flow. This surface water body is used both as a culinary water supply source and for recreational purposes. Assuming – in addition to the water intake – an average daily consumption of aquatic organisms, DIA, of 6.5g/day, and a BCF of 37.5 L/kg for ethylbenzene, then the health-based exposure levels for the ingestion of both water and fish is determined from the following modified equation:

$$ACEL_{ebz}\,[\text{mg/L}] = \frac{[\text{RfD x BW}]}{[2 + (0.0065 \text{ x BCF})] \text{ x } 1}$$

$$= \frac{[0.1 \text{ x } 70]}{[2 + (0.0065 \text{ x } 37.5)]} = 3{,}120 \text{ µg/L}$$

Thus, the allowable exposure concentration (represented by the water ACEL) for drinking water and eating aquatic organisms contaminated with ethylbenzene is approximately 3,120 µg/L.

9.4. Establishing Risk-Based Cleanup Limits for Contaminated Lands

Risk assessment has become particularly useful in determining the level of cleanup most appropriate for potentially contaminated lands. By utilizing methodologies that establish cleanup criteria based on risk assessment principles, corrective action programs can be conducted in a cost-effective and efficient manner. Once realistic risk reduction levels potentially achievable by various remedial alternatives are known, the decision-maker can then use other scientific criteria (such as implementability, reliability, operability, and cost) to select a final design alternative. Subsequently, an appropriate corrective action plan can be developed and implemented for the contaminated land. In fact, a major consideration in developing a remedial action plan for a contaminated land is the level of cleanup to be achieved – which could become the driving force behind remediation costs. The site cleanup limit concept generally facilitates decisions as to the effective use of limited funds to clean a site to a level appropriate/safe for its intended use. It is therefore be prudent to allocate adequate resources to develop the appropriate cleanup criteria.

In principle, the cleanup criteria selected for a potentially contaminated land may vary significantly from one site to another – due especially to the prevailing site-specific conditions. Similarly, mitigation measures may be case-specific for various hazardous situations and problems. In general, preliminary remediation goals (PRGs) are usually established as cleanup objectives early in a site characterization process. The development of PRGs requires site-specific data relating to the impacted media of interest, the chemicals of potential concern (CoPCs), and the probable future land uses.

The early determination of remediation goals facilitates the development of a range of feasible corrective action decisions, which in turn helps focus remedy selection on the most effective remedial alternative(s). It is noteworthy that an initial list of PRGs may have to be revised when new data becomes available during the site characterization process. In fact, PRGs are refined into final remediation goals throughout the process leading up to the final remedy selection. Consequently, it is important to iteratively review and re-evaluate the media and CoPCs, future land uses, and exposure assumptions originally identified during project formulation.

In addressing potentially contaminated land problems, soils can become the major focus of attention in the risk management decisions; this is because soils at such sites could serve as a major long-term reservoir for chemical contaminants – with the capacity to release contamination into several other environmental media. As such, the importance of soil cleanup for such contaminated lands cannot be over-emphasized. Indeed, the soil media typically requires a particularly close attention in most risk-based evaluations carried out for contaminated lands – albeit groundwater contaminant plumes underlying such sites are proving to be equally, if not more, problematic in some situations.

Consider, for illustrative purposes, a potentially contaminated land that is being considered for remediation so that it may be re-developed for either residential or industrial purposes. Contaminant levels in residential soils in which children might play (which allows for pica behavior in toddlers and other infants) must necessarily be lower than the same contaminant levels in soils present at a site designated for large industrial complexes (which effectively prevent direct exposures to contaminated soils). Also, the release potential of several chemical constituents will usually be different from sandy soils vs. clayey soils; this will affect the possible exposure scenarios, and therefore the acceptable soil contaminant levels that is designated for the different types of soils. Consequently, it is generally preferable to establish and use site-specific cleanup criteria for most contaminated land problems, especially where soil exposures is critical to the site restoration decisions.

To determine the risk-based cleanup level for a chemical compound present in soils at a contaminated land, algebraic manipulations of the hazard index and/or carcinogenic risk equations together with the exposure estimation equations discussed in Chapters 6 through 8 can be used to arrive at the appropriate analytical relationships. The step-wise computational efforts involved in this exercise consist of a 'back-calculation' process that yields an acceptable soil concentration (ASC) predicated on health-protective exposure parameters; as an example, the ASC generally results in a cumulative non-cancer hazard index of ≤ 1 and/or a cumulative carcinogenic risk $\leq 10^{-6}$. Indeed, for chemicals with carcinogenic effects, a target risk of $[1 \times 10^{-6}]$ is typically used in the 'back-calculation'; and a target hazard index of 1.0 is typically used for non-carcinogenic effects.

The processes involved in the determination of the ASCs are summarized in the proceeding sections. For substances that are both carcinogenic and possess systemic toxicity properties, the lower of the carcinogenic or non-carcinogenic criterion should be used for the relevant site restoration and/or risk management decisions.

9.4.1. SOIL CHEMICAL LIMITS FOR CARCINOGENIC CONTAMINANTS

Box 9.3 shows a general equation for calculating the risk-based site restoration criteria for a single carcinogenic chemical present in soils at a contaminated land. This has been derived by 'back-calculating' from the risk and chemical exposure equations associated with the inhalation of soil emissions, ingestion of soils, and dermal contact with soils. It is noteworthy that, where appropriate and necessary, this general equation may also be re-formulated to incorporate the receptor age-adjustment exposure factors developed and presented earlier on in Chapter 6.

Box 9.3. General equation for calculating risk-based soil cleanup level for a carcinogenic chemical constituent

$$ASC_c = \frac{TCR}{\left(\frac{EF \times ED \times CF}{BW \times AT \times 365}\right) \times \{[SF_i \times IR \times RR \times ABS_a \times AEF \times CF_a] + [(SF_o \times SIR \times FI \times ABS_{si}) + (SF_o \times SA \times AF \times ABS_{sd} \times SM)]\}}$$

$$= \frac{(TCR) \times (BW \times AT \times 365)}{(EF \times ED \times CF) \times \{[SF_i \times IR \times RR \times ABS_a \times AEF \times CF_a] + SF_o[(SIR \times FI \times ABS_{si}) + (SA \times AF \times ABS_{sd} \times SM)]\}}$$

where:

ASC_c	= acceptable soil concentration (i.e., acceptable risk-based cleanup level) of carcinogenic contaminant in soil (mg/kg)
TCR	= target cancer risk, usually set at 10^{-6} (dimensionless)
SF_i	= inhalation slope factor ($[mg/kg\text{-}day]^{-1}$)
SF_o	= oral slope factor ($[mg/kg\text{-}day]^{-1}$)
IR	= inhalation rate (m^3/day)
RR	= retention rate of inhaled air (%)
ABS_a	= percent chemical absorbed into bloodstream (%)
AEF	= air emissions factor, i.e., PM_{10} particulate emissions or volatilization (kg/m^3)
CF_a	= conversion factor for air emission term (10^6)
SIR	= soil ingestion rate (mg/day)
CF	= conversion factor (10^{-6} kg/mg)
FI	= fraction ingested from contaminated source (dimensionless)
ABS_{si}	= bioavailability absorption factor for ingestion exposure (%)
ABS_{sd}	= bioavailability absorption factor for dermal exposures (%)
SA	= skin surface area available for contact, i.e., surface area of exposed skin (cm^2/event)
AF	= soil to skin adherence factor, i.e., soil loading on skin (mg/cm^2)
SM	= factor for soil matrix effects (%)
EF	= exposure frequency (days/year)
ED	= exposure duration (years)
BW	= body weight (kg)
AT	= averaging time (i.e., period over which exposure is averaged) (years)

An Illustrative Example

In a simplified example of the application of the above equation (for calculating media-specific ASC for a carcinogenic chemical), consider a hypothetical site located within a residential setting where children might become exposed to site contamination during

recreational activities. It has been found that soil at this playground for young children in the neighborhood is contaminated with methylene chloride. It is expected that children aged 1 to 6 years could be ingesting approximately 200 mg of the contaminated soils per day during outdoor activities at the impacted playground. The ASC associated with the *ingestion only exposure* of 200 mg of soil (contaminated with methylene chloride, with an oral SF of 7.5×10^{-3} [mg/kg-day]$^{-1}$) on a daily basis, by a 16-kg child, over a 5-year exposure period is conservatively estimated to be:

$$ASC_{mc} = \frac{[10^{-6} \times 16 \times 70 \times 365]}{[0.0075 \times 200 \times 1 \times 1 \times 365 \times 5 \times 10^{-6}]} \approx 149 \text{ mg/kg}$$

That is, the allowable exposure concentration (represented by the ASC) for methylene chloride in soils within this residential setting, assuming a benchmark excess lifetime cancer risk level of 10^{-6}, is estimated to be approximately 149 mg/kg. Thus, if environmental sampling and analysis indicates contamination levels in excess of 149 mg/kg at this residential playground, then immediate risk control action (such as restricting access to the playground as an interim measure) should be implemented. It is noteworthy that, other potentially significant exposure routes (e.g., dermal contact and inhalation) as well as other sources of exposure (e.g., via drinking water and food) have not been accounted for in this illustrative example. However, all such other exposure routes and sources may require the need to further lower the calculated ASC for any site restoration decisions. Indeed, regulatory guidance would probably require reducing the contaminant concentration, ASC_{mc}, to only a fraction (e.g., 20%) of the calculated value in view of the fact that there could be other sources of exposure (e.g., air, food, etc.). This thinking should generally be factored into the overall risk management decisions about contaminated land management problems.

9.4.2. SOIL CHEMICAL LIMITS FOR THE NON-CARCINOGENIC EFFECTS OF SITE CONTAMINANTS

Box 9.4 shows a general equation for calculating the risk-based site restoration criteria for the non-carcinogenic effects of a single chemical constituent found in soils at a contaminated land. This has been derived by 'back-calculating' from the hazard and chemical exposure equations associated with the inhalation of soil emissions, ingestion of soils, and dermal contact with soils.

An Illustrative Example

In a simplified example of the application of the ASC equation (for calculating media-specific ASC for the non-carcinogenic effects of a chemical constituent), consider a hypothetical site located within a residential setting where children may be exposed to site contamination during recreational activities. It has been found that soil at this playground for young children in the neighborhood is contaminated with ethylbenzene. It is expected that children aged 1 to 6 years could be ingesting approximately 200 mg of contaminated soils per day during outdoor activities at the impacted playground. The ASC associated with the *ingestion only exposure* of 200 mg of soil (contaminated with ethylbenzene, with an oral RfD of 0.1 mg/kg-day) on a daily basis, by a 16-kg child, over a 5-year exposure period is conservatively estimated to be:

$$ASC_{ebz} = \frac{0.1 \times [1 \times 16 \times 5 \times 365]}{[200 \times 1 \times 1 \times 365 \times 5 \times 10^{-6}]} \approx 8{,}000 \text{ mg/kg.}$$

Box 9.4. General equation for calculating risk-based soil cleanup level for the non-carcinogenic effects of a chemical constituent

$$ASC_{nc} = \frac{\text{Target Hazard Quotient}}{\left(\frac{EF \times ED \times 10^{-6}}{BW \times AT \times 365}\right) \times \left\{\left[\frac{IR \times RR \times ABS_a}{RfD_i} \times AEF \times CF_a\right] + \left[\left(\frac{SIR}{RfD_o} \times FI \times ABS_{si}\right)\right] + \left[\frac{SA \times AF \times ABS_{sd} \times SM}{RfD_o}\right]\right\}}$$

$$= \frac{(THQ) \times (BW \times AT \times 365)}{(EF \times ED \times CF) \times \left\{\left[\frac{IR \times RR \times ABS_a}{RfD_i} \times AEF \times CF_a\right] + \frac{1}{RfD_o}[(SIR \times FI \times ABS_{si}) + (SA \times AF \times ABS_{sd} \times SM)]\right\}}$$

where:

ASC_{nc}	= acceptable soil concentration (i.e., acceptable risk-based cleanup level) of non-carcinogenic contaminant in soil (mg/kg)
THQ	= target hazard quotient (usually equal to 1) (unitless)
RfD_i	= inhalation reference dose (mg/kg-day)
RfD_o	= oral reference dose (mg/kg-day)
IR	= inhalation rate (m^3/day)
RR	= retention rate of inhaled air (%)
ABS_a	= percent chemical absorbed into bloodstream (%)
AEF	= air emission factor, i.e., PM_{10} particulate emissions or volatilization (kg/m^3)
CFa	= conversion factor for air emission term (10^6)
SIR	= soil ingestion rate (mg/day)
CF	= conversion factor (10^{-6} kg/mg)
FI	= fraction ingested from contaminated source (dimensionless)
ABS_{si}	= bioavailability absorption factor for ingestion exposure (%)
ABS_{sd}	= bioavailability absorption factor for dermal exposures (%)
SA	= skin surface area available for contact, i.e., surface area of exposed skin (cm^2/event)
AF	= soil to skin adherence factor, i.e., soil loading on skin (mg/cm^2)
SM	= factor for soil matrix effects (%)
EF	= exposure frequency (days/year)
ED	= exposure duration (years)
BW	= body weight (kg)
AT	= averaging time (i.e., period over which exposure is averaged, equals ED for non-carcinogens) (years)

That is, the allowable exposure concentration (represented by the ASC) for ethylbenzene in soils within this residential setting is estimated to be approximately 8,000 mg/kg. Thus, if environmental sampling and analysis indicates contamination levels in excess of 8,000 mg/kg at this residential playground, then immediate risk control action (such as restricting access to the playground as an interim measure) should be implemented. It is noteworthy that, other potentially significant exposure routes (e.g., dermal contact and inhalation) as well as other sources of exposure (e.g., via drinking water and food) have not been accounted for in this illustrative example.

However, all such other exposure routes and sources may require the need to further lower the calculated ASC for any site restoration decisions. Indeed, regulatory guidance would probably require reducing the contaminant concentration, ASC_{ebz}, to only a fraction (e.g., 20%) of the calculated value in view of the fact that there could be other sources of exposure (e.g., air, food, etc.). This thinking should generally be factored into the overall risk management decisions about contaminated land management problems.

9.5. Establishing Risk-Based Cleanup Limits for Contaminated Waters

To determine the risk-based cleanup level for a chemical compound present in water, algebraic manipulations of the hazard index and/or carcinogenic risk equations together with the exposure estimation equations discussed in Chapters 6 through 8 can be used to arrive at the appropriate analytical relationships. The step-wise computational efforts involved in this exercise consist of a 'back-calculation' process that yields an acceptable water concentration (AWC) predicated on health-protective exposure parameters; as an example, the AWC generally results in a cumulative non-cancer hazard index of ≤ 1 and/or a cumulative carcinogenic risk $\leq 10^{-6}$. Indeed, for chemicals with carcinogenic effects, a target risk of [1×10^{-6}] is typically used in the 'back-calculation'; and a target hazard index of 1.0 is typically used for non-carcinogenic effects.

The processes involved in the determination of the AWCs are summarized in the proceeding sections. For substances that are both carcinogenic and possess systemic toxicity properties, the lower of the carcinogenic or non-carcinogenic criterion should be used for the relevant corrective action and/or risk management decisions.

9.5.1. WATER CHEMICAL LIMITS FOR CARCINOGENIC CONTAMINANTS

Box 9.5 shows a general equation for calculating the risk-based restoration criteria for a single carcinogenic constituent present in potable water. This has been derived by 'back-calculating' from the risk and chemical exposure equations associated with the inhalation of contaminants in water (for volatile constituents only), ingestion of water, and dermal contact with water. It is noteworthy that, where appropriate and necessary, this general equation may also be re-formulated to incorporate the receptor age-adjustment exposure factors developed and presented earlier on in Chapter 6.

An Illustrative Example

In a simplified example of the application of the above equation (for calculating media-specific AWC for a carcinogenic chemical), consider the case of a contaminated site that is impacting an underlying water supply aquifer as a result of contaminant migration into groundwater. This groundwater resource is used for culinary water supply purposes. The AWC associated with the *ingestion only exposure* to 2 liters of water (contaminated with methylene chloride, with an oral SF of 7.5×10^{-3} [mg/kg-day]$^{-1}$) on a daily basis, by a 70-kg adult, over a 70-year lifetime is given by the following approximation:

$$AWC_{mc} = \frac{[10^{-6} \times 70 \times 70 \times 365]}{[0.0075 \times 2 \times 1 \times 365 \times 70]} \approx 0.005 \text{ mg/L} = 5\mu\text{g/L}$$

That is, assuming a benchmark excess lifetime cancer risk level of 10^{-6}, the allowable exposure concentration for methylene chloride (represented by the AWC) is estimated at 5 μg/L. Obviously, the inclusion of other pertinent exposure routes (such as inhalation of vapors, and dermal contacts during showering/bathing activities, etc.) would likely call for a lower AWC in any aquifer restoration decision. Indeed, regulatory guidance would probably require reducing the contaminant concentration, AWC_{mc}, to only a fraction (e.g., 20%) of the calculated value in view of the fact that there could be other sources of exposure (e.g., air, food, etc.). This thinking should generally be factored into the overall risk management decisions about contaminated water management problems.

Box 9.5. General equation for calculating risk-based water cleanup level for a carcinogenic chemical constituent

$$AWC_c = \frac{TCR}{\left(\frac{EF \times ED}{BW \times AT \times 365}\right) \times \{[SF_i \times IR_w \times RR \times ABS_a \times CF_a] + [(SF_o \times WIR \times FI \times ABS_{si}) + (SF_o \times SA \times K_p \times ET \times ABS_{sd} \times CF)]\}}$$

$$= \frac{TCR \times (BW \times AT \times 365)}{(EF \times ED) \times \{[SF_i \times IR_w \times RR \times ABS_a \times CF_a] + SF_o[(WIR \times FI \times ABS_{si}) + (SA \times K_p \times ET \times ABS_{sd} \times CF)]\}}$$

where:

AWC_c	= acceptable water concentration (i.e., acceptable risk-based cleanup level) of carcinogenic contaminant in water (mg/L)
TCR	= target cancer risk, usually set at 10^{-6} (dimensionless)
SF_i	= inhalation slope factor ($[mg/kg\text{-}day]^{-1}$)
SF_o	= oral slope factor ($[mg/kg\text{-}day]^{-1}$)
IR_w	= intake from the inhalation of volatile compounds (sometimes equivalent to the amount of ingested water) (m^3/day)
RR	= retention rate of inhaled air (%)
ABS_a	= percent chemical absorbed into bloodstream (%)
CF_a	= conversion factor for volatiles inhalation term (1,000 L/1 m^3 = 10^3 L/m^3)
WIR	= water ingestion rate (L/day)
CF	= conversion factor (1 L/1,000 cm^3 = 10^{-3} L/cm^3)
FI	= Fraction ingested from contaminated source (unitless)
ABS_{si}	= bioavailability absorption factor for ingestion exposure (%)
ABS_{sd}	= bioavailability absorption factor for dermal exposures (%)
SA	= skin surface area available for contact, i.e., surface area of exposed skin (cm^2/event)
K_p	= chemical-specific dermal permeability coefficient from water (cm^2/hr)
ET	= exposure time during water contacts (e.g., during showering/bathing activity) (hr/day)
EF	= exposure frequency (days/years)
ED	= exposure duration (years)
BW	= body weight (kg)
AT	= averaging time (i.e., period over which exposure is averaged) (years).

9.5.2. WATER CHEMICAL LIMITS FOR THE NON-CARCINOGENIC EFFECTS OF SITE CONTAMINANTS

Box 9.6 shows a general equation for calculating the risk-based restoration criteria for a single non-carcinogenic constituent present in potable water. This has been derived by 'back-calculating' from the risk and chemical exposure equations associated with the inhalation of contaminants in water (for volatile constituents only), ingestion of water, and dermal contact with water.

Box 9.6. General equation for calculating risk-based water cleanup level for non-carcinogenic effects of a chemical constituent

$$AWC_{nc} = \frac{THQ}{\left(\frac{EF \times ED}{BW \times AT \times 365}\right) \times \left\{\left[\frac{IR_w \times RR \times ABS_a \times CF_a}{RfD_i}\right] + \left[\left(\frac{WIR}{RfD_o} \times FI \times ABS_{si}\right)\right] + \left[\frac{SA \times K_p \times ET \times ABS_{sd} \times CF}{RfD_o}\right]\right\}}$$

$$= \frac{THQ \times (BW \times AT \times 365)}{(EF \times ED) \times \left\{\left[\frac{IR_w \times RR \times ABS_a \times CF_a}{RfD_i}\right] + \frac{1}{RfD_o}\left[(WIR \times FI \times ABS_{si}) + (SA \times K_p \times ET \times ABS_{sd} \times CF)\right]\right\}}$$

where:

AWC_{nc}	= acceptable water concentration (i.e., acceptable risk-based cleanup level) of non-carcinogenic contaminant in water (mg/L)
THQ	= target hazard quotient (usually equal to 1)
RfD_i	= inhalation reference dose (mg/kg-day)
RfD_o	= oral reference dose (mg/kg-day)
IR_w	= inhalation intake rate (m^3/day)
RR	= retention rate of inhaled air (%)
ABS_a	= percent chemical absorbed into bloodstream (%)
CF_a	= conversion factor for volatiles inhalation term (1,000 L/1 m^3 = 10^3 L/m^3)
WIR	= water intake rate (L/day)
CF	= conversion factor (1 L/1,000 cm^3 = 10^{-3} L/cm^3)
FI	= fraction ingested from contaminated source (dimensionless)
ABS_{si}	= bioavailability absorption factor for ingestion exposure (%)
ABS_{sd}	= bioavailability absorption factor for dermal exposures (%)
SA	= skin surface area available for contact, i.e., surface area of exposed skin (cm^2/event)
K_p	= chemical-specific dermal permeability coefficient from water (cm^2/hr)
ET	= exposure time during water contacts (e.g., during showering/bathing activity) (hr/day)
EF	= exposure frequency (days/years)
ED	= exposure duration (years)
BW	= body weight (kg)
AT	= averaging time (i.e., period over which exposure is averaged) (years).

An Illustrative Example

In a simplified example of the application of the above equation (for calculating media-specific AWC for a non-carcinogenic chemical), consider the case of a contaminated site that is impacting an underlying water supply aquifer as a result of contaminant

migration into groundwater. This groundwater resource is used for culinary water supply purposes. The AWC associated with the *ingestion only exposure* to 2 liters of water (contaminated with ethylbenzene, with an oral RfD of 0.1 mg/kg-day) on a daily basis, by a 70-kg adult is approximated by:

$$AWC_{ebz} = \frac{0.1 \text{ x } [1 \text{ x } 70 \text{ x } 70 \text{ x } 365]}{[2 \text{ x } 1 \text{ x } 1 \text{ x } 365 \text{ x } 70]} \approx 3{,}500 \text{ µg/L}$$

Thus, the allowable exposure concentration (represented by the AWC) for ethylbenzene is estimated to be 3,500 µg/L. Of course, additional exposures via inhalation and dermal contacts during showering/bathing and washing activities may also have to be incorporated to yield an even lower AWC, in order to arrive at a more responsible water restoration decision. Indeed, regulatory guidance would probably require reducing the contaminant concentration, AWC_{ebz}, to only a fraction (e.g., 20%) of the calculated value in view of the fact that there could be other sources of exposure (e.g., air, food, etc.). This thinking should generally be factored into the overall risk management decisions about contaminated water management problems.

9.6. A 'Preferable' Health-Protective Chemical Level

Oftentimes, the RBCEL that has been established based on an acceptable risk level or hazard index are for a single contaminant in one environmental matrix or exposure media. Therefore the risk and hazard associated with multiple contaminants in a multi-media setting are not fully accounted for during the 'back-modeling' process used to establish the RBCELs. In contrast, the evaluation of risks associated with a given chemical exposure problem usually involves a set of equations designed to estimate hazard and risk for several chemicals, and for a multiplicity of exposure routes. Under this latter type of scenario, the computed 'acceptable' risks could indeed exceed the health-protective limits; consequently, it becomes necessary to establish a modified RBCEL for the requisite environmental or public health risk management decision. To obtain the modified RBCEL, the 'acceptable' chemical exposure level is estimated in the same manner as elaborated in the preceding sections – but with the cumulative effects of multiple chemicals being taken into account through a process of apportioning target risks and hazards among all the CoPCs.

9.6.1. THE MODIFIED *RBCEL* FOR CARCINOGENIC CHEMICALS

A modified RBCEL for carcinogenic constituents may be derived by the application of a 'risk disaggregation factor' – that allows for the apportionment of risk amongst all CoPCs. That is, the new RBCEL may be estimated by proportionately aggregating – or rather disaggregating – the target cancer risk amongst the CoPCs, and then using the corresponding target risk level in the equation presented earlier on in Boxes 9.1. The assumption used for apportioning the excess carcinogenic risk may be that all carcinogens have the same mode of biological actions and target organs; otherwise, excess carcinogenic risk is not apportioned among carcinogens, but rather each assumes the same value in the computational efforts. A more comprehensive approach to 'partitioning' or combining risks would involve more complicated mathematical manipulations, such as by the use of linear programming algorithms.

In general, the acceptable risk level may be apportioned between the chemical constituents contributing to the overall target risk by assuming that each constituent contributes equally or proportionately to the total acceptable risk. The 'risk fraction' obtained for each constituent can then be used to derive the modified RBCEL – by working from the relationships established previously for the computation of RBCELs (Section 9.3); by using the approach to estimating media RBCELs, the modified RBCEL is derived in accordance the following approximate relationship:

$$RBCEL_{c\text{-}mod} = \frac{[\%] \times CR}{\{[INHf \times SF_i] + [INGf \times SF_o] + [DEXf \times SF_o]\}} \qquad (9.13)$$

All the terms are the same as defined previously in Section 9.3 and [%] represents the proportionate contribution from a specific chemical constituent to the overall target risk level. One may also choose to use weighting factors in apportioning the chemical contributions to the target risk levels; for instance, this could be based on carcinogenic classes – such that class A carcinogens are given twice as much weight as class B, etc.; or chemicals posing carcinogenic risk via all exposure routes are given more weight than those presenting similar risks via specific routes only. Overall, the use of the modified RBCEL approach will ensure that the sum of risks from all the chemicals involved over all exposure pathways is less than or equal to the set target *de minimis* risk (e.g., $\leq 10^{-6}$).

9.6.2. THE MODIFIED *RBCEL* FOR NON-CARCINOGENIC CONSTITUENTS

A modified RBCEL for non-carcinogenic constituents may be derived by application of a 'hazard disaggregation factor' – that allows for the apportionment of target hazard index amongst all CoPCs. That is, the new RBCEL may be estimated by proportionately aggregating – or rather disaggregating – the non-cancer hazard index amongst the CoPCs, and then using the corresponding target hazard level in the equation presented earlier on in Box 9.2.

In general, the acceptable hazard level may be apportioned between the chemical constituents contributing to the overall hazard index by assuming that each constituent contributes equally or proportionately to the total acceptable hazard index. The 'hazard fraction' obtained for each constituent can then be used to derive the modified RBCEL – by working from the relationships established previously for the computation of RBCELs (Section 9.3). By using the approach to estimating media RBCELs, the modified RBCEL is derived in accordance the following approximate relationship for non-carcinogenic effects of chemicals having the same toxicological endpoints:

$$RBCEL_{nc\text{-}mod} = \frac{[\%] \times 1}{\{[\frac{INHf}{RfD_i}] + [\frac{INGf}{RfD_o}] + [\frac{DEXf}{RfD_o}]\}} \qquad (9.14)$$

All the terms are the same as defined previously in Section 9.3 and [%] represents the proportionate contribution from a specific chemical constituent to the overall target hazard index for the non-carcinogenic effects of chemicals with same physiologic endpoint. Overall, the use of the modified RBCEL approach will ensure that the sum of

hazard quotients over all exposure pathways for all chemicals (with the same physiologic endpoints) is less than or equal to the hazard index criterion of 1.0.

9.6.3. INCORPORATING DEGRADATION RATES INTO THE ESTIMATION OF ENVIRONMENTAL QUALITY CRITERIA

The effect of chemical degradation is generally not incorporated into estimated RBCELs. However, since exposure scenarios used in calculating the RBCELs or similar criteria usually make the assumption that exposures could be occurring over long time periods (up to a lifetime of 70 years), it is prudent, at least in a detailed analysis, to consider the fact that degradation or other transformation of the CoPC could occur. Under such circumstances, the degradation properties of the CoPCs should be carefully evaluated. Subsequently, an adjusted RBCEL (or its equivalent) can be estimated – that is based on the original RBCEL (or equivalent), a degradation rate coefficient, and the specified exposure duration. The new adjusted RBCEL is then given by:

$$RBCEL_a = \frac{\text{RBC}}{\text{degradation factor (DGF)}} \tag{9.15}$$

where $RBCEL_a$ is the adjusted RBCEL or its equivalent, and that incorporates a degradation rate coefficient. Assuming first-order kinetics, as an example, an approximation of the degradation effects can be obtained as follows:

$$\text{DGF} = \frac{(1 - e^{-kt})}{kt} \tag{9.16}$$

where k is a chemical-specific degradation rate constant (days^{-1}), and t is time period over which exposure occurs (days). For a first-order decaying substance, k is estimated from the following relationship:

$$T_{1/2}\ [\text{days}] = \frac{0.693}{k} \quad \text{or} \quad k\ [\text{days}^{-1}] = \frac{0.693}{T_{1/2}} \tag{9.17}$$

where $T_{1/2}$ is the half-life, which is the time after which the mass of a given substance will be one-half its initial value. Consequently,

$$RBCEL_a = \text{RBCEL} \times \frac{kt}{(1 - e^{-kt})} \tag{9.18}$$

This relationship assumes that a first-order degradation/decay is occurring during the complete exposure period; decay/degradation is initiated at time, $t = 0$ years; and the RBCEL is the average allowable concentration over the exposure period. In fact, if significant degradation is likely to occur, the $RBCEL_a$ calculations become much more complicated; in that case, predicated source chemical levels must be calculated at frequent intervals and summed over the exposure period.

9.7. Public Health Goals *vs.* Risk-Based Chemical Exposure Levels

Pre-established public health goals (PHGs) are often used to define acceptable chemical exposure limits for human exposure – i.e., if they are determined to represent 'safe' or 'tolerable' benchmark levels for the case-specific situation. However, such generic PHGs may not always be available, or may not even offer adequate public health protection under certain circumstances. For instance, the presence of multiple constituents, multiple exposure routes, or other extraneous factors could result in 'unacceptable' aggregate risk being associated with a PHG for the particular situation. Under such circumstances, a new 'acceptable' or 'safe' level may be better represented by the RBCEL – that are derived for the various exposure routes, and from elaborately defined exposure scenarios. As the preferred risk-based benchmark, the RBCEL can then be used as a surrogate or replacement for the PHG of the CoPC.

Typically, risk-based benchmarks are developed via 'back-modeling' from a target risk level that produces an acceptable RBCEL – which can serve as a surrogate PHG. Invariably, the type of exposure scenarios envisioned as well as the exposure assumptions used may predicate the new benchmark level. It is noteworthy that, when the calculated RBCEL based on non-cancer toxicity is less protective of public health than the cancer-based value, the surrogate PHG for the CoPC is set at the lower of the two – usually the one based on the cancer effects. In any case, even for a criteria predicated on the cancer toxicity, the adopted PHG is considered to contain an adequate margin of safety for the potential non-carcinogenic adverse effects, such as adverse effects on the renal, neurological and reproductive systems.

In general, the risk-based benchmarks predicated on RBCELs may be used to: determine the degree of chemical exposures; evaluate the need for intervention and receptor monitoring; provide guidance on the need for risk control and/or corrective actions; establish safer PHGs; and verify the adequacy of possible remedial/corrective actions. Overall, the use of risk assessment principles to establish case-specific benchmarks for chemical exposure problems represent an even better and more sophisticated approach to designing cost-effective public health risk management programs – in comparison with the use of generic benchmarks. Ultimately, the use of such an approach aids in the development and/or selection of appropriate public health risk management strategies capable of achieving a set of performance goals – such that public health is not jeopardized.

9.8. Suggested Further Reading

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