Tier II Report

Development Of Sediment Quality Criteria For The Protection Of Human Health

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Page Content

1.0 INTRODUCTION

Sediments are a known reservoir for many non-ionic organic chemicals discharged to surface waters. Because some aquatic organisms bioaccumulate and biomagnify sediment-bound contaminants to levels that may impact human health when seafood species are consumed, Washington State Department of Health (DOH) developed a two-tiered approach to establish sediment quality criteria (SQC) for the protection of human health from contaminated seafood. For the first tier, DOH outlined a process which uses default parameters to derive protective sediment contaminant levels (DOH, 1995). These SQC were developed under WAC 173-204 which states that the purpose of sediment management standards (SMS) (of which SQC are a subset) is to "... reduce and ultimately eliminate adverse effects on biological resources and significant health threats to humans from surface sediment contamination ...". The second tier builds on the Tier I process by describing how site-specific parameter values may be used to calculate SQC for a given location.

The goal of this report is to provide a framework for incorporation of site- and chemical-specific data to calculate a level of sediment chemical contamination unlikely to result in adverse human health impacts to people who eat fish and shellfish from Puget Sound. As in Tier I, consumption of fish is assumed to be the primary pathway for human exposure to chemical contaminants in sediments. SQC determined by a Tier II assessment can be used in the management of dredged materials, establishment of cleanup levels, and assessment of source controls.

2.0 BACKGROUND

DOH and the Washington State Department of Ecology (Ecology) initiated development of health-based SQC in 1991 to address concerns that humans are at risk from consuming contaminated seafood. To address these concerns, DOH developed a process to determine sediment chemical concentrations unlikely to result in adverse human health impacts. This process was documented in *Tier I, Development of Sediment Quality Criteria For The Protection of Human Health* (DOH, 1995). The Tier I report focused on the first tier of a two-tiered analysis of contaminated sediments in Puget Sound, while this report documents the second tier (Tier II) of this process.

SQC are maximum allowable sediment chemical concentrations unlikely to result in adverse human health effects from consumption of contaminated fish and shellfish. Seafood may become contaminated through bioaccumulation and biomagnification of sediment-bound chemicals. DOH derived SQC from modified versions of U.S. Environmental Protection Agency (EPA) Water Quality Criteria risk equations (DOH, 1995). SQC were developed for chemicals with existing EPA reference dose values (RfD) and cancer potency factors (CPF). As part of Tier I, SQC are applicable to all areas of Puget Sound and take into consideration regional background chemical concentrations.

tissue sample size, the appropriate sediment sample size, and the appropriate sediment station location.

The use of fish tissue chemical data is not recommended to regulate sediments. Basing sediment regulation on current fish tissue concentrations would not meet the goal of establishing SQC to prevent seafood from becoming contaminated but would be limited to issuance of fish advisories after fish are contaminated.

In the Tier I and Tier II processes, SQC methodologies were developed for non-ionic organic chemicals but not for metals or ionic organic chemicals. Additionally, multiple chemical effects were not considered in this report. DOH recommends the development of SQC for metals and ionic organic chemicals and the consideration of multiple chemical effects as science and technology advance.

relies on risk management considerations. DOH recommends the use of risk values consistent with federal and state regulatory programs for Tier II.

Body weight values other than 70 kg may be justified when a chemical is of greater toxicity to a specific population segment such as women or young children than to the general public. For Tier II SQC calculations, DOH recommends that the Tier I default body weight value of 70 kg be used for adults unless average body weight data for local anglers or for sensitive subpopulations are available for the site in question.

Exposure duration (ED) and averaging time (AT) are used in the calculation of human exposure to sediment chemicals through ingestion of contaminated seafood. Although an individual may consume local fish for most of his or her life, the individual's fish consumption rate may not be constant over this entire period. Some Puget Sound residents may have high fish consumption over their entire lifetimes which would justify alterations in ED and AT for Tier II calculations from typical default values. Averaging times should also be shortened when appropriate to reflect chemical-specific acute toxicity.

Cancer potency factors and reference dose values which reflect new scientific information on chemical-specific toxicity may be considered for Tier II. Any change from current regulatory values would require a scientific peer review process. Furthermore, chemicals currently lacking regulatory values may undergo toxicological review for establishment of a Tier II regulatory value provided that enough toxicological information is available.

Ingestion frequency is also used to calculate exposure. For Tier II, the Tier I default value for seafood consumption rate may be altered to reflect local or site-specific conditions within a given basin. The species chosen to determine a local consumption rate for Tier II should likewise reflect basin-wide conditions. Additionally, consideration should be given to consumption practices of subpopulations that consume seafood at higher rates than the general population.

Fish lipid percentages used to normalize consumption rates based on the amount of lipid in a fish should be matched with the fish species used to calculate ingestion frequency. DOH recommends that fish lipid values be determined for fish species caught within the biogeographical area impacted by the site being evaluated.

Biota-sediment accumulation factor (BSAF) values indicate the extent to which chemical contaminants in sediment bioaccumlate and biomagnify through the food web. DOH recommends incorporating Puget Sound site-specific BSAF values into Tier II SQC calculations. Puget Sound site-specific BSAF values require collection of fish (or shellfish) tissue chemical concentrations, fish (or shellfish) tissue lipid concentrations, sediment chemical concentrations, and sediment total organic carbon concentrations.

Determination of site-specific BSAFs for Tier II should consider which chemical is under evaluation, which fish species is targeted, which fish tissue is analyzed, the appropriate fish

EXECUTIVE SUMMARY

Marine sediments serve as a repository for many non-ionic organic chemicals discharged to fresh and marine surface waters. Bioaccumulation and biomagnification of chemical pollutants found in sediments may result in high levels contaminates in aquatic organisms. These levels may reach concentrations of concern to consumers of seafood. To address this potential problem, Washington State Department of Health (DOH) developed a two-tiered approach to establish Sediment Quality Criteria (SQC) for protection of human health from contaminated fish and shellfish. SQC are maximum allowable sediment chemical concentrations which will not result in adverse human health effects resulting from consumption of contaminated seafood. SQC can be applied to management of dredged materials, establishment of cleanup levels, and assessment of source controls. This document describes the second tier of a two-tiered process to determine SQC protective of human health. While the goal of Tier I was to determine numeric SQC for organic chemicals of concern based on default values, the goal of Tier II is to provide a framework for incorporation of site- and chemical-specific data into the SQC process.

Within the Tier II framework, an applicant may calculate Tier II SQC based on site-specific parameter values using a modified risk equation for either carcinogens or non-carcinogens. Following calculation, Tier II SQC are compared with established background chemical concentration standards; whichever value is greater will become the Tier II SQC regulatory value for that chemical. Sediment chemical concentrations from the investigation site are then compared to the regulatory value. Ecology will determine appropriate remedial action if the sediment concentration exceeds the SQC regulatory value.

An applicant may decide to conduct a Tier II evaluation upon failing Tier I SQC or may proceed directly to Tier II for an SQC determination. Tier II SQC are expected to be less stringent than Tier I because they will directly reflect local conditions rather than conservative default values as in Tier I. The Tier I - Tier II process may result in multiple SQC for a given chemical in Puget Sound.

Equation parameters that may be modified for Tier II SQC include:

- Risk (R),
- Body weight (BW),
- Exposure duration (ED)/Averaging time (AT),
- Cancer potency factor (CPF)/Reference dose (RfD),
- Ingestion frequency (IF),
- Fish lipid (FL), and
- Biota-sediment accumulation factor (BSAF).

Risk levels less stringent than 1 X 10^{-6} may be acceptable based on site and regulatory factors. The selection and implementation of a specific risk level is not a scientific decision but rather

Page Tables

Page **Figures**

Tier I SQC were designed to be efficient and cost-effective for regulators and the regulated community while ensuring protection of individuals who are highly exposed to sediment-bound chemicals which bioaccumulate. Each parameter used in the SQC equation has an associated uncertainty because of its generic nature; for example, Tier I biota-sediment accumulation factor (BSAF) values are based on national bioaccumulation data rather than on data collected from Puget Sound. The Tier II option attempts to reduce this and other uncertainties. Several parameter values within the SQC equation may be modified by the use of regional or localized data thereby resulting in a more accurate SQC value for a chemical at a specific location within Puget Sound. Parameters within the SQC equation which may be modified for Tier II include:

- Risk,
- Body weight,
- Exposure duration/Averaging time,
- CPF/RfD,
- Ingestion frequency/Fish lipid, and
- Biota-sediment accumulation factor (BSAF).

Accordingly, the objective of Tier II is to determine a SQC value for each chemical of concern by incorporation of site-specific data. Additionally, the Tier II process may be used to calculate SQC for chemicals not addressed in Tier I because they lack a toxicity value or are not identified as a chemical of concern. Tier II may be implemented by the regulator or regulated community (with Ecology's approval) when sediment chemical concentrations at a site exceed Tier I SQC values (Figure 1). Once a chemical exceeds a Tier I SQC and the Tier II process is initiated, parameters derived from site-specific data may be used to calculate SQC for Tier II.

Two parameters listed above have the greatest likelihood of being influenced by data from specific locations in Puget Sound: ingestion frequency (IF) and BSAF. IF, also referred to as the seafood consumption rate, will vary from site to site based on species availability, which relates to life history, habitat, and habitat contamination level. Harvest patterns and ingestion of fish that move to and from a contaminated site should be considered when determining a local fish consumption rate; i.e., a local fish consumption rate should be based on harvest patterns in the entire basin in which a sediment site is located to account for fish movement and behavior. Additional site-specificity for Tier II SQC may be obtained by the use of empirically-derived BSAF values based on local fish and sediment samples. For comparative purposes, BSAF values are lipid- and organic carbon-normalized to reduce variability due to variations in the amount of fat in fish tissue and amount of organic carbon in sediment.

This report first reviews the Tier I process, presents SQC equations, and describes the proposed Tier II framework and equation parameters. Next, the report discusses the six or seven parameters (for non-carcinogens or carcinogens, respectively) within each equation and offers options for altering Tier I default values to more accurately calculate a Tier II SQC for a specific site and chemical. A discussion of the use of fish tissue chemical data to determine

SQC values follows. Other issues such as exposure to multiple chemicals, metals and ionic organic contaminants, distributional analyses, and caged fish studies are briefly mentioned. Finally, the report lists DOH recommendations and conclusions.

3.0 OVERVIEW OF TIER I PROCESS

The Tier I regulatory framework assumes that sediment chemicals have been characterized (Figure 1). Chemical characterization includes: (1) a review of past and present industrial activities and discharges which may have contributed to sediment contamination, and (2) compilation and review of sediment contaminant and biota data. If data are insufficient for initial sediment characterization (i.e., quality of data is poor, no data exists for suspected chemicals, too few data exist, or available data do not provide adequate spatial representation), collection of additional sediment chemistry data is necessary.

The second step of Tier I compares sediment chemical concentrations determined during initial site characterization to background chemical concentrations. If concentrations are lower than background values, no further action is necessary. Unfortunately, background concentrations of certain chemicals may pose some risk to seafood consumers based on calculations by DOH (see DOH, 1995). Such sediment chemical concentrations may require a public health advisory even though concentrations are less than background area concentrations.

Next, site-specific sediment chemical concentrations which exceed background concentrations are compared to Tier I health-based SQC. Tier I SQC were calculated for Group 1 and Group 2 Puget Sound chemicals of concern (DOH, 1995). Tier I provides numeric SQC for chemicals with an oral RfD or CPF human toxicity value. Chemicals lacking a RfD or CPF but detected in sediments may be evaluated as part of Tier II where a toxicological review would be necessary.

Sites with sediment chemical concentrations below Tier I SQC values require no regulatory action for protection of human health. If chemical concentrations exceed Tier I SQC, resulting options include: (1) regulatory actions to address potential human health impacts posed by contaminated sediments, or (2) site-specific evaluation under Tier II. Regulatory actions include reduction of point source discharges and remediation of contaminated sediments. Also, Tier I SQC can be used to make management decisions for dredged material. Male (1991) discusses implementation of the Tier I regulatory structure to specific applications. Chemicals which exceed background concentrations and are Group 3 chemicals of concern (which by definition do not have SQC under Tier I) require evaluation under Tier II.

4.0 CALCULATION OF SQC

Human health SQC values for carcinogenic and non-carcinogenic chemicals are calculated using modified EPA risk assessment equations (DOH, 1995; EPA, 1993a). Equations used to calculate SQC for carcinogens and non-carcinogens follow.

Equation parameters include chemical-specific human toxicity values (CPF and RfD), risk (R), and human exposure through ingestion of aquatic biota [IF, averaging time (AT), body weight (BW), and exposure duration (ED)] (Equations 1 and 2). IF differs slightly from EPA's definition in that IF is normalized to fish tissue lipid (see discussion of IF, below). BSAF, which relates a fish tissue chemical concentration to a sediment chemical concentration, is included in the calculation. Tier I SQC are limited to chemicals having RfD and/or CPF values.

For carcinogens: (1)

$$SQC = \frac{RxBWxATxUCF}{CPFxBSAFxIFxED}$$

For non-carcinogens: (2)

$$SQC = \frac{RfDxBWxATxUCF}{BSAFxIFxED}$$

Where:

SQC	=	organic carbon-normalized sediment chemical concentration (ug chemical/kg organic carbon)
R	=	selected risk level (unitless)
RfD	=	oral reference dose for a chemical (mg/kg/day)
BW	=	typical body weight of a population (kg)
AT	=	averaging time (years)
UCF	=	unit conversion factor
CPF	=	cancer potency factor for a chemical $(mg/kg/day)^{-1}$
IF	=	lipid-normalized seafood ingestion frequency (g lipid/day)
ED	=	exposure duration (year)
BSAF	=	biota-sediment accumulation factor for a chemical (ug chemical/gm fish lipid per ug chemical/gram sediment organic carbon)

5.0 TIER II FRAMEWORK

DOH has developed a general framework for conducting Tier II site-specific sediment chemical contamination evaluations (Figure 2). Tier II evaluations may be initiated when Tier I SQC are exceeded for one or more chemicals at a site or when the health significance of a chemical lacking a CPF or RfD value is evaluated. Regulators or the regulated community (with Ecology's approval) may choose to conduct a site-specific Tier II assessment rather than proceed with sediment remediation based on Tier I SQC.

Tier II SQC assessments are relevant to sediment quality decision-making and regulatory enforcement activities. Such activities include identification of contaminated sediments, management of dredged materials, establishment of cleanup levels, and assessment of source controls.

Regulatory precedent for the use of a second tier evaluation methodology is contained in WAC 173-460. Although this code pertains to air emissions, similarities in regulatory structure exist between programs. Sources discharging air pollutant concentrations in excess of established criteria may be allowed to conduct a Tier II analysis to demonstrate that human health is not adversely impacted. The burden of proof that human health will not be adversely impacted from a specific environmental discharge or combined discharges rests with the regulated community. Under WAC 173-460, Tier II evaluations are intended to allow for incorporation of new scientific information, including chemical-specific toxicological data.

Tier II assessments allow for incorporation of site-specific data or new scientific information. Parameter values in the Tier II SQC for risk, body weight, exposure duration/averaging time, chemical toxicity, ingestion frequency/fish lipid, and biota-sediment accumulation factor may be changed from Tier I default values to reflect localized conditions in Puget Sound. In the following sections, SQC parameters are described along with recommendations for changing Tier I default values. Alternative values incorporated into site-specific Tier II evaluations must be scientifically defensible to ensure protection of public health from contaminated sediments.

Site-specific parameters and values selected for incorporation into the calculation of Tier II SQC may vary between assessments. This may be due to specific needs or conditions which exist for a particular site or to the relative ease of collecting site-specific data for one parameter over that of another. Because Tier II is intended to be flexible with regard to incorporation of newly collected or published scientific data, applicants may choose (with Ecology's approval) which data to collect and incorporate into their Tier II evaluation.

In addition to incorporation of site-specific SQC equation parameters, further collection and chemical analyses of sediment samples may be appropriate for sites where data used in the Tier I evaluation are no longer representative due to changes in sediment chemistry. Collection of additional site-specific sediment chemistry data may be justified to supplement older data, to allow for current characterization of sediments undergoing natural recovery, to allow for further characterization of contaminated sediment site boundaries, or to consider reduced or increased point source discharges. Quality control measures are needed to guarantee that sediment chemistry data reflect current (as defined by Ecology) sediment chemical contamination levels. Sediment chemistry data collected as part of a Tier II evaluation should include locations sampled for the Tier I evaluation to allow for direct comparison of sediment chemical concentrations over time. All sediment chemistry data should adhere to Puget Sound Estuary Program (PSEP) data quality guidelines and be reviewed by Ecology for completeness.

The applicant incorporates site-specific and chemical-specific parameter values into the calculation of SQC for carcinogens and non-carcinogens (equation 1 or 2, respectively). The rationale for selection of particular site-specific values should be thoroughly documented and should include supporting scientific studies. The completed Tier II application is submitted with all supporting documentation to Ecology for review by a scientific advisory committee. If the Tier II application fails this review, Ecology returns the application to the applicant with comments detailing shortcomings or errors. If the Tier II application passes committee review, Tier II assessment can continue (Figure 2).

To ensure that cleanup levels are above background sediment contaminant levels, Tier II SQC are compared to known background levels for Puget Sound (DOH, 1995). If Tier II SQC are greater than background levels, Tier II SQC are used as the regulatory value. If background levels are greater than Tier II SQC, background levels are used for regulation. After determining the appropriate regulatory value, site-specific sediment chemical concentrations are compared to the value to determine if further sediment remedial action is necessary. Sites with sediment chemical concentrations below Tier II SQC require no remedial action, while sites with sediment contaminant concentrations which exceed the SQC may require remedial action.

6.0 REVIEW OF SQC

Site- and chemical-specific parameter values used to calculate Tier II SQC as well as resulting Tier II SQC values should be reviewed for scientific validity by a science advisory committee convened by Ecology. A primary consideration of the committee will be the suitability of each parameter value to the site and chemical in question. Review of Tier II SQC and equation parameters should be conducted in a timely manner. DOH recommends that the committee be comprised of representatives from DOH, Ecology, and other appropriate agencies such as Washington State Department of Fish and Wildlife and EPA. Such a committee should be independent in nature, have the technical knowledge or background needed to address sediment related issues, and base discussions on scientific merit of the information provided. Comments and conclusions of the committee should be provided to Ecology and the applicant.

7.0 SQC EQUATION PARAMETERS

For Tier I, DOH chose default SQC parameters known to be protective of a highly exposed population (Table 1). For Tier II, DOH presents the option to change these default parameters to reflect site-specific conditions using localized data. Resulting SQC values will predict sediment concentrations that are protective of consumers of seafood from or affected by that site. The following discussions focus on the use of alternative parameter values in the calculation of human health-based SQC for Tier II. These parameters include: (1) risk, (2) body weight, (3) exposure duration/averaging time, (4) cancer potency factor/reference dose, (5) ingestion frequency, (6) fish lipid, and (7) biota-sediment accumulation factor. In each section, values used to calculate Tier I SQC are reviewed and options for changing each parameter to incorporate site-specific data for Tier II are discussed.

Unit conversion factors (UCF) convert milligram (mg) chemical contaminant to micrograms (ug) chemical contaminant and gram (g) lipid to kilogram (kg) lipid. These factors are necessary to express the final SQC in terms of mg chemical contaminant per kg organic carbon (ppb) and cannot be altered for Tier II SQC calculations.

Table 1. Parameter Values Used To Calculate Tier I SQC. (CPF, RfD, and BSAF values are chemical-specific and are not included.)

Parameter		Value	Units	Source
Risk (R)		10^{-6}	unitless	EPA, 1993b
Body Weight (BW)	(adult)	70	kg	"
	(child)	15	kg	"
Averaging Time (AT)		70	years	"
Ingestion Frequency (IF):				
	(fish, distribution)*	26.1	grams/day	DOH, 1995
	(fish, point)	95.1	grams/day	"
	(shellfish, point)	8.58	grams/day	"
Exposure Duration (ED)		30	years	EPA, 1993b
Fish Lipid (FL)		3.5	percent	DOH, 1995

* For use with a distributional analysis.

7.1 RISK

Risk represents the theoretical probability of developing cancer from exposure to a particular chemical in a given population. "For carcinogens, risks are estimated as the incremental probability of an individual developing cancer over a lifetime as a result of exposure to the potential carcinogen" (EPA, 1989). Carcinogenic risk is an upper-bound estimate while an individual's actual risk is likely to be less than that predicted. For non-carcinogens, a probabilistic approach is not used in order to be consistent with EPA methodology.

Risk is calculated by multiplying the CPF by the chronic daily dose of a chemical. Use of risk in the SQC equation is associated with the assessment of chemicals having CPF values; i.e., chemicals known or suspected of producing cancer. Levels of risk accepted by agencies vary between agencies and between programs within agencies (e.g., EPA, Ecology). For Tier I SQC, a risk of 1×10^{-6} was recommended by DOH, a value which is generally considered *de minimis* (defined as a level of risk below which no threat is assumed).

For Tier II assessments, less stringent risk levels may be acceptable based on site and regulatory considerations. Such considerations may include the need for mixing zones for industrial or urban discharges that allow for increased localized risk. Unconfined disposal of contaminated dredged material may also require a range of risk levels to establish less stringent SQCs for industrial areas based on Ecology's need for political flexibility. Other issues related to setting risk levels include cost, technical feasibility, and public acceptability. Cost and technical issues may dictate the need for a mixing zone (i.e., a dilutional zone around a point source discharge which results in decreased sediment chemical concentrations with distance from the source). Lowering risk levels will increase resulting SQC, with less protective concentrations closest to the point of discharge. Finally, public concerns should be considered when selecting alternative risk levels.

Each incremental change in risk level (typically by one order-of-magnitude) will result in an order-of-magnitude change in the SQC. The impact of changes in the risk parameter on resulting SQC values is great relative to other calculation parameters. The selection and implementation of a specific risk level is not a scientific decision; therefore selection of a specific risk level for Tier II SQC requires careful policy consideration. For Tier II, DOH recommends use of risk values consistent with federal and state regulatory programs.

7.2 Body Weight

Body weight (BW) is used in risk assessments to calculate exposure on a per kilogram basis (i.e., a daily dose). By convention, assessors use a constant body weight over the period of exposure. The default body weight used in risk assessments for men is 78 kg and for women is 65 kg (EPA, 1993a). The default value for children less than six years old is 14.5 kg. EPA recommends that 70 kg be used to assess exposure for the general adult population in the United States. This value reflects the average combined body weight of adult men and women ages 18 to 75 years old (rounded to 70 kg) based on data collected by the National Center for Health Statistics between February 1976 and February 1980 (EPA, 1989). If exposure occurs during childhood, EPA recommends use of an average childhood body weight during the exposure period. Alternatively, doses can be calculated separately for specific age groups based on average group weight.

BW values other than 70 kg are justified when a chemical is of greater toxicity to a specific segment of the general population (e.g., women or young children) or for sub-populations culturally predisposed to greater exposure (e.g., Native Americans). Such populations may have average body weights different from the average weight of the general population. An example of population-specific body weight data is seen in a seafood consumption study of the Tulalip and Squaxin Tribes (Toy et al., 1995). Mean body weights of male, female, and child tribal members were 88.6 kg (SD=16.6), 72.2 kg (SD=17.3), and 15 kg (SD=5.1), respectively.

For the calculation of Tier I SQC, a BW of 70 kg was assumed for adults and a BW of 15 kg was assumed for children. Increased body weight values result in a reduction in calculated human chemical dose and an increase in the resulting SQC. Conversely, a reduction in the default body weight value results in an increased dose (assuming that seafood consumption remains constant), with the net result a reduced SQC value. Use of body weights other than default values are justified as discussed above; however, differences in average body weights from one ethnic group to another (or from a subgroup within the general population) are not likely to result in significant changes in resulting SQC. For Tier II, DOH recommends that the default BW of 70 kg be used for adults and 15 kg for children, unless average body weight data for local fishers or for sensitive subpopulations are available for the site in question.

7.3 EXPOSURE DURATION AND AVERAGING TIME

Exposure duration (ED) and averaging time (AT) are related parameters in the calculation of human exposure. "The exposure duration is the time period over which an individual is exposed to one or more contaminants. In the case of an individual fisher, the exposure duration is equivalent to the time interval over which he or she catches and consumes fish (EPA, 1994)." AT is the time period of concern chosen for use in exposure assessments. For Tier I, DOH calculated SQC using an ED of 30 years and an AT of 70 years (DOH, 1995). The ED value represents the ninetieth percentile number of years an individual lives in a particular home, based on the cumulative distribution of data from 18,825 owner occupied residences (EPA, 1989). An individual's length of residency at a particular location is assumed to be synonymous with catch and consumption of fish from that location. In Tier I, DOH incorporated 70 years as the default value for AT to be consistent with other agencies.

Life expectancy is another measure of individual ED. The average life expectancies for males and females in Washington State are 74 and 80 years, respectively, with a combined mean life expectancy of 77 years (DOH, 1994). Use of life expectancy values as an measure of ED may be justified for Native Americans who live near Puget Sound. Tribal members within Washington State typically reside on reservations for their lifetime and consume locally-caught fish and shellfish for subsistence purposes. Current treaty rights allow Native Americans to harvest fish and shellfish at most locations in Puget Sound. Given the cultural significance of fish consumption, a Puget Sound tribal member may consume local fish and shellfish over his or her lifetime. Therefore, use of the mean human life expectancy value for Washington citizens (77 years instead of the Tier I default value of 30 years) may be justified for ED, given tribal member cultural habits and dependence on local seafood. Additionally, use of life expectancy values (i.e., 77 years) may be appropriate for members of the general population who change residences frequently but remain in the same general region.

Although an individual may consume local fish for most of his or her life, his or her fish consumption rate may not be constant over this entire period. Periods in which fish are consumed during one's exposure duration must be averaged with periods in which no fish are consumed to estimate exposure and to account for health effects from chronic and short-term exposures (e.g., cancer and reproductive or developmental effects). An AT of 70 years was assumed in the calculation of Tier I SQC. As stated in *Risk Assessment Guidance For Superfund* (EPA, 1989): "The AT selected depends on the type of toxic effect being assessed. When evaluating exposures to developmental toxicants, intakes are calculated by averaging over the exposure event (e.g., a day or a single exposure incident). For acute toxicants, intakes are calculated by averaging over the shortest exposure period that could produce an effect, usually an exposure event or a day. When evaluating longer-term exposure to non-carcinogenic toxicants, intakes are calculated by averaging intakes over the period of exposure." Use of an AT of 70 years assumes a constant rate of fish consumption over one's lifetime and does not account for chemical-specific acute toxicity.

Another consideration is that AT must be based in the same terms as the toxicity value (CPF or RfD). For example, one must use average lifetime exposure to calculate a SQC for a carcinogen. To calculate a SQC for a non-carcinogen with shorter exposure duration, one must use subchronic or shorter-term toxicity values to evaluate short-term exposures. In some cases, potential non-carcinogenic effects are based on lifetime exposures. In other words, the AT for SQC calculations for a chemical for Tier II should match the exposure duration used in that particular chemical's toxicity assessment.

Alterations in ED and AT have differing effects on resulting SQC. Increases in ED result in decreases in resulting SQC; decreased SQC are more protective of human health. Increases in AT result in increases in resulting SQC; increased SQC are less protective of human health. For Tier II, alterations in ED and AT values from typical default values may be justified. Since Puget Sound tribal members have access to most locations in Puget Sound, values for ED and AT reflective of lifetime exposure (e.g., 77 years for both ED and AT) should be considered. Additionally, averaging times reflective of chemical-specific acute toxicity should be incorporated when appropriate.

7.4 Carcinogenic Potency Factor and Reference Dose

A chemical's toxicological potency is measured from a dose-response relationship. Toxicological potency indices have been developed for two broad classifications of chemicals: those which are known or suspected to produce cancers, and those that result in non-cancerous effects. Resulting indices are defined as follows:

- "Carcinogens are each characterized by a CPF, a measure of the cancer-causing potential of a substance estimated by the upper ninety-fifth percent confidence limit of the slope of a straight line calculated by the linearized multistage model or another appropriate model" (EPA, 1994a). Cancer risk estimates are intended to be protective but are not predictive of specific cancer incidence (EPA, 1994a). Cancer risk is assumed to be proportional to cumulative exposure and, at low exposures, may be very small or even zero.

- "Non-carcinogens are each characterized by a RfD value, the highest average daily exposure over a lifetime that would not be expected to produce adverse effects" (EPA, 1986). A RfD is "an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime" (EPA, 1994a). However, all doses below the RfD are not necessarily risk-free and all doses in excess of the RfD will not result in harm (EPA, 1993c). RfDs reflect the assumption that a chronic exposure threshold exists below which adverse health effects are unlikely due to homeostatic, compensating, adaptive, or other protective mechanisms. Assessments based on RfDs do not involve calculation of risk.

In the development of Tier I SQC, DOH used oral RfD and CPF values from EPA's Integrated Risk Information System (IRIS) database (December, 1994) and Health Effects Assessment Summary Tables (HEAST) (FY - 1994). Approximately, one third of the over 200 chemicals of concern identified in Tier I had an RfD or CPF value from these sources (Table 2) (DOH, 1995). Chemicals lacking an RfD or CPF value were listed separately and identified as "Group 3" chemicals of concern, for which no SQC were proposed (Table 3).

For the development of Tier II SQC, current CPF and RfD values or new scientific information on toxicological dose-response may be considered. New information on toxicological characteristics of pollutants may be used to justify modifications of the CPF or RfD if DOH and/or Ecology determines there is compelling scientific data which demonstrates that the use of methods other than those recognized or approved by EPA are appropriate. Other sources of toxicity data include Agency for Toxic Substances and Disease Registry (ATSDR) chemical-specific toxicity profiles and toxicological reports presented in peer-reviewed journals. Use of alternative data sources may allow incorporation of recent scientific information in assessments of chemical-specific toxicity. Additionally, this use allows for the development of SQC for chemicals which may not have CPF or RfD values.

Consideration of additional toxicity data for chemicals which have CPF or RfD values requires development of a standardized method of investigation and review. A detailed description of a standardized review method is beyond the scope of this document. In general, such a standardized method would include review of all pertinent scientific toxicity studies to revise or establish a human health-based toxicity value for carcinogens or non-carcinogens. More specifically, this would involve identifying multiple cancer studies to establish a dose-response relationship, extrapolating from high to low doses, and determining the cancer risk for carcinogens. For non-carcinogens, this would involve reviewing multiple toxicity studies to determine the most sensitive end-point, establishing a no observable adverse effect level (NOAEL) then extrapolating this level to humans through the use of appropriate safety factors. Independent scientific review of all conclusions is necessary. A considerable number of chemicals of concern to human health concern do not have Tier I SQC due to lack of CPF or RfD values. For these chemicals, use of alternative toxicity data in the development of SQC is an option, provided there is a review process as mentioned above. Alternative toxicity data could be used to develop health criteria similar to RfD or CPF indices which would allow for regulation of additional chemicals under Tier II. Incorporation of other toxicity data may be allowed as part of a Tier II site-specific evaluation or as part of Ecology's criteria review process.

CPF and RfD values incorporate absorption (as an absorption coefficient) in their toxicity values. In general, toxicity values which are developed for carcinogens and non-carcinogens are calculated from critical effect levels based on intake (corresponding to administered doses) rather than absorbed doses. In developing new toxicity values or reviewing current CPF or RfD values, one must compare the new toxicity value to exposure estimates which are expressed as intakes, not as absorbed doses. Adjustments may be necessary to match the exposure estimate with the toxicity value if one is based on an absorbed dose and the other is based on an administered dose.

Absorption of a pollutant is chemical-specific and may be influenced by an individual's age, general health, nutritional status, and the chemical is concentration. Absorption coefficients are used to adjust results of animal toxicity studies to humans as well as to express exposure estimates in terms of either an absorbed dose or an administered dose. When reviewing toxicity data, one can search for an absorption coefficient for a chemically related substance if there is no information on absorption efficiency by the oral route of exposure for the chemical in question. If no absorption coefficient is available for the chemical or for a chemically-related substance, a default value of 100 percent should be used.

7.5 INGESTION FREQUENCY

Human exposure to non-ionic organic chemicals in sediments may result from consumption of contaminated fish or shellfish from Puget Sound. Seafood consumption rate, also known as ingestion frequency (IF), here defined as the rate of consumption of fish or shellfish (grams per day) (g/l/d after lipid normalization; see FL, below). For Tier I, a point value of 95.1 g/day was recommended based on a review of Puget Sound seafood consumption studies (DOH, 1995). Studies included a boat and shore investigation of Commencement Bay (Pierce et al., 1981), an investigation of fish and shellfish from Puget Sound (DOH, 1985), a consumption survey of shore anglers (Landolt et al., 1985) and a survey of boating anglers (Landolt et al., 1987). Data from the above studies were normalized to determine a frequency distribution for the combined dataset (EPA, 1988). The value of 95.1 g/day was the ninety-fifth percentile of median values from this combined dataset and represents the mean value from the 1987 boating study (Landolt et al., 1987). If a distributional analysis was to be used, DOH recommended a value of 26.1 g/day as a median value from a shore consumption study in Puget Sound (fifth percentile = 2.8 g/day, and ninety-fifth percentile = 246.2 g/day)(EPA, 1988).

For Tier II, Tier I default parameter values may be altered to reflect local or site-specific conditions. First, a Tier II consumption rate for a basin containing the specific site may be determined based on literature values. One such study includes data for various fish species from different Puget Sound embayments (Landolt et al., 1985). Secondly, a seafood consumption survey may be conducted for the basin in which the site is found. Such a survey should consider seasonal harvest of fish, shore and boat harvesting, and subpopulation differences in fishing habits and preferences. Third, a consumption rate for a site may be chosen from a comparable basin for use as a surrogate Tier II IF value, given similar habitats and aquatic species in both bays. Finally, the Tier I default value of 95.1 g/day could be incorporated into Tier II.

Unfortunately, several problems are associated with the use of fish consumption rates from a specific contaminated site. First, if a site is highly contaminated, no fish or shellfish may be available from that location and the site-specific consumption rate would be zero. This becomes a "depletion of resource" issue, where the applicant for Tier II SQC must use an IF value that would reflect consumption if there was no contamination at that site. A second issue is that most fish do not live in one location for their entire life history. Fish move around; therefore, a Tier II value for IF must reflect a basin-wide IF rather than a site-specific consumption rate. People may not fish at a contaminated site although fish may be impacted by sediments from that site. A third point associated with the use of current consumption rate information is the problem of data gaps. For example, little is known about fish and invertebrate consumption practices of Asian Pacific Islander populations living near Puget Sound and only recently were data gathered on seafood consumption practices of two Puget Sound Native American tribes. While IF data reflect consumption practices of subgroups of the general population, individuals within specific ethnic populations may consume a greater variety and differing amounts of seafood than available data indicate.

A final problem in determining a representative IF value for a given site is the choice of appropriate seafood species. A given consumption rate may represent one to many species and may or may not include shellfish. The IF value should represent fish species affected by the locality and chemical under question; that is, the consumption rate for the site should represent fish that are caught and consumed from the basin. A complicating issue in consideration of representative fish species is the coexistence of bottomfish with migratory salmonids. Fish such as salmon that spend part of their life in freshwater, part in Puget Sound, and part in the Pacific Ocean may not be directly linked to site-specific contamination. The percentage of a given consumption rate attributed to these fish should be subtracted from the total consumption rate to determine a Tier II site-specific IF value because the Tier II process does not look at total exposure pathways to the consumer but attempts to attribute potential exposure from a specific location. Furthermore, the IF value chosen for the basin in which the Tier II evaluation is being conducted should consider metabolism of the chemical contaminant, which may be related to fish or shellfish species. For example, a comparison of a SQC based on fish consumption rates and a SQC based on shellfish consumption rates should be conducted for certain chemicals such as polycyclic aromatic hydrocarbons (PAHs) since shellfish metabolize these chemicals much slower than fish. The more restrictive value should be used in the regulatory setting.

DOH recommends the use of a basin-wide consumption rate for fish or shellfish species, whichever results in the more restrictive Tier II SQC. Anadromous fish consumption rates should be subtracted from total consumption values to determine an IF for calculation of a site-specific Tier II SQC value. The consumption rate should incorporate the most recent IF data (from the literature or from a new survey) and should consider subpopulation consumption patterns whenever possible. If no data are available for the site in question, no similar embayments have comparable consumption values, and no consumption study is planned, Tier I default values should be used to calculate Tier II SQC.

7.6 FISH LIPID

Partitioning of non-ionic organic compounds in fish tissue and water is highly correlated with fish lipid (FL) content. The greater the lipid content, the greater the capacity of fish tissue to bind non-ionic organic compounds. To compare non-ionic organic concentrations in different fish species and between sites, fish tissue concentrations should be normalized to FL. Because FL concentrations vary by age and season within and between species, one must normalize IF to fish lipid to calculate comparable SQC standards. Among species, lipid concentrations can range from less than one percent up to 20 percent. Furthermore, lipid content changes seasonally for each species, over an individual's lifetime, and by sex. Also, diet, which may be dependent on habitat, is a factor in fish lipid variability. Thus, sample design for collection of fish tissue and determination of lipid concentration should account for these elements.

For calculation of Tier I SQC, FL values for eight of the most commonly consumed Puget Sound fish species were used to normalize fish tissue for a weighted-average Tier I fish lipid consumption rate (IF). These eight species were Pacific cod, tomcod, Pacific hake, walleye pollock, English sole, starry flounder, sablefish, and squid (Landolt et al., 1985). The resulting weighted-average lipid concentration for fish muscle tissue was 3.5 percent. This weighted average was used to calculate a lipid-normalized IF for fish consumed from Puget Sound.

FL values for calculation of Tier II SQC depend on the fish species chosen to calculate ingestion frequency (see IF, above). Ingestion frequency must be normalized to FL to result in units of g/l/day and in SQC values in units of mg/kg organic carbon. FL should represent a weighted average lipid value for those fish species used to calculate ingestion frequency for the Tier II site in question. Lipid analysis must be determined using an accepted analytical protocol consistent with other Ecology programs. Development of a sampling protocol for lipid should take into consideration season, sex, and age of fish, all of which influence lipid concentrations. In conclusion, DOH recommends that Tier II SQC FL values be determined from local fish species caught within the biogeographical area impacted by the site being evaluated.

7.7 BIOTA-SEDIMENT ACCUMULATION FACTOR (BSAF)

Background - The biota-sediment accumulation factor (BSAF) is a partition coefficient describing the distribution of a chemical between an organism and sediment. BSAF values indicate the extent to which contaminants in sediments bioaccumulate and biomagnify through the foodweb. Within the Tier I framework, empirical BSAF data from a variety of fish species and chemicals are used to calculate surrogate BSAF values. Next, a surrogate BSAF value for each chemical along with the chemical's CPF or RfD value is used in equations 1 and 2 to calculate a SQC for a given carcinogen or non-carcinogen.

Tier I empirical BSAF values are derived from a variety of fish species collected from several geographical areas for numerous of non-ionic organic chemicals in the United States. Because this empirical dataset is based on various species from many geographical areas, these BSAF values are generic in nature; however, BSAF values can be refined using site-specific information. Site-specific BSAF values will reduce uncertainty associated with generic BSAF values, because BSAF values can be influenced by a variety of biological, chemical and physical parameters, and are therefore species-, chemical-, and site-specific.

BSAF Values in Tier I - In Tier I, DOH relied on empirical BSAF values gathered from published and gray literature to calculate SQC values (DOH, 1995). Several large databases of BSAF values were identified, including Parkerton (1991), COBIAA (1992), and EPA's Great Lakes Water Quality Initiative (EPA, 1994b). In total, over 6,000 individual BSAF data points were obtained. These data represented numerous chemicals and aquatic species from various habitats. A combined database of BSAF values was organized to allow the user to query for parameters such as chemical, species, and chemical log K_{ow}. From this collated database, DOH identified over 1,200 BSAF values representing upper trophic level fish species.

For Tier I, the following options were outlined for deriving BSAF values: (1) K_{ow} values, (2) chemical class and K_{ow} values, and (3) chemical-specific data. At the time the Tier I report was published, empirical data were sufficient to derive BSAF values based on the first two options only because chemical-specific BSAF values were available for few non-ionic organic chemicals.

For Tier I, DOH relied on surrogate BSAF values derived from empirical BSAF data using option number 2: categorizing BSAF values by chemical class and log K_{ow}. A surrogate BSAF value was then chosen for any non-ionic organic chemical with a known log K_{ow} by matching that chemical's log K_{ow} to the range of log K_{ow}s from empirical data. The assigned BSAF served as a surrogate BSAF for that chemical or any other non-ionic organic chemical having a log K_{ow} within that range and chemical class. Accordingly, surrogate BSAF values along with a chemical's CPF or RfD value were substituted into the SQC equation to calculate SQC for carcinogens or non-carcinogens.

A third option identified in the Tier I report but not adopted relies on the use of chemical-specific empirical BSAF data to derive a BSAF value for that chemical rather than on the use of a surrogate BSAF value. This approach is more accurate because it relies on chemical-specific information to estimate a BSAF. Uncertainties in this approach can be reduced further by segregating empirical BSAF data by species as well as by relying on data from the geographical area in question. Combining chemical-, species-, and site-specific empirical BSAF data will result in the most accurate BSAF value of all. This option is the basis for the Tier II approach outlined below, which incorporates site-specific information to calculate the bioaccumulation potential of a chemical into aquatic organisms from a given location.

BSAF Values in Tier II - The goal of Tier II is to reduce uncertainties associated with default parameters used to calculate SQC values in Tier I by replacing them with site-specific data, including BSAF values. Incorporating Puget Sound site-specific BSAF values into Tier II will help meet this goal.

DOH outlines two approaches for deriving site-specific BSAF values for Tier II analysis. These approaches are based on:

- Field data used to calculate an empirical BSAF value, and
- Models which can be used to predict bioaccumulation potential.

Empirical BSAF Values - Calculation of Tier II chemical- and site-specific empirical BSAF values requires four parameters:

- Fish (or shellfish) tissue chemical concentration,
- Fish (or shellfish) tissue lipid concentration,
- Sediment chemical concentration, and
- Sediment total organic carbon concentration (TOC).

BSAF values are calculated from empirical data based on the following formula:

$$\text{empirical BSAF} = \frac{\text{fish tissue chemical concentration} / \text{fish tissue lipid concentration}}{\text{sediment chemical concentration} / \text{sediment total organic carbon concentration}}$$

To derive site-specific BSAF values, fish or shellfish chemical concentrations must be matched with each organism's tissue lipid concentration to allow for accurate lipid normalization. Sediment chemical samples should also be matched with TOC concentrations taken from the same sample to normalize sediment chemical concentrations to TOC. In lieu of paired lipid and TOC data, average lipid concentrations or sediment TOC levels may be calculated based on an average fish lipid or sediment TOC concentration collected from a given location. Average fish or shellfish lipid concentrations must be from the same species, while sediment TOC concentrations may be averaged over an area, providing an adequate number of samples are taken. The number of samples must be determined by a statistician during the Tier II process.

In addition to the four parameters mentioned above that are used to calculate an empirical BSAF value, other considerations may influence the quality and specificity of data. Such factors include:

- Chemicals,
- Fish species,
- Tissue type, and
- Sediment sampling size and location.

Chemicals - Site-specific BSAF values can be determined for chemicals whose sediment concentrations exceed Tier I SQC standards (Table 2). Chemicals in these two groups have EPA's CPF or RfD values. Furthermore, chemicals lacking CPF or RfD values that are likely candidates for Tier II analysis include, but are not limited to, chemicals listed as Group 3 chemicals of concern (Table 3).

Fish Species - A variety of upper trophic level fish species were listed in national databases used in Tier I to derive BSAF values. Due to the inclusion of many species with a wide range of habitats, these fish may not best represent Puget Sound conditions for Tier II. To reduce uncertainty related to use of non-native species, DOH recommends the use of fish from Puget Sound to derive empirical BSAF values for Tier II. To further increase accuracy of calculating a site-specific SQC value, species selection should be based on the fish species that anglers are catching and consuming from the area under investigation. Ecology should check with Washington State Department of Fish and Wildlife for recent creel surveys which are conducted annually to determine local catch. Species selected could be a single fish or shellfish species or a combination of species.

In addition to species presently caught and consumed, it may be necessary to include fish and shellfish species which once inhabited an area. Species may no longer occupy a given area as a result of direct toxic effects of sediment chemical contamination or may avoid a contaminated area based on indirect factors such as loss of habitat or prey items. Such circumstances warrant the use of empirical BSAF values for species taken from locations with lower sediment contamination within Puget Sound with similar physical characteristics (e.g., salinity, sediment type, slope, current, and wave action) and similar food web structure (e.g., neritic, rocky/kelp bed, sublittoral, rocky littoral, cobble/littoral, shallow sublittoral zones of gravel-cobble, sand-gravel/eelgrass, and mud/eelgrass habitats). Because an empirically-derived BSAF is the ratio of chemical in tissue (lipid-normalized) to chemical in sediment (organic carbon-normalized), the ratio between the two media should remain the same regardless of the actual amount of sediment contamination. This would allow an empirically-derived BSAF value from one site to be used for the contaminated area, given that each area has similar physical and biological characteristics.

Tissue Type - Choice of appropriate fish tissue is important to determine an empirical BSAF. One should chemically analyze the portion of fish or shellfish actually consumed by the population in question, as determined from literature values or from new consumption studies (see IF, above). Tier I BSAF values are based on fillet data. Tier II fish tissue samples may be either fillet or whole body samples depending on what people are consuming from a site. Whole body sampling is likely to result in slightly higher empirical BSAF values than muscle tissue alone due to higher concentrations of fat in tissues and organs relative to muscle tissue in most fish. Ideally, fish tissue samples should be taken over time to account for seasonal or age-related variations in lipid and chemical concentrations.

Species-specific lipid concentrations should be used to normalize fish tissue data. Lipid normalization can be conducted for a given site based on consumed fish species. Individual fish tissue normalization is preferred over averaging from composite samples. Furthermore, joint analyses should be conducted at the time fish are sampled so that tissue chemical and lipid concentrations can be matched.

Sediment Sample Size and Location - Sample area size and location must also be considered to determine a site-specific BSAF. Regulators must define the smallest area that can constitute a potential human health threat. Regulators can take several options, such as: (1) including or excluding "hot spots," (2) averaging samples over time and space, (3) weighted-averaging of samples, or (4) looking at whole watersheds. Ecology will need to investigate these approaches. Regulatory action may vary depending on what chemical is present and on its concentration. The above options allow flexibility for the regulatory and regulated community when applying SQC values to a site.

Sediment samples should be based on data taken over time to ensure that an average concentration is used rather than a low or high single point value. TOC concentrations should be taken at the same time and location as sediment chemical concentrations to insure appropriate TOC normalization. Sampling techniques and sample size should follow PSEP sampling protocols (PSEP, 1990).

Model-Derived BSAF Values - An alternative approach to the use of Puget Sound empirical BSAF data for Tier II analysis is the derivation of BSAF values from bioaccumulation models. Such models are used to predict bioaccumulation potential of a chemical from sediments to aquatic organisms. If parameters are available, bioaccumulation models are a cost-effective alternative that allows prediction of fish tissue or sediment concentrations when field data are unavailable to derive empirical BSAF values.

Two general types of bioaccumulation models have been developed and are referred to as either equilibrium-based or kinetic-based models (Lee, 1992). As the name implies, equilibrium-based models assume steady-state environmental, physical, and chemical conditions. Under this category are the bioaccumulation factor (BAF) model and the equilibrium partitioning bioaccumulation model. In contrast, kinetic models describe bioaccumulation as the net effect of various chemical and biological rate processes. This type of model includes kinetic process models and bioenergetics-based toxicokinetic models.

Currently, neither DOH nor EPA has endorsed one model over another. The success of using a model is in the model's ability to predict fish-tissue or sediment chemical concentrations. Regardless of model type, accurate input parameters used to calculate BSAF values are necessary. Input parameters should be site-, chemical- and species-specific. Furthermore, some models require incorporation of food-web information which greatly expands input parameter requirements.

Model-derived BSAF values must be validated by comparison with empirical site-specific fish tissue and sediment chemical data. Predicted BSAF values calculated from models should be within an order of magnitude (ideally, within two-fold) of BSAF values determined empirically.

Previously, DOH documented the use of a bioenergetics bioaccumulation model (Thomann et al., 1992) to derive model-based BSAF values for use in developing SQC values (DOH, 1993). DOH discontinued this effort for two reasons: (1) a lack of species and foodweb specific input parameters required for the model, and (2) a lack of site-specific data needed for model validation. If input parameters (approximately 72 or more different values, see Draft Tier I Report, DOH 1993) were available and if the models could be validated by site-specific data (such as TOC-normalized sediment concentrations and lipid-normalized fish tissue chemical concentrations), predictive bioaccumulation models would be a valuable, flexible, and cost-effective alternative to the use of Puget Sound empirical BSAF values.

BSAF Recommendations - The purpose of developing Tier II SQC values is to reduce uncertainties associated with the use of default parameters used to calculate Tier I SQC values by using site-specific information. Accordingly, uncertainties involving BSAF values may be reduced by applying site-specific data to calculate Tier II BSAF values.

DOH recommends that Tier II BSAF values be calculated based on Puget Sound sediment and fish or shellfish data. Such data considerations include:

- Which fish and shellfish species are caught and consumed from the area under investigation,
- Whether empirical BSAF data are segregated by fish or shellfish species,
- Whether fillet or whole body samples are needed (based on consumption patterns),
- The use of chemical-specific information for sediment and tissue data,
- Whether empirical BSAF data are site-specific,
- Matching of empirically-derived site-specific BSAF values for fish or shellfish with the organism's tissue lipid concentration, and
- Matching of sediment chemical samples with TOC concentrations taken from the same sample.

8.0 USE OF FISH TISSUE CHEMICAL DATA

The ultimate goal of the Tier I, Tier II process is to establish sediment chemical concentrations which will not result in accumulation of contamination in fish or shellfish to levels harmful to people. The use of fish tissue data alone from a contaminated site does not allow for quantification of acceptable sediment chemical contamination. Empirical fish tissue data are not recommended for regulating sediments because sediment chemical contamination can result in alterations in the natural biodiversity of benthic communities and fish populations within an area, impacting the food web by reduction of fish populations. Many organic chemicals found in sediments also impact fish and shellfish reproductive success. Additionally, some fish species simply avoid areas of high chemical contamination. Finally, if a safe tissue level is determined for a chemical, calculation of the appropriate sediment cleanup level is not possible without linking fish tissue values with sediment concentrations.

Another barrier to basing decisions only on fish tissue is that territory size varies for different fish species and may be limited to a few square meters or encompass large areas of Puget Sound. Since some fish species roam extensively, it is difficult to attribute tissue chemical concentrations to specific sediment contamination from a particular location. As a result, the use of empirically-measured fish tissue chemical concentrations as a direct indicator of acceptable sediment chemical concentrations could result in false conclusions regarding acceptability of sediment chemical concentrations and the protection of human health. For example, cleanup decisions based on fish tissue contaminant data could result in failure to identify the need for cleanup of smaller highly contaminated areas (i.e., "hot spots") due to the averaging effect of tissue contaminant accumulation. In another example, if a safe tissue level is sampled from an area, one cannot assume that fish will not become contaminated in the future due to the length of time required for sediment and fish tissue chemical concentrations to equilibrate.

It has been mentioned that BSAF values rely on fish tissue data. BSAF values also rely on sediment data, which together with fish tissue concentrations establish a link to reflect chemical partitioning. Without this link, fish tissue data cannot be used to regulate sediments. Again, fish tissue concentrations alone do not provide the link with sediments necessary for regulatory action, given the goal of establishing sediment chemical concentrations protective of human health.

9.0 OTHER ISSUES

Multiple Chemicals - Tier I and Tier II analyses of contaminated sediments do not consider regulatory implications of multiple chemical impacts on human health. The Tier I/II approach regulates on a chemical-by-chemical basis and does not consider additive, antagonistic, or synergistic effects of multiple chemicals. Due to the complex nature of chemical interactions, current regulatory actions do not address multiple chemicals in sediments. If scientific information becomes available to simultaneously address multiple chemicals, it should be incorporated into the Tier I/II process.

Metals and Ionic Organic Contaminants - SQC for Tier I and Tier II are applicable to non-ionic organic chemicals. Metals and ionic organic contaminants will be considered as scientific information becomes available and technology advances. Use of BSAFs does not account for partitioning of these chemicals; thus development of SQCs for metals and ionic organic contaminants is reserved for the future.

Distributional Analysis - DOH does not incorporate the use of distributional analyses such as Monte Carlo for parameters incorporated into Tier II calculations. Certain biological parameters used in the SQC equation which are known to have reliable data from which to derive a distribution may lend themselves to such an approach. Those with no known or scientifically defensible distributions (i.e., risk, CPF, or RfD) are not recommended for distributional analysis.

Caged Fish Studies - The use of caged fish or shellfish studies to determine BSAF was discussed in relation to Tier II SQC development. In theory, bioassays incorporating local fish species that are held over, in, or near specific contaminated sediment sites would seem an appropriate tool to determine bioaccumulation. DOH believes that too many problems exist with current technology to recommend this approach. For example, it is difficult to determine when a chemical is in equilibrium with sediment and fish or shellfish tissue; equilibrium could take up to a year or longer to occur. Again, it is difficult to keep animals alive *in situ* for the length of time necessary to determine an accurate BSAF value. Other concerns include the difficulty in differentiating between chemical uptake from the water column and chemical uptake from sediments, choice of an appropriate organism (i.e., mussel accumulation reflects water column not sediment pollution), problems inherent with any field experiment, and cost.

10.0 DISCUSSION

Sediments are a major sink for organic chemicals in the aquatic environment. Since contaminants bioaccumulate from sediments to benthic organisms and subsequently transfer through the food web to higher trophic level organisms, development of human health criteria for contaminated sediments was deemed necessary to protect people who eat seafood from Puget Sound. Regulators saw the need for an objective method to characterize sediment chemical contaminants to be used in cleanup, disposal of dredged material, and assessment of source controls. National and state governments initiated efforts to develop sediment criteria standards in the mid-1980s. The approach by DOH in developing human health criteria for contaminated sediments is believed to be the first large-scale effort (i.e., over a hundred chemicals of concern) in the country to be completed.

Currently, other government agencies in the United States are working to develop human health-based SQC. Concerns over sediment contamination by mercury and PCBs, among other chemicals, has stimulated an effort to develop SQC by EPA Region 5 (Great Lakes Region). Their approach recommends the use of empirical BSAFs as the most reliable predictor of sediment contamination uptake by fish. New York, California, and Florida have also begun development of SQC.

In Washington State, Ecology promulgated sediment management standards (SMS) for the state under WAC 173-204 in March 1991. The purpose of these standards was to reduce and eliminate adverse effects on biological resources and from significant human health threats resulting from contaminated sediments. SMS provided for marine, low salinity, and freshwater surface sediment quality standards. Ecological evaluation of sediments uses Apparent Effects Threshold (AET) values which are sediment chemical concentrations above which a particular adverse biological effect is always expected.

After Ecology developed ecological criteria, DOH and Ecology began work on SQC to protect human health. A draft report on the first tier of a two-tiered approach to SQC was completed in May 1993, with a final report on Tier I completed in June 1995. Tier I focused on two tasks: (1) development of a framework for implementing numeric SQC, and (2) development of numerical SQC for assessment of human health impacts from contaminated sediments. The intent of Tier I was to provide an objective means to identify contaminated sediments which do not pose a human health concern. Because Tier I relied on existing chemical-specific CPFs for carcinogens and RfDs for non-carcinogens, Tier I did not provide SQC for chemicals without CPFs or RfDs. These chemicals may be assessed under Tier II.

The goal of Tier II is similar to the goal of Tier I: to provide a framework to calculate sediment chemical contamination levels unlikely to result in adverse human health impacts to people of Puget Sound. SQC equations used to calculate criteria are the same for Tier I and Tier II. The difference between Tier I and II SQC lies in the use of site-specific parameter values for Tier II while Tier I relies on a broader data base to derive default values applicable for the entire Puget Sound region. Together, Tier I and Tier II cover all non-ionic organic chemicals in Puget Sound. Moreover, this process may be applicable to regulating sediments in freshwater and other marine waters in Washington State.

Conceptually, Tier I and Tier II are alike in their approach. For example, both Tier I and II SQC are compared with established background chemical concentration standards. If Tier I or II SQC is greater than background levels, it will be used for regulatory purposes. If Tier I or II SQC is lower than background standards, background standards will be used for regulatory purposes. Chemical concentrations from the investigation site are compared to the appropriate regulatory value. If the sediment concentration exceeds the regulatory value, Ecology will determine the appropriate remedial action.

In general, Tier II SQC values will be less stringent than Tier I SQC due to the use of conservative Tier I default parameter values. DOH anticipates that Tier II SQC will be more stringent than current ecological SMS for some chemicals. More stringent SQC will most likely occur for those chemicals with high K_{ow} values (chemicals that tend to bioaccumulate with high toxicity) such as pesticides, PCBs, high molecular weight PAHs, and dioxins and furans. Ecological standards are often based on gross endpoints (i.e., death of five percent of a species or loss of a certain percentage of the total number of species present) whereas human health endpoints are much more sensitive [i.e., a risk of less than 1,000,000 (10^{-6}) of developing cancer after a chronic exposure or the possibility of a non-cancerous health effect after a chronic low-level exposure]. Multiple SQCs within Puget Sound are possible for a given chemical due to the use of site-specific data for a specific location; i.e., a Tier II SQC for Bellingham Bay may not be the same as a Tier II SQC calculated for Elliott Bay. For Puget Sound this may result in a range of SQC values for a given chemical.

The strength of the Tier I approach is that it can be applied broadly and quickly for many chemicals. However, the broad-based approach of Tier I carries more associated uncertainty than Tier II in SQC calculations in order to guarantee protection of most of the Puget Sound population. In contrast, the strength of Tier II is that it is based on site-specific parameter values which will decrease the associated uncertainties of ensuing SQC while protecting the local population. Furthermore, Tier II allows incorporation of new scientific toxicity data, bioaccumulation data, and exposure (ingestion) data.

DOH recommends that there be some flexibility in parameter choice for Tier II calculations to account for site-specific conditions. Nonetheless, all values shall be objectively chosen and based on scientific evidence. Regulators and applicants should not lose sight of the goal of SQC development, which is to ensure the protection of humans that consume seafood contaminated by Puget Sound sediments. For this reason, DOH recommends establishment of a committee to review parameter values used to calculate Tier II SQC.

The choice of some parameter values in the SQC calculations involves assumptions. For example, picking a risk value is not a scientific decision but is a risk management decision. In Tier I, the default value for R is 1×10^{-6}. In Tier II, risk values can be chosen based on site considerations but the choice remains a risk management decision. The body weight parameter value will most likely be based on a group average, either the general population or a sub-group. This value will not be protective of the most sensitive individual; however, differences in BW relative to other parameter values will not influence the resulting SQC value greatly. Although, the Tier I default value for averaging time assumes that an individual's lifespan is 70 years, the actual average lifespan in Washington State is 77 years. Likewise, exposure duration in Tier I is based on the assumption that exposure is limited to 30 years, although many individuals are likely to have a lifetime exposure which nears 77 years. Fish lipid values are averaged over many species for Tier I; for Tier II DOH recommends a lipid value associated with species used for the fish ingestion parameter. This value will still be an average fish lipid concentration rather than an exact value. BSAF assume that all bioaccumulation is from sediment. This may not be true for chemicals with a lower K_{ow} where the contribution of water column contaminants may contribute to the overall tissue contaminant concentration.

CPF and RfD values contain many inherent protective assumptions. RfDs are oral doses, derived from epidemiologic studies or from controlled animal studies to determine a No Observed Adverse Effect Level (NOAEL) and divided by several factors of ten to account for data uncertainties. CPFs reflect probabilities of contracting specific cancers, most often derived from animal studies, using protective assumptions. CPFs also assume a daily exposure to the contaminant for a lifetime (seventy years). Tier II offers the opportunity to incorporate scientific information on toxicity to recalculate CPF and RfD values or to establish new toxicity values for those chemicals currently lacking CPFs or RFDs.

SQC may be based on fish or shellfish ingestion rates. Although shellfish ingestion rates may be lower than fish ingestion rates, the concentration of certain chemicals in shellfish (those which are metabolized and excreted by fish species but poorly metabolized by shellfish species) may be greater, resulting in greater exposure from the consumption of shellfish. A SQC should be calculated for both fish and shellfish for certain chemicals such as PAHs; regulatory action should be based on the more restrictive value.

Regulating sediments based on fish tissue contamination levels is not recommended because resulting criteria will not protect fish from becoming contaminated to levels of human health concern. Use of BSAF values in the development of sediment criteria provides the essential link between fish tissue and sediment contamination that is missing if regulating from fish tissue chemical concentrations alone. Use of fish tissue allows regulators and health advisors to determine when fish are unsafe to consume rather than meeting the SMS goal of preventing fish from becoming contaminated to unsafe levels. Furthermore, this approach would not be useful to determine discharge limits for source control or cleanup levels.

Further research should address the need for BSAF data specific to Puget Sound. DOH highly encourages the collection of concurrent fish tissue and sediment data from contaminated areas, whenever possible. Compilation of these findings will result in Puget Sound BSAF data for many chemicals. Another issue is depletion of fishing resources and sediment management. For example, if fish are no longer present due to sediment contamination, no exposure occurs because no one is eating fish. Regulators should view a remedial site from a broad biogeographical perspective with regard to fisheries resources. Finally, the Tier I/II regulatory framework does not consider economic impacts. Cost considerations will be evaluated by Ecology as part of rule development.

11.0 CONCLUSIONS AND RECOMMENDATIONS

This report documents the second tier of a two-tiered process to determine SQC protective of human health. SQC are maximum allowable sediment chemical concentrations unlikely to result in adverse human health effects from consumption of contaminated fish and shellfish. SQC can be applied to management of dredged materials, establishment of cleanup levels, and assessment of source controls.

Tier II provides a framework to incorporate site-and chemical-specific data in the calculation of SQC. First, the applicant may calculate Tier II SQC based on site-specific parameter values. Next, Tier II SQC are reviewed by a scientific advisory committee for accuracy and validity. The Tier II SQC are then compared with established background chemical concentration standards. If the Tier II SQC are greater than background levels, they will be used for regulatory purposes. If the Tier II SQC are lower than background standards, background standards will be used for regulatory purposes. Sediment chemical concentrations from the site under investigation are compared to the appropriate regulatory value. If the sediment concentration exceeds the SQC regulatory value, Ecology will determine the appropriate remedial action.

Parameters used to calculate SQC that may be modified for Tier II include:

- Risk (R),
- Body weight (BW),
- Exposure duration (ED)/Averaging time (AT),
- Cancer potency factor (CPF)/Reference dose (RfD),
- Ingestion frequency (IF),
- Fish lipid (FL), and
- Biota-sediment accumulation factor (BSAF).

Each parameter was discussed with reference to Tier I default values, and options for incorporation of site-specific data into SQC calculations were presented.

Risk levels less stringent than 1×10^{-6} may be acceptable based on site and regulatory considerations. The selection and implementation of a specific risk level is not a scientific decision; therefore selection of a specific risk level for calculation of SQC requires careful policy consideration. For Tier II, DOH recommends use of risk values consistent with federal and state regulatory programs.

Body weight values other than 70 kg are justified when a chemical is of greater toxicity to a specific population segment (e.g., women or young children) than to the general population or for sub-populations culturally predisposed to greater exposure (e.g., Native Americans). For Tier II, DOH recommends that the default BW value of 70 kg be used for adults unless average BW data for local fishers or for sensitive subpopulations are available for the site in question.

Exposure duration and averaging time are related parameters in the calculation of human exposure to environmental contaminants, here defined as exposure to sediment chemicals through ingestion of contaminated seafood. Although an individual may consume local fish for most of his or her life, the individual's fish consumption rate may not be constant over this entire period. Alterations in ED and AT from typical default values may be justified since some Puget Sound residents may have high fish consumption over their lifetime. Furthermore, AT should be shortened when appropriate to reflect chemical-specific acute toxicity.

DOH used oral RfD and CPF values from EPA's IRIS and HEAST databases in the calculation of Tier I SQC. For Tier II, updated CPF and RfD values or new scientific information on chemical-specific toxicity may be considered. For chemicals which presently have CPF or RfD values, consideration of additional toxicity data would require the development of a standardized method of investigation and review. For chemicals presently lacking RfD or CPF values, use of alternative toxicity data is an option for calculation of Tier II SQC. DOH recommends that incorporation of other toxicity data be allowed as part of a site-specific evaluation or as part of Ecology's criteria review process.

Humans are exposed to sediment chemical contaminants from Puget Sound through consumption of contaminated fish or shellfish. The rate of consumption is known as ingestion frequency and is defined as the amount (grams) of fish or shellfish consumed per day. For Tier II, Tier I default values for IF may be altered to reflect local or site-specific conditions but must incorporate basin-wide consumption rates. Other considerations include consumption practices of specific populations that may consume seafood at higher rates than the general population and choice of the appropriate seafood species consumed.

Fish lipid is used to calculate a lipid-normalized consumption rate for fish consumed from Puget Sound. FL will vary for Tier II depending on the fish species chosen to calculate ingestion frequency. DOH recommends that FL values be determined for local fish species caught within the biogeographical area impacted by the site being evaluated.

The biota-sediment accumulation factor is a partition coefficient describing the distribution of a chemical between an organism and sediment. BSAF values indicate the extent to which contaminants in sediment bioaccumulate and biomagnify through the food web. DOH recommends incorporating Puget Sound site-specific BSAF values into Tier II SQC calculations. Calculation of a site-specific BSAF requires collection of fish (or shellfish) tissue chemical concentration, fish (or shellfish) tissue lipid concentration, sediment chemical concentration, and sediment total organic carbon concentration. In addition, other factors that must be considered in determination of site-specific BSAFs include which chemical isomer to consider (i.e., PCBs), which fish species to target, which fish tissue to analyze, fish tissue sample size, sediment sample size, and sediment station location.

The direct use of fish tissue chemical data is not recommended to regulate sediments. This approach would not meet the goal of establishing SQC to prevent seafood from becoming contaminated but would be limited to issuance of fish advisories after fish are contaminated.

In the Tier I and Tier II process, SQC methodology was developed for non-ionic organic chemicals but not for metals or ionic organic chemicals. In addition, multiple chemical effects were not considered in this report. DOH recommends the development of SQC for metals and ionic organic chemicals and the consideration of multiple chemical effects as science and technology advance.

Certain biological parameters used in the SQC equations that are known to have reliable data from which to derive a distribution (e.g., body weight, life expectancy) may lend themselves to distributional analyses. Those with no known or scientifically defensible distributions (e.g., risk, CPF, and RfD) do not lend themselves to this approach.

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Figure 1. Tier I Human Health Sediment Quality Criteria Regulatory Framework.

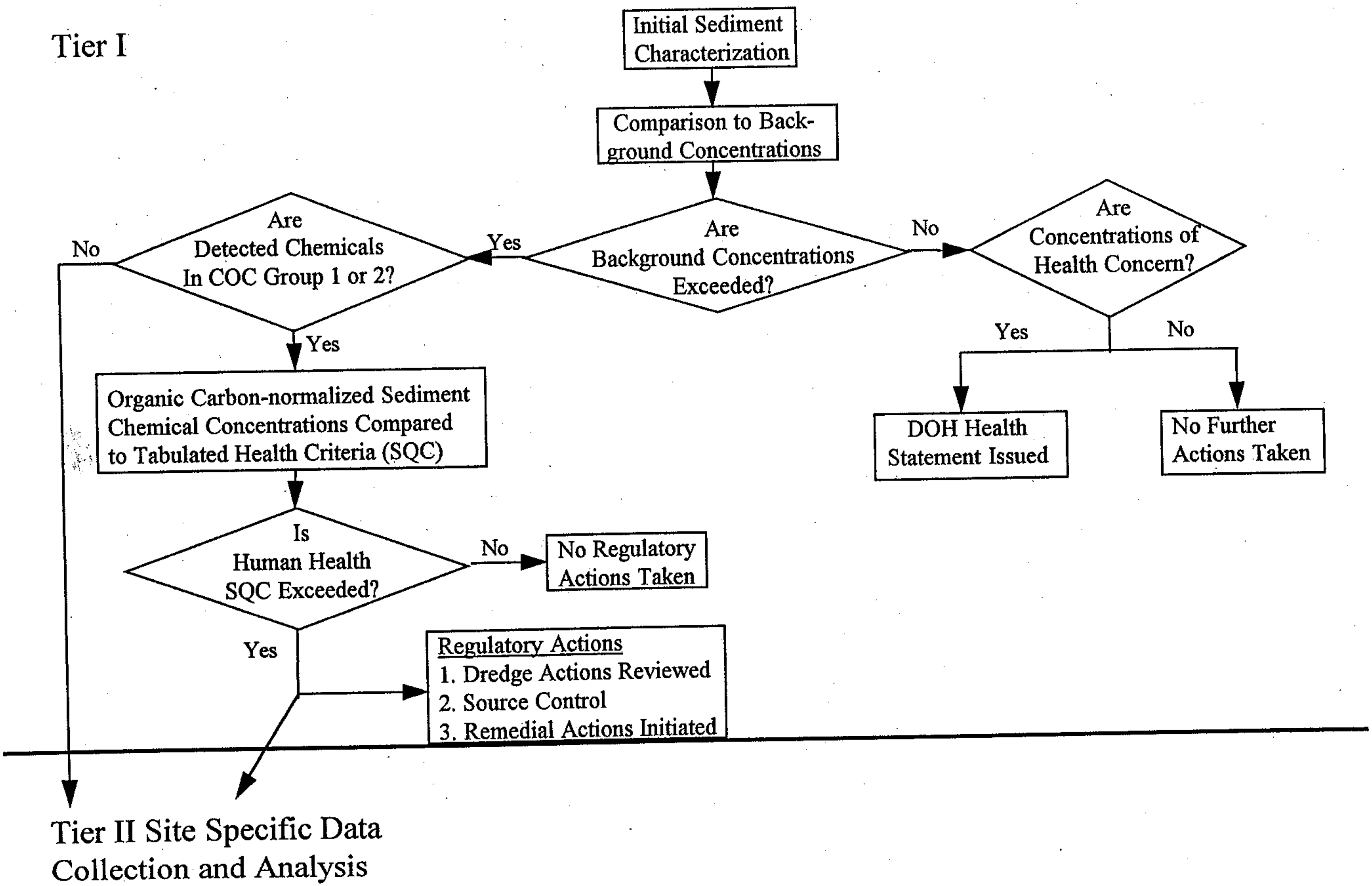

Figure 2. Tier II Human Health Sediment Quality Criteria Regulatory Framework.

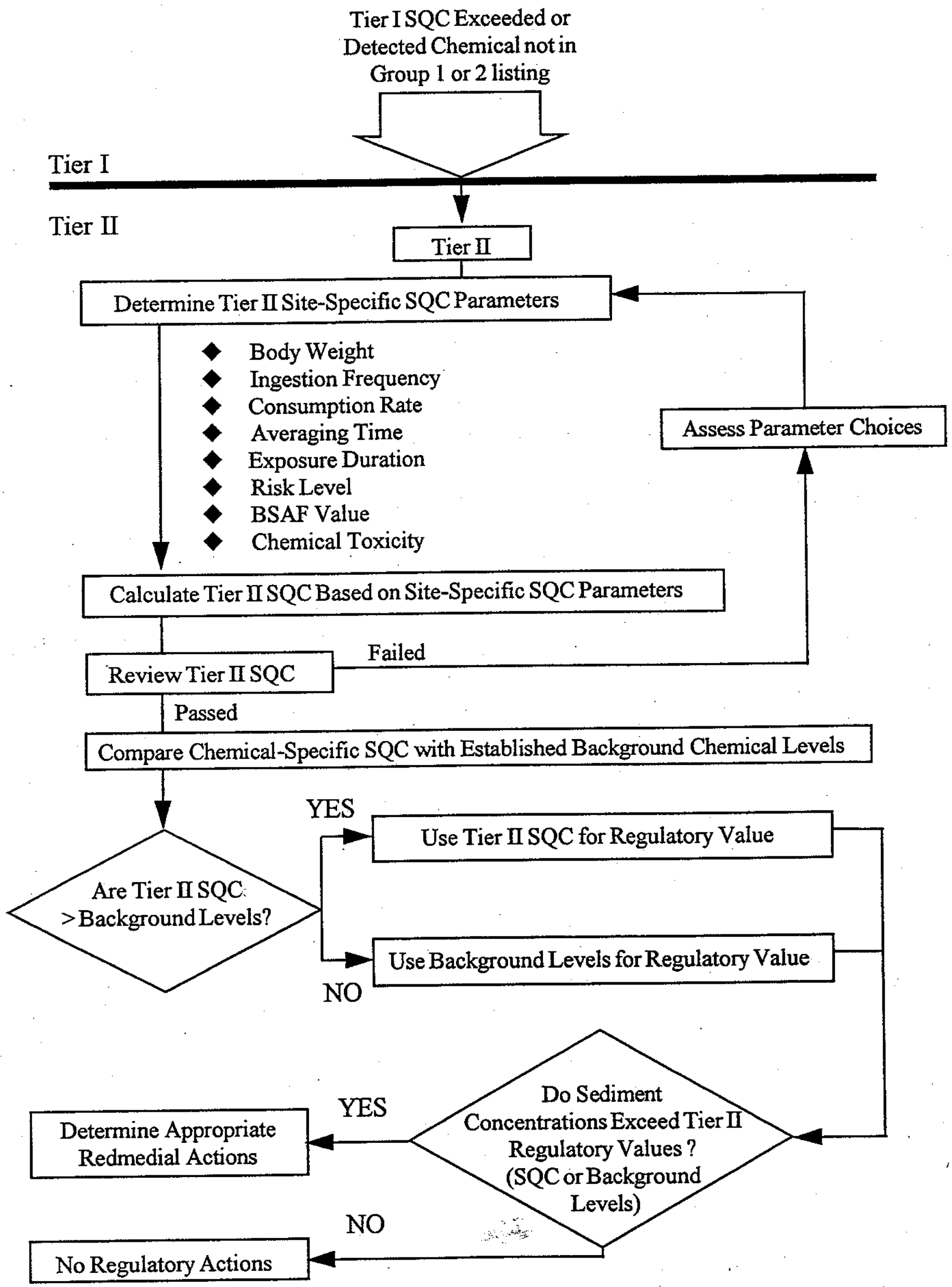

Table 2. Group 1 and 2 Chemicals of Concern
(Group 1 and 2 chemicals have EPA RfD and/or CPF values. Group 1 chemicals have greater than 5 percent detection frequency in urban bay sediments. Group 2 chemicals were detected in 5 percent or fewer sediment samples.)

Group 1

1,4-dichlorobenzene
2,3,4,6-tetrachlorophenol
2,4,6-trichlorophenol
aldrin
aluminum[1]
antimony[1]
arsenic[1]
beryllium[1]
biphenyl
bis(2-ethyl hexyl)phthalate
butyl benzyl phthalate
cadmium[1]
chromium[1]
copper[1]
DDD, DDE, DDT
di-n-butyl phthalate
di-n-octyl phthalate
hexachlorobenzene
hexachlorobutadiene
manganese[1]
mercury[1]
n-nitroso diphylamine
nickel[1]
PAHs
- acenaphthene
- anthracene
- benz(a)anthracene
- benzo(a)pyrene
- benzo(b)fluoranthene
- benzo(k)fluoranthene
- chrysene
- dibenzo(a,h)anthracene
- fluoranthene
- fluorene
- indeno(1,2,3-cd)pyrene
- naphthalene
- pyrene

PCBs
pentachlorophenol
polychlorinated dibenzofurans
polychlorinated dibenzodioxins
selenium[1]
silver[1]
thallium[1]
tin[1]
vanadium[1]
zinc[1]

Group 2

1,1-dichloroethane
1,1-dichloroethene
1,2-dichlorobenzene
1,2-dichloroethene
1,2-diphenylhydrazine
1,2,4-trichlorobenzene
2,4-dichlorophenol
2,4-dimethylphenol
2,4-dinitrotoluene
2,6-dinitrotoluene
2,4,5-trichlorophenol
2-butanone (methyl ethyl ketone)
2-chloronaphthalene
2-chlorophenol
2-methylphenol
3,3-dichlorobenzidine
4-methylphenol (p-cresol)
4-methyl-2-pentanone (methyl isobutyl ketone)
acetone
aniline
benzene
benzidine
carbazole, 9(H)
carbon disulfide
chlordane
chlorobenzene
chloroform
cyanide
dichloromethane (methylene chloride)
dieldrin
diethyl phthalate
dimethyl phthalate
endosulfan
endrin
ethylbenzene
hexachlorocyclohexane (HCH); a, b, d(lindane) and technical
heptachlor
heptachlor epoxide
hexachloroethane
isophorone
n-nitroso di-n-propylamine
n-nitroso dimethylamine
nitrobenzene
p-chloroaniline
phenol
styrene
tetrachloroethylene
toluene
trichlorofluoromethane
xylene

Table 3. Group 3 Chemicals of Concern
(Group 3 chemicals lack EPA toxicity values.)

<u>Group 3</u>

1-methylnaphthalene
1--+
1-methylpyrene
1,2-chlorodehydroabietic acid
1,2,4-trithiolane
1,3-dichlorobenzene
1,4-chlrodehydroabietic acid
2-methoxyphenol (guaiacol)
2-methylnaphthalene
2-methylphenanthrene
2-methylpyrene
2-nitroaniline
2-nitrophenol
2,6-dimethylnaphthalene
2,3,5-trimethylnaphthalene
3-methylphenanthrene
3-nitroaniline
3,4,5-trichloroguaiacol
4-bromophenyl phenyl ether
4-chloro-3-methylphenol
4-chlorophenyl phenyl ether
4-nitrophenol
4,6-dinitro-o-cresol
4,5,6-trichloroguaiacol
6-dimethylnaphthalene
abietic acid
acenaphthylene
aromatic hydrocarbons, total
benz[a]anthracene/chrysene
benzo(e)pyrene
benzo(g,h,i)perylene
benzofluoranthenes, total
chlordane, alpha
chlordane, gamma
chlorinated benzenes, total
chlorobutadienes, total
chlorodehydroabietic acid
cobalt
cymene (1-methylethyl benzene)
DDD, o,p-
DDD, p,p- and o,p'-DDT
DDE, o,p-
DDE, p,p- and o,p'-DDE
DDT, DDE, and DDD (sum p,p'- and o,p'-)
DDT, p,p- and o,p'-DDT
dehydroabietic acid
dibenzofuran
dibenzothiophene
dichloro biphenyls
dichlorodehydroabietic acid
dioxins, total
endosulfan, beta
endrin aldehyde
endrin ketone
guaiacol (o-methoxyphenol)
HCH (hexachlorocyclohexane), delta
heptachloro biphenyls
heptachlorodibenzofurans, total
heptachlorodibenzo-p-dioxins, total
hexachloro biphenyl
hexachlorodibenzofurans, total
hexadecanoic acid (palmitic acid)
hexadecanoic acid, methyl ester
hexadecenoic acid, methyl ester
iron
isopimaradiene
isopimaric acid
lead
magnesium
naphthalene
neoabietic acid
nonachlor, trans
nonachloro biphenyl
p-chloro-m-cresol (pcmc)
PAHs, high molecular weight
PAHs, low molecular weight
pentachloro biphenyls
pentachlorobutadiene
pentachlorocyclopentane
pentachlorodibenzofurans, total
pentachlorodibenzo-p-dioxins, total
perylene
phenanthrene
phthalates, total
pimaric acid
polychlorodibenzodioxins
polychlorodibenzofurans
retene
sandaracopimaric acid
tetrachloro biphenyls
tetrachlorobutadiene
tetrachlorodibenzofuran, total
tetrachlorodibenzo-p-dioxins, total
tetrachloroguaiacol
titanium
trichloro biphenyls
trichlorobutadiene
trichloroethene