A REVIEW OF METHODS FOR DERIVING HUMAN HEALTH-BASED WATER QUALITY CRITERIA WITH CONSIDERATION OF PROTECTIVENESS

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AN OVERVIEW OF PARAMETERS USED IN THE DERIVATION OF EPA HUMAN HEALTH AMBIENT WATER QUALITY CRITERIA

1.0 EXECUTIVE SUMMARY

Consistent with the requirements of the Clean Water Act, states are obligated to establish numeric water quality criteria for toxic substances and to periodically consider the need for revisions to those criteria. Toxics criteria are designed to protect both resident aquatic life and humans exposed via drinking water, consumption of fish, and/or dermal contact. Criteria for the protection of human health (i.e., Human Health Ambient Water Quality Criteria, or HHAWQC) are traditionally derived using EPA-recommended equations that include parameters for risk, toxicity, and exposure. The values used for these parameters are revisited and adjusted periodically in response to the availability of new science and shifts in policy.

The material presented in this paper includes an overview of the derivation procedures for HHAWQC, focusing especially on the selection of values for the parametric components in the HHAWQC derivation equations. Particular attention is given to the use of conservative (i.e., over-protective) choices for multiple parameter values and the overall effect of compounded conservatism on the resulting criteria relative to health protection targets established by state and federal agencies.

1.1 Parameters Used in HHAWQC Derivation and Frequently Used Values

The equations used to derive HHAWQC are composed of explicit parameters (i.e., those that are listed and defined), and implicit parameters (i.e., those that are embodied with the application of the explicit parameters). The equations and rationales for selection of specific parameter values were developed by EPA more than twenty years ago and while updates in parameter values have been made periodically, the basic methodology remains unchanged. **Table 1.1** lists the explicit and implicit parameters used in the HHAWQC derivation. Also shown are typical parameter values recommended by EPA. The third column in the table provides an indication regarding whether the typical value reflects a central, upper-end, or maximum in the range of values that could be chosen for each parameter. It is clear from the table that, in nearly every case, the typical values used for explicit and implicit parameters are selected from the upper end of the range of possible values.

It is well-known, and mathematically intuitive, that the practice of selecting "upper end of range" values for multiple parameters in a risk equation will lead to over-conservative estimates of risk or, in the case of HHAWQC, overly restrictive criteria. Indeed, EPA's Risk Assessment Task Force has suggested that "when several parameters are assessed, upper-end values and/or central tendency values are generally combined to generate a risk estimate that falls within the higher end of the population risk range" and "an exposure estimate that lies between the 90th percentile and the maximum exposure in the exposed population [should] be constructed by using maximum or near-maximum values for one or more of the most sensitive variables, leaving others at their mean values" (EPA 2004). This concept, however, has not been embraced in the current practice for deriving HHAWQC.

Table 1.1 Parameter Values used in HHAWQC Derivation and Location in the Range of Possible Values

Parameter	Typical Value	Location in Range of Possible Values[1] (maximum possible, upper-end, or central tendency)
Explicit Parameters		
substance toxicity	substance-specific	upper-end
body weight of a person	70 kg (actual mean is 80kg)	central tendency
drinking water intake	2 L/day (86th percentile), but assumes drinking water is untreated surface water	(extreme) upper-end
fish ingestion/consumption rate	17.5 g/day (90th percentile of sport fishers)	upper-end
substance exposure from other sources	80%	upper-end
Implicit Parameters		
cooking loss	0% (no loss due to cooking)	maximum possible
duration of exposure	70 years	(extreme) upper end
exposure concentration	at HHAWQC 100% of the time	maximum possible
relative bioavailability	1	maximum possible
bioaccumulation/concentration factor of fish	substance-specific	substance-specific (not evaluated)

[1]"maximum possible" would be the most conservative (over protective) choice possible, "upper-end" a very conservative choice, and "central tendency" a typical or average value for a population. "Extreme" denotes a value that is very near maximum.

1.2 Degree of Conservatism in HHAWQC

Section 6 of this report details the degree of protectiveness, conservatism, and the combined effect of conservative parameter value choices in the derivation of HHAWQC. The information provided shows that the values commonly used for each parameter can have the effect of lowering the calculated HHAWQC by large factors. For example:

- substance toxicity values are commonly reduced by 10 to 3000 times below demonstrated toxicity thresholds as a means of ensuring protection of human health
- assumptions about chemical exposure via drinking water results in some criteria being as much as 30 times lower than needed to afford the degree of protection targeted by most states and EPA

- the assumption that a person lives in the same place and is exposed to the same level of contamination for a 70 year lifetime results in criteria that are up to 8 times more stringent than if a median exposure period were assumed
- the assumption that waters would exist at the allowable HHAWQC for 70 years is in opposition to water management policies in virtually all states and results in criteria values that are 1.5 to 6 times more stringent than would be the case if actual water quality management practices were considered

Each of the factors listed above, and several others discussed in more detail in the following sections, can combine (i.e., compound) when applied in the same calculation, such as that used for deriving HHAWQC. The result is criteria that are many times lower than would be the case if the advice of the Risk Assessment Task Force regarding use of upper range values for one or more sensitive values and leaving others at their mean values (EPA 2004) were followed.

1.3 Comparison of HHAWQC with other Regulatory Mechanisms for Human Health Protection

The summary above, and supporting sections of this report, offer observations suggesting that HHAWQC are considerably more protective (i.e., lower in concentration, or over-protective) than are necessary to achieve the health protection targets described by EPA and many state environmental agencies. Section 7 of this report considers other evidence that might confirm or refute this observation. It contains a comparison of fish tissue concentrations corresponding to EPA recommended HHAWQC with (a) existing fish tissue concentration data, (b) concentrations found in other foods, and (c) allowable concentrations (such as fish consumption advisory "trigger levels") set by other US and international health agencies.

Findings from this comparison support the observation that HHAWQC are over-protective. Specifically:

- For higher assumed fish consumption rates and based on EPA fish tissue data, virtually all surface waters in the US would exceed the HHAWQC for PCB, mercury, and likely a number of other substances. In contrast, for example, health agencies have established fish consumption advisories for PCBs on only about 15% of water bodies (Appendix C) indicating that assumptions used by EPA are more conservative than the assumptions used by state agencies to derive fish consumption advisories.
- A comparison of the daily intake of several example substances for which HHAWQC exist, showed that intakes from other foodstuffs was greater than from fish and was already exceeding the allowable intakes used to establish HHAWQC. Thus, establishment and enforcement of more stringent HHAWQC may not provide a measureable public health benefit.
- Various federal and international agencies have established concentration limits for fish as a food in commerce. Levels set by these agencies (whose goal is to insure the safety of edible fish) show that EPA HHAWQC are limiting fish tissue concentrations to levels substantially (10s to 1000s of times) below those considered to be without significant risk.

1.4 Other Observations

Other observations from this review are noted as follows.

- Target cancer risk levels between 10^{-6} and 10^{-4} have become widely accepted among the different EPA programs, including the derivation of HHAWQC. The HHAWQC methodology document states that a risk level of 10^{-4} for highly exposed populations is acceptable (EPA 2000a). This is sometimes interpreted as meaning that highly exposed populations are not as well protected by the HHAWQC. However, as noted by Kocher (1996) "if only a small population would be at greatest risk, the expected number of excess cancers corresponding to individual risks at the *de minimis* level of 10^{-4} would still be [essentially] zero."

- The fish consumption rates used in calculating HHAWQC can have a significant impact on the resulting HHAWQC. This is because the HHAWQC are proportional to the fish consumption rates - as the rate increases, the HHAWQC decreases, and the decrease is particularly pronounced for high BAF/BCF substances. Potential exposure through the fish consumption pathway is dependent upon a number of different variables including the types of fish consumed, the sources of those fish (particularly anadromous fish such as salmon, see Appendix B), and the rates at which they are consumed, all of which vary widely among the population. The quantification of fish consumption rates is complicated by the methods used to collect consumption information, the interpretation of such data (particularly extremes in the distribution of individual consumption rates obtained from survey data), the availability of fish from regulated sources, and the habits of the targeted population of fish consumers. Without extreme diligence in data interpretation, most of these complications are likely to manifest in overestimations of fish consumption rates.

- The selection of some exposure parameters are unrealistic because, as a practical matter, other environmental management programs would ensure that such conditions did not occur (or would not persist for a person's lifetime). Assumptions concerning ambient water column concentrations (and related fish tissue concentrations) and drinking water concentrations are examples.

Finally, it is noteworthy that the values used for parameters in a health risk equation like that for deriving HHAWQC involve a combination of science and policy choices. And, while evolving science and policy may sometimes indicate that revisiting these choices is warranted, responsible evaluation of risk (and thus protection of health) is best considered in total rather than by simple alteration of a single parameter value without due consideration of the others. The information presented herein suggests that the degree of protection embodied in the current HHAWQC derivation method, using typically applied values for each parameter, exceeds by a large margin the health protection targets expressed by EPA and many states.

2.0 INTRODUCTION

Section 304(a) (1) of the Clean Water Act (CWA) requires the United States Environmental Protection Agency (EPA) to develop and publish recommended numeric ambient water quality criteria (AWQC) for limiting the impact of pollutants on human health and aquatic life. These recommended human health-based AWQC (HHAWQC) are intended to provide guidance for states and tribes to use in adopting their own water quality standards and are meant to "minimize the risk of adverse effects occurring to humans from chronic (lifetime) exposures to substances through the ingestion of drinking water and consumption of fish obtained from surface waters" (EPA 2000a). Water quality criteria recommendations are derived by EPA using equations that express a risk analysis. The value of each parametric component of the criteria equations represents policy choices made by the Agency, though several of those choices are derived from scientific data (EPA 2011a).

In a staff policy paper from the Office of the Science Advisor, EPA discussed the bases for these policy choices (EPA, 2004). They noted that "Congress establishes legal requirements that generally describe the level of protectiveness that EPA regulations must achieve" and that individual statutes identify the risks that should be evaluated and protected against and also mandate the required levels of protection (EPA 2004). The Clean Water Act, which mandates the development of AWQC, simply requires that AWQC must "protect the public health or welfare, enhance the quality of water and serve the purposes of this Act" and "be adequate to protect public health and the environment from any reasonably anticipated adverse effects of each pollutant." In order to meet these requirements, EPA "attempts to protect individuals who represent high-end exposures (typically around the 90th percentile and above) or those who have some underlying biological sensitivity" (but not hypersensitive individuals) (EPA 2004). EPA (2004) notes that "[p]rograms may approach the problem semi-quantitatively (e.g., selecting individual parameter values at specified percentiles of a distribution) or qualitatively (e.g., making conservative assumptions to ensure protection for most individuals), though no overall degree of protection can be explicitly stated."

While EPA is obligated to develop and publish AWQC guidance, adoption and implementation of criteria for most fresh waters in the U.S. is an activity mandated to states. Many states choose to adopt EPA's AWQC guidance values but states are free to depart from EPA's criteria guidance provided that there is a scientifically valid rationale for doing so. Departure from the EPA AWQC guidance values is commonly accomplished by altering one or more of the values used to represent the parametric components of the risk analysis equation used to derive the criteria guidance values.

This document contains a discussion of each parametric component of the risk analysis equation that is used to derive HHAWQC. As noted earlier, selection of parameter values for risk analyses is primarily a policy choice and it is typical that such choices are conservative in favor of protecting public health. The combined degree of conservatism embodied in the final AWQC guidance is not usually expressed quantitatively by EPA. The primary purpose of this document is to provide an exploration of the combined conservatism that may be embodied in AWQC calculated using typically chosen values for the explicit parametric components of the HHAWQC equation and use of implicit assumptions also embodied in the criteria derivation.

3.0 EQUATIONS USED FOR THE DERIVATION OF HHAWQC

In calculating HHAWQC, EPA differentiates between carcinogenic and noncarcinogenic effects. Three risk analysis equations are used, the first for noncarcinogenic effects, the second for carcinogenic effects that are assumed to have a nonlinear dose-response, and the third for carcinogenic effects that are assumed to have a linear dose-response. These are shown in Table 3.1.

Table 3.1 Equations for Deriving Human Health Water Quality Criteria

Substance Category	HHAWQC Equation	Eq. #
Noncarcinogenic effects	$RfD*RSC*(BW/(DI + (\Sigma FI_i*BAF_i)))$	**Eq. 3.1**
Carcinogenic effects (non-linear)	$(POD/UF)*RSC*(BW/(DI + (\Sigma FI_i*BAF_i)))$	**Eq. 3.2**
Carcinogenic effects (linear)	$RSD*(BW/(DI + (\Sigma FI_i*BAF_i)))$	**Eq. 3.3**

where:

HHAWQC = human health ambient water quality criterion (mg/L);

RfD = reference dose for noncancer effect (mg/kg-day);

RSC = relative source contribution factor to account for non-water sources of exposure (typically expressed as a fraction of the total exposure);

POD = point of departure for carcinogenic effects based on a nonlinear low-dose extrapolation (mg/kg-day), usually a LOAEL, NOAEL, or LED_{10};

UF = uncertainty factor for carcinogenic effects based on a nonlinear low-dose extrapolation (unitless);

RSD = Risk-specific dose for carcinogenic effects based on a linear low-dose extrapolation (mg/kg-day) and on the selected target risk level;

BW = human body weight (kg);

DI = drinking water intake (L/day);

FI_i = fish intake at trophic level (TL) i (i = 2, 3, and 4); this is the fish consumption rate (kg/d); and

BAF_i = bioaccumulation factor at trophic level i, lipid normalized (L/kg)

The first portion of each equation in Table 3.1 contains parameters that represent a measure of the toxicity of a substance and are unique to each equation. The latter portion of each equation is common for the three substance categories and describes assumed human exposure to a substance. Implicit, and not obvious, with the practice of using these equations are other assumptions concerning exposure (i.e., a duration of exposure equal to a full lifetime, an average ambient water concentration equal to the HHAWQC, and bioavailability of chemicals from fish and water equal to that observed in the toxicity experiment). Finally, and also not obvious, is that an assumed incremental risk of illness is also part of the overall algorithms. Taken collectively, these explicit and implicit elements yield a risk analysis in the form of an acceptable water column concentration for a substance.

Although the parameters in the risk equations used for deriving a HHAWQC are most accurately represented by a range or distribution of values, it has been typical for EPA to select a single value for each parameter. EPA has recognized that there are elements of both variability and uncertainty in each parametric value but has generally not implemented specific procedures to account for variability and uncertainty. However in some cases, EPA has intentionally chosen parametric values that are conservative (i.e., over-, rather than under-, protective of human health) with respect to the general population.

The sections below discuss the parametric components of the toxicity portion (Section 4) and the exposure portion (Section 5) of each equation in Table 3.1. Section 6 includes discussion of variability and uncertainty in parameter values and, where evident, conservatism embodied in typical choices made for parameter values. Also in Section 6, consideration is given to the combined effect on conservatism of typical parameter value choices in HHAWQC derivation.

4.0 TOXICITY PARAMETERS USED FOR DERIVATION OF HHAWQC

Each of the three equations used to develop HHAWQC contains a factor that represents the toxicity of the substance of concern. Equation 3.1 (Table 3.1), which is used for non-carcinogenic effects, employs the reference dose (RfD), the derivation of which incorporates various uncertainty factors (UFs) and sometimes an additional modifying factor (MF). Equation 3.2 (Table 3.1), which is used for carcinogenic effects that have a nonlinear dose-response curve (i.e., there exists some level of exposure below which no carcinogenic response is expected to occur), employs a factor calculated by dividing the "point of departure" (POD) by UFs. Equation 3.3 (Table 3.1), which is used for substances that are assumed to have a linear dose-response (i.e., some probability of a carcinogenic response is presumed to exist at any level of exposure), employs a Risk-Specific Dose (RSD). It is EPA's policy to assume that all carcinogenic effects can be described using a linear dose response unless non-linearity has been clearly demonstrated. Typically, if a compound is considered to have both carcinogenic and non-carcinogenic health effects, HHAWQC are calculated for both the cancer and noncancer endpoints and the lower of the two concentrations is selected as the HHAWQC. The derivation of these components is described in the "Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (EPA 2000a) (hereafter referred to as the "HHAWQC methodology document") and its Technical Support Document Volume 1: Risk Assessment" (EPA 2000b).

4.1 Reference Dose (RfD)

A reference dose (RfD) is defined as "an estimate (with uncertainty spanning approximately an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious effects over a lifetime" (EPA 2000b).

The development of an RfD begins with a review of all available toxicological data. Relevant studies are evaluated for quality and a "critical effect" is identified. The critical effect is defined as "the first adverse effect, or its known precursor, that occurs to the most sensitive species as the dose rate of an agent increases" (EPA 2002a). The underlying assumption is that if the RfD is derived to prevent the critical effect from occurring, then no other effects of concern will occur (EPA 2002a).

The next step is the identification of a POD based on the study in which the selected critical effect has been identified. The POD may be derived from a No Observed Adverse Effect Level (NOAEL), a Lowest Observed Adverse Effect Level (LOAEL) or Benchmark Dose Lower Confidence Level (BMDL). The NOAEL is defined by USEPA as "the highest exposure level at which there are no biologically significant increases in the frequency or severity of an adverse effect between the exposed population and its appropriate control; some effects may be produced at this level, but they are not considered adverse or precursors of adverse effects."[1] If a NOAEL cannot be identified, a LOAEL may be used instead. The LOAEL is defined by USEPA as "the lowest exposure level at which there are biologically significant increases in frequency or severity of adverse effects between the exposed population and its appropriate control group."[2]

When study data are suitable, the Benchmark Dose BMD approach is sometimes used as an alternative to the NOAEL/LOAEL approach. The BMD is the dose at which the critical effect occurs at a rate 5-10% above the rate observed in the control group (other rates could possibly be used, but 5% or 10% are most common). The BMDL, which is typically the lower 95% confidence limit of the BMD, is used as the POD when the BMD approach is used.

Once the POD is identified, the RfD is derived according to equation 4.1:

$$RfD = POD/(UF_i * MF) \qquad \textbf{Eq. 4.1}$$

where:

RfD = reference dose for noncancer effect (mg/kg-day);

POD = NOAEL, LOAEL, or BMDL (mg/kg-day);

UF_i = uncertainty factors for various circumstances (see Table 4.1) (unitless) ; and

MF = modifying factor (unitless)

[1] Taken from USEPA's online IRIS glossary (http://www.epa.gov/iris/help_gloss.htm#n)
[2] Taken from USEPA's online IRIS glossary (http://www.epa.gov/iris/help_gloss.htm#n)

Uncertainty factors are used to reduce the dose in order to account for areas of scientific uncertainty in the supporting toxicity databases (EPA 2000b). The standard UFs are 1, 3, and 10. A modifying factor further adjusts the dose in order to provide for additional uncertainty not explicitly included in the UFs, such as the completeness of the overall database (EPA 2000b). The MF is a matter of professional judgment and ranges between 0 and 10, with the standard values being 0.3, 1, 3, and 10 and the default value being 1 (EPA 2000b). Table 4.1 defines the various UFs.

Table 4.1 Uncertainty Factors (adapted from EPA 2000b)

Uncertainty Factor	Description
Intraspecies variation (UF_H)	Accounts for uncertainty associated with variations in sensitivity among members of the same species (e.g., differences in age, disease status, susceptibility to disease due to genetic differences)
Interspecies variation (UF_A)	Accounts for uncertainty involved in extrapolating from animal data to humans; used when the POD is derived from an animal study
Subchronic-to-chronic (UF_S)	Accounts for uncertainty involved in extrapolating from studies with a less-than-chronic[1] duration of exposure; used when the POD is derived from a study in which exposures did not occur over a significant fraction of the animal's or the individual's lifetime
LOAEL-to-NOAEL (UF_L)	Accounts for uncertainty associated with the use of a POD derived from a LOAEL rather than a NOAEL or BMDL
Incomplete database (UF_D)	Accounts for uncertainty associated with the use of an incomplete database to derive the POD, for example, the lack of a study of reproductive toxicity

[1] Chronic Exposure: Repeated exposure for more than approximately 10% of the life span in humans (more than approximately 90 days to 2 years in typically used laboratory animal species).

In application, the various UFs and any MF are multiplied to obtain the final factor by which the POD is to be divided. In general, EPA follows a policy that a final factor greater than 3000 indicates that the existing toxicity database is inadequate to support the derivation of an RfD. In this case, no RfD is calculated (EPA 2002a).

Although instructions for calculating an RfD are provided in the documentation for HHAWQC, in actual practice, the RfD is typically obtained from EPA's IRIS database (http://www.epa.gov/iris/).

4.2 Cancer Effects: Nonlinear Low-Dose Extrapolation

In deriving a HHAWQC, a nonlinear low-dose extrapolation may be used for carcinogenic effects when there are sufficient data available to understand the mode of action (MOA) and conclude that it is nonlinear at low doses (EPA 2005). In practical application, this is interpreted to mean that a threshold of exposure exists below which no carcinogenic response will occur.

For nonlinear carcinogenic effects, the factor representing toxicity in Equation 3.2 is calculated by dividing the POD by UFs. The recommended POD is the Lower Limit on Effective Dose$_{10}$, or LED$_{10}$, which is determined by calculating the lower 95 percent confidence limit on a dose associated with an estimated 10 percent increased tumor or tumor precursor response (EPA 2000b). A NOAEL or LOAEL value from a precursor response may also be used in some cases (EPA 2000b). When animal data are used to determine the POD, the selected dose is converted to a human equivalent dose using a default interspecies dose adjustment factor or a toxicokinetic model. However, as noted above, it is EPA's policy to assume that all carcinogenic effects have a linear dose response unless non-linearity has been clearly demonstrated. Thus, the non-linear low dose extrapolation procedure is rarely used.

The HHAWQC methodology document provides no specific guidance on the selection of UFs (EPA 2000a). Instead, it defers to the "upcoming cancer risk assessment guidelines," which were subsequently released in 2005.

The 2005 Cancer Risk Assessment Guidelines took a somewhat different approach than anticipated by EPA in 2000 when the HHAWQC methodology guidelines were developed. The 2005 guidelines instead recommended that for nonlinear carcinogenic effects, "an oral reference dose…should be developed in accordance with EPA's established practice for developing such values" (EPA 2005). This does not have much practical impact on HHAWQC calculation, as comparison of equations 3.2 and 4.1 reveals that the process for calculating the factor that represents the toxicity of nonlinear carcinogenic effects in HHAWQC derivations is essentially the same as that for calculating an RfD.

Given that (1) the documentation for HHAWQC derivation does not provide complete guidance on the calculation of the POD/UF factor, and (2) the 2005 Cancer Risk Assessment Guidelines took a somewhat different approach than anticipated by the HHAWQC methodology guidelines, in actual practice, the POD/UF factor will be typically be replaced by an RfD for some noncancer endpoint (e.g., a cancer precursor event) obtained from EPA's IRIS database (http://www.epa.gov/iris/).

4.3 Cancer Effects: Linear Low-Dose Extrapolation

In deriving a HHAWQC, a linear low-dose extrapolation is used for compounds that are believed to have carcinogenic potential when the chemical has direct effects on DNA, the MOA analysis indicates that the dose-response relationship will be linear, human exposures or body burdens are already near the doses associated with key events in the carcinogenic process, or there is an absence of sufficient data to elucidate the MOA.

The RSD, which is used in Equation 3.3 (Table 3.1), is derived according to Equation 4.2:

RSD = Target Incremental Cancer Risk/m **Eq. 4.2**

where:

RSD = Risk-Specific dose (mg/kg-day);

Target Incremental Cancer Risk = Typically a value ranging from10^{-6} to 10^{-4}; and

m = cancer potency factor $(mg/kg\text{-}day)^{-1}$

The HHAWQC methodology document (EPA 2000a) states that the Agency will calculate recommended HHAWQC using at a Target Incremental Cancer Risk level of 10^{-6}. However, in deriving their own HHAWQC, states and authorized tribes may choose a risk level as low as 10^{-7} or as high as 10^{-5}, as long as the risk to more highly exposed subgroups (e.g., sport or subsistence anglers) does not exceed 10^{-4}. (The rationale for this is discussed further in Section 6.1.3.)

The cancer potency factor may be calculated by first modeling the relationship between tumor incidence and dose and then selecting a POD (generally the LED$_{10}$). When animal data are used to determine the POD, the selected dose is converted to a human equivalent dose using a default interspecies dose adjustment factor or a toxicokinetic model. Finally, a straight line is drawn between the POD and the origin (zero). The slope of that line, which will be "m" in Equation 4.2, is calculated. If the LED_{10} is used as the POD, m is equal to $0.10/LED_{10}$ (EPA 2000b).

Instructions for calculating m are provided in the documentation for HHAWQC. In actual practice, however, the value of m is typically obtained from EPA's IRIS database (http://www.epa.gov/iris/). Note that EPA terminology has changed somewhat since the HHAWQC methodology document was released and what was referred to as "m" or "cancer potency factor" in the methodology document is more commonly identified as "slope factor" in the IRIS database.

5.0 EXPOSURE PARAMETERS USED FOR DERIVATION OF HHAWQC

As noted above, both explicit and implicit elements are used to yield a risk analysis in the form of an acceptable water column concentration for a substance. This section summarizes each of these elements and the manner in which they are used for deriving HHAWQC.

5.1 Relative Source Contribution (RSC)

When deriving a HHAWQC for noncarcinogenic or nonlinear carcinogenic effects, a factor is included in the equation to account for non-water sources of exposure to a substance. For example, a particular chemical may be found not only in water sources, but also in some food items or in ambient air (from which it could be inhaled). This factor is known as the Relative Source Contribution (RSC) and it acts to reduce the amount of the RfD that is apportioned to water and fish consumption. The rationale for using the RSC factor in calculating a HHAWQC is to ensure that an individual's total exposure does not exceed the threshold level (EPA 2000a).

The HHAWQC methodology document (EPA 2000a) creates an "Exposure Decision Tree" procedure to be used in the selection of an RSC. In the absence of sufficient data to support the use of the Exposure Decision Tree, EPA uses 20% as a default RSC (EPA 2000a). The methodology also sets 80% as the maximum allowable RSC and 20% as the minimum (EPA 2000a). EPA encourages states and authorized tribes to develop alternate RSC values based on local data (EPA 2000a). Although the Exposure Decision Tree approach does theoretically allow for the use of an RSC other than the 20% default, in actual practice, use of values other than the default is very rare.

Note that while the methodology (EPA 2000a) specifies that the RSC value must be between 20 and 80% and states that "EPA intends to use 20 percent of the RfD (or POD/UF), which has also been used in past water program regulations, as the default value," the current EPA HHAWQC are calculated using RSCs ranging from 20 to 100%. This is because many of the HHAWQC remain unchanged from earlier years or have been updated to reflect changes in fish consumption rates or RfD, but were not recalculated using the 2000 methodology.

The RSC factor is not used in the derivation of HHAWQC for carcinogenic effects with linear low-dose extrapolation. For these substances, the only sources considered are drinking water and fish ingestion. This is because for these substances, the HHAWQC is being determined with respect to the *incremental* lifetime risk posed by a substance's presence in water, and is not being set with regard to an individual's total risk from all sources of exposure (EPA 2000a). Thus, the HHAWQC for any substance represents the concentration of that substance in water that would be expected to increase an individual's lifetime cancer risk by no more than the target risk level, regardless of any additional lifetime cancer risk contributed by potential exposures from other sources (EPA 2000a).

5.2 Body Weight (BW)

The HHAWQC methodology document (EPA 2000a) recommends using a default body weight of 70 kg for calculating HHAWQC. This is considered to be a representative average body weight for male and female adults, combined. Adult values are used because the HHAWQC are intended to be protective over the full lifespan. The methodology also notes that 70 kg is used in the derivation of cancer slope factors and unit risks that appear in IRIS and advocates maintaining consistency between the dose-response relationship and exposure factors (EPA 2000a).

5.3 Drinking Water Intake (DI)

EPA recommends using a default drinking water intake rate of 2 L/day, which is believed to represent a majority of the population over the course of a lifetime (EPA 2000a).

The basis for the drinking water intake rate is the 1994-96 Continuing Survey of Food Intake by Individuals *(*CSFII) conducted by the U.S. Department of Agriculture (EPA 2000a). The CSFII survey collected dietary intake information from nationally representative samples of non-institutionalized persons residing in United States households (EPA 2000a). Households in these national surveys were sampled from the 50 states and the District of Columbia (EPA 2000a). Each survey collected daily consumption records for approximately 10,000 food codes across nine food groups (EPA 2000a). This included the number of fluid ounces of plain drinking water consumed and also information on the household source of plain drinking water, water used to prepare beverages, and water added during food preparation (EPA 2000a).

The results of the 1994-96 CSFII analysis indicated that the arithmetic mean, 75th, and 90th percentile values for adults 20 years and older were 1.1, 1.5, and 2.2 L/day, respectively (EPA 2000a). The 2 L/day value selected by EPA represents the 86th percentile for adults (EPA 2000a).

5.4 Fish Ingestion Rate (FI)

Because the level of fish intake in highly exposed populations varies by geographical location, EPA suggests a four preference hierarchy for states and authorized tribes to follow when deriving consumption rates that encourages use of the best local, state, or regional data available (EPA 2000a). The four preference hierarchy is: (1) use of local data; (2) use of data reflecting similar geography/population groups; (3) use of data from national surveys; and (4) use of EPA's default intake rates (EPA 2000a).

EPA's first preference is that states and authorized tribes use the results from fish intake surveys of local watersheds within the state or tribal jurisdiction to establish fish intake rates that are representative of the defined populations being addressed for the particular waterbody (EPA 2000a). EPA also recommends that the fish consumption rate used to develop the HHAWQC be based only on consumption of freshwater/estuarine species (EPA 2000a). In addition, for noncarcinogens and nonlinear carcinogens, any consumption of marine species of fish should be accounted for in the calculation of the RSC (EPA 2000a). States and authorized tribes may use either high-end values (such as the 90th or 95th percentile values) or average values for the population that they plan to protect (e.g., subsistence fishers, sport fishers, or the general population) (EPA 2000a).

If surveys conducted in the geographic area of the state or tribe are not available, EPA's second preference is that states and authorized tribes consider results from existing fish intake surveys that reflect similar geography and population groups (e.g., from a neighboring state or tribe or a similar watershed type) (EPA 2000a). As with the use of fish intake surveys of local watersheds, consumption rates based on data collected from similar geographic and population groups should be based only on consumption of freshwater/estuarine species with any consumption of marine species accounted for in the calculation of the RSC (EPA 2000a).

If applicable consumption rates are not available from local, state, or regional surveys, EPA's third preference is that states and authorized tribes select intake rate assumptions for different population groups from national food consumption surveys (EPA 2000a). The HHAWQC methodology document (EPA 2000a) references a document titled "Estimated Per Capita Fish Consumption in the United States" (EPA 2000c) as the source for this information, however, there is a more recent document, "Exposure Factors Handbook: 2011 Edition" (EPA 2011b) that provides more current regional and subpopulation data and is also useful for this purpose. Again, EPA recommends that fish consumption rates be based on consumption of freshwater and estuarine species only and any consumption of marine species of fish should be accounted for in the calculation of the RSC (EPA 2000a).

As their fourth and last preference, EPA recommends the use of a default fish consumption value for the general adult population of 17.5 grams/day (EPA 2000a). This default value is used by EPA in its derivation of HHAWQC. This represents an estimate of the 90th percentile per capita consumption rate for the U.S. adult population based on the CSFII 1994-96 data (EPA 2000a). EPA believes that this default value will be protective of the majority of the general population (EPA 2000a). If a state or authorized tribe identifies specific populations of sportfishers or subsistence fishers that may represent more highly exposed individuals, EPA recommends default fish consumption rates of 17.5 grams/day and 142.4 grams/day, respectively, though in such cases a subpopulation risk level may also be appropriate (EPA 2000a) as explained in Section 6.1.3.

5.5 Bioaccumulation Factors (BAF) and Trophic Level

Bioaccumulation is the process in which aquatic organisms accumulate certain chemicals in their tissues when exposed to those chemicals through water, their diet, and other sources, such as sediments. In order to account for potential exposures to these chemicals through the consumption of fish and shellfish, EPA uses national bioaccumulation factors (BAFs) in the derivation of HHAWQC. The HHAWQC methodology document (EPA 2000a) defines BAF as the ratio (in L/kg tissue) of a concentration of a chemical in the tissues of commonly consumed aquatic organisms to its concentration in the surrounding water in situations where the organisms and their food are exposed and the ratio does not change substantially over time (i.e., the ratio which reflects bioaccumulation at or near steady-state).

The HHAWQC methodology document (EPA 2000a), the "Technical Support Document Volume 2: Development of National Bioaccumulation Factors" (EPA 2003a), and the "Technical Support Document Volume 3: Development of Site-Specific Bioaccumulation Factors" (EPA 2009) describe procedures for deriving national and site-specific BAFs. Separate procedures are provided for different types of chemicals (i.e., nonionic organic, ionic organic, inorganic and organometallic) (EPA 2000a). Also, EPA states that national BAFs should be derived separately for each trophic level because the concentrations of certain chemicals may increase in aquatic organisms of each successive trophic level due to increasing dietary exposures (e.g., increasing concentrations from algae, to zooplankton, to forage fish, to predatory fish) (EPA 2000a). In addition, because lipid content of aquatic organisms and the amount of organic carbon in the water column have been shown to affect bioaccumulation of nonionic organic chemicals, the national BAFs should be adjusted to reflect the lipid content of commonly consumed fish and shellfish and the freely dissolved fraction of the chemical in ambient water for these chemicals (EPA 2000a).

Even though the 2000 Methodology (EPA 2000a) and subsequent Technical Support documents (EPA 2003a, 2009) provide directions for the derivation of national BAF factors, EPA has, as yet, not calculated any BAFs for individual chemicals. Instead, when calculating national HHAWQC, EPA has replaced the factor "$\Sigma FI_i * BAF_i$" with the factor "FI*BCF," where BCF is the bioconcentration factor. A BCF is defined in the HHAWQC methodology document (2000a) as the ratio (in L/kg tissue) of the concentration of a substance in tissue of an aquatic organism to its concentration in the ambient water, in situations where the organism is exposed through the water only and the ratio does not change substantially over time. Like the BAF, the BCF represents a ratio that relates the concentration of a chemical in water to its expected concentration in commonly consumed aquatic organisms, but unlike the BAF, it does not consider uptake from the diet or potential sources such as sediments. BAFs are intended to be reflective of real environmental exposures and thus also reflect factors such as bioavailability and biodegradation. Thus, BAFs can be higher or lower than BCFs.

The factor FI*BCF is a single calculation rather than the summing of multiple trophic levels. In the most recent National Recommended Water Quality Criteria: 2002, Human Health Criteria Calculation Matrix tables, the BCF values used are accompanied by a footnote that reads, “The fish tissue bioconcentration factor (BCF) from the 1980 criteria documents was retained unless otherwise noted” (EPA 2002b).

States are free to calculate their own site-specific BAFs or follow the current EPA practice of using BCFs.

5.6 Implicit Elements in the Derivation of HHAWQC

The derivation of HHAWQC incorporates assumptions about exposure that are not explicitly recognized in the formal equations shown in Table 3.1. These include bioavailability, cooking loss, exposure duration, and exposure concentration.

5.6.1 *Relative Bioavailability*

Bioavailability may be defined as the degree to which a substance contained in water, food, soil, air, or other media can be absorbed by living organisms. Bioavailability is an important component of toxicity assessment since absorption is an essential prerequisite to systemic toxicity and the degree of bioavailability is an important determinant of the ultimate exposure level. EPA’s recommendations for the derivation of HHAWQC do not account for the bioavailability of substances and thus implicit is the assumption that the bioavailability of chemical substances in drinking water and fish tissue obtained from regulated waterbodies is the same as the bioavailability of those chemical substances in the studies from which the toxicity parameters (RfD, POD, cancer potency factor) were derived.

5.6.2 *Cooking Loss*

Chemical substances that may be present in fish tissue can be lost as part of the cooking process. Many substances that accumulate in fish tissues are associated with the lipid (i.e., fatty) content in the tissues. Most cooking practices result in partial loss of lipid and associated chemical substances. Other substances may be volatilized during the cooking process.

EPA’s recommendations for the derivation of HHAWQC do not account for chemical loss during cooking. Thus implicit is the assumption that 100% of chemical substances present in raw fish remain in edible portions of fish tissue after cooking.

5.6.3 *Exposure Duration*

EPA’s intentions for HHAWQC are to “minimize the risk of adverse effects occurring to humans from chronic (lifetime) exposures to substances through the ingestion of drinking water and consumption of fish obtained from surface waters” (EPA 2000a). Lifetime exposure is assumed to be 70 years. Thus the derivation of HHAWQC implicitly assumes that exposure to the criteria substance occurs continuously over 70 years.

5.6.4 *Exposure Concentration*

The combination of explicit toxicity and exposure elements as typically used in the HHAWQC derivation equation act to form an implicit assumption that the average concentration of regulated substances in water and fish tissue exist in the environment at their maximum allowed concentrations at all times over the course of a person's lifetime (presumed to be 70 years).

6.0 PROTECTIVENESS, CONSERVATISM, AND THE COMBINED EFFECT OF CONSERVATIVE PARAMETER VALUE CHOICES IN DERIVATION OF HHAWQC

The Clean Water Act, from which authority for the designation of HHAWQC is derived, specifies, in a very broad sense, the level of protectiveness that should be embodied in the HHAWQC. The Clean Water Act includes language such as "protect the public health and welfare," "protect public health… from any reasonably anticipated adverse effects of each pollutant," and "[not] pose an unacceptable risk to human health."

In its HHAWQC methodology document, EPA provides another fairly broad description of its desired level of protectiveness: "Water quality criteria are derived to establish ambient concentrations of pollutants which, if not exceeded, will protect the general population from adverse health impacts from those pollutants due to consumption of aquatic organisms and water, including incidental water consumption related to recreational activities" (EPA 2000a). They also note that HHAWQC are usually derived to protect the majority of the general population from chronic adverse health effects and that they consider their target protection goal to be satisfied if the population as a whole will be adequately protected by the human health criteria when the criteria are met in ambient water (EPA 2000a).

In order to derive HHAWQC that are "adequately protective," EPA states that they have selected default parameter values that are "a combination of median values, mean values, and percentile estimates [that target] the high end of the general population" (EPA 2000a). EPA (2000a) "believes that this is reasonably conservative and appropriate to meet the goals of the CWA…"

The term "conservatism," in the context of derivation of HHAWQC, is used to describe the use of assumptions and defaults that are likely to overstate the true risks from exposure to substances in drinking water and fish tissues. The policy choice to use such overstatements is rooted in EPA's approach to dealing with uncertainty and variability in the data upon which defaults and assumptions are based.

Uncertainty is an inherent property of scientific data and thus of the process of risk assessment and the derivation of HHAWQC. Since uncertainty is due to lack of knowledge, it can be reduced by the collection of additional data, but never eliminated completely. Variability is an inherent characteristic of a population because people vary in their levels and types of exposures and their susceptibility to potentially harmful effects of the exposures (NRC 2009). Unlike uncertainty, variability cannot be reduced but can be better characterized with improved information (NRC 2009).

In a staff paper[3] on risk assessment principles and practices, EPA (2004) discussed its approach to dealing with uncertainty and variability:

> Since uncertainty and variability are present in risk assessments, EPA usually incorporates a "high-end" hazard and/or exposure level in order to ensure an adequate margin of safety for most of the potentially exposed, susceptible population, or ecosystem. EPA's high-end levels are around 90% and above…

[3] Staff paper prepared by the Risk Assessment Task Force through the Office of the Science Advisor at EPA. The document presents an analysis of EPA's general risk assessment practices.

> …EPA's policy is that risk assessments should not knowingly underestimate or grossly overestimate risks. This policy position prompts risk assessments to take a more "protective" stance given the underlying uncertainty with the risk estimates generated. Another framing policy position is that EPA will examine and report on the upper end of a range of risks or exposures when we are not very certain about where the particular risk lies… Further, when several parameters are assessed, upper-end values and/or central tendency values are generally combined to generate a risk estimate that falls within the higher end of the population risk range.
>
> [The] issue regarding the appropriate degree of "conservatism" in EPA's risk assessments has been a concern from the inception of the formal risk assessment process and has been a major part of the discussion and comments surrounding risk assessment…

Given the attention focused on the issue of "the appropriate degree of conservatism," it is not surprising that many researchers have studied ways in which uncertainty and variability can be better characterized and reduced, with the ultimate goal of developing risk estimates that better achieve EPA's stated goals of neither underestimating nor grossly overestimating risk without the use of highly conservative default assumptions. The sections below summarize some of these efforts and, where data are available, attempt to quantify the level of conservatism embodied in EPA's current policy choices related to the selection of parameters for use in calculating HHAWQC.

As means of examining the implications of conservatism embodied in the HHAWQC derivation process, several examples are presented in the following sections. The example substances, which include mercury, arsenic, methyl bromide, chlordane, bis (2-ethylhexyl)-phthalate (or BEHP), and polychlorinated biphenyls (PCBs), were chosen for illustration purposes because they represent broad chemical categories (e.g., metals and organics), current and legacy substances, and substances with low and high bioconcentration factors.

6.1 Toxicity Factors

Derivation of an RfD, selection of a POD and UFs, modeling the dose-response for carcinogens, and calculating the slope factor (m) are based on science, but also involve a variety of policy decisions. These policy decisions all embody some degree of conservatism. This section addresses in greater detail the conservatism associated with the lack of consideration of bioavailability and the selection of default values for uncertainty factors and cancer risk levels.

6.1.1 *Relative Bioavailability*

As noted in Section 5, an implicit assumption in the HHAWQC derivation equation is that the bioavailability of chemical substances in drinking water and fish tissue obtained from regulated waterbodies is the same as the bioavailability of those chemical substances in the studies from which the toxicity parameters (RfD, POD, cancer potency factor) were derived. However, a RfD is often based on an animal toxicity study in which exposures occurred via drinking water and for some substances, the bioavailability from fish tissue will be different from that from drinking water. In some cases, bioavailability from foods might be reduced by, for example, the formation of indigestible complexes with other food components or conversion to ionized forms that cannot pass through biological membranes and thus cannot be absorbed. For example, arsenic in drinking water is primarily inorganic arsenic, which is absorbed well, but almost all of the arsenic in fish tissues is organic arsenic, which is not highly bioavailable. Arsenic may also form insoluble complexes with, for example, iron, aluminum, and magnesium oxides, which limits bioavailability. For these substances, any particular dose consumed in fish tissue would result in a lower absorbed dose than the same dose consumed in drinking water. Thus, a RfD based on a drinking water study would be lower than a RfD based on a dose administered in fish tissue. Use of this lower RfD will overestimate the potential hazards associated with the ingestion of fish tissue and will yield a lower HHAWQC (see, e.g., EPA 2000b).

EPA rarely provides information on the potential impacts of bioavailability on their RfDs and does not typically calculate alternative RfDs that might be used when expected exposures are via a route that is likely to result in reduced bioavailability. For example, most inorganic contaminants, particularly divalent cations, have bioavailability values of 20 percent or less from a food matrix, but are much more available (about 80 percent or higher) from drinking water (EPA 2000b). The Technical Support Document Volume 1: Risk Assessment (EPA 2000b) for the HHAWQC methodology document (EPA 2000a) does allow for the selection of an alternative RfD in cases where there is lower bioavailability of the contaminant when ingested in fish than when ingested in water and the existing RfD is based on a study in which the contaminant was administered through drinking water. However, in actual practice, this has not been done.

6.1.2 *Uncertainty Factors*

The UF methodology, which has its origins in the concept of "safety factors," has been the subject of discussion among scientists in many forums over the years. One of the most common issues of discussion is the scientific basis for the default factor of 10. It is generally accepted that selection of the first safety factors was based on qualitative judgment (Nair et al. 1995). Subsequently, however, attempts were made to justify the use of 10-fold factors based on data collected to characterize the uncertainty and variability associated with parameters such as intra- and interspecies differences.

One commonly accepted justification for the selection of 10 as the standard default uncertainty factor is that for any given chemical, the dose at which the endpoint of concern will be observed in the population of concern (e.g., the most sensitive subpopulation of humans) will be less than 10 times higher than the dose at which the endpoint of concern will be observed in the population that serves as a surrogate (e.g., average humans) for the purposes of deriving an RfD (Dourson et al. 1996).

The degree of conservatism embodied in the use of default factors of 10 has been examined by researchers who have summarized published data and determined the actual distributions of these ratios. Dourson et al. (1996) noted that "there is growing sentiment that …routine application [of 10-fold UFs] often results in overly conservative risk assessments."

For example, Nessel et al. (1995) were interested in the scientific basis for the application of an uncertainty factor of 10 when using a sub-chronic study instead of a chronic study to derive the RfD. The underlying assumption is that for any given chemical, the NOAELs and LOAELs of sub-chronic studies will be within a factor of 10 of the NOAELs and LOAELs of chronic studies. So, Nessel et al. (1995) compared NOAELs and LOAELs from 23 different sub-chronic oral toxicity studies to the NOAELs and LOAELs of chronic studies that were identical except for the study duration. The mean and median $NOAEL_{subchronic}/NOAEL_{chronic}$ ratios were 2.4 and 2.0, respectively. Twenty-two of the 23 studies had NOAEL ratios of 5 or less; only one had a ratio of 10. The LOAEL ratios' mean and median were also 2.4 and 2.0, with all 23 studies having $LOAEL_{subchronic}/LOAEL_{chronic}$ ratio of 5 or less. So, based on this study, an uncertainty factor of 5 is sufficient to account for differences between sub-chronic and chronic studies in 98% of studies. Kadry et al. (1995) reported similar findings as did the review conducted by Dourson et al. (1996).

Similarly, differences between LOAELs and NOAELs are typically less than 10 fold. Ninety-six percent of all LOAEL-to-NOAEL ratios in one study were 5 or less and 91% were 6 or less in another (summarized by Dourson et al. 1996). Kadry et al. (1995) reported similar findings.

The decision to use conservative default UFs has particular significance on the overall conservatism of the RfD that is derived using the UFs. Gaylor and Kodell (2000) examined this issue and quantified the increasing degree of conservatism as the number of default UFs applied increases.

When ratios are calculated for UFs as described in the two previous paragraphs, the distributions of these ratios are lognormal, with the value of 10 typically representing the 95th percentile (Swartout et al. 1998). Gaylor and Kodel (2000) calculated the uncertainty factors that would be required to maintain an overall 95th percentile level when multiple default uncertainty factors are applied. They found that for the use of any two UFs, for which the current default total UF would be 100, the UF required to maintain the 95th percentile level ranged from 46 to 85. For the use of any three UFs, for which the current default total UF would be 1000, the UF required to maintain the 95th percentile level ranged from 190 to 340. Swartout et al. (1998) conducted a similar analysis using a different technique and reported similar findings, concluding that default UFs of 100, 1000, and 3000, for application of two, three, and four UFs, respectively, can be replaced with UFs of 51, 234, and 1040, while maintaining the 95th percentile level.

If a composite UF calculated to maintain the desired 95th percentile level is used instead of the default values of 100, 1000, and 3000, the resultant RfD and subsequently calculated HHAWQC could be as much as 5x higher. For example, if the RfD for methyl bromide was calculated using an UF of 340 (the top of the range calculated by Gaylor and Kodel (2000)) instead of 1000, the RfD would be 0.0041 mg/kg/day rather than the existing value of 0.0014 mg/kg/day. This would yield a HHAWQC of 139 µg/L rather than 47 µg/L.

6.1.3 *Cancer Risk Levels*

EPA chose to use the one-in-one-million (10^{-6}) risk level as the default value when calculating HHAWQC because it believes this risk level "reflects an appropriate risk for the general population" (EPA 2000a). However, EPA (2000a) also notes that risk levels of 10^{-5} for the general population and 10^{-4} for highly exposed populations are acceptable.

The frequent use of the 10^{-6} risk level to represent "an appropriate risk for the general population" appears to be simply a policy choice with no solid scientific basis. In a paper[4] presented at the 84th Annual Meeting of the Air & Waste Management Association in 1991, Kelly reported that:

> …despite its widespread use: no agencies we contacted could provide documentation on the origins of 10^{-6}; its origin was determined to be a completely arbitrary figure adopted by the FDA as an "essentially zero" level of risk for residues of animal drugs; there was virtually no public debate on the appropriateness of this level despite requests by the FDA; this legislation stated that 10^{-6} was specifically not intended to be used as a definition of acceptable risk; 10^{-6} is almost exclusively applied to contaminants perceived to be of great risk (hazardous waste sites, pesticides); and 10^{-6} as a single criterion of "acceptable risk" is not and has never been in any EPA legislation or guidance documents.

The decision of which cancer risk level to use in any particular circumstance is, for the most part, something that has evolved over many years through policy positions put forth in various EPA reports and legislation, but the idea that cancer risk levels between 10^{-6} and 10^{-4} are acceptable have become widely accepted among the different EPA programs. For example, the 1990 Clean Air Act Amendments endorse a 1989 EPA assessment for benzene in which EPA identified 1 in 10 thousand (10^{-4}) as being an "acceptable" risk level and 1 in a million (10^{-6}) as representing "an ample margin of safety." An EPA Region 8 superfund site discussion[5] stated that:

> In general, the USEPA considers excess cancer risks that are below about 1 chance in 1,000,000 (1×10^{-6} or 1E-06) to be so small as to be negligible, and risks above 1E-04 to be

[4] Available online at http://www.deltatoxicology.com/pdf/10-6.pdf
[5] http://www.epa.gov/region8/r8risk/hh_risk.html

> sufficiently large that some sort of remediation is desirable. Excess cancer risks that range between 1E-06 and 1E-04 are generally considered to be acceptable, although this is evaluated on a case-by-case basis and EPA may determine that risks lower than 1E-04 are not sufficiently protective and warrant remedial action.

Jones-Otazo et al. (2005) compared screening level risk assessment practices among different regulatory agencies and found that most have adopted acceptable risk levels in the same range as EPA. The European Union (EU) and World Health Organization (WHO) both identify risks in the range of 10^{-6} to 10^{-4} as acceptable, while Health Canada uses 10^{-5} as their acceptable risk level (Jones-Otazo et al. 2005). With respect to cancer risks associated with pollutants in drinking water, WHO uses a 10^{-5} risk level: "In this and previous editions of the Guidelines [for Drinking Water Quality], an upper-bound excess lifetime risk of cancer of 10^{-5} has been used, while accepting that this is a conservative position and almost certainly overestimates the true risk" (WHO 2008).

Population Risk - One factor that has a significant effect on the magnitude of acceptable risk is the size of the affected population. Exposure of a population of 1 million to a carcinogen at the risk level of 1 in a million theoretically results in one additional case of cancer among those 1 million people over the course of 70 years. If the size of the population of concern is decreased to 100,000 instead of 1 million, the theoretical additional cases of cancer among those 100,000 individuals decreases to only 0.1 case over the course of 70 years. Population risk is an important consideration in selecting a fish intake rate for use in developing AWQC because as the size of the exposed population decreases, the population risks also decrease when the same target risk level is used. The higher the FI rate selected for a particular population, the smaller the population to which that rate applies. For example, if the FI rate selected is a 95th percentile rate, it is assumed that it is protective of all but 5 percent of the exposed population or 50,000 of the 1 million people provided in the example above. Thus, if the same target risk level of 1E-06 is used with this reduced population, the resulting population risk is 0.05 excess cancers within a population of 1 million people. In other words, in order to reach the target risk of 1 excess cancer, it would be necessary for a population of 20 million people to have lifetime exposures equivalent to the estimated exposure conditions. This topic is discussed in much greater detail in Appendix A, Section 4.0 Population Risk.

This concept is particularly relevant to HHAWQC derivation because very small populations of fish consumers with high intake rates are frequently identified as being of special concern during the HHAWQC derivation process. The HHAWQC methodology document states that a risk level of 10^{-4} for highly exposed populations is acceptable (EPA 2000a). This is sometimes interpreted as meaning that highly exposed populations are not as well protected by the HHAWQC. However, as noted by Kocher (1996) in a discussion of cancer risks at hazardous waste sites, "if only a small population would be at greatest risk, the expected number of excess cancers corresponding to individual risks at the *de minimis* level of 10^{-4} would still be [essentially] zero." Travis et al. (1987) reviewed 132 federal regulatory decisions and concluded that in actual practice, for small population risks, the *de minimis* lifetime risk was considered to be 10^{-4}.

Given that the 10^{-4} risk level has been identified as an acceptable/*de minimis* risk level for highly exposed populations, it may be useful to consider exactly what that risk level represents in terms of FI. If the default FI of 17.5 g/day represents a 10^{-6} target risk level, then a highly exposed population that eats as much as 1750 g/day will still be protected at a 10^{-4} risk level.

6.2 Explicit and Implicit Exposure Factors

The specific exposure factors that EPA uses in the derivation of HHAWQC include human body weight, drinking water consumption rates, and fish ingestion rates. In the HHAWQC methodology document, EPA states that the selection of specific exposure factors is "based on both science policy decisions that consider the best available data, as well as risk management judgments regarding the overall protection afforded by the choice in the derivation of AWQC" (EPA 2000a). This section addresses the levels of conservatism represented by the default values selected by EPA for individual explicit and implicit exposure factors.

6.2.1 *RSC*

The RSC determines what portion of the RfD will be allocated to the consumption of water and fish from regulated waterbodies. For example, if the RfD for a particular substance is 1 mg/kg/day and the RSC is 20%, then the HHAWQC must be set such that exposures to that substance via water and fish can be no more than 0.2 mg/kg/day. Thus, the lower the RSC, the lower the HHAWQC that will be derived.

Although EPA (2000a) does provide a decision tree methodology for calculating chemical- or site-specific RSCs, the lowest allowable value, 20%, is specified as the default RSC by EPA in its calculations of HHAWQC. EPA explains this in the HHAWQC methodology document (EPA 2000a) with the statement that "[the default value of 20%] is likely to be used infrequently with the Exposure Decision Tree approach, given that the information [required to calculate a chemical-specific RSC]…should be available in most cases. However, EPA intends to use 20 percent…" This statement clearly indicates that for most chemicals, an RSC greater than 20% is appropriate, but EPA has chosen to use the most conservative 20% default value. Use of an RSC of 20% when data indicate that a larger percentage is more appropriate can result in as much as a 4-fold reduction in the HHAWQC.

The California Office of Environmental Health Hazard Assessment (OEHHA) concluded that the default use of an RSC of 20% is "unreasonably conservative for most chemicals" (Howd et al. 2004). For 22 of the 57 chemicals listed by Howd et al. (2004), a RSC value greater than 20% was used in the calculation of California Public Health Goals for those chemicals in drinking water. Howd et al. (2004) also noted that "[a] default RSC of 0.2 is based on tradition, not data."

A recent Government Accountability Office report (GAO (2011) calculated the effect of using different RSC factors on the determination of drinking water health reference levels (HRLs) for a hypothetical chemical with an RfD of 0.5 µg/kg/day. While holding all other variables constant, RSC values of 20%, 50%, and 80% were inserted into the equation. The corresponding HRLs were 3.5 ppb (20%), 8.8 ppb (50%), and 14 ppb (80%).

A RSC may be calculated in two ways. The subtraction method allocates 100% of the RfD among the various sources of exposure. So, the daily exposure from all exposure routes other than drinking water and fish consumption are first subtracted from the RfD, then the remainder of the RfD is allocated to drinking water and fish consumption. The percentage method does not attempt to quantify exposures from other sources, but rather simply allocates a percentage of total exposure to drinking water plus fish consumption and to other sources.

EPA has chosen to use the percentage method as the default approach. EPA states that in most cases, they lack adequate data to use the subtraction method and that the percentage method is more appropriate for situations in which multiple media criteria exist (EPA 2000a). The GAO report (GAO 2011) notes that the percentage method is considered to be the more conservative option and generally yields a lower water quality criteria value. The GAO illustrated the difference in outcome by using the data for a hypothetical chemical to calculate drinking water health reference values (HRV) using both methods. Using the subtraction method, the HRV was 12.3 ppb. Using the percentage method, the HRV was 8.8 ppb, a 1.4-fold reduction.

6.2.2 *Body Weight*

The HHAWQC methodology document (EPA 2000a) recommends using a BW of 70 kg. This number was chosen in part because it is in the range of average values for adults reported in several studies and in part because it is the default body weight used in IRIS calculations. However, in 2011, EPA released an updated edition of the Exposure Factors Handbook (EPA 2011b). Based on data from the National Health and Nutrition Examination Survey (NHANES) 1999-2006, the new handbook recommends a mean BW value of 80 kg for adults.

The RfD is defined as "an estimate (with uncertainty spanning approximately an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious effects over a lifetime" (EPA 2000b). The RfD expresses this daily exposure as a function of body weight (mg of chemical per kg of body weight), so the daily exposure that is likely to be without appreciable risk will be lower for an individual with a lower body weight than for an individual with a higher body weight. Thus, the lower the body weight used in the calculation of the HHAWQC, the lower the resulting criteria. For this reason, the choice to use 70 kg as the default body weight adds to the conservatism of the HHAWQC and yields criteria values approximately 12.5% lower than those calculated using the more accurate population mean of about 80 kg BW recommended by EPA in the latest Exposure Factors Handbook (EPA 2011b).

6.2.3 *Drinking Water Intake*

EPA (2000a) cites several reasons for including the drinking water exposure pathway in the derivation of HHAWQC:

(1) Drinking water is a designated use for surface waters under the CWA and, therefore, criteria are needed to assure that this designated use can be protected and maintained.

(2) Although rare, there are some public water supplies that provide drinking water from surface water sources without treatment.

(3) Even among the majority of water supplies that do treat surface waters, existing treatments may not necessarily be effective for reducing levels of particular contaminants.

(4) In consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users to bear the costs of upgraded or supplemental water treatment.

These reasons make it clear that 2 L/day was selected as the default water consumption rate in support of larger goals related to pollution prevention and maintenance of designated use and does not represent a consideration of actual direct risk of adverse effect to any individual consumer. As EPA itself noted, it would be rare for anyone to use untreated surface water as a source of drinking water. The only direct consumption of untreated surface waters that might be considered to be routine is incidental ingestion during swimming, for which the EPA (2011b) recommended upper percentile default rates are 120 mL/hr for children and 71 mL/hour for adults. Using the 95th percentile estimate for time spent swimming each month (181 minutes) (EPA 2011b), annual daily average water consumption rates of 0.012 L/day (children) and 0.007 L/day (adults) can be calculated.

The default water consumption rate of 2L/day represents reported consumption of water from "community water," which is defined as tap water from a community or municipal water source. It does not represent a realistic level of consumption of untreated surface waters, which is likely to occur only as an incidental event of water-related recreational activities. However, by using 2 L/day in the calculation of the HHAWQC, EPA is deriving criteria values that are based on the assumption that the general population is indeed consuming 2 L/day of untreated surface water. Thus, the use of 2 L/day in the HHAWQC can insert a significant level of conservatism into the calculations.

The impact of the use of 2 L/day varies according to the BAF/BCF of the chemical. For chemicals with high BAFs/BCFs, the impact of drinking water intake on the ultimate HHAWQC is minimal due to the much larger contribution of the "fish intake x BAF" factor in the equation. However, for substances with low BAFs/BCFs, the impact is much greater. Table 6.1 shows the effect of changing drinking water intake rates on the HHAWQC of some example compounds with different BCFs.

Table 6.1 Human Health Ambient Water Quality Criteria Calculated for Varying Drinking Water Intakes

		HHAWQC (µg/L)		
Compound	BCF	DI = 2L/day (current default)	DI = 1L/day (mean DI for adults[1])	DI = 0.007L/day (ingestion while swimming)
Methyl bromide	3.75	47.4	91.96	1,349.40
Arsenic	44	0.017	0.031	0.137
BEHP[2]	130	1.17	1.53	2.19
Chlordane	14100	0.000804	0.000807	0.000811
PCBs	31200	0.0000639	0.0000640	0.0000641

[1]EPA 2011
[2]Bis(2-ethylhexyl)-phthalate

6.2.4 *Fish Consumption*

Note: Appendix A of this document contains a thorough treatment of topics related to the collection and interpretation of data used for deriving fish intake rates (FIs) (or fish consumption rates, FCRs) and applied in the derivation of HHAWQC. The appendix was prepared by Ellen Ebert, a recognized expert on interpretation of fish collection and consumption survey data.

Surveys of Fish Consumption - FIs tend to be overestimated in most surveys for a number of reasons. Individuals who respond to surveys with long recall periods tend to overestimate their participation in activities that are pleasurable to them. Creel surveys tend to be biased toward higher representation of more avid anglers who have high success rates and, thus, may consume at higher rates than the typical angler population. Short-term diet recall surveys tend to incorrectly classify people who eat a particular type of food infrequently as "non-consumers" and overestimate consumption by "consumers." Often people classified as "non-consumers" are excluded from the summary statistics of short-term diet recall survey resulting in an overestimate for ingestion rates for the entire survey population. Finally, when specific information is lacking from survey data, decisions are generally made during analysis of the survey data to ensure that consumption will not be underestimated (e.g., relatively large meal sizes will be substituted for unknown meal sizes, frequency of meals reported will be assumed to be consistent throughout the year regardless of fishing season, etc.) More detailed discussion of surveys used to determine FIs may be found in Appendix A.

Consumption of Marine and Imported Fish - As noted in Section 5.4 above, EPA's HHAWQC methodology document recommends that fish consumption rates be based on consumption of freshwater and estuarine species only and that any consumption of marine species of fish should be accounted for in the calculation of the RSC (EPA 2000a). However, the surveys used as the basis for EPA's recommended default fish consumptions rates collected information on the total consumption of fish of any species and from all sources, e.g., purchased or sport-caught fresh, frozen, or canned fish from local, domestic, or international sources (EPA 2011b). Surveys that collect information on the specific species consumed reveal that the majority of finfish consumed by Americans are marine species (Table 6.2). Also, as reported by the NOAA Fisheries Service[6], most of the seafood consumed in the U.S. is not caught in U.S. waters. In fact, about 86 percent of the seafood consumed in the U.S. is imported. Thus, the fish consumption rate used in the calculation of HHWQC significantly overestimates consumption of fish from regulated freshwater/estuarine waters by the majority of the population.

Table 6.2 Per Capita Consumption of Seafood in the U.S. – Top 10 Species (MBA 2011)

Type of Seafood	Pounds Consumed per Person/Year	Additional Comments
Shrimp	4	85% imported, mostly farmed, some wild caught
Canned tuna	2.7	Marine species
Salmon	2	Marine species
Tilapia	1.5	Farmed fish, most are imported
Pollack	1.2	Marine species
Catfish	0.8	Farmed fish, from both domestic and imported sources
Crab	0.6	
Cod	0.5	Marine species
Pangasius	0.4	Primary source is fish farms in Asia
Clams	0.3	

Additional discussion of the basis for excluding marine fish from fish consumption rate determinations may be found in Appendix B, which addresses issues relevant to the accumulation of persistent, bioaccumulative, and toxic chemicals by salmon in the context of the development of fish consumption rates in the state of Washington.

Consumption of Fish from Regulated Waters - Default assumptions that the general population consumes fish taken from contaminated water bodies every day and year of their entire life represent additional conservative assumptions. When applied to establishing permit limits or the risk

[6] http://www.noaanews.noaa.gov/stories2011/20110907_usfisheriesreport.html

assessment of a specific site or waterbody, the HHAWQC inherently assumes that 100 percent of the fish consumed over a lifetime are taken from that waterbody. This may be a reasonable assumption when the chemical constituents of concern are ubiquitous so that it is possible that individuals might receive similar levels of exposure even if they fish multiple waterbodies, but is likely to overestimate potential risk when applied to a single waterbody or one that is unique in terms of its chemical concentration or sources of the chemical in question. While it is possible individuals could obtain 100 percent of their fish from a single waterbody, this is not typical unless the waterbody is very large or represents a highly desirable fishery. In addition, individuals are likely to move many times during their lifetimes and, as a result of those moves, may change their fishing locations and the sources of the fish they consume. Finally, it is likely that most anglers will not fish every year of their lives. Health issues and other demands, like work and family obligations, will likely result in no fishing activities or reduced fishing activities during certain periods of time that they live in a given area. Thus, these assumptions add conservatism to the derivation of HHAWQC.

Implied Harvest Rate - EPA's default rate of 17.5 g/day indicates the amount of fish that is actually consumed. In order to achieve that rate, one must harvest 58 g/day of whole fish [assuming EPA's recommended edible portion of 30 percent (EPA 1989)] to yield 17.5 g/day of edible fish. When annualized, this results in 21,300 grams of fish per person or 47 pounds of fish per consumer per year. When considered over the 70-year exposure period (as assumed in the HHAWQC calculation), this results in the total removal of 3,300 pounds of fish/person during that period. In addition, if that individual is providing fish to a family of four, it would be necessary to remove roughly 13,000 pounds of fish from a single waterbody during that 70-year span. This represents a significant level of fishing effort and harvest and likely represents a substantial overestimate of any actual fish that is likely to be harvested from a single waterbody by a single individual.

Source of HHAWQC Default FIs - The food intake survey upon which the default fish consumption rates were based were short-term surveys. Numerous researchers have reported that the long-term average daily intake of a food cannot be determined using these short-term cross-sectional surveys (Tran et al. 2004). The use of short-term surveys has been shown to overestimate long-term food intakes in the upper percentile ranges (Tran et al. 2004) that are typically used by EPA in exposure assessments, especially for infrequently consumed foods (Lambe and Kearney 1999) like fish. Additional discussion of the limitations of the use of short-term survey data on fish consumption may be found in Appendix A, Section 3.2.2.

Summary - The fish consumption rates used in calculating HHAWQC can have a significant impact on the resulting HHAWQC. This is because the HHAWQC are proportional to the fish consumption rates (as the rate increases, the HHAWQC decreases) and there is substantial variability in the rates of fish consumption among the consuming population. In addition, the potential exposure through the fish consumption pathway is dependent upon a number of different variables including the types of fish consumed, the sources of those fish, and the rates at which they are consumed. The quantification of fish consumption rates is complicated by the methods used to collect consumption information, the availability of fish from regulated sources, and the habits of the targeted population of fish consumers.

The selection of fish consumption rates when calculating HHAWQC is discussed in more detail in Appendix A.

6.2.5 *Cooking Loss*

The derivation of HHAWQC is based on the assumption that there will be no loss of chemicals from fish tissues during the cooking process. However, numerous studies have shown that cooking reduces the levels of some chemicals. For example, Zabik et al. (1995) reported that cooking significantly reduced levels of the DDT complex, dieldrin, hexachlorobenzene, the chlordane complex, toxaphene, heptachlor epoxide, and total PCBs. Similarly, Sherer and Price (1993), in a review of published studies, reported that cooking processes such as baking, broiling, microwaving, poaching, and roasting removed 20-30% of the PCBs while frying removed more than 50%.

In its development of Fish Contaminant Goals (FCGs) and Advisory Tissue Levels, the State of California uses a cooking reduction factor to account for cooking loses for some chemicals:

> FCGs take into account organochlorine contaminant loss during the cooking process. The concentration of PCBs and other organic contaminants in fish are generally reduced by at least 30 percent, depending on cooking method… As such, a cooking reduction factor of 0.7 was included in the FCG equation for organic compounds (allowing for 70 percent of the contaminant to remain after cooking) (CA 2008).

By not incorporating a chemical-specific factor to adjust for cooking loss, the exposure level from fish consumption will be overestimated for organic compounds, thus lending an additional layer of conservatism to the resulting HHAWQC.

6.2.6 *Exposure Duration*

As noted in Section 5, exposure duration is an implicit element in the derivation of HHAWQC and a value of 70 years, or an approximate lifetime, is assumed. While average lifetimes may be approximated by 70 years, it is generally considered conservative to assume that an individual would be continuously exposed to substances managed through the development of HHAQWC because waters contaminated with such substances do not exist everywhere and it is unlikely that many persons would reside only in contaminated areas, and drink and fish only in these waters for an entire lifetime. Choosing to assume a 70-year exposure duration may be justified in cases where a pollutant is ubiquitous in the environment and thus it could reasonably be assumed that ingestion of drinking water and locally caught fish from essentially all freshwater locations would lead to similar levels of exposure. There is little evidence, however, supporting the ubiquity of most substances for which HHAWQC have been established (though an exception might be justified for mercury or other pollutants for which atmospheric deposition is the dominant mechanism contributing substances to surface waters).

Perhaps more significantly, however, it is uncommon for people to reside in a single location for their entire life. EPA's Exposure Factors Handbook (EPA 2011) contains activity factors, including data for residence time, from several US studies. Table 6.3 summarizes some of these results.

Table 6.3 Values for Population Mobility

	Mean	90^{th} Percentile	95^{th} Percentile
Residential Occupancy Period (Johnson and Capel 1992)	12 years	26 years	33 years
Current Residence Time (US Census Bureau 2008)	8 years (median) 13 years (mean)	32 years	46 years

As with other survey results, there is some uncertainty and potentially some bias associated with the residency periods reported in these studies. Additional studies are discussed (EPA 2011) concerning the distance people move, when they do move. However, the data clearly suggest that the central tendency (mean or median) and upper percentile values are substantially less than the 70 year exposure period assumed by EPA. The assumption of a 70 exposure duration overestimates median exposure duration by 8-fold, mean exposure duration by approximately 6-fold and the 90th percentile by 2- to 3-fold. Thus, the choice to use 70 years is conservative for most non-ubiquitous chemicals. Table 6.4 shows the effect on some example HHAWQC when assuming exposure durations of 70 and 30 years.

Table 6.4 HHAWQC Calculated Based on 70 and 30 Year Exposure Durations

	HHAWQC (µg/L)	
Compound	70 year exposure duration	30 year exposure duration
Arsenic	0.017	0.040
BEHP	1.17	2.73
Chlordane	0.000804	0.00187
PCBs	0.0000639	0.000149

6.2.7 *Exposure Concentration*

As noted in Section 5, implicit with the derivation of HHAQWC is the assumption that both the water column and fish tissue concentrations exist at their maximum allowed values for the entire 70 year exposure duration. In reality, water column concentrations vary over time and space. The assumption that concentrations are always the maximum allowed is unnecessarily conservative as a practical matter because, as described in the following paragraphs, regulations governing water quality in the US would not allow a substance to persist in a water body at the HHAQWC concentration for such a period.

EPA's Impaired Waters and Total Maximum Daily Load Program provides guidance to states concerning when waters are considered to be impaired. The EPA guidance is not specific as to recommendations for identifying stream impairments due to exceedances of HHAWQC and many state impaired stream listing methodologies lack specific provisions unique to the basis for establishing HHAWQC (i.e., exposure over a 70 year lifetime). However, it is common that states will consider listing a stream that exceeds WQC for chronic aquatic life (i.e., the CCC) and human health more than 10% of the time (i.e., the "10% rule"). Indeed, EPA guidance for listing impaired surface waters (EPA 2003b) states:

> "Use of the '10% rule' in interpreting water quality data in comparison with chronic WQC will generally be more appropriate than its use when making attainment determinations where the relevant WQC is expressed "concentration never to exceed ___, at any time." Chronic WQC are always expressed as average concentrations over at least several days. (EPA's chronic WQC for toxics in freshwater environments are expressed as 4-day averages. On the other extreme, EPA's human health WQC for carcinogens are calculated based on a 70-year lifetime exposure period.) Using the '10% rule' to interpret data for comparison with chronic WQC will often be consistent with such WQC because it is unlikely to lead to the conclusion that water conditions are better than WQC when in fact, they are not."

The guidance above suggests that listing of waters using the 10% rule is likely to be over protective for chronic aquatic life criteria. That is, it is considered unlikely that a water exceeding the chronic WQC 10% or less of the time would exist, on average, at the criterion value for the 4-day averaging period on which chronic WQC are based. By this same logic, it is an essentially impossible scenario that a water exceeding a HHAWQC 10% or less of the time would average at the criterion value for the 70 year averaging period on which HHAWQC are based.

It may be more realistic, instead, to predict a mean or median water column concentration using the HHAWQC as an upper percentile value occurring in the stream. Considering the 10% rule, one might predict the average water column concentration by assuming that the HHAWQC is the 90th percentile value in a distribution of water column concentrations existing over 70 years. By way of example, Table 6.5 illustrates the effect of variable stream concentrations on the ratio of the 90th percentile concentration to the mean concentration. An approximately normal distribution is assumed for these examples.

Table 6.5 Ratio of 90th Percentile Upper Bound Concentration to the Mean (normal distribution)

	Assumed Distribution	HHAWQC	Standard Deviation and Coefficient of Variation[1]	Estimated Mean[2]	Ratio HHAWQC/Mean
Substance X	Normal	1	0.25	0.68	1.5x
Substance Y	Normal	1	0.50	0.36	2.8x
Substance Z	Normal	1	0.60	0.23	4.3x

[1]The coefficient of variation (or relative standard deviation) is the ratio of the standard deviation to the mean and represents the degree of relative variability of the data around the mean.
[2]The 90th upper percentile of a normal distribution lies about 1.28 standard deviations from the mean.

The same general characteristic would be expected for stream concentrations that are log-normally distributed, which is a more common situation. Assuming that the values used in the normal distribution case in the previous table apply to the logarithms of the original data, a ratio of the antilogs of the HHAWQC (90th percentile value) and mean values in the normal distribution case can be calculated. Results are shown below in Table 6.6.

Table 6.6 Ratio of 90th Percentile Upper Bound Concentration to the Mean (lognormal distribution)

	Assumed Distribution	Antilog of HHAWQC	Standard Deviation of log concentrations	Estimated Geometric Mean[1]	Ratio HHAWQC/Geometric Mean
Subst. X	Lognormal	10	0.25	4.8	2.1x
Subst. Y	Lognormal	10	0.50	2.3	4.4x
Subst. Z	Lognormal	10	0.60	1.7	5.9x

[1]The geometric mean is equal to the antilog of the Estimated Mean in the normal distribution table.

As can be seen in Tables 6.5 and 6.6, the actual mean can be a small fraction of the upper 90th percentile value. In these examples the degree of conservatism embodied in the HHAWQC value ranges between 1.5x and 5.9x.

6.3 Compounded Conservatism

Compounded conservatism is the term used to describe the "impact of using conservative, upper-bound estimates of the values of multiple input variables in order to obtain a conservative estimate of risk…" (Bogen 1994). Bogen (1994) pointed out that "safety or conservatism initially assumed for each risk component may typically magnify, potentially quite dramatically, the resultant safety level of a corresponding final risk prediction based on upper-bound inputs." In the HHAWQC derivation process, compounded conservatism plays a role both in the determination of individual factors of the Equations 3.1, 3.2, and 3.3 (i.e., in the toxicity factors and explicit and implicit exposure elements) and in the equations' use of multiple factors, each based on upper bound limits and/or conservative assumptions.

In addition to the conservatism embodied in the selection of individual components of the calculations (both explicit and implicit), the fundamental underlying assumption, which is that the most sensitive subpopulations will be exposed to maximum allowable concentrations over a full lifetime, is a highly unlikely and highly protective scenario. For example, the derivation of HHAWQC is based on the assumptions that an individual will live in the same place for their entire life (70 years) and that 100% of the drinking water and fish consumed during those 70 years will come from the local water body being regulated.

The suggestion that the use of multiple default factors based on upper bound limits and/or conservative assumptions lead to a situation of compounded conservatism has been the subject of considerable discussion (see Section 6.0). However, in a staff paper, EPA suggests that "when exposure data or probabilistic simulations are not available, an exposure estimate that lies between the 90th percentile and the maximum exposure in the exposed population [should] be constructed by using maximum or near-maximum values for one or more of the most sensitive variables, leaving others at their mean values" (EPA 2004). This appears to be an acknowledgement that adequately protective assessments do not require that each, or even most, component parameter(s) be represented by a 90th or 95th percentile value.

Similarly, in the 2005 Cancer Risk Assessment Guidelines, EPA (2005) stated:

> Overly conservative assumptions, when combined, can lead to unrealistic estimates of risk. This means that when constructing estimates from a series of factors (e.g., emissions, exposure, and unit risk estimates) not all factors should be set to values that maximize exposure, dose, or effect, since this will almost always lead to an estimate that is above the 99th-percentile confidence level and may be of limited use to decision makers.

Viscusi et al. (1997) provided a simple example to illustrate compounded conservatism. In Superfund exposure assessments, EPA states that they consider "reasonable worst case" exposures to be in the 90-95th percentile range (Viscusi et al. 1997). However, the use of just three conservative default variables (i.e. 95th percentile values) yields a reasonable worst case exposure in the 99.78th percentile. Adding a fourth default variable increases the estimate to the 99.95th percentile value. In a survey of 141 Superfund sites, the authors reported that the use of conservative risk assessment parameters in site assessments yields estimated risks that are 27 times greater than those estimated using mean values for contaminant concentrations, exposure durations, and ingestion rates.

In a recent report on the economics of health risk assessment, Lichtenberg (2010) noted that the use of conservative default parameters is intended to deliberately introduce an upward bias into estimates of risk. Lichtenberg (2010) also stated that "the numbers generated by such procedures can't really be thought of as estimates of risk, since they bear only a tenuous relationship to the probability that individuals will experience adverse health consequences or to the expected prevalence of adverse health consequences in the population." Indeed, he pointed out that the number of actual cancer deaths that can be attributed to all environmental and occupational causes is much lower than the number that is predicted by risk assessments (Doll and Peto 1981, as cited by Lichtenberg 2010). Lichtenberg (2010) describes concerns about compounded conservatism by saying:

> …regulators continue to patch together risk estimates using a mix of "conservative" estimates and default values of key parameters in the risk generation process. Such approaches give rise to the phenomenon of compounded conservatism: The resulting estimates correspond to the upper bound of a confidence interval whose probability is far, far greater than the probabilities of each of the components used to construct it and which depends on arbitrary factors like the number of parameters included in the risk assessment.

6.4 Summary

Most of the components of the equations used to calculate HHAWQC contain some level of conservatism. The toxicity factors in and of themselves contain multiple conservative parameters, leading to a compounding of conservatism in their derivation. The default RSC is the most conservative allowable level derived using the more conservative of two possible approaches. The default body weight of 70 kg is 10 kg less than the EPA currently recommended value of 80 kg. The derivation process for the HHAWQC does not take into account expected cooking losses of organic chemicals. The compounded conservatism that results from the use of multiple conservative factors yields a HHAWQC that provides a margin of safety that is considerably larger than EPA suggests is required to be protective of the population, even when sensitive or highly exposed individuals are considered. Tables 6.7 and 6.8 illustrate the impact of replacing just two default parameters, body weight and drinking water intake, with average values and allowing for cooking loss on the HHAWQC for methyl bromide and bis(2-ethylhexyl)-phthalate (BEHP).

Table 6.7 Impact of Multiple Conservative Defaults/Assumption on Methyl Bromide HHAWQC

Parameters Used	HHAWQC (µg/L)
Default	47
Factor of 0.7 included for cooking loss	48
Factor of 0.7 included for cooking loss + DI default (2 L/day) replaced by mean value of 1 L/day	94
Factor of 0.7 included for cooking loss + DI default (2 L/day) replaced by mean value of 1 L/day + Default BW of 70 kg replaced by current EPA recommended BW of 80 kg	107

Table 6.8 Impact of Multiple Conservative Defaults/Assumption on BEHP HHAWQC

Parameters Used	HHAWQC (µg/L)
Default	1.17
Factor of 0.7 included for cooking loss	1.39
Factor of 0.7 included for cooking loss + DI default (2 L/day) replaced by mean value of 1 L/day	1.93
Factor of 0.7 included for cooking loss + DI default (2 L/day) replaced by mean value of 1 L/day + Default BW of 70 kg replaced by current EPA recommended BW of 80 kg	2.20

Not only do the individual components of the equations represent a variety of conservative assumptions, the underlying premise upon which calculations of HHAWQC are based is itself highly conservative. It assumes that 100 percent of the fish and drinking water consumed by an individual over a 70 year period is obtained from a single waterbody (or that a chemical is ubiquitous in all water), that the chemical is present at the HHAWQC at all times, an individual consumes fish every year at the selected upper bound consumption rate, and that no loss of the chemical of interest occurs during cooking.

In addition, the toxicological criteria used to develop the HHAWQC have been selected to be protective of the most sensitive individuals within the exposed population and have been combined with conservative target risks. It is unlikely that this combination of assumptions is representative of the exposures and risks experienced by many, if any, individuals within the exposed population.

Tables 6.9 and 6.10 summarize the primary sources of conservatism found in both the explicit and implicit toxicity and exposure parameters of HHAWQC derivation and, for some parameters, quantify the extent of that conservatism.

Table 6.9 Conservatism in Explicit Toxicity and Exposure Parameters

Explicit Exposure Parameter	Default Value	Represents:	Default is conservative because:	Impact of conservatism on HHAWQC (if known)
RfD	N/A	Estimate of daily exposure likely to be without appreciable risk of adverse effects over a lifetime	Bioavailability not typically considered, effects of compounded conservatism in use of multiple UFs	Larger RfD yields higher HHAWQC, magnitude uncertain and varies between compounds
RSD	N/A	Dose associated with incremental risk level of 10^{-6}	based on upper bound risk estimate	Magnitude uncertain, varies between compounds
Relative Source Contribution (RSC)	20%	Fraction of total exposure attributable to freshwater/ estuarine fish	For most chemicals, available data support a larger RSC	Larger RSC yields 1.5x to 4x higher HHAWQC
Body Weight (BW)	70 kg	Adult weight, average for the general population	Mean body weight for adults is now 80 kg	Use of 80 kg yields 1.125x higher HHAWQC
Drinking Water Intake (DI)	2 L/day	86^{th} percentile of general population	Assumes all water consumed is at HHAWQC and that all drinking water is untreated surface water	Magnitude is compound specific[7]
Fish Intake (FI)	17.5 grams/ day for general population and sportfishers 142.4 grams/ day for subsistence fishers	90th percentile per capita consumption rate for the U.S. adult population	Represents an upper percentile, most people eat less fish	Magnitude is compound specific[8]
Bioconcentration Factor (BCF)	Substance specific	Tissue:water ratio at 3% tissue lipid	NA	NA

[7] HHAQWC are inversely proportional to DI value for substances with low BCFs. The DI value has very little influence on HHAWQC for substances with high BCFs.
[8] HHAQWC are inversely proportional to FI value for substances with high BCFs. The FI value has very little influence on HHAWQC for substances with low BCFs.

Table 6.10 Conservatism in Implicit Exposure Parameters

Implicit Exposure Parameter	Default Value	Represents:	Default is conservative because:	Impact of conservatism on HHAWQC (if known)
Cooking Loss	zero	loss of organic chemical during cooking	Does not account for the known 20-50% reduction in concentration of organic chemical in fish tissues following cooking	Inclusion of a factor to account for cooking loss yields 1.25x to 2x higher HHAWQC
Exposure Duration	70 years	Length of time a person is exposed	Assumes 100% of drinking water and fish consumed over the course of 70 years will come from a regulated water body	For non-ubiquitous compounds, recognizing that residency periods are much shorter than 70 years yields HHAQWC that are 2x to 8x higher.
Exposure Concentration	HHAWQC	Concentration in water body of interest equal to HHAWQC	Assumes concentration is always equal to HHAWQC without regard for changes in input or in flow characteristics	Magnitude uncertain but could easily be 1.5x to more than 4x
Relative Bioavailability	1	Bioavailability from fish and water compared to bioavailability in the experiment from which the toxicity benchmark was derived.	Some chemicals are less bioavailable in water or fish tissue than in the experiments from which toxicity benchmarks were derived.	Magnitude is chemical specific

7.0 IMPLICATIONS OF HHAWQC FOR FISH TISSUE CONCENTRATIONS AND CHEMICAL EXPOSURES VIA FISH CONSUMPTION

7.1 Fish Tissue Concentrations

The purpose for including factors for fish intake and bioaccumulation/bioconcentration in the derivation of HHAWQC is to account for consumption of chemicals that are contained within fish tissues. An underlying assumption of this approach is that the HHAWQC correspond to a chemical concentration in edible fish tissue that yields an acceptable daily intake when fish from surface waters are consumed at the default intake rates (e.g., 17.5 g/day general population or 142 g/day subsistence anglers). Once a HHAWQC is calculated, the allowable fish tissue concentration (FTC) associated with that HHAWQC can be easily derived using the same equation. One way of assessing the overall conservatism of the process through which HHAWQC are derived is to compare the associated allowable fish tissue concentrations to existing fish tissue concentration data and concentrations found in other foods, as well as other guidelines or risk-based levels used to regulate chemical concentrations in edible fish tissues (e.g., fish consumption advisory "trigger levels," US Food and Drug Administration (FDA) tolerances).

Appendix C, "Fish Tissue Concentrations Allowed by USEPA Ambient Water Quality Criteria (AWQC): A Comparison with Other Regulatory Mechanisms Controlling Chemicals in Fish," illustrates this type of analysis using six example compounds: arsenic, methyl bromide, mercury (total, inorganic, organic), PCBS (total), chlordane, and bis-(2-ethylhexyl)phthalate (BEHP). The analysis revealed that:

- Concentrations of PCBs and mercury in fish from virtually all surface waters in the U.S. exceed FTCs associated with HHAWQC derived using the FI rate for subsistence anglers (142 g/day).
- FTCs associated with HHAWQC derived using the FI rate for the general public (17.5 g/day) are 20 times to 4,000 times lower (more stringent) than fish consumption advisory "trigger levels" commonly used by state programs.
- Although about 50% of fish samples collected during a national survey had PCB levels greater than the allowable PCB FTC associated with the HHAWQC, only about 15% of the nation's reservoirs and lakes (on a surface area basis) are subject to a fish consumption advisory. When the FI for subsistence anglers is used to calculate a HHAWQC for PCBs, the percentage of samples exceeding the associated FTC increases to 95%.
- The FDA food tolerances for PCBs, chlordane, and mercury in fish are, respectively, 500, 27, and 2.5 times greater than the FTCs associated with the HHAWQC for those chemicals. If the subsistence angler FI rate (142 g/day) is used to calculate the HHAWQC, the FDA food tolerances for those chemicals are, respectively, 4,000, 214, and 20 times greater.

These results indicate that, with respect to FTCs, the HHAWQC as they are currently calculated, with a default FI rate of 17.5 g/day, provides a wide margin of safety below the FTCs considered acceptable by states (as indicated by FCA trigger levels) and by the FDA (as indicated by food tolerances).

7.2 Chemical Exposures via Fish Consumption

Once the FTC associated with a HHAWQC is calculated, that value can also be used to estimate the allowable daily dose of that chemical. Comparing the allowable daily dose associated with HHAWQC with actual exposures to the general population via other sources provides an indication of the potential health benefits that might be gained by increasing the default fish consumption rate and thus lowering the HHAWQC. Appendix C shows the results of such a comparison for six example compounds (arsenic, methyl bromide, mercury (total, inorganic, organic), PCBS (total), chlordane, and BEHP and indicates that for all of these chemicals, exposure via consumption of fish from surface waters to which HHAWQC apply represents only a small percentage of the total exposure from all sources. Therefore, reducing exposures to chemicals via fish consumption by lowering HHAWQC may not provide any measurable health benefits.

8.0 CONCLUSIONS

HHAWQC are derived by EPA, or by authorized states or tribes, under the authority of Section 304(a) (1) of the Clean Water Act (CWA). The methodology by which HHAWQC are derived is based on equations that express a risk analysis. The values used in the HHAWQC equation are based on scientific observations (generally a range of observations) and, thus, have a scientific basis. However, the selection of a single value to represent the full range of observations represents a policy choice and is a subjective decision. Therefore, HHAWQC, though based on science, represent a policy (i.e., non-scientific) choice (EPA 2011a). EPA has stated that their goal in setting HHAWQC is to "protect individuals who represent high-end exposures (typically around the 90th percentile and above) or those who have some underlying biological sensitivity" (EPA 2004). To that end, its selections for individual default parameter values are typically upper percentiles of a distribution (e.g., a 90th percentiles value for fish consumption rate) or conservative assumptions (e.g., 100% of water used for drinking and cooking during a 70 year lifespan is untreated surface water).

The parameters used in the derivation of HHAWQC may be divided into two categories, toxicity parameters and exposure parameters. Toxicity parameters fall into three categories: 1.) non-carcinogenic effects, for which the parameter is the RfD, 2.) non-linear carcinogenic effects, for which the parameters are the POD and UF, and 3.) linear carcinogenic effects, for which the parameter is the RSD, which is derived from the slope factor and the target incremental cancer risk. Derivation of an RfD, selection of a POD and UFs, modeling the dose-response for carcinogenic effects, and calculating the slope factor (m) are based on science, but also involve a variety of policy decisions. These policy decisions all embody some degree of conservatism, such as the use of multiple 95th percentiles and upper bound confidence limits. Thus, the factors representing toxicity in the HHAWQC derivation equation certainly represent conservative (i.e., selected to more likely overestimate than underestimate risks) estimates of toxicity and act to drive HHAWQC toward lower concentrations.

Explicit exposure parameters include the RSC, BW, DI, FI, and BAF. There are also implicit parameters that, while not components of the equations used to calculate HHAWQC, are assumptions that underlie HHAWQC derivation. As with the toxicity parameters, most of the exposure parameters are based on scientific observations, generally a range of observations and thus have a scientific basis. However, selection of a single value to represent the full range of observations is a policy choice. Default values for these parameters and the degree of conservatism associated with them are summarized in Tables 6.9 and 6.10, which shows that these parameter values represent upper percentile values and highly conservative assumptions that act to drive HHAWQC toward lower concentrations.

EPA acknowledges in more recent guidance that the existence of the phenomenon of compounded conservatism, which occurs when the combination of multiple highly conservative assumptions leads to unrealistic estimates of risk. It suggests that in order to avoid this problem when constructing estimates from a series of factors (e.g., exposure and toxicity estimates), not all factors should be set to values that maximize exposure, dose, or effect (e.g., EPA 2005). However, in spite of that, most of the parameters used for the derivation of HHAWQC are set at the 90th (or higher) percentile level.

The overall level of conservatism embodied within the HHAWQC derivation process is illustrated by comparing the allowable fish tissue concentration implied by the designation of HHAWQC to existing guidelines or risk-based levels used to regulate chemical concentrations in edible fish tissues, such as fish consumption advisory "trigger levels" and US Food and Drug Administration (FDA) tolerances. Fish tissue concentrations associated with HHAWQC derived using the fish intake rate for the general public (17.5 g/day) are 20 times to 4,000 times lower (more stringent) than fish consumption advisory "trigger levels" commonly used by state programs. Similarly, FDA food tolerances for PCBs, chlordane, and mercury in fish are, respectively, 500, 27, and 2.5 times greater than the HHAWQC-associated fish tissue concentrations and if the subsistence angler fish intake rate (142 g/day) is used to calculate the HHAWQC, the FDA food tolerances for those chemicals are, respectively, 4,000, 214, and 20 times greater.

Following a consideration of the overall level of conservatism contained within the HHAWQC, the level of protectiveness that EPA has indicated that states should achieve, and concerns that have been expressed by certain segments of the public and some state regulators and elected officials, three issues in particular seem to stand out. The first is the idea that HHAWQC represent an estimate of likely actual exposures to the public, such that, for example, if a HHAWQC is set at 42 ppb, the general public will be exposed to 42 ppb and therefore, any subgroups that may, e.g., consume more fish than average, will not be adequately protected by a 42 ppb HHAWQC. However, a consideration of the sources of the various parameters used to calculate the HHAWQC, as provided in preceding sections of this report, clearly shows that this is not the case.

The second is the idea that, because the HHAWQC for carcinogens are based on a 10^{-6} risk level for the general population, highly exposed subgroups whose risk level might be 10^{-5} or 10^{-4} are not being adequately protected. A consideration of the concept of population risk, as described in Section 6.1.3 demonstrates that this is not the case. Even if a small subgroup of the general population has higher exposures (e.g., higher rates of fish consumption), the expected number of excess cancers corresponding to individual risks at the 10^{-4} risk level is essentially zero. Indeed, in actual practice, in Federal regulatory decisions related to small population risks, the *de minimis* lifetime risk is typically considered to be 10^{-4}.

Finally, there is the belief that increasing the fish consumption rates used to derive HHAWQC which will, in turn, lower HHAWQC, will benefit public health, particularly for populations of high level consumers of fish from regulated surface waters. However, an analysis of six chemicals, selected to represent a range of chemical classes, clearly shows that exposures via consumption of fish from regulated water bodies is only a small percentage of the total dietary exposure from all sources. Thus, the establishment of more stringent HHAWQC may not provide any measurable public health benefit.

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APPENDIX A

FISH CONSUMPTION RATE (FCR)

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1.0 INTRODUCTION

A key component of the equation used to derive ambient water quality criteria (AWQC) is the long-term fish consumption rate (FCR). Selection of an appropriate FCR can be challenging for a number of reasons. In certain cases, there may not be relevant, local or regional fish consumption data available from which to select rates. In other instances, numerous studies of fish consumption behaviors may have been conducted, but the studies report a wide range of FCRs for similar consumer populations. Often, in light of the variability in FCRs, there is a tendency for regulators to select the most conservative (highest) of the available rates to ensure that HHAWQC will be protective of potentially exposed populations, thereby adding considerable conservative bias to the HHAWQC. While there is always variability in consumption rates due to differing behaviors among the consumers, in many cases, the variability among the reported rates for similar populations is a consequence of the survey design, methodology, and approach used to analyze the data, rather than actual variability in consumption rates. It is important to understand how the approaches used to collect and analyze fish consumption data may bias results so that the most appropriate and representative rates can be selected for the development of HHAWQC.

2.0 CURRENT EPA GUIDANCE

EPA's (2000) methodology for deriving AWQC recommends that, when available, consumption rates for populations of concern should be drawn from local or regional survey data. The consideration of local and regional survey data is important in deriving AWQC because these data may vary widely depending upon the waterbodies to which the AWQC will be applied, the population of individuals who may consume fish from those waterbodies, seasonal influences on fishing, availability of desirable species, and the particular consumption habits of those individuals. In many situations, the population of consumers may be the general population who consume fish from commercial sources; in other situations, the only consumers may be the population of fishermen who catch and consume their own fish from a particular waterbody. Typically, recreational fishermen are the population that is likely to consume the most fish from a specific waterbody as they may repeatedly fish that waterbody over time. This is a common rationale for using the habits of this population as a basis for deriving an FCR to be used in developing AWQC.

When local or regional survey data are not available, EPA has historically recommended that a default FCR of 17.5 g/day be used (EPA 2000). This rate is an estimate of the 90th percentile rate of consumption of freshwater and estuarine finfish and shellfish by adults in the general population of the United States. It is an annualized, long-term rate that indicates that the targeted population may consume roughly one half-pound fish meal every two weeks (28 meals/year) from the waterbodies to which the AWQC will be applied. It is based on the USDA's Continuing Food Studies data (USDA 1998) and is recommended by EPA for deriving AWQC because it represents an estimate of high end fish consumption by the general population and average consumption among sport anglers. If subsistence populations are present, EPA (2000) states that a default consumption rate of 142.4 g/day may be used. This rate indicates that this population may consume roughly 229 half-pound meals of fish per year or more than four meals per week.

In addition, EPA (2011) has evaluated a substantial portion of the fish consumption literature and has presented the results of its analysis in its revised *Exposure Factors Handbook*. This guidance presents the findings of the studies and the estimates that EPA has derived based on its analysis of the data. A variety of recommended FCRs are presented for the general population of the United States, individuals who consume sport-caught fish from marine waters, individuals who consume sport-caught fish from freshwaters, and various subpopulations of fishermen. While the previous version of the *Exposure Factors Handbook* made specific recommendations of FCRs to be used, the revised version does not provide specific recommendations. Instead, it presents a range of values from studies that it identified as being relevant and reliable and instructs readers to select the value that is most relevant to their needs.

One difficulty with the way that the FCRs are presented in EPA's tables of recommendations is that not all studies are conducted in the same way. While the text of that guidance discusses the methodologies, strengths and weaknesses of each of those studies, it presents the resulting rates as if they are equivalent. However, the choices made in study design, target population, and approach to data analysis result in a wide range of FCRs. This variability among the FCRs presented can be confusing, resulting in a tendency for risk managers to select rates at the high end of those ranges to ensure protection of public health. The variability, however, is primarily the result of differences in the types of populations and fisheries studied, and the study designs employed. It is important to consider all of these factors in selecting an FCR (Ebert et al. 1994). When setting AWQC, it is important to select values that are representative of the target population to ensure that public health is being protected without putting unmanageable or unnecessary burdens on those who must comply with the AWQC (Ebert et al. 1994).

3.0 ANALYSIS OF FCR SURVEY DATA

While there are many studies of fishing consumption behavior available, it is important to consider the quality of the studies for the purpose of estimating FCRs. Many fishing surveys include collection of some data related to consumption of fish but often that is not the purpose for which the surveys were designed. Instead they may have been designed to determine dietary preferences, assess compliance with advisories, estimate fishing effort and success, determine angler preferences, etc. As such, while they may contain some information about consumption by the surveyed individuals, the data collected may not be adequately detailed or comprehensive to permit the estimation of reliable, long-term FCRs for that population.

For example, Connelly et al. (1992) conducted a survey of New York recreational anglers that provided information about sport-caught fish consumption but the study was designed for the purpose of providing information about anglers' knowledge of fishing advisories in New York and the impacts of the advisories on their fishing and consumption behavior. While it collected information about the number of meals and species consumed, it did not collect information about the size of fish meals. In order to use these data, one must make an assumption about the size of each meal, which in turn affects the rates derived from the study. When EPA (2011) analyzed these data to derive consumption rates, they assumed that each meal was 150 g in size based on a study of the general population conducted by Pao et al. (1982). Had EPA made different assumptions about meal size, they might have derived substantially higher or lower consumption rate estimates. It cannot be determined from the available data whether the rates derived by EPA were actually representative of consumption rates for the surveyed population.

There are a number of other survey design and analysis issues that affect the estimation of FCRs that may be considered in deriving AWQC. To better understand the nuances of FCRs derived from surveys of target populations, it is important to understand the influence that survey design and analysis can have on consumption rate estimates. These issues are discussed below.

3.1 Survey Methods

Fish consumption surveys can be conducted in a number of different ways. These methods include creel (or intercept) surveys, recall mail and telephone surveys, fishing diaries, and dietary recall studies. Each of these methods can be designed to provide information based on short- or long-term periods of recall (periods of time over which individuals are asked to remember their fish consumption behaviors).

While each of the survey methods can be used to estimate rates of consumption, each method has particular strengths and weaknesses and the survey design can greatly affect the resulting FCR estimates. Thus, the survey method used, the recall period, and the target population all need to be considered carefully when comparing FCRs that are reported. Many times the magnitude of the estimated FCRs are an artifact of the study methodology rather than a reflection of actual differences in fish consumption behaviors.

3.1.1 Creel Surveys

Historically, creel surveys have been used by fisheries managers to collect information about catch and harvest rates and determine the adequacy and characteristics of fishery stock. In some cases, however, creel surveys are modified to collect specific information about fish consumption based on individual fishing trips to a particular waterbody. Generally, survey clerks make contact with individuals who are fishing on a particular survey day to ask them what they have caught and what they intend to eat. Typically individuals are only interviewed once during a survey period (no repeat interview) although sometimes repeat interviews are part of the survey design and the responses on multiple interview days are combined for the individual.

Creel surveys are very effective for collecting information about consumption from a specific waterbody by the individuals who use that waterbody. In addition, if there is a particular subpopulation that uses the fishery differently from the general angler population, those individuals will be identified and their consumption habits captured.

While creel surveys provide reliable information about the fish catch on the day of the interview, they are subject to a number of limitations when attempting to estimate long-term average FCRs, which are the rates that are generally used in developing AWQC.

- Consumption rates based on creel surveys are subject to avidity bias; that is, there is a greater chance of interviewing more avid anglers because they are present at the fishery more frequently. More avid anglers are likely to be more successful anglers and, if they harvest fish for consumption, their rates of consumption are likely to be higher than the typical anglers' consumption rates. In order to use creel survey data to estimate consumption habits of the total user population, it is necessary to make a correction for avidity bias so that the results are representative of the entire angler population that uses the fishery (EPA 2011).

  EPA (2011) discusses this phenomenon in its discussion of FCRs in its 2011 *Exposure Factors Handbook*, stating that "in a creel study, the target population is anyone who fishes at the locations being studied. Generally in a creel study, the probability of being sampled is not the same for all members of the target population. For instance, if the survey is conducted for one day at a site, then it will include all persons who fish there daily but only about 1/7 of the people who fish there weekly, 1/30th of the people who fish there monthly, etc. In this example, the probability of being sampled … is seen to be proportional to the frequency of fishing...[B]ecause the sampling probabilities in a creel survey, even with repeated interviewing at a site, are highly dependent on fishing frequency, the fish intake distributions reported for these surveys are not reflective of the corresponding target populations. Instead, those individuals with high fishing frequencies are given too big a weight and the distribution

> is skewed to the right, i.e., it overestimates the target population distribution." (EPA 2011, p. 10-3)

To correct for avidity bias, the survey sample is typically weighted based on the reported frequency of fishing by survey participants (EPA 2011; Price et al. 1994). For example, a single day of surveying may have encountered three individuals: 1) one individual who fished with a frequency of one day per year; 2) one individual who fished with a frequency of one day per month; and 3) one individual who fished daily. If those individuals ate one half pound (227 g) fish meal on each day of fishing, their annualized average daily FCRs would be 0.62, 7.5 and 227 g/day, respectively. Based on this 3-person sample, one would conclude that the average consumption rate for these three individuals was 78 g/day. However, if the survey were to be conducted at that location daily throughout the year, it is likely that it might have encountered 365 individuals who fished once per year, 12 individuals who fished once per month, and one individual who fished daily. Thus, the total user population would be 396 individuals, representing 396 points on the fish consumption distribution for the total user population. If their FCRs were identical to the rates for the individuals interviewed during the single day of the survey, the result would be 365 individuals consuming 0.62 g/day, 30 individuals consuming 7.5 g/day, and 1 individual consuming 227 g/day. Thus, for this total angler population, the average rate would be 1.7 g/day. This is substantially lower than the average of 78 g/day based on the actual sample of three individuals. This demonstrates the considerable conservative bias introduced to the FCR estimate if avidity bias is not corrected. Actual corrections depend on the frequency of sampling and the population sampled and so need to be made on a study-by-study basis.

While it is now recognized that avidity bias needs to be considered when analyzing survey data to derive estimates that are representative of the total consuming population, this was not generally done for historical surveys and is still often not done by current study authors. Instead, the consumption rates presented in many survey reports reflect the consumption rates derived from only those individuals who were sampled and thus are biased toward more frequent anglers and consumers. Sometimes it is possible to make these corrections retroactively if the raw data are still available, but often this is not the case. As a result, many consumption estimates that are presented based on creel survey data have not been adjusted to reduce this conservative bias and consequently overestimate consumption rates for the total target population.

- Short-term behavior captured during a single snapshot in time may not be representative of long-term behavior because of variability in fishing effort and success. There may be substantial seasonal variations in the habits of anglers due to fishing regulations, climate, and the availability of target species. Consequently, information collected during a single interview may not be representative of activity on previous or subsequent trips or at other times of the year. Because of limited time for conducting interviews, it is difficult to ask enough detailed questions to allow development of a reliable estimate of the long-term rates of consumption. In addition, the assumptions that must generally be made to extrapolate from short-term data to estimate long-term behaviors add greatly to the uncertainties associated with those estimates.

  Creel surveys are effective at characterizing the consumption habits of individuals who use a specific fishery and are helpful in identifying any subpopulations of fish consumers that are present. It is more challenging, however, to derive a long-term estimate of consumption or to expand the results to a larger geographic area unless very detailed information is collected and there is an appropriate correction for avidity bias.

3.1.2 *Mail Surveys*

Mail surveys are a good tool for collecting detailed information about fishing and consumption behaviors. Generally, mail surveys are designed to randomly sample the target population. Often, for fish consumption, the target population is recreational anglers and mailing addresses are obtained from fishing licenses sold within the target area. Mail surveys can generally collect more detailed information over a longer period of recall, ranging from months to a year. There are, however, some limitations associated with the use of mail surveys.

- Response rates may be low, unless there is a concerted follow-up effort. If rates are very low, then the resulting FCRs may not be representative of the entire target population. In this case, rates are generally overestimated due to the fact that individuals who choose to respond to the survey tend to self-select; that is, the individuals who are most likely to return a mail survey are those for which fishing is an important activity. These individuals tend to be more avid anglers who fish more frequently than the typical angler population and have a higher rate of success in catching fish. Thus, consumption rates based on data collected in a survey with a low response rate may be biased higher than rates that would be estimated if the entire angler population was equally represented in the survey data.

- Because mail surveys often focus on a longer period of recall, the resulting FCRs are subject to recall bias. It is possible that difficulties in recalling specific information about fishing activity may result in the omission of some meals; however, data on the biases associated with long-term recall periods for recreational activities indicate that individuals tend to overestimate their participation, particularly if the issue being investigated is salient for them (Westat 1989). Thus, the tendency is for FCRs to be overestimated with longer recall periods.

- It can be difficult to target certain subpopulations of fish consumers (e.g., high end consumers, specific ethnic groups, individuals who fish a particular waterbody, etc.) with a mail survey. Individuals who are homeless or migrant will not be captured, and those individuals who have limited language skills and/or low levels of literacy may not understand the survey questions and, thus, may choose not to complete and return it. Thus, these groups may be under-represented in the survey sample.

Mail surveys are often conducted to collect information on a statewide or regional basis. If well designed, they can provide detailed information about the fish consumption behaviors of study participants as they can be completed at the respondent's leisure rather than requiring instantaneous recall of past events. However, FCRs derived from mail surveys may be overestimated if recall periods are long. They may also be overestimated if response rates are low because often non-respondents are less interested in the subject of the survey and, therefore, choose not to participate. In this case, however, data collected through follow-up contact with non-respondents can be used to adjust survey results.

3.1.3 *Telephone Surveys*

Telephone surveys generally consist of the one-time collection of data from a survey participant by telephone. Lists of telephone numbers of individuals within the target population are developed either through the random selection of telephone numbers from all telephone listings in a given area (e.g., statewide, population within certain counties, or population within certain zip codes near a specific waterbody or fishery) or, in the case of surveys of recreational anglers, may be based on information obtained from fishing licenses purchased. Survey respondents are asked to recall information about past fishing trips and fish consumption behavior.

Telephone surveys are rarely used in isolation, however, and are often a follow-up to surveys that have been previously sent to the targeted individuals, thereby providing an opportunity for those individuals to review the survey questions before being asked to respond to them (EPA 1992). They may also be conducted to provide information about non-response bias (for those individuals who did not respond to a mail survey effort) or to confirm or add to data that were collected in the field during a creel survey (EPA 1992).

Telephone surveys are effective in evaluating regional information and can reach large numbers of individuals (EPA 1992) but also have limitations, including the following:

- Individuals who are being interviewed by telephone are rarely willing to spend more than 10 or 15 minutes participating in a telephone interview, particularly when they have had no warning that they will be called. This limits the amount of information that can be captured from them and is likely to result in recall bias due to the fact that individuals may not recall information completely or accurately when they are unprepared to do so. In addition, because of limited time, they can only be asked general information about their long-term fish consumption habits or specific information about their most recent activities.
- Because telephone surveys generally only include a single interview with an individual, they are subject to bias due to the fact that the responses of the participants may only reflect their most recent activities. Thus, if the telephone interview occurs at a time that the respondent is actively fishing or consuming fish, the resulting data may over-estimate his long term level of activity. At the same time, if the telephone interview occurs during a period of inactivity, his long term consumption activity may be under-estimated.
- Individuals who do not have telephones cannot be included in the sample population. Because those individuals are likely to be low income individuals who cannot afford the cost of a telephone, this segment of the population is likely to be under-represented in the survey sample. Similarly, individuals with unlisted numbers will not be included in the survey.
- Recent telephone surveys may be biased toward an older, higher income population if they have not included the sampling of cell phones in addition to land lines, as younger people are more likely than older individuals to rely completely on cell phones. In addition, even if cell phones are sampled, it is not always possible to accurately sample the geographic location targeted because cell phones are not tied to specific addresses (individuals may move to a different home or area but retain the same cell phone number).
- Telephone surveys can be useful if the general population of a given area is being targeted or if anglers are being targeted and the telephone numbers have been obtained from recent fishing licenses. However, if the target population is a particular socioeconomic subpopulation (e.g., ethnicity or income level), it is very difficult to identify those individuals in advance when selecting a list of telephone numbers. Thus, the smaller the target population, the larger the survey effort necessary to gain enough data about the subpopulation or group of interest.

All of these issues can affect the FCR estimates that are derived based on a telephone survey. The most important considerations are the way that the short-term recall information has been used to estimate long term consumption rates and the attention to avoiding the bias introduced in survey results if certain segments of the population are not well represented in the sampling.

3.1.4 *Fishing Diaries*

Diary studies are an excellent means of collecting detailed information about specific fishing trips and fish meals. In these studies, individuals from the targeted population are recruited to participate in the study and are asked to keep a diary of the fishing trips taken. These studies can be short- or long-term studies. For long-term studies, individuals are generally asked to complete monthly diaries and can record very detailed information about every trip taken and every harvested fish that was consumed. If the individuals complete the diaries in a timely fashion, these studies minimize the potential for recall bias and also increase the level of detail that the person is able to recall (e.g., the size of a fish meal, the species consumed, the number of people who shared in the meal, etc.). If this information is collected over a long time period (e.g., for example, monthly diaries completed over a one year period), it can result in very accurate estimates of long-term fish consumption.

One difficulty with long-term diary studies is that there can be a high level of attrition because people tire of recording their information and so stop completing the diaries. However, while the information gathered may only be partial (e.g., several months of the targeted one-year period for the study), the level of detail provided in the diary and the partial data can still yield valid estimates of long-term fish consumption behaviors by the study participants (Balogh et al. 1971).

3.1.5 *Diet Recall Studies*

Diet recall studies are a form of diary study but are generally shorter term. In these studies, individuals are commonly asked to record all foods eaten during a one- or two-day period. The days may be consecutive days or two different days during the study period. These recall studies work well for foods that are consumed on a regular basis (i.e., foods that are consumed daily or at least once every two days) and when evaluating population-level trends, but are not as effective for developing reliable estimates of long-term consumption behavior of foods that are consumed less regularly (as discussed in more detail in Section 3.2.2)). Thus, for those individuals who consume fish daily or several times per week, the estimated rates of consumption based on these data may be representative of their behavior.

However, for many individuals, fish is not consumed on a daily or regular basis. This is particularly true of sport-caught fish, which may only be consumed occasionally (e.g., once per week or less or only during a specific time of the year) (Ebert et al. 1994). As discussed in more detail in Section 3.2.2, short-term recall periods may substantially bias the results by incorrectly assuming that individuals who did not consume during the recall period are non-consumers, and leaving them out of the consumption rate distribution, thereby skewing that distribution toward more frequent consumers. This results in overestimated consumption rates for the total population. In addition, the timing of the diet recall study can substantially affect the resulting consumption estimates if there is a seasonal component to the consumption habits of sport-fishermen. For example, in most states, fishing regulations limit the harvest for individual fish species to certain times of the year. Some individuals have a strong preference for a certain species and only consume fish when those species are available. Thus, while they may consume those fish regularly during that season, they may not consume fish at all during the remainder of the year. If the diet recall survey is conducted during the season when they are regularly consuming those fish, and the survey is not carefully designed to address seasonal variations, their annualized, average FCRs will be overestimated. Conversely, if the diet recall study is conducted during the time when these fish are not being consumed, their FCR will be underestimated as it will, by necessity (due to lack of consumption information) be assumed that they are non-consumers. Because of this, their consumption will not be included in the consumption rate distribution from the survey, thereby biasing that distribution to more frequent consumers and higher consumption rates.

3.2 Analysis of Survey Data to Derive FCRs

Data from surveys can be analyzed a number of different ways and the approach to analysis will depend, in part, on survey design. The key consumption metric for deriving AWQC is to derive an annualized average daily FCR. When estimating these FCRs, it is necessary to understand the size of each meal consumed and the frequency with which those meals are consumed.

There are two common approaches for estimating consumption rates. These include an approach based on reported meal frequency and size, and an approach based on the amount of fish harvested and consumed on a yearly basis.

The meal frequency approach requires that information on the number and size of meals consumed by the surveyed individual over a period of time be collected and then extrapolated to the extent necessary to derive an annualized daily average FCR. Thus, for example, if the survey respondent indicates that he or she eats 26 half-pound [227 gram (g)] fish meals per year, the ingestion rate would be calculated as follows:

$$FCR = 26 \text{ meals/yr} * 227 \text{ g/meal} * 1 \text{ yr/365 days} = 16.2 \text{ g/day}$$

Similarly, if the respondent indicates that she eats 1 meal every two weeks, her FCR is calculated as follows:

$$FCR = 0.5 \text{ meal/week} * 227 \text{ g/meal} * 52 \text{ weeks/year} * 1 \text{ yr/365 days} = 16.2 \text{ g/day}$$

Alternatively, the harvest rate approach uses information about the mass of fish actually harvested by the survey participant over time, adjusts that mass by the edible portion of the fish (total mass minus the mass of the parts not consumed by the angler, such as viscera, head, bones, etc.) and the number of people to share in the fish meal. Thus, if a survey respondent indicates that he or she harvested 40 kg (88 pounds) of fish during a year, the default edible fraction of 30 percent (EPA 1989) is used, and it is reported that a total of 2 adults consumed the fish, the FCR would be calculated as follows:

$$FCR = 40{,}000 \text{ g whole fish/yr} * 0.30 \text{ g edible/g whole} * 1/2 \text{ persons} * 1\text{yr/365 days} = 16.4 \text{ g/day}$$

Depending upon the survey approach used and the questions asked, one method may be more appropriate than the other. There are some limitations of each of these approaches, however, that need to be considered.

- There are uncertainties about the meal method due to the fact that the size of fish meals may vary considerably. Meals of store-purchased fish are likely to be fairly consistent due to the fact that a consistent amount of fish may be purchased for consumption. The same is not true for sport-caught fish. Meal sizes will vary depending upon the mass of fish harvested on a given day and the number of individuals consuming it. Thus, because individuals are generally asked to estimate the size of fish meals consumed, they may or may not accurately represent the variety of meal sizes that are actually consumed over time if the fish are sport-caught fish. While individuals involved in the surveys are often provided with photographs of meals of different sizes, these estimated meal weights may not be representative of the fish actually consumed due to differences in mass resulting from cooking, the way the fish were prepared, and the density of the fish tissue. In addition, although they may provide their estimated average weekly rate of consumption, this weekly rate may vary considerably by season due to changes in weather, fishing time, or availability of target species. Unless data are collected to specifically capture these variations, there is substantial uncertainty introduced by this approach.

- There are also uncertainties introduced when using the harvest method because individuals may not recall exactly how much fish they have harvested over time, and the portion sizes of the individuals who share in the consumption of the fish may vary. Thus, if two people share in the catch it will normally be assumed that the total mass should be divided by two; however, the portions consumed by those individuals may not be equivalent. In addition, there may be some variability around the edible portion of the fish depending on the parts consumed by the survey participants, the fact that edible portions vary somewhat by species, and the number of individuals who share in individual fish meals.

3.2.1 *Identifying "Consumers" and "Non-Consumers"*

When determining the population to be targeted in selecting an FCR for use in developing AWQC, it is important to determine who is likely to be exposed to that chemical via the consumption of fish. Clearly, individuals who never consume fish will have no potential for exposure via this pathway so that the emphasis needs to be on the individuals who actually consume fish as this will be the potentially exposed population. However, depending upon the waterbodies to which the AWQC will be applied, the fish consuming population will vary. If the AWQC will be applied to waterbodies that are commercially fished, then there is potential for exposure to the general population, because they will have access to that fish through commercial sources such as fish markets, grocery stores and restaurants. However, if the waterbodies that are the focus of the AWQC are not commercially fished, then the fish from those waterbodies will not be available to the general population. The only sources of those fish are the recreational anglers who fish those waterbodies.

Once the target population has been identified, it is necessary to identify the FCRs for the individuals within that population who consume fish. Depending upon the survey approach used, this determination can be challenging. For example, if the AWQC are to be applied to commercially fished waterbodies, then the general population who have access to those fish is the target population. However, most surveys of the general population collect information about total fish consumption including consumption of fresh, frozen, canned and prepared fish and shellfish obtained from stores and restaurants, which are most often imported from locations outside of the area of influence of the AWQC, as well as sport-caught fish and shellfish from local sources.

Even if the survey has distinguished among different sources of fish, the identification of consumers may be affected by the survey method. As discussed in more detail in Section 3.2.2 below, short-term diet recall studies, which are often used to evaluate food consumption within the general population, often misclassify individuals as non-consumers. Thus, while the rates are reportedly based on consumers of those fish, they are likely to be excluding a large proportion of actual consumers who have lower frequency of consumption.

3.2.2 *Limitations on the Use of Short Recall Period Survey Data*

Attempting to extrapolate long-term FCRs based on short recall period survey data presents a number of problems. These include the potential misclassification of non-consumers, the overestimation of FCRs based on data collected as a snapshot in time, and the lack of consideration of variation over time.

In general, the length of recall period affects the resulting estimated rates of consumption with shorter term studies resulting in higher estimated rates of consumption than studies with longer recall periods. The higher rates of consumption from the short-term studies may not be a reflection of actual differences in the behaviors within the surveyed populations but may instead be an artifact of the short recall period (EPA 2011; Ebert et al. 1994).

Short-term dietary recall studies can result in misclassification of participants as non-consumers and consequently overestimate consumption rates for true consumers within the surveyed population. Essentially, when a diet recall survey is conducted, if an individual does not indicate that fish was consumed during the recall period, that individual is identified as a non-consumer and is assumed to have zero consumption. When this occurs, rates are reported as either "per capita" rates (which include the non-consumers and their estimated rates of 0 g/day) or as "consumers only" rates, which means that all of the individuals who did not consume fish during that period of time are excluded from the reported results and only those individuals who did consume fish during that period are counted in the consumption rates.

The USDA dietary data that form the basis for EPA's (2000) default FCR of 17.5 g/day were collected using a dietary recall study of survey participants during two non-consecutive 24-hour periods (EPA, 2000). Because of the way in which sampling was conducted, the actual fish consumption behaviors reported are strongly biased toward those respondents who consume fish with a high frequency. All of the individuals included as fish consumers in the USDA estimate consumed fish at least once during the 2-day sampling period. To use these data to estimate long-term consumption rates, EPA assumes that the consumption behavior that occurred during the 2-day period is the same as the consumption behavior that occurs throughout every other 2-day period during the year. Thus, if an individual reported eating one fish meal during the sampling period, the extrapolation used to estimate long-term consumption was the assumption that the individual continues to eat fish with a frequency of one meal every two days, or as many as 183 meals per year. If it is assumed that an individual eats one-half pound (227 g) of fish per meal, this results in a consumption rate of 114 g/day. However, the individual who consumed fish during that sampling period may not actually be a regular fish consumer. In fact, that fish meal could have been the only fish meal that the individual consumed in an entire year. Thus, that person's FCR would be substantially overestimated using this extrapolation method.

Conversely, individuals who did not consume fish during the 2-day sampling period were assumed to be non-consumers of fish, despite the fact that those individuals may simply have been fish consumers who coincidentally did not consume fish during the 2-day sampling period. Because there are no data upon which to base consumption estimates for these individuals, they were assumed to consume 0 g/day. However, they may in fact consume fish with a frequency ranging from as little as zero meals per year to as much as one meal per day (or even more than one meal per day) on all days except the two that USDA conducted the survey. As with the high consumers identified in the USDA database, there is no way to determine whether 0 g/day consumers are actually non-consumers or just individuals who did not consume fish during the 2-day survey period.

There can be enormous variability in the frequency of consumption of specific foods (Balogh et al. 1971; Garn et al. 1976), and the variability in the number of fish meals may be further enhanced by seasonal effects. For example, recreational fishermen in many states are only permitted to fish during certain months due to fishing regulations. Thus, it is possible that their sport-caught fish ingestion rates are substantially higher during the fishing season, when fresh fish are readily available, than they are during the remainder of the year. In addition, many anglers target specific species and only fish when those species are available. For example, many anglers in the Pacific Northwest target salmon, which are only available during their time-limited spawning runs. Thus, they may not fish at all or consume sport-caught fish during other times of the year when the salmon are not available.

Because of this phenomenon, there is a tendency, if only "consumers" are considered, for short-term recall surveys to report substantially higher FCRs than do surveys with longer periods of recall. This is well demonstrated in EPA's (2011) tables of relevant fish consumption studies. For example, when reviewing EPA's relevant studies of statewide[9] freshwater recreational fish intake (EPA 2011, Table 10-5), FCRs appear to be highly variable, with means for "consuming" anglers ranging from 5.8 to 53 g/day and 95th percentile (95th %ile) values ranging from 26 to 61 g/day.[10] However, one of those studies collected data from individuals on a single day (ADEM 1994), one involved a single interview but also included a 10-day dietary diary component (Balcom et al. 1999), one involved a 90-day recall period (Williams et al. 1999), one included a 7-day recall period but also collected some

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[9] There are additional studies provided on EPA's table of relevant studies but those studies are waterbody specific and thus are not directly comparable with the statewide studies.
[10] 95th percentiles are not available for all studies listed in EPA's Table 10-5. For example, EPA reports the highest mean rates for studies conducted in Alabama and Connecticut but provides no 95th percentile values from those studies. Thus, those studies cannot be included in the comparison of 95th %ile rates.

information on seasonal variation for the remainder of the year (West et al. 1989), and the remainder of the studies collected data for a 1-year recall period. When the statewide studies are segregated by recall period, the bias toward higher consumption rates based on shorter recall periods is apparent, as shown below.

Rates for Sport-caught Freshwater Fish Consumption (Adult consumers) from Statewide Studies by Recall Period (Table 10-5, EPA 2011)

Recall Period	1-day		1-day interview and 10-day diary		90 day				1 year	
Metric	Mean	95th %ile	Mean	95th %ile	Mean	95th %ile	Mean	95th %ile	Mean	95th %ile
FCR (g/day)	53	NA	53	NA	20	61	14	39	5.8-14	26-43
Study	ADEM 1994		Balcom et al. 1999		Williams et al. 1999		West et al. 1989		Ebert et al. 1993; Benson et al. 2001, Connelly et al. 1996, Fiore et al. 1989	

NA: Not available. This value was not presented by EPA (2011)
[a]The West et al. 1989 study requested information about a 7 day recall period but also collected some information on variation in behavior during different seasons of the year which were used to estimate long-term FCRs.
[b]A subsequent West et al. (1993) study collected information for a 7-day recall period but collected no longer term information that could be used to annualize the rates. While the means from the 1989 and 1993 surveys were nearly identical, the 95th percentile for the 1993 study (78 g/day; EPA 1997) was substantially higher than the 95th percentile of 39 g/day that was derived from the 1989 survey data.

Consumption of sport-caught fish is likely to have a seasonal component, particularly in states where fishing may occur for only a portion of the year. Like other seasonal foods, it is likely that these foods are eaten more frequently during their seasons than they are at other times of the year. For example, fresh, local strawberries are only available in the northeastern United States for a few weeks during the summer. When they are available locally, it is likely that strawberries are consumed in greater quantities than they are when they are out of season and can only be imported from other locations and purchased from supermarkets. That is not to say that they are never eaten when they are out of season but rather that if individuals were to be asked about their strawberry consumption during the time that fresh strawberries are in-season, it is likely that they would overestimate their consumption for other times of the year when local strawberries are not available. At the same time, if they were asked in the winter to report their strawberry consumption, it is likely that they would underestimate their strawberry consumption during the summer when fresh, local strawberries are readily available. These seasonal variations are important in terms of their affect on estimating long term consumption rates. While the USDA survey (upon which EPA's rate of 17.5 g/day is based) collected data on two different days, the survey days were no more than 10 days apart. Thus, the rates of consumption for all foods that are seasonally affected would have been dependent upon the timing of those survey days and would not necessarily reflect the participants' long-term average consumption rates.

EPA (2011) has acknowledged that short-term dietary records are problematic when attempting to estimate long-term rates of consumption, particularly for upper bound FCR estimates. In its review of NHANES 2003-2006 study data, EPA (2011, p. 10-16) stated, "the distribution of average daily intake rates generated using short-term data (e.g., 2-day) does not necessarily reflect the long-term distribution of average daily intake rates." In addition, in its discussion of the limitation of the West et al. (1993) study of Michigan anglers EPA (2011, p. 10-38) stated: "However, because this survey only measured fish consumption over a short (1 week) interval, the resulting distribution will not be indicative of the long-term fish consumption distribution, and the upper percentiles reported from the U.S. EPA analysis will likely considerably overestimate the corresponding long-term percentiles. The overall 95th percentile calculated by U.S. EPA (1995) was 77.9; this is about double the 95th percentile estimated using yearlong consumption data from the 1989 Michigan survey." In addition, when discussing the USDA methodology, EPA (1998, p. 10-107) stated that "[t]he non-consumption of finfish or shellfish by a majority of individuals, combined with consumption data from high-end consumers, resulted in a wide range of observed fish consumption. This range of fish consumption data would tend to produce distributions of fish consumption with larger variances than would be associated with a longer survey period, such as 30 days." As a result, upper-bound fish consumption estimates based on these data will be biased high and overestimate actual upper-bound consumption rates for the total population of consumers.

Short-term recall periods generally result in an overestimate of consumption behavior, particularly for foods that are not eaten on a daily basis. While this does not appear to greatly affect central tendency values for the populations studied (EPA 2011; Garn et al. 1976), the inverse relationship between upper-bound FCRs and the length of survey recall period has been clearly demonstrated (Ebert et al. 1994).

3.2.3 *Estimating Means and Upper Percentiles*

Once FCRs have been calculated for the individual survey respondents, they are typically evaluated statistically to define a central tendency or upper-bound estimate of consumption to be used in deriving AWQC. The central tendency may be an arithmetic mean, geometric mean, or a median (50th percentile value) of the range of consumption rates derived. Because the estimated FCR distribution (the range of rates) is generally very highly skewed, as are consumption rates for most foods (Garn et al. 1976), with a very large number of individuals consuming fish at very low FCRs and a few individuals consuming at high rates, the arithmetic mean is typically not a good estimate of actual central tendency. For example, in the statewide survey of Maine's recreational anglers, which included rates ranging from 0.02 to 183 g/day, the median rate of consumption by individuals who ate at least one fish meal from Maine's freshwater bodies during the year was 2 g/day but the arithmetic mean FCR for this same population was 6.4 g/day and represented the 77th percentile of the distribution of FCRs from that survey (Ebert et al. 1993).

Upper-bound FCRs may be calculated in a number of ways. For some surveys, they may be calculated as the 95th upper confidence limit of the arithmetic mean consumption rate. Alternatively, for some surveys, FCR results are ranked in order of magnitude and then the upper-bound value is selected as the 95th percentile of that distribution. Thus, for example, in the same Maine survey for which there were 1,053 FCRs calculated, the 95th percentile value of 26 g/day represented the FCR reported for angler 1,000 after order ranking of the results (Ebert et al., 1993).

3.2.4 *Consumption of Resident and Anadromous Fish Species*

It is important that the FCR used in deriving AWQC reflects consumption of the fish species that will be affected by the AWQC. This will ensure that FCRs are not overestimated.

Estimated FCRs are generally based on the total consumption of fish, and may include fish of a variety of types, including resident finfish, anadromous finfish, and shellfish. For example, the FCR recently adopted by Oregon Department of Environmental Quality was supported by state-specific data on consumption for which a substantial portion of the consumption was the ingestion of anadromous species such as salmon and steelhead. Anadromous species are not substantially affected by local water quality in estuaries and rivers because they are only present in those waterbodies when they are juveniles and when they return as adults to spawn. They spend the majority of their lives in marine waters and are typically harvested during their return spawning runs. As a result, any chemical constituents that are present in their bodies are predominantly the result of exposures they have received during their time in marine waters. Thus, changes in AWQC for local waterbodies will not affect the concentrations of those chemicals in their edible tissues. Instead the fish that are sensitive to changes in local water quality are the resident species that spend their entire life stages in local waters.

This is an important consideration for states, such as Oregon and Washington, where a substantial portion of the fish harvested for consumption are anadromous fish. For example, the Columbia River tribes consume, on average, nearly three times more anadromous fish (including salmon, trout, lamprey and smelt) as they do resident species (CRITFC 1994). Similarly, Toy et al. (1996) reported that at the 95th %ile consumption rate for the combined Tulalip and Squaxin tribes, who fish Puget Sound, 95% of the total finfish consumed were anadromous species.

Because the AWQC approach incorporates a chemical-specific bioaccumulation factor, it essentially assumes that fish are in equilibrium with constituent concentrations in the water bodies of interest. This is not likely to be the case for anadromous species because of the short time period during which they are in fresh and estuarine waters. For example, after hatching, juvenile Chinook salmon spend several months in the Columbia River before they begin their out-migration to marine feeding areas. They generally return to the river to spawn between the ages of two and six years (ODFW, 1989) and do not generally feed during their spawning run. These fish, which provide a substantial portion of the freshwater fish harvested both commercially and recreationally from the river, are clearly not at equilibrium with their surroundings.

Because migrating fish do not spend adequate time in a particular river reach to achieve equilibrium with concentrations in the water column and sediments there, the bioaccumulation factor used in developing the AWQC overestimates the tissue concentrations in such fish that can be attributed to that reach. It is only the resident species that will be impacted by local water quality. Consequently, the use of an FCR that includes anadromous fish substantially overestimates exposure to local chemicals. For example, if an individual has a total FCR of 20 g/day and 90 percent of the fish consumed during the year are anadromous fish, only 10 percent of the fish consumed, or 2 g/day, are resident fish that are likely to be affected by changes in local water quality. Thus, to use a total FCR of 20 g/day overestimates the individuals' actual potential for exposure due to local contaminants by a factor of 10. Instead, it is the consumption rates for resident species that should be used to derive AWQC because it is these species that will be affected by changes in water quality.

Not all states have the type of access to anadromous species that occurs in the Pacific Northwest. Thus, these fish will not constitute a substantial fraction of consumers' diets in many areas of the country. This makes it extremely important to ensure that the FCRs that are used in developing AWQC for a specific region are based on fish consumption information for that region and not simply based on a one-size-fits-all approach for selecting consumption rates.

3.2.5 *Consumption of Freshwater and Estuarine Species*

In developing AWQC in coastal states, the FCRs that are used typically do not differentiate between the ingestion of freshwater and estuarine finfish and shellfish. This is because AWQC need to be applied to a number of different types of water bodies. However, this assumption is very conservative when one considers permitting of individual discharges that occur in specific areas of individual water bodies and may only affect freshwater areas. If there is a permitted discharge to a freshwater body, the consumption of estuarine fish and shellfish is likely to be irrelevant. Similarly, if there is a discharge to an estuarine area, the freshwater fish upstream will likely not be affected by that discharge. Thus, inclusion of rates of consumption of freshwater and estuarine finfish and shellfish is a very conservative assumption for these specific applications, providing an additional level of health protection when AWQC are applied to specific waterbodies.

4.0 POPULATION RISK

AWQC are typically derived using a target individual risk level of 1 in 1,000,000 million (1E-06) risk for carcinogens and a hazard index of 1 for non-carcinogens. For carcinogens, this target risk represents the increased probability that an individual will develop cancer as a result of exposure through the consumption of fish tissue. The background rate for contracting cancer is roughly 30 percent; thus, when a 1E-06 risk level is selected as the target risk, this means that the probability of an individual contracting cancer increases from 30 percent to 30.0001 percent.

There is, however, another risk metric that should be considered in selecting an FCR. This risk metric is known as the population risk. It is calculated by multiplying the target risk level by the size of the affected population to predict the number of excess cancer cases that might result from that exposure. Thus, if the target risk is 1 in one million, and the size of the population is one million people, the population risk will be calculated as 1 excess cancer over the combined lifetimes of 1 million individuals who are actually exposed as a result of the modeled exposures.

Population risk is an important consideration in selecting an FCR for use in developing AWQC because as the size of the exposed population decreases, the population risks also decrease when the same target risk level is used. The higher the FCR selected for a particular population, the smaller the population to which that FCR applies. For example, if the FCR selected is a 95th percentile rate, it is assumed that it is protective of all but 5 percent of the exposed population or 50,000 of the 1 million people provided in the example above. Thus, if the same target risk level of 1E-06 is used with this reduced population, the resulting population risk is 0.05 excess cancers within a population of 1 million people. In other words, in order to reach the target risk of 1 excess cancer, it would be necessary for a population of 20 million people to have lifetime exposures equivalent to the estimated exposure conditions.

EPA (2000) states that both a 1E-06 and 1 in 100,000 (1E-05) target risk level may be acceptable for the general population as long as highly exposed populations do not exceed a target risk level of 1E-04 or 1 in 10,000. In other words, if an AWQC is based on a 1E-06 risk level and an FCR if 17.5 g/day is used, this means that if there is a subpopulation of individuals who consume fish at a rate of 175 g/day, they will be protected at a risk level of 1E-05, and in order for a subpopulation to exceed the recommended upper bound risk level of 1E-04 outlined in EPA's (2000) methodology, they would have to consume more than 1,750 g of fish daily throughout their lifetimes.

EPA (2000) states that "[a]doption of a 10-6 or 10-5 risk level, both of which States and authorized Tribes have chosen in adopting water quality standards to date, represents a generally acceptable risk management decision, and EPA intends to continue providing this flexibility to States and Tribes. EPA believes that such State or Tribal decisions are consistent with Section 303(c) if the State or authorized Tribe has identified the most highly exposed subpopulation, has demonstrated that the chosen risk level is adequately protective of the most highly exposed subpopulation, and has completed all necessary public participation" (EPA 2000).

Selection of an FCR to be used in developing AWQC is as much a policy decision as a technical decision. There are wide ranges of FCRs available depending upon the population targeted for study and it is important that the target population be identified so that the selection of an FCR rate can be based on that target population and the target risk level can consider both individual and population risks for that population.

5.0 DISCUSSION

When selecting an FCR for establishing HHAWQC, it is critical that a number of important issues be considered. These include: 1) identifying the target population of fish consumers and the waterbodies that will be affected by changes in HHAWQC; 2) evaluating and selecting FCRs based on fish consumption studies that provide reliable, long-term information on the fish consumption habits of the target populations and waterbodies; and 3) consideration of both individual and population risks in selecting an FCR.

Generally speaking, the population of interest for the development of HHAWQC consists of those individuals who consume freshwater or estuarine finfish and/or shellfish from the area of interest. If the waters to which HHAWQC are to be applied are commercially fished, then this population will include members of the general population who may consume fish from a wide variety of commercial and recreational sources. In this case, FCRs should be based on general population studies of good quality. If, however, the waterbodies of interest are not commercially fished, then the target population includes those anglers who catch and consume their own fish from those waterbodies and the FCR should be selected from regionally-appropriate studies of consumption by recreational anglers.

HHAWQC are used as environmental benchmarks and as objectives in the development of environmental permits. While they are applicable to all ambient waters in a state, they are most often considered for individual water bodies when state regulatory agencies are developing permitting and effluent limits. Thus, assumptions that are already judged and selected to be conservative when one is attempting to develop statewide criteria, become extremely conservative when considering individual water bodies.

In light of the way in which HHAWQC are applied in permitting, the approach used to develop HHAWQC includes a number of highly conservative assumptions, particularly for constituents that are limited and localized. The conservative assumptions used in the development of HHAWQC and subsequently applied to permitting typically include:

- FCRs that include the combined consumption of freshwater and estuarine fish and shellfish and, in some areas, include anadromous species that are not impacted by local water quality conditions;
- 100 percent of the fish consumed in a lifetime are obtained from a single, impacted waterbody;
- There is no reduction in chemical concentration that occurs as a result of cooking or preparation methods;
- Concentrations of compounds in fish are in equilibrium with compound concentrations in the water body; and,
- The allowable risk level upon which they are typically based is one in one million. This means that the probability of developing cancer over a lifetime increases from 30% to 30.0001%.

There are a very small number of individuals, if any, to whom all of these conservative assumptions would apply.

EPA's recommended FCR of 17.5 g/day can reasonable be judged as conservative and protective when used in establishing AWQC for a number of reasons.

- It is based on survey data collected by the USDA, which are surveys of the general population, and includes information about many species and meals of fish that would not be found in the waterbodies that are subject to the HHAWQC. The reported fish meals were obtained from numerous sources and included fresh, frozen, prepared and canned fish products that may have been produced in other regions of the United States or other countries and, consequently, not derived from local waterbodies. Thus, the USDA data overestimate the consumption of locally caught fish, particularly if there are no commercial fisheries, and certainly overstate consumption from individual waterbodies that are regulated under the HHAWQC.

- As discussed previously, this rate is based on 24-hour dietary recall data. Use of such data to estimate long term consumption rates for any population results in biased and highly uncertain estimates.

- HHAWQC based on that consumption rate, combined with other very conservative assumptions that are included in the HHAWQC calculation, ensure that risks of consuming fish from a single regulated waterbody are likely to be substantially overestimated and, therefore, will also be protective of individuals who are at the high end of the consumption distribution.

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APPENDIX B

A BRIEF REVIEW OF ISSUES RELEVANT TO THE ACCUMULATION OF PERSISTENT, BIOACCUMULATIVE, AND TOXIC (PBT) CHEMICALS BY SALMON

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1.0 INTRODUCTION

In September 2011 Washington State Department of Ecology (WDOE) issued Publication No. 11-09-050, *Fish Consumption Rates Technical Support Document, A Review of Data and Information about Fish Consumption in Washington*. This technical support document (TSD) was generated to support decision making regarding how to obtain an appropriate fish consumption rate (FCR) for use in calculating water quality standards for protecting human health (HHWQS). One of the issues WDOE raised in this TSD was whether consumption of salmon should be included in whatever FCR is ultimately used in these calculations, and if it is concluded that salmon should be included in an FCR, how to do so.

The driver behind this is human exposure to toxic chemicals, specifically via consumption of fish (or aquatic tissue in general). The greatest risk to human health from consumption of fish is generally understood to result from the presence of persistent, bioaccumulative, and toxic (PBT) chemicals. Thus the primary factor in determining the appropriateness of including consumption of salmon in an FCR is where salmon actually pick up these contaminants. A brief review of what is known about this subject is presented herein.

2.0 WHERE SALMON ACCUMULATE PBT CHEMICALS

As discussed by NOAA (2005), different runs of salmon exhibit different life histories. More specifically, NOAA described stream-type and ocean-type life histories. Behavioral attributes of these two general types of salmon are summarized in Table B1.

From Table B1, different species of salmon and different runs of the same species can exhibit distinctly different life histories, including how much time is spent in freshwater and where in freshwater systems this time is spent. These differences are potentially significant in that they may lead to differences in the mass (burden) of chemical contaminants (e.g., PBT chemicals) ultimately accumulated by the salmon, and in the fraction of this ultimate burden accumulated in freshwater vs. saltwater. Although the latter may not be relevant when assessing the risk to human health resulting from eating contaminated fish in general, it is relevant when considering what fraction of this overall risk results from accumulation of contaminants in freshwater systems vs. saltwater systems.

This last point is directly relevant to the question of whether there is any utility in including consumption of salmon in an FCR that will be used to drive remedial action(s) on the geographically limited scale of a single state. If a significant fraction of the contaminant burden found in salmon is accumulated in true freshwater systems it makes sense that the consumption of salmon be included in an FCR. However, if accumulation in the open ocean dominates, inclusion of salmon in an FCR makes no sense because there is no action the state can take that will have a significant effect on the contaminant burden found in returning adult salmon.

Table B1 A Summary of the Juvenile Characteristics of Stream and Ocean Life History Types

Stream-Type Fish	Ocean-Type Fish
Species	
Coho salmon	Coho salmon
Some Chinook populations	Some Chinook populations
Steelhead	Chum
Sockeye	Pink
Attributes	
Long period of freshwater rearing (>1 yr)	Short period of freshwater rearing
Shorter ocean residence	Longer ocean residence
Short period of estuarine residence	Longer period of estuarine residence
Larger size at time of estuarine entry	Smaller size at time of estuarine entry
Mostly use deeper, main channel estuarine habitats	Mostly use shallow water estuarine habitats, especially vegetated ones

[SOURCE: NOAA 2005]

Exclusion of salmon from an FCR does not imply that human exposure to contaminants due to consumption of salmon should not be accounted for when assessing overall risks to human health. Instead, these issues should be weighed when deciding whether salmon are accounted for when assessing the risks resulting from consumption of freshwater fish (by including consumption of salmon in an FCR) or when assessing the risks resulting from consumption of saltwater or marine fish (salmon would be backed out of the risk assessment for deriving a freshwater HHWQS via the relative source contribution or RSC). Ultimately, the issue of where the risks from consumption of salmon are counted appears to be an academic question. The more important factor (from the perspective of characterizing risk) is to ensure that consumption of salmon is not double counted by including it in both an FCR and as a component of the RSC.

In any case, the issue of salmon (or anadromous fish in general) is unique in that it is quite likely that a generic salmon will accumulate contaminants in both freshwater and saltwater habitats, and that the relative fraction accumulated in one habitat vs. the other will vary with species, run, and even individual. Taken to the extreme, this implies that each run needs to be evaluated independently to determine where contaminants are accumulated. However, much of the scientific literature supports accumulation in the open ocean as the dominant pathway for uptake of PBT chemicals by salmon, with the work of O'Neill, West, and Hoeman (1998), West and O'Neill (2007), and O'Neill and West (2009) providing perhaps the most thorough examination of the issue.

Figure B1 is taken from O'Neill and West (2009) and shows that levels of polychlorinated biphenyls (PCBs) in adult Chinook salmon (fillets) collected from a wide range of geographic locations are relatively uniform except for fish taken from Puget Sound, which show three to five times higher levels of PCBs than fish taken from other locations. As discussed by the authors, these data can be interpreted as indicating accumulation of PCBs in Puget Sound and/or along the migratory routes of these fish, which, depending on the specific runs, can pass through some highly contaminated Superfund sites (e.g., Duwamish Waterway). However, O'Neill and West (2009) concluded that, on average, >96% of the total body burden (mass) of PCBs in these Puget Sound Chinook was accumulated in the Sound and not in natal river(s).

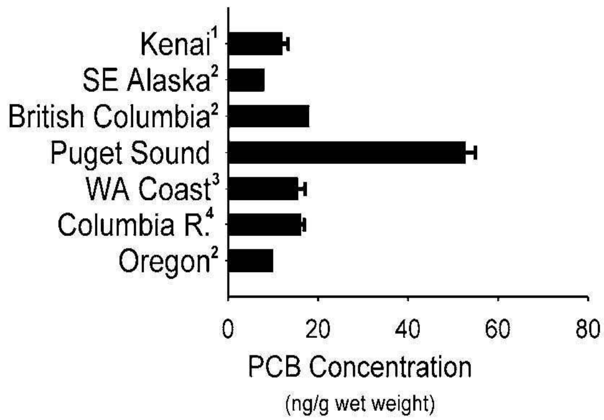

Figure B1 Average (±SE) PCB Concentration in Chinook Salmon Fillets
Data for Puget Sound were based on 204 samples collected by the Washington Department of Fish and Wildlife from 1992 to 1996; data for other locations were taken from the following (indicated by superscript numbers): [1]Rice and Moles (2006), [2]Hites et al. (2004; estimated from publication), [3]Missildine et al. (2005), and [4]United States Environmental Protection Agency (USEPA 2002) [SOURCE: O'Neill and West 2009]

The basis for this conclusion is presented in Table B2, which compares PCB concentrations and body burdens in out migrating Chinook smolts collected from the Duwamish River and adults returning to the Duwamish.

Table B2 Concentration of PCBs (ng/g) and Body Burden of PCBs (total ng/fish) in Out-migrating Chinook Salmon Smolts and Returning Adults from the Contaminated Duwamish River, Washington

Variable	Smolts	Adults
Number of samples	80	34
Mean fish weight (g)	10	6,000
Whole body PCB concentration (ng/g)[a]		
Mean	170	57
95th percentile	860	88
PCB body burden (ng/fish)[a]		
Mean	2,100	350,000
95th percentile	9,200	800,000
Mean % of PCB body burden from the most contaminated smolts[b]	—	3.8

[a] Values for smolts are from J. P. Meador (National Oceanic and Atmospheric Administration Fisheries, Northwest Fisheries Science Center, personal communication); values for adults were estimated from measured muscle tissue concentration using the fillet–whole-body regression (see Methods) for PCBs.

[b] Contaminant data were only available for out-migrating subyearling smolts, so only samples with adults that went to sea as subyearlings were included in the analysis.

[SOURCE: O'Neill and West 2009]

These data show that even the most contaminated out migrating smolts contained no more than 4% of the body burden (mass) of PCBs found in returning adults. Thus, >96% of the PCB mass (burden) found in the returning adults was accumulated in Puget Sound. Even allowing for an order of magnitude underestimate in the body burden of out migrating smolts, O'Neill and West (2009) concluded that accumulation in freshwater would account for <10% of the average PCB burden ultimately found in adults returning to the Duwamish. By extension, this analysis supports the conclusion that Chinook salmon passing through uncontaminated estuaries during out migration accumulate a dominant fraction of their ultimate PCB body burdens in the open ocean. Other researchers have also reached this conclusion using their own data (e.g., Johnson et al. 2007; Cullon et al. 2009).

However, this analysis does not explain why Chinook salmon collected in Puget Sound exhibit higher concentrations of PCBs than Chinook salmon collected from other locations (Figure B1). Ultimately, O'Neill and West (2009) attributed this to a combination of factors, specifically PCB contamination of the Puget Sound food web (e.g., West, O'Neill, and Ylitalo 2008) combined with a high percentage of Chinook displaying resident behavior. That is, a large fraction of out migrating Chinook smolts take up permanent residence in the Sound, where they feed from a more contaminated food web than found in the open ocean. These factors would not affect Chinook runs or runs of any other species associated with natal rivers that discharge to saltwater outside Puget Sound.

Overall, these data support the position that, as a general rule, the predominant fraction of the ultimate PCB burden found in harvested adult fish is accumulated while in the ocean-phase of their life cycle (e.g., Cullon et al. 2009; Johnson et al. 2007; O'Neill and West 2009). Although this conclusion is specific to PCBs, there is no reason to suppose that it would not also hold for other legacy PBTs (e.g., DDT, dioxins) or globally ubiquitous PBTs (e.g., PBDEs, methylmercury) in general (e.g., Cullon et al. 2009). Because concerns about human consumption of fish are driven by risks from exposure to PBTs, driving the FCR higher by including salmon would thus appear to be of limited utility from the perspective of protecting human health simply because these contaminants are accumulated in the ocean.

With that said, there are sufficient data to conclude that the food web in Puget Sound is contaminated with PCBs to a greater degree than the food web in the open ocean. To the extent that this is a result of true local sources (e.g., sediment hotspots), there may in fact be some “local” action that can be taken to reduce PCBs, or potentially other PBTs, in Puget Sound salmon. However, this is totally dependent on identification of localized sources amenable to remediation, and not simply a conclusion that the food web is contaminated (e.g., West and O’Neill 2007).

Again, simply increasing the FCR by including salmon will have essentially no positive effect on human health given that the dominant fraction of PBT body burdens in salmon appears to be accumulated in the open ocean, and not in waters immediately subject to in-state loadings.

3.0 PBT ACCUMULATION BY DIFFERENT SALMON SPECIES

As discussed, there is ample evidence that the body burdens of PBTs found in returning adult Chinook salmon depend to a significant extent on the life history of the specific run. Beyond this, there are interspecies differences in migratory and feeding behavior that suggest Coho, sockeye, pink, and chum salmon will not accumulate PBTs to the same extent as Chinook salmon under similar exposure scenarios (Groot and Margolis 1991; Higgs et al. 1995). Perhaps the most significant factor differentiating Chinook from the other salmon species is that Chinook tend to eat more fish (Higgs et al. 1995). Thus they effectively feed at a higher trophic level than the other species of salmon, and would be expected to accumulate greater burdens of PBT chemicals even when sharing the same habitat. This is in fact observable. For example, when looking at adult Chinook and Coho returning to the same rivers, O’Neill, West, and Hoeman (1998) found that Chinook muscle contained, on average, almost twice the total PCB concentrations found in Coho muscle. This was also true for adults collected in Puget Sound proper (O’Neill, West, and Hoeman 1998).

Differences between species can also manifest in sub-adults. For example, Johnson et al. (2007) reported ΣPCB concentrations in juvenile wild Coho collected from five different estuaries ranging from 5.9 to 27 ng/g (wet weight; whole body minus stomach contents). The corresponding range for wild Chinook juveniles collected from the same estuaries was 11 to 46 ng/g (wet weight; whole body minus stomach contents). Overall, PCB concentrations in juvenile Coho were, on average, equivalent to nominally 50% of those found in the paired Chinook juveniles. This is essentially the same ratio observed by O’Neill, West, and Hoeman (1998) in adult fish.

All this indicates that PBT residues in salmon will vary within species depending on the specific run, and between species regardless (i.e., even when different species share the same general habitat). Thus, grouping all salmon together does not provide an accurate assessment of PBT doses delivered to human consumers due to consumption of salmon. This suggests that human health risk assessments should, as a general rule, incorporate salmon on a species-specific basis, if not a run-specific basis.

Certainly, none of this is supportive of adopting a single default value for the dose of any contaminant received by humans via consumption of salmon. Thus adoption of a single default FCR for salmon is also not supported.

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APPENDIX C

FISH TISSUE CONCENTRATIONS ALLOWED BY USEPA AMBIENT WATER QUALITY CRITERIA (AWQC): A COMPARISON WITH OTHER REGULATORY MECHANISMS CONTROLLING CHEMICALS IN FISH

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1.0 INTRODUCTION

For chemicals that are capable of concentrating in fish, Ambient Water Quality Criteria for the Protection of Human Health (HH-WQC) are derived based on the uptake of the chemical by edible fish and an assumed level of fish consumption by anglers (USEPA 2000). It follows that for these chemicals, there is an allowable fish tissue concentration corresponding with each HH-WQC. The associated allowable concentrations are risk-based benchmarks analogous to other risk-based thresholds applied to edible fish in other circumstances and, therefore, the comparison with the more formal screening levels or guidelines is of interest. This appendix first describes how these allowable fish tissue concentrations, which are an integral component of the HH-WQCs, are derived. Next, several comparisons are presented between these allowable fish tissue concentrations and existing fish concentration data, concentrations found in other foods, as well as other guidelines or risk-based levels used for regulating chemical concentrations in edible fish, such as fish consumption advisory (FCA) “trigger levels” issued by state and federal agencies, and U.S. Food and Drug Administration (USFDA) tolerances, illustrating the differences in these values.

These comparisons will focus on a short list of chemicals for which an HH-WQC has been established and for which fish tissue concentration data are likely to be available. This list is comprised of the following chemicals:

- arsenic
- methyl bromide
- mercury (total, inorganic and organic)
- PCBs (total)
- chlordane; and
- bis-(2-ethylhexyl)phthalate (DEHP)

These six chemicals were selected based on several considerations: 1) propensity for accumulating in fish; 2) inclusion in fish tissue monitoring programs; 3) inclusion in recent studies measuring chemicals in other foods; 4) inclusion in specific analyses estimating human (dietary) intake; and 5) subject of FCAs in at least one state. Not all of these criteria were satisfied for each of the six example chemicals; nor did the available data allow comparisons to be made for all six chemicals; however, in general, at least four of the six chemicals could be included in each of the comparisons that were undertaken as part of this analysis.

2.0 ALLOWABLE FISH TISSUE CONCENTRATIONS DERIVED FROM THE HH-WQCS

The HH-WQCs are established based on two exposure pathways: use of surface water as a source of drinking water; and the consumption of fish that may be caught and eaten from the surface water. The same algorithms that are used to calculate the HH-WQC can be rearranged to "back-calculate" an allowable fish tissue concentration.[11] Such values could be termed a water quality-based fish tissue concentration (FTC_{WQ}). These values are therefore a function of the same exposure assumptions, toxicity values and target risk level of 1 x 10^{-6} (for carcinogenic effects) used in calculating the HH-WQC.

The fish consumption rate (FCR) is an important factor in determining the HH-WQCs for chemicals having a moderate or high bioaccumulation potential. This analysis employs three different FCRs. As intended for the general population of fish consumers, we used the U.S. Environmental Protection Agency's (USEPA's) previously recommended default FCR of 6.5 grams/day or the current USEPA-recommended FCR of 17.5 grams/day. The choice between these two FCRs for each of the six chemicals was based on the derivation of the current HH-WQC, as published by USEPA. Specifically, the FCR used by USEPA to derive the current WQC for each chemical was selected for this analysis. For all but one chemical, this FCR was 17.5 grams/day. The exception was arsenic, where the HH-WQC is still based on an FCR of 6.5 grams/day. (The FTCs based on a FCR of 17.5 grams/day are referred to as the $FTC_{WQ-17.5}$ in the remainder of this appendix. Note that the recreational consumption rate FTC for arsenic is also referred to as $FTC_{WQ-17.5}$ despite being based on a FCR of 6.5 grams/day.)

Applying a FCR of 142.4 grams/day produced another set of FTC_{WQ} (referred to as the FTC_{WQ-142} in this appendix); this FCR represents a higher-end fish intake, which USEPA specifically recommends for subsistence anglers and is similar to the FCR recently adopted by the state of Oregon for state-wide ambient water quality criteria (Oregon DEQ 2011). The resulting FTC_{WQ} for the six chemicals represent concentrations a regulatory agency might use to restrict consumption of fish in areas where there was reason to believe that subsistence fishing was known to occur. FTC_{WQ} calculated for the six chemicals are summarized in Tables C1a (based on a FCR of 6.5 or 17.5 gram/day) and C1b (based on a FCR of 142 gram/day).

FTC_{WQ} were derived from both the "water + organism" and the "organism only" HH-WQC. The former assumes that a surface water body is used as a source of drinking water and a source of fish consumption. The latter assumes that a surface water body is used only for consumption of fish. The influence of the drinking water consumption pathway is minor, or negligible for chemicals with a high bioconcentration factor (BCF), such as polychlorinated biphenyls (PCBs) and chlordane; however, it is important for chemicals with lower BCFs, such as methyl bromide, arsenic, and BEHP. For these chemicals, the use of the water and organism HH-WQC means that the allowable fish tissue concentration (i.e., FTC_{WQ}) will be substantially lower, because the target risk levels must be split between these pathways. However, the resulting FTC_{WQ} would be assumed to be applicable in most areas because most states require that surface water bodies be protected for use as a source of drinking water.

[11] Mathematically, this is the equivalent of multiplying the HH-WQC by the BCF, as long as a pathway-specific HH-WQC is used, i.e., based on the "organism only" or "water+organism" HH-WQC values.

Table C1a Allowable Fish Tissue Concentrations Derived from HH-WQC ($FTC_{WQ-17.5}$) for Six Chemicals: FCR = 17.5 g/day[1]

		HH-WQC Category[2]			
		Water+Organism		Organism Only	
Chemical	BCF (L/kg)	HH-WQC (µg/L, ppb)	$FTC_{WQ-17.5}$ (µg/kg, ppb)	HH-WQC (µg/L, ppb)	$FTC_{WQ-17.5}$ (µg/kg, ppb)
PCBs	31,200	6.4E-05	2.0	6.4E-05	2.0
Methyl bromide	3.75	47	178	1,493	5,600
Arsenic	44	0.018	0.77(1)	0.14	6.2
Mercury	7,343	0.054	394(3)	0.054	400
Chlordane	14,100	8.0E-04	11.3	8.1E-04	11.4
BEHP	130	1.2	15	2.2	286

Notes:
[1] Tissue concentration for arsenic was calculated based on former FCR of 6.5 g/day, because current HH-WQC still uses this value.
[2] Assumed use of the surface water body
[3] USEPA has established a Fish Tissue WQC for methylmercury of 300 ppb, which would be expected to supersede this value.

Despite the limited applicability of "organism only" FTC_{WQ} concentrations, they are still presented in some of the comparisons below because some regulatory agencies have derived FCA trigger levels based on fish consumption only or such triggers may be applied to waters not designated as a drinking water source (e.g., estuaries).

Table C1b Allowable Fish Tissue Concentrations Derived from HH-WQC (FTC_{WQ-142}) for Six Chemicals: FCR = 142 g/day

		HH-WQC Category[1]			
		Water+Organism		Organism Only	
Chemical	BCF (L/kg)	HH-WQC (µg/L, ppb)	FTC_{WQ-142} (µg/kg, ppb)	HH-WQC (µg/L, ppb)	FTC_{WQ-142} (µg/kg, ppb)
PCBs	31,200	7.9E-6	0.25	7.9E-6	0.25
Methyl bromide	3.75	38.7	145	184	690
Arsenic	44	4.9E-3	0.21	6.4E-3	0.28
Mercury	7,343	6.7E-3	49.2(2)	6.7E-3	49.3(2)
Chlordane	14,100	1.0E-04	1.4	1.0E-04	1.4
BEHP	130	0.24	31.8	0.27	35.2

Notes:
[1] Assumed use of the surface water body
[2] USEPA has established a Fish Tissue WQC for methylmercury of 300 ppb; this value does not apply to subsistence levels of fish consumption, but the unique approach applied to mercury by USEPA could have an effect on these values.

3.0 MEASURED FISH TISSUE CONCENTRATIONS IN U.S. LAKES AND RESERVOIRS: COMPARISON WITH FTC_{WQ}

Several federal and state programs have provided data on the fish tissue concentrations of environmental chemicals in U.S. lakes and rivers. In addition to nationwide programs sponsored by USEPA, such as the National Study of Chemical Residues in Fish (USEPA 1992), some states have ongoing fish monitoring programs or have sponsored targeted studies. Many of these programs are focused on a particular set of compounds or a particular area.

The National Study of Chemical Residues in Lake Fish Tissue (or "National Lake Fish Tissue Study", or NLFTS) was a statistically-based study conducted by USEPA Office of Water, with an objective of assessing mean levels of selected bioaccumulative chemicals in fish on a national scale. The results represent concentrations throughout the U.S. based on samples collected from 500 lakes and reservoirs in 48 states (USEPA 2009; Stahl et al. 2009). The sampling phase was carried out from late 1999 through 2003. The focus on lakes and reservoirs, rather than rivers and streams, was based on the greater tendency of lakes for receiving and accumulating environmental chemicals. A *National Rivers and Streams Assessment*[12] is currently in progress, and it would be of interest to examine the fish tissue concentration data from this survey when the data become available. It is likely that any fresh water survey of a national scope, whether it included bound or flowing water bodies would find a broad range of fish tissue concentrations, with the concentrations being more highly influenced by the location and history of the water body.

The NLFTS included PCBs, dioxins, polycyclic aromatic hydrocarbons (PAHs), 46 pesticides, arsenic and mercury. Adult fish were collected from two categories: predator and bottom-dwelling, with the predatory fish comprised of largemouth bass (50%), walleye (10%) and northern pike (7%), and bottom-dwelling species comprised of common carp (26%), white sucker (20%) and channel catfish (16%). A summary of the results from this study is shown in Table C2a.

Table C2a Concentrations in Fish as Reported by the National Lake Fish Tissue Study (USEPA 2009)

	Predator (Fillets) (µg/kg, ppb)			FTC_{WQ} Water+Organism (µg/kg, ppb)	
Chemical	Mean	50^{th} %ile	90^{th} %ile	$FTC_{WQ\text{-}17.5}$	$FTC_{WQ\text{-}142}$
PCBs	13.2	2.2	18.2	2.0	0.25
Arsenic	ND(2)	ND(2)	ND(2)	0.77	0.21
Mercury	352	285	562	394	49
Chlordane	ND(2)	ND(2)	3.6	11.3	1.4

Notes:

1 National Lake Fish Tissue Study (NLFTS) (USEPA 2009); data from 486 predator fillet samples

2 Infrequent detection in fish. Arsenic was detected at <1% of sampling locations, for predatory fish with a detection limit of 30 ppb. Chlordane was detected at 1-5% of sampling locations (for predatory fish) with a detection limits of 0.02 (alpha) and 0.49 (gamma) ppb. BEHP was detected at 1-5% of sampling locations (for predatory fish) and results are not provided by USEPA (2009).

12 http://water.epa.gov/type/rsl/monitoring/riverssurvey/index.cfm

The NLFTS was not focused on areas specifically affected by industrial activities or historic releases. The water bodies included in this survey were selected at random with an objective of capturing typical levels of the chemicals analyzed. In fact, many lakes were included that could be regarded as pristine, likely to have been affected by only minimal human activity. Therefore, the resulting data could be representative of ‘background’ concentrations, which are from unavoidable depositional inputs of the chemicals of interest. However, because many of the water bodies included the NLFTS may have been affected by specific discharges or historic releases, we refer to the resulting data being only representative of typical levels for U.S. lakes. For simplicity, only the data representing predatory fish were included in this analysis, because these are the species likely to be targeted by anglers. The bottom-dwelling fish, which were included in the NLFTS to represent ecological (wildlife) exposures, contained substantially higher concentrations of PCBs (6 times greater at the median) and chlordane (1.7 ppb vs. ND), but lower concentrations of mercury (4 times lower at the median).

As shown in Table C2a, this study provided data for PCBs and mercury, as well as for arsenic and chlordane. Arsenic and chlordane were reported at very low frequencies of detection making quantitative comparisons between fish concentrations and FTCs challenging. Nevertheless, because the detection limits for chlordane (0.02 ppb for alpha and 0.5 ppb for gama) are less than the $FTC_{WQ-17.5}$ (11.3 ppb), and the 90^{th} percentile of the distribution of chlordane concentrations is roughly 3 times lower than the $FTC_{WQ-17.5}$, NLFTS data do demonstrate that chlordane concentrations in predatory fish from the large majority of U.S. surface waters are below the $FTC_{WQ-17.5}$. This also suggests that current concentrations of chlordane in most U.S. surface waters are unlikely to be above the HH-WQC derived based on the consumption rate of recreational anglers.

A similar evaluation could not be conducted for arsenic. The reported arsenic detection limits was above the $FTC_{WQ-17.5}$ derived from the HH-WQC, precluding a comparison with the $FTC_{WQ-17.5}$ absent making assumptions about the concentration of arsenic in fish samples with non-detectable concentrations. As a specific example, the NLFTS reported a method detection limit (MDL) for inorganic arsenic of 30 ppb, even using a state-of-the-art analysis, Method 1632A for the speciation of arsenic. Given that the $FTC_{WQ-17.5}$ for arsenic is 0.77 ppb, it is not possible to determine whether concentrations in predator fillets are above or below that $FTC_{WQ.}$ Assuming detection limits for arsenic cannot be easily refined, this comparison does suggest that it is not possible to demonstrate compliance with the arsenic $FTC_{WQ-17.5.}$

For PCBs, the NLFTS data indicate that a substantial portion of predatory fish from U.S. lakes exceed the $FTC_{WQ-17.5}$ for PCBs (2 ppb). The extent of this exceedance depends on whether the data are represented by the mean concentration (13.2 ppb), which exceeds the $FTC_{WQ-17.5}$ by a factor of about 6x, or the median (i.e., 50^{th} percentile) concentration (2.3 ppb), which is nearly equivalent to the $FTC_{WQ-17.5}$. While this comparison indicates the average concentration of PCBs in fish throughout the U.S. is substantially higher than the $FTC_{WQ-17.5}$, it does not follow that fish in most surface waters of the U.S. have PCB concentrations greater than both of the FTC_{WQ}s. The difference between the mean and median concentration comparisons for this data set likely arises because the data are skewed, with the majority of samples having relatively low concentrations. As noted above, the 50^{th} percentile of the distribution of PCB concentrations in predatory fish from U.S. lakes is approximately equal to the $FTC_{WQ-17.5}$. Assuming the BCF accurately reflects the relationship between the PCB concentration in fish and water, the comparison of the $FTC_{WQ-17.5}$ to the 50^{th} percentile indicates that roughly half of sampled U.S. waters had PCB concentrations that met or were below the HH-WQC derived based on the consumption of recreational anglers. .

The mean mercury concentration of the NLFTS data (352 ppb) is slightly lower than the $FTC_{WQ-17.5}$ for mercury (394 ppb). The percentile data provided by USEPA (2009) indicate the distribution of mercury concentrations in predatory fish is also skewed, though a smaller proportion of the samples (approximately 25%) exceed the mercury $FTC_{WQ-17.5}$ than exceeded the PCB $FTC_{WQ-17.5}$.

The results of parallel comparisons with FTCs derived based on subsistence anglers (i.e., FTC_{WQ-142}) lead to a different conclusion for three for the four compounds (chlordane, PCBs and mercury). The arsenic FTC_{WQ-142} is about four times lower than the $FTC_{WQ-17.5}$ and is also below the typical detection limits for inorganic arsenic, precluding any meaningful quantitative comparisons with the FTC_{WQ-142}.

The detection limit for alpha chlordane is slightly above the FTC_{WQ-142} and the detection limit for gamma is slightly below (see footnotes to Table C2a). Additionally, the 90th percentile of the distribution of chlordane concentrations is only about 2.5 times higher than the FTC_{WQ-142}. These comparisons suggest that typical concentrations of chlordane may be similar to or less than the FTC_{WQ-142} in many U.S. surface waters, though the upper percentiles of the distribution do exceed the FTC_{WQ-142}, in some cases, substantially (Table C2a).

The FTC_{WQ-142} is about 10 times lower than the $FTC_{WQ-17.5}$ for PCBs and mercury (Table C2a). With the increase in FCR, the average fish tissue concentration exceeds the FTC_{WQ-142} by approximately 50x and 7x for PCBs and mercury, respectively (Table C2a). Additionally, the majority of the distribution of PCB and mercury concentrations is above the FTC_{WQ-142}. For both chemicals, the concentration at the 5th percentile of the distribution exceeds the FTC_{WQ-142}. These comparisons indicate that if HH-WQC were to be revised using an FCR of 142 grams/day, assumed to be representative of subsistence anglers, the concentrations of PCBs and mercury in fish from virtually all surface waters in the U.S. would exceed the allowable fish concentration associated with such an HH-WQC.

Several state programs have surveyed fish tissue concentrations, often including PCBs, metals and/or pesticides. The state data assembled for our analyses included surveys conducted by Washington State Department of Ecology (WA-DOE) and by the Florida St. Johns River Water Management District (SJRWMD). Overall, the state programs include more recent data (through 2011) than those presented in the NLFTS (through 2003). These are much more limited data sets compared to the data from the NLFTS. Additionally, the number of observations from each state varies by chemical and in some instances all the data points are from a single state (e.g., all PCB data are from Washington).

Table C2b Measured Concentrations in Fish Samples from Washington and Florida

	Data from State Programs (µg/kg, ppb)			FTC_{WQ}[1] (µg/kg, ppb)	
Chemical	Mean[2]	50th %ile	90th %ile	$FTC_{WQ-17.5}$	FTC_{WQ-142}
PCBs	27.4	22.1	49.8	2.0	0.25
Mercury	191	120	408	394	49
Chlordane	1.4	0.62	2.8	11.3	1.4

Notes:
Based on data provided by J. Beebe (NCASI) and comprised of data from Washington State WA-DOE (2011), WA-EIMS, http://www.ecy.wa.gov/eim), and St. Johns River Water Management District (SJRWMD), Florida (http://sjr.state.fl.us).
[1] FTC_{WQ} derived from water and organism HH-WQC.
[2] Data included: for PCBs, 45 samples from WA-EIMS; for mercury, 1598 samples from WA-EIMS and SJRWMD; and for chlordane, 382 samples from SJRWMD.

The mean concentration of PCBs in predatory fish (27.4 ppb), is about 14 times and 100 times higher than the $FTC_{WQ-17.5}$ and FTC_{WQ-142}, respectively. In fact, both FTC_{WQ}s are well below the minimum reported concentration (9.7 ppb) from this data set. Assuming these data were collected from waters potentially affected by PCB releases suggests that meeting the HH-WQC, based on either the recreational of subsistence FCR, in such waters is likely to be a challenge. To the extent these data are only from Washington, this finding may only apply to waters of that state.

The mean concentrations of mercury and chlordane from state programs are below their respective $FTC_{WQ-17.5}$ by approximately 2x- and 8x-, respectively (Table 4-2b) suggesting that a substantial portion of the surface waters in these states would meet an HH-WQC derived based on an FCR assumed to be representative of a recreational angler. The mean concentration of chlordane is equal to the FTC_{WQ-142}. If the chlordane distribution from these two states has a similar "shape" to the distribution in the national survey, this comparison suggests that a substantial portion of surface waters in these two states would meet an HH-WQC based on an FCR representative of a subsistence angler. Fewer waters are likely to meet such an HH-WQC for mercury, given that the mean concentration exceeds the FTC_{WQ-142} by approximately 4x.

Arsenic was included in several of the state databases, however, inorganic arsenic was not detected at measurable concentrations. As discussed above for the NLFTS data, meaningful comparison of inorganic arsenic concentrations to FTCs is precluded because MDLs are greater than the FTCs.

4.0 COMPARISON OF FTC_{WQ} TO FCA TRIGGER LEVELS ESTABLISHED BY STATE OR OTHER PUBLIC HEALTH AGENCIES

Most states and various federal agencies have programs for the protection of anglers who may eat fish containing trace amounts of chemicals. These programs are responsible for issuing FCAs for lakes and reservoirs where particular chemicals have been detected at levels in fish that exceed some risk-based "trigger level." While the approach to setting FCAs may differ, most programs use a risk-based approach to develop guidelines that are intended to be protective of the health of the angler communities with a wide margin of safety. USEPA (2000) issued guidance that could be used to establish some uniformity in the methods used to derive FCAs, but most states are maintaining programs and guidelines that have served them for many years. A common feature of both federal and state guidelines is the movement away from a single trigger level and towards a progression of trigger levels, each associated with an increasing level of restricted intake for the fish (and chemical) in question. Despite this increased complexity, USEPA (2000) also provided screening values (SV) based on moderate (recreational) and high (subsistence) levels of fish consumption, termed SVrec and SVsub, respectively, and shown in Table 4-3 for PCBs, arsenic, chlordane, and mercury.

Also shown in Table 4-3 are examples of FCA trigger levels from state programs that publish numerical benchmarks for this purpose. For states that have adopted a series of trigger levels, this analysis presents the levels based on either a "no more than 2 meal per month" restriction (noted as "L2" in Table 4-3), or a 'do not eat' advisory (complete restriction, notes as "R" in Table 4-3). Two 8-ounce (227 g) meals per month is assumed to be comparable to the 17.5 gram/day FCR applied by USEPA to the derivation of HH-WQC.[13]

[13] The guidelines from WI-DNR and MI-DCH, however, only included a one meal per month advisory level, and the concentrations accompanying this advisory level are shown for these two agencies (noted as "L1" in Table 4-3).

Table C3 USEPA Screening Values for Fish and FCA Trigger Levels Used by Select State Agencies[1]

	Federal USEPA (2000)[2] (μg/kg, ppb)		Select State Programs (μg/kg, ppb)			FTC_{WQ} Organism Only Values (μg/kg, ppb)	
Chemical	SV(rec)[3]	SV(sub)[3]	WI-DNR	MI-DCH	WV-DHHS	$FTC_{WQ-17.5}$	FTC_{WQ-142}
PCBs	20	2.5	220 (L1) 2,000 (R)	200 (L1) 2,000 (R)	150 (L2) 1,340 (R)	2.0	0.25
Arsenic	26	3.3	--	NA	140 (L2) 1,250 (R)	6.2	0.28
Mercury	400	50	500-1000 (NS)	500 (L) 1,500 (R)	220 (L2) 1,880 (R)	400	49
Chlordane	114	14	660 (L1) 5,620 (R)	300 (NS)	880 (L2) 7,660 (R)	2.2	1.4

Notes:
R: Restricted, referring to 'do not eat' advisory.
L: Limited, or a limited amount of consumption is advised.
L1: Limited to 1 meal per month.
L2: Limited to 2 meals per month.
NS: Not stated whether the value represents a restriction or a limit.
[1] Wisconsin Department of Natural Resources (WI-DNR), 2007, 2011; Michigan Department of Community Health (MI-DCH), 2008; West Virginia Department of Health and Human Services (WV-DHHS).
[2] USEPA, 2000. Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories, Volume 1.
[3] Screening values (SV) for the recreational and subsistence angler.

When compared to these FCA trigger levels, the $FTC_{WQ-17.5}$ for PCBs, arsenic and chlordane are 20-4,000 times lower (more stringent) (Table C3). For mercury, the $FTC_{WQ-17.5}$ is comparable to the trigger levels prompting some restriction on fish consumption, but is as much as 4x lower than the level where a 'do not eat' advisory is prompted. FTC_{WQ-142} are between 200-8,000 times lower than the FCA trigger levels for PCBs, arsenic, and chlordane, and 4 to 40 times lower than the trigger levels for mercury (Table C3).

As shown in Table C3, the USEPA SVs are either similar or 10x higher than the FTC_{WQ} derived from the HH-WQC. Because these USEPA values are intended to be generic screening-level benchmarks, they are very conservative compared to the trigger levels used by the most state programs (discussed further below).

Comparing the USEPA SVs to FTC_{WQ} for chemicals for which noncancer endpoints are the driver, such as mercury, SVs are the same as the FTC_{WQ}s. For the other three constituents, for which the cancer endpoint is most sensitive, the SVs are approximately 10 times higher, because SVs are derived based on a $1x10^{-5}$ target risk level, rather than a $1x10^{-6}$ target risk level.

In contrast, fish advisory trigger levels used by public health agencies in Wisconsin, Michigan, and West Virginia (Table C3) are less stringent, and in general, would require substantially higher concentrations of arsenic, chlordane and PCBs than allowed by the HH-WQC before issuing even a moderate restriction on fish consumption. Based on our survey of state "trigger levels" and recent reviews comparing the FCAs between states (IWG-ACA, 2008; Scherer et al. 2008), we believe that the FCAs from Wisconsin, Michigan, and West Virginia are likely to be representative of the FCAs from many state programs. Scherer et al. (2008) found the FCAs among states to be quite similar, despite some variation in the methods used to develop the FCAs. Many state programs rely on less-stringent food tolerance levels as the basis for their trigger levels; this choice is consistent with the desire by States to consider the value of their recreational fisheries and the benefits of fish consumption, while protecting the public from potential chemical risks. The difference in the State vs. EPA trigger levels is due to several factors. As noted previously, state guidelines are typically based on a series of FCA trigger levels, giving the States the ability to partially restrict fish consumption at many concentration levels. Further, the ability to issue consumption limits for specific target fish species also permits states to allow higher fish tissue concentrations. Lastly, state agencies are more likely to apply lower assumed fish consumption rates based on local or regional surveys conducted within the state.

A key illustration of the conservative nature of the FTCs is provided by a comparison of the proportion of samples in the NLFTS data set that exceed an FTC_{WQ} to the proportion of waters in the U.S. that have a fish consumption advisory. As described above approximately 50% of fish samples have PCB concentrations that exceed the $FTC_{WQ\text{-}17.5}$ and over 95% exceed the $FTC_{WQ\text{-}142}$. Yet, only about 15% of the nation's lakes are subject to a fish consumption advisory (USEPA 2009). Given that a goal of both an HH-WQC and an FCA is protection of the health of anglers, the much larger proportion of waters estimated to potentially pose an unacceptable risk when an HH-WQC is used than measured by the posting of an FCA, suggests that the derivation of HH-WQC by USEPA is substantially more conservative than the derivation of FCAs by state agencies.

5.0 COMPARISON OF FTC_{WQ}S TO HEALTH-BASED LIMITS FOR FISH OR OTHER FOODS

Other federal and global agencies charged with protection of food safety have established guidelines for ensuring the safety of foods in commerce. The most notable examples in the U.S. are the food tolerances established by USFDA. These tolerances have been used as a guideline for assessing the safety of food, largely animal products, such as beef, chicken, fish, milk and eggs. These tolerances are typically less stringent than analogous values derived using USEPA methods for risk assessment. Unlike the USEPA, the USFDA must balance potential economic concerns with the potential benefits to public health; in other words, the USFDA must consider the consequences of its actions on the U.S food supply. USEPA exposure limits and screening levels may also be considered for their economic consequences, but this review is conducted outside of the Agency and only after the value has been derived. Regardless, USFDA tolerances are risk-based concentrations and many risk assessors and scientists support the idea that the tolerances are protective of the public health (Cordle et al. 1982; Maxim and Harrington 1984; Boyer et al. 1991). Due to recent incidents in Europe in which PCBs were accidentally introduced into animal feeds, the European Commission (EC) has set maximum levels for PCBs in foods and feedstuffs, including fish (EC, 2011). The limits were based on a report of the European Food Safety Authority (EFSA) deriving allowable exposure levels, and on monitoring data compiled throughout the European Union (EU). The EU considered both the public health protection and the feasibility of attaining these limits, based on current levels measured in foods.

FTC_{WQ} derived from the HH-WQC are in all cases well below both the USFDA and EU food tolerance levels (Table C4). The USFDA tolerance for PCBs in fish of 2,000 ppb is 1,000 times higher than the $FTC_{WQ\text{-}17.5}$ and 8,000 times higher than the $FTC_{WQ\text{-}142}$.

Table C4 Comparison of FTC_{WQ} to Food Safety Guidelines for Chemical Concentrations in Fish

	Food Safety Standards		HH-WQC-Based Threshold for Fish	
Chemical	USFDA Tolerance for Fish[1] (µg/kg, ppb)	EU Limit for Fresh Fish[2] (µg/kg, ppb)	FTC_{WQ} FCR = 17.5 (µg/kg, ppb)	FTC_{WQ} FCR=142 (µg/kg, ppb)
PCBs	1,000 (action level) 2,000 (limit)	250[(3)]	2.0	0.25
Mercury	1,000 (action limit)	--	394	49.2
Chlordane	300	--	11.3	1.4

Notes:
[1] USFDA (1998, 2011); Values are based on wet weight.
[2] European Commission (EC) 2011. Commission Regulation No. 1259/2011.
[3] EC Limit for PCBs is 125 ng/g wet wt. for the sum of 6 'marker' congeners, which comprise about 50% of the PCBs in fish. Therefore, to be applicable to a measure of total PCBs, this value was multiplied by a factor of 2 (EC, 2011).

6.0 TYPICAL INTAKES OF THE CHEMICALS IN THE U.S. POPULATION: COMPARISON TO THE ALLOWABLE DAILY INTAKES DERIVED FROM THE HH-WQC

The goal of an HH-WQC is to limit exposure of the population to chemicals in water such that an allowable dose (or risk) is not exceeded. If the dominant exposure pathway for a chemical is direct contact or use of surface water, then compliance with the AWQC may, indeed, limit overall exposure to allowable levels. However, if other pathways also contribute to overall exposure and, in particular, if the other pathways represent larger exposures than surface water, then establishment and enforcement of a stringent surface water criterion may not provide a measurable public health benefit. This section compares exposures allowed by the HH-WQC to the potential exposures from a limited set of other exposure sources or pathways for five chemicals.

One of the key assumptions used to derive FTC_{WQ} is an allowable daily intake of each constituent in question. This allowable daily intake is a toxicologically-derived value and is represented by a reference dose (RfD) (for noncancer endpoints) or a risk-specific dose (RSD) (when cancer is the endpoint). The RSD is equal to the target risk level (typically 1×10^{-6}) divided by the cancer slope factor (CSF) for a particular constituent.

As shown in Table C5, the RfDs and RSDs for the six chemicals evaluated in this appendix range from 0.35 µg/day for PCBs to 98 µg/day for methyl bromide.[14] These are the toxicity values chosen by USEPA for the derivation of HH-WQC.

Another way to estimate the allowable daily dose associated with the HH-WQC, and the FTC_{WQ} in particular, is to multiply the allowable fish tissue concentrations (i.e., the FTC_{WQ}) by the assumed FCR of 17.5 grams/day. The results, as shown in Table C5 as "Fish Dose", represent the dose of each chemical that someone would receive who ate fish containing chemicals at concentrations equal to the FTC_{WQ}.

[14] Traditional units of dose in mg/kg-day are converted to units of intake (µg/day) by multiplying by an adult body weight of 70 kg and a conversion factor of 1000 µg/mg.

For PCBs, mercury and arsenic, very low, but measurable daily intakes by the U.S. population are based on releases of these substances into the environment and their presence in trace quantities in the food supply. Arsenic occurs naturally in soils and groundwater and, therefore, there is a normal daily intake that varies by region. For BEHP, the presence of trace amounts in food stems from its use in plastic food packaging materials (Fromme et al. 2007). A summary of the data used to provide an estimate of the typical daily intake of each chemical is presented below.

PCBs: The intake of PCBs through foods, mainly animal products, has declined dramatically in the last 30 years. However, Schecter et al. (2010) recently carried out a market-basket survey of several types of foods and found measurable levels in enough foods to propose a daily intake of about 0.1 µg/day for a typical resident of the U.S. Other studies in Europe have proposed slightly higher intake levels (as high as 0.8 µg/day), but overall, corroborate the findings of Schecter et al. (2010). This range of typical dietary intakes of PCBs is 3 times to as much as 20 times greater than the risk-specific dose (RSD) used to derive the HH-WQC (0.035 µg/day) (Table C5). Thus, the HH-WQC is based on an exposure limit for PCBs that is routinely exceeded by the typical PCB intake that occurs through dietary exposures.

BEHP: Considerable effort has been made to estimate the human exposure to phthalate esters, which arises from food packaging materials, e.g., plastic food wraps. A German study by Fromme et al. (2007) provides the most reliable estimates of intake, based on a study using both samples of dietary items and biomonitoring data. Because phthalate ester exposures are derived from plastic packaging/wrapping that is sold across the globe, intakes estimated by this study for a German population are likely to be comparable to those in U.S. The authors report a median BEHP intake of 2.4 µg/kg-day (162 µg/day) which is approximately 30 times greater than the RSD used by the HH-WQC (Table C5). Thus, the HH-WQC is based on an exposure limit for BEHP that is routinely exceeded by the typical intake that occurs through dietary exposures.

Table C5 Allowable vs. Actual Daily Intakes for Select Chemicals

	Allowable Daily Intakes Used as the Basis for the HH-WQCs		Measured or Estimated Average Daily Intakes Derived from Food		
	Value [RfD or RSD] (μg/day)	Fish Dose[1] (μg/day)	Intake (μg/day)	Group	Note
PCBs	0.035 [RSD]	0.035	0.1-0.8	all	(a)
Methyl bromide	98 [RfD]	3.1	6.5 (mean); 310 (95th %ile)	male	(b)
			10 (mean); 350 (95th %ile)	female	
Arsenic	0.04 [RSD]	0.014	3.6 / 2.7 (avg.); 9.4 (90th %ile)	male	(c)
			2.8 / 2.4 (avg.); 11.4 (90th %ile)	female	
Mercury	7 [RfD]	7	8.6 (mean); 166 (90th %ile)	male	(d)
			8.2 (avg.); 204 (90th %ile)	female	
BEHP	5 [RSD]	0.26	162 (median); 309 (95th %ile)	all	(e)

Notes:
RfD, Reference Dose; RSD, Risk-Specific Dose
[1] Computed as FTC_{WQ} [from Table C1a] x FCR [17.5 g/day]
(a) Range is based on the results of several studies (Darnerud et al. 2006; Arnich et al. 2009; Roosens et al. 2010; Schecter et al. 2010).
(b) Cal-EPA 2002; assumed body weight of 70 kg for adults.
(c) Meacher et al. 2002; assumed body weight of 70 kg for adults.
(d) MacIntosh et al. 1996.
(e) Fromme et al. 2007.

Arsenic: A study by Meacher et al. (2002) represents a comprehensive evaluation of total inorganic arsenic exposure in the U.S. population. The authors discuss other studies with a similar aim and conclude that the average daily intake, primarily from food and drinking water, is in the range of 1 to 10 μg/day. Estimates of average daily intakes are 60 to 90 times greater than the RSD. Thus, the HH-WQC is based on an exposure limit for arsenic that is exceeded by a wide margin, by typical dietary intakes of arsenic.

Methyl bromide: The concentrations detected in foods are mainly in animal products, such as milk, which makes estimates of a one-time exposure as high as 4-5 μg/kg-day, but with average daily exposures likely to be less than 1 μg/kg-day, according to a study by Cal-EPA (2002). While 95th percentile values (310-350 μg/day) are more than 40 times higher that the mean intake estimates, it can be concluded that typical methyl bromide intakes based on diet are likely to be below the RfD of 98 μg/day. Thus, for methyl bromide, dietary intakes would not appear to hinder the objective of limiting the exposures based on fish consumption.

Mercury: The predominant human intake is from concentrations in predatory and deep-sea fish such as tuna. Average daily intakes are estimated to be about 8 μg/day (MacIntosh et al. 1996) and are comparable to the RfD of 7 μg/day (Table C5). Thus, for mercury, it is not uncommon for the consumption of store-bought tuna to provide an intake equivalent to the RfD; achieving this level of exposure would at least appear to be an achievable public health objective.

In summary, estimated daily intakes for five of the six chemicals could be obtained from the literature (Table C5). For PCBs, arsenic and BEHP, the chemicals for which potential cancer risk is the most sensitive endpoint, the estimated daily intake for the U.S. population is between 3 times to 90 times greater than the RSD. In surface waters with fish that have concentrations that are no more than a 2-times lower than the FTC, based on the comparisons shown in Table C5, decreasing exposures to the levels associated with HH-WQC would be likely to have no discernible effect on the intake of these chemicals in the community.

7.0 SUMMARY AND CONCLUSIONS

This paper described the derivation of allowable fish tissue concentrations (referred to as FTC_{WQ}) associated with HH-WQC for a select group of chemicals. FTC_{WQ} are based on the same exposure and toxicity factors used to derive the HH-WQC. Separate FTC_{WQ} were derived for USEPA's recommended fish consumption rate for recreational anglers (17.5 grams/day, $FTC_{WQ\text{-}17.5}$) and subsistence anglers (142 grams/day, $FTC_{WQ\text{-}142}$). Given the nearly 10x higher consumption rate assumed for subsistence anglers compared to recreational anglers, $FTC_{WQ\text{-}142}$ were lower than the $FTC_{WQ\text{-}17.5}$ for every chemical by about 10x. FTC_{WQ} were compared to: (1) concentrations measured in fish from U.S. water bodies; (2) trigger levels used by State agencies to set fish consumption advisories; and (3) allowable concentrations set by other US and international health agencies. Additionally, ADIs used to derive FTC_{WQ} were compared to estimated daily dietary intakes from all sources.

PCB concentrations in about half of the fish from the NLFTS exceeded the $FTC_{WQ\text{-}17.5}$ and PCB concentrations in essentially all fish from the NLFTS exceeded the $FTC_{WQ\text{-}142}$. (Additionally, all of the fish from two state-specific surveys had PCB concentrations above the $FTC_{WQ\text{-}17.5}$ and the $FTC_{WQ\text{-}142}$.) The mercury concentrations for the majority of fish in the NLFTS were below the $FTC_{WQ\text{-}17.5}$ but most fish had mercury concentrations above the $FTC_{WQ\text{-}142}$. Chlordane was not detected in the majority of NLFTS samples with detection limits below the $FTC_{WQ\text{-}17.5}$ and the $FTC_{WQ\text{-}142}$ suggesting the majority of fish have chlordane concentrations below either FTC_{WQ}. Arsenic was not detected in majority of NLFTS; however, unlike chlordane, the method detection limit for arsenic exceeds both the $FTC_{WQ\text{-}17.5}$ and the $FTC_{WQ\text{-}142}$ by more than 30x, precluding the possibility of determining whether arsenic concentrations meet the HH-WQC. Thus, whether nationwide fish tissue concentrations meet the FTC_{WQ} depends upon the chemical of interest and whether recreational or subsistence angler consumption rates are used to derive the FTC_{WQ}. It does appear that if HH-WQC were to be revised using an FCR of 142 grams/day, the concentrations of PCBs and mercury in fish from virtually all surface waters in the U.S. would exceed the allowable fish concentration associated with such HH-WQC.

$FTC_{WQ\text{-}17.5}$ for PCBs, arsenic, and chlordane were 20 to 4,000 times lower (more stringent) than FCA trigger levels commonly used by state programs. For mercury, the $FTC_{WQ\text{-}17.5}$ was comparable to typical state trigger levels prompting some restriction on fish consumption, but it was as much as 4 times lower than the level where a 'do not eat' advisory is prompted. Again, the comparisons were much more remarkable using the $FTC_{WQ\text{-}142}$. $FTC_{WQ\text{-}142}$ were between 200 times and 8,000 times lower than the FCA trigger levels for PCBs, arsenic, and chlordane, and 4 times to 40 times lower than the state trigger levels for mercury. These comparisons were based on the guidelines from a select number of states, including Wisconsin, Michigan, and West Virginia; however, the FCA trigger levels were comparable among this small group of states, and based on our review of guidelines in many other states not included in this analysis, we believe that these states can be considered representative of many other state programs.

A comparison of FCAs to the NLFTS data provides another comparison that highlights the conservatism of the FTC_{WQ} (and the HH-WQC from which they were derived). Approximately 50% of fish samples from the NLFTS had PCB concentrations that exceeded the $FTC_{WQ-17.5}$ and over 95% exceeded the FTC_{WQ-142}. However, only about 15% of the nation's lakes and reservoirs (on a surface area basis) are subject to a FCA based on PCBs (USEPA 2009). Thus, use of HH-WQC indicated that a much larger proportion of US surface waters pose an unacceptable risk than indicated by FCA postings. This comparison further illustrates that the assumptions used by USEPA to derive HH-WQC are more conservative than the assumptions used by state agencies to derive FCAs.

Various agencies, both Federal and international, have established concentration limits for fish as a food in commerce. The FDA food tolerances are the most notable example. FTC_{WQ} were compared to FDA tolerance limits and a recently established EU limit for PCBs in fish. The $FTC_{WQ-17.5}$ for PCBs of 2 ppb is 500 times lower than the FDA action limit of 1,000 ppb and 125 times lower than an EU limit of 250 ppb. The FTC_{WQ-142} is 1,000x and 4,000x lower than the EU and FDA action limits, respectively. The FDA tolerance of 300 ppb for chlordane is similarly much less stringent than either the $FTC_{WQ-17.5}$ (11.3 ppb) or the FTC_{WQ-142} (1.4 ppb) for chlordane. The FDA action level for mercury of 1,000 ppb is similar to but still higher than either the $FTC_{WQ-17.5}$ (394 ppb) or the FTC_{WQ-142} (49 ppb) for mercury. These comparisons indicate that HH-WQCs are limiting fish tissue concentrations to levels substantially below those considered to be without significant risk by public health agencies whose goal is to ensure the safety of edible fish.

Lastly, allowable daily intakes (RfDs for noncancer endpoints, RSDs for the cancer endpoint) assumed by the FTC_{WQ} were compared to estimates of the daily intake of arsenic, BEHP, mercury and PCBs obtained from the open literature. Specifically, daily intakes were taken from studies that measured concentrations in various foodstuffs. Typical daily dietary intakes of arsenic, BEHP and PCBs exceeded the allowable daily intakes used to derive HH-WQC by a substantial margin. The typical daily dietary intake of mercury, mostly from tuna, is comparable to the RfD used to derive the HH-WQC. Thus, for those compounds whose daily dietary intake is greater than the intake associated with surface water and already exceeds the allowable daily intakes used to establish HH-WQC, the establishment and enforcement of a more stringent HH-WQC may not provide a measurable public health benefit.

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