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January 20, 2015

Paula Wilson
Idaho Dept. of Environmental Quality
Attorney General's Office
1410 North Hilton
Boise, ID 83706

**RE: Docket No. 58-0102-1201 - Negotiated Rulemaking
Risk Levels for Idaho HHWQC – ARCADIS White Paper**

Dear Ms. Wilson:

Please find the attached “white paper” prepared by ARCADIS addressing risk policy and calculational choices associated with setting Idaho’s human health water quality criteria (HHWQC). ARCADIS is a consulting company with internationally recognized expertise in toxicology and risk assessment. This white paper was funded by several IACI members and was developed for IACI to support the Idaho Department of Environmental Quality (IDEQ) in the use of the best available science and setting of public policy choices that balance risk, achievability and level of public and private resources available to implement these important choices.

IACI respectfully urges IDEQ to review this work and use the approaches and public policy considerations as IDEQ does the important work of making risk policy choices and setting HHWQC.

Sincerely,

A handwritten signature in blue ink, appearing to read "Alex LaBeau", with a long horizontal flourish extending to the right.

Alex LaBeau
President

Attachment – ARCADIS Risk White Paper

cc: Alan Prouty, Chair
IACI Environment Committee

**White Paper Responding to the
Idaho Fish Consumption Rate and
Human Water Quality Criteria—
Discussion Paper #7: Risk
Management and Protection of
Human Health**

January 20, 2015



A handwritten signature in black ink, appearing to read "Paul D. Anderson".

Paul D. Anderson, Ph.D.
Vice President, Principal Scientist

A handwritten signature in black ink, appearing to read "Michele Buonanduci".

Michele Buonanduci
Scientist

**White Paper Responding to the
Idaho Fish Consumption Rate
and Human Water Quality
Criteria—Discussion Paper #7:
Risk Management and
Protection of Human Health**

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Acronyms and Abbreviations

AT _c	averaging time for carcinogenic effects
AT _{nc}	averaging time for noncarcinogenic effects
ATSDR	Agency for Toxic Substances and Disease Registry
AWQC	ambient water quality criteria
BCF	bioconcentration factor

BCF _{lipid}	lipid-based bioconcentration factor
BCF _{tissue}	tissue-based bioconcentration factor
BW	body weight
CL	cooking loss
CLF	catch location factor
CRITFC	Columbia River Inter-Tribal Fish Commission
CSF	cancer slope factor
CSFII	Continuing Survey of Food Intake by Individuals
DI	drinking water intake
ED	exposure duration
ELCR	excess lifetime cancer risk
FCR	fish consumption rate
FDEP	Florida Department of Environmental Protection
g/day	grams per day
HEAST	Health Effects Assessment Summary Tables
HQ	hazard quotient
IDEQ	Idaho Department of Environmental Quality
IRIS	Integrated Risk Information System
kg	kilogram
L/day	liters per day
LHF	life history factor
L/kg	liters per kilogram
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
mg/kg-day	milligrams per kilogram per day
NCI	National Cancer Institute
NHANES	National Health and Nutrition Examination Survey

PAWQCC	Probabilistic Ambient Water Quality Criteria Calculator
PCB	polychlorinated biphenyl
PPRTV	Provisional Peer Reviewed Toxicity Values
PRA	probabilistic risk assessment
RBA _w	relative bioavailability, water
RBA _f	relative bioavailability, fish
RfD	reference dose
RSC	relative source contribution
TELCR	target excesslifetime cancer risk
THQ	target hazard quotient
ug/L	micrograms per liter
USDA	United States Department of Agriculture
USEPA	United States Environmental Protection Agency
USFDA	United States Food and Drug Administration
WDOE	Washington Department of Ecology



Executive Summary

This white paper offers comments on the Idaho Department of Environmental Quality's (IDEQ's) Policy Discussion Paper #7 on risk management (IDEQ 2014a), with the larger goal of advancing the discussion about how we think about acceptable risk and use those concepts to develop ambient water quality criteria (AWQC) for surface waters.

Early efforts to evaluate the risk of exposure to chemicals in the environment necessarily used relatively simple calculation methods. As our understanding of regulatory toxicology has grown, however, the scientific and regulatory communities have developed techniques to more accurately represent potential risks and to allow for more transparent decision-making. This white paper explores how such techniques can be applied to determining AWQC. The crux of the discussion is the distinction between deterministic risk assessment and probabilistic risk assessment (PRA) and how the differences between the two affect risk management decision-making. A deterministic risk assessment approach uses single values (also referred to as point estimates) to represent factors determining exposure and results in a single discrete estimate of risk. This approach, used since the early days of regulatory toxicology, is typically used to derive AWQC. It does not allow a decision maker to capture and understand the range of exposures by a disparate population, nor does it provide a quantitative basis for evaluating the possible consequences of different risk management decisions. Probabilistic risk assessment methods use distributions of values to represent factors determining exposure and allow for the estimation of a distribution of potential risks. This allows for more informed risk management decisions.

Beside factors that determine exposure and toxicity, another critical factor that must be selected when setting AWQC is the level of risk that is considered to be acceptable. As most readers of this white paper know, human health risk is evaluated with respect to two classes of endpoints: cancer and noncancer. Judgments about allowable risk associated with each of these types of effects needs to be made when setting AWQC.

For compounds that may cause cancer, acceptable risk is often described as an excess lifetime cancer risk of one in ten thousand to one in one million (or 1×10^{-4} to 1×10^{-6}). This white paper explores two key concepts. First, the appropriateness of this risk range is much debated and the benchmarks themselves are not applied consistently in different regulatory programs. For example, Maximum Contaminant Levels (MCLs) for some carcinogens in public drinking water supplies actually present a higher risk than this range. Second, because the level of estimated risk relates to the

degree of exposure, utilizing deterministic risk assessment methodology to derive AWQC means that only a portion of the population is actually facing the level of risk that was used to derive the regulatory standard; the risk to others in the community is unknown. Probabilistic risk assessment methods allow one to develop AWQC that meet a *de minimus* level of risk for the majority of a population and to be sure that highly exposed sub-populations would still have an acceptable level of risk. Probabilistic risk assessment methods, through calculations that are explained in detail in this white paper, also allow one to evaluate the consequences (i.e., number of cancers) that could result from modifying the value of an AWQC. Thus, this method provides more transparency in regulatory decision-making than does the deterministic approach.

Chemicals that cause adverse health effects other than cancer are assumed to have some threshold dose below which no adverse health effects are expected to occur. For noncarcinogenic chemicals, a hazard quotient (HQ) of less than or equal to one (1) indicates that the estimated exposure is less than or equal to the allowable dose and that no adverse health effects are expected, even over a lifetime of continuous exposure. In other words, such exposures are considered safe. An HQ of greater than one indicates that estimated exposure is greater than the allowable dose and the potential exists for an adverse health effect to occur. However, a HQ may need to reach several times 1 before an adverse effect actually occurs. Goals for protecting human health and the environment from the effects of exposure to a noncarcinogen often correspond to a $HQ \leq 1$. However, in some regulatory programs – MCLs allowed in public drinking water supplies – HQs greater than 1 may be allowed.

In support of a probabilistic approach, this white paper explores some of the critical variables that help to determine human health risk. These include the rate of fish consumption among the general population and Native American population, among other variables.

Finally, to illustrate these various points, this white paper uses a PRA approach to derive hypothetical AWQC for six compounds. The detailed results presented in this white paper reflect variations in the allowable risk level and fish consumption rate, among other factors, and show the resulting estimated risks to various segments of the population. These calculations illustrate several important points.

- The PRA approach can be used to derive AWQC that provide appropriate levels of protection to people who have a range of exposures. For example, an AWQC based on a hypothetical cancer risk of 1×10^{-6} for a person who

experiences an average level of exposure would correspond to a potential risk of 2×10^{-6} for a person at the 90th percentile of exposure. A PRA approach also allows one to demonstrate that the most highly exposed people have a potential risk of less than 1×10^{-4} (in other words, within the United States Environmental Protection Agency's allowable risk range). In a second set of illustrative calculations, AWQC were based on a HQ of 1 for those at the 90th percentile level of exposure. Such criteria would correspond to HQ approximately 0.5 for the average person and a HQ of somewhat greater than 1 for the most highly exposed members of the population. One need not calculate AWQC using deterministic methods that compound conservative assumptions in an unquantifiable fashion to develop criteria that protect people who may be exposed to chemicals in the environment at different levels.

- The PRA approach allows risk managers to evaluate the effect of changing baseline assumptions on the value of the AWQC. As the calculations presented in this white paper show, varying the amount of fish intake (reflecting different degrees to which people eat locally-caught fish and even considering heritage fish consumption rates of Native Americans) has a relatively small effect on AWQC. Using PRA methods allows stakeholders to see the consequences of risk management decisions more clearly than with deterministic calculations.

No discussion of rulemaking based on the potential risks of exposure is complete without the context provided by considering the benefits of related behaviors and the perspective of other risks that we commonly face. Many authorities have described the benefits of eating fish, specifically the reduced risk of mortality from coronary heart disease; such benefits far outweigh any increased cancer risks that might be associated with the allowable risk levels used in the derivation of AWQC. Those risk levels are in fact dwarfed by the other risks that we face in our daily lives. If a 'micromort' is defined as a one in one million chance of death, statistics show that the average American faced an unintentional injury-related mortality risk (e.g., from poisoning, motor vehicle traffic, firearms, falls) of 1.3 micromorts per day in 2010. This far outweighs a 1×10^{-6} lifetime risk of cancer resulting from chemical exposure, equal to about 0.00004 micromorts per day. Put another way, PRA allows us to determine that on an annual basis, only a fraction of an additional cancer would be expected in Idaho at an allowable risk of 1×10^{-6} or 1×10^{-5} and only about 2 additional cancers would be expected even at an allowable risk of 1×10^{-4} . This means that using allowable risk levels of 1×10^{-6} and 1×10^{-5} would effectively not result in a change in the number of annual cancer deaths, consistent with the notion that such allowable risk levels are *de minimus*.



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In conclusion, this white paper presents the scientific basis for determining AWQC using a PRA approach and recommends that Idaho adopt a PRA approach. AWQC derived using a PRA approach will account for the full range of exposures experienced by Idahoans and will allow IDEQ to demonstrate that all segments of the population are protected at appropriate allowable risk levels.



1. Introduction

The purpose of this white paper is to provide a response to the Idaho Department of Environmental Quality's (IDEQ's) request for comments on Policy Discussion Paper #7 on risk management (IDEQ 2014a). That discussion paper describes issues related to the selection of an allowable risk level for the setting of ambient water quality criteria (AWQC).

Policy Discussion Paper #7 and the IDEQ presentation at the rulemaking meeting on December 3, 2015 focused on issues related to selection of a single allowable risk level, which needs to be selected if a deterministic risk assessment approach is used to derive AWQC. A deterministic risk assessment approach uses single point estimate values to represent factors determining exposure and results in a single discrete estimate of risk. This approach is typically used to derive AWQC but has a substantial weakness: the degree of protection afforded either for the average Idahoan or a highly exposed Idahoan is unclear. In practice this means that most of the population is protected at the risk management benchmark (e.g., allowable risk level) used to set the AWQC but that highly exposed members of the population have risks that exceed the cancer and noncancer risk management benchmarks. The level of protection can be made far more transparent through the use of a probabilistic risk assessment (PRA) approach, which uses distributions of values to represent factors determining exposure, therefore resulting in a distribution of potential risk estimates. Not only is the information generated by a PRA approach more transparent, but it can also be used to reach far more defensible public health policy decisions than is possible using a deterministic approach.

Consequently this white paper describes a recommended PRA methodology for IDEQ to consider employing when deriving AWQC. The methodology is one that will allow IDEQ to derive AWQC using the Idaho-specific fish consumption rates once those become available as well as make risk management choices discussed in the various discussion papers IDEQ has prepared over the past 15 months (IDEQ 2013a,b; 2014a,b,c,d). After presenting the methodology, this white paper discusses various factors that affect the selection of allowable risk levels. Finally, this white paper presents the derivation of example AWQC for chemicals with carcinogenic and noncarcinogenic health endpoints, utilizing the PRA methodology.

2. Background

This section provides some background relevant to the topics discussed in this white paper. It begins with a general discussion of how both cancer and noncancer risks are evaluated by the United States Environmental Protection Agency (USEPA) (Section 2.1), then explains how a PRA approach improves transparency of the risk assessment and risk management processes (Section 2.2), provides a brief introduction to the selection of allowable risk levels (Section 2.3) and concludes with a discussion of how a PRA approach can improve public health policy decision making (Section 2.4).

2.1 Evaluation of Cancer and Noncancer Health Endpoints

Human health risk is evaluated with respect to two classes of endpoints: cancer and noncancer. Judgments about allowable risk associated with each of these types of effects needs to be made when setting AWQC.

Chemicals with a carcinogenic endpoint are, with a very few exceptions, conservatively assumed to have some probability of causing an adverse health effect (cancer) at any dose, by typical risk assessment practice. Unlike the noncarcinogenic endpoint (discussed below), there is no safe dose. Thus, any exposure to a chemical believed to cause cancer has associated with it a risk. Carcinogenic risk is expressed as a probability of developing cancer as a result of a given level of exposure over a lifetime (USEPA 1989) above and beyond the background risk that is already incurred. This additional risk of getting cancer associated with exposure to chemicals is often referred to as the excess lifetime cancer risk (ELCR). Without a clear health effects threshold, public health policy makers must choose some “acceptable” ELCR (also referred to in this white paper as an allowable risk) to set an AWQC for chemicals with a carcinogenic endpoint.

Chemicals that cause noncarcinogenic adverse health effects are assumed to have some threshold dose below which no adverse health effects are expected to occur. For noncarcinogenic chemicals, a hazard quotient (HQ) of less than or equal to one (1) indicates that the estimated exposure is less than or equal to the allowable dose (referred to by the USEPA as a reference dose or RfD) and that no adverse health effects are expected, even over a lifetime of continuous exposure. In other words, such exposures are considered safe. An HQ of greater than one indicates that estimated exposure is greater than the RfD. An exceedance of the RfD indicates that the potential exists for an adverse health effect to occur. However, because of the multiple conservative assumptions used to derive RfDs, HQs that slightly exceed one are



generally not considered to represent substantial public health threats. The USEPA has offered this perspective (USEPA 1996):

Because many reference [doses] incorporate protective assumptions designed to provide a margin of safety, a hazard quotient greater than one does not necessarily suggest a likelihood of adverse effects. A hazard quotient less than one, however, suggests that exposures are likely to be without an appreciable risk of noncancer effects during a lifetime. Furthermore, the hazard quotient cannot be translated into a probability that an adverse effects [sic] will occur, and is not likely to be proportional to risk. A hazard quotient greater than one can be best described as only indicating that a potential may exist for adverse health effects.

The United States Department of Health and Human Services (2013) provides further perspective:

If the hazard quotient exceeds unity, the toxicant may produce an adverse effect but normally this will require a hazard quotient of several times unity; a hazard quotient of less than one indicates that no adverse effects are likely over a lifetime of exposure.

In short, while a HQ less than one provides substantial certainty that exposure will not result in a risk, exposure that results in a HQ of slightly greater than one (even up to several times one) is also unlikely to result in an adverse effect.

2.2 Probabilistic Risk Assessment Improves Transparency

AWQC are determined by a combination of both science and policy. The probabilistic approach described in this white paper allows for a clearer separation of the two than is possible with a deterministic approach. When using the probabilistic approach, the full range of values for one or several input parameters can be employed rather than having to select a single value for each parameter from a range of possible values. The selection of a single value for an exposure or toxicity parameter from a range of possible values constitutes one set of risk management choices made when setting AWQC. The other risk management decision, the one more commonly recognized as such, is the selection of allowable risk levels (discussed further below).

The risk management choices that arise when a single value for an exposure or toxicity factor is selected from a range of values are not exclusive to deterministically derived

AWQC. The probabilistic methodology described in this white paper uses single values for some of the inputs, such as bioconcentration factors, reference doses and cancer slope factors, among others. Selection of a single value to represent these parameters represents a risk management choice within the probabilistic methodology. Use of single values for the reference doses or the cancer slope factors that represent upper bound estimates of the potential toxicity of chemicals leads to distributions of risk that overestimate potential risk. The choice to use such single estimates of potential toxicity is a risk management decision, one that is consistent with a common overall goal of erring on the side of overestimating rather than underestimating potential risk when conducting risk assessments and setting criteria. Therefore, when setting criteria and selecting allowable risk levels, it is important to recognize that certain risk management decisions that lead to overestimates of potential risk have already been made.

AWQC are intended to protect public health from the adverse effects of chemicals in surface water. We know that each Idahoan is unique and that all Idahoans have varying levels of exposure to any chemicals that may be in surface water. Some Idahoans who do not drink from such water and rarely eat fish from such water have low exposures, while others who might live near the water, drink from such water and regularly eat fish from such water might have higher exposures. Ideally, public health policy would recognize that variation in exposure and support appropriate protection for all segments of the population.

It bears mentioning that “appropriate” cannot mean “identical” precisely because all Idahoans are not all identical. That means that different segments of the population are going to have different levels of risk. Furthermore, it means that when public health policy makers select a single level of allowable risk associated with a deterministic AWQC, they are protecting different segments of the population at different risk levels. Because a deterministic risk calculation reflects only one level of exposure, those who are exposed to a chemical at different levels will face different levels of risks. However, the degree of risk (or conversely, protection) afforded to those different segments of the population by a deterministically derived AWQC is unknown. As an alternative, public health policy makers can understand that such differences exist and use a PRA approach to explicitly set allowable risk levels for different segments of the population that reflect varying degrees of exposure. In that way, the level of protection afforded by AWQC is both known and transparent.

2.3 Allowable Risk

Public health policy makers are faced with two realities when selecting allowable risk levels. The first is that cancer and noncancer risks vary among different members of the population, depending for example on their degree of exposure. Public health policy makers do not have control over that variation. It cannot be reduced. However, it can be better understood using PRA. The second reality is that an allowable risk level (or levels) must be selected. Public health policy makers do have control over that selection. Precedents exist for selecting allowable risk levels as they apply to the results of deterministic risk assessment, but little guidance exists on how to set allowable risk levels for different segments of the population. Fortunately, with respect to setting AWQC, the USEPA has acknowledged that acceptable risk can vary across a population and that different levels of allowable risk are appropriate for different segments of the population. In its 2000 AWQC guidance, USEPA states that an allowable ELCR of 1 in 1,000,000 (1×10^{-6}) or 1 in 100,000 (1×10^{-5}) is appropriate for the general population and that the risk of highly exposed individuals should not exceed 1 in 10,000 (1×10^{-4}) (USEPA 2000). This range is consistent with the range of risk USEPA considers to be acceptable in its hazardous waste programs and is also generally consistent with the range of risks used by many state regulatory agencies. For example, it is consistent with the allowable risk levels used by Florida in establishing their draft AWQC derived using probabilistic methods (FDEP 2014).

The key concept is the establishment of an allowable risk level for the general population and another allowable risk level (or levels) for highly exposed members of the population. The baseline allowable risk level for the general population sets the overall level of protection for the population as whole. As discussed below, it can also provide a benchmark for understanding the change in public health benefits afforded by a change in AWQC (or by the selection of alternative allowable risk levels to use in revised AWQC). Requiring that individuals with high-end exposures do not exceed a different (higher) allowable risk level also provides crucial assurance that appropriate protection is afforded to all members of the population, including those who are most highly exposed, such as Native American populations who may consume large amounts of fish.

How public health officials determine an acceptable level of risk is complicated and has been much written about and discussed (Lowrance 1976, Breyer 1993, Wilson and Crouch 2001, Blastland and Spiegelhalter 2014). It reflects many elements including what risks society views as acceptable and all the factors that influence that determination, what risks other regulatory programs have viewed as acceptable, the

change in the incidence of a particular adverse health effect with the passage of a regulation and the costs to society associated with that new regulation. It may also reflect technological limitations on analytical chemistry or treatment technologies. For perspective, Section 6.1 of this white paper summarizes allowable risks as defined by some other regulatory programs. Section 6.2 of this white paper summarizes some risks residents of the United States face every day and compares those to the risks that might be considered allowable and used to set AWQC. Section 6.2 also discusses how selection of different allowable risk levels for AWQC in Idaho might change cancer incidence in Idaho.

2.4 Probabilistic Risk Assessment Informs Health Policy Decision-making

The improved understanding of the distribution of risk provided by PRA is also essential to making sound public health policy decisions. The results of a PRA approach can be used to determine the level of protection afforded the average Idahoan and that information can be used to estimate the number of cancers that are avoided by the selection of alternative AWQC. The latter should represent a critical public health policy decision: increasing the stringency of AWQC beyond the point where meaningful reductions in cancer incidence are achieved represents a poor public health policy choice, unless of course, such reductions can be achieved at no cost or risk to society. If a substantial cost is associated with marginal or immeasurable reductions in cancer incidence achieved by AWQC, then those resources are better spent on other public health programs that lead to measureable health benefits. Similarly, if additional treatment steps to achieve more stringent AWQC could in themselves pose a risk then the added benefit might not be worth it. Consider the example below, which demonstrates how the arithmetic mean risk predicted by a PRA approach can be used to estimate the increased cancer incidence in a population as a basis for understanding the implications of a public health policy decision.

The hypothetical example assumes a population of 1.1 million people. For simplicity, people in the population are assumed to either have excess lifetime cancer risks (ELCRs) of 1×10^{-7} (one in ten million), 1×10^{-6} (one in one million) or 1×10^{-5} (one in one hundred thousand). In a real population, the people would have potential risks across the entire range (i.e., between 1×10^{-7} and 1×10^{-5}). Additionally, consistent with the findings of PRAs, relatively few people have either very low or very high risks; most have intermediate risks. Therefore, the example assumes that 50,000 people will have an ELCR of 1×10^{-7} , one million people will have an ELCR of 1×10^{-6} , and 50,000 will have an ELCR of 1×10^{-5} . With that information, the expected number of extra cancers associated with each group of people can be estimated by multiplying the number of



people in each group times the ELCR associated with each group.¹ When that is done, an extra 0.005 cancers are expected over the course of 70 years in the subset of 50,000 with an ELCR of 1×10^{-7} :

$50,000 \text{ people} \times 1 \times 10^{-7} \text{ ELCR per person} = 0.005 \text{ additional cancers.}$

(Obviously, 0.005 cancers cannot exist, but for the sake of this hypothetical example that value will be carried through the calculations.) Following the same approach, 1.0 extra cancer is expected over the course of 70 years in the subset of 1,000,000 people with an ELCR of 1×10^{-6} , and 0.5 extra cancers are expected in the most highly exposed subset of people. Combined, that means that a total of 1.505 extra cancers are expected across the entire population of 1.1 million people over the next 70 years. Dividing the total number of extra cancers by the total number of people in the population results in an estimate of the average ELCR for the population. The average ELCR is 1.4×10^{-6} ($1.505 \text{ extra cancers} \div 1.1 \times 10^6 \text{ people}$). This average has several important characteristics from a public health policy perspective.

First, if you know the average ELCR for a population and the size of the population, then you can estimate the expected number of extra cancers in that population. Deterministic risk assessments don't develop an estimate of the average risk; the result of a deterministic risk assessment is an estimate of some upper bound ELCR. Precisely which upper bound is not known (i.e., it is not known whether the estimated ELCR applies to the 90th, 95th, 99.9th, etc. percentile of the population). Upper bound estimates of ELCR should not be used to estimate the number of excess cancers in the

¹ This hypothetical example assumes that the estimated ELCR for each segment of the population represents the actual ELCR for all the people in that segment. The ELCRs estimated using typical risk assessment methods *do not* represent actual ELCRs. Rather, they represent upper bound estimates of individual cancer risk. Actual cancer risks, if they exist, are lower—possibly substantially lower—and may even be zero (USEPA 1986). It is important to recognize that the ELCRs are upper bounds (overestimates) of actual risks because it means the estimate of increased incidence of cancers is also an overestimate. If actual individual ELCRs are ten times lower, the actual increase in cancer incidence would also be ten times lower than estimated by using the upper bound estimate of risk. Additionally, the ELCRs estimated using typical risk assessment methods (be those deterministic or probabilistic methods) are probabilities of getting cancer, not dying from cancer. Many cancers are not fatal. For simplicity this hypothetical example assumed incidence will result in mortality. In reality many cancers are survived and any actual mortality would be lower than the estimates used in the example.

population. In the hypothetical example above, if one assumes that the ELCR of 1×10^{-5} assigned to the high-end subset represents the single estimate of ELCR estimated by a deterministic risk assessment, there is no way to estimate the expected cancers in that population with only that information. One might try to use that estimate of upper bound ELCR to estimate expected excess cancers in the population, but when the high end estimate of 1×10^{-5} is combined with the total population, the estimated number of excess cancers is 11 (1,100,000 people \times 1×10^{-5} ELCR per person = 11 additional cancers). This estimate is nearly ten times greater than the correct estimate based on the arithmetic average ELCR estimate. Thus a critical advantage of using PRA is that it allows you to determine the number of excess cancers that might result in the population in question based on exposure to a chemical in the environment.

Second, because distributions of risk are not normal (they are typically log normal, see distributions in Figures 2 and 3), the arithmetic average and median are not identical. The average is higher than the median. In the above example the median ELCR is 1×10^{-6} while the average is 1.4×10^{-6} . This means that the median of the distribution cannot be used to estimate the expected excess cancers in the population. Doing so results in an underestimate of the total expected cancer incidence.

Third, knowing the arithmetic average ELCR associated with different policy options allows a public health policy maker to compare the change in cancer incidence resulting from a change in the average allowable risk levels. The policy maker can then make an informed judgment as to whether the differences in estimated cancers associated with different allowable risk levels (and resulting criteria) represent sound public health policy. Using the above example, if one is deciding whether to derive a criterion such that the arithmetic average ELCR is either 1×10^{-4} , 1×10^{-5} , or 1×10^{-6} one can estimate that 111, 11, or 1.1 excess cancers, respectively, are expected under the three different allowable risk levels over the course of 70 years. Such information alone may not be sufficient to select an allowable risk level upon which to set an AWQC but certainly such information can be very helpful in determining whether changes in cancer incidence associated with a possible AWQC indicate it should be adopted when compared to other causes of mortality as discussed later in this white paper.

Finally, for Idaho, knowing the arithmetic average ELCR associated with an AWQC (or any other criterion) allows estimation of the change in overall cancer incidence associated with that AWQC. Based on 2012 data, Idaho had a population of 1,595,728 people and experienced 2,570 deaths from cancer and 11,993 deaths from all causes (Johnson and Carson 2013). This means about 21% of deaths were caused by cancer,

which is consistent with national cancer mortality statistics. That information can be combined with the average ELCR associated with a theoretical AWQC to determine how cancer incidence might change with different allowable risk levels. If Idaho were to adopt an AWQC which had associated with it an average ELCR of 1×10^{-5} , that would mean that given the Idaho population size in 2012, such an AWQC would have associated with it approximately a quarter of an excess cancer (1,595,728 people in Idaho in 2012 $\times 1 \times 10^{-5}$ ELCR per person \div assumed 70 year lifetime = 0.23 excess cancers in 2012). Stated another way it would take between 4 and 5 years before one extra cancer associated with the AWQC would be expected to occur in Idaho; that cancer case would not necessarily be fatal. Given that only a fraction of an extra cancer that would be expected in 2012, the number of deaths from cancer in 2012 (2,570) would not be expected to change, nor would the number of overall deaths (11,993) or the number of people alive (1,583,735). For an AWQC that has associated with it a 1×10^{-6} ELCR, about one fiftieth of an extra cancer case would be expected in 2012 (0.023 extra cancers) or alternatively, it would take more than 40 years for one additional case of cancer to occur in Idaho as a result of a 1×10^{-6} average allowable risk.

In summary, this white paper recommends and uses a PRA approach to derive AWQC. A PRA approach creates transparency that allows for the demonstration that both average and highly exposed Idahoans are protected and can be used to estimate the average ELCR which in turn can be combined with the population size of Idaho to quantify the overall protectiveness afforded by AWQC. The remainder of this white paper describes the probabilistic approach to deriving AWQC, the selection of input assumptions (including fish consumption rates as a primary factor), risk management considerations, and the hypothetical water and organism AWQC derived for three carcinogenic chemicals (benzene, benzo(a)pyrene, chlordane) and three noncarcinogenic chemicals (selenium, fluorene, endrin).

3. Probabilistic Approach

Traditionally, regulatory agencies have derived AWQC using deterministic risk assessment methods (e.g., USEPA 2000). Those methods assign a single value (from a range of possible values) to each parameter in an equation that yields an AWQC. Parameters include those that represent an exposure scenario, toxicity, and allowable risk level. Some view the selection of the allowable risk level as the only risk management decision in the setting of AWQC. That is incorrect. Selecting a single value from a range entails an element of subjectivity and is often a topic of debate (Finley and Paustenbach 1994, Burmaster 1995). In the context of setting criteria,

selection of a single input value from a range of values represents a risk management decision or policy choice (Tatum et al. 2014). Unfortunately, the effect of the choice relative to the intended risk management goal is not always apparent.

Because regulatory agencies follow a mission to protect public health and the environment, the derivation process typically incorporates the selection of conservative values (i.e., high-end or maximum values) for several parameters establishing the AWQC (USEPA 1989, 1991a, 2011). Collectively, using multiple conservative assumptions for AWQC may be far more protective than necessary to meet a stated risk management goal. This phenomenon of greater conservatism embodied by the whole than the conservatism of each individual part is referred to as "compounded conservatism" (Nichols and Zeckhauser 1986). When using a deterministic risk assessment approach, it is impossible to discern the degree to which AWQC are more protective than implied by the risk management goal and the actual level of protection afforded different segments of the population. PRA is an alternative to the traditional deterministic risk assessment methods. It uses the range of values for a particular parameter thereby reducing the need for risk management decisions tied to each parameter. Because the outcome of PRA is a distribution of risk, it makes the risk management decisions (i.e., the level of protection afforded to different segments of the population) more transparent within the AWQC derivation process.

The concept of probabilistic assessment is not a new one; the USEPA has issued formal guidance for conducting probabilistic risk assessments (USEPA 2001) as well as a white paper encouraging the use of probabilistic risk assessment in decision making (USEPA 2014a,b). However, many agencies, including USEPA, have continued to use the traditional deterministic approach to deriving AWQC, despite criticism that the deterministic approach is overly conservative and can lead to unrealistic estimates of risk (Nichols and Zeckhauser 1986, Burmaster and Harris 1993). Furthermore, although USEPA guidance recommends basing deterministic risk assessments on exposure assumptions representing a combination of median values, mean values, and upper percentile estimates to avoid compounded conservatism (USEPA 2005), agencies continue to derive AWQC using conservative upper-percentile defaults for most of the variables (e.g., USEPA 2014c).

The USEPA Risk Assessment Forum states that PRA can "facilitate better characterization of uncertainty and improve the overall transparency and quality of EPA assessments" and describes the following situations in which PRA is useful (USEPA 2014a,b).

1. A specified target level of protection in a population is identified by the manager (e.g., the 95th percentile), and it is necessary to demonstrate that this goal is met.
2. Significant equity or environmental justice issues are raised by variation in risks among the exposed population of concern.
3. Screening-level point estimates of risk are higher than an accepted level of concern.
4. Uncertainty in some aspect of the risk assessment is high, and decisions are contentious or have large resource implications.
5. Specific critical risk estimates and assumptions point to different management options.
6. The scientific rigor and quality of the assessment is critical to the credibility of the EPA decision.
7. When a screening-level deterministic risk assessment indicates that risks are possibly higher than a level of concern and a more refined assessment is needed.
8. When the consequences of using point estimates of risk are unacceptably high.
9. When significant equity or environmental justice issues are raised by interindividual variability.
10. When exploring the impact of the probability distributions of the data, model and scenario uncertainties as well as variability together to compare potential decision alternatives.

Many of the situations described by USEPA (2014a,b) apply directly to the establishment of national AWQC. Recently, the benefits of using the probabilistic approach to derive AWQC have been recognized by state regulatory agencies. For example, the Florida Department of Environmental Protection (FDEP) has developed proposed state criteria using probabilistic methods that allow the State to demonstrate all segments of the population, including high end consumers, are protected at appropriate acceptable risk levels.

3.1 Equations

The general AWQC derivation process uses equations that account for the key exposure pathways. For AWQC intended to protect human health, which are the focus of this white paper, exposure results from consumption of water and fish. Deterministic AWQC are derived using equations that include both exposure and toxicity parameters combined with a risk management goal (i.e., an acceptable risk level). Probabilistic AWQC are derived by using these same equations, combined with distributions for one or more parameters representing the inherent variability in a population's physical characteristics and behaviors, or the uncertainty surrounding a parameter, to generate

a distribution of risk. The AWQC derived using probabilistic methods is the water concentration that has associated with it a distribution of potential risk that meets (i.e., does not exceed) the risk management goal(s) selected by the regulatory agency. In some cases, a regulatory agency may select a single risk management goal. For example, a regulatory agency might require that the HQ for the 90th percentile of the population be equal to or less than 1.0. Alternatively, a regulatory agency may select multiple risk management goals that need to be met by an AWQC. For example, an agency may specify that the 50th percentile of the population (the median) must have an ELCR equal to or less than 1×10^{-5} and that the 99th percentile of the population must have an ELCR equal to or less than 1×10^{-4} .

AWQC are derived using the fundamental human health risk equations employed by (USEPA 2000). The USEPA equation for chemicals with carcinogenic endpoints is:

$$AWQC = \frac{TELCR \times BW}{[DI + (FCR \times BCF_{tissue})] \times CSF} \quad \text{(Equation 1)}$$

The USEPA equation for chemicals with noncarcinogenic endpoints is:

$$AWQC = \frac{THQ \times BW \times RSC \times RfD}{DI + (FCR \times BCF_{tissue})} \quad \text{(Equation 2)}$$

Where:

- TELCR = target excess lifetime cancer risk (unitless);
- THQ = target hazard quotient (unitless);
- DI = drinking water intake (L/day);
- FCR = fish consumption rate (kg/day);
- BCF_{tissue} = tissue-based bioconcentration factor (L/kg tissue);
- BW = body weight (kg);
- RSC = relative source contribution (unitless);
- RfD = reference dose (mg/kg-day); and
- CSF = cancer slope factor (mg/kg-day)⁻¹.

In addition to the parameters explicitly listed in the USEPA equations, additional implicit parameters also affect the characterization of risk and can be included in the AWQC derivation equations. The expanded equation for chemicals with carcinogenic health endpoints is:

$$AWQC = \frac{TELCR \times BW \times AT_c}{\left[(RBA_w \times DI) + (RBA_f \times FCR \times CLF \times BCF_{lipid} \times lipid \times (1-CL)) \right] \times ED \times CSF} \quad \text{(Equation 3)}$$

The expanded equation for chemicals with noncarcinogenic health endpoints is:

$$AWQC = \frac{THQ \times BW \times AT_{nc} \times RSC \times RfD}{\left[(RBA_w \times DI) + (RBA_f \times FCR \times CLF \times BCF_{lipid} \times lipid \times (1-CL)) \right] \times ED} \quad \text{(Equation 4)}$$

Where the additional implicit parameters include:

- BCF_{lipid} = lipid-based bioconcentration factor (L/kg lipid);
- RBA_w = relative bioavailability, water (unitless);
- RBA_f = relative bioavailability, fish (unitless);
- CLF = catch location factor (unitless);
- LHF = life history factor (unitless);
- CL = cooking loss (unitless);
- ED = exposure duration (years);
- AT_{nc} = averaging time for noncarcinogenic effects (years); and
- AT_c = averaging time for carcinogenic effects (years).

When AWQC are derived using Equations 1 and 2, these implicit parameters are each effectively incorporated at their highest possible value, thereby resulting in AWQC with additional layers of conservatism (Tatum et al. 2014). For example, excluding the relative bioavailability and cooking loss terms assumes that the chemical in water and fish is 100% bioavailable and that none of the chemical in fish is lost during the cooking process. Excluding the exposure duration and averaging time terms assumes that exposure duration is equal to averaging time – in other words, it assumes an exposed individual will live in the same place for their entire life (e.g., 70 years) and that 100% of the water and fish they consume during those 70 years will come from the regulated water body. Excluding the catch location factor and life history factor terms assumes that 100% of fish consumed are caught from local regulated waters and spend the entirety of their lives in the same regulated waters. While USEPA has indirectly accounted for life history by excluding marine and a portion of anadromous fish from the overall fish consumption rate (e.g., USEPA 2014c), the remaining implicit parameters are often left unaddressed. These parameters should be included in the AWQC derivation equations to make the level of conservatism embodied in AWQC clear.

3.2 Using PRA to Derive AWQC

The equations presented in Section 3.1 are sometimes referred to as “backward” risk equations. That is, USEPA uses equations that predict an allowable water concentration (i.e., the AWQC) based on an allowable risk, exposure scenario, and toxicity. These equations are typically used for deterministic calculation of risk-based acceptable media concentrations (e.g., AWQC or preliminary remediation goals at waste sites).

As described by Burmaster et al. (1995) and Ferson (1996), deriving AWQC using probabilistic methods requires “forward” equations. That is, the equations estimate risk from a chemical concentration, exposure scenario, and toxicity. In essence, the forward equation will yield a distribution of risks dependent on several inputs that are also distributions. If the equation is “flipped” to solve for one of the inputs, the resulting distribution and the original input distribution may have similar means, but the spread of the distributions will be different. Because the tails of a distribution (e.g., highly exposed individuals) are often of interest when setting acceptable risk or acceptable media concentrations, this disparity has marked effects on the outcome of the calculation. Therefore, USEPA recommends using forward equations when conducting probabilistic assessments to avoid the mathematical limitations associated with back-calculation (USEPA 2001).

For probabilistic derivation of AWQC, the process of estimating risk by selecting from the input point estimates or distributions is repeated, selecting new values for various parameters with each iteration, until the number of desired iterations (e.g., 10,000 iterations for the AWQC presented herein) is complete. As long as one or more of the input parameters are distributions, the final output of a simulation will be a distribution of risks associated with a particular concentration of a chemical in water. If the estimate of risk matches the desired risk management goal(s), the chemical concentration that was used to generate the output is the AWQC.

Typically, multiple simulations are required to derive probabilistic AWQC. Two methods can be used to develop the AWQC: the iterative approach and systematic linear derivation (USEPA 2001). Both require that allowable risk goals be established for at least one, and possibly several, statistics of the risk distribution (e.g., the mean, median, 90th percentile, 95th percentile).

- In the **iterative approach**, a water concentration is selected and the resulting risk distribution is compared to risk management goal(s). If one or more goals is

exceeded, the process is repeated using alternative chemical concentrations until a concentration is identified that results in a risk distribution that meets all risk management goals. That concentration is the AWQC.

- The **systematic linear derivation** approach is recommended by USEPA (2001) as a “shortcut” for the trial-and-error method when using probabilistic methods to calculate risk-based acceptable media concentrations. Typically, simulations are run at three alternative chemical concentrations. The estimated risks at the percentile of the risk distribution corresponding to the risk management goal versus the chemical concentration used for each simulation are plotted. A least-squares linear regression line is fit to the paired ELCR and concentrations for each statistic of the distribution corresponding to the risk management goal. The equation for each statistic is used to solve for the chemical concentration that corresponds to the risk management goal (e.g., allowable risk level) for that statistic. If only one risk management goal needs to be met (e.g., ELCR at the 90th percentile must be equal to or less than 1×10^{-5}), the concentration that meets that goal is the AWQC. When more than one risk management goal needs to be met, the AWQC is the lowest of the concentrations derived from all of the risk management goals.

Excel add-in programs [i.e., @RiskTM (Palisade 2013), Crystal BallTM (Oracle 2008)] are readily available to facilitate probabilistic analysis, and an Excel-based calculator tool employing @RiskTM software, the Probabilistic Ambient Water Quality Criteria Calculator (PAWQCC, available on the IDEQ website at <http://www.deq.idaho.gov/media/1117556/58-0102-1201-probabilistic-ambient-wq-criteria-calculator.xlsm>), has been developed to facilitate the derivation of probabilistic AWQC. These tools make the otherwise computationally intensive process of deriving probabilistic AWQC both quick and straightforward.

The remainder of this white paper focuses on the application of PRA to setting AWQC for the State of Idaho.

4. Fish Consumption Rates

Over the course of the series of Discussion Papers, IDEQ has raised numerous considerations related specifically to selection of a fish consumption rate statistic. Presumably the final methodology selected by IDEQ will address all of (or at least most of) those concerns. Because we do not yet have results of an Idaho-specific survey, this white paper develops fish consumption rate distributions by combining a fish

consumption rate distribution representative of the general population with a distribution representative of Native Americans to derive a composite distribution that includes both the general and Native American populations. When the results of the Idaho-specific fish consumption surveys become available, they can be incorporated into the PRA based methodology described above.

To account for several of the issues raised by IDEQ in the discussion papers, this white paper employs four hypothetical fish consumption rate distributions where each one exemplifies the effect of considering one or more of the issues raised by the IDEQ Discussion Papers. The considerations related to developing fish consumption distributions are described below followed by a summary of the four fish consumption rate distributions employed in this white paper.

4.1 Consumers and Nonconsumers

Most AWQC are designed to be protective of a lifetime of fish consumption, not behaviors that occur over the period of a week, a month, or even a year. Many regulators face a challenge in determining the proportion of fish consumers and non-fish consumers and the amount of fish that people actually eat based on short term surveys. The next few paragraphs of this white paper examine those challenges.

The challenges in distinguishing between fish consumers and nonconsumers arise because short-term dietary surveys are not representative of long-term dietary behaviors. Just because a person who responds to a one-day or one-week dietary recall survey indicates that he or she did not eat any fish in the past day or week, does not mean that he or she does not eat any fish. Yet, based on his or her response to the short time interval survey, he or she would be categorized as a nonconsumer. For many people, such a categorization would be incorrect including most Idahoans. Policy Discussion Paper #1 reports that a high proportion of Idahoans (i.e., more than 90%) consume fish at least once per year (IDEQ 2013a). When viewed over a year, and especially a lifetime, the vast majority of people likely eat some fish.

The approach of defining “consumers” as those respondents who ate fish on one or both dietary recall days and drawing survey data only from those respondents tends to “underestimate the number of consumers and overestimate consumption rates” (Polissar et al. 2012). Statistically, individuals who are frequent fish consumers are much more likely to have consumed fish on one or both dietary recall days. Therefore, data for infrequent consumers—individuals who are likely to have been non-consumers on both recall days—are excluded from analysis, deflating the resulting consumer

count. Furthermore, given that there may be a correlation between consumption frequency and consumption amount (i.e. individuals who frequently consume certain foods are likely to do so in larger amounts) (Tooze et al. 2006), the resulting consumption rates are likely to be biased high.

The National Cancer Institute (NCI) methodology outlined by Tooze and others accounts for several of the factors that tend to overestimate the upper percentile consumption rates when extrapolating from short-term dietary survey data. The NCI methodology has a more inclusive definition of “consumers”—respondents were excluded only if they indicated on their food frequency questionnaire that they never consume fish (regardless of whether they actually consumed fish on the two dietary recall days). The NCI statistical model incorporates within-person daily variability in fish consumption as well as the positive correlation between consumption frequency and amount. Thus, NCI-adjusted data from the 2003 to 2006 National Health and Nutrition Examination Survey (NHANES) reported by Polissar et al. (2012) were used in this white paper to represent fish consumption rates of the general population of Idaho State (**Table 1**). When Idaho-specific fish consumption rate data become available, this white paper recommends that data representative of long-term fish consumption rates be used.

4.2 General Population and Targeted Subpopulations

When selecting a single statistic to represent a fish consumption rate that will be used to derive AWQC following a deterministic approach, the question arises of whether to select a statistic representative of the general population or a targeted subpopulation expected to be at greater risk. Policy Discussion Paper #2 recommends selecting a statistic representative of high consumers within the general population and then comparing this statistic to distributions representative of targeted subpopulations (i.e., recreational anglers and tribal members) to ensure that the AWQC is protective of highly exposed subpopulations as well (IDEQ 2013b).

As discussed previously, one of the advantages of using a probabilistic approach is the ability to use all available data to represent variables used to derive AWQC, including fish consumption rates. Rather than choosing to select a single value representative of either the general population or a targeted subpopulation, this white paper recommends that distributions representative of both populations be fully incorporated into the analysis.

As described in Section 4.1, NCI-adjusted NHANES data are used in this white paper to represent the general Idaho population. Given that results of an Idaho-specific tribal fish consumption survey are not yet available, data from four Washington State tribal fish consumption surveys are used in this white paper to represent current fish consumption rates of Idaho's tribal population (WDOE 2011, Table C-4). As discussed during the October 2, 2014 Negotiated Rulemaking Meeting (Policy Discussion #6), contemporary tribal fish consumption rates for some tribal members may be a fraction of what they were historically due to depleted stocks. Historic estimates of Shoshone Bannock Tribe consumption of Salmon River fish are approximately 700 pounds of fish per person per year (870 g/person/day) in the 1840s. Historical Nez Perce Tribe fish consumption estimates are approximately 300 to 650 pounds per person per year (373 to 808 g/person/day) circa 1780.

The current fish consumption rate distribution for tribal members based on Washington data ranges from 10.4 grams per day (g/day) at the 1st percentile to 291 g/day at the 99th percentile. To approximate a distribution representative of historic (i.e., heritage) fish consumption rates, the current fish consumption rate distribution was adjusted upward by a factor of 3.0. In other words, heritage fish consumption rates of consumption are assumed to be three times greater than current rates consumption for tribal members. This produces a heritage consumption rate distribution ranging from 31.2 at the 1st percentile to 873 g/day at the 99th percentile, the latter of which corresponds to the high end of heritage estimates.

The general population and tribal population distributions are combined into a single composite distribution by weighting the two distributions according to the sizes of their respective populations (97.6% and 2.4% for the general and tribal populations, respectively). Population statistics reported in the 2009-2013 American Community Survey (USCB 2015) were used for this purpose, with the percentage of Idahoans identifying as American Indian or Alaska Native (alone or in combination with one or more races) taken to represent the tribal population of Idaho. This white paper derives AWQC for the state of Idaho using current tribal consumption rates and alternatively using estimated heritage tribal consumption rates (**Table 1**).

4.3 Market Fish

Policy Discussion Paper #4 raises the philosophical issue of whether AWQC are designed to protect people from all chemicals in all fish in their diet or only from chemicals in fish from Idaho waters (IDEQ 2014c). AWQC are not derived to protect people from all potential water-related exposures, regardless of the nature and location

of the water causing the exposure. Rather, surface water criteria are intended to protect people from surface water-related exposures that can be affected by regulations promulgated by either the state or USEPA. This is consistent with USEPA's exclusion of marine fish from the national criteria. USEPA is not able to regulate concentrations of chemicals in fish caught from open ocean waters. Similarly, ambient air quality guidelines are not derived to protect people from all possible air exposures, such as those that a person may experience when they have purchased a new appliance for their home that may be releasing volatile chemicals into indoor air. Control of exposure to indoor air releases occurs by limiting the amount of a chemical that may be released by new appliances not by adjusting ambient air quality guidelines. Such guidelines could be set to zero and still not reduce indoor air exposures from new appliances. Similarly, if concentrations of chemicals in fish from non-Idaho sources need to be controlled, that could be accomplished by regulating the amount of chemicals in such non-Idaho fish separately from Idaho AWQC. The state-specific AWQC will have no effect on the concentrations of chemicals in non-Idaho fish. Thus, this white paper recommends that only fish caught from waters of the state be included in the derivation of state-specific AWQC.

IDEQ is currently implementing a survey on general population fish consumption in Idaho. The survey will identify the source of fish consumed so that consumption of market fish and consumption of fish caught from Idaho waters may be calculated separately. Because the state-specific survey is still underway, this white paper assumes the portion of fish consumed by the general population which is attributable to freshwater/estuarine fish from NHANES approximates the portion of overall consumption attributable to Idaho-caught fish. For simplicity, this white paper conservatively assumes that 100% of tribal population consumption is attributable to fish caught in waters of the state.

Because the Polissar (2012) general population data are based on total fish consumption and include offshore marine species such as tuna, data from the United States Department of Agriculture's (USDA) Continuing Survey of Food Intake by Individuals (CSFII) 1994 to 1996 were used to adjust the distribution to reflect only freshwater and near-shore (estuarine) fish consumption. Adjustment of the NCI-adjusted NHANES distribution in this manner reflects the assumption that the relative proportions of fresh, near-shore marine, and off-shore marine fish in the American diet have not shifted dramatically in the period of time (about ten years) between the two surveys. USDA's CSFII survey data (USEPA 2002a, Section 5.1.1.1 Table 4) provide estimates of consumption rates of uncooked finfish and shellfish for the US population age 18 and older and were the basis of USEPA's current national recommended

default fish consumption rate of 17.5 g/day. The reported mean consumption rates of freshwater/estuarine and all fish were 7.5 and 19.91 g/day, respectively. The ratio between the mean freshwater/estuarine rate and the all fish consumption rate was calculated (0.377) and used as an adjustment factor for the NCI-adjusted NHANES distribution. This ratio represents the average percentage (37.7%) of freshwater/estuarine fish in Americans' total fish diet. Adjustment of the NCI-adjusted NHANES distribution was accomplished by multiplying the mean and each percentile by the freshwater/estuarine adjustment factor (0.377), based on the assumption that the average rate of freshwater/estuarine fish consumption can be applied across the entire distribution (**Table 1**). Note that ratios between freshwater/estuarine and total fish consumption in USDA's CSFII survey data are 0.232 and 0.445 at the 90th and 95th percentiles, respectively, suggesting that application of the mean ratio is in fact conservative for the majority of consumers (>90%). Although this white paper recommends including only Idaho-caught fish in the derivation of state-specific AWQC and therefore derives AWQC using the "fresh and estuarine adjusted" consumption rates, alternative AWQC are also derived using the "all fish" consumption rates to illustrate the effect of selecting alternative fish consumption rate distributions on the resulting AWQC.

4.4 Anadromous Fish

As IDEQ describes in Policy Discussion Paper #5, anadromous species include salmon and steelhead (IDEQ 2014d). These species spend a substantial fraction of their life in marine or ocean environments that are outside the jurisdiction of Idaho. If a substantial fraction of the chemical-specific body burden (mass per fish) found in returning adult salmon is acquired during time spent in the ocean, there is effectively nothing Idaho will be able to do to reduce potential risks to humans resulting from exposure to chemicals in the salmon they eat.

Studies show that anadromous fish accumulate most of the mass of persistent, bioaccumulative, and toxic compounds while they live in the ocean. More specifically, the predominant fraction of the PBT compounds such as polychlorinated biphenyls (PCBs) burden found in harvested adult salmon, even salmon passing through highly contaminated fresh and estuarine waters during out migration, is accumulated while in the ocean phase of their life cycle (e.g., Cullon et al. 2009; O'Neill and West 2009). This conclusion is supported by modeling as well (Hope 2012). Thus, because the body burdens of bioaccumulative chemicals present in anadromous fish are likely to have been accumulated while the fish were outside of Idaho waters, and Idaho-specific AWQC will have little or no effect on such body burdens, this white paper recommends

that anadromous fish be excluded from the fish consumption rates used to derive Idaho AWQC.

Because the “fresh and estuarine adjusted” consumption rates used to represent the general population’s consumption of Idaho-caught fish do not include anadromous fish, no further adjustment is needed to account for this recommendation. To estimate the amount of anadromous fish consumed by the tribal population, data provided in Washington Department of Ecology’s (WDOE’s) Fish Consumption Rate Technical Support Document, version 2 (WDOE 2013) were used. The amount of anadromous fish as a percentage of the total fish and shellfish diet for these tribes ranges from 23% for the Suquamish Tribe to about 66% for the Squaxin Island Tribe. The Tulalip Tribe seafood diet is about 46% anadromous fish. Data for the Columbia River Inter-Tribal Fish Commission (CRITFC) tribes are not directly comparable to the other tribal data because the survey did not reflect any consumption of shellfish. Nonetheless, CRITFC tribes ate anadromous fish equivalent to about 48% of all harvested fish from all sources. If one assumes that the CRITFC tribes consume only small amounts of shellfish relative to finfish, then 48% represents an approximate maximum value for the CRITFC tribes. A simple average of these percentage values for each of the four tribes (46%) was used to estimate the proportion of tribal consumption represented by anadromous fish. For the fish consumption rate distribution that excludes tribal consumption of anadromous fish from the analysis, the tribal consumption rate distribution was reduced by this percentage (**Table 1**).

4.5 Final Fish Consumption Rate Distributions

IDEQ has held the following discussions regarding potential fish consumption rates to be used in the derivation of AWQC:

- Policy Discussion #1 – Fish Consumers and Nonconsumers;
- Policy Discussion #2 – General Population versus Targeted Subpopulation ;
- Policy Discussion #4 – Market (All) or Local;
- Policy Discussion #5 – Anadromous Fish; and
- Policy Discussion #6 – Suppression of Fish Consumption.

This white paper evaluates four fish consumption rate distributions to determine the potential effect of these policy considerations on resulting AWQC (**Table 1**). Composite 1 uses contemporary tribal fish consumption rates and excludes consumption of market and anadromous fish (**Table 1**). This is the fish consumption rate distribution recommended by this white paper because it is based on current consumption rates

and excludes fish that may have chemicals in them but over which Idaho-specific AWQC can have little or no effect. Nevertheless, to explore the potential effect of making different decisions about which fish consumption rates to include in a fish consumption rate distribution, three other distributions are included in the calculations in this white paper for illustrative purposes. Composite 2 uses heritage tribal fish consumption rates and excludes consumption of market and anadromous fish (**Table 1**). Composite 3 uses contemporary tribal fish consumption rates and includes consumption of all fish (**Table 1**). Composite 4 uses heritage tribal fish consumption rates and includes consumption of all fish (i.e., market and anadromous) (**Table 1**). While additional distributions could be derived (e.g., distributions including anadromous fish but excluding market fish), these four distributions are used in this white paper to characterize the range of potential distributions (and resulting AWQC) that could result from considering the various policy issues raised by IDEQ.

Using @Risk, distributions were fit to the data using the range of percentiles as fit parameters (i.e., the “distribution fitting” function in @Risk was used to find the best-fitting distributions for the percentiles shown in **Table 1**). The resulting distributions were truncated at a lower limit of 0 g/day. Upper truncation limits for the fish consumption rate distribution was not defined, meaning that the fitted distributions can theoretically extend to any positive value. The actual maximum values achieved by the distributions, averaged over 500 simulations of 10,000 iterations each, are 108, 123, 281, and 310 g/day for Composite 1, 2, 3, and 4, respectively. Summary statistics for the fish consumption rate distributions are provided in **Table 2**.

5. Other Input Parameters

To derive AWQC using a probabilistic approach, distributions or point estimates were selected to represent a number of the other input parameters as described below.

5.1 Toxicity

The toxicity values used to derive AWQC were obtained from the following sources in order of priority, in accordance with the recommended hierarchy presented in USEPA guidance (2003):

- USEPA's Integrated Risk Information System (IRIS) (USEPA 2015a);
- USEPA's Provisional Peer Reviewed Toxicity Values (PPRTVs) (USEPA 2015b);
- and

- Additional USEPA and non-USEPA sources of toxicity information, including but not limited to the California Environmental Protection Agency toxicity values, the Agency for Toxic Substances and Disease Registry (ATSDR) minimum risk levels, and toxicity values published in the USEPA Health Effects Assessment Summary Tables (HEAST) (USEPA 1997).

The derivation of probabilistic AWQC presented in this report treats all toxicity values as point estimates (**Table 3**).

5.2 Relative Source Contribution

Relative source contribution (RSC) refers to the portion of an individual's daily exposure to a chemical that is allocated to exposure from the regulated surface water (i.e., the consumption of water and fish). The RSC accounts for the possibility that individuals can be exposed to a chemical through sources other than surface water (e.g., food other than fish from Idaho waters, or air). If data indicate that background exposures (i.e., exposures not affected by surface water criteria) are potentially large, then the RSC is set such that a relatively small proportion of a person's total exposure can come from regulated surface waters. If the data indicate that background exposures are relatively small, then the RSC is set such that a relatively large proportion of a person's total exposure can come from regulated surface waters. The RSC applies only to AWQC with noncarcinogenic health endpoints.

USEPA (2000) describes a decision process to select an RSC. That process leads to RSCs of no greater than 0.8 and as low as 0.2. Recently, FDEP (2014) developed parameter-specific RSCs based on extensive literature review for 21 noncarcinogenic chemicals. In cases where the RSC values exceeded the 0.8 ceiling recommended by USEPA (2000), FDEP felt the robustness of the data and weight of evidence supported higher RSCs and retained those values. The RSCs developed by FDEP (2014) are used to derive AWQC for noncarcinogenic chemicals in this white paper (**Table 3**).

5.3 Bioconcentration and Percent Lipid

Bioconcentration refers to the process by which a chemical present in ambient water accumulates in fish tissue. The lipid-based bioconcentration factor (BCF) used in Equations 1 and 2, expressed in units of liters per kilogram lipid, is defined as the ratio of the concentration of the chemical in fish lipid to its concentration in the surrounding water. The lipid-based BCF is multiplied by the proportion of lipid in fish tissue to ultimately express bioconcentration on a fish tissue basis (i.e., units of liters per

kilogram tissue). USEPA (2002b) provides default BCFs expressed on a fish tissue basis and normalized to a default lipid content of 3%. The default USEPA BCFs and 3% lipid were used to derive the AWQC presented in this report (**Table 3**).

The derivation of probabilistic AWQC presented in this report treats all BCFs and lipid content as point estimates.

5.4 Cooking Loss

Cooking loss refers to the proportion of the chemical present in fish tissue that is lost as part of the cooking process. The AWQC presented in this report conservatively assume no cooking loss and that all of the chemical in raw fish remains in cooked fish. This assumption is consistent with the approach USEPA has used to derive national AWQC. For lipophilic chemicals (e.g., polychlorinated biphenyls [PCBs] and many chlorinated pesticides) this is likely to lead to conservative AWQC because concentrations of such chemicals tend to be reduced by cooking. The amount of loss depends upon cooking method and the frequency at which various methods are used. Sufficient data are available for some chemicals (e.g., PCBs) to develop an input distribution for cooking loss. Thus, cooking loss could be incorporated in AWQC in the future.

5.5 Exposure Duration

As a matter of default, exposure duration was assumed to occur over an entire lifetime (equal to 70 years). This conservative approach assumes that every member of the population lives in the same place and is exposed to the same chemical concentration in water and/or fish tissue each day over the duration of their 70-year lifetime. In reality, this is unlikely to be the case; the mean residential occupancy period according to USEPA is 12 years, and the 95th percentile is only 33 years (USEPA 2011). Even if an individual lives in the same state their entire life, it is highly unlikely that they will live only near (and thus be exposed only to) waters having chemical concentrations equal to the AWQC over the course of their lifetime.

5.6 Body Weight

The 2011 Exposure Factors Handbook (USEPA 2011) provides age-specific distributions of body weight computed by Portier et al. (2007) using NHANES II, III, and IV data. USEPA recommends using the Portier et al. (2007) data when body weight distributions are required, because the data are based on a large sample size and are

representative of the general United States population. The body weight distribution derived from the NHANES IV survey for ages 18-65, males and females combined, was used to develop the AWQC presented in this report (USEPA 2011; Table 8-25). Body weight was truncated at a lower limit of 44 kilograms (97 pounds), corresponding to the 1st percentile of the distribution. Summary statistics for the body weight distribution are provided in **Table 2**.

5.7 Drinking Water Intake

In 2010, USEPA analyzed the 2003-2006 NHANES survey data to assess water ingestion rates across the general United States population. The results of the USEPA analysis are presented in the 2011 Exposure Factors Handbook (USEPA 2011). The consumer-only direct and indirect water intake distribution for ages 21 and above was used to derive the AWQC presented in this report (USEPA 2011; Table 3-36). Using @Risk, a distribution was fit to the data using the range of reported percentiles as fit parameters. The resulting distribution was truncated at a lower limit of 0 liters per day. Summary statistics for the drinking water intake distribution are provided in **Table 2**.

6. Risk Management

Once the risk associated with continual lifetime exposure to chemicals in ambient water is characterized, be that a point estimate of risk associated with deterministically derived criteria or a distribution of risk derived using a probabilistic approach, public health policy makers must decide what level of health risk is acceptable².

Selection of an allowable excess lifetime risk level is likely the most visible and often most contentious risk management decision associated with setting AWQC. A great deal has been written about this process and much information is available to provide perspective about whether a risk should be considered allowable or not (Lowrance 1976, Breyer 1993, Wilson and Crouch 2001, Blastland and Spiegelhalter 2014). Some

² As noted above in Section 2, the selection of an allowable risk level (or levels) is typically viewed as the *only* risk management decision in the derivation of AWQC. While this choice represents a crucial risk management decision that has a substantial effect on the AWQC value, implicit risk management choices are made throughout the AWQC derivation process (e.g., through the selection of a single value for an exposure or toxicity parameter from a range of possible values) and either singly or when combined can have a substantial effect on AWQC.

of the factors that are taken into account when selecting an allowable risk level include: precedent associated with allowable risk levels select previously when setting AWQC, be that USEPA or other agencies; allow risk levels used in other regulatory programs; every day risks experienced by the general population; the benefits associated with activities that may be limited by a potential regulation; and the potential change in overall mortality associated with a particular allowable risk. Each of these factors is discussed below.

6.1 USEPA Allowable Risk Levels

USEPA uses a target ELCR of one in one million (1×10^{-6}) to derive national AWQC for carcinogenic endpoints, recommending the 10^{-6} risk level for being “consistent with Agency-wide practice (USEPA 2000). In its 2000 AWQC methodology, USEPA also states that it “believes that both 10^{-6} and 10^{-5} may be acceptable [risk levels] for the general population and that highly exposed populations should not exceed a 10^{-4} risk level”. These risk ranges recommended by USEPA (2000) (i.e., 1×10^{-6} to 1×10^{-4}) are consistent with benchmark criteria used by USEPA in other regulatory programs (**Table 4**). However, it should be noted they are lower (more stringent) than the allowable risk levels USEPA uses in its safe drinking water regulations.

USEPA sets two kinds of standards for chemicals in public water supplies, Maximum Contaminant Level Goals (MCLGs) and Maximum Contaminant Levels (MCLs). USEPA has described the Drinking Water Specific Risk Level Concentration as being based on the 1×10^{-4} risk level (USEPA 2012). In some cases, adjustments to the MCL have resulted in a concentration limit that corresponds to a risk higher than 1×10^{-4} (i.e., 1,1-dichloroethylene, 2,3,7,8-tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD), arsenic, bromate) (**Table 5**). In other cases, the MCL for a chemical is lower than the concentration corresponding to the 1×10^{-4} risk level. As these examples show, the cancer risks associated with a single drinking water contaminant present in a water supply at its MCL may fall within a range of several orders of magnitude. While the USEPA may consider the benchmark criterion of 1×10^{-4} in setting a standard, the requirement to set the MCL as close to the MCLG as feasible or to adjust the MCL to a level that “maximizes health risk reduction benefits at a cost that is justified by the benefits” may result in a MCL that represents a very different risk level for that chemical.

Beyond consistency with pre-existing policy, USEPA offers no additional justification for its selection of 1×10^{-6} to derive AWQC for carcinogenic endpoints or explanation for why it considers 1×10^{-6} to be an “acceptable” level of risk for the general population.

Within and beyond USEPA guidance, the origins of 1×10^{-6} as a widely used acceptable risk level are difficult to trace. The benchmark appears to have originated in early work by the United States Food and Drug Administration (USFDA), within the narrow context of a discussion of testing methods for pesticide residues in processed food. The debate over what level of exposure to a carcinogen could be considered safe began in the U.S. when people became concerned about pesticide residues in processed foods. This debate produced the 1958 Food Additives Amendment (section 409) to the 1954 Federal Food, Drug and Cosmetic Act, which said:

...no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal...

This “zero risk” clause, named for Congressman James Delaney, was a landmark decision in the regulation of compounds that might cause cancer. The Delaney Clause sounds simple enough, but soon ran into practical limitations: How low of a dose do we need to test to assure ourselves that a chemical does not cause cancer? And how, given the limits of analytical chemistry, do we know when a chemical that can induce cancer is present in a food product? The USFDA faced this challenge in regulations proposed in 1973 (USFDA 1973), saying:

If the results of the test for carcinogenicity establish that the compound or its metabolites will induce cancer in test animals, the required sensitivity of the regulatory assay method will be determined based on the Mantel-Bryan procedure

Absolute safety can never be conclusively demonstrated experimentally. The level defined by the Mantel-Bryan procedure is an arbitrary but conservative level of maximum exposure resulting in a minimal probability of risk to an individual (e.g., 1/100,000,000), under those exposure conditions of the basic animal studies.

In describing the benchmark ($1/100,000,000$ or 10^{-8}) provided as an example of minimal probability of risk to an individual, the USFDA cited a groundbreaking paper by Mantel and Bryan (1961) that said, in a scientific discussion of testing chemicals for carcinogenicity:

We may, for example, assume that a risk of 1/100 million is so low as to constitute “virtual safety.” Other arbitrary definitions of “virtual safety” may be employed as conditions require.

Many of the comments on the regulation proposed in 1973 pertained to how the proposed regulation dealt with the risk of cancer. After considering those comments the USFDA promulgated a final regulation in 1977. In doing so it re-defined the benchmark risk level. The preamble to the final rule explains that tests for carcinogens must be able to measure the concentration corresponding to the 1/1,000,000 (or 1×10^{-6}) risk level, which the USFDA described as an “insignificant public health concern”. (USFDA 1977)

In this rulemaking, the USFDA was careful to point out that it was not making an explicit judgment on an acceptable level of risk, simply seeking to set a practical benchmark that could be used to design animal experiments:

[10⁻⁶] does not represent a level of residues “approved” for introduction into the human diet. The purpose of these regulations is to establish criteria for the evaluation of assays for the measurement of carcinogenic animal drugs. These criteria must include some lowest level of reliable measurement that an assay is required to meet. In defining a level of potential residues that can be considered “safe”, therefore, the Commissioner is establishing a criterion of assay measurement that, if it can be met for a compound, will ensure that any undetected residues resulting from the compound’s use will not increase the risk of human cancer.

Despite this caution, many people took this regulatory action as a precedent for defining an “acceptable” level of risk as 1×10^{-6} . As this brief narrative shows, our current views about acceptable risk grew from a discussion among a small group of scientists about “arbitrary definitions of ‘virtual safety’” and related efforts to define parameters for safety testing. They did not originate with a broad national debate or consensus on acceptable risk from environmental exposures. The USFDA’s determination that a 1×10^{-6} risk level was an “insignificant public health concern” was erroneously interpreted to mean that anything over that arbitrary level must be significant.

Turning from consideration of carcinogenicity to other potential health effects, USEPA uses a target HQ of 1 to derive national AWQC for noncarcinogenic endpoints. While an HQ of 1 is generally used when deriving criteria for noncarcinogenic endpoints,

regulators recognize that highly exposed members of a population will have HQs greater than one and that HQs that slightly exceed one are generally not considered to represent substantial public health threats (e.g., USEPA 1996, USDHHS 2013). One example of this is seen in USEPA's Drinking Water Specific Risk Level Concentrations, which are described as being based on an HQ of 1 (USEPA 2012). In some cases, adjustments to the MCL have resulted in a concentration limit that corresponds to a hazard higher than 1 (i.e., chloramine, oxamyl, xylenes, uranium) (**Table 6**).

Furthermore, USEPA selected a drinking water intake rate of two liters per day for the establishment of MCLs. Two liters per day represents approximately the 70th percentile of drinking water intake for United States residents (USEPA 2011). That means that 30 percent of U.S. residents have drinking water intakes of greater than two liters per day and have HQs of greater than one. In fact, the 99th percentile of drinking water intake for United States residents is approximately five liters per day (USEPA 2011), which is about 2.5 times greater than the drinking water consumption rate assumed by MCLs. That means that approximately 1% of the population of the United States is recognized by USEPA to potentially have a HQ of 2.5 or greater associated with consumption of drinking water containing chemicals with a noncarcinogenic endpoint and ELCRs as high as 1×10^{-3} or greater for chemicals with a carcinogenic endpoint (**Tables 5 and 6**). Florida has also recognized that AWQC can have HQs that exceed one for the upper percentiles of the population and still be health protective. When setting their proposed AWQC for noncarcinogenic endpoints Florida selected the 90th percentile of the population as having an HQ of one. In other words, 10% of the population could have an HQ greater than 1 and still be considered protected by the AWQC.

6.2 Risks in Perspective

Consider how a 1×10^{-6} lifetime risk of developing cancer compares to risks we face in our daily lives. For ease of discussion, we can refer to mortality risks in terms of micromorts, units representing a one in one million chance of death. For example, one micromort is the risk incurred by the average person driving 240 miles in the United States. The micromort allows different kinds of risk to be compared on a similar scale. Motorcycling 20 miles or undergoing anesthesia are equivalent to 5 micromorts apiece, skydiving or running a marathon are equivalent to 7 micromorts apiece, and giving birth in the United States is equivalent to 210 micromorts (Blastland and Spiegelhalter 2014).

In 2010, approximately 140,000 people died in the United States from unintentional injury-related deaths (e.g., poisoning, motor vehicle traffic, firearms, falls) (Murphy et al. 2013). This means that given a total population of 300 million, the average American

faced an unintentional injury-related mortality risk of approximately 467 micromorts per year in 2010, or 1.3 micromorts per day. Compare this to an ELCR of 1×10^{-6} , which (if we assume a lifetime corresponds to 70 years as does USEPA) translates to a worst-case 0.01 micromorts per year or 0.00004 micromorts per day; this is worst case from the perspective that not all cancers are fatal and the risk estimated by risk assessments are upper bound *estimates* of risk and do not represent *actual* risks. Thus, USEPA's definition of "acceptable" risk is several orders of magnitude below the average American's risk of dying from an unintentional injury; it is also approximately 3,500 times lower than the 2010 risk of dying from a murder/homicide (16,259 deaths or 0.1 micromorts per day), 20 times lower than the 2010 risk of dying from a flood (103 deaths or 0.001 micromorts per day) and 10 times lower than the 2010 risk of dying from a lightning strike (29 deaths or 0.0003 micromorts per day) in the United States (Murphy et al. 2013; NOAA 2015a,b) (**Figure 1**). This is consistent with the concept of 1×10^{-6} being a *de minimus* level, because risks within this range are not risks that most members of the general public are concerned with and attempt to actively avoid.

Consider next that many regulatory agencies employ the USEPA-recommended 1×10^{-6} risk level in a deterministic approach to deriving AWQC that relies on conservative upper-end values to estimate exposure. If one were to derive organism-only AWQC by selecting a fish consumption rate of 175 g/day and targeting a risk level of 1×10^{-6} , this means that a person would need to consume approximately 4,500 kilograms of locally-caught fish in his or her lifetime just to reach this *de minimus* level of risk, assuming ambient water always contains chemicals present at the resulting AWQC. This also means that the risk associated with a single 8 ounce meal of fish would be 5×10^{-11} , or 0.00005 micromorts, which for perspective should be noted is 20,000 times lower than the risk an average person faces when driving 250 miles in the United States (1 micromort) (**Figure 1**). Given that 175 g/day is an upper-end consumption rate estimate, the average member of the population would have an ELCR lower than 1×10^{-6} . For example, if we assume the average member of the population eats 8 g/day of fish, he or she would have an ELCR of 5×10^{-8} , roughly 20 times lower than the high-end consumer. If, on the other hand, one were to derive organism-only AWQC by selecting an average fish consumption rate of 8 g/day and targeting a risk level of 1×10^{-6} , the high-end consumer eating 175 g/day would have an ELCR of 2×10^{-5} , higher than 1×10^{-6} but still nearly an order of magnitude below the level USEPA (2000) recommends for highly exposed populations. Risk managers must make decisions such as these, recognizing that if highly exposed individuals are protected at 1×10^{-6} , the average member of the population – and in fact the majority of the population itself – will have risks well below this *de minimus* level.

Another perspective when thinking about allowable risk is to consider the reduction or change in cancers associated with a particular allowable risk level. Allowable risk levels that results in large reductions in expected cancers clearly have a greater public health benefit than risk levels that result in little change. As discussed in the introduction to this white paper, the average ELCR can be combined with the size of the population of Idaho and the number of cancer deaths in Idaho to see how large of a change in deaths is associated with various allowable risk levels. For added perspective, one can also look at how many Idahoans remain unaffected by cancer that may be caused by exposure to chemicals in Idaho surface waters. This is a bit different than the usual focus on the adverse effects that are associated with a regulation; it is instead a characterization of all the people who will not experience the adverse effect despite also being exposed to the chemical as allowed by the criterion. **Table 7** summarizes some of these comparisons. On an annual basis (based on 2012 population and mortality statistics), only a fraction of an additional cancer would be expected in Idaho at an allowable risk of 1×10^{-6} or 1×10^{-5} and only about 2 additional cancers would be expected even at an allowable risk of 1×10^{-4} . This means that using allowable risk levels of 1×10^{-6} and 1×10^{-5} would effectively not result in a change in the number of cancer deaths in 2012 (2,570 Idahoans died from cancer in 2012) nor in the total number of deaths in 2012 (11,993 Idahoans died in 2012). This also means that the total number of Idahoans (1,583,735) who did not get cancer or die from other causes in 2012 also would not die from cancer because of possible exposures to chemicals in Idaho surface waters associated with AWQC based on allowable risk levels for the average Idahoan of 1×10^{-6} or 1×10^{-5} . Even at allowable risk level of 1×10^{-4} , approximately 2 additional cancers are expected. Assuming that those cancers result in deaths would mean that 2,572 instead of 2,570 deaths from cancer would have occurred in 2012 and that total deaths would have increased from 11,993 to 11,995.

As discussed in this white paper, the risk assessment methods used by USEPA (and in this white paper because of that USEPA assumption) assume a lifetime (70 years) of exposure to chemicals in surface water. Instead of looking at increased cancers and overall mortality in a single year, one can also look at the number of excess cancers associated with various allowable risk levels over a 70 year period and compare those to background cancer and mortality rates. When summed over 70 years 1.6, 16 or 160 additional cancers would be expected in Idaho assuming allowable average excess lifetime cancer risks of 1×10^{-6} , 1×10^{-5} or 1×10^{-4} , respectively (**Table 7**). While these certainly represent a greater number of cancers than when increased cancer incidence is viewed on an annual basis, one has to keep in mind that the number of cancer deaths and deaths from all causes are also much greater over a 70 year period. In fact, even at an allowable risk of 1×10^{-4} for the average Idahoan, the change is less than

one tenth of a percent of total cancer deaths (179,900 baseline cancer deaths compared to 180,060 with an allowable risk of 1×10^{-4} for AWQC) and two hundredths of a percent change in overall deaths (839,510 baseline total deaths compared to 839,670 with an allowable risk of 1×10^{-4} for AWQC). Changes in deaths for an allowable risk level of 1×10^{-5} are 10 times smaller and changes associated with an allowable risk level of 1×10^{-6} would hardly be noticeable. Clearly, compared to total cancer deaths and to overall deaths in Idaho, the increase in cancers associated with the above allowable risk levels are small and are swamped by other causes of death and other causes of cancer. This finding is consistent with the comparisons of mortality risk associated with various allowable risk levels to mortality risk from various activities that are part of everyday life shown above.

Finally, risk managers should also consider how the risks incurred from eating fish compare to the benefits gained. Researchers and public health officials have been aware for several decades that consumption of fish has associated with it many benefits. Early comparisons of those benefits to the potential risks associated with exposure to possible chemicals contaminants suggested that the benefits (specifically the reduced risk of mortality from coronary heart disease) far outweighed any increased cancer risks that might be associated with the allowable risk levels used in the derivation of AWQC (e.g., 1×10^{-6} , 1×10^{-5} , and 1×10^{-4}) (Anderson and Weiner 1995, Patterson 2002, Daviglius et al. 2002, Dourson et al. 2002, Anderson et al. 2002). A great deal of research continues on the health benefits and risks of consuming fish with measurable levels of chemicals. A literature search of publications since 2005 revealed over 400 citations, including three recent reviews by expert panels or recommendations by regulatory agencies (Nesheim and Yaktine 2007, WHO 2011, EFSA 2014). All of those recent expert reviews and regulatory agency recommendations continue to urge that people regularly consume fish. In fact, in the recommendation is that the general population eat 1-2 meals per week and that pregnant women eat 2-4 meals per week because of the benefits to the infants they are carrying (EFSA 2011). Such benefits almost always outweigh the possible risks of chemical exposure.

6.3 Risk Management Goals Evaluated

For chemicals with carcinogenic health endpoints, this white paper derives AWQC based on a target ELCR of 1×10^{-6} at the arithmetic mean of the risk distribution and 1×10^{-5} at the 90th percentile of the risk distribution. This is consistent with the USEPA (2000) methodology described above. To illustrate the potential impact of risk management decisions on resulting AWQC, alternative AWQC are also derived for the

carcinogenic chemicals based on a) a target ELCR of 1×10^{-5} at the arithmetic mean and 1×10^{-4} at the 90th percentile and b) a target ELCR of 1×10^{-6} at the 90th percentile. For chemicals with noncarcinogenic health endpoints, this white paper derives AWQC based on a target HQ of 1.0 at the 90th percentile of the risk distribution.

Though this white paper strongly recommends that Idaho use a PRA approach to derive AWQC, if Idaho decides to use deterministic risk assessment methods to derive AWQC then an allowable risk level should be selected that is commensurate with the segment of the population being protected. As shown by the examples presented in this white paper, a large range of risk exists within the Idaho population. AWQC derived using assumptions that are representative of high-end exposures (for example using a drinking water or fish consumption rate representative of a 95th or greater percentile of the population) should be coupled with allowable risk levels appropriate for high-end populations. As noted earlier in this white paper USEPA in its 2000 AWQC guidance stated that allowable risk levels of one in ten thousand (1×10^{-4}) are appropriate for such populations. AWQC derived using assumptions that are representative of average exposures (for example using a mean drinking water or fish consumption rate) should be coupled with allowable risk levels appropriate for the general population such as 1×10^{-5} or 1×10^{-6} as discussed in USEPA 2000. Idaho should not derive AWQC that couple high-end exposure assumptions with allowable risk levels representative of the general population as that will result in AWQC that are not practical and are associated with a level of protection far greater than implied by the allowable risk level used to set the AWQC.

7. Results

To illustrate the concepts discussed in this white paper, a probabilistic approach was used to derive water and organism AWQC protective of Idaho residents for three carcinogenic chemicals (benzene, benzo(a)pyrene, chlordane) and three noncarcinogenic chemicals (selenium, fluorene, endrin). As described above, the approach recommended in this white paper uses a composite fish consumption rate distribution that combines general population and contemporary tribal consumption rates in proportion to their relative population size. Market and anadromous fish are excluded from the recommended approach because state-specific AWQC can only protect Idaho residents from chemical concentrations in locally caught, non-anadromous fish. This distribution is referred to herein as Composite 1. However, for illustrative purposes, this white paper also develops AWQC using alternative distributions that contain market fish and anadromous fish as well as estimated

heritage fish consumption rates for the Native American population if IDEQ ultimately determines that inclusion of such fish and fish consumption rates is appropriate.

For chemicals with carcinogenic health endpoints, AWQC were based on a target ELCR of 1×10^{-6} at the arithmetic mean of the risk distribution and 1×10^{-5} at the 90th percentile of the risk distribution (**Figure 2**). Because more than one risk management goal needs to be met, the AWQC are the lowest of the concentrations derived from both of the risk management goals. For the three carcinogenic chemicals evaluated in this white paper, while the risks to the average member of the population are equal to the risk management goal of 1×10^{-6} , the risks associated with the 90th percentile at that same concentrations are approximately 2×10^{-6} , which is about five times lower (more stringent) than required by the risk management goal of 1×10^{-5} for the 90th percentile. (That finding may be confusing: why is the calculated value lower than the initially assumed value? Simply put, the two target ELCRs are not completely independent values; in this case, the AWQC calculated based on the possible risk to the average member of the population drives the risk calculation for the 90th percentile.) Furthermore, the maximum risks for the three chemicals (averaged over 500 simulations of 10,000 iterations each) ranged from 7×10^{-6} to 2×10^{-5} , which is about an order of magnitude below the 1×10^{-4} risk level USEPA (2000) recommends for highly exposed populations.

For chemicals with noncarcinogenic health endpoints, AWQC were based on a target HQ of 1.0 at the 90th percentile of the risk distribution (**Figure 3**). The HQ for the average member of the population are approximately 0.5 and the maximum HQs (averaged over 500 simulations of 10,000 iterations each) range from 4 to 7, depending upon the chemical.

To evaluate the effect of using a range of hypothetical fish consumption rates on potential AWQC, three additional distributions were developed. Composite 2, like Composite 1, excludes market and anadromous fish but unlike Composite 1 incorporates heritage tribal consumption rates rather than contemporary tribal consumption rates. Composites 3 and 4 include all fish and incorporate contemporary and heritage tribal rates, respectively. For chemicals with high BCFs (e.g., chlordane and endrin), the fish consumption rate distributions have a significant impact on resulting AWQC, which increase by three-fold from the low to high end (**Figure 4**). For chemicals with low BCFs (e.g., benzene and selenium) or mid-range BCFs (e.g., benzo(a)pyrene and fluorine), bioaccumulation and fish consumption have little effect on resulting AWQC, which increase by only 5% to 25%, respectively, from the low to high end. All resulting AWQC, regardless of the composite fish consumption rate

distribution used, meet the risk management goal of 1×10^{-6} for the average member of the population, with 90th percentile risks falling below 1×10^{-5} and maximum risks falling below 1×10^{-4} .

Two additional sets of AWQC were developed for the three carcinogenic chemicals to evaluate the effect of using various risk management decisions on potential AWQC. For all three chemicals, the choice of risk management criteria has a significant impact on AWQC, which increase approximately 20-fold from the low to high end (**Figure 5**). The first additional set of AWQC was based on a target ELCR of 1×10^{-5} at the arithmetic mean and 1×10^{-4} at the 90th percentile. These risk management criteria resulted in AWQC ten times greater (less stringent) than the AWQC based on a target ELCR of 1×10^{-6} at the arithmetic mean and 1×10^{-5} at the 90th percentile. However, the resulting criteria still conform to USEPA's risk guidance, with potential risks for highly exposed members of the population (i.e., the 99th percentile) falling below 1×10^{-4} and maximum risks (averaged over 500 simulations of 10,000 iterations each) ranging from 7×10^{-5} to 2×10^{-4} . The second additional set of AWQC was based on a target ELCR of 1×10^{-6} at the 90th percentile. This risk management criterion resulted in AWQC two-fold lower (more stringent) than the AWQC based on a target ELCR of 1×10^{-6} at the arithmetic mean and 1×10^{-5} at the 90th percentile. The resulting criteria are more stringent than necessary to conform to USEPA's risk guidance, with risks for the average member of the population ranging from 5×10^{-7} to 6×10^{-7} .

8. Conclusions

This white paper was written in response to IDEQ's request for comments on Policy Discussion Paper #7 related to selection of risk management benchmarks (IDEQ 2014a). Discussion Paper #7 focuses on single allowable risk levels as they apply to deterministically derived AWQC. This white paper begins with a discussion of the shortcomings of deterministically derived AWQC and how those shortcomings can be overcome using probabilistically derived AWQC. The two most important advantages are the ability of probabilistically derived AWQC to separate risk assessment from risk-management and to make transparent the protection afforded different segments of the population of Idaho. Because of those advantages this white paper recommends that IDEQ derive Idaho-specific AWQC using a PRA methodology. This white paper then proposes such a methodology and demonstrates how it can be applied to the derivation of Idaho-specific AWQC once Idaho-specific fish consumption rate data are available that permit the derivation of Idaho-specific fish consumption rate distributions.

To demonstrate the application of the proposed methodology, this white paper develops potential AWQC for six different chemicals. Several of the inputs used by the proposed methodology are likely to be the same as those used by IDEQ were it to adopt a probabilistic approach. Those inputs include distributions for drinking water consumption rate and body weight and point estimates used for a variety of the other input parameters (e.g., relative source contribution, bioconcentration factor, duration of exposure, reference dose, cancer slope factor). Because fish consumption rate information specific to Idaho is not yet available and because IDEQ has over the past year and a half released a series of discussion papers related to treatment of fish consumption rate information, the white paper develops four alternative fish consumption rate distributions to examine their effect on potential AWQC. Each of the fish consumption rate distributions represents a combination of fish consumption rate distributions assumed to be representative of the general population of Idaho and fish consumption rate distributions assumed to be representative of the Native American population of Idaho. The contribution of the general and tribal populations to the final distribution is weighted according to the fraction of the total population of Idaho each represents. The four distributions vary because they use either contemporary or assumed historic (i.e., heritage) tribal consumption rates and they either include market and anadromous fish or exclude such fish. Thus, the distribution with the lowest fish consumption uses contemporary tribal consumption rates and excludes market and anadromous fish. The distribution with the highest fish consumption rates assumes historical tribal consumption rates and includes market and anadromous fish.

After presenting the PRA methodology and the information required by such a methodology to estimate potential risks from chemicals in surface water, the white paper then discusses risk-management decisions necessitated by a PRA approach. This information is most directly related to the allowable risk information discussed in Discussion Paper #7 and is applicable to risk-management decisions necessitated by either a deterministic or a PRA approach.

The white paper reviews USEPA guidance in establishing AWQC that states the general population can be protected at an allowable risk level of 1 in 1,000,000 to 1 in 100,000 (1×10^{-6} to 1×10^{-5}) and that highly exposed populations should not exceed a risk level of 1 in 10,000 (1×10^{-4}). Allowable risk levels used by other regulatory programs are also reviewed. For example, the Safe Drinking Water Act requires that USEPA establish national allowable concentrations of chemicals in drinking water. These are referred to as Maximum Contaminant Levels (MCLs). Of the 29 chemicals that are assumed to potentially cause cancer and have MCLs, the acceptable risk associated with nine chemicals is between 1×10^{-6} and 1×10^{-5} . Fifteen chemicals have

an acceptable risk of between 1×10^{-5} and 1×10^{-4} . Four of the 29 chemicals have an acceptable risk of greater than 1×10^{-4} , the level USEPA has indicated should not be exceeded by highly exposed population exposed to chemicals in surface water. The finding that the Safe Drinking Water Act considers risks of 1×10^{-4} acceptable for the general population indicates that the 1×10^{-4} allowable risk level for highly exposed populations is not a bright line allowable risk that cannot be exceeded. It is particularly notable that the acceptable risks associated with MCLs are based on drinking water consumption rates that are exceeded by a relatively large portion of the population. In other words, potential excess lifetime cancer risks associated with high-end consumers of water (for example, the one percent of the U.S. population that consumes 5 or more liters of water a day) are likely substantially greater than 1×10^{-4} and may even approach one in one thousand (1×10^{-3}) for chemicals such as arsenic.

Additional perspective about how to judge whether a risk is allowable is provided by comparing the risks associated with various causes of death and comparing those to allowable risk levels that might be used in the setting of AWQC. In general, the range of allowable risks for the general population typically used to set AWQC (i.e., 1×10^{-5} and 1×10^{-6}) are much smaller than the daily risks we encounter simply by being alive (such as the daily risk of dying from an unnatural cause such as a fall or other accident) or activities we partake in on a regular basis (e.g., walking, driving a car, running). Additionally, the allowable risks USEPA indicates are appropriate for the general population when setting AWQC are consistent with or less than causes of death that most members of society view as being rare, inconsequential and involuntary. These include causes of death such as floods, drowning, lightning, fires, tornadoes and bites or stings from venomous snakes and insects. These comparisons support the notion that risks of 1×10^{-6} , 1×10^{-5} and even greater can be considered acceptable for the general population.

The change in number of deaths associated with adopting an AWQC with a particular allowable risk level also provides perspective about the public health benefits associated with the AWQC. If large changes in mortality are expected as a result of using a particular allowable risk level, then the adoption of that AWQC might be expected to result in substantial public health benefit. Alternatively, if the adoption of an AWQC results in minimal changes in mortality, then perhaps little public health benefit will be gained by implementing the AWQC. Based on the size of the Idaho population in 2012 and the total number of cancer and overall deaths reported in Idaho in 2012, the use of an allowable risk level of 1×10^{-5} and 1×10^{-6} to derive AWQC results in essentially no change in the annual number of deaths (even making the conservative but incorrect assumption that all excess cancers assumed to result from chemical

exposure are fatal). Like the comparisons discussed above, this comparison too suggests that allowable risk levels of 1×10^{-6} , 1×10^{-5} and perhaps even higher are appropriate for the general population.

The white paper also briefly reviews the health benefits of eating fish. It turns out those benefits greatly outweigh any potential increased cancer risk associated with consuming fish that contain chemicals. If AWQC based on acceptable risks of 1×10^{-6} , 1×10^{-5} and even 1×10^{-4} are in some way restricting people from consuming fish from a particular water body, then precluding those people from realizing the health benefits of eating those fish is almost certainly a greater public health risk than the estimated increased cancer risk that might be associated with chemicals in those fish.

This white paper combines the proposed PRA methodology with three different sets of allowable risk levels to derive hypothetical AWQC for six different chemicals. For each set of allowable risk levels, four different hypothetical AWQC are derived. Each one of the four corresponds to a different fish consumption rate distribution. For compounds that tend to not bioaccumulate in fish (e.g., benzene, benzo(a)pyrene, selenium and fluorene), AWQC associated with the four different fish consumption rate distributions are not very different (within 25% of each other) despite the fish consumption rate distributions varying by nearly three-fold. This lack of a large difference is expected for these compounds because most of the exposure arises from assumed consumption of drinking water and the distribution describing drinking water intake is identical across all hypothetical AWQC. Hypothetical AWQC for chlordane and endrin, two compounds that do bioaccumulate in fish, varied by about three-fold across the four different fish consumption rate distributions. This is consistent with the variation in the fish consumption rate distributions themselves and reflects that fish consumption is the dominant exposure pathway for these two compounds. Interestingly, despite the inclusion of some very high fish consumption rates in the two distributions that included assumed heritage consumption rates for tribal members, the AWQC derived from those distributions are not substantially more stringent than the AWQC from non-heritage consumption rates. The reason is that tribal members with historic rates of consumption comprise a small proportion of the Idaho population. However, the great advantage of the PRA approach is that it is able to demonstrate that even tribal members with such high rates of consumption have excess lifetime cancer risks below or similar to the allowable risk level USEPA has indicated is appropriate for highly exposed populations (i.e., 1×10^{-4}).

Based on the information summarized in this white paper and the result of the PRA approach presented herein, several recommendations for deriving AWQC are apparent.

First, IDEQ should use a PRA methodology to derive AWQC because of its ability to distinguish between risk assessment and risk management and, perhaps more importantly, because of its ability to make transparent the levels of protection afforded different segments of the population and document that all segments are being protected at the stated risk management goals.

Second, a fish consumption rate distribution that represents all members of the Idaho population should be employed. Such a distribution should include the fish consumption rates representative of the general Idaho population as well as consumption rates representative of tribal populations in Idaho.

Third, the fish consumption rate distribution should be based on fish caught or raised in Idaho waters. AWQC applied to Idaho waters only affect fish in such waters. Anadromous and market fish may or may not contain elevated levels of chemicals, but the content of chemicals in those fish are not affected by Idaho AWQC and, therefore, such fish should not be included in the fish consumption rates used to set Idaho AWQC.

Fourth, the fish consumption rate distribution used to represent tribal consumption should reflect current, not heritage consumption rates. Many causes exist for current consumption rates to be lower than assumed heritage rates. When those causes change and consumption rates begin to increase, AWQC can be revised as appropriate and as supported by consumption rate information available at that time.

Fifth, at least two allowable risk benchmarks should be used when setting an AWQC. One allowable risk level should be applied to the average member of the Idaho population. A second allowable risk level should be used to document that highly exposed populations are protected. If necessary, a third allowable risk level can be applied to an upper percentile (e.g., the 90th percentile) of the distribution of excess lifetime cancer risk.

Sixth, this white paper does not recommend specific allowable risk levels. However, from the information presented in this white paper it is clear that an allowable risk level of no lower than 1×10^{-6} should be applied to the average member of the Idaho population and that an allowable risk level of 1×10^{-5} for the general Idaho population is

supported by regulatory precedent and other considerations. An allowable risk level of no less than 1×10^{-4} should be used to demonstrate protection of highly exposed populations. Based on the use of allowable risk levels of greater than 1×10^{-4} for safe drinking water standards for the general United States population, regulatory precedent exists for the use of an allowable risk of somewhat greater than 1×10^{-4} for highly exposed populations.

Finally, while this white paper strongly recommends that Idaho use a PRA approach to derive AWQC, if IDEQ decides to use deterministic risk assessment methods to derive AWQC, then an allowable risk level should be selected that is commensurate with the segment of the population represented by the assumptions used to derive the deterministic AWQC. As shown by the examples presented in this white paper, a large range of risk exists within the Idaho population. AWQC derived using assumptions that are representative of high-end exposures should be coupled with allowable risk levels appropriate for high-end populations (e.g., 1×10^{-4} as noted in USEPA 2000). AWQC derived using assumptions that are representative of average exposures should be coupled with allowable risk levels appropriate for the general population (e.g., 1×10^{-5} or 1×10^{-6} as noted in USEPA 2000). Idaho should not derive AWQC that couple high-end exposure assumptions with allowable risk levels representative of the general population as that will result in AWQC that are not practical and are associated with a level of protection far greater than implied by the allowable risk level used to set the AWQC.

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**White Paper Responding to
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Tables

Table 1. Derivation of Composite Fish Consumption Rate Distributions

Statistic	Contemporary Tribal Population		Heritage Tribal Population ^c		General Population		Composite Population ^f			
	All Fish (g/day) ^a	Non-Anadromous Fish (g/day) ^b	All Fish (g/day)	Non-Anadromous Fish (g/day)	All Fish (g/day) ^d	Freshwater and Estuarine Fish (g/day) ^e	Composite 1 (g/day)	Composite 2 (g/day)	Composite 3 (g/day)	Composite 4 (g/day)
mean	71.12	38.40	213.36	115.21	18.8	7.09	7.83	9.64	20.04	23.4
1%	10.41	5.62	31.23	16.86	0.9	0.34	0.46	0.73	1.12	1.62
5%	16.96	9.16	50.88	27.48	2	0.75	0.95	1.39	2.35	3.16
10%	22	11.88	66	35.64	3	1.13	1.39	1.95	3.45	4.49
25%	33.97	18.34	101.91	55.03	6.2	2.34	2.72	3.58	6.86	8.46
50%	55.05	29.73	165.15	89.18	12.7	4.79	5.38	6.78	13.7	16.31
75%	89.22	48.18	267.66	144.54	24.8	9.35	10.27	12.55	26.32	30.54
80%	100.55	54.30	301.65	162.89	28.9	10.90	11.92	14.49	30.59	35.35
85%	115.6	62.42	346.8	187.27	34.5	13.01	14.18	17.13	36.42	41.89
90%	137.77	74.40	413.31	223.19	42.5	16.02	17.4	20.92	44.75	51.27
95%	178.69	96.49	536.07	289.48	56.6	21.34	23.12	27.68	59.49	67.94
99%	291.03	157.16	873.09	471.47	90.8	34.23	37.14	44.57	95.54	109.3

Notes:

g/day = grams per day

^a Composite tribal distribution #6 from Table C-4 in WDOE (2011) (tribal-specific distributions weighted according to relative population); assumes 100% of tribal populations are consumers and all fish are from waters of the state.

^b Component of all fish that are not anadromous [all fish x (1 - 0.46)].

^c Contemporary distributions adjusted upward by factor of 3.

^d NCI-adjusted NHANES distribution from Table 4 in Polissar (2012).

^e Component of all fish that are freshwater or estuarine fish [all fish x 0.377]

^f Composite distributions [(tribal x 0.024)+(general x 0.976)]:

1. Contemporary tribal rates, exclude market and anadromous fish.
2. Heritage tribal rates, exclude market and anadromous fish.
3. Contemporary tribal rates, all fish.
4. Heritage tribal rates, all fish.

Table 2. Input Distribution Summary Statistics

Input Parameter	Body Weight	Drinking Water Intake	Fish Consumption Rate			
			Composite 1	Composite 2	Composite 3	Composite 4
Units	kilograms (g)	liters per day (L/day)	grams per day (g/day)			
Distribution Type	Lognormal	Pearson Type V	Inverse Gaussian	Inverse Gaussian	Inverse Gaussian	Inverse Gaussian
Minimum	44	0	0	0	0	0
Maximum	∞	∞	∞	∞	∞	∞
Mean	80.5	1.72	7.96	9.74	20.4	23.7
Mode	72.5	1.20	2.14	2.93	5.34	6.81
Median	77.7	1.53	5.37	6.77	13.7	16.3
Std Dev	20.3	1.07	8.20	9.55	21.2	23.7
1%	46.6	0.110	0.360	0.611	0.865	1.31
5%	52.4	0.358	0.949	1.37	2.35	3.12
10%	56.8	0.552	1.45	2.00	3.62	4.63
15%	60.1	0.703	1.89	2.54	4.74	5.95
20%	63.1	0.835	2.32	3.07	5.84	7.23
25%	65.7	0.957	2.75	3.60	6.95	8.52
30%	68.2	1.07	3.20	4.15	8.10	9.86
35%	70.6	1.19	3.68	4.73	9.33	11.3
40%	72.9	1.30	4.19	5.35	10.6	12.8
45%	75.3	1.41	4.75	6.02	12.1	14.5
50%	77.7	1.53	5.37	6.77	13.7	16.3
55%	80.2	1.66	6.07	7.60	15.5	18.3
60%	82.9	1.79	6.86	8.54	17.5	20.6
65%	85.7	1.93	7.78	9.63	19.9	23.3
70%	88.7	2.09	8.87	10.9	22.7	26.5
75%	92.2	2.27	10.2	12.5	26.1	30.4
80%	96.2	2.48	11.9	14.5	30.5	35.3
85%	101	2.75	14.2	17.1	36.4	41.9
90%	108	3.12	17.6	21.1	45.2	51.7
95%	118	3.73	23.8	28.2	61.4	69.6
99%	140	5.15	40.0	46.8	104	116

Table 3. Summary of Point Estimate Inputs

CAS Number	Chemical	Reference Dose (RfD)		Cancer Slope Factor (CSF)		Relative Source Contribution (RSC)		Tissue-Based Bioconcentration Factor (BCF _{tissue})	
		mg/kg-day	source	(mg/kg-day) ⁻¹	source	unitless	source	L/kg tissue	source
71-43-2	Benzene	0.004	IRIS	0.015	IRIS ^a	NA		5.2	USEPA
50-32-8	Benzo(a)pyrene	NA		7.3	IRIS	NA		30	USEPA
12789-03-6	Chlordane	0.0005	IRIS	0.35	IRIS	NA		14100	USEPA
72-20-8	Endrin	0.0003	IRIS	NA		0.8	FDEP	3970	USEPA
86-73-7	Fluorene	0.04	IRIS	NA		0.92	FDEP	30	USEPA
7782-49-2	Selenium	0.005	IRIS	NA		0.76	FDEP	4.8	USEPA

Sources:

FDEP = FDEP. 2014. Draft Technical Support Document: Derivation of Human Health-Based Criteria and Risk Impact Statement. Division of Environmental Assessment and Restoration, Tallahassee, Florida. February.

IRIS = USEPA Integrated Risk Information System

USEPA = USEPA. 2002. National Recommended Water Quality Criteria: 2002 Human Health Criteria Calculation Matrix. EPA-822-R-02-012. Washington, DC: United States Environmental Protection Agency Office of Water Office of Science and Technology.

Notes:

CAS = Chemical Abstracts Service

FDEP = Florida Department of Environmental Protection

L/kg tissue = liters per kilogram tissue

mg/kg-day = milligrams per kilogram per day

NA = not available

USEPA = United States Environmental Protection Agency

^a The CSF for benzene ranges from 1.5×10^{-2} to 5.5×10^{-2} per mg/kg-day. The lower value was used (1.5×10^{-2}).

Table 4. Benchmarks for “Acceptable” Risk

Law / Regulation	Focus	Risk Standard	Acceptable Risk for Carcinogens	Source/Note
Clean Water Act	Surface water	Adverse health impacts	10^{-6} to 10^{-4}	USEPA (2000)
Safe Drinking Water Act	Public drinking water	Any adverse effect	Goal: 0 Enforceable standard: 10^{-4}	USEPA (2012); enforceable standards stated as 10^{-4} but Maximum Contaminant Levels for some compounds exceed 10^{-4}
Toxic Substances Control Act	Chemicals manufactured or imported into U.S.	Unreasonable risk	$\approx 10^{-4}$	USEPA (1995)
Occupational Safety and Health Act	Worker protection	No significant risk	$\leq 10^{-3}$	NIOSH (2013); based on a 45-year working lifetime exposure
Comprehensive Environmental Response, Compensation, and Liability Act, or Superfund	Uncontrolled hazardous waste sites	No significant risk	10^{-6} to 10^{-4}	USEPA (1991b)

Table 5. USEPA Drinking Water Specific Risk Level Concentrations for Chemicals with Carcinogenic Effects

Chemical	MCLG ^a (mg/L)	MCL ^{a,b} (mg/L)	Concentration at 10 ⁻⁴ Cancer Risk ^a (mg/L)	Approximate Level of MCL Risk	Approximate Level of MCL Risk at 5 L/day
Organics					
Alachlor	zero	0.002	0.04	5.0E-06	1.3E-05
Benzene	zero	0.005	1 to 10	5E-07 to 5E-06	1.3E-06 to 1.3E-05
Benzo(a)pyrene	zero	0.0002	0.0005	4.0E-05	1.0E-04
Bromodichloromethane	zero	0.08	0.1	8.0E-05	2.0E-04
Bromoform	zero	0.08	0.8	1.0E-05	2.5E-05
Carbon tetrachloride	zero	0.005	0.05	1.0E-05	2.5E-05
Chlordane	zero	0.002	0.01	2.0E-05	5.0E-05
Di(2-ethylhexyl)adipate	0.4	0.4	3	1.3E-05	3.3E-05
Di(2-ethylhexyl)phthalate	zero	0.006	0.3	2.0E-06	5.0E-06
Dibromochloromethane	0.06	0.080	0.08	1.0E-04	2.5E-04
Dibromochloropropane (DBCP)	zero	0.0002	0.003	6.7E-06	1.7E-05
Dichloroacetic acid	zero	0.060	0.07	8.6E-05	2.1E-04
Dichloroethane (1,2-)	zero	0.005	0.04	1.3E-05	3.1E-05
Dichloroethylene (1,1-)	0.007	0.007	0.006	1.2E-04	2.9E-04
Dichloromethane	zero	0.005	0.5	1.0E-06	2.5E-06
Dichloropropane (1,2-)	zero	0.005	0.06	8.3E-06	2.1E-05
Ethylene dibromide (EDB)	zero	0.00005	0.002	2.5E-06	6.3E-06
Heptachlor	zero	0.0004	0.0008	5.0E-05	1.3E-04
Heptachlor epoxide	zero	0.0002	0.0004	5.0E-05	1.3E-04
Hexachlorobenzene	zero	0.001	0.002	5.0E-05	1.3E-04
Pentachlorophenol	zero	0.001	0.009	1.1E-05	2.8E-05
Polychlorinated biphenyls (PCBs)	zero	0.0005	0.01	5.0E-06	1.3E-05
2,3,7,8-TCDD (Dioxin)	zero	0.00000003	0.00000002	1.5E-04	3.8E-04
Toxaphene	zero	0.003	0.003	1.0E-04	2.5E-04
Trichloroethane (1,1,2-)	0.003	0.005	0.06	8.3E-06	2.1E-05
Trichloroethylene	zero	0.005	0.3	1.7E-06	4.2E-06
Vinyl chloride	zero	0.002	0.002	1.0E-04	2.5E-04
Inorganics					
Arsenic	zero	0.01	0.002	5.0E-04	1.3E-03
Bromate	zero	0.01	0.005	2.0E-04	5.0E-04

Notes:

L/day = liters per day

MCL = Maximum Contaminant Level

MCLG = Maximum Contaminant Level Goal

mg/L = milligrams per liter

^a USEPA (2012)

^b Based on drinking water intake of 2 L/day.

Table 6. USEPA Drinking Water Specific Risk Level Concentrations for Chemicals with Noncarcinogenic Effects

Chemical	MCLG ^a (mg/L)	MCL ^{a,b} (mg/L)	Concentration at Hazard Quotient of 1 ^a (mg/L)	Approximate Level of MCL Hazard	Approximate Level of MCL Hazard at 5 L/day
Organics					
Alachlor	zero	0.002	0.4	0.005	0.013
Aldicarb	0.001	0.003	0.035	0.086	0.21
Aldicarb sulfone	0.001	0.002	0.035	0.057	0.14
Aldicarb sulfoxide	0.001	0.004	0.035	0.11	0.29
Atrazine	0.003	0.003	0.7	0.0043	0.011
Benzene	zero	0.005	0.1	0.05	0.13
Bromodichloromethane	zero	0.08	0.1	0.8	2
Bromoform	zero	0.08	1	0.08	0.2
Carbon tetrachloride	zero	0.005	0.1	0.05	0.13
Chlordane	zero	0.002	0.02	0.1	0.25
Chloroform	0.07	0.08	0.35	0.23	0.57
2,4-D (2,4- dichlorophenoxyacetic acid)	0.07	0.07	0.2	0.35	0.88
Dalapon (sodium salt)	0.2	0.2	0.9	0.22	0.56
Di(2-ethylhexyl)adipate	0.4	0.4	20	0.02	0.05
Di(2-ethylhexyl)phthalate	zero	0.006	0.7	0.0086	0.021
Dibromochloromethane	0.06	0.08	0.7	0.11	0.29
Dichloroacetic acid	zero	0.06	0.1	0.6	1.5
Dichlorobenzene o-	0.6	0.6	3	0.2	0.5
Dichlorobenzene p-	0.075	0.075	4	0.019	0.047
Dichloroethylene (1,1-)	0.007	0.007	2	0.0035	0.0088
Dichloroethylene (cis-1,2-)	0.07	0.07	0.07	1	2.5
Dichloroethylene (trans-1,2-)	0.1	0.1	0.7	0.14	0.36
Dichloromethane	zero	0.005	2	0.0025	0.0063
Dinoseb	0.007	0.007	0.035	0.2	0.5
Diquat	0.02	0.02	0.02	1	2.5
Endothall	0.1	0.1	0.25	0.4	1
Endrin	0.002	0.002	0.01	0.2	0.5
Ethylbenzene	0.7	0.7	3	0.23	0.58
Ethylene dibromide (EDB)	zero	0.00005	0.3	0.00017	0.00042
Glyphosate	0.7	0.7	70	0.01	0.025
Heptachlor	zero	0.0004	0.02	0.02	0.05
Heptachlor epoxide	zero	0.0002	0.0004	0.5	1.3
Hexachlorobenzene	zero	0.001	0.03	0.033	0.083
Hexachlorocyclopentadiene	0.05	0.05	0.2	0.25	0.63
Malathion	0.0002	0.0002	0.2	0.001	0.0025
Methoxychlor	0.04	0.04	0.2	0.2	0.5
Monochloroacetic acid	0.03	0.06	0.35	0.17	0.43
Monochlorobenzene	0.1	0.1	0.7	0.14	0.36
Oxamyl (Vydate)	0.2	0.2	0.035	5.7	14
Pentachlorophenol	zero	0.001	0.2	0.005	0.013
Picloram	0.5	0.5	0.7	0.71	1.8
Simazine	0.004	0.004	0.7	0.0057	0.014
Styrene	0.1	0.1	7	0.014	0.036
2,3,7,8-TCDD (Dioxin)	zero	0.00000003	0.00000004	0.75	1.9
Tetrachloroethylene	zero	0.005	0.5	0.01	0.025
Toluene	1	1	3	0.33	0.83
Toxaphene	zero	0.003	0.01	0.3	0.75

Table 6. USEPA Drinking Water Specific Risk Level Concentrations for Chemicals with Noncarcinogenic Effects

Chemical	MCLG ^a (mg/L)	MCL ^{a,b} (mg/L)	Concentration at Hazard Quotient of 1 ^a (mg/L)	Approximate Level of MCL Hazard	Approximate Level of MCL Hazard at 5 L/day
2,4,5-TP (Silvex)	0.05	0.05	0.3	0.17	0.42
Trichloroacetic acid	0.02	0.06	1	0.06	0.15
Trichlorobenzene (1,2,4-)	0.07	0.07	0.35	0.2	0.5
Trichloroethane (1,1,1-)	0.2	0.2	70	0.0029	0.0071
Trichloroethane (1,1,2-)	0.003	0.005	0.1	0.05	0.13
Trichloroethylene 1	zero	0.005	0.2	0.025	0.063
Vinyl chloride	zero	0.002	0.1	0.02	0.05
Xylenes	10	10	7	1.4	3.6
Inorganics					
Antimony	0.006	0.006	0.01	0.6	1.5
Arsenic	zero	0.01	0.01	1	2.5
Barium	2	2	7	0.29	0.71
Beryllium	0.004	0.004	0.07	0.057	0.14
Bromate	zero	0.01	0.14	0.071	0.18
Cadmium	0.005	0.005	0.02	0.25	0.63
Chloramine	4	4	3.5	1.1	2.9
Chlorine	4	4	5	0.8	2
Chlorine dioxide	0.8	0.8	1	0.8	2
Chlorite	0.8	1	1	1	2.5
Chromium (total)	0.1	0.1	0.1	1	2.5
Mercury (inorganic)	0.002	0.002	0.01	0.2	0.5
Selenium	0.05	0.05	0.2	0.25	0.63
Uranium	zero	0.03	0.02	1.5	3.8

Notes:

L/day = liters per day

MCL = Maximum Contaminant Level

MCLG = Maximum Contaminant Level Goal

mg/L = milligrams per liter

^a USEPA (2012)

^b Based on drinking water intake of 2 L/day.

Table 7. Hypothetical Change in Annual Cancer and Total Deaths In Idaho Assuming Three Different Allowable Risk Levels

Allowable Risk Level ^a	2012 Estimates				Lifetime (70-Year) Estimates ^f			
	Hypothetical Excess Cancers ^b	Total Cancer Deaths ^c	Total Deaths ^d	Number Alive ^e	Hypothetical Excess Cancers	Total Cancer Deaths	Total Deaths	Percent Change From Baseline ^g
Baseline ^h	0	2,570	11,993	1,595,728	0	179,900	839,510	0%
1x10 ⁻⁶	0.023	2,570	11,993	1,595,728	1.6	179,902	839,512	0.0002%
1x10 ⁻⁵	0.23	2,570	11,993	1,595,728	16	179,916	839,526	0.002%
1x10 ⁻⁴	2.3	2,572	11,995	1,595,726	160	180,060	839,670	0.02%

Notes:

^a Hypothetical estimates of of excess cancers assume the actual arithmetic average excess lifetime cancer risk is used to estimate the increase in cancers and change in number of deaths. Most regulatory risk assessments estimate upper bound excess lifetime cancer risks. Such assessments also estimate increased risk of cancer incidence, not increased mortality. Use of excess lifetime cancer risks from such regulatory risk assessments will result in overestimates of hypothetical excess cancers, total cancer deaths and total deaths.

^b Hypothetical excess cancers estimated by multiplying the Idaho population in 2012 (1,595,728) times the allowable risk level and dividing by 70 years.

^c Total cancer deaths estimated by adding the number of hypothetical excess cancers to the number of cancer deaths reported for Idaho in 2012.

^d Total deaths estimated by adding the number of hypothetical excess cancers to the number of total deaths reported for Idaho in 2012.

^e Number alive estimated by subtracting the number of hypothetical excess cancers from the Idaho population size in 2012.

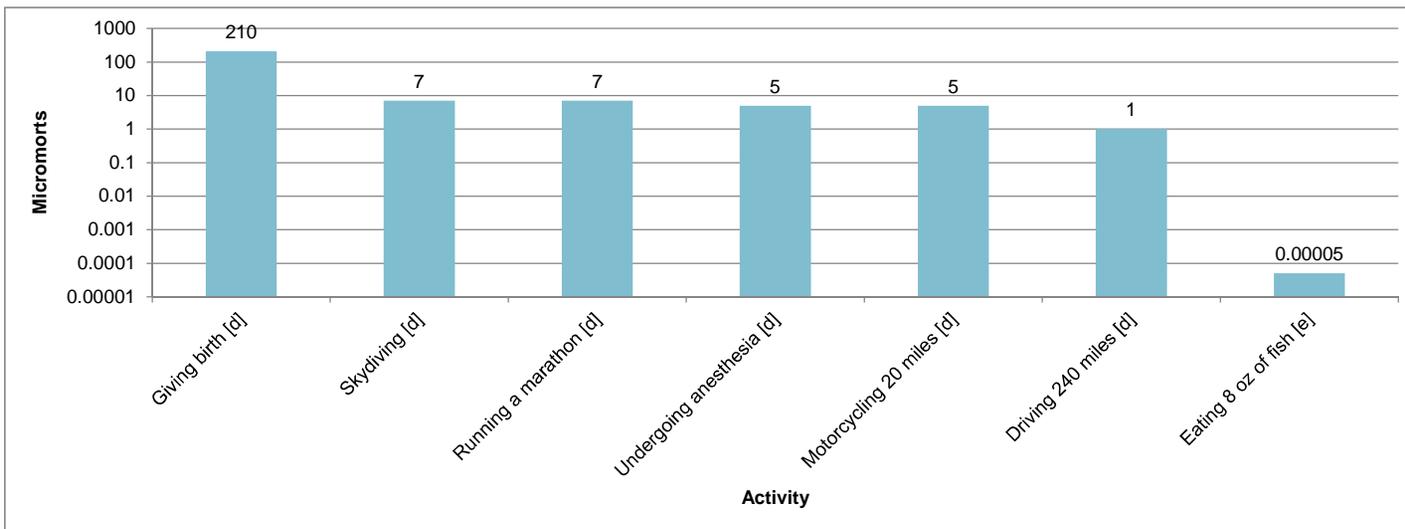
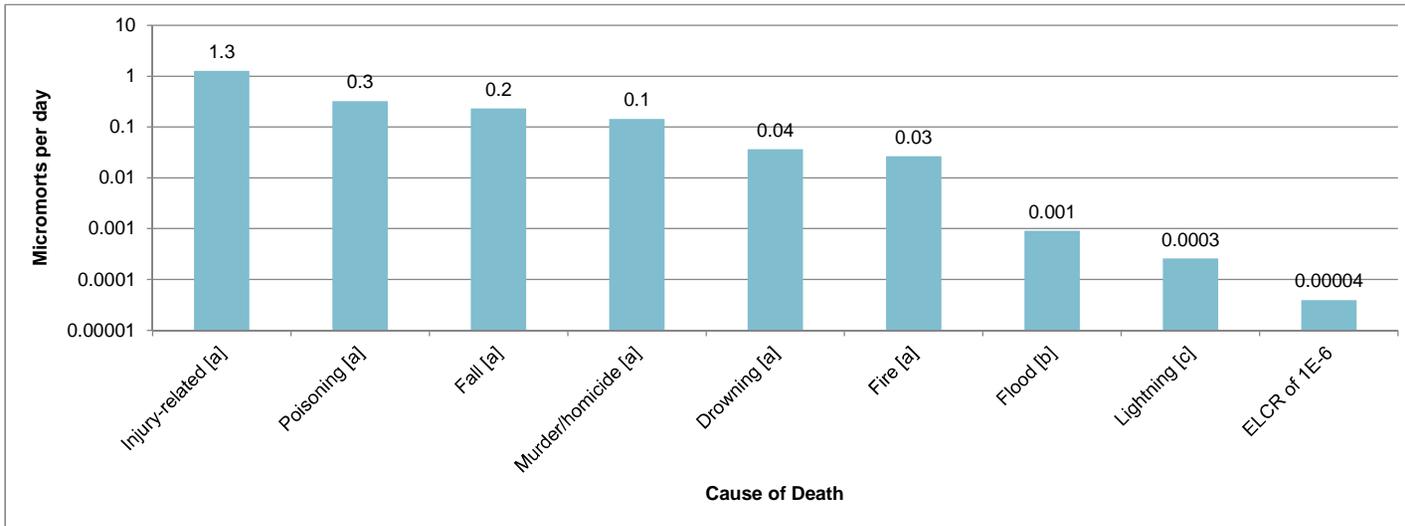
^f Lifetime hypothetical excess cancers and deaths estimated by multiplying the 2012 estimates by an assumed lifetime of 70 years.

^g Percent change from baseline estimated by dividing the number hypothetical excess cancers by the total number deaths estimated for the 70 year period.

^h Baseline Idaho population, cancer deaths, and total deaths based on Johnson and Carson (2013).



Figures



Notes:

[a] Murphy et al. (2013)

[b] NOAA (2015a)

[c] NOAA (2015b)

[d] Blastland and Spiegelhalter (2014)

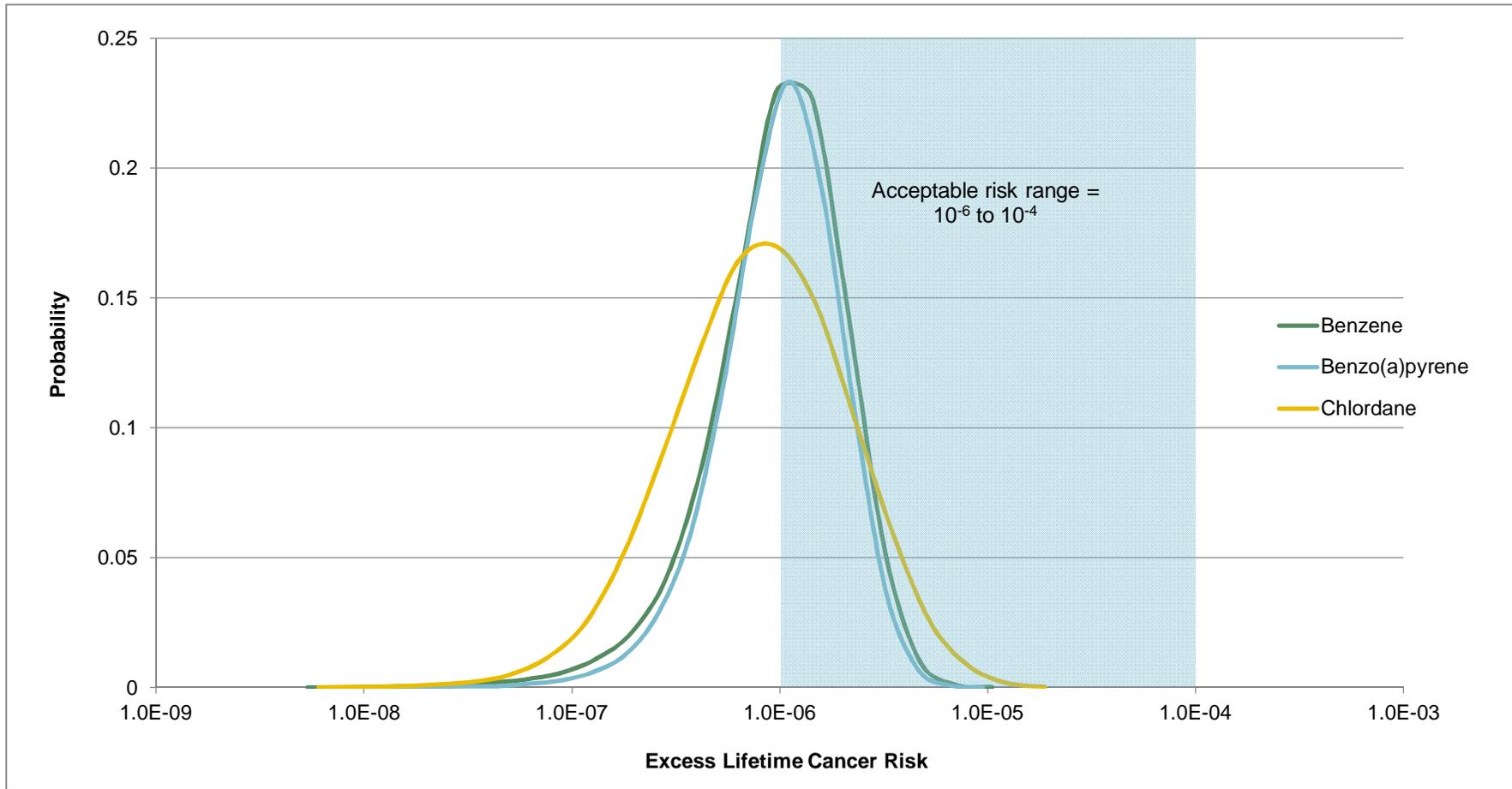
[e] Assuming organism-only AWQC are based on a fish consumption rate of 175 grams per day and risk level of 1×10^{-6} .

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COMMON RISKS EXPRESSED AS MICROMORTS



FIGURE
1



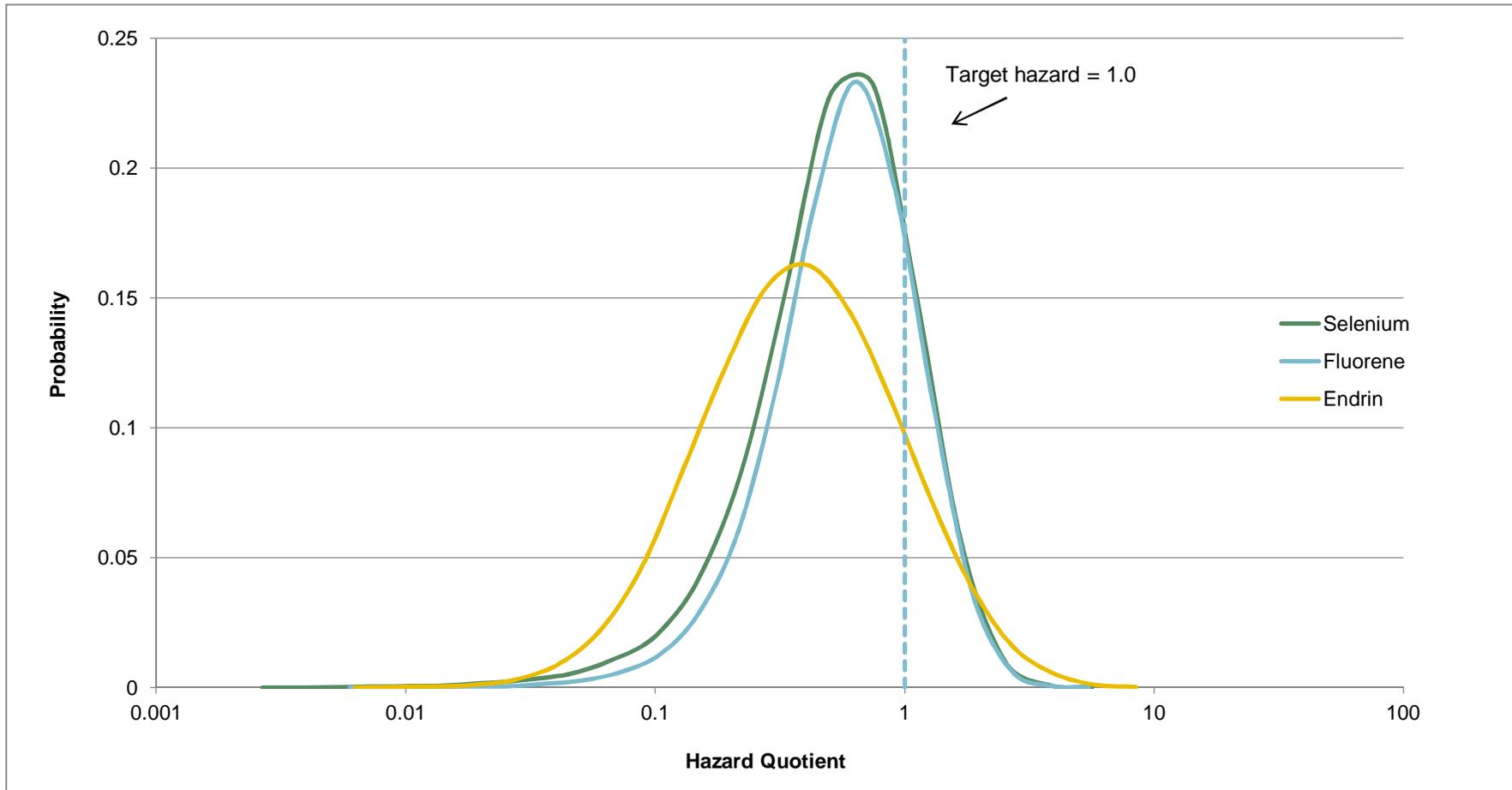
Chemical	AWQC (ug/L)	Excess Lifetime Cancer Risk			
		Mean	Median	90th Percentile	95th Percentile
Benzene	2.9	1.0E-06	8.7E-07	1.9E-06	2.3E-06
Benzo(a)pyrene	0.0053	1.0E-06	8.8E-07	1.8E-06	2.2E-06
Chlordane	0.0019	1.0E-06	6.6E-07	2.2E-06	3.0E-06

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BENZENE, BENZO(A)PYRENE, AND CHLORDANE EXCESS LIFETIME CANCER RISK



FIGURE 2



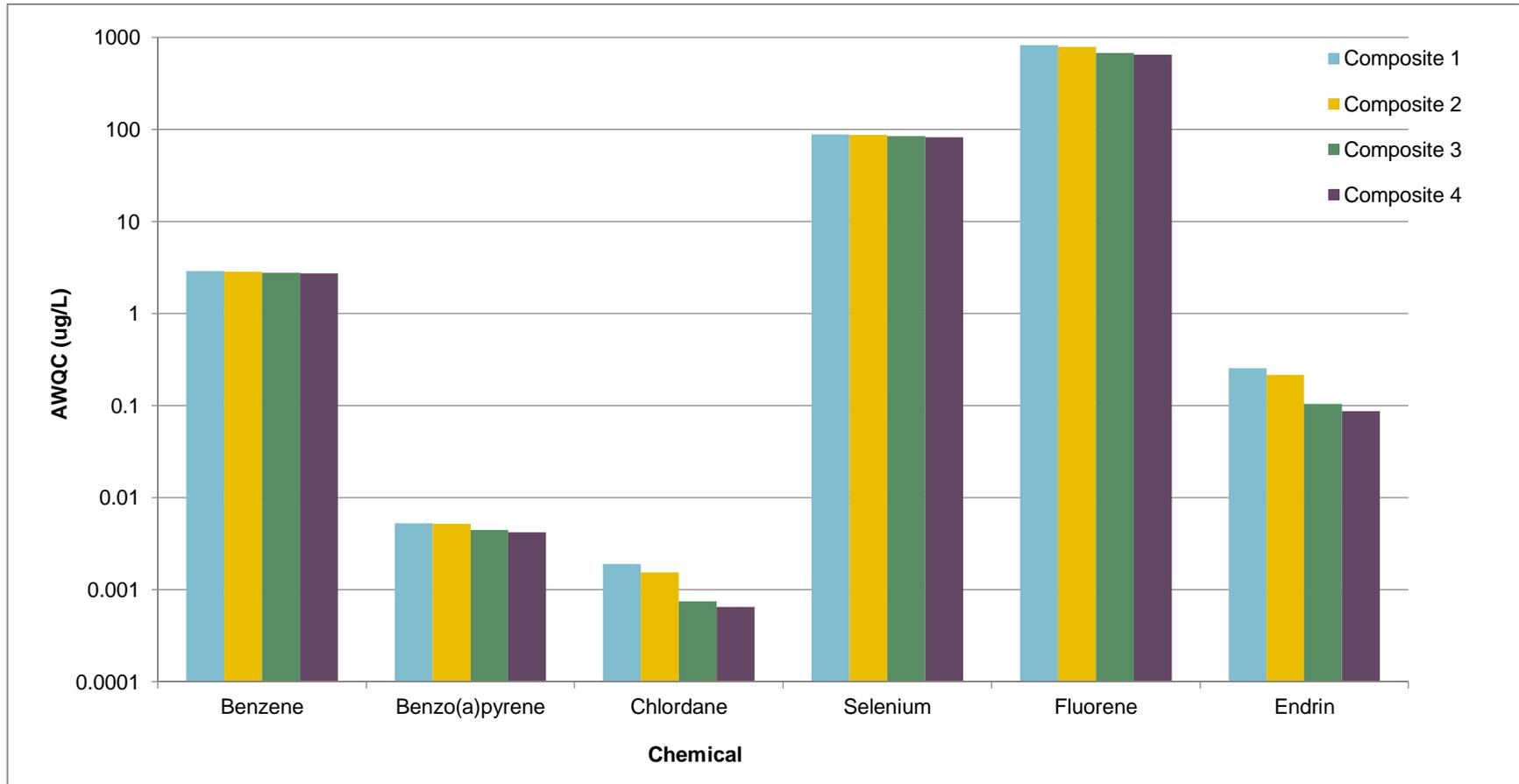
Chemical	AWQC (ug/L)	Hazard Quotient			
		Mean	Median	90th Percentile	95th Percentile
Selenium	88	0.54	0.46	1.0	1.2
Fluorene	820	0.58	0.50	1.0	1.3
Endrin	0.26	0.47	0.32	1.0	1.4

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SELENIUM, FLUORENE, AND ENDRIN HAZARD



FIGURE 3



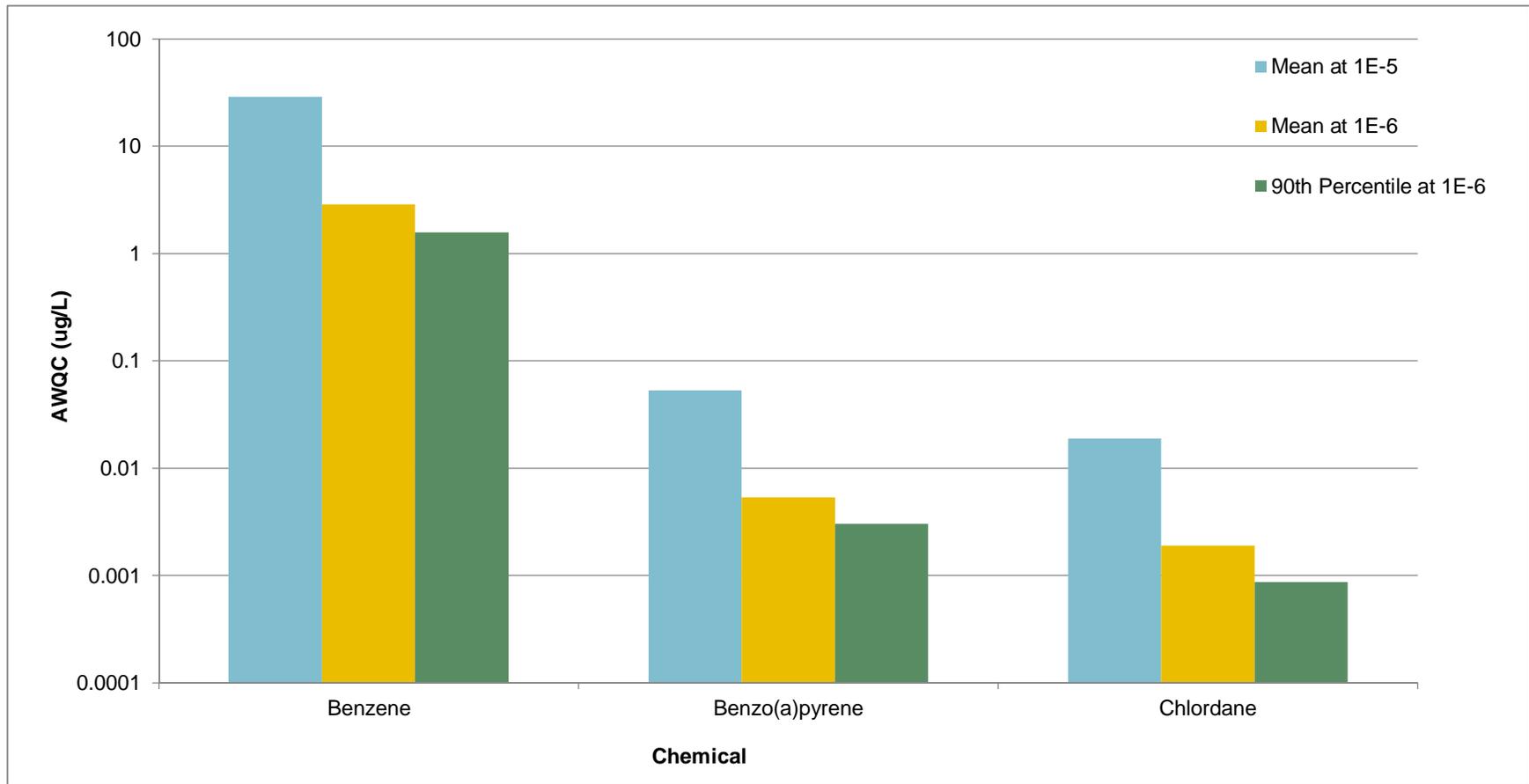
Chemical	AWQC (ug/L)			
	Composite 1	Composite 2	Composite 3	Composite 4
Benzene	2.9	2.9	2.8	2.8
Benzo(a)pyrene	0.0053	0.0052	0.0045	0.0043
Chlordane	0.0019	0.0016	0.00075	0.00066
Selenium	88	87	85	83
Fluorene	820	790	680	650
Endrin	0.26	0.22	0.10	0.087

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EFFECT OF FISH CONSUMPTION RATE ON AMBIENT WATER QUALITY CRITERIA



FIGURE 4



Chemical	AWQC (ug/L)		
	Mean at 1E-5	Mean at 1E-6	90th Percentile at 1E-6
Benzene	29	2.9	1.6
Benzo(a)pyrene	0.053	0.0053	0.0030
Chlordane	0.019	0.0019	0.00087

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EFFECT OF RISK MANAGEMENT CRITERIA ON AMBIENT WATER QUALITY CRITERIA



FIGURE 5