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Fish Consumption as a Driver of Risk-Management Decisions and Human Health–Based Water Quality Criteria

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Abstract—*The use and interpretation of fish consumption surveys and interviews, the application of fish consumption rates for sediment evaluation and cleanup, and the development of human health water quality criteria (HH WQC) are complex and interrelated issues. The present article focuses on these issues using examples from the United States, although the issues may be relevant for other countries. Some key considerations include the fact that there are many types of fish consumption surveys (e.g., 24-h recall surveys, food frequency questionnaires, creel surveys), and these surveys have different advantages and limitations. Identification of target populations for protection, identification of the species and quantities of fish consumed, and determination of bioaccumulation assumptions are important factors when developing water quality and sediment screening levels and standards. Accounting for the cultural importance of fish consumption for some populations is an even more complex element. Discussions about HH WQC often focus only on the fish consumption rate and may not have broad public input. Some states are trying to change this through extensive public participation efforts and use of probabilistic approaches to derive HH WQC. Finally, there are limits to what WQC can achieve. Solutions beyond the establishment of WQC that target toxics reduction from other sources may provide the greatest improvements to water quality and reductions in human health risks in the future. Environ Toxicol Chem 2015;34:2427–2436.* © 2015 SETAC

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Introduction

In the United States, there are 2 sets of water quality criteria (WQC): one for the protection of aquatic life and one for the protection of human health. Some other countries may regulate surface water differently. For example, the European Union has water quality standards for the drinking of surface water, for the protection of fish life/fisheries, and for water used for bathing and recreation. Human health WQC (HH WQC) in the United States are largely the product of assumptions about fish consumption rates, bioconcentration factors, surface water ingestion, and decisions about acceptable risk levels [1]. These criteria should also take into account regional differences in potentially affected populations. The physical and ecological conditions of the locations where people fish and specifically how best to characterize what they are eating (e.g., shellfish, salmon) are important factors in determining human exposures and should be considered in HH WQC development. Many groups (e.g., Native American tribes, recent immigrants) are very concerned about the ability of HH WQC to adequately ensure the safety of the fish that they catch and consume because fish are a central part of their diet and fishing is an important part of their cultural identity. These issues of protecting populations with high fish consumption rates may apply to WQC and other regulations in many countries besides the United States.

State WQC are required to be reviewed triennially. Deliberations regarding these issues are taking place now in many US states (e.g., Florida, Washington, Idaho, Alaska, Maine) as part of the development of HH WQC, and the outcomes will have tremendous impacts on the future management of surface waters, National Pollutant Discharge Elimination System permits, and storm water. Many of the same factors come into play in the management of contaminated sediment. Thus, what people eat and the exposure conditions of those organisms are critical to understanding exposures and determining appropriate site-specific cleanup levels.

At the November 2014 SETAC North America meeting in Vancouver, British Columbia, Canada, several experts involved in efforts to characterize fish consumption and/or apply fish consumption rates for the development of water quality and/or sediment cleanup standards presented talks during a session entitled Fish Consumption as a Driver of Risk Management Decisions and Human Health–Based Water Quality Criteria. The research and experiences of the authors of the present article (all of whom were presenters at the conference session) provide important perspectives in considering these issues. Their key findings are presented in the present article under 3 main topics: the collection of information on fish consumption, the application of fish consumption rates for sediment evaluation and cleanup, and considerations for developing HH WQC. These discussions are followed by a summary of common themes and issues.

Collecting Information on Fish Consumption

Human health WQC and sediment quality standards include assumptions about the uptake of chemicals by fish and the consumption of those fish by people. The fish consumption rates used to derive these regulations are usually based on dietary surveys of fish consumption. Use of the most appropriate survey methodology is critical for the development of reliable and accurate estimates of fish consumption. Methodological considerations include the type of survey tool and the survey approach used. There is particular interest in Alaska Natives, Native American tribes, anglers, and some immigrant groups because they often have rates of fish consumption many times higher than that of the general US population, making them more vulnerable to exposure from this pathway. The present section includes a comparison between 2 types of survey tools used with Alaska Natives, discussions of a recent creel-style survey of New Jersey anglers, and a community-based consumption survey in Oklahoma (USA) that involved the collection of biomarker information and personal consumption logs. These examples illustrate some of the complexities of gathering and interpreting data to characterize fish consumption (e.g., temporal variation, geographic variation, and variations among individuals and populations in sources of fish consumed and species of fish consumed).

Fish consumption survey tool considerations

The 2 basic survey instrument types used in most fish consumption studies conducted for use in regulatory decision making are food frequency questionnaires and 24-h recall surveys. Food frequency questionnaires cover a longer period of time and, thus, may reveal long-term intake patterns; but the accuracy of recall suffers over the longer period of time. Respondents are typically asked to reflect on frequency of consumption over the past year. This accounts, to some degree, for the variability of consumption patterns by season. Shorter recall periods may marginally improve accuracy but with a corresponding loss of the ability to characterize longer-term population variability. The 24-h recall is likely to more accurately reflect intake during the survey period (i.e., 24 h) but may miss daily variation on the individual level or seasonal variation on the population level (see *Fish Consumption Estimates in Regulatory Decision Making*).

The food frequency questionnaire and 24-h recall methods can result in substantially different estimates of fish consumption, as demonstrated in studies in which both survey instruments have been administered to the same population (Figure 1) [2,3]. The representativeness of a fish consumption estimate of long-term daily intake can be greatly improved by administering the survey 2 or more times over multiple seasons to capture individual and seasonal variation [4]. Nobmann et al. [5] administered multiple 24-h recall surveys over several seasons in 11 Alaska Native communities and measured total energy intake. The results demonstrated a large degree of variability both between seasons and for the same season in different years.

The focus of a study on 1 food type can also introduce error in the resulting fish consumption estimate. Surveying the intake of an individual food or a subset of the diet outside the context of the whole diet can result in an overestimation or underestimation of the usual intake of that food. For example, based on 24-h recall surveys conducted from 2002 to 2004, Johnson et al. [6] reported mean total energy intake (from total diet) for males and females among Native Alaskans in northwest Alaska of 2210 kcal, with 20% of calories (442 kcal) derived from subsistence foods and 80% (1768 kcal) from nonsubsistence foods. Data from surveys

Fish Consumption Estimates in Regulatory Decision Making

Fish consumption rate estimates used for regulatory decision making may exclude nonconsumers; anyone who did not eat any fish type on the day preceding a 24-h recall is treated as a nonconsumer and excluded. This tends to bias the dataset toward higher consumption rates, overestimating actual fish consumption in the full population. Although the 24-h recall does not capture day-to-day variability on the individual level, it may provide a more accurate account of the consumption rate for the population level than does the food frequency survey method, because recall is more accurate for a recent, short period [28]. A 24-h recall survey is used in the Continuing Survey of Food Intakes by Individuals conducted annually by the US Department of Agriculture, which is the basis of the fish consumption rates derived in the US Environmental Protection Agency (USEPA) study, Estimated Per Capita Fish Consumption in the United States [4]. The rates for the Continuing Survey of Food Intakes by Individuals are used for the derivation of current national ambient water quality criteria (WQC) for the protection of human health and for human health WQC in many states. Recently, researchers at the National Cancer Institute developed a statistical methodology to extrapolate long-term consumption patterns from short-term (24-h recall) survey data [29,30]. Using a similar statistical methodology to better account for episodic consumption, the USEPA has updated its default estimate of per capita fish consumption using data from the 2003 to 2010 National Health and Nutrition Examination Survey, which includes both 24-h recall and fish consumption frequency data [31]. The new default national consumption estimate was used in updates to human health–based ambient WQC for 94 chemicals [32].

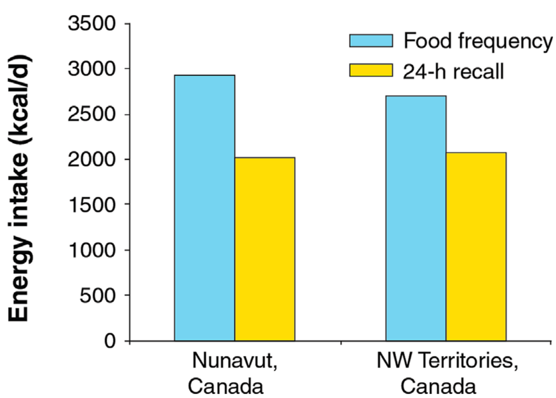

FIGURE 1: Comparison of total energy intake estimates derived from food frequency and 24-h recall surveys for 2 groups of Canadian fish consumers [2,3]. Three 24-h recall surveys conducted over multiple seasons; comparison of energy intake, same populations, same time period.

focused only on subsistence food intake in the same population [7], combined with nutrient content information for these foods from the US Department of Agriculture National Nutrient Database [8], give an estimate of daily energy intake from subsistence foods of 1260 kcal, nearly 3 times higher than the estimate from Johnson et al. [6]. Thus, confidence in a fish consumption estimate can be improved if information on intake of other dietary components is collected along with fish consumption to validate the fish consumption rates in the context of total energy intake.

Creel survey for a New Jersey Superfund site

Another approach to collect information about fish consumption is through a creel survey, where anglers are intercepted as they are fishing and asked about their catch and/or allow their catch to be examined. This approach provides high-quality information about what species are caught/harvested from a specific body of water and often other information about fishing and consumption behaviors.

Creel surveys provide valuable data for use in human health risk assessments of contaminated sediment sites where fish consumption is an important exposure pathway. For water bodies where fishing licenses are not required, the target population is diverse or unknown, or literacy or language barriers may be issues, creel surveys are the preferred method for collecting data on anglers' fishing and consuming behaviors [9,10]. From September 2011 to September 2012, a creel/angler survey was conducted in the industrialized and urbanized lower Passaic River study area, a Superfund site in New Jersey with an "eat none" consumption advisory. The survey was conducted to understand fishing patterns, catch and consumption behaviors, and demographics of anglers [11]. Boat- and land-based counts provided information on the spatial and temporal patterns of fishing over the survey year.

On-site interviews of 294 unique anglers provided detailed information on the fishing population, including demographics, trip-taking behaviors, distance traveled, probability of catching fish, percentage consuming lower Passaic River study area fish, species preferences, and cooking practices [11]. The lower Passaic River study area creel/angler survey found that most angling occurs in warm weather months and in the freshwater reach, the majority of anglers lived within 5 miles of the lower Passaic River study area, and the angler population reflected the diverse demographics of the study area. However, most consumers of lower Passaic River study area fish were male, and the average age was 40. Based on the unweighted responses of consuming anglers, species preferred included white perch, striped bass, catfish, carp, northern pike, largemouth and smallmouth bass, and American eel (Figure 2) [11]. Only 3 anglers reported crabbing in the study area.

Using different variance models to calculate statistical sampling weights, the size of the fishing population for the

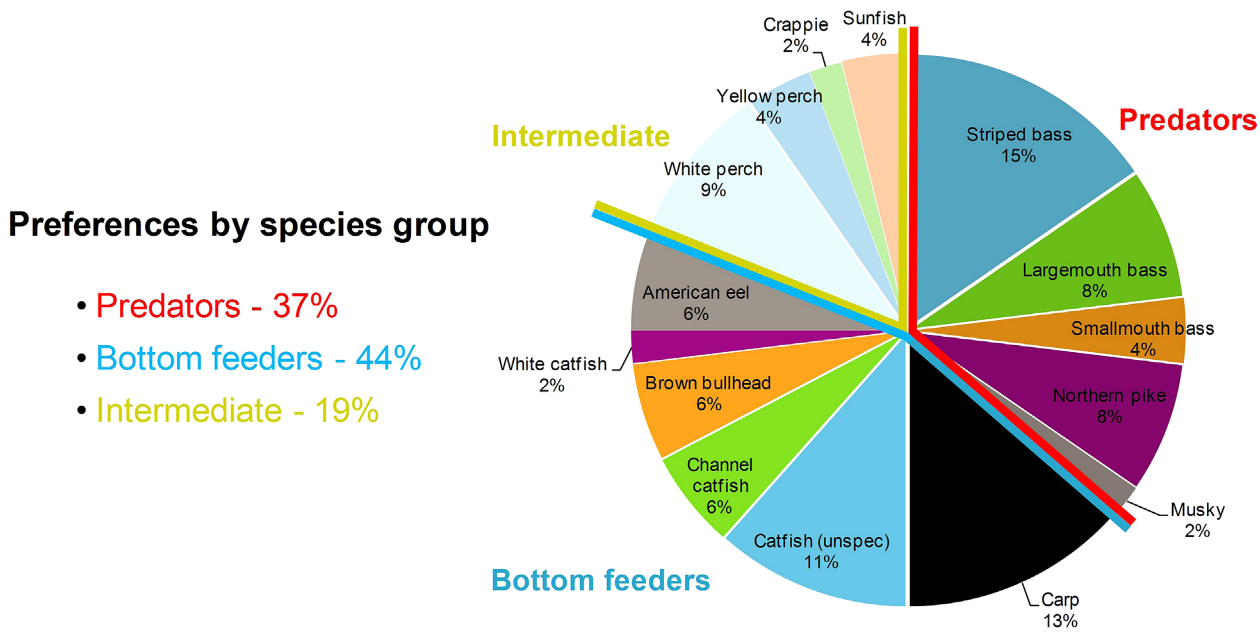

FIGURE 2: Species preferences of lower Passaic River consuming anglers [11].

lower Passaic River study area was estimated to be approximately 1500 to 3300 anglers. The size of the consuming angler population was estimated to be approximately 180 to 300 anglers. The fish consumption rate for the consuming angler population was estimated to range from 1 g/d to 30 g/d, with a mean of 5.7 g/d and a 90th percentile of 8.4 g/d. The creel/angler survey provided valuable site-specific data for use in a human health risk assessment of the lower Passaic River study area.

Community-based participatory research approach and the use of biomarkers in an Oklahoma fish consumption survey

Fish consumption survey information may be augmented by the collection of biomarker data from fish consumers, and the quality of the information collected may be improved by engaging community members. This combined survey approach was employed in a study conducted in Oklahoma, where a rural, low-income community provided insight into important considerations for designing and implementing food frequency questionnaires to assess fish consumption rates and chemical exposures at the community level. The Grand Lake Watershed Mercury Study was a community-based participatory research study that assessed the influence of fishing behaviors, local fish consumption, and season on mercury (Hg) exposure in freshwater anglers and their families who consumed fish from Grand Lake (OK, USA) [12]. To assess general and species-specific fish consumption, 151 participants were interviewed during 5 seasonal visits using a 90-d recall food frequency questionnaire; hair samples also were collected and tested as a biomarker of total Hg exposure.

The Grand Lake Watershed Mercury Study's [12] approach and results highlight several important considerations when assessing fish consumption. Although fish consumption rates are often assessed just once, significant seasonal variations in fishing behaviors, fish consumption rates, and hair Hg were found in the study (Figure 3). These differences may be even more pronounced in areas with highly contaminated local fish that are more frequently consumed during certain times of year, so single food frequency questionnaires may not accurately reflect integrated exposures over the course of a year. By asking about both portion size and number of portions at a typical meal, the study team was able to capture important variations in consumption patterns for calculating fish consumption rates.

The food frequency questionnaire included questions about both general fish consumption and consumption of individual species of local and saltwater fish to quantify fish consumption rates and better characterize Hg exposure. In this way, the study team was able to account for overestimation of general fish consumption that often occurs when summing the consumption of individual species [13,14]. To improve recall accuracy, participants were asked to fill out a fish consumption log between visits; this is similar to a 24-h recall in that respondents report only on what they consume in a specific day (rather than reporting on consumption in past days). The use of these logs significantly reduced discrepancies between species-specific and general fish consumption rates, particularly for participants with very low or high fish consumption rates.

By involving and engaging community members throughout the design and implementation of the entire study, the study team was able to draw on local knowledge, strengthen collaboration, establish trust, and build capacity within the community. The study team was composed of researchers and local environmental activists, as well as members of a community advisory board; multiethnic focus groups, including members of local Native American tribes, provided

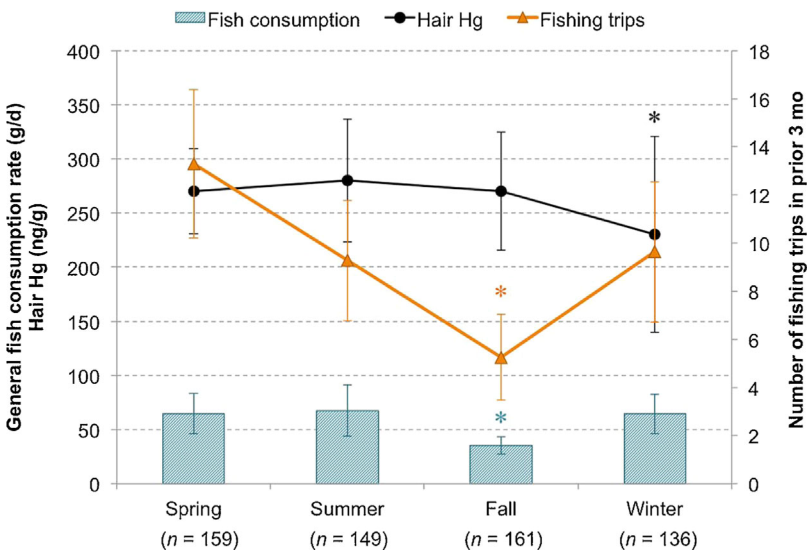

FIGURE 3: Seasonal trends in fish consumption rates, hair Hg, and number of fishing trips over 3 mo for an Oklahoma (USA) community [12].

feedback on the food frequency questionnaire to improve its relevance to the local community. Recruiting both anglers, who were primarily male, and their spouses revealed interesting exposure patterns between genders and within households. The study team found that although fish consumption rates of husbands and wives were significantly correlated ($p < 0.0001$), women generally had lower dietary Hg exposure relative to men despite higher fish consumption rates per unit body weight. Furthermore, women who lived with an angler ate more fish and had higher hair Hg than women who did not ($p < 0.001$).

The Oklahoma fish consumption study indicates the utility of community-based participatory research and biomarkers in conjunction with fish consumption surveys (including both food frequency questionnaires and consumption logs) to better understand fish consumption behaviors. The role of biomarker data and cultural context information (as from community-based participatory research studies) in developing fish consumption rates for use in regulatory applications has not yet been established. Currently, the numeric fish consumption rate is generally all that is applied in the development of water and sediment criteria for the protection of human health and in sediment cleanup decisions.

Application of Fish Consumption Rates for Sediment Evaluation and Cleanup

As discussed, there are many approaches for evaluating fish consumption, including food frequency questionnaires, 24-h recalls, food diaries, biomarkers, and creel studies. Fish consumption rates derived from these types of studies are relevant in the screening of sediment chemical concentrations for potential human health–associated risks as well as for the consideration of cleanup options. The present section discusses the application of sediment quality objectives to screen sediment in California (USA) and the protectiveness of sediment management standards for Native American fish consumers in Washington State (USA).

Application of sediment quality objectives for California

The state of California recently established a sediment quality objective to protect human health from the consumption of fish exposed to sediment-associated contaminants. The narrative sediment quality objective establishes that "pollutants shall not be present in sediments at levels that will bioaccumulate in aquatic life to levels that are harmful to human health" [15]. A draft framework has been developed to assess whether sediment at a site or water body meets the sediment quality objective. The framework follows a multitiered approach [16] using 2 indicators: consumption risk to humans and sediment linkage. Only the first 2 tiers (Tiers 1 and 2) of the framework's 3 tiers were investigated.

A Tier 1 screening is used to determine if sediment in a water body poses a potential human health hazard and warrants further evaluation. It is an optional but recommended step for prescreening a site using existing data. The framework recommends that, when available, both tissue and sediment data be used for this analysis. Tissue screening thresholds based on a specified fish consumption rate and acceptable risk level are compared with measured tissue contaminant concentrations. Similarly, measured sediment contaminant concentrations are compared with site-specific sediment screening thresholds. When tissue and/or sediment concentrations do not exceed the thresholds, the sediment is not considered to be degraded, and no further assessment is needed. When tissue and/or sediment concentrations exceed the thresholds, the framework recommends further evaluation using Tier 2 screening.

A Tier 2 screening is used to determine whether human consumers are at risk from bioaccumulated contaminants and the degree to which the bioaccumulation is linked to sediment contamination. Tier 2 values are calculated using bioaccumulation models and Monte Carlo simulations. The consumption rate used for this Tier 2 screening (32 g/d) was based on consumption rates corresponding to 1 meal per week. This is the rate used by the Office of Environmental Health Hazard Assessment to develop fish contamination goals [17]. Tier 2 is the actual site assessment and should be conducted with both tissue and sediment chemistry data; it also requires site-specific information to assess both human risk and the link to sediment contaminants. A Tier 3 screening (not conducted in the present study) is performed to address unique situations and/or improve precision and accuracy. For example, a Tier 3 screening can be used to evaluate different risk-related assumptions, incorporate additional spatial and temporal factors, or evaluate specific subareas and contaminant gradients.

A study was conducted to investigate the outcome of applying Tiers 1 and 2 of the draft framework to data from California coastal estuaries, harbors, and embayments to evaluate sediment quality impacts from chlordanes, DDTs, polychlorinated biphenyls (PCBs), and dieldrin. The main objectives of the study were to evaluate sediment quality in California embayments and to identify areas of improvement for the draft framework. To meet these objectives, the study analyzed fish tissue and sediment chemistry data from 6 California embayments. The compiled information was screened through several steps to obtain high-quality data (e.g., from appropriate locations and species, having acceptable detection limits).

Tier 1 results indicated that all of the investigated sites posed potential human health risks associated with the consumption of seafood for PCBs and some of the sites for DDT and chlordane. The results also showed that during the Tier 1 analysis the potential exceedances for chlordane and DDT were usually based on sediment screening, not tissue (Table 1). For evaluation purposes, a Tier 2 analysis was carried out for all sites and analytes, even those for which there were no Tier 1 threshold exceedances.

Tier 2 assessment results indicated that sediment concentrations of DDTs, dieldrin, and chlordanes were unlikely to cause unacceptable human health risks; therefore, the sites were assessed as unimpacted or likely unimpacted. However, sediment PCBs were assessed under Tier 2 as being linked to unacceptable health risk in some areas, including Los Angeles and Long Beach Harbors, San Gabriel River Estuary, and San Diego Bay.

The study also showed that the Tier 1 assessment accurately predicted Tier 2 results on many occasions (74% of the time). When Tier 1 results did not match Tier 2 results, Tier 1 flagged the site as potentially impacted because of the conservative nature of the screening process. The study also demonstrated that assessment outcomes can be strongly affected by factors such as seafood species choice. For example, the San Francisco Bay Tier 2 analysis was conducted by combining the chemistry information for 4 different fish species; however, if the analysis would have been conducted with only 1 fish species, the results could change from likely unimpacted to clearly impacted, depending on the species choice. This occurred because 2 of the species (California halibut and white croaker) had a higher sediment linkage than the other 2 species evaluated. The results will help to refine the draft framework and produce a standardized assessment method for use in the identification of California water bodies of concern and to determine permit compliance and inform management actions.

Use of fish consumption rate as it relates to a Washington State tribal community

In Washington State, there are 29 federally recognized tribes [18]. The results of many surveys have indicated that tribal members consume fish and shellfish at much higher rates than the general US population. Per treaty-reserved rights and as affirmed by the Boldt Decision [19], tribes retain rights to half the salmon catch in Washington State. One of the

Table 1. Tier 1 sediment screening analysis results by site for California (USA) embayments

	Tier 1 site screening											
	Chlordanes			DDTs			Dieldrin			PCBs		
Site	Tiss	Sed	Final	Tiss	Sed	Final	Tiss	Sed	Final	Tiss	Sed	Final
San Francisco Bay	U	U	U	U	U	U	U	U	U	P	P	P
Los Angeles and Long Beach Harbors	NA	P	P	U	P	P	NA	U	U	P	P	P
San Gabriel River Estuary	U	P	P	U	U	U	U	U	U	P	P	P
Newport Bay	U	U	U	U	P	P	U	U	U	U	P	P
Mission Bay	U	U	U	U	U	U	U	U	U	P	P	P
San Diego Bay	U	U	U	U	U	U	U	U	U	P	P	P

PCB = polychlorinated biphenyl; Tiss = tissue; Sed = sediment; Final = final assessment; U = unimpacted (tissue and/or sediment concentration thresholds were not exceeded); P = proceed to Tier 2 analysis (tissue and/or sediment concentration thresholds were exceeded); NA = not available.

greatest concerns and challenges for tribal, federal, and state governments is how to address human health risk from contaminants in Native American traditional foods, such as fish and shellfish. Fish consumption advisories have frequently proven to be an ineffective tool for risk management in tribal communities. These advisories do not take into account cultural significance, treaty rights, economics, nutrition, lack of access to other food sources, and other social factors for tribal members. Tribal lifeways and the well being of tribal community health have been strongly associated with the health of natural resources [20–24]. Chemical contamination has been shown to adversely impact these resources; therefore, tribes should be integrally involved in any decision regarding the current and future health of these treaty resources.

Because of the high rates of fish and shellfish consumption by tribal members, a water quality or sediment standard developed using these consumption rates can create a low risk–based standard. To resolve this, the revised Washington Sediment Management Standards [25] incorporate a framework that selects the highest of risk-based concentrations, background concentrations, or practical quantitation limit as the standard for regulating sediment cleanups. However, there is no plan in place for how these sediment standards will be protective of human health for tribal members or how contaminant concentrations in sediment will eventually reach human health–based goals in fish and shellfish tissue. To reach these goals, an overall toxics reduction strategy that addresses additive exposures as well as non–point sources needs to be implemented. Also, governments need to develop a path forward that will provide 5-yr reviews and technological advances, background concentrations, and practical quantitation limit standards that can eventually be lowered to meet human health risk–based goals.

Considerations for Developing HH WQC

In addition to their applications for sediment evaluation and remediation decision-making, fish consumption rates are used in the calculation of HH WQC in the United States. A state's HH WQC are only applicable to the waters of that state, so there is particular interest in the consumption of fish whose body burden might come from state waters (e.g., inland waters such as lakes and rivers and some nearshore waters). The US Environmental Protection Agency (USEPA) and several states are currently revising HH WQC while trying to take into account new information on fish consumption rates from studies such as those described in the present article. The present section addresses the incorporation of the new fish consumption rates and issues related to the calculation of HH WQC (i.e., probabilistic vs deterministic), efforts to expand the role of public participation in the process, and limits to what can be achieved through the application of more stringent WQC.

Probabilistic development of HH WQC

Human health WQC are a function of 3 elements: a health protection target, substance toxicity, and an exposure scenario. Very often, the derivation of an HH WQC focuses on 1 or 2 parameters within an element (e.g., fish consumption rate within the exposure scenario) when, in fact, the level of protection afforded by an HH WQC is a function of all of the assumptions in all of the elements. When using the traditional deterministic approach to derive HH WQC, point estimates are selected to represent toxicity and exposure parameters, such as body weight, drinking water intake, and fish consumption rate. Typically, high-end or maximum values are chosen to represent most of these parameters, which, when combined, lead to unlikely exposure scenarios and overestimates of potential risk. The phenomenon of a combination of high-end assumptions leading to an overestimate of risk is known as "compounded conservatism" [26].

In contrast to the deterministic approach, the probabilistic approach accounts for variability within populations by allowing 1 or more of the exposure parameters to be defined as distributions of potential values (i.e., probability density functions). The result is a distribution of potential risk representing a range of possible exposures. The probabilistic approach, therefore, provides explicit estimates of potential risk for different segments of the population, including both the typical members of the population (e.g., arithmetic mean or 50th percentile) and individuals with high-end exposures (e.g., the 90th or 95th percentile). As long as 1 or more of the exposure parameters used to estimate risk is defined as a distribution of values, the outcome will be a distribution of estimated risks.

To derive HH WQC from the information developed using the probabilistic approach, regulators need to determine the level of protection afforded to a given segment of the population, recognizing that different segments of the population by definition will always have varying levels of potential risk (Figure 4). Consequently, the probabilistic approach explicitly separates risk assessment from risk management, greatly improving the transparency of the HH WQC-setting process. The resultant HH WQC depend on both the inputs to the probabilistic approach and the risk-management decisions made when interpreting the resulting distributions of risk; therefore, probabilistically derived HH WQC can be more or less stringent than existing deterministically derived HH WQC. Florida has developed draft HH WQC based on a probabilistic derivation process [27].

Public participation and HH WQC development in Washington State

Washington State has recently engaged in a very public process for revising HH WQC. Development of HH WQC includes many decisions based on science, science policy, and risk management. This process is sometimes referred to by observers as the "fish consumption" question/issue, even

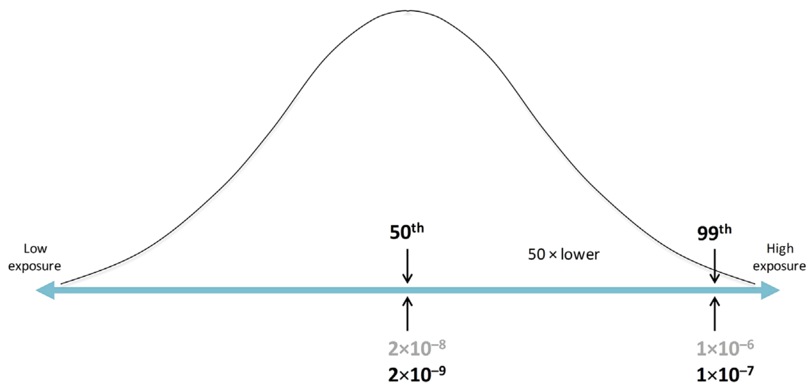

FIGURE 4: Hypothetical risk distribution with 99th percentile protected at 1×10^{-6} leads to the 50th percentile being protected at 2×10^{-8}. Conservatism in the remaining deterministic assumptions likely results in an actual risk to the 99th percentile of less than 1×10^{-7}.

though there are many other considerations. The first step in supporting this decision-making process is to differentiate the issues and clearly state the questions that need answers (e.g., What cancer risk slope factor should be included in the equations?). Washington State used an approach of intense public education in the first stage of its rule-making process to separate the science issues from the risk-management issues and to develop clear risk-management questions. A main goal of this process was to provide enough information to support participants' understanding of the difference between science and risk management and the role that science and feasibility could play in supporting risk-management decisions.

Numerous public daylong seminar-type webinars/meetings (called "policy forums") were held over a year to educate and prompt public discussion. This immersion approach was chosen because of the highly charged emotional environment already present prior to the beginning of the criteria-adoption process, the divergent views on many of the equation inputs (e.g., fish consumption rates), the complexity of the equations used to calculate the criteria, and the expectations associated with new criteria. During the public education portion of the process, the questions and concepts discussed by the participants generally became more complex and sophisticated as their participation in the public process continued.

An outcome of the process was a list of discrete science policy and risk-management questions that needed specific decisions to proceed with the calculation of criteria values. This parsing-out process clarified and focused attention on the important risk-management decisions inherent in human health criteria development. One issue that became clear early on was the expectation from some participants that the "fish consumption rate is a science decision." The risk-management and policy issues that emerged included how to account for fish versus shellfish, how to account for salmon consumption (which is sometimes included in fish consumption rates for HH WQC and sometimes not), identification of the population for the focus of the fish consumption rate in the HH WQC equations, and what statistic (or distribution) represents the population of focus. Public discussion and feedback on these issues were important as the state considered development of HH WQC for Washington State.

Limits to what WQC can achieve

In Idaho, the process for revising HH WQC is underway. This has led to contemplation of what can and cannot be achieved through HH WQC. Expectations that more stringent WQC will lead to significant pollution reductions and consequent reductions in risk from the ingestion of surface water and fish/shellfish may be unreasonable. Many people perceive a direct 1:1 relation between more stringent criteria and decreased risk. Although that is theoretically possible, the anticipated reduction in risk is likely not to be fully realized and likely to be less than proportional. There are several reasons for this.

First, although the consumption of fish is a primary source of human exposure to highly bioaccumulative substances such as methylmercury and PCBs, the levels of these chemicals present in fish are somewhat disconnected from their WQC. This can be said for banned (i.e., legacy) contaminants such as PCBs. It is also true for pesticides, some of which are legacy but all of which are largely non–point source and so not controlled by water quality–based effluent limitations. Although methylmercury exposure is primarily through the consumption of fish, the vast majority of environmental Hg contamination is the result of air deposition and, thus, not controlled through WQC. In addition, because WQC are only applicable to state waters, they cannot influence chemical concentrations in imported seafood. Second, where water quality is better than current criteria, adopting lower WQC will produce less improvement than that calculated from a change in criteria. This is the case for many waters. Third, there are many chemicals in water for which there are no criteria. Fourth, although fish consumption may be the most significant pathway for some chemicals, such as Hg and PCBs, for high fish consumers, human exposure to many toxicants of human health concern is not attributable to the consumption of water and fish. Exposure to these chemicals (e.g., polybrominated diphenyl ethers) comes largely from other sources; the reduction in risk as a result of lower WQC will be small, perhaps very small. Fifth, with some harmful materials, such as Hg and arsenic, new criteria levels may be such that naturally occurring levels will exceed criteria. It will be impossible to meet the criteria in this case and thus realize the expected improvement in water quality and reduction in risk to health. Furthermore, the increase in Hg above natural background is largely attributable to deposition from air sources, sources not regulated by WQC. Finally, treatment and measurement limitations may also limit the effectiveness of much lower criteria. Other regulatory mechanisms, such as direct toxics reduction efforts aimed at reducing the use of toxic substances, are likely to be more effective than the treatment of effluent in achieving the reductions in exposure.

Summary and Conclusions

There are numerous issues associated with the collection and interpretation of fish consumption information and the application of fish consumption rates to set screening and cleanup goals for sediment and to develop HH WQC. Key considerations discussed in the present article are summarized below.

Characterizing fish consumption is complex

Many populations consume much more fish than the general US population, and there are questions about whether the health of these groups is adequately protected. A first step is to better characterize fish consumption. There are numerous challenges related to how people report their consumption and how that information is interpreted; these challenges relate to the species and quantities of fish consumed, the source of the fish, and temporal (e.g., seasonal) changes in consumption. Multiple tools have been developed to assess consumption (24-h recall, creel studies, food frequency questionnaires); each has benefits and limitations. More recent approaches that rely on the use of biomarkers (e.g., hair and nail samples) have been employed to further the understanding of fish consumption and related exposures.

Identification of target populations for protection, the species of fish consumed, and bioaccumulation assumptions are all important issues in developing criteria

Water quality and sediment screening levels and standards can be helpful tools in evaluating and prioritizing cleanups and in environmental enforcement. Assumptions regarding the species consumed and bioaccumulation are critical in developing these sediment and water quality screening levels and standards. Other important issues to consider include whether standards are protective of all consumers, including tribes whose members may consume fish at higher rates than the general population.

WQC discussions often focus only on the fish consumption rate and may not have broad public participation

The fish consumption rate is just one of many factors involved in the calculation of HH WQC. The criteria can also take into account distributions for other input parameters (i.e., using a probabilistic approach). Defining the level of protection for the population of concern is an important part of the HH WQC process. Questions regarding fish consumption and the protection of human health are of broad interest to anglers, environmental groups, tribal governments, individuals who eat fish, and entities that will be affected by water and sediment regulations. The role of treaty rights for tribes and the cultural value of fish consumption are unique and special for each group. Discussions about HH WQC tend to focus on numeric fish consumption rates, whereas tribes and some other consumer groups may be more concerned with preservation of the cultural values associated with fish consumption. Engaging interested parties in a way that includes educational components promotes discussion and allows a more broad and sophisticated level of participation.

Beyond WQC

Great improvements in water quality have been made over the past several decades as a result of the Clean Water Act. However, WQC apply primarily to wastewater and storm water dischargers, and not all problem pollutants have criteria. Analytical capabilities are improving, but approved methods for many important chemicals, such as PCBs, cannot determine compliance with many existing or proposed WQC (i.e., detection limits are higher than the criteria). Furthermore, the most important sources of PCBs and Hg (the chemicals that lead to most fish consumption advisories) are non–point sources or global sources that are not regulated under the Clean Water Act. Solutions beyond WQC that target toxic reduction from other sources may provide the greatest improvements to water quality and reductions in human health risks in the future.

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Data availability

The data presented are publicly available using the references cited in the document.

REFERENCES

[1] Tatum V, Wiegand P, Stratton S, Louch J, Ebert E, Anderson P. 2014. Derivation of human health-based ambient water quality criteria: A consideration of conservatism and protectiveness goals. *Integr Environ Assess Manag* 11:298–305.

[2] Pakseresht M, Sharma S. 2010. Validation of a culturally appropriate quantitative food frequency questionnaire for Inuvialuit population in the Northwest Territories, Canada. *J Hum Nutr Diet* 23(Suppl. 1):75–82.

[3] Pakseresht M, Sharma S. 2010. Validation of a quantitative food frequency questionnaire for Inuit population in Nunavut, Canada. *J Hum Nutr Diet* 23(Suppl. 1):67–74.

[4] US Environmental Protection Agency. 2002. Estimated per capita fish consumption in the United States. EPA 821/C-02/003. Washington, DC.

[5] Nobmann ED, Byers T, Lanier AP, Hankin JH, Jackson MY. 1992. The diet of Alaska Native adults: 1987–1988. *Am J Clin Nutr* 55:1024–1032.

[6] Johnson JS, Nobmann ED, Asay E, Lanier AP. 2009. Dietary intake of Alaska Native people in two regions and implications for health: The Alaska Native dietary and subsistence food assessment project. *Int J Circumpolar Health* 68:109–122.

[7] Alaska Department of Fish and Game, Division of Subsistence. 2000. Community profile database technical documentation. Juneau, AK, USA.

[8] US Department of Agriculture. 2011. *USDA National Nutrient Database for Standard Reference*. [cited 2014 November 3]. Available from: http://ndb.nal.usda.gov/

[9] US Environmental Protection Agency. 1992. Consumption surveys for fish and shellfish: A review and analysis of survey methods. EPA 822/R-92/001. Washington, DC.

[10] US Environmental Protection Agency. 1998. EPA guidance for conducting fish and wildlife consumption surveys. EPA 823/B-98/007. Washington, DC.

[11] AECOM. 2014. Analysis of catch preferences of lower Passaic River study area anglers. Chelmsford, MA, USA.

[12] Dong Z, Jim RC, Hatley EL, Backus ASN, Shine JP, Spengler JD, Schaider LA. 2015. A longitudinal study of mercury exposure associated with consumption of freshwater fish from a reservoir in rural south central USA. *Environ Res* 136:155–162.

[13] Bjornberg KA, Vahtera M, Grawe KP, Berglund M. 2005. Methyl mercury exposure in Swedish women with high fish consumption. *Sci Total Environ* 341:45–52.

[14] Lincoln RA, Shine JP, Chesney EJ, Vorhees DJ, Grandjean P, Senn DB. 2011. Fish consumption and mercury exposure among Louisiana recreational anglers. *Environ Health Perspect* 119:245–251.

[15] California State Water Resources Control Board. 2009. Water quality control plan for enclosed bays and estuaries—Part 1. Sediment quality. California Environmental Protection Agency, Sacramento, CA, USA.

[16] Greenfield BK, Melwani AR, Bay SM. 2015. A tiered assessment framework to evaluate human health risk of contaminated sediment. *Integr Environ Assess Manag* 11:459–473.

[17] Klasing S, Brodberg R. 2008. Development of fish contaminant goals and advisory tissue levels for common contaminants in sport fish: Chlordane, DDTs, dieldrin, methylmercury, PCBs, selenium, and toxaphene. Final report. Office of Environmental Health Hazard Assessment, Oakland, CA, USA.

[18] Governor's Office of Indian Affairs, Washington State. 2015. Frequently asked questions. [cited 2015 February 4]. Available from: http://www.goia.wa.gov/FAQ/FAQ.htm

[19] Boldt GH. 1974. *The Boldt Decision: United States vs. the State of Washington*. 384 F. Supp. 312 (1974 U.S. Dist. LEXIS 12291).

[20] Berkes F. 1999. *Sacred Ecology: Traditional Ecological Knowledge and Resource Management*. Taylor and Francis, Philadelphia, PA, USA.

[21] Harris S, Harper BL. 2000. Using eco-cultural dependency webs in risk assessment and characterization of risks to tribal health and cultures. *Environ Sci Pollut Res* 2(special issue):91–100.

[22] Arquette M, Cole M, Cook K, LaFrance B, Peters M, Ransom J, Sargent E, Smoke V, Stairs A. 2002. Holistic risk-based environmental decision making: A native perspective. *Environ Health Perspect* 110:259–264.

[23] Donatuto J, Satterfield TA, Gregory R. 2011. Poisoning the body to nourish the soul: Prioritizing health risks and impacts in a Native American community. *Health Risk Soc* 13:103–127.

[24] Wolfley J. 1998. Ecological risk assessment and management: Their failure to value indigenous traditional ecological knowledge and protect tribal homelands. *Am Indian Cult Res J* 22:151–169.

[25] Washington State Department of Ecology. 2013. Sediment management standards. Chapter 173–204 WAC. Toxics Cleanup Program. Olympia, WA, USA.

[26] Nichols AL, Zeckhauser RJ. 1986. The perils of prudence: How conservative risk assessments distort regulation. *Regulation* November/December:13–24.

[27] Florida Department of Environmental Protection. 2013. Technical support document: Derivation of human health-based criteria and risk assessment. Draft. Tallahassee, FL, USA.

[28] Witschi JC. 1990. Short-term dietary recall and recording methods. In Willett W, ed, *Nutritional Epidemiology: Monographs in Epidemiology and Biostatistics*. Oxford University Press, New York, NY, USA, pp 52–68.

[29] Tooze JA, Midthune D, Dodd KW, Freedman LS, Krebs-Smith SM, Subar AF, Guenther PM, Carroll RJ, Kipnis V. 2006. A new statistical method for estimating the usual intake of episodically consumed foods with application to their distribution. *J Am Diet Assoc* 106:1576–1587.

[30] Dodd KW, Guenther PM, Freedman LS, Subar AF, Kipnis V, Midthune D, Tooze JA, Krebs-Smith SM. 2006. Statistical methods for estimating usual intake of nutrients and foods: A review of the theory. *J Am Diet Assoc* 106:1640–1650.

[31] US Environmental Protection Agency. 2014. Estimated fish consumption rates for the US population and selected subpopulations (NHANES 2003-2010). EPA 820/R-14/002. Washington, DC.

[32] US Environmental Protection Agency. 2015. Final 2015 Updated National Recommended Human Health Criteria. Available from http://water.epa.gov/scitech/swguidance/standards/criteria/current/index.cfm#hhtable