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Framework for Selecting and Using Tribal Fish and Shellfish Consumption Rates for Risk-Based Decision Making at CERCLA and RCRA Cleanup Sites in Puget Sound and the Strait of Georgia

Working Document

To Be Applied in Consultation with Tribal Governments
on a Site-specific Basis

Revision 00

Office of Environmental Cleanup
Office of Air, Waste and Toxics
Office of Environmental Assessment

This Framework is not intended to replace government-to-government consultation on specific sites. EPA's release of the Framework does not imply concurrence by the Tribes. Nothing in this Framework will limit, modify, or change Tribal treaty rights.

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Executive Summary

This document presents a conceptual Framework for selecting and using Tribal fish and shellfish consumption rates for purposes of estimating site-related risks at U.S. Environmental Protection Agency (EPA) hazardous waste cleanup sites in Puget Sound and the portion of the Strait of Georgia that is within the United States. It is specifically intended for use at sites that are addressed through the Resource Conservation and Recovery Act (RCRA) and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA, also known as Superfund.) EPA will consult with Tribes on site-specific exposure assumptions and cleanup decisions at each Superfund and RCRA site within a Tribal fishing area or on Tribal land. The Framework's function is to assist EPA Region 10 staff in managing RCRA and CERCLA cleanups in consideration of information that reflects Tribal exposures and concerns.

The Framework is not intended to replace government-to-government consultation on specific sites. EPA's release of the Framework does not imply concurrence by the Tribes. Nothing in this Framework will limit, modify, or change Tribal treaty rights.

One of the numerous pieces of information needed to estimate potential human health risks due to chemical contamination at cleanup sites is exposure to site-related contamination via consumption of fish and shellfish. Consumption of locally harvested fish and shellfish by American Indians is likely to be higher than it is for the general U.S. population. Consumption rates may be drawn from various sources. In this document, highest preference is given to consumption rates derived from well-designed consumption surveys of Puget Sound Tribes, and lowest preference to default values from nationwide food intake studies. Local consumption rate data (95th percentile, uncooked weight, harvested from Puget Sound) were derived from fish and shellfish consumption studies for the Suquamish Tribe and the Tulalip Tribes. Consumption rates derived from the Suquamish Tribe data are most applicable to cleanup sites with extensive intertidal habitat capable of sustained shellfish harvest. Consumption rates derived by EPA from the Tulalip Tribes data are more applicable where such habitat is not extensive. In addition, where a Tribal-specific survey exists and where a cleanup site is within that Tribe's exclusive usual and accustomed harvesting areas, the fish consumption exposure scenarios should include the consumption rate based on that Tribe's survey data.

Site-specific and Tribal-specific factors should be considered when applying the Framework. If justifiable, specific chemicals may be excluded from the estimates of site-related risks. For example, chemicals may be excluded if they do not accumulate in a particular type of locally harvested fish and shellfish, or if the chemicals are unrelated to the site. Modification of exposure assumptions may be appropriate for exposure duration and consumer body weight, depending upon availability of data for the potentially exposed Tribal population. In this Framework, it is assumed that Tribal members substitute different types of fish and shellfish when those that would preferentially be harvested are unavailable.

Uncertainties are inherent in all risk assessments, including those performed using this Framework. A number of those uncertainties are summarized in the Framework. Site-specific risk characterizations should include a description of uncertainties and their potential effects on estimated risks.

I. Introduction

Potential human health risks[1] due to chemical contamination are among the many factors that affect EPA Region 10's cleanup decisions at RCRA and CERCLA sites in Puget Sound and the portion of the Strait of Georgia that is within the United States. Many CERCLA and RCRA cleanup sites located in EPA Region 10 have contaminated sediments or surface water, or include upland soil and groundwater that may release hazardous substances or hazardous constituents to sediment and surface water. Contaminants in sediments and surface water may then contaminate fish and shellfish. One of the inputs needed to calculate human health risks is exposure to contaminants via consumption of fish and shellfish. On the basis of data from the few fish and shellfish consumption surveys by or of American Indian Tribes within Region 10, Tribal consumption rates at cleanup sites within reservation lands or Tribal usual and accustomed harvesting areas[2] (U&A) are likely to be higher than for the general U.S. population. The National Congress of American Indians (2004) published a resolution calling for EPA to "use fish and shellfish consumption rates appropriate to Tribal consumers when it makes cleanup decisions." Modifications to standard risk assessment assumptions thus may be warranted. This document presents a conceptual Framework for selecting Puget Sound and the Strait of Georgia Tribal fish and shellfish consumption rates.

Risk assessment is the process used by EPA to estimate the degree of risk posed by exposure to site-related chemical contaminants. It is also used to develop preliminary cleanup goals. Risk management is a subsequent agency process that deals with decisions regarding how much of the contaminant should be removed from the environment, based on considerations of background concentrations, site-specific contributions, human health and ecological impacts, cost-effectiveness of remedial options, and state, Tribal and community input. By Federal law, Superfund and RCRA risk assessments and selection of remedies must be protective of human health and the environment.

The Framework provides a recommended approach for selecting fish and shellfish consumption rates where Tribal consumption of fish and shellfish from Puget Sound and the Strait of Georgia is evaluated in EPA's risk assessment process for RCRA and CERCLA sites. The approach reflects existing EPA guidance and policies regarding the exposures due to releases from contaminated sites. This Framework is designed to provide a consistent approach to developing fish and shellfish consumption rates and to assist decision makers with risk management decisions. The process used to develop this Framework is summarized in Appendix A.

[1] The term "risk" in this Framework primarily is used to generically describe both excess cancer risks and noncancer hazards. Where quantitatively addressed, cancer risks and noncancer hazards are distinguished.

[2] Usual and accustomed harvesting areas is a term described by the Northwest Indian Fisheries Commission, at http://www.nwifc.wa.gov/shellfish/faq.asp.

II. Application of the Framework

This Framework is intended to be applicable at EPA cleanup sites within Puget Sound and the Strait of Georgia. It does not attempt to include risks from all fish and shellfish consumed by Tribal members, but only that portion potentially affected by contaminants released at a cleanup site.

The fish and shellfish consumption data used in this Framework are derived from two Tribes in Puget Sound: the Suquamish Tribe (Suquamish Tribe, 2000) and the Tulalip Tribes (Toy *et al*., 1996). The studies were designed to include all Tribal members, not only "subsistence" consumers of fish and shellfish. Definitions of "subsistence" vary, but include "fishers who rely on noncommercially caught fish and shellfish as a major source of protein in their diets" (EPA, 2000c).

Fish and shellfish consumption rates developed for risk assessments for the general U.S. population may not be adequately protective for other populations in Puget Sound and the Strait of Georgia. For example, rates of fish and shellfish consumption by Seattle-area Asians and Pacific Islanders in one study were higher than those of the general U.S. population (Sechena *et al*., 1999). However, this Framework does not address exposure assumptions for groups other than American Indians. It does not address ecological risks, which are typically evaluated separately when conducting a baseline risk assessment or establishing risk-based cleanup levels. As the Framework addresses only fish and shellfish consumption, other site-specific exposures to Tribal members, such as direct contact with contaminated sediment and surface water, also should be considered and evaluated.

The Framework is a working document, to be modified as new information is acquired on Tribal consumption patterns, contaminant accumulation in fish tissues, and other scientific advances, or as agency policies change. The Framework's function is to assist EPA Region 10 staff in managing RCRA and CERCLA cleanups in consideration of information that reflects Tribal exposures and concerns. The Framework does not substitute for statutes EPA administers or their implementing regulations, nor does it hold the status of a regulation. Thus, it does not impose legally binding requirements on EPA, Tribes, states, or the regulated community. EPA Region 10 staff retains the discretion to use other scientifically defensible methods to select exposure assumptions on a case-by-case basis.

Although CERCLA and RCRA share a common goal – to protect human health and the environment by cleaning up contaminated sites – they were mandated separately by Congress and follow different administrative procedures. This Framework is intended to be applied to future decisions in the RCRA and CERCLA programs.

For baseline risk assessments, the Framework may be appropriate to use when contaminated soils, groundwater, surface water, or sediments may affect fish and shellfish harvested and consumed by Tribal members. At CERCLA sites where a remedy is required, the Framework may be used to evaluate various remedial alternatives. At RCRA sites where interim

or final corrective measures are necessary, the Framework may be used in the development of risk-based cleanup levels.

In keeping with EPA Region 10's Tribal Consultation Framework (EPA, 2001), EPA will continue to consult with Tribes on site-specific exposure assumptions and cleanup decisions at each Superfund and RCRA site within a Tribal fishing area or on Tribal land. If only one Tribal fish consumption exposure scenario is analyzed, this Framework encourages development of that scenario using the exposure assumptions established herein. Additional exposure assumptions should be considered, if the Tribe believes they would better represent exposure of Tribal members. In addition, where a Tribal-specific survey exists and where a cleanup site is within that Tribe's exclusive U&A, the fish consumption exposure scenarios should include the consumption rate based on that Tribe's survey data. EPA expects site-specific consultation with Tribes on other issues related to the application of this Framework typically will occur.

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EPA risk assessments should include both central and high-end estimates of exposure (EPA, 2000d, 2002c). Risk assessments based on Tribal fish and shellfish consumption studies with sufficient information concerning the responses of individual consumers should generally use the consumption rate associated with the 95th percentile of adult fish and shellfish consumers. The 95th percentile represents an appropriate high-end exposure scenario, consistent with EPA's *Risk Assessment Guidance for Superfund, Volume I, Part A* (EPA, 1989).

EPA recognizes that the quantitative nature of the risk assessment process inadequately addresses the impacts of fish and shellfish chemical contamination on Tribal culture and lifeways. As part of EPA's site-specific consultation, EPA will invite Tribes to provide a qualitative discussion of their perceptions as to how fish and shellfish chemical contamination has affected them. This information would be forwarded to EPA risk managers along with the quantitative risk assessment.

An EPA Region 10 advisory inter-program review group will be established to review site-specific applications of this Framework, as needed and appropriate.

III. Key Considerations

For this Framework, several key factors affect the exposure parameters:

- Hierarchy of preferred data sources
- Current conditions as predictors of future conditions
- Use of substitute fish and shellfish sources ("resource switching")
- Use of anadromous fish data
- Use of child-specific consumption rates
- Other exposure considerations

A. Hierarchy of Preferred Data Sources

Ambient water quality criteria (AWQC) published by EPA serve as one basis for regulatory protection of surface water quality and human health. The agency's methodology for deriving AWQC (EPA, 2000a, b) provided useful direction in the development of the Framework.

The AWQC methodology (EPA, 2000a, b) ranks four types of consumption data, in order of preference, as reflected in the Flow Sheet (Step 1) of the Framework:

- Fish and shellfish consumption surveys of local watersheds representative of the people being addressed for the particular water body
- Fish and shellfish consumption surveys that reflect geography and population groups similar to those under evaluation
- National food consumption surveys
- Default values

To address the first two tiers of this hierarchy, fish and shellfish consumption surveys of Puget Sound Tribes were reviewed. Two studies, one of the Tulalip and Squaxin Island Tribes (Toy *et al*, 1996) and one of the Suquamish Tribe (Suquamish Tribe, 2000) were available. For a number of reasons, EPA believes these studies were well designed. They consisted of personal interview surveys conducted by Tribal members that elicited fish and shellfish consumption information over the course of an entire year. Participants in the surveys reviewed for this Framework were randomly selected, providing an unbiased estimate of fish and shellfish consumption. Interviewers in the surveys were trained, enhancing the consistency and accuracy of survey administration and data recording. The surveys were pilot-tested to identify and address survey administration problems. Professional statisticians participated in survey design and data analyses. Transcription of data from paper to computer file format was quality controlled.

Though not relevant to the studies EPA is using for this version of the Framework, other survey methodology types are sometimes used to estimate fish and shellfish consumption rates. Because of the issues discussed below, EPA Region 10 would prefer not to use survey data collected

using these methods to develop Tribal fish and shellfish consumption rate estimates. Much of the following discussion is based on an EPA review of fish and wildlife survey methodologies (EPA, 1998c). Other types of surveys commonly employed are mail and creel surveys. Mail surveys typically are limited to reports of types and amounts of fish caught, with no opportunity for question clarification or interviewer probing to obtain correct responses. Creel surveys are conducted by inspecting an angler's catch in the field. Creel surveys have a number of issues, including: difficulties in eliciting year-round consumption information; difficulties in using visual aids or other materials to assist in quantifying consumption; inability to obtain a random, unbiased sample of the study population; the willingness of the interviewee to provide information in a field situation when the interviewee would rather be angling; and problems in relating an angler's catch to consumption rates of the angler's family and community. Creel surveys of Tribes typically are not conducted by Tribal members, which could decrease the comfort of interviewees and the probability of complete and accurate transmission of information.

Because of the quality of the survey methodology used in the available Puget Sound Tribal studies, EPA believes that these studies are appropriate to use to develop Puget-Sound harvested fish and shellfish consumption rates. Further, EPA believes that the rates developed from the aforementioned studies should be used in preference to an estimate of an average subsistence consumption rate, as recommended in the EPA AWQC methodology (EPA, 2000a,b). Site-specific factors should enter into the process of selecting a consumption rate, as discussed in more detail in Section IV of the Framework.

Where no Tribal-specific data are available for use, a non-Tribal fish consumption report based on nationwide studies with acceptable levels of scientific quality is *Estimated Per Capita-Fish Consumption in the United States* (EPA, 2002a). It is of limited value in estimating long-term consumption rates for American Indians. The consumption rates reported in the document are from the combined 1994-1996 and 1998 Continuing Survey of Food Intakes by Individuals (CSFII), conducted by the U.S. Department of Agriculture. The CSFII surveys were designed and conducted to support unbiased estimation of food consumption across the United States, based on fish and shellfish consumption as reported by individuals during two non-consecutive days. EPA considers this methodology appropriate for estimating mean intake values of the U.S. population in general, based on fish and shellfish consumption reported by individual survey participants, but because of insufficient numbers of participants in certain populations, including American Indians, the fish consumption estimates are not considered to be representative of such populations. In the AWQC methodology (EPA 2000a, b), EPA recommends a default consumption rate for subsistence fishers, when local or regional data are unavailable. The 99th percentile consumption rate from the 1994-1996 CSFII respondents who reported eating fish during the two-day survey period as well as those who reported not eating fish during that period fell within the range of average values for subsistence fishers, based on studies available at that time. The 99th percentile consumption rate for this group is 215.7 g/day for all finfish and shellfish (EPA, 2002a). This Framework recommends using this value only when no Tribal-specific data are appropriate for use.

Concerns have been expressed regarding the methodology used by EPA to establish the default AWQC subsistence fish consumption rates. In *Fish Consumption and Environmental Justice*

(EPA, 2002b), the National Environmental Justice Advisory Council (NEJAC), a federal advisory committee that provides independent advice, consultation, and recommendations to the EPA administrator on matters related to environmental justice, took issue with the use of a fish consumption rate for Tribes that includes survey respondents who reported eating no fish during the survey period. The report could be interpreted to call for using consumer-only rates from the CSFII surveys:

> EPA's default values are based on *per capita* consumption rates from the general population - that is, "fish consumption" rates that include fish consumers and fish non-consumers alike. The CSFII study on which the EPA's defaults are based for its Draft Methodology surveyed 11,912 individuals annually for 3-day periods[3]. Of the 11,912 participants, only 3,972 actually ate fish during the three days surveyed. These were the fish consumers; their fish consumption rates were recorded. The 7,940 participants who didn't eat fish during the [survey] period were the fish nonconsumers; their fish consumption rates were entered as "0." The CSFII study then generated two sets of figures: a set considering only the fish consumers and a set considering both the fish consumers and the fish nonconsumers. EPA chose to base its default values on the latter, *per capita* figures. Importantly, the effect of this choice is again to decrease the resulting default [fish consumption rates]- with so many "zero" values factored in, the point estimates are decreased at every point of comparison. So, for example, whereas the mean value for fish consumers is 106.39 g/day, the mean value once fish nonconsumers are also included sinks to 18.01 g/day; similarly, whereas the 99th percentile value for fish consumers is 399.26 g/day, the 99th percentile value drops to 142.96 g/day.[4]

B. Current Conditions as Predictors of Future Conditions

Where Tribal members have already reduced their harvest of fish and shellfish from impaired habitat, the use of current consumption rates could result in underestimations of potential fish and shellfish consumption rates. As noted in the NEJAC report (EPA, 2002b):

> "A suppression effect occurs when a fish consumption rate for a given subpopulation reflects a current level of consumption that is artificially diminished from an appropriate baseline level of consumption for that subpopulation . . . When agencies set environmental standards using a fish consumption rate based upon an artificially diminished consumption level, they may set in motion a downward spiral whereby the resulting standards permit further contamination and/or depletion of the fish and aquatic resources."

Cleanup levels in the local aquatic environment, if they are based on current fish and

[3] The survey period was decreased to two (non-consecutive) days as of the 1994 survey period. Previously, it was three days.

[4] The value of 142.96 g/day in this quotation refers to freshwater and estuarine species only; 215.7 g/day is the comparable consumption rate that includes all fish, a combined value representing survey respondents who did and did not report eating fish on at least one day of the survey period. The 95th and 99th percentiles for survey respondents who reported eating fish on at least one day of the survey period are 333.8 and 518.7 g/day, respectively (EPA, 2002a).

shellfish consumption rates in the vicinity of the cleanup site, may not reflect the potential for the water body to rebound from its current, relatively contaminated state. This should be considered when deciding whether the use of a surrogate Tribal fish and shellfish consumption rate would better represent potential future consumption rates than would consumption rates that represent only current or near-term contamination and habitat conditions.

C. Use of Substitute Fish and Shellfish Resources

For purposes of the Framework, if certain species or types of fish and shellfish are not present, or will not be present in the future, Tribal members are assumed to substitute other species or types of fish or shellfish that may be equally affected by the site. This assumption of "resource switching" among local fish and shellfish is incorporated into the Framework by holding constant the total amount of fish and shellfish consumed.

The policy decision to assume that resource switching occurs is supported by limited data and examples in Puget Sound. For example, individuals in the Suquamish Tribe (2000) study eat "more geoduck now, because they are more available to us, but we used to dry oysters and clams...." Two other respondents reported "reduced consumption of butter clams, cockles, and other clams and shellfish due to pollution," but that this "reduced consumption was offset by the higher availability of geoducks from the Suquamish Tribe." Resource switching has been documented in other areas affected by contamination, such as Alaska (Fall and Utermohle, 1999).

The use of fisheries resources is important to Tribes for economic, dietary and cultural reasons. Tribes will likely use whatever fisheries resources are available to them. The following observation is made in the NEJAC report (EPA, 2002b):

> "For many communities of color, low-income communities, Tribes, and other indigenous peoples, there are no real alternatives to eating and using fish, aquatic plants, and wildlife. For members of these groups it is entirely impractical to "switch" to "substitutes" when the fish and other resources on which they rely have become contaminated. There are numerous and often insurmountable obstacles to seeking alternatives (*e.g.*, fishing "elsewhere," throwing back "undesirable" species of fish, adopting different preparation methods, or substituting beef, chicken or tofu). For some, not fishing and not eating fish are unimaginable for cultural, traditional, or religious reasons. For the fishing peoples of the Pacific Northwest, for example, fish and fishing are necessary for survival as a people – they are vital as a matter of cultural flourishing and self-determination."

D. Use of Anadromous Fish Data

Salmon and other anadromous fish species are addressed separately from other species in this Framework. This distinction is based largely on differences in life cycles. [Note: steelhead, the anadromous strain of rainbow trout, are included with salmon in the Puget Sound Tribal studies.]

Salmon

For sites in Region 10, particularly PCB-contaminated sediment sites, salmon have typically been excluded from the fish consumption rate used to estimate site-related risks. This exclusion has been based on the assumption that adult salmon spend most of their lives in the open ocean and take up bioaccumulative and persistent contaminants almost exclusively via the food chain in that environment. It also has been presumed that site-related chemicals are not transported to that relatively distant aquatic environment, where adult salmon might be exposed to them through the food chain.

In this Framework, risks associated with the consumption of salmon may be eliminated from consideration as contributing to site-related risks, on a site-specific and chemical-specific basis. Factors that could be considered in decisions to include or exclude risks from persistent, bioaccumulative chemicals in salmon include salmon residence time near the site; evidence that salmon harvested near the site have higher concentrations of the contaminant of concern than salmon harvested in cleaner areas; and the relative likelihood that site-related contaminants are being transported to areas remote from the site, where salmon may accumulate them via the food chain.

For site-related contaminants that are not considered bioaccumulative and persistent, the potential for salmon to take up such chemicals via epithelial tissue or gill contact while present in the vicinity of the site should generally be evaluated for inclusion in estimating site-related risks. Examples of other circumstances where it may be appropriate to exclude certain chemicals are provided in the Framework narrative and in the Flow Sheet.

Because information to fully evaluate these factors may be limited, decisions will, of necessity, be based on best professional judgment along with available, relevant scientific information.

Other Anadromous Fish

Anadromous fish other than salmon (and steelhead trout) that have been harvested in Puget Sound may be consumed by Tribal members (Toy *et al*., 1996; Suquamish Tribe, 2000). Because these species may spend relatively more of their lives in the local aquatic environment than do salmon, and because the data generally are not available to determine whether or not contaminant body burdens may be locally acquired, it is recommended that non-salmon anadromous species that commonly occur at the site be included in the assessment of site-related risks.

E. Inclusion of Child-Specific Consumption Rates

The Framework recommends that child exposures to site-related contaminants due to fish and shellfish consumption be included in assessments of risks and development of media cleanup levels when the necessary data are available. Consistent with a 1997 Presidential Executive Order (The White House, 1997), EPA "shall ensure that its policies, programs, activities, and standards address disproportionate risks to children that result from environmental health risks." The risk assessment results of EPA's 1994-1996 Columbia River Basin fish contaminant survey demonstrated that, for Tribal members eating fish harvested from the Columbia River, noncancer health hazards to children were approximately twice those for adults (EPA, 2002d).

The two studies that EPA used as sources for Tribal adult consumption rates also surveyed children's fish and shellfish consumption. However, there are a number of issues that would need to be resolved before EPA would be prepared to include the Suquamish or Tulalip Tribes' children's consumption rate estimates into the Framework. EPA is planning to request the assistance of the Tribes and statisticians to address these issues and will expand this Framework to include child consumption information related to these Tribal studies as it becomes available.

When adequate Tribal-specific studies for children's consumption rates are unavailable, other options may be considered to estimate Tribal child fish and shellfish consumption rates in Puget Sound and the Strait of Georgia. Four are presented here without implying or recommending a preference. Other approaches also may be proposed for consideration. The decision as to how best to estimate child consumption rates should be considered on a site-specific basis and in consultation with Tribes.

1) Fish and shellfish consumption rates are provided for age categories from ages 3 to 17 in EPA, 2002a (Section 5.1.1.1, Table 5). The 99th percentile consumption rate of 100.5 g/day is identified for consumer and non-consumer children, ages 3 to 5, in the general U.S. population.[5]

2) A ratio of adult to child consumption rates from another Tribal study could be applied to a Puget Sound Tribal- specific adult consumption rate to estimate a fish and shellfish consumption rate for children. For example, using data in the Columbia River Inter-Tribal Fish Commission (CRITFC, 1994) study, the median consumption rate for consumer-only children under six years of age can be calculated to be 40% of the median consumer-only adult consumption rate from the same study.[6] This percentage could be applied to a Puget Sound

[5] A higher consumption rate should be used for contaminants with reference doses based on developmental effects, when using this option. See Section VI.F. in this Framework.

[6] Based on a comparison of the 50th percentile median consumer-only adult rate with the 65th percentile consumer-only child rate. Actual child fish consumption data were unavailable for the 50th percentile.

Tribal-specific adult consumption rate to estimate a fish and shellfish consumption rate for children.

3) The fish and shellfish consumption rate for children ages 3 to 5 is 38.9% of the adult rate, using a comparison of mean consumption rates for the general U.S. population from EPA, 2002a (Section 5.1.1.1, Tables 4 and 5). This percentage could be applied to the adult rate used in a specific assessment to provide an estimate of children's consumption rates.

4) Total adult consumption rates (in units of grams per day) may be used in combination with children's body weights to assess children's. While this would likely result in an overestimation of children's consumption rates, it would be inappropriate to attribute adult consumption rates in terms of grams per kilogram of body weight to children, since children generally consume more food per kilogram of body weight than do adults (EPA, 2000a; EPA, 2002a).

F. Other Exposure Considerations

An assessment of estimated risks associated with fish and shellfish consumption must include an assumption of the number of years Tribal members obtain fish from a specific harvesting area. Tribal-specific demographics that provide a high-end estimate of this exposure duration should be used if available. Otherwise, an assumption of 70 years, used as the standard default in Superfund and RCRA risk assessments to represent the lifetime of an individual, is recommended for use as the exposure duration when estimating Tribal risks from consuming fish and shellfish harvested in a given location.

This Framework recommends that risk assessments be performed using the weight of uncooked fish, with no modification for potential contaminant losses or gains during cooking. The use of uncooked weights is consistent with the fact that uncooked fish consumption rates were measured in the Tribal fish and shellfish consumption studies cited in the Framework. Furthermore, results of fish tissue analyses in Region 10 are reported as contaminant concentrations in uncooked samples.

Estimation of risks from eating fish and shellfish requires an assumption of the body weight of the consumer. This Framework recommends using the average body weight from the study selected for estimating the fish consumption rate. If body weights other than EPA's default of 70 kg are used, EPA risk assessors may need to determine whether corrections to dose-response relationships incorporated into risk calculations are necessary on a chemical-specific basis.

IV. Steps for Selecting the Tribal Fish and Shellfish Consumption Rate

The following sections are to be read in conjunction with the Flow Sheet provided with this Framework. Items in boldface type are quoted directly from the Flow Sheet.

Application of this Framework requires many site-specific decisions and these decisions are expected to be made in consultation with the Tribe or Tribes interested in or affected by the site. These decisions and their supporting rationale should be documented in writing as part of EPA's risk assessment and risk management processes.

Step 1: Select Basis for Tribal Fish and Shellfish Consumption Rate

The adjudicated U&A of the Tulalip Tribes extends from the Canadian border south 120 miles to the northern end of Vashon Island, encompassing areas of both Puget Sound and the Strait of Georgia. The U&A of the Suquamish Tribe encompasses waters of Puget Sound and the Strait of Georgia from the northern tip of Vashon Island to the Fraser River in Canada, including Haro and Rosario Straits, the streams draining into the western side of Puget Sound, and Hood Canal.

Consumption rates were derived for this Framework from participants in the Suquamish Tribe and Tulalip Tribes studies (Suquamish Tribe, 2000; Toy *et al.*, 1996) who reported consuming shellfish or specific categories of fish that were harvested from Puget Sound. Consumption rates of fish and shellfish harvested from Puget Sound were much higher for members of the Suquamish Tribe than for the Tulalip Tribes. A large percentage of this difference is shellfish consumption, particularly clams. A careful reading of the Suquamish Tribe (2000) study presents some of the cultural and historic basis for this difference. Extensive shellfish habitat is found in many areas of Puget Sound, including in the U&A of the Suquamish Tribe, but is uncommon in many other areas.

As part of the Framework, Region 10 recommends, as a policy decision, that for CERCLA and RCRA sites in Puget Sound or the Strait of Georgia with extensive intertidal habitat, the consumption rate derived by EPA from data collected by the Suquamish Tribe represents a sustainable consumption rate suitable for estimating site-related risks. Again, as a policy decision, for sites in Puget Sound and the Strait of Georgia that lack extensive intertidal habitat, the consumption rate derived by EPA from data from the Tulalip Tribes represents a sustainable consumption rate. While less than for the Suquamish Tribe, significant quantities of shellfish are included in the total consumption rate of the Tulalip Tribes. Where a Tribal-specific survey exists, and where a cleanup site is within that Tribe's exclusive U&A, the fish and shellfish consumption exposure scenarios also should include the consumption rate based on that Tribe's data.

Box PS-1. Are Puget Sound fish and shellfish consumption studies relevant to the Tribe(s)? ("The Tribe(s)" refers to a Tribe or Tribes whose U&A is at or near the site.)

The Puget Sound Tribal fish and shellfish consumption data used in this Framework are for the Tulalip Tribes (Toy *et. al.*, 1996) and the Suquamish Tribe (2000). If the answer is "no," move to Box PS-3. If the answer is "yes," move to Box PS-2.

Box PS-2. Does the site or its environs have (existing or potential) high quality physical habitat to support substantial shellfish harvest in the absence of contamination?

If the answer is "yes," move to Box PS-6, use the consumption rate derived from data collected by the Suquamish Tribe study as a basis for selecting the Tribal fish and shellfish consumption rate, and move to Box PS-8. If the answer is "no," move to Box PS-5. The consumption rate derived by EPA from data from the Tulalip Tribes may be used as the basis for the Tribal fish and shellfish consumption rate. The answer might be "no" where, for example, some intertidal habitat exists, but does not include extensive shellfish beds. Move to Box PS-8.

In addition, where a Tribal-specific survey exists and where a cleanup site is within the Tribe's exclusive U&A, the fish and shellfish consumption exposure scenarios should include the consumption rate based on that Tribe's survey data. Depending on the location of the cleanup site and other factors, this fish and shellfish consumption rate may not be the only consumption rate evaluated.

The following information is provided to support the assessment of shellfish habitat quality. The assessment can be done by assembling existing information for the categories given below, discussing how the parameters affect physical habitat quality, and using the results of the assessment to help make the Yes/No determination for Box PS-2. Because information to fully evaluate these factors may be limited, decisions will, of necessity, be based on best professional judgment along with the available relevant scientific information, as well as oral history or other information a Tribe would like to contribute to the evaluation. This evaluation is expected to be performed in consultation with the Tribe or Tribes interested in or affected by the site.

Given the wide variety of feeding, growth, and survival strategies of shellfish, high quality and quantity of shellfish harvest relies on many interacting parameters. Assessing the *available information* for the following can help determine whether high quality physical habitat exists (or could exist) at the site or its environs, regardless of the presence or absence of site-related contaminants:

- **Basic characteristics**

Food availability – are levels of food in the water column or sediment sufficient to support high shellfish growth rates? If not, then even optimal physical substrate, temperatures, absence of predators or other factors important to survival and growth will not be good indicators of high harvest potential.

Water quality – are the basic water quality parameters (not related to site releases) in optimal ranges for shellfish growth? This determination will likely be species-specific.

Substrate quality – are the basic sediment parameters (not related to site releases of contaminants) in optimal ranges for shellfish growth? This determination will be species-specific since different habitats (mudflat, sand, hard substrates, dredged channels, *etc*., will support different species with different productivities). A second, important aspect of substrate physical quality to assess is harvestability, i.e., does the physical habitat such as debris or soft mud affect access to the shellfish?

- **Existing shellfish quality/quantity**

The shellfish may or may not be a useful indicator of high quality physical habitat. Sampling shellfish to evaluate condition, growth rates, survivorship, and reproduction can provide information that integrates multiple parameters influencing shellfish productivity. If existing shellfish populations are high in quality (*e.g.*, tissue mass per individual) and quantity (*e.g.*, density), then it is reasonable to conclude the physical habitat is of high quality. However, if existing shellfish populations are absent or low in quality, then the assessment of high quality physical habitat will rely on the evaluation of food availability and water and sediment quality as outlined above.

- **Site context**

Site context is an important element in the assessment of high quality habitat that will support substantial shellfish harvest in the absence of contamination. It may be useful to consider the quantity of high quality shellfish habitat within a reasonable geographic area (river, bay, *etc*.) at or around the site. Areal estimates of existing or potential habitat could be described for the intertidal, shallow subtidal, and deeper subtidal areas. For example, in an urban river estuary, total intertidal area might be estimated as approximately 500 acres, whereas high quality intertidal shellfish habitat is approximately 20 acres, whereas a large bay might have 10,000 acres of shallow subtidal habitat with 9,000 estimated as high quality.

- **Other considerations**

Additional parameters may affect the overall assessment of high quality physical habitat (*e.g.*, disease, predation, competition, settlement cues, *etc*.).

- **Existing v. potential quality**

It is important in the assessment to evaluate existing conditions and also consider whether future likely conditions could change the physical habitat quality/quantity.

Table 1 describes specific examples of the above-defined parameters that may be evaluated on a site-specific basis to provide input to the assessment of high quality physical habitat for shellfish harvest. Characterizing habitat quality will ultimately depend on the species of shellfish evaluated and their tolerances for existing and potential habitat parameters. Habitat quality should be evaluated for a variety of shellfish. For example, for bivalves, several example species

of both surface deposit feeders and suspension feeders (*e.g.*, mussels, geoducks, soft-shell clams, horse clams, cockles, *etc*.) selected on the basis of their ecological and human health importance (*e.g.*, Tribal preferences) should be included in the assessment. The habitat characteristics, both existing and potential (i.e., in the absence of site-related and non-site-related contamination) at a site may then be compared with the shellfish habitat requirements.

Table 1. Characteristics for evaluating high quality shellfish habitat to support substantial shellfish harvest and examples of types of parameters that can be evaluated for both existing and future conditions		
Basic Characteristics – not related to site releases of contaminants		
	Food (water column and sediment)	Chlorophyll a, Total Suspended Solids, nutrients (NO_3, NH_4) Source of food (stable isotope ratios)
	Water Quality	Temperature range, dissolved oxygen, salinity range, pH, turbidity
	Sediment Quality	Temperature range, dissolved oxygen, salinity range (including ground water discharges such as seeps), tidal range, organic carbon, grain size distribution (surface and at depth) Access to harvest (debris, shore/water access, substrate)
Existing Shellfish Quality/Quantity		
	Quality	Condition index, scope for growth, survivorship, reproduction, growth rate (mm/month, growth rings, *etc*.), adult size
	Quantity	Density (#/m^2), recruitment, survivorship
Site Context		
	Context of the amount of high quality habitat	For example, estimate both total intertidal area and the high quality intertidal area in a reasonable geographic area (river, bay, *etc*.) at or around the site. Estimates can be made for shallow subtidal and deeper subtidal areas.
Other Considerations		
	Larval pool and settlement cues	Recruitment
	Predation	Density, shell indicators (breaks, drill holes, *etc*.), refugia (substrate, debris, plants, *etc*.)
	Background levels of non-site-related contaminants	Tissue residues, sediment or water concentrations, fecal coliforms, PSP, Domoic acid, *etc*.
	Competition	Density and growth rates
	Disease	Shellfish pathology

Box PS-3. Will there be (or has there been) a fish and shellfish consumption study conducted for the potentially affected Tribe**s?** A study of this nature would be preferred if the Tribal data used in this Framework are inappropriate. However, because of time, cost, and information constraints, the preparation of site- and Tribe-specific fish and shellfish consumption studies is likely to be the exception, not the rule. In addition, artificially suppressed consumption rates may be present if the local aquatic environment has been significantly impaired by contamination. In such cases, use of a surrogate study may be preferable. If the answer is "yes," move to Box PS-4. If the answer is "no," move to Box PS-7.

Box PS-4. The Tribal-specific consumption study may be used as the basis for fish and shellfish consumption rates.

Box PS-7. The default consumption rate of 215.7 g/day (EPA, 2002a) may be used when no Tribal-specific value is available or appropriate. This is the least preferred option, consistent with the hierarchy in the AWQC Methodology (EPA, 2000a). Move to Box PS-8.

Box PS-8. Proceed to Step 2 of the Flow Sheet to select the consumption rate.

Step 2: Select Fish and Shellfish Consumption Rate

The Puget Sound Tribal fish consumption studies cited in this Framework include information on all fish and shellfish consumed by the surveyed Tribal members, including, for example, fish and shellfish purchased in stores or restaurants, some of which may have come from other water bodies. The studies may also reflect fish and shellfish harvested by Tribal members far from the cleanup site. To assume that the total quantity of fish and shellfish consumed by the participants in the studies was harvested from the local aquatic environment would likely result in a significant overestimate of risks and hazards due to site-impacted fish and shellfish. To estimate the portion of consumption rates that may be impacted by site releases, the Framework includes consumption rates only for fish and shellfish identified by individual survey participants as having been harvested from Puget Sound. All fish and shellfish identified as being obtained from grocery stores, restaurants, or locations outside Puget Sound were eliminated from the consumption rates presented herein for use in estimating risks and developing cleanup levels. (See Appendix C for further details on the method for calculating the rates in Box PS-9.)

Box PS-9. Select the fish and shellfish consumption rates corresponding to the information source selected in Step 1.

Box PS-9 lists the 95th percentile consumer-only consumption rates of fish and shellfish harvested from Puget Sound derived from the data collected by the two Puget Sound Tribes. Also listed is the default value recommended when appropriate Tribal-specific data are not available.

Box PS-10. Select a mix of categories or species of fish and shellfish to reasonably represent consumption patterns, while holding constant the total consumption rate. This task is not necessary where only a total consumption rate is needed, regardless of species. Most of the data in the Puget Sound Tribal seafood consumption studies are available by fish types (bottom, pelagic, anadromous, and shellfish). (See Appendix B.)

- If a Tribe-specific consumption study is available and applicable to the site in question, calculate the ratio of fish types or species from average consumption rates, and apply those ratios to the 95th percentile consumption rate.

- Where the consumption rate is based on the Tulalip or Suquamish Tribal survey results, the ratios of fish types provided in Appendix B of this Framework should generally be used. Where necessary, these values may serve as a starting point for further decisions, for instance, the percentages of shellfish consumed represented by crab and by clams. If the values in Appendix B are not appropriate to a particular site, consideration should be given to adjusting these rates, based on information about the types and abundance of fish and shellfish present at the site and/or information provided by the affected Tribes about preferred catch.

- For sites where the general U.S. population per capita consumption rate (EPA, 2002a) is used, apply either ratios based on one of the two Puget Sound Tribal studies (if considered appropriate to the local aquatic environment) or develop ratios relevant to the affected Tribe(s). In general, the ratios reported in EPA (2002a) are unlikely to be relevant, because they are based on the types of fish available and consumed throughout the country.

Other assumptions about the mix of species that constitutes the Tribal fish and shellfish diet may be used for additional risk calculations. Such analyses might focus on species or groups of species (*e.g.*, those with relatively small home ranges) thought to present the largest source of risk to Tribal members. In addition to potentially affecting remedy selection, this type of analysis can help characterize the uncertainty or sensitivity of the calculated risks to assumptions about species ratios within the diet.

Box PS-11 and Box PS-12 reflect possible species-specific or contaminant-specific modifications. A hypothetical case applying the information in Boxes PS-11 and PS-12 is provided in Appendix D.

Box PS-11. Salmon.

A decision must be made to include or exclude risks associated with consumption of salmon on a site-specific and contaminant-specific basis. See Section III.D for examples of factors to consider when making this decision, Section V for associated uncertainties, and Box PS-12 for other considerations.

Box PS-12. Additional contaminant and aquatic life issues.

This step may be used in consultation with a fish biologist or other expert to determine whether it is appropriate to reduce estimates of site-related risks due to consumption of fish. A contaminant may be eliminated from consideration for certain species or groups of species if sufficient evidence demonstrates that it does not accumulate or is not otherwise present in the tissue when harvested; that it is present but from a source other than the cleanup site; or that it is present but not of concern to human health. Examples of such evidence may include but are not limited to the following:

- Residence time in the vicinity of the site precluding more than *de minimis* uptake of the contaminant into tissue of the fish type being evaluated

- Adequate sampling/chemical analysis demonstrating that a contaminant is absent from tissue, using analytical methods sufficiently capable of detecting concentrations of concern to the maximum degree practicable

- Scientific literature providing significant evidence that the contaminant as found in fish is not of concern for human health

- Modeling of the contaminant demonstrating no significant bio-concentration or bioaccumulation in tissue of the relevant category or species of fish, regardless of residence time in the local aquatic environment

- Metabolism in the organism rendering the contaminant of no concern to human health upon consumption of the fish

- K_{ow}/water solubility characteristics substantially limiting uptake of the contaminant into tissue of the fish.

For discussions of some of these issues, see Barnhard (2003), Roose and Blindman (2000) and Hall (2002).

V. Selection of Species for Collection of Chemical Contaminant Data and Derivation of Exposure Point Concentrations

A. Selection of species for collection of chemical contaminant data

In preparing to collect contaminant data for aquatic biota that may be affected by site- specific contamination**,** considerations in determining which species should be analyzed for contaminants should include:

- Which species are most commonly consumed by Tribal members;

- Which species may have the highest levels of contamination (*e.g.*, predators, bottom feeding species);

- Area fidelity of species: species that tend to stay in a specific area are more likely to be impacted by site-related contaminants than are species with large home ranges;

- Relative abundance of a species; and

- Which species may have the highest lipid content; species with higher fat-containing tissue are likely to have higher wet weight contaminant concentrations of lipophilic contaminants.

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B. Derivation of exposure point concentrations when data for multiple species are available.

When chemical contaminant concentrations are available for multiple species within a species group (i.e., benthic, pelagic, shellfish, anadromous. *etc*.), the question arises as to how to utilize these data to derive an overall species group contaminant concentration for computation of total contaminant dose and consequent risks. There are a number of ways by which this issue could be addressed. The site-specific approach is expected to be selected in consultation with the Tribe or Tribes interested in or affected by the site. Approaches may include:

1. Weighting contribution of individual species contaminant concentrations on the basis of species-specific consumption rates from seafood consumption surveys.

When species-specific consumption rates and contaminant concentrations are available, those consumption rates may be used to develop a weighted contaminant concentration for that species group. Average consumption rates are based on consumption of a species regardless of source (*e.g.* harvested, purchased in grocery stores, consumed in restaurants) and would be obtained from either published study results or by analyzing the data associated with a study. The equation for computing a weighted species group concentration is as follows:

$$C_{weighted} = C_1 \times (IR_1 / \Sigma IR) + C_2 \times (IR_2 / \Sigma IR) + \ldots + C_n \times (IR_n / \Sigma IR)$$

Where:
$C_{weighted}$ = the weighted contaminant concentration for the species group

$C_1, C_2, \ldots C_n$ = 95% upper confidence level (UCL) on the mean contaminant concentrations for individual species within the species group (an estimate of the true average concentration);

$IR_1, IR_2, \ldots IR_n$ = average ingestion rates for individual species within the species group regardless of fish and shellfish source; and

ΣIR = the sum of the average ingestion rates for all species for which chemical contaminant data are available

In some instances, there may be data on a species that is representative of more than one species within a species group. This is particularly likely for shellfish. For example, concentration data for a single species of clam may be used to represent contaminant concentrations in all bivalves; concentration data from a single species of crab may be used to represent contaminant concentrations in all crabs. In cases where a species may be representative of multiple species within a species group, the combined ingestion rate for these multiple species should be used to develop the weighted concentration rather than the consumption rate of the individual species. For example, if data were available for a bivalve species and a crab species, the weighted concentration would be computed using: the 95% UCL species-specific bivalve contaminant concentration, the average consumption rate for all bivalves, the 95% UCL species-specific crab contaminant concentration, and the average consumption rate of all crab species.

2. Weighting contaminant concentrations based on best professional judgment. Such weighting factors may include the following considerations:

- Average 95% UCLs for all species:
  The average of the 95% UCL concentrations for all species could be used for the species group concentration.

- Use of the highest concentration:
  The entire species group concentration could be based on the highest 95% UCL concentration obtained for an individual species.

- Development of weighting factors based on the relative biomass of the different species:
  This approach assumes that consumption is directly proportional to the availability of different species.

It may be helpful to employ several of these approaches to characterize the uncertainty contributed by a lack of knowledge of the consumption rates for different species within a species group. The site-specific approach is expected to be selected in consultation with the Tribe or Tribes interested in or affected by the site.

VI. Uncertainties

To promote transparency, EPA risk characterizations associated with risk assessment and the derivation of cleanup levels should include a statement of relative confidence and protectiveness. All major uncertainties should be identified, along with commentary regarding their influence on the assessment, consistent with agency guidance (EPA, 1989, 2000d). All uncertainties inherent in this Framework, as presented below, should also be described. The degree to which this Framework provides a protective estimate of exposure to contamination from consumption of fish will depend upon the choices made in its implementation.

A. Use of a Tribal-specific fish and shellfish consumption study as a surrogate for another Tribe's consumption rate

The use of consumption rates of Puget Sound-harvested fish and shellfish derived using Tulalip and Suquamish Tribal data as a surrogate for another Tribe in Puget Sound or the Strait of Georgia could lead to either an overestimate or an underestimate of the actual fish and shellfish consumption rate potentially associated with site releases. For many reasons (*e.g.* cultural practices, treaty rights, types and quantities of seafood species available), Tribes surveyed in local fish and shellfish consumption studies may eat different quantities and ratios of fish and shellfish than do those who harvest near a cleanup site. Habitat quality and thus the quantity of fish and shellfish available for sustainable harvest may also be different. If the surrogate study is based on fish and shellfish habitat of higher quality and greater sustainable harvest capacity than would ever be possible for the water body under evaluation, use of the surrogate data could lead to an overestimate of risks at the site. There is also the possibility that the Tribe affected by site-related releases may have higher quality resources than the study Tribe, in which case consumption rates may be underestimated. The development of additional appropriately designed and conducted Tribal consumption studies in Puget Sound and in the Strait of Georgia would contribute to the reduction of these uncertainties.

B. Degree to which traditional lifeways or subsistence fish and shellfish consumers are included in existing Tribal consumption studies

The studies for the Suquamish and Tulalip Tribes did not attempt to quantify or otherwise distinguish fish and shellfish consumption for Tribal members who consider themselves to be subsistence consumers or who practice traditional lifeways, although fish and shellfish consumption rates for some individuals who fall into these categories are almost certainly included in the studies. Without a Tribal-specific definition of subsistence fish and shellfish consumption and without data on the subsistence use of areas affected by the cleanup site, it is difficult to determine the degree to which subsistence consumers are protected by the consumption rates recommended in this Framework.

C. Percentage of consumed fish and shellfish assumed to be adversely affected by site-related contamination

For purposes of this Framework, consumption rates for fish and shellfish harvested only from Puget Sound were derived from the Tulalip and Suquamish Tribal data, for use in determining the amounts of consumed fish and shellfish that may be impacted by a cleanup site located in Puget Sound. This Framework also recommends the use of these studies to derive consumption rates for a Tribe potentially affected by cleanup sites in the Strait of Georgia, on a site-specific basis. The quantities of fish and shellfish identified in the surveys as having been obtained in restaurants or grocery stores or harvested from areas outside Puget Sound were excluded from the consumption rates, for purposes of estimating risks that could be associated with site releases. If none of the Tribal study consumption rates is determined to be appropriate for a particular cleanup site or Tribe, and the default consumption rate is used, no downward adjustment of the total fish and shellfish consumption rate is recommended in this Framework.

Although the degree to which site-related risks could be overestimated by the use of any of the fish and shellfish consumption rates presented in this Framework cannot be known precisely, these methods are preferable to alternatives that would be likely to underestimate site-related risks, such as basing a consumption rate (or site-related estimates of risk) on the size of the cleanup site, or reducing the site's estimated contribution to fish and shellfish contamination because nearby sites or sources are associated with similar contaminants. This Framework includes the assumption that the selected Tribal fish and shellfish consumption rates and their associated risk estimates will not be reduced based on consideration of the size of the cleanup site or the presence of additional sources of contamination.

The use of a consumption rate based on all fish and shellfish harvested from Puget Sound as a surrogate for a consumption rate based on fish and shellfish affected by a cleanup site is likely to overestimate the risk of eating fish and shellfish from the site, since only a portion of the fish and shellfish diet will have actually come from the site in question. The degree of overestimation depends upon such factors as size and location of the site, type and degree of contamination, and habits of affected fish and shellfish. On the other hand, some of the fish and shellfish consumed in restaurants or obtained in grocery stores may have been harvested in Puget Sound, which could lead to an underestimate of exposure.

D. Exclusion or inclusion of risks associated with salmon consumption on contaminant-specific basis

This Framework allows exclusion of risks associated with salmon consumption if warranted by site-specific and chemical-specific circumstances, particularly for persistent and bio-accumulative contaminants. Some of the uncertainties in this exclusion arise from the degree of historical contaminant transport offsite and from salmon residence time near the site.

PCBs and other bio-accumulative and persistent chemicals found in contaminated sediments can be moved from their site of release via erosion, dredging, tidal currents, flood events, and vapor transport. Offsite transport is also possible when aquatic organisms become contaminated near a cleanup site and then migrate to distant locations, where they contribute to food chain effects that eventually affect fish, including adult salmon. However, adult salmon body burdens of bio-accumulative and persistent contaminants typically come from many sources and cannot currently be apportioned with confidence to specific locations. An assumption that contaminants present in harvested salmon are not associated with the site, even when the same chemicals have been released from the site, is likely to underestimate the site's contribution to risks from consuming such fish. The degree of underestimation is not known.

If the full body burden of bio-accumulative and persistent contaminants released at a site and found in local salmon is attributed to a single source (*i.e.*, the site under evaluation), site contributions to risk are likely to be overestimated, since some portion of the body burden likely has been acquired elsewhere.

Some site-related contaminants may bio-concentrate in adult salmon due to epithelial tissue or gill contact, depending in part upon the salmon residence time in the vicinity of the site-related contamination. Making an assumption that adult salmon do not reside in the vicinity of the site long enough for bio-concentration to occur could result in an erroneous exclusion of contaminants in salmon from the site-related risk assessment. An assumption that bio-concentration does occur could lead to an overestimation of risks if uptake does not occur.

E. Use of the National Fish and Shellfish Consumption Rate to Characterize Tribal Consumption

The fish and shellfish consumption rate of 215.7 g/day from *Estimated Per Capita Fish Consumption in the United States* (EPA, 2002a) is a high-end (99th percentile) estimate of total fish and shellfish consumption for the general U.S. population, including both people who consume fish and shellfish and those who do not. It is identified as an appropriate value to represent an average subsistence consumption rate (EPA, 2000b). Its use is recommended in this Framework as a default Tribal consumption estimate when relevant Tribal-specific studies are not available.

EPA's preference and general practice is to use the 95th percentile consumption rate for purposes of estimating risks to a given population, when that information is available (EPA, 1989). Use of the default consumption rate of 215.7 g/day may either over- or underestimate the actual 95th percentile consumption rate of fish and shellfish of the Tribal population being evaluated. Using consumer-only consumption rates would be expected to overestimate the consumption rate of the general population, but it may not result in overestimates for populations that consume seafood on virtually a daily basis.

F. Special Considerations of Vulnerable Individuals and Exposures to Chemicals with Selective Endpoint

Many of EPA's risk assessments and cleanup levels for the protection of human health are based on estimated carcinogenic and noncancer adverse effects. Not all effects can be quantified, due to scientific limitations concerning dose-response effects, exposures to multiple chemicals, and factors such as individual variability. As a result, for example, for contaminants such as methyl mercury that have reference doses based on developmental effects, EPA's AWQC methodology (EPA 2000a) recommends that higher fish consumption rates be assumed for children and for women of child-bearing age, when using fish and shellfish consumption rates that are based on consumers and non-consumers, such as the default recommended in this Framework. (See Sections III.A and III.E of this Framework for discussions of default rates.) Under these circumstances, the AWQC methodology recommends that consumption rates be based on data for consumers only[7], as differentiated from the AWQC recommendation to use consumption rates based on both consumers and nonconsumers for other population groups (EPA, 1998b; 2000a). This is an acknowledgment of the potentially increased sensitivity of certain segments of the general population to chemical-specific effects.

Chemicals that cause human developmental, neurotoxic, endocrine-disruption or other adverse effects at potentially lower concentration than reflected by reference doses or other indicators of safe exposure levels, may affect individuals within a population differently. Within a Tribal community, individuals who may have increased vulnerabilities to potentially toxic chemicals include "elders, pregnant women, young children, persons who are ill, and individuals who have compromised immune systems or limited liver and kidney function" (Arquette *et al*., 2002).

Decision documents for risk assessment and cleanup level development should include discussions of uncertainties in risk characterization associated with fish and shellfish consumption. Where appropriate, such discussions should include potential site-related risks that are not quantifiable, such as for health effects not addressed by chemical-specific reference doses or cancer potency factors, and the presence of exposed individuals within a population who may be more susceptible than those for whom risks are quantitatively estimated. For site-related contaminants in fish and shellfish that have reference doses based on developmental effects, or for early-life exposure to carcinogens, current EPA guidance on the assessment of risk and associated uncertainty should be consulted.

G. Use of Uncooked Fish and Shellfish Rates as Representative of Weight of Fish and Shellfish Consumed

Because of the many ways in which fish may be served, quantitative assumptions regarding preparation methods and their effects on contaminant concentrations would be unreliable. Depending upon the preparation and cooking procedures, and upon the nature of

[7] See Section 5.2.1.1 Tables 3 and 5 in EPA, 2002a.

the contaminants in the fish, concentrations may decrease or increase (EPA, 1998a). For fat-soluble compounds such as PCBs, trimming and removing adipose tissue reduces the mass of contaminants in the consumed portion of the fish. Similarly, broiling, frying, or grilling fish is likely to result in reductions of fat-soluble compounds (Sherer and Price, 1993). Cooking is not likely to change the level of exposure to mercury because it is bound to muscle tissue and is not lost by cooking, which mostly removes moisture and fat (Morgan *et al.*, 1997). Fish cooked with no prior preparation, as in a stew, might show negligible loss of contaminants, except perhaps for volatile contaminants. Because lead concentrates in bones, preparations where bones are discarded are likely to result in reductions in lead exposure (Ay *et al.*, 1999).

H. Use of An Exposure Duration of 70 Years

A 70-year exposure period, that is, the number of years a Tribal member is expected to consume fish and shellfish from a specific harvesting area, is encouraged in this Framework where Tribal specific demographic data are not available. Risks and hazards will be overestimated for Tribal members who obtain fish and shellfish from the harvest area for fewer than 70 years, but underestimated for those exposed for more than 70 years. Uncertainties associated with such surrogate values should be discussed in the risk characterization document, including any assumptions made regarding future exposure durations.

I. Assumption that Resource Switching Occurs

If certain types of fish or shellfish preferred by Tribal members are not present in their U&A, this Framework assumes that Tribal members will substitute alternative local types of fish or shellfish in their diets, generally within the same category of fish or shellfish. Thus, the total consumption rate remains the same, regardless of the availability of a particular type of fish or shellfish. This is a reasonable and protective assumption for Tribal members who, for economic, ceremonial, religious, or personal preference reasons, are likely to substitute one species for another. The assumption that resources will be switched is likely to result in an overestimate of risks for other Tribal members who may decrease their overall fish and shellfish consumption rate because their preferred types are unavailable. Risks may be underestimated if the actual dietary practices of a Tribe would result in consumption of species that have higher contaminant levels than the preferred or assumed types of fish or shellfish.

J. Exposure to Contaminants in Fish and Shellfish Other Than by Consumption

To the extent that Tribal members are exposed by methods other than consumption and these exposure pathways can be identified, such exposure should be incorporated into a risk assessment, even if only qualitatively. Examples are use of bones as whistles and use of fish fat as a basis for skin paints. Omission of these potential exposures may underestimate risks and hazards, but to an unknown degree.

K. Potential Overestimation of Bottom and Pelagic Fish Consumption in the Suquamish Study

Some of the bottom and pelagic fish included in the Suquamish study as being harvested from Puget Sound were harvested in the Strait of Juan de Fuca. Assuming that these fish are harvested in Puget Sound, and including them in the Framework, may overestimate hazards and risks due to site-related contamination, although the degree of such overestimation is unknown.

L. Uncertainty in Developing Weighted Species Group Concentrations in Situations Where Data on Multiple Species are Available

Weighted species group contaminant concentrations (Section V) may be overestimated if the EPA derived consumption rates for species with higher contaminant concentrations are greater for the Suquamish or Tulalip Tribes than the consumption rate for these species for the Tribe or Tribes affected by a site. Conversely, species group contaminant concentrations may be underestimated if the consumption rates for species with higher contaminant concentrations are greater for the affected Tribe or Tribes than for the EPA derived consumption rate for the Suquamish or Tulalip Tribes.

VII. Risk Communication and Risk Management Issues

The following risk communication and risk management ideas may be useful for project managers to consider when implementing this Framework at RCRA and CERCLA cleanup sites.

As much as possible, the risk assessment should include a description of consumption rates in terms that are meaningful to the intended audience (*e.g.*, number of 8-oz meals per week, number of pounds per week). A consumption rate of 32.4 g/day is equivalent to one-half pound of fish and shellfish per week; 143 g/day is equivalent to 4.4 – one-half pound meals of fish and shellfish per week or an average of 2.2 lbs per week. The terms to describe consumption rates should be decided on a case-by-case basis.

Once it is determined that action is necessary to protect human health, site managers should consider including at least one remedial alternative that could reduce the excess cancer risk to the most protective end of EPA's acceptable risk range, using exposure rates selected under this Framework. Even if not practicable to implement, such an alternative would provide a point of comparison for risk management decisions.

The effect of the assumptions on the potential for over- or underestimating risk is an important aspect of EPA's risk management and cleanup decisions. All discussions and presentations about risk should clearly describe assumptions and uncertainties in the characterization of risk. One format that may be useful for EPA's risk management

discussions is the table presented in Part A, Exhibit 6-21 of EPA's (1989) risk assessment guidance for Superfund. This table lists each assumption or factor producing the uncertainty and its potential to over- or underestimate exposure.

VIII. Five-Year Review Considerations

Based on EPA's knowledge of sediment clean-up sites in Puget Sound, the Framework may have limited application for those CERCLA and RCRA sites where the remedy has already been selected.

After a remedy has been selected, CERCLA requires that five-year reviews be conducted at any remedial action site that does not allow for unlimited use or unrestricted exposure. The purpose of the five-year review is to assure that human health and the environment will be protected by the remedial action.

As part of the five-year review process, Tribes can provide new information to be considered or request that the lead federal agency evaluate particular aspects of a remedy relative to Tribal interests. Such requests are most helpful when provided to the lead federal agency early in the five-year review process. Such requests would be evaluated on a site-specific basis and consistent with EPA's five-year review guidance. EPA would generally discuss the appropriate means for addressing a Tribe's concern with the Tribe during the review process.

While a CERCLA five-year review includes considering new information, such as new information regarding exposure rates and assumptions, it is important to keep in mind that remedies and cleanup levels at CERCLA sites are determined by many factors. In determining whether a recalculation of site risks or any other detailed analysis is needed as part of the five-year review, EPA would review the basis of the selection of the remedial action and cleanup levels and other relevant information to determine whether further analysis of such updated information is appropriate, and focus our analysis on matters that would help assess the protectiveness of the selected remedy.

It is important to note that even when a five-year review recommends that a remedy change be considered, such a change would happen through a CERCLA decision process. This process would require a ROD Amendment or Explanation of Significant Differences, not just a five-year review report, and would include consideration of the NCP's nine criteria. Such changes would include consultation with the affected Tribes and would be subject to appropriate public review.

The RCRA program does not have an equivalent five-year review process. For RCRA corrective actions being conducted as part of an operating or post-closure permit, a new permit must be applied for prior to expiration of the current permit (typically every 10 years). The selected clean-up standards and selected remedy would be reviewed during the permit renewal to assure that the new permit is based upon currently applicable standards and regulations.

EPA acknowledges that a Tribe's interest in or need for public health related information, such as data about existing or residual health risks to Tribal populations, may be better served outside the five-year review. EPA is available to work with Tribes interested in this type of information.

IX. References

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Appendix A

Development of the Framework for Selecting and Using Tribal Fish and Shellfish Consumption Rates for Risk-Based Decision Making at CERCLA and RCRA Cleanup Sites in Puget Sound and the Strait of Georgia

This document presents a conceptual Framework for a consistent approach for selecting and using Tribal fish and shellfish consumption rates for purposes of estimating site-related risks at U.S. Environmental Protection Agency (EPA) hazardous waste cleanup sites in Puget Sound and the portion of the Strait of Georgia that is within the United States. The decision to develop this Framework to support EPA Region 10 RCRA and CERCLA risk-based decision making was made in 2003 by an executive team representing EPA Region 10's Offices of Environmental Assessment; Environmental Cleanup; Air, Waste and Toxics; and Ecosystems, Tribal and Public Affairs. Professionals representing each of the first three offices were selected to be responsible to prepare a draft of the Framework, with the assistance of their colleagues as appropriate. Remedial project managers, permit writers, human health risk assessors, senior policy analysts and managers were among those representing Region 10 who contributed to this document.

The Framework was developed to be consistent with the following:

1) EPA's overarching mission to protect human health and to safeguard the natural environment upon which life depends;

2) EPA Region 10's commitment to protecting human health and the environment throughout the Region, including the lands and resources of Indian Tribes, while supporting Tribal self-government, fulfilling the federal trust responsibility, and strengthening the government to government relationship between the Tribes of our Region and EPA; and

3) "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency" (EPA, 2002e).

Selection and acquisition of Tribal survey data for incorporation into the Framework

Two seafood consumption surveys that assess Tribal seafood consumption in Puget Sound and the Strait of Georgia were used by EPA in developing this Framework. Section III A. discusses methodological strengths of these surveys and why EPA chose to use the surveys. These surveys are the Suquamish Tribe (2000) survey, which addresses Suquamish Tribe seafood consumption, and the Toy *et al.* (1996) study, which addresses seafood consumption of the Squaxin Island and Tulalip Tribes.

The data as summarized in the Suquamish Tribe (2000) and Toy *et al*. (1996) study reports were not adequate to meet the needs of the Framework in that published survey results did not provide consumption rates for seafood harvested from Puget Sound. The need for this formulation of consumption rates derived from a policy decision that the fraction of seafood affected by site-specific contamination would be defined as the fraction of seafood harvested from Puget Sound. Rationale for this policy decision is provided in section VI.C. of the Framework.

The methodology used to compute consumption rates of seafood harvested from Puget Sound is provided in Appendix B. EPA initially analyzed the Toy *et al*. (1996) data on both the Tulalip and Squaxin Island Tribes. Permission to use the original data from the Toy *et al*. (1996) study was received from the Tulalip Tribes. Dr. Shiquan Liao, a statistician involved in data analysis for both the Toy *et al.* (1996) and Suquamish Tribe (2000) studies, was custodian of the Toy *et al.* (1996) data and transmitted data for both the Tulalip and Squaxin Island Tribe data to EPA. In consultations with the Squaxin Island Tribe, it was later determined that the Tulalip Tribes' permission to use the Toy *et al*. (1996) data did not include use of Squaxin Island Tribe data. Squaxin Island Tribe data analysis results included in an earlier draft of the Framework were subsequently withdrawn. EPA and the Squaxin Island Tribe reached the understanding that both parties would continue to discuss the potential use of the Squaxin Island Tribe's data in a later version of the Framework.

The Suquamish Tribe data were not analyzed by EPA but rather by Dr. Liao, as the Suquamish Tribe has chosen to retain custody of its data. EPA explained the need for this data analysis to the Suquamish Tribe environmental staff, who then gave permission to Dr. Liao to conduct his analysis and transmit the results to EPA. Dr. Liao's analysis was used to support the Suquamish Tribe consumption rate used in this Framework.

During the development of the Framework, national EPA guidance and policies were reviewed, as were historic Region 10 site-specific approaches to the selection of fish and shellfish consumption rates for cleanup sites.

Review of the draft Framework

The initial draft Framework underwent extensive internal review by staff and managers within the participating offices, the Office of Ecosystems, Tribal and Public Affairs, and by the Senior Tribal Policy Advisor. After incorporating numerous changes based on review comments, in December 2004 the draft Framework was sent to the chairpersons of all the federally-recognized Tribes in Puget Sound and the Strait of Georgia, listed below. Copies of the letter and Framework were also sent to

an environmental director or staff person at each Tribe, based on information collected during a phone call to each Tribe.

Jamestown S'Klallam Tribe	Port Gamble S'Klallam Tribe
Muckleshoot Tribe	Chehalis Tribe
Swinomish Tribe	Suquamish Tribe
Lower Elwha Klallam Tribe	Nooksack Tribe
Suak-Suaittle Tribe	Lummi Nation
Makah Tribe	Samish Indian Tribe
Stillaquamish Tribe	Skokomish Tribe
Tulalip Tribes	Nisqually Tribe
Puyallup Tribal Council	Yakama Nation
Squaxin Island Tribe	Upper Skagit Tribe
Snoqualmie Tribal Council	

The Tribes were asked to participate in a dialogue on the draft Framework, and meetings between EPA and individual or multiple Tribes were encouraged. EPA invited the Tribes named above to an initial conference call on January 11, 2005, to present the draft Framework and discuss the anticipated process for meetings and the submittal of comments. EPA met with the Water Quality Group of the NW Indian Fisheries Commission on February 2, 2005 and September 9, 2005, and with the Suquamish Tribe on December 6 and December 15, 2005. In March 2005, a Web-based "QuickPlace" was set up by EPA to facilitate dialogue among Tribes and with EPA regarding the draft Framework. Oral or written comments additionally were received from four Tribes As a result of these comments and conversations, EPA made numerous additional changes to be responsive to comments from these Tribes and sent revised versions of the draft Framework to all the Tribal chairpersons with copies to their natural resource or environmental director or staff person on March 23, 2005, October 11, 2005, and February 22, 2006.

The draft Framework went through more extensive internal reviews and revisions, resulting in a draft final version, which was transmitted to all the Tribes in March 2006. The proposed changes were also presented to the Water Quality Group of the NW Indian Fisheries Commission in June 2006. EPA continued to work with the Suquamish Tribe during the summer of 2006 in order to address its concerns. Several elements of the Framework were modified as a result of these conversations, and these changes are described in EPA's transmittal letter to the Tribes, dated August 2007.

In spring 2007, while EPA and the Suquamish Tribe were working with the Suquamish Tribe's data, a discrepancy between the consumption calculations in the data and those used in the Framework was recognized. The Suquamish Tribe reviewed the data and modified its consumption rate. This change is also described in EPA's transmittal letter to the Tribes.

As explained to the Tribes in December 2004, EPA needed to use the Framework as a pilot, that is, before it would be finalized, at one or more cleanup sites affecting the Duwamish River. It is currently being used in the Superfund Lower Duwamish Waterway risk assessment. Lessons learned from the pilot application of the Framework have been incorporated into this version.

In summary, this Framework provides a recommended approach for selecting fish and shellfish consumption rates where Tribal consumption of fish and shellfish is evaluated in EPA's risk assessment process for CERCLA and EPA-lead RCRA sites in Puget Sound and the Strait of Georgia. The approach reflects EPA guidance and policies regarding the exposures due to releases from contaminated sites. The Framework is designed to provide a consistent approach to developing fish and shellfish consumption rates and to assist decision makers in making risk management decisions.

Application of this Framework in EPA's RCRA and CERCLA cleanup programs is expected to be performed in consultation with the Tribal governments on a site-specific basis. This Framework is not intended to replace government-to-government consultation on specific sites.

EPA's release of the Framework does not imply concurrence by the Tribes. The Framework is an EPA cleanup program document that has been improved through dialogue with Tribes. Nevertheless, EPA's release of the Framework should not be construed as any Tribe's concurrence with either the Framework in general or any specific statements or recommendations included in the Framework.

EPA considers the Framework to be a working document that may be revised periodically to incorporate new information and lessons learned.

Nothing in the Framework will limit, modify, or change Tribal treaty rights.

Appendix B

Fish and Shellfish Mixtures from Tribal Consumption Studies

The consumption rate in grams per day for each group of species listed in Appendix B, including salmon, was calculated using the following steps:

1. The mean consumption rate for adult Tribal members for each group of species was taken from averages reported in Toy *et al*. (1996) and the Suquamish Tribe (2000).

2. The mean consumption rates were added, and this sum was used to estimate the percentage of total fish consumption ascribed to each group of species. This estimate is presented in the column "Percent of Diet."

3. These percentages were applied to the total ingestion rate selected in Box PS-9 to calculate an estimated consumption rate (g/day) for each group of species.

Step 2, Box PS-10 of this Framework requires the user to select a "reasonable mix of classes of fish and shellfish." The following tables specify such mixes for the Tulalip and Suquamish Tribes.

Table B-1.
Distribution among species groups if the Tulalip Tribes consumption rate is used in Box PS-9

Species	**Grams per day (1)**	**Percent of diet (2)**
Salmon	96.4	49.7
Pelagic fish	8.1	4.2
Bottom fish	7.5	3.9
Shellfish	81.9	42.2
Total Ingestion Rate	194 (3)	100

(1) The average body weight for use with this study is 81.8 kg.
(2) Percent of diet is based upon mean data in Table 3, Toy *et al*., 1996.
(3) The value of 194 g/day in this table is the 95th percentile total consumption rate for fish and shellfish after adjusting the total consumption rate of 243 g/day to include only fish and shellfish harvested from Puget Sound, Kissinger, 2005.

Table B-2.
Distribution among species groups if the Suquamish Tribe
consumption rate is used in Box PS-9.

Species	Grams per day (1)	Percent of diet (2)
Salmon (Group A)	183.5	23.9
Pelagic Fish (Groups B and C)	56.0	7.3
Bottom Fish (Group D)	29.1	3.8
Shellfish (Groups E and G)	498.4	65
Total Ingestion Rate	766.8 (3)	100

(1) The average body weight for use with this study is 79 kg.
(2) Percent of diet is based upon mean data in Table T-3, The Suquamish Tribe, 2000. Group F is primarily canned and fresh tuna and is not included in these calculations.
(3) The value of 766.8 g/day in this table is the 95th percentile total consumption rate for fish and shellfish after adjusting the total consumption rate of 796 g/day to include only fish and shellfish harvested from Puget Sound, The Suquamish Tribe, 2007

Appendix C

Background Information on the Calculation of Puget Sound Fish and Shellfish Consumption Rates

The 95th percentile, consumer-only Puget Sound fish and shellfish consumption rate for the Tulalip and Suquamish Tribes, as shown in Step 2, Box PS-9 of this Framework, was determined as follows. For each individual, the consumption rate was obtained for each fish and shellfish group (*i.e.*, bottom, pelagic, anadromous, and shellfish). The consumption rate for each group was then multiplied by the fraction of that group obtained by the individual from Puget Sound. The overall consumption rate of fish and shellfish harvested from Puget Sound for each individual was derived by summing all of the adjusted results.

RateA: Anadromous fish consumption rate, g/kg/day

FPSA: Fraction of anadromous fish harvested from Puget Sound (unitless)

RateP: Pelagic fish consumption rate, g/kg/day

FPSP: Fraction of pelagic fish harvested from Puget Sound (unitless)

RateB: Bottom fish consumption rate, g/kg/day

FPSB: Fraction of bottom fish harvested from Puget Sound (unitless)

RateS: Shellfish consumption rate, g/kg/day

FPSS: Fraction of shellfish harvested from Puget Sound (unitless)

BW: Body weight, kg

Rate (g/day) = [RateA * FPSA + RateP * FPSP + RateB * FPSB + RateS *FPSS] * BW

After a Puget Sound fish and shellfish consumption rate was computed for each individual, rates were ranked from lowest to highest consumption rate. Results for individuals who did not consume any fish harvested from Puget Sound (non-consumers) were discarded from the analysis. From rates for the remaining individuals (*i.e.*, consumers), the rank of the 95th percentile respondent was identified by multiplying the number of consumers by 0.95. Where this computation did not result in a whole number rank that identified a specific individual and associated consumption rate, the 95th percentile consumption rate was linearly interpolated from the rates of the individuals bracketing the position of the 95th percentile rank (Kissinger, 2005; The Suquamish Tribe, 2007)

Appendix D

Section IV Applied to a Simple Hypothetical Site

Background

A hypothetical site in Puget Sound is within the U&A of the ABC Tribe. The site has released only one contaminant, X, to groundwater, surface water and sediments. X has cancer and noncancer toxicity values available on the IRIS database. The contaminant is prevalent throughout Puget Sound and the Strait of Georgia waters and is bioaccumulative. The exposure duration for the ABC Tribe is assumed to be the Framework's default of 70 years, as there is no site-specific information indicating that Tribal members consume fish and shellfish from their U&A for fewer than 70 years during their lifetimes.

Site-specific considerations (see Section IV and the Flow Sheet)

Box PS-1: Are Puget Sound fish and shellfish consumption studies relevant?
There are no obvious reasons why any of the existing Puget Sound studies are inappropriate for characterization of the ABC Tribe's seafood consumption. Proceed to Box PS-2.

Box PS-2: Does the site have extensive shellfish habitat?
The site has limited intertidal habitat. Consequently, proceed to Box PS-5.

Box PS-5: What Tribal study is appropriate for sites with limited shellfish habitat?
For sites with limited intertidal habitat, use Tulalip Tribes data to characterize the consumption rate. Proceed to Box PS-8.

Box PS-8: Proceed to Box PS-9, Selection of a consumption rate.

Box PS-9: Consult the table in Box PS-9 associating the Tribe and the consumption rate.
The consumption rate associated with the Tulalip Tribes is 194 g/day. Proceed to Box PS-10.

Box PS-10: What are appropriate percentages of the different fish and shellfish categories?
It is determined that the percentages for the Tulalip Tribes as provided in Appendix B, Table B-1 are appropriate. These are as follows, along with consumption rates:

Species	Grams per day	Percent of diet
Salmon	96.4	49.7
Pelagic fish	8.1	4.2
Bottom fish	7.5	3.9
Shellfish	81.9	42.2
Total Ingestion Rate	194	100

Proceed to Box PS-11

Box PS-11: Are salmon affected by local contamination?
Adult salmon returning to spawn are known to reside in the general vicinity of the cleanup site for a few days to a week, during which time they are not feeding. The contaminant is known to be readily accumulated by salmon via the food chain. Adult salmon harvested from the vicinity of the site have concentrations of contaminant X that are similar to those found in salmon harvested in other areas within Puget Sound and the Strait of Georgia. While the site has released contaminant X, the lines of evidence indicate that the preponderance of the adult salmon's body burden of contaminant X was probably acquired in the open ocean or other areas of Puget Sound and the Strait of Georgia, remote from the site. The degree to which site-related releases of contaminant X may have been transported to more remote areas of Puget Sound and the Strait of Georgia is unknown. A best professional judgment decision is made to not include the contaminant present in locally harvested salmon in the calculation of site-related risk from fish and shellfish consumption. This decision and rationale are discussed with the EPA Region 10 advisory inter-program review group.

Box PS-12: Are there any additional issues to consider in determining whether or not the contaminant might pose site-related risks via consumption of other categories of fish or shellfish?

There are no additional contaminant and aquatic life issues. Bottom and pelagic fish and shellfish tissue of representative species will be sampled and the results of the analysis used in the risk assessment. [Note: concentrations in these fish could also be estimated through modeling, if appropriate.]

Calculating the intake rate of the contaminant

The intake rate of the contaminant via consumption of fish and shellfish tissue may be computed from the following formula. This formula is used to compute the intake rate of the contaminant based on tissue concentrations in each category of fish/shellfish, and is specific to exposures to tissue contaminants that are expected to be potentially site-related. The total site-related intake of contaminant X via fish and shellfish consumption is computed by summing the individual rates for each category.

Intake of contaminant in mg/kg-day (IR_c) = (CF_i x CR_{PS} x $\%_i$ x UCF_1) /BW [Equation 1]

Where:

IR_c = Intake rate of contaminant X by category of fish/shellfish.

CF_i = contaminant concentration (milligrams per kilogram, mg/kg) in the tissue of the particular fish or shellfish category, (also referred to as the exposure point concentration).

CR_{PS} = the total consumption rate of fish and shellfish harvested from Puget Sound, 194 grams per day.

$\%_i$ = the percentage of the ingestion rate that consists of the category of fish or shellfish, unitless (see table provided for box PS-10, above)

BW = body weight, 81.8 kilograms, observed from the Tulalip Tribes'study (See Appendix B)

UCF_1 = conversion factor 1, 0.001 kilograms per gram

Intake rates of Contaminant X, by category of fish/shellfish

Overall Fish/Shellfish Consumption Rate, g/day	Category	Percent of Consumption Rate Represented by Category	Site-related concentration of contaminant X, mg/kg, in fish tissue (1)	Category-Specific Exposure, mg/kg-day computed using Equation 1
194	Salmon	49.7	0 (2)	0
194	Pelagic Fish	4.2	1.1	0.0001
194	Bottom Fish	3.9	3.1	0.0003
194	Shellfish	42.2	18.6	0.0186
Sum, $IR_{total,}$				0.0190

(1) Concentrations from sampling of bottom and pelagic fish and shellfish.
(2) Any amount of contaminant X present in salmon tissue is assumed in this case to be from sources remote from and unrelated to the site.

The overall site-related intake rate of contaminant X, IR_{total}, via fish and shellfish consumption is 0.0190 mg/kg-day. This value is now used with appropriate cancer and non-cancer toxicity information to calculate the potential risks and hazards to Tribal members

from consuming this quantity of contaminant X. This is conducted using routine risk algorithms, shown below.

Cancer risk and non-cancer hazard estimates associated with site-related intake of Contaminant X

Oral cancer slope factor for Contaminant X	Oral reference dose for Contaminant X
1.4E-2 $(mg/kg\text{-}day)^{-1}$	2E-2 mg/kg-day

Estimated cancer risk = $(IR_{total}$ x ED x EF x CSF) / (AT x $UCF_2)$ [Equation 2]

Where:

IR_{total} = Total intake of contaminant X from site-related fish and shellfish consumption, 0.0190 mg/kg-day

ED = exposure duration, 70 years

EF = exposure frequency, 365 days per year

CSF = oral cancer slope factor for contaminant X, 1.4E-2 $(mg/kg\text{-}day)^{-1}$

AT = averaging time, 70 years for carcinogens

UCF_2 = conversion factor 2, (365 days/year)

Estimated cancer risk =
[(.0190 mg/kg-day x 70 yr x 365 d/yr) x (1.4E-2 per mg/kg-day)] / [(70 years) x (365 days/yr)] = 3E-4

Estimated hazard index = (IR_{total} x ED x EF x UCF_2) / (RfD x AT) [Equation 3]

Where:

IR_{total} = Total intake of contaminant X from site-related fish and shellfish consumption, 0.0190 mg/kg-day

ED = exposure duration, 70 years

EF = exposure frequency, 365 days per year

RfD = Oral reference dose for contaminant X, 2E-2 mg/kg-day

AT = averaging time, the same as exposure duration for non-carcinogenic effects

UCF_2 = conversion factor 2, (1 yr/365 days)

Estimated hazard index = (0.0190 mg/kg-day x 70 y x 365 d/y x 1 y/365 days) / (2E-2 mg/kg-day x 70 years = 0.95

Summary

The excess individual lifetime cancer risk from Tribal consumption of fish and shellfish that may be affected by site-related releases of contaminant X is estimated to be 3E-4.

The hazard quotient from Tribal consumption of fish and shellfish that may be affected by site-related releases of contaminant X is estimated to be 0.95.

These estimates, and their associated exposure and toxicity uncertainties, will be presented and evaluated in the risk characterization document to be used in making risk management decisions for the site.