Agenda
August 9th, 2007
Human Health Focus Group
Oregon DEQ building, 811 SW 6th Avenue, PDX, OR 97204
Room EQC-A 10th Floor
10:00 – 4:00
Call in = 1-877-214-5010 (code=898168)

10:00 Introductions & Agenda review

10:15 Report back on Workshop #3 – Human Health Risks

10:30 Review 3 main questions we are asking the HH focus group (refer to handout)

10:40 Considering the available local, regional and national information on fish consumption, what is the scientific evidence Oregon should rely on in selecting a fish consumption rate to use in setting water quality standards? (refer to table in handout)

a. What scientifically credible studies are available?
b. How relevant are the studies to Oregon?
c. Should some studies be weighted more heavily?
d. Do some provide information that is likely to be relevant to certain locations within the State?
e. Trends between studies?
f. Summary Statements, findings?

Lunch break

<u>AS TIME ALLOWS</u>

- Using the Relative Source Contribution (RSC) variable to account for marine fish
  a. Review RSC variable
  b. Which criteria currently use the RSC?
  c. Should it only be used for non-carcinogens?
  d. In the absence of data is it appropriate for Oregon to use the default RSC value of 20% in establishing HH criteria
     a. Options DEQ, EPA, and CTUIR are considering include:
        i. Salmon in the rate / no RSC used
        ii. Salmon in the rate / RSC used
        iii. No salmon / RSC used
        iv. No salmon / no RSC

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- Meeting notes – timeline for review

3:30 HH Focus Group Report
   a. Discuss structure and content
   b. Timeline?

3:45 Next meeting?

4:00 Adjourn

Questions for Human Health Focus Group

Oregon Fish Consumption Rate Project

1. Considering the available local, regional and national information on fish consumption, what is the scientific evidence Oregon should rely on in selecting a fish consumption rate to use in setting water quality standards? (One purpose of the standards is to protect people's ability to eat fish and shellfish caught from Oregon waters without unacceptable risk to human health.)

    a. What scientifically credible studies are available?
    b. How relevant are the studies to Oregon? Should some studies be weighted more heavily? Or do some provide information that is likely to be relevant to certain locations within the State?
    c. How were the consumption rates derived? What species were included? What populations were surveyed?
    d. What are the assumptions and uncertainties associated with fish consumption rate options?

2. How should anadromous fish be considered in selecting a fish consumption rate and/or calculating criteria?

3. To what extent are populations who consume more than the current fish consumption rate of 17.5 grams/day at a greater risk for health impacts?
    a. What are the assumptions and uncertainties around this risk?

	EPA Region 10 Seafood Consumption Rates Used for Risk Analysis - Adapted for use in the Oregon Fish Consumption Rate Project (DRAFT for discussion purposes ONLY)										
	Group	Subgroup	Consumer/ Non Consumer	Seafood Source	Species included in consumption rate evaluation	Statistic (grams/day)					
						Mean	Median	Percentile			
								75th	90th	95th	99th
1	Tulalip Tribe[v]	Children (0-5 years old)	Consumer	All	Anadromous & resident finfish & shellfish	3.6	1.2	4.5	11.2		
2	Squaxin Tribe[v]	Children (0-5 years old)	Consumer	All	Anadromous & resident finfish & shellfish	12.5	7.7	18.2	31.3		
3	Suquamish Tribe[u]	Children (9 months to 6 years old)	Consumer	All	Anadromous & resident finfish & shellfish	24	12		57		
4	Columbia River Tribes[p]	Children (0-5 years old)	Consumer	All	Anadromous $ resident fish	19.6		~22	~40	~68	~129
5	Columbia River Tribes - Reevaluation of data[bb]	Children (0-5 years old)	Consumer	All	Anadromous $ resident fish	26.7	16.2		64.8	81	162
6	General Population[q]	Children (3-5 years old)	Nonconsumer	All	Resident finfish & shellfish from fresh and estuarine environments	2.19		NA	0.05	12.17	52.46
7	General Population[q]	Children (3-5 years old)	Nonconsumer	All	Anadromous & resident finfish & shellfish from fresh, estuarine, and marine environments	7.7		NA	32.56	51	100
8	General Population[r]	Children (3-5 years old)	Consumer	All	Anadromous & resident finfish & shellfish from fresh, estuarine, and marine environments	74	64	NA	149	184	363
9	General Population[r]	Children (3-5 years old)	Consumer	All	Resident finfish & shellfish from fresh and estuarine environments	40	23	NA	95	129	205
10	Lake Whatcom (WA) Fisherman[x]	Children	Consumer	Lake Whatcom (WA)	Resident fish		3.6				

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						Mean	Median	Percentile			
								75th	90th	95th	99th
11	Columbia River Tribes[c]	Women who have breastfed (36% of survey respondents)	Consumer	All	Anadromous $ resident fish	59.1		~58.5	~112	~174	~278
12	General Population[s]	Women (15-44 years old)	Consumer	All	Anadromous & resident finfish & shellfish from fresh, estuarine, and marine environments	108	77	NA	221	315	494
13	General Population[t]	Women (15-44 years old)	Consumer	All	Resident finfish & shellfish from fresh and estuarine environments	75	36	NA	172	273	502
14	Tulalip Tribe[w]	Adult (males)	Consumer	All	Anadromous & resident finfish & shellfish	76	53		212	247	
15	Tulalip Tribe[w]	Adult (females)	Consumer	All	Anadromous & resident finfish & shellfish	68	34		187	218	
16	Tulalip Tribe[a]		Consumer	All	Anadromous & resident finfish & shellfish	72	45	85	186	244	312
17	Tulalip Tribe[a]		Consumer	Harvested anywhere	Anadromous & resident finfish & shellfish	63	37	80	159	236	311
18	Tulalip Tribe[a]		Consumer	Harvested from Puget Sound	Anadromous & resident finfish & shellfish	54	30	74	139	194	273
19	Tulalip Tribe[a]		Consumer	All	Resident finfish & shellfish	36	18	41	116	132	168
20	Tulalip Tribe[a]		Consumer	Harvested anywhere	Resident finfish & shellfish	32	14	40	103	116	157
21	Tulalip Tribe[a]		Consumer	Harvested from Puget	Resident finfish & shellfish	31	14	39	90	113	157
22	Suquamish Tribe[b]	Adults (16 or older)	Consumer	All	Anadromous & resident finfish & shellfish	214	132		489	NA	NA

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						Mean	Median	Percentile			
								75th	90th	95th	99th
23	Suquamish Tribe[c]	Adults (16 or older)	Consumer	Harvested from Puget Sound	Anadromous & resident finfish & shellfish	NA	111	NA	534	785	NA
24	Suquamish Tribe[c]	Adults (16 or older)	Consumer	Harvested from Puget	Resident finfish & shellfish	NA	65	NA	380	680	NA
25	Columbia River Tribes[d]	Adult	Consumer	All	Anadromous & resident fish	63	40	60[e]	113[f]	176[g]	389
26	Columbia River Tribes[m]	Adult	Nonconsumer	All	Anadromous & resident fish	58.7	~40	~56.7	~113	170	389
27	Columbia River Tribes[n]	Adult	Consumer	All	Resident fish	~43		~41	~82	~124	~284
28	Asians & Pacific Islanders[aa]	Adults (18 or older)	Consumer	All	Anadromous & resident finfish & shellfish	132	100		274		
29	Asians & Pacific Islanders[h]		Consumer	All	Anadromous & resident finfish & shellfish	NA	78	NA	236	306	NA
30	Asians & Pacific Islanders[h]		Consumer	Harvested anywhere	Anadromous & resident finfish & shellfish	NA	6.9	NA	49.1	76.3	NA
31	Asians & Pacific Islanders[h]		Consumer	Harvested from King County	Anadromous & resident finfish & shellfish	NA	5.8	NA	25.5	57.1	NA
32	Asians & Pacific Islanders[h]		Consumer	Harvested anywhere	Resident finfish & shellfish	NA	7.1	NA	54.2	72.3	NA
33	Asians & Pacific Islanders[h]		Consumer	Harvested from King County	Resident finfish & shellfish	NA	6.6	NA	33.4	57.3	NA
34	General Population[i]	Adults (18 or older)	Nonconsumer	All	Resident freshwater/estuarine finfish & shellfish[j]	7.5	0	NA	17.4	50	143

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						Mean	Median	Percentile			
								75th	90th	95th	99th
35	General Population[k]	Adults (18 or older)	Nonconsumer	All	Anadromous & resident finfish & shellfish from fresh, estuarine, and marine environments	20	0	NA	75	111	216
36	General Population[l]	Adults (18 or older)	Consumer	All	Anadromous & resident finfish & shellfish from fresh, estuarine, and marine environments	127	99	NA	248	334	519
37	General Population[l]	Adults (18 or older)	Consumer	All	Resident finfish & shellfish from fresh and estuarine environments	81	47	NA	199	278	505
38	Columbia Slough Fisherman[w]	Adult	Consumer	Columbia Slough	Resident finfish & shellfish from fresh and estuarine evironments		24	36			
39	Sauvie Island Fisherman[w]	Adult	Consumer	Sauvie Island	Anadromous & resident finfish & shellfish from fresh and estuarine evironments		4	6			
40	Lake Whatcom (WA) Fisherman[x]	Adult	Consumer	Lake Whatcom (WA)	Resident fish	6					
41	Lake Roosevelt(WA) Fisherman[y]	Adult	Consumer	Lake Roosevelt (WA)	Resident fish	42					90[z]

[a]Values computed from Toy et al. 1996 study data (Kissinger 2003).

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					Mean	Median	Percentile			
							75th	90th	95th	99th

[b]Values g/kg/day for "all seafood" taken from Table T-3 of the Suquamish Survey (Suquamish 2000) and converted to g/day by multiplying by the average body weight for men and women of 79 kg

[c]Values computed by ShiQuan Liao of the Mountain Whisper Light Statistical Consulting company for the Suquamish Tribe (Liao 2003)

[d]Values compiled from Table 10 "Number of Grams per Day Consumed by Adult Fish Consumers" of the Columbia River Intertribal Fish Commission Study (CRITFC 1994)

[e]A value of 60 g/day was derived by linearly interpolating between the consumption rate/cumulative percentiles bracketing the 75th percentile (48.6 g/day, 65.1%) and (64.8 g/day, 79.1%)

[f]A value of 113 g/day was derived by linearly interpolating between the consumption rate/cumulative percentiles bracketing the 90th percentile (97.2 g/day, 88.5%) and (130 g/day, 91.6%)

[g]A value of 176 g/day was derived by linearly interpolating between the consumption rate/cumulative percentiles bracketing the 95th percentile (170 g/day, 94.4%) and (194 g/day, 97%)

[h]Values computed from 1999 EPA Asian Pacific Islander seafood consumption survey data (Kissinger 2005). Kissinger (2005) converted mixed cooked and raw wet weight consumption rate information from the 1999 publication into a wet weight consumption rate.

[i]Values taken from EPA 2002 Section 5.1.1.1, Table 4: Uncooked fish consumption estimates, U.S. Population – Finfish and Shellfish, Individuals Age 18 and Older. Values from the "freshwater/estuarine" section of the table are used. Earlier derivations of the 90th and 99th percentile values were used in developing Ambient Water Quality Criteria protective of human health (EPA 2000). The values presented here differ slightly from the 90th and 99th percentile values of 17.5 and 142.4 g/day respectively that were used in the methodology.

[j]Pacific salmon were assigned to consumption of marine species rather than estuarine species (SEE Section 2.1.1 of EPA 2002 for an explanation).

[k]Values taken from EPA 2002 Section 5.1.1.1, Table 4: Uncooked fish consumption estimates, U.S. Population – Finfish and Shellfish, Individuals Age 18 and Older. Values from the "all fish" section of the table are used. These values were used by EPA Region 10 in developing tribal seafood consumption rates for risk assessment when existing tribal data are judged to be inappropriate.

[l]Values taken from EPA 2002 Section 5.2.1.1, Table 4: Uncooked fish consumption estimates, U.S. Population – Finfish and Shellfish, Individuals Age 18 and Older. Values from the "all fish" section of the table are used. It has been suggested that EPA Region 10 may find these values to be useful in developing estimates of tribal subsistence consumption rates when existing tribal data are deemed to be inappropriate. The methodology of the "Continuing Survey of Food Intake by Individuals" (USDA 2000) developed consumer only numbers by extracting data on individuals who consumed seafood on one or more of the two days individuals were surveyed. It has been proposed that subsistence seafood consumers are likely to consume seafood daily, and that the CSFII methodology is an appropriate way to develop subsistence consumption rate estimates.

[m]Values compiled from Table 7 "Number of Grams per Day of Fish Consumed by Adult Respondents (Fish consumers and non-fish consumers) combined - Throughout the year" of the Columbia River Intertribal Fish Commission Study (CRITFC 1994)

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						Mean	Median	Percentile			
								75th	90th	95th	99th

[n]Values compiled from Tables 10, 18 and 19 from CRITFC 1994. The average consumption rate for Pacific Northwest Salmon was estimated to be 20 grams/day. That was subtracted from the average for all fish for consumers only to result in 43 grams/day as the average fish consumption for adult consumers only for resident fish. The ratio of .73% (all fish/resident) was then applied to the other percentiles. All values are estimates.

[o]The mean values was taken from Table 16 and all other percentiles were estimated from Table 15 in CRITFC 1994. All calculated values are estimates.
[p]The mean values was taken from Table 24 and all other percentiles were estimated from Table 24 in CRITFC 1994. All calculated values are estimates.
[q]All values taken from EPA 2002 Section 5.1.1.1, Table 5
[r] All values taken from EPA 2002 Section 5.2.1.1, Table 5
[s] All values taken from EPA 2002 Section 5.2.1.1, Table 3
[t] All values taken from EPA 2002 Section 5.2.1.1, Table 1
[u] All values calculated using 16.8 as the average body weight of children and applying that body weight to values in Table T-14 in Suquamish 2000
[v] All values were calculated using an average child BW of 15.2 kg (from Table A1) and the consumption rates Toy et al., 1996, Table A9
[w] All values taken from Adolphson 1996, Table 4, page 20. Values were converted to grams/day from kg/person/year.
[x] All values taken from Dave McBride's summary of the Lake Whatcom 2001 study. Adult average consumption of 225 g/meal was used along with a median children rate of 131 g/meal. 10 meals were assumed per year

[y] All values taken from Dave McBride's summary of the Lake Roosevelt 1997 study.

[z] All values taken from Dave McBride's summary of the Lake Roosevelt 1997 study. 90g/day was labelled as "high end consumers" and placed in the 99th percetile column for that reason.
[aa] All values taken from Sechena, et al, 1999, Table R-1. A body weight of 70 kg was used to calculate grams/day.
[bb] All values taken from Rhodes 2006, Table 32.

References

Columbia River Intertribal Fish Commission. 1994. A Fish Consumption Survey of the Umatilla, Nez Perce, Yakima, and Warm Springs Tribes of the Columbia River Basin

EPA. 1999. Asian & Pacific Islander Seafood Consumption Study in King County Washington. EPA Region 10, Office of Environmental Assessment, Risk Evaluation Unit. EPA 910/R-99-03.

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						Mean	Median	Percentile			
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EPA. 2000. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health. Office of Water, Office of Science and Technology. EPA-822-B-00-004

EPA. 2002. Estimated per Capita Fish Consumption in the United States.

Kissinger, L. 2003. Development of Tulalip and Squaxin Tribe Seafood Ingestion Rates for Puget Sound Tribal Seafood Risk Analysis Based on Individual Interview Results

Kissinger, L. 2005. Application of Data from an Asian and Pacific Islander (API) Seafood Consumption Study to Derive Fish and Shellfish Consumption Rates for Risk Assessment

Liao, S. 2003. Development of Suquamish Tribe Seafood Ingestion Rates for Puget Sound Tribal Seafood Risk Analysis Based on Individual Interview Results

Suquamish Tribe. 2000. Fish Consumption Survey of the Suquamish Indian Tribe of the Port Madison Indian Reservation, Puget Sound Region

Toy, K; N.L. Polissar, S. Liao, G. Mittelstaedt. 1996. A Fish Consumption Survey of the Tulalip and Squaxin Island Tribes of the Puget Sound Region.

U.S. Dept. of Agriculture, Agricultural Research Service. 2000. 1994-1996, 1998 Continuing Survey of Food Intakes by Individuals.

Adolphoson 1996. Technical Memorandum on the Results of the 1995 Fish Consumption and Recreational Use Surveys - Amendment No. 1. City of Portland, Bureau of Environmental Services.

Lake Whatcom 2001. Lake Whatcom Residential and Angler Fish Conumption Survey. Washington Department of Health, April 2001.

Lake Roosevelt 1997. Consumption Patterns of Anglers Who Frequently Fish Lake Roosevelt. Washington State Department of Health, September 1997.

Sechena, et al 1999. Asian and Pacific Islander Seafood Consumption Study. (EPA 910/R-99-003)

Rhodes 2006. Fish Consumption, Nutrition, and Potential Exposure to Contaminants Among Columbia River Basin Tribes. Masters of Public Health Thesis, Oregon Health and Science University.

Survey Name	*CRITFC Fish Consumption Study(1994)*	*Re-evaluation of 1994 CRITFC Fish Consumption Study (2006)*	*EPA's Review of CSFII (1998)*	*Tulalip and Squaxin Island Tribes Fish Consumption Study (1996)*	*Suquamish Tribe Fish Consumption Study (2000)*	*Sauvy Island Fish Consumption Survey (1995)*	*Asian and Pacific Islander Seafood Consumption Study (1999)*
Survey Methodology	interview/questionnaire and dietary recall	interview/questionnaire and dietary recall	dietary recall	interview/questionnaire	interview/questionnaire	creel survey	interview/questionaire
Description	Fish consumption survey including information on the amount of fish harvested from the Columbia River and its tributaries. 513 adults and 204 children were surveyed. Children were between 0 and 6 years of age. No adolescents were surveyed. Random selection from Indian Health Service of enrolled members on or near reservation. Particpants were compensated $40/person.	Reanalyzed the data from the 1994 CRITFC study focusing on children, women of child-bearing age and elders	stratified random; low income; no ethnic or Indian specific interviews	Seafood consumption survey including information on whether or not adults harvested fish & shellfish from Puget Sound. 190 adults and 69 children were surveyed. Children were between 0 and 6 years of age. No adolescents were surveyed.Randomly selected tribal members	Seafood consumption survey including information on whether or not adults harvested fish & shellfish from Puget Sound. 92 adults and 31 children were surveyed. Children were between 0 and 6 years of age. No adolescents were surveyed. Randomly selected tribal members.	Survey of local anglers at Sauvie Island and Columbia Slough; 20 sample days over one month period	Seafood consumption survey characterizing fish and shellfish consumption by Asian Pacific Islanders residing in King County, including information on the quantity of self-harvested seafood. 202 adults were surveyed. No children or adolescents were surveyed. Participants were compensated by $25 check or grocery store gift certificate.
Cost	$300,000	see CRITFC, 1994	N/A	N/A	~$150-250K	N/A	~$750K
Population Interviewed	744 called; 125 per tribe; Representing:yakama 3872; nez perce 1446; umatilla 818; warm springs 1531	Re-evaluation focused on Women who gave birth in the past 5 years, eladers aged 55 years (+), and children age <5 years	21000; Represents the general US population (281 million people)	150 Tulalip; 120 Suquaxin Island; Represents 2 tribes 2 tribes = 14 Puget Sound Tribes;Tulalip 1398;Squaxin Island 500	Represents 831 people	91 anglers (ethnicity includes E. Europeans, Hispanics, Asians, African Americans and Native Americans)	202 Asian Pacific Islanders within King County, Washington; 1st or 2nd generation 18+ years of age; consumers only
Number of Children	204; (0-6 years)	200; (0-5 years old)	2000 in 1996 (0-10 years old); add 4000 in 1998 (add 3 year old girls in 1998)	69 (0-6 years old)	31 (0-6 years old)	N/A	N/A
Number of Adults	513 (>18 years of age)	see CRITFC, 1994	15000 (>18 years of age)	190	92		202 (at or >18 years of age)
age range	58% 18-39;31% 40-59: 9.9% 60	see CRITFC, 1994	N/A	N/A	N/A	N/A	
elders	N/A	94 g/day	N/A	N/A	N/A	N/A	
elder ages	N/A	55-92	N/A	N/A	N/A	N/A	

elder average	N/A	65.1 g/day (avg); 97.2 g/day (90th percentile); 170 g/day (95th percentile); 486 g/day (99th percentile)	N/A	N/A	N/A	N/A	
elder range	N/A	0-972 g/day	N/A	N/A	N/A	N/A	

EPA has implied that incidental ingestion occurs every day. However, other commenters believed that this route should be considered for waters not designated as drinking water sources. One of these requested that EPA provide additional guidance on incidental ingestion relevant to acute toxicity and exposures. Another recommended that EPA evaluate the circumstances to determine whether the incidental ingestion rate would make a difference. A commenter recommended that EPA use a 30 mL/hour assumption in cases where short-term effects may be considered in criteria derivation. One commenter stated that the 10 mL/day value would be too restrictive for use in all nonpotable waterbodies and would conflict with existing State guidance on incidental ingestion.

Response—EPA acknowledges that much of the population consumes water from public water supplies that receive treatment. However, we intend to continue including the drinking water exposure pathway in deriving AWQC for the reasons clearly stated in the 1998 draft Methodology revisions. Refer to that discussion for clarification on this issue [see **Federal Register** Notice, August 14, 1998; Appendix III, C.1.(b)]. We encourage States and Tribes to use alternative intake rates if they believe that water consumption is higher in arid climates than the recommended default rate. We have not assumed that incidental ingestion occurs every day. We have estimated an averaged rate based on available study information. When initiating the process to revise the methodology, several stakeholders identified recreational or accidental water ingestion as a potential health concern. A couple of States have indicated that they already have established incidental ingestion rates for use in developing water quality criteria. EPA agrees that the averaged amount is negligible and will not have any impact on the chemical criteria values representative of both water and fish ingestion. The lack of impact would likely also be true for chemical criteria based on fish consumption only, unless the chemical exhibits no bioaccumulation potential. However, we believe that the issue could be important for the development of microbial contaminant water quality criteria, and for either chemical or microbial criteria for States where recreational uses such as swimming and boating are substantially higher than a national average would indicate. Although we will not use the incidental ingestion intake parameter when deriving our 304(a) national chemical criteria, we will leave the guidance language in the final Exposure Assessment TSD in order to assist States and authorized Tribes that face situations where this intake parameter would be of significance.

7. Default Fish Intake Rates

Comments—EPA received strong support for its hierarchy of preferences regarding fish intake values; that is, use of local or regional studies, and studies characterizing similar populations and/or geography, over default values. EPA also received support for encouraging decisions on intake rates to be made at the State or Tribal level. EPA generally received support for its default fish consumption rates, including the national 304(a) criteria value of 17.8 g/day (now 17.5 g/day based on the 1994–96 CSFII data). There was support for the new default rates as more accurately representing current levels of fish consumption among the general population than the old assumption of 6.5 g/day. Support was also received for providing the variety of default values to protect highly sensitive or highly exposed population groups. One commenter advocated that EPA clearly state that using the 90th percentile value is a risk management decision. However, others stated that EPA has overestimated fish consumption for the population at large. A commenter stated that EPA should use the intake value that its Superfund program utilizes (*i.e.*, 54 g/day). EPA also received support for the default of 86.3 g/day for subsistence fishers (now 142.4 g/day based on the most recent USDA survey data). Some commenters disagreed with the use of a subsistence default as contrary to the purpose of AWQC (while conceding its use for site- or region-specific criteria) or recommended that EPA caution against the use of subsistence values without risk management decisions balancing risk benefits and costs. One commenter stated that subsistence populations are very rare and cannot generally be defined by socioeconomic factors and, thus, EPA's assumption of 86.3 g/day may be over-or underprotective. Several commenters stated their support for the subsistence default but also advocated that EPA should require States to consult with Tribes in order to select an adequate fish consumption rate. Other comments expressed the opinion that a Tribe would be obligated to use EPA's default value if the Tribe could not conduct its own survey or expressed concern over the extrapolation of data from the general population to subsistence populations. Several commenters questioned EPA's choice in selecting a value to represent the 90th percentile of the general population, in contrast to selecting average values for sportfishers and subsistence fishers. A commenter stated that the assumption of 17.8 g/day as a default for sport anglers was not supported by peer-reviewed studies and contradicts the EPA's Exposure Factors Handbook. Another commented that because 17.8 g/day is recommended to represent the general population, it should not be used to represent sportfishers and indicated that 39 g/day may be more appropriate. Other comments advocated the use of actual sportfisher/subsistence population data or making sure that the defaults chosen appropriately correspond to these groups.

Two commenters stated that the recommended values for children and women of childbearing age were overly conservative and inappropriate because developmental effects would not result from short-term exposures. However, another commenter stated that evidence on reproductive/developmental effects should make EPA take the most conservative approach to protect pregnant women, fetuses, and young children. Other commenters found these values acceptable and believed that the approach is consistent with EPA developmental toxicity guidelines. One commenter noted that single meal or short-term consumption for these groups could easily exceed the EPA defaults. Other comments cautioned EPA to make sure that the exposure assumptions to protect against developmental health effects be used only with chemicals causing acute toxicity, or believed the defaults are unrealistically high and favored an averaged daily equivalent (mean or median value). Two commenters believed that basing both national and regional criteria on a fish consumption rate in the 90th to 95th percentile would be most appropriate, and one stated that the high-end percentile should be used with rates for children and women of childbearing age to protect against reproductive or developmental effects. Another commented that criteria to protect subsistence fishers or pregnant women should be left to the States and Tribes to consider. Still another suggested that EPA develop special fish consumption rates for populations that consume much higher amounts than average and, thus, not be overly conservative in its default assumptions. Two commenters questioned EPA's assumption that children consume more fish on a body weight basis than adults, and one commenter advocated use of childhood fish consumption rates. Concern was also expressed that all of the default rates assume that consumers eat from a single source only, and that the RSC factor results in a double-counting of fish intake rates. One commenter said that EPA should not establish default values. Finally, one commenter advocated using mean consumption rates (not the 90th percentile) if the Agency intends on retaining its RSC factor.

Response—EPA acknowledges the support for the default fish intake rates. Our national 304(a) water quality criteria serve as guidance to States and authorized Tribes, who must in turn adopt legally enforceable water quality criteria into water quality standards. States and authorized Tribes have the option to develop their own criteria and the flexibility to base those criteria on population groups that they determine to be at potentially greater risk because of higher exposures, yet, EPA cannot oblige the States to specific consulting agreements because, again, criteria are guidance, not enforceable regulations, and do not impose legally binding requirements. Therefore, we recommend that States and Tribes give priority to identifying and adequately protecting their most highly exposed population by adopting more stringent criteria, if the State or Tribe determines that the highly exposed populations would not be adequately protected by criteria based on the general population. In all cases, States and authorized Tribes have the flexibility to use local or regional data that they believe to be more indicative of the population's fish consumption—instead of EPA's default rates—and we strongly encourage the use of these data. In most instances, using alternate fish intake rates should not be difficult, once the value has been determined, in that the criteria calculation is performed by substituting the State/Tribal intake rate in place of EPA's default rate. We believe that the assumption of 17.5 g/day (again, based on the recent 1994–96 CSFII data) will protect a majority of the population of consumers of fresh/estuarine finfish and shellfish, especially population groups who rely on a particular waterbody for most or all of their fresh/estuarine intake. It is our goal to utilize an intake rate that represents more of the population than would a central tendency value. Thus, we intend to derive our national 304(a) criteria using this 90th percentile assumption, based on the updated analysis of the 1994–96 CSFII data. EPA also acknowledges that other Agency programs may utilize different default assumptions. In the case of the Superfund program, the value used (54 g/day) represents a default used for recreational fishers. It reflects total fish consumption from both marine and fresh/estuarine sources; however, it includes only finfish, not shellfish. As such, it cannot be directly compared to our default based on the general population for finfish and shellfish from fresh/estuarine sources only. [*Note*: The comparable 90th percentile CSFII value from the 1994–96 data, if marine species were included, would be 74.87 g/day.] For the AWQC program, EPA believes it has selected an appropriate, not overly conservative default value, given the goals of the CWA and the criteria program.

For the rationale stated above, we strongly believe that providing a default rate for subsistence fishers is important for States and Tribes, if they choose to use it in lieu of their own study data. We disagree with the commenter that the concept is contrary to the purpose of AWQC. Moreover, the commenter appears to have incorrectly assumed that EPA would base its national 304(a) water quality criteria on the subsistence fishers intake value. We intend to base our national criteria on the recommended value for the general population. We emphasized in our 1998 draft Methodology revisions that States and Tribes should consider developing criteria based on highly exposed populations when those populations would not be adequately protected by criteria based on the general population. This is, in fact, consistent with the purpose of AWQC. We also acknowledge that there is variation in fish consumption patterns, especially among subsistence fishers. For the purpose of providing one national intake rate for subsistence fishers, we believe that the value of 142.4 g/day (an estimated national average value based on comparing the CSFII 1994–96 data with subsistence fisher studies) is appropriate. Although the exact percentile represented by the arithmetic mean varies from survey to survey, we believe this value is more appropriate and protective than a median or central tendency value—which we cautioned against using in the 1998 draft Methodology revisions, because median values in the available short-duration surveys may be zero. However, as indicated above, EPA strongly encourages the use of site or regional-specific studies instead of this default value, and the State's/Tribe's discretion in considering higher intake rates than an arithmetic mean. We reemphasize here our four-preference hierarchy, which is designed to give States and Tribes more options than simply conducting a survey or using our default. EPA's national 304(a) criteria are health-based values only and are not intended to account for cost/benefit analyses. As indicated in our 1998 draft Methodology revisions, risk management decisions regarding balancing risk benefits should be made at the State or Tribal level.

EPA believes it is appropriate to offer default fish intake rates for children and women of childbearing age for States and authorized Tribes to consider if exposures resulting in health effects in children or developmental effects in fetuses are of primary concern. We have recommended a 90th percentile from the 1994–96 CSFII for this potential situation, in order to protect a majority of these population groups. As stated in the 1998 draft Methodology revisions, EPA is not recommending the development of additional water quality criteria, similar to the drinking water health advisories, which focus on acute or short-term effects because these are not seen routinely as having a meaningful role in the water quality standards program. However, we disagree with the commenter that developmental effects cannot result from short-term exposures. To the contrary, we believe there may be instances where the consideration of acute or subchronic toxicity and exposure in the derivation of AWQC is warranted—specifically when such toxicity and exposure are the basis of an RfD, not a chronic effect. Only in this situation would EPA consider such a basis for its national 304(a) criteria. Using long-term consumption rates to evaluate potential developmental effects would not accurately reflect meal size and would be inappropriate for use in such assessments. The separate distribution of short-term (*i.e.*, consumers-only) consumption estimates represents the amount of fish an individual consumes in a day, or multiple days in a short time period, if the person eats fish on that day. The consumers-only consumption estimate approximates a serving size for women of childbearing age or for children. The intent is to characterize consumption over a very short period of time, not as an average or per capita value over a longer period of time. We recommend the use of the short-term (consumers-only) consumption values in assessing developmental risks to children or women of childbearing age. However, we intend to routinely base our national 304(a) criteria on the recommended fish intake rate for the general population. One commenter appears to have incorrectly assumed that EPA would normally base its national criteria on

1b

acute toxicity scenarios. EPA acknowledges that it may have overstated the likelihood that children are more highly exposed in terms of the frequency of their consumption of freshwater and estuarine fish, although this may certainly be true for various subpopulation groups. However, the CSFII data clearly show that children do consume more fish per unit body weight than do adults. Therefore, as stated above, we believe it is useful to provide intake defaults to States and authorized Tribes for children, and we have specifically used childhood fish consumption rates (to the extent allowable by the CSFII data) as advocated by the commenter.

EPA disagrees with the comment that the sportfisher default assumption (*i.e.*, that 17.5 g/day based on the 1994–96 CSFII data represents average consumption rates for this population group) is not supported by available studies or by the Exposure Factors Handbook. The value of 17.5 g/day falls within the range of mean values from sportfisher/angler studies reviewed by EPA. The Exposure Factors Handbook indicates that mean intakes from recreational freshwater studies ranged from 5 to 17 g/day, with mean values from the key West *et al.* studies used in the GLI between 12.1 and 16.7 g/day (USEPA, 1997a). Furthermore, the default rate recommended here for the AWQC is representative of consumption of both freshwater and estuarine fish species, not freshwater species only. We are also aware that some of the sportfisher studies that support higher estimates (*e.g.*, 39 g/day) include marine species.

EPA's fish intake assumption is that all of the consumed fish is taken from one particular waterbody. This is to ensure that any population can safely eat fish from waters designated for fishing, including those who may rely on a single source for their fish (for additional discussion on this issue, see response to Comment E.2, Assumption That All Fish Consumed Is Contaminated at the Criteria Level).

EPA disagrees with the idea that using a 90th percentile value as a default is inappropriate because of the RSC factor. The RSC is used to account for other sources of exposure and, thus, is independent of potential exposures from fresh/estuarine fish. The fresh/estuarine species are not double-counted, as the commenter suggests. (For additional discussion on RSC, refer to the responses in the RSC section below.)

8. Effect of Cooking on the Contaminant Concentration

Comments—Commenters stated that the concept of changes in contaminant level caused by cooking is important to recognize. They recommended that a loss from cooking should be accounted for and that EPA should provide factors in order to calculate this loss into criteria. However, one commenter did not believe that increases caused by cooking should be factored into criteria. One commenter stated that it is not appropriate to assume no loss as a default when no data exist to account for it. Another recommended that the chemical structure be assumed as constant before and after cooking. One commenter stated that the relevance of cooking methods is not clear.

Response—EPA has stated its intention to assume no loss from cooking unless there are adequate data to characterize such a loss. We are aware of some studies on cooking loss and provide reference to quantified information in the 2000 Human Health Methodology. However, we believe it is important to consider both losses and gains in the chemical contaminant from cooking. EPA has also received input from several States regarding the difficulty in making such adjustments on a routine basis. We continue to evaluate this issue in the context of the national 304(a) criteria. We believe that providing guidance on making such adjustments may be useful in the Exposure Assessment TSD volume for States or Tribes that wish to modify their criteria accordingly. However, EPA does not intend to provide specific cooking loss default factors.

9. Inclusion of Marine Species in the Default Rate

Comments—A commenter stated that coastal States have a need to derive water quality criteria for saline waters under their jurisdiction and, therefore, requested additional consideration of marine fish consumption. Another commenter requested that EPA provide greater clarification on its policy not to include marine species, again believing that States and Tribes need to include this in their criteria development.

Response—In the 1998 draft Methodology revisions, EPA recommended inclusion of fresh/estuarine species only for the intake parameter, and accounting for the intake of marine species as part of the RSC. We consider this appropriate because the 304(a) water quality criteria are applicable to discharges from fresh and estuarine waters, not deep marine waters. EPA's 304(a) water quality criteria apply to navigable waters of the United States up the three miles off-shore. However, EPA also says that coastal States and authorized Tribes could consider total fish consumption (fresh/estuarine and marine species) when appropriate for protecting the population of concern. It is important that the marine intake component not be double-counted with the RSC estimate. We maintain our default policy decision and the flexibility afforded to a State or authorized Tribe to base its criteria on alternative assumptions.

10. Precision of the Drinking Water Parameter

Comments—A commenter interpreted EPA's discussion on significant figures as indicating that the drinking water intake should not be factored into that determination because the number represents a science policy value. The commenter also requested that EPA specify a level of protection represented by the AWQC.

Response—The commenter has misunderstood EPA's discussion in the 1998 draft Methodology revisions on significant figures; they have extended the discussion to an evaluation of overall criteria conservativeness via statistical analysis. We stated that the AWQC should not necessarily always be limited to one significant figure because the 2 L/day drinking water value, although supported by data, represents a science policy decision. The discussion only addresses the issue of significant figures, not characterization of criteria protectiveness. For discussion of the issue regarding the population protected by the criteria level, refer to the response for Comment B.3, Protectiveness of the Methodology.

11. Redesignation of Salmon as a Marine Species

Comments—Some commenters disagreed with EPA's reclassification of salmon to the marine category. They stated that EPA has ignored salmon biology and life history, that salmon is an anadromous species, and that salmon eggs, fry, and juveniles take up chemicals. Commenters specifically criticized EPA for ignoring steelhead salmon's life history. Three commenters thought the redesignation is reasonable. One had no objection to the redesignation for threshold toxicants but did object for carcinogenic effects based on a linear low-dose extrapolation, because it would not account for exposures of salmon to ubiquitous chemicals (*e.g.*, PCBs) contributing a substantial portion to total exposure. Another commenter who supported the redesignation advocated flexibility regarding coastal sportfisher consumption.

Response—EPA has not ignored the life history of salmon. We provided information on the known biology and life history of the species consumed that were included in the CSFII survey, the basis of the default values, in our 1998 draft Methodology revisions. The term anadromous generally refers to a species that spawns in fresh water or near-fresh water and then migrates into the ocean to grow to maturity. It can also refer to an ocean species that spawns in fresh/near-fresh waters. The life cycles of anadromous species vary as to whether they remain in fresh/near-fresh waters until they die or whether they return to ocean waters after spawning. As such, the description provided by EPA in the 1998 draft Methodology revisions is correct and does not conflict with the term anadromous. The CSFII food codes for salmon do not indicate the source of the salmon (*e.g.*, land-locked freshwater, farm-raised, or wild). We based our allocation of salmon between freshwater and marine habitats on commercial landings data provided by the National Marine Fisheries Service for the period 1989–1991. All landings of Pacific salmon, including chum, coho, king, pink, or sockeye, were assigned to the marine habitat. All land-locked Great Lakes salmon and farmed salmon received the classification of fresh water. The resulting apportionment for salmon was 1.18% to the fresh-water habitat and 98.82% to the marine habitat. We believe this is appropriate for our national default intake rates.

EPA understands that steelhead salmon, also known as steelhead trout (*Oncorhynchus mykiss*), is an oceangoing version of rainbow trout with a complicated life history, and may spend a significant portion of its lifetime in fresh waters. States and authorized Tribes have the flexibility to use different assumptions in deriving their water quality criteria, as we stated in the 1998 draft Methodology revisions. That is, States and authorized Tribes could make alternative assumptions to specifically account for steelhead salmon intake. We strongly encourage States and authorized Tribes to do so, as reflected by the recommended fish intake hierarchy of preferences. However, we do not intend to ignore the contribution from salmon in the calculation of our 304(a) criteria. We recommended accounting for this as part of the RSC, thereby ensuring that the criteria would account for the contribution of a contaminant from marine salmon.

12. Studies on Sportfishers and Subsistence Fishers

Comments—Two commenters stated that in summarizing various sportfisher and subsistence fisher studies, EPA failed to provide direction on how States or Tribes can use and interpret the information. One commenter requested additional guidance on the use of local data, while cautioning about such data's reliability. Commenters also listed errors, discrepancies, or missing information from numerous studies that appear in the 1998 draft TSD. One commenter recommended separating studies by type, population, and basis for consumption rate (presumably referring to habitat designations of fish), along with providing comments on the studies. Another stated that many angler studies are biased because the respondents are more "avid" in their fishing habits, and a study of fresh-water anglers from Maine might serve better as the basis of EPA's default for sportfishers.

Response—It is EPA's intention to provide summaries of various studies for States and Tribes to consider using and, as such, the Agency is merely providing information, not critiquing or endorsing particular studies. We do not intend to rank the studies because there are significant differences in the purposes and limitations of each study, in addition to the fact that consumption rates vary significantly throughout the country. Therefore, any particular study may be most appropriate to the State or Tribe's particular circumstances. However, we are committed to providing accurate information and intend to correct errors or missing information that would make the summaries of greater use to States and Tribes. We have reviewed the commenters' listed errors or omissions and made appropriate changes. EPA disagrees that any of the sportfisher studies are biased from "avidity" among recreational anglers. Although the rates may vary significantly from study to study, the studies specifically sample fishing patterns of these groups and are the most appropriate data for prospective use by States and Tribes. We considered the Maine angler study along with the others presented in the 1998 draft TSD to evaluate the range of mean values before recommending the default value. However, we do not believe this particular study is necessarily best suited for deriving a national default value. Just as with EPA's national 304(a) criteria, States and Tribes always have the flexibility to use other local- or regional-specific studies. We have provided additional guidance on how to consider the studies included in the Exposure Assessment TSD.

13. USDA Continuing Survey of Food Intake by Individuals (CSFII)

Comments—Some commenters believed that the CSFII data are appropriate for deriving AWQC and supported their use in the hierarchy of choices. Others stated that the CSFII data are not appropriate because they include marine species, and combine recreationally and commercially acquired species. One commenter suggested that a significant fraction of the default rate would include farm-raised fish, which would not bioaccumulate the same as wild fish. One commenter stated that the default inappropriately assumes consumption from a single waterbody. Two commenters stated that the CSFII data are biased toward individuals consuming large quantities of fish (assuming constant consumption every day and failing to consider those people who consume less frequently). One of these stated that the CSFII assumes that participants who did not eat fish during the study period are not fish eaters. Several commenters recommended that longer term studies be used, one specifically stating the difficulty in estimating the upper end of the distribution. Comments also referred to or recommended data from NPD Research Inc. or the Tuna Research Institute, presumably referring to the National Purchase Diary (NPD). One commenter assumed that the CSFII default estimates exclude individuals who consume fish but did not report consumption during the sampling period. Another questioned dividing reported consumption by the days of the survey and incorporating nonconsumption. Instead, this commenter recommended using the positive values only ("acute consumers") for determining default intake rates, which it believed to be consistent with the concept of identifying the population to be protected. One commenter also indicated that intake rates do not vary significantly for fish obtained from different sources—that is, fresh or marine waters. Another stated that the CSFII data assume short-term consumption is representative of long-term consumption. One commenter advocated that EPA use probabilistic methods to derive AWQC.

Response—The comments are incorrect about the exclusion of respondents who did not report fish consumption during the CSFII sampling period. The general population,

18

recreational fisher, and subsistence fisher default values all include both CSFII respondents who reported eating fish during the sampling period and respondents who reported zero consumption (what the commenter referred to as "non-consumers"). The CSFII mean values are not biased. Specifically, the intraindividual variation does not bias estimates of the mean intake of the population. The estimates of the upper percentiles of per capita fish consumption based on the short sampling period data may be biased upward, thereby resulting in a conservative estimate of risk. However, the extent to which this is overestimated is not knowable. We note that we did not rely exclusively on the CSFII data; rather, the data were analyzed with those from other studies (especially for recreational fisher and subsistence fisher estimates) to evaluate and corroborate our decision. We believe the CSFII data are representative of fish intake rates among the general population. As part of the CSFII analysis, sampling weights were adjusted to account for nonresponse and were subsequently reweighted using regression techniques that calibrated the sample to match characteristics correlated with eating behavior.

EPA generated mean and percentile estimates of daily average per capita fish consumption based on the USDA 1994–96 CSFII. The strengths of this survey for supporting estimates of per capita food consumption are twofold. First, the survey design is structured to obtain a statistically representative sample of the U.S. population. Second, the survey is designed to record daily intakes of foods and nutrients and to support estimation of food consumption. These features are in direct alignment with the objective of producing current, per capita fish consumption estimates for the U.S. population. The 1994–96 CSFII collected two non-consecutive days of food consumption data from a sample of 11,912 individuals in the 50 states and the District of Columbia. The method employed to collect dietary intake data also strengthened the CSFII design for supporting per capita consumption estimates. For example, the survey was administered by an interviewer on both days of data collection. For these reasons, we believe that the 1994–96 CSFII is the best source of data on a nationwide basis for estimating fish consumption by the U.S. population.

The NPD study was conducted over 25 years ago. The NPD is the basis of the 6.5 g/day default value that EPA has historically used for fresh/estuarine fish consumption. We have received consistently strong input from many of our stakeholders (including States and Tribes) who consider the 6.5 g/day value inadequate and advocate the use of much more recent data. The Agency also believes that such an update is needed. We are not aware of any subsequent major survey conducted during a 30-day period as was done by the NPD. The Agency does not believe that the year-long study of 29 people mentioned by one commenter is appropriate to use for a national default value. The use of probabilistic methods was discussed earlier in our response to Comment B.3, Protectiveness of the Methodology.

EPA also believes that its discussion of identifying population groups to protect is not contradicted by its combining positive and zero values to estimate long-term or average consumption. We reiterate here that we believe the summation of the amounts of fish consumed by each individual across the 2-day reporting period for the CSFII 1994–96 data (formerly a 3-day reporting period), followed by dividing that total individual consumption by 2, is a reasonable approach to estimating average consumption. The CSFII did not specifically ask questions on whether respondents consume fish or how often and, therefore, it is not possible to distinguish fish consumers from fish nonconsumers. EPA is aware from other major surveys that most people consume fish—at least episodically—and, therefore, believes that using the positive and zero values from the CSFII is a reasonable method of estimating average intake. We contrast this to using only the subset of survey responses where fish was actually consumed as a method to estimate an "acute consumer," that is, to provide an estimate of the amount of fish consumed in the context of acute or short-term exposures (not in the context of average or long-term exposures).

The commenters are also incorrect about the inclusion of marine species. The proposed default rates for the general population, as well as for children and women of childbearing age, are based on freshwater and estuarine species only. The CSFII study does include marine species and EPA has additionally provided States and Tribes with these data in the Exposure Assessment TSD; however, they are not included in the default estimates of national freshwater and estuarine fish consumption. According to the CSFII data, most persons in the general population appear to consume more marine species than fresh/estuarine species. However, EPA supports State/Tribal use of local or regional data that indicate otherwise. We have not made any specific assumptions regarding farm-raised fish and their contribution to the default intake rate, nor have we received any information that would allow us to characterize (or discount) the amount that farm-raised fish contributes to the national default value or to differentiate bioaccumulation levels.

14. Use of Uncooked or As Consumed Fish Weight for Default Intake Rates

Comments—One commenter stated that either raw weight or cooked weight can be appropriate as long as the effect of cooking on the contaminant is accounted for. Some commenters stated that the cooked weights are the most technically defensible, because they are the basis for the consumption estimates. However, others believed the default intakes should be adjusted to reflect uncooked weights, with one commenter concerned that a cooked weight would result in incomplete accounting of exposure to threshold toxicants. One commenter also pointed out the difficulty of making appropriate adjustments to the BAF because of uncertainties in concentration levels of contaminant due to cooking and that many cooking techniques result in retention of fish fluids. Another commenter stressed the need to use uncooked weights in order to be consistent with fish tissue studies and BAF values. One commenter expressed concern that use of cooked weights would produce an inadequately protective criterion for mercury, while another believed that cooked values introduce a source of uncontrolled variability.

Response—We have considered the pros and cons of using uncooked/as consumed weights on several levels. First, the intake parameters of the criteria derivation equation are intended to capture ingestion—that is, what people actually consume and are exposed to. By and large, people consume cooked fish, and if raw shellfish or sushi was consumed by the CSFII respondents, those intakes were included in the as consumed weights. This assumption is also consistent with the dietary estimates based on prepared foods (not raw commodities) that are made by both EPA's pesticide program and the Food and Drug Administration (FDA) Total Diet Study program. We also considered the "consistency" issue in the context of the fact that the CSFII survey respondents estimated the weight of fish that they consumed. Similar to the CSFII, EPA's GLI was based on a consumption survey of fish intakes for prepared meals. EPA additionally considered the effect of the cooking process. There are comparatively few chemicals for which measurements are available, and the process is complicated further by the different parts of a fish where the chemical may accumulate, the method of preparation, and how the cooking process may transform the chemical. What is certain is that the mass of the contaminant will either remain constant or be reduced. The resulting concentration is harder to predict. In the 1998 draft Methodology revisions, we recommended the use of as consumed weights and an adjustment of the bioaccumulation factor for cooking loss, if information was available. Otherwise, we recommended using the as consumed weight along with the full bioaccumulation factor (unadjusted for cooking loss), which would produce slightly more stringent AWQC. We have also received input from stakeholders regarding potential confusion over the fact that uncooked weights are used in the Agency's fish advisory program and that having two sets of values may prove confusing to States and Tribes, as well as the general public. Furthermore, the measures of a contaminant in fish tissue samples that would be applicable to either compliance monitoring or the permitting program are related to the uncooked fish weights.

Therefore, EPA has reconsidered its position based on these facts and despite the fact that the as consumed values more accurately represent actual intake, we will derive our national 304(a) criteria on the uncooked weight fish intakes. The approach of using an uncooked weight in the calculation will result in somewhat more stringent AWQC (studies indicate that, typically, the weight loss in cooking is about 20%). We will also provide guidance on site-specific modifications in the Exposure Assessment TSD. Specifically, we will describe an alternative approach for calculating the AWQC using the as consumed weight (again, more directly associated with exposure and risk) which is subsequently adjusted by the approximate 20% cooking loss to a resultant uncooked equivalent. Thus, the AWQC conversion to an uncooked equivalent can be consistently used between State/Tribal standards programs and still represent the same relative risk as the as consumed value. It is important to understand that the two approaches will not result in the same AWQC value. Whereas the as consumed approach is more scientifically rigorous and represents a more direct translation of the as consumed risk to the uncooked equivalent, it may be too intensive a process to expect of State and Tribal organizations whose resources are already constrained.

Relative Source Contribution (RSC)

15. Default Percentages and RSC Floor of 20% and Ceiling of 80%

Comments—A commenter criticized EPA's recommended RSC default rate in the face of uncertainty about other routes of exposure. Another commenter considered the ceiling of 80% to be a redundant uncertainty factor. Other comments suggested the use of an 80% RSC for bioaccumulative chemicals so that the contribution from fish consumption would not be underestimated, did not support the range of 20% to 80%, or requested additional justification for the assignments of 20%, 50%, or 80%.

Response—EPA has recommended using the 20% RSC default when routes of water exposure other than oral or sources of exposure other than fish and water are anticipated, but adequate data are lacking to quantify those exposures. When data are adequate, they should be used instead of the default. If it can be demonstrated that other sources and routes of exposure are not anticipated for the chemical in question (based on information about its known/anticipated uses and chemical/physical properties), then the 80% ceiling is recommended. The ceiling is intended to provide adequate protection for those who experience exposures (from any or several sources) higher than available data indicate. For many of the chemical contaminants that EPA evaluates, data are not available on multipathway exposures. It is possible that as we progress with our development of a cumulative risk policy, we may find an 80% RSC to be underprotective. This concern was expressed during the scientific peer review workshop on the Methodology. One commenter misunderstood the application of lower ceilings (*i.e.*, 50%, 20%) when existing information indicates no other media-specific uses or sources. Also, some chemicals that bioaccumulate in fish also bioaccumulate in other meat and dairy products (*e.g.*, dioxins). Therefore, to simply assume an 80% default in all cases would not be appropriate. The RSC approach allows for an apportionment of 80% when information indicates that other exposures are not relevant for the chemical being evaluated. EPA has added discussion in the final Methodology to address these situations and to better explain the application of the lower ceilings.

16. Duplication of Fish Intake Assumptions

Comments—Commenters stated that applying an RSC factor results in a double-counting of fish from other sources.

Response—The commenters are incorrect. The fish intake default used in the equation accounts for fresh and estuarine species only. The RSC factor potentially applies to nonfish dietary intake, air exposures, and marine fish species. To protect humans who additionally consume marine species of fish, the marine portion should be considered as part of the "other sources of exposure," that is, part of the RSC or dietary value. EPA specifically emphasized in the 1998 draft Methodology revisions that States and authorized Tribes need to ensure, when evaluating overall exposure to a contaminant, that the marine fish intake is not double-counted with the dietary intake estimate used. This applies if the State or authorized Tribe chooses to account for total fish consumption (*i.e.*, fresh/estuarine and marine species) in the fish intake parameter used in the AWQC equation.

17. Exposure Route Differences

Comments—EPA received support for its rationale on accounting for differences in bioavailability and absorption between exposure routes when data are available, and assuming equal rates when data are absent.

Response—We acknowledge this support.

18. Need for an RSC Factor/Considering Multiple Routes of Exposure

Comments—Commenters supported the greater emphasis on RSC, including the use of empirical data. Some stated that EPA should give full consideration to multiple routes of exposure (*i.e.*, ingestion, inhalation, dermal), with emphasis on the variety of water-related activities, cultural practices, and lifestyles. Several commenters pointed to published studies on assessing inhalation and dermal exposures, and two commenters advocated that EPA determine when there is a need to factor in these exposures, based on available information on the chemical. One commenter stated that there are circumstances where inhalation exposures can be a significant portion of total exposure (*e.g.*, for some chemicals during showering). However, another suggested that consideration of inhalation and dermal exposures is premature. Two commenters stated that uncertainty factors, severity of effects, essentiality, and additive/synergistic

20

effects should be factored into the RfD apportionment, with one believing that this should also include the option of developing less stringent criteria when there is great uncertainty in the data. Five commenters stated that they believe the RSC/Exposure Decision Tree concepts represent an unnecessary safety factor or should not be considered. One suggested that the water quality criterion should relate only to water exposures. Two commenters suggested that factoring in other exposures is "penalizing" the AWQC and makes them overall environmental exposure criteria. Another questioned the need to apportion the RfD, but focused on drinking water regulations, stating that accounting for other sources of exposure would likely have no benefit, presumably due to conservatism in the RfD derivation (yet acknowledging that those uncertainty factors are independent of the exposure assessment). Several commenters recommended that EPA reconsider the SAB's advice not to routinely apportion the RfD. Others believed that the RSC should be used only for site-specific criteria, or that States should have the flexibility to make adjustments for local conditions. Two commenters also stated that the Exposure Decision Tree is unclear, is overly complicated, or has unrealistic data requirements. Another stated that the approach is generally desirable but that EPA needs to provide a greater and more easy-to-follow explanation of the rationale, indicating policy judgments where they occur. However, other commenters supported the Decision Tree approach for its facilitation of identifying the decisions necessary to select the most appropriate RSC value and considered it scientifically valid. One commenter cautioned that if probabilistic analysis techniques are used, their application must be valid and underlying assumptions clearly indicated. Commenters expressed the need for data to avoid the 20% default, others stated that defaults should be avoided altogether, and one recommended a 100% RSC for highly bioaccumulative chemicals. One of the supporters believed that the approach is a reasonable compromise between avoiding problematic increases in exposures to substances and not setting unduly restrictive requirements. A commenter questioned how new data would be considered in the context of RSCs based on older data. Another recommended that non-zero values for other exposure sources not be assumed unless a significant number of samples are positive. It was also recommended that EPA coordinate the RSC policy with other Agency programs.

Response—EPA disagrees that the RSC represents an excessive or unnecessary safety factor. The purpose of the RSC is to ensure that the level of a chemical allowed by a criterion or multiple criteria, when combined with other identified sources of exposure common to the population of concern, will not result in exposures that exceed the RfD or POD/UF. The policy of considering multiple sources of exposure when deriving health-based criteria has become common in EPA's program office risk characterizations and criteria and standard-setting actions. Since the SAB expressed concerns in 1993, numerous Agency workgroups have evaluated the appropriateness of factoring in such exposures and concluded that it is important for adequately protecting human health. Consequently, Agency policy has evolved significantly over the last 6 years. Various EPA program initiatives and policy documents regarding aggregate exposure and cumulative risk have been developed, and include consideration of inhalation and dermal exposures. Additionally, accounting for other exposures has been discussed in recent mandates (*e.g.*, the Food Quality Protection Act) and, thus, is becoming a requirement for the Agency. The RSC approach has been shared with other EPA offices, and efforts to coordinate policies on aggregate exposure, where appropriate, have begun. EPA intends to continue developing guidance on the RSC issue and guidance to address the concern that human health may not be adequately protected if criteria allow for higher levels of exposure that, combined, may exceed the RfD or POD/UF. We also intend to refine the 2000 Human Health Methodology in the near future to incorporate guidance on inhalation and dermal exposures. As stated previously, we are required to derive water quality criteria under Section 304(a) of the CWA and do not intend to derive site-specific criteria for individual waterbodies. However, States and authorized Tribes do have the flexibility to make different exposure and RSC estimates based on local data.

Uncertainty factors used in the derivation of the RfD to account for intra-and interspecies variability and the incompleteness of the toxicity dataset(s)/animal studies are specifically relevant to the chemical's internal toxicological action, irrespective of the sources of exposure to humans. The Agency's policy is to consider and account for other sources of exposure in order to set protective health criteria. We disagree that uncertainty in the data should result in less stringent criteria. However, we have provided additional clarification on the guidance allowing less stringent assumptions when multiple sources of exposure are not anticipated.

The adequacy requirements for the Exposure Decision Tree are not unduly restrictive. The ideas of representativeness, quality assurance, and sampling size are fundamental to properly conducted monitoring studies. Furthermore, the minimal requirement of samples to make an (at least, nominally) acceptable estimate of average and high-end exposure from that relative source (*i.e.*, 45 samples) is not unreasonable guidance. EPA also believes that the number of decision points in the Decision Tree for any particular chemical are not excessive. We have provided additional discussion in the 2000 Human Health Methodology in order to clarify numerous issues on the Decision Tree approach, including the discussion on the use of defaults. We believe that probabilistic techniques are potentially appropriate for use and agree that they must be valid, appropriately applied, and clearly presented.

Regarding changes in ambient chemical concentrations that would affect the RSC calculation, States and authorized Tribes have the opportunity to make changes in their water quality standards during triennial reviews, and EPA would evaluate those changes based on information submitted with the proposed changes. Similarly, EPA would consider changes to AWQC when significant changes in sources of exposure occur that affect the default values.

19. Use of RSC With Carcinogenic Effects Based on Linear Low-Dose Extrapolation

Comments—A commenter advocated the use of an RSC factor with carcinogenic effects based on linear low-dose extrapolation in order to account for other sources of exposure.

Response—EPA does not apply the RSC to carcinogenic effects based on linear low-dose extrapolation because the AWQC are being determined with respect to the incremental lifetime cancer risk posed by a substance's presence in the exposure sources relevant to the specific criterion, not in terms of an individual's total cancer risk from all sources of exposure. In the case of carcinogens based on nonlinear low-dose response extrapolation or a noncancer endpoint where a threshold is assumed to exist, non-water

21

exposures (*i.e.*, non-drinking water and non-fish ingestion exposures, and inhalation or dermal exposures) are considered when deriving the AWQC. The rationale for this approach has been that for pollutants with effect thresholds, the objective of the AWQC is to ensure that an individual's total exposure does not exceed that threshold level. Health-based and medium-specific criteria values for carcinogens based on a linear low-dose extrapolation typically vary from other medium-specific criteria values in terms of the concentration value, and often the associated risk level. Therefore, the RSC concept could not apply unless all risk assessments for a particular carcinogen based on a linear low-dose extrapolation used the same concentration value and same risk level; that is, an apportionment would need to be based on a single risk concentration value and level.

20. Use of Subtraction or Percentage Methods in RSC Apportionment

Comments—One commenter advocated the subtraction method instead of the percentage method for RfD apportionment, and advocated the use of central tendency values. This commenter criticized the percentage method as irrational and likely to produce overly stringent criteria. In addition, it was stated that the percentage method would allow criteria that could result in exposure levels that exceed the RfD when combined exposures are high. Other commenters expressed concern over basing the RSC on current levels of contamination. However, one believed that the percentage apportionment was reasonable given the difficulty in alternative apportionment methods (for example, an apportionment that would minimize the costs of reducing total exposure to/below a certain amount). One commenter suggested using a multiple default system.

Response—The first commenter has significantly misunderstood EPA's policy goals. The argument against use of the percentage approach is based on the idea that the maximum possible amount of chemical concentration, after subtracting other sources, should be allocated to drinking water criteria or standards. This is not EPA's goal nor is it stated in any relevant mandate. The rationale of deliberately removing the entire cushion between precriteria levels (*i.e.*, actual levels) and the RfD, and thereby setting criteria at the highest levels short of exceeding the RfD, is counter to the goals of the CWA for maintaining and restoring the nation's waters. It is also directly counter to Agency policies, explicitly stated in numerous programs, regarding pollution prevention. EPA has advocated that it is good health policy to set criteria such that exposures are kept low when current levels are already low. The subtraction method generally results in prospective criteria values for a contaminant in a particular medium at significantly higher levels than the percentage method and, in this respect, is contradictory to these Agency goals. In fact, many chemicals have existing levels in environmental media, based on available monitoring data, substantially lower (compared with the RfD) than the resulting criteria allow. This is the case with most of the theoretical examples that one commenter provided to refute the method.

The Agency has modified its policy with the Exposure Decision Tree approach to allow use of the subtraction method when multiple media criteria are not relevant. The Agency RSC Workgroup recommended that, although combined exposures above the RfD may or may not present an actual health risk, a combination of health standards exceeding the RfD may not be sufficiently protective. Therefore: (1) Maintaining total exposure below the RfD is a reasonable health goal; (2) there are circumstances where health-based criteria for a chemical should not exceed the RfD (either alone or in combination); and (3) the best way to prevent exceedance of the RfD is to apportion it when multiple health criteria are relevant to a given chemical. We believe that the percentage method is rational in the context of the above goals when multiple media criteria are at issue. However, as a commenter suggested, the percentage method does not simply depend only on the amount of the contaminant in the prospective criterion source. It is not a set amount. It is intended to reflect health considerations, the relative contribution of other sources, and the likelihood for ever-changing levels in each of those multiple sources (due to ever-changing sources of emissions and discharges). The percentage method does not break any "logical link," as a commenter suggested (the commenter referenced an unpublished report from discussions prior to the development of the Exposure Decision Tree approach). EPA is interested in knowing the amounts of current exposures, including water, and is always cognizant of their relationship to the RfD (one commenter suggested that EPA does not compare actual exposures to the RfD; this comparison is always known). We have historically evaluated chemicals in the context of their current levels (*i.e.*, ambient levels prior to either criteria development or regulatory activity). Evaluating these levels, along with the hazard identification, has historically formed the basis for prioritization and whether the Agency would pursue criteria or standards development. We disagree with the comment that criteria should be set without regard to the actual level of the contaminant. Actual levels are advocated by a commenter for use with the subtraction method. In the case of multiple criteria for a given chemical, the commenter's claim that the subtraction method will ensure that "an individual's exposure to a chemical does not exceed the RfD" is not necessarily guaranteed if criteria for other media allow for concentrations in environmental media that, combined, may result in exposures greater than the RfD. EPA acknowledges that the percentage approach outcome varies depending on the magnitude of current exposures, and we have sought to provide greater clarification on this policy issue in the 2000 Human Health Methodology. Of course, depending on the levels from each source, the subtraction method can also produce unstable values—that is, they could vary from very high, to moderate, to very low, even to a negative number.

As previously indicated, probabilistic analyses are appropriate when they are validated techniques that are applied correctly and supported by adequate data. However, much of the time, the amount of data available to describe distributions of exposure from various known sources to the U.S. population—for use in setting nationwide criteria—is inadequate to support meaningful probabilistic analyses. Nevertheless, rather than simply using a default value in every instance, the Agency attempts to compare exposure intakes based on available data to estimate their relative contribution to the total—given that understanding the degree to which their concentrations vary, or making any distributional analysis, is not possible. When multiple criteria are at issue, the criteria values are based on the best available information, with an assumption that there may be enough relative variability such that an apportionment (relating that percentage to the RfD) is a reasonable way of accounting for the uncertainty regarding that variability. Again, in the context of making an estimate of potential national exposures, there is great uncertainty in the range of exposures, and as previously stated, the goal is not to allow a water criterion to use up the "space" between the total exposure and the RfD. An example of the percentage apportionment's potential use is when pesticides are at issue. It does not make sense to allow the water criterion to use up that space when (in terms of the chemical's intended uses) the dietary route is obviously the "direct" source of exposure. When the course of pesticide tolerance-setting activities may, over time, vary the exact amount of the RfD taken up, an apportionment may also be best for pesticide program planning. The Exposure Decision Tree has allowed for the use of the subtraction approach when only one criterion is relevant. Also, given the future need to develop cumulative risk policies, the subtraction method in these cases could be a short-lived option.

Finally, one commenter incorrectly assumed that the percentage method would allow criteria that could result in exposure levels that exceed the RfD when combined exposures are high. Again, this commenter incorrectly assumed that EPA is not aware of the relationship of the estimated exposures to the RfD. The Exposure Decision Tree approach states that, in these situations, a risk management decision would be made in order to reduce exposures to levels that would prevent exceedance of the RfD. We have provided greater clarification on this issue in the 2000 Human Health Methodology. We have also provided clarification on the use of central tendency values when estimating exposures, which we do not believe to be fully adequate for protection of human health when setting national 304(a) criteria.

F. Bioaccumulation

1. Use of Bioaccumulation Factors (BAFs) in General

Comments—Overall, commenters were not adverse to incorporating bioaccumulation into criteria derivation, but were concerned with the methodology EPA proposed to use. Most comments received were focused on the general use of BAFs. Because of the site-specific nature that BAFs can take, several commenters are concerned with applying national BAFs developed from a limited set of data and array of aquatic systems, or from a model, to all waterbodies in the United States. Some commenters did not agree with EPA's proposed BAF tiered hierarchy. These commenters stated that EPA should not derive single national BAFs because there is substantial variation among waterbodies in factors that influence bioaccumulation (*e.g.*, food chain, metabolism, bioavailability, loading history). They recommended that BAFs be calculated on a site-specific basis, or that field-derived BAFs be used in conjunction with modeled BAFs in a weight-of-evidence approach to select a final BAF. Some commenters also wanted the BAF guidance to more clearly state how it applies to different groups of compounds (*e.g.*, nonionic organics, ionic organics, metals, organometallics). Several commenters did agree with EPA that field-derived BAFs better reflect potential exposure to chemicals from all sources than BCFs and incorporate factors in the field (*e.g.*, food chain, metabolism, chemical loading history, temperature) that can affect bioaccumulation.

Response—Although EPA acknowledges there are site-specific factors that affect bioaccumulation, we disagree that national BAFs should not be derived. For some pollutants (*e.g.*, PCBs, methylmercury), biomagnification through the food chain can be substantial. Using a BCF, which only accounts for exposure from the ambient water, could substantially underestimate the potential exposure to humans for some chemicals and result in criteria that are underprotective of the designated uses. Since publishing the 1980 Methodology, there has been a growing body of scientific knowledge that clearly supports the observation that bioaccumulation and biomagnification occur and are important exposure issues to consider for many highly hydrophobic organic compounds and certain organometallics (Russell *et al.*, 1999; Fisk *et al.*, 1998; USEPA, 1998d; Watras and Bloom, 1992; Oliver and Niimi, 1988; Swackhammer and Hites, 1988; Niimi, 1985; Oliver and Niimi, 1983). For highly persistent and bioaccumulative chemicals that are not easily metabolized, BCFs do not reflect what the science indicates. For this group of chemicals, bioaccumulation (*i.e.*, accumulation of a chemical in aquatic biota from all routes of exposure) should be accounted for in the derivation of water quality criteria in order to protect against unacceptable risks from contaminated biota. The use of properly derived BAFs will enable chemical exposure from all sources to be accounted for in water quality criteria. The lack of national BAFs would greatly hinder the development of water quality criteria because many States and authorized Tribes may not have the resources to develop site-specific BAFs. We continue to believe that using national BAFs is the most scientifically valid approach to deriving national AWQC.

EPA acknowledges that data available to derive national BAFs and to validate the overall bioaccumulation methodology are primarily limited to persistent, hydrophobic chemicals from selected locations (*e.g.*, Lake Ontario, Green Bay, Bayou d'Inde, Hudson River). However, we believe these chemicals and sites encompass a reasonable range of chemicals, locations, and ecosystems from which to evaluate the appropriateness of the bioaccumulation methodology. To obtain better representation of lotic (*e.g.*, river) systems, we also performed evaluation of the predictive BAF methods with PCB, pesticide, and chlorinated benzene data from the Hudson River and Fox River/Green Bay. In the vast majority of comparisons between the predicted BAFs and field-measured BAFs using all four methods, the predicted BAFs were in very good agreement with the field-measured BAFs. We further acknowledge commenters' concerns that certain portions of the methodology may not be applicable to some types of chemicals. As a result, we have developed additional guidance that restricts some aspects of the methodology to certain types of chemicals. For example, we have revised the 1998 draft Methodology revisions to remove the use of K_{ow}×FCM to estimate BAFs for chemicals that have been consistently shown to be metabolized substantially in aquatic biota (*e.g.*, certain PAHs) and have clearly differentiated which methods apply to ionizable chemicals and which do not.

We also recognize that there were some uncertainties in the 1998 draft Methodology revisions on how the BAF methodology would be applied both nationally and on a site-specific basis. In response to this, we made substantial revisions to the 1998 draft bioaccumulation methodology which we believe makes the revised methodology applicable on a national basis. First, we improved the readability and guidance presented in the bioaccumulation methodology based on public and peer reviewers' comments. Specifically, we separated guidance for developing national BAFs from guidance for developing site- or region-specific BAFs and revised the Methodology document to make it more clear to the reader on how EPA will derive national BAFs. Second, EPA expanded the guidance for deriving site- or region-specific BAFs to better enable such adjustments to be made by States and authorized Tribes. For example, we updated, expanded, and made more accessible the databases used to develop national values for lipid content in aquatic biota and organic carbon content

23

in water. Third, we plan to develop detailed guidance to assist States and authorized Tribes in designing and conducting field studies to measure site-specific BAFs and BSAFs (biota-sediment accumulation factors). This guidance will specify our recommendations for how, when, where, and how often one should sample water, biota, and sediment for producing reliable measurements of BAFs and BSAFs.

In addition to improved clarity and expanded guidance, EPA believes the changes we made to the national BAF methodology address concern indicated by some public commenters about uncertainty in various aspects of the methodology. We believe the changes we have made reduce the uncertainty in several components of the national BAF methodology. For example, development of separate procedures for deriving BAFs for different chemical classes (*e.g.,* high vs. low hydrophobicity, high vs. low metabolism in biota, ionic vs. nonionic organics) will reduce uncertainty in national BAFs and simplify procedures. As part of these revisions, we recommended that K_{ow}-based estimates of BAFs and food chain multipliers (FCMs) not be used for nonionic organics that are known to be metabolized substantially in targeted biota (*e.g.,* some PAHs). Restrictions have also been placed on the use of the BSAF methodology so that the method is used for the chemicals for which it is most appropriate.

We clearly recognize that even with these revisions incorporated into the national BAF methodology, significant uncertainty might exist in the assessment and application of national BAFs at some sites throughout the United States because of the influence of site-specific factors. Therefore, we have more clearly indicated that development of site-specific BAFs is encouraged and supported when it can be shown that a national BAF is inappropriate, or when a State or authorized Tribe prefers to derive a site-specific BAF.

EPA agrees with commenters that in some cases it may be appropriate to derive a BAF using several of the recommended methods (Methods 1–4), with the final BAF chosen using a weight-of-evidence approach. We have provided general guidance on the assessment of uncertainty in using field-measured BAFs (and BAFs derived using the other methods) when deriving national BAFs. However, we do not believe that the mere existence of uncertainty means that national BAFs (and resulting national 304(a) water quality criteria) cannot be implemented effectively throughout the United States. For more than two decades, we have developed and implemented our national 304(a) water quality criteria (aquatic life and human health) through State, Tribal, and on occasion, Federal water quality standards programs. Implementation of this program has relied on the use of national 304(a) criteria as a cornerstone but has evolved to allow the use of procedures to modify national criteria by States and authorized Tribes where appropriate. EPA's national bioaccumulation methodology is consistent with this programmatic practice, by enabling States and authorized Tribes to readily adopt national 304(a) water quality criteria into standards (based on National BAFs) that achieve the CWA goals of protecting public health while also allowing site- or State-specific adjustments in situations where national AWQC may be considered overprotective or in some cases, underprotective.

Comments—Some commenters questioned the application of the BAF prediction approaches (Tiers 2–4; referred to as Methods 2–4 in the revised Methodology) on a national scale because the data used to validate the approaches and develop predicted BAFs come primarily from chemical partitioning relationships observed from a limited set of studies (*e.g.,* Great Lakes region).

Response—EPA agrees that the locations for which the BAF methodology has been fully applied are limited in number (*e.g.,* Lake Ontario, Green Bay). To address this concern, we have conducted additional assessments and comparisons among the bioaccumulation approaches (Methods 1–4) to further validate their usefulness and have validated the methods using other locations (*e.g.* Bayou d'Inde, LA, Fox River/Green Bay, Hudson River, NY). We acknowledge that a model prediction is not a perfect simulation of what occurs in a natural aquatic ecosystem and that uncertainty exists in the BAFs. However, this does not invalidate the usefulness of models validated using data from the Great Lakes and Hudson River in predicting bioaccumulation in other ecosystems. Results of analyses that support using a predictive bioaccumulation approach for a variety of chemicals and aquatic ecosystems can be found in Burkhard et al. (1997), Burkhard (1998), Oliver and Niimi (1988), Swackhammer and Hites (1988), and Oliver and Niimi (1983). Data from these studies clearly indicate that the food web is a dominate exposure route for many highly hydrophobic chemicals and that use of BCFs only underestimates exposure. EPA's proposed BAF methodology does account for some site-specific differences in bioaccumulation (an issue expressed by commenters) by considering factors such as percent lipid in the fish consumed and the freely dissolved concentration of the chemical in the ambient water (*i.e.,* a baseline BAF). This allows a BAF developed from one set of data and location(s) to be "normalized" and applied to another location. We believe the approach in the 2000 Human Health Methodology appropriately balances protectiveness with the uncertainties surrounding the science currently available to predict bioaccumulation. Comparisons of field-measured and predicted BAFs demonstrate agreement within an order of magnitude in the vast majority of cases, and often within a factor of two to five. Burkhard (1998) observed good agreement between measured and predicted BAFs for the Lake Ontario food web using the Gobas and Thomann food web models. For individual commonly detected PCBs and chlorinated pesticides, the BAFs estimated using the two Gobas and Thomann models were on average within a factor of 1.2 and 2.5 of the observed (*i.e.* field-measured) BAFs, respectively (Burkhard 1998). The overall uncertainties in each of these two bioaccumulation models (expressed as the ratio of the 90th to 10th percentile predicted BAF for each model) were a factor 3.6 and 4.0 for the Gobas and Thomann models, respectively (Burkhard 1998). Furthermore, Burkhard et al. (1997) reported that predicted BAFs (using EPA's national BAF methodology) were within a factor of 5 for 94% (n=32, using laboratory measured BCFs and FCMs) and 90% (n=48, using predicted K_{ow}s and FCMs) in Bayou d'Inde (Lake Charles, LA). These data comparisons show the good predictability of the methods used in the national BAF methodology. Should States or authorized Tribes have information to suggest that a national BAF is inappropriate for their situation, the 2000 Human Health Methodology specifically allows and encourages development of site-specific BAFs. With this in mind, we will be developing guidance on how to collect and interpret field data for the purpose of deriving site-specific field BAFs. This guidance will specifically address major sources of variability, including spacial and temporal factors and species life history.

Finally, to further address concerns that the predictive approaches used to derive BAFs may not be applicable at a national scale, we revised the 1998 draft Methodology to clarify and limit for which chemicals and under what conditions BAFs based on Methods 2 to 4 are most applicable. For example, chemicals were grouped into broad categories based on their persistence and bioaccumulation potential (*e.g.*, high vs. low hydrophobicity, high vs. low biota metabolism, ionic vs. nonionic), and we have limited the use of predicted BAF approaches to selected groups of chemicals for which the data reasonably support their use (*i.e.*, highly hydrophobic chemicals that are not expected to be metabolized appreciably). The national BAF methodology was also changed to indicate that for those chemicals with sufficient data to indicate they are metabolized, model-predicted BAFs are not recommended; rather, field BAFs or laboratory BCFs are recommended. The use of the BSAF methodology has been restricted to chemicals that are highly hydrophobic (*e.g.*, log $K_{ow} \geq 4$).

EPA believes these revisions to the 1998 draft Methodology have improved the Methodology and have addressed many of the commenters' concerns and questions about uncertainty in applying the various approaches and BAFs on a national scale.

Comments—One commenter suggested that it is "scientifically indefensible to use the field-measured BAF procedure to derive BAFs for benthic systems." They commented that in a benthic-based aquatic food web, the water column concentration of a chemical is not directly related to aquatic organism exposure potential for that chemical. Therefore, their view is that a field-measured BAF may over- or underestimate bioaccumulation in benthic-based systems.

Response—EPA acknowledges that the concentration of a chemical in the water column is not directly related to what pelagic organisms (*i.e.*, fish) are exposed to in a benthic-based system. However, the concentrations of a chemical in water, sediment, and fish are interconnected, although they may not be equally partitioned into each compartment, and residues in fish can be predicted equally well using either a sediment or water concentration as the starting basis. In the revised TSD on Bioaccumulation, the relationships between BAFs and BSAFs have been shown more clearly in order to demonstrate this interconnectedness. In the BAF methodology, we are assessing exposure through all routes (*i.e.*, from water, sediment, and contaminated food) in the aquatic ecosystem. By including all routes of exposure, the BAFs do not assume simple water-fish partitioning; rather they are an overall expression of the total bioaccumulation using the concentration of the chemical in water column as a reference point. Thus, a field-measured BAF or BASF at any given time is reflective of historic chemical loadings and bioaccumulation that has occurred. EPA does agree that a BAF may change over time because of differential chemical loadings; however, some frame of reference has to be chosen as the starting point to assess bioaccumulation. EPA has chosen to use the water concentration as that reference point. Science has shown that bioaccumulation occurs and is an important exposure pathway to humans for many chemicals, and EPA cannot ignore bioaccumulation in development of its AWQC simply because variability and uncertainty exist. In situations where chemical loadings are highly variable or are reduced substantially, EPA believes that a field-measured BAF will still be predictive of what will bioaccumulate in fish until the concentrations in sediments and benthic organisms are reduced enough to lead to reduced bioaccumulation. In situations such as this, a revised site-specific field BAF can be developed to reflect the change in chemical loading and partitioning.

This issue of field-measured BAFs and benthic-based food webs was also brought up in public comments made at the stakeholders meeting held in May 1999. At that time, we asked commenters if they could recommend another approach to assess bioaccumulation in benthic-based systems. No other approaches were suggested. We have concluded that in the absence of any other approaches, field-derived BAFs are good predictors of bioaccumulation because they integrate biological, chemical, and physical factors that influence bioaccumulation.

2. Guidance for Deriving Field Bioaccumulation Factors (BAFs)

Comments—Several commenters agreed with EPA that field-derived BAFs should take precedence over modeled BAFs. However, many commenters discussed the need for guidance on how to collect and review field data so that high-quality, field-based BAFs can be derived. Commenters noted that there are numerous site-specific biological, chemical, and physical factors that affect bioaccumulation, which should be considered during design of field sampling programs.

Response—We agree that properly derived field BAFs should take precedence over modeled BAFs; we have clearly indicated in the 2000 Human Health Methodology that this is our preferred approach for deriving a BAF. We also acknowledge that, as with any field measurement, there can be errors in determining field-measured BAFs. In the development of national BAFs, EPA will attempt to minimize potential errors or uncertainties by carefully screening the data based on the criteria outlined in the Bioaccumulation TSD. Furthermore, an additional validation of national BAFs will be conducted as part of the external peer review process that occurs for all published 304(a) water quality criteria. We continue to assert that for many chemicals, a field-measured BAF is a better gauge of what is occurring in nature than a laboratory-measured or predicted BCF; the BAF measures the actual effects of bioavailability, concentration in the water or sediment, growth dilution, metabolism, and biomagnification rather than predicting them through use of a model. We do agree with commenters concerned about the difficulty of collecting and interpreting field-measured BAFs; however, we believe that States and Tribes can adequately design and interpret field studies. To assist them in this task, we will be developing guidance concerning field data collection and interpretation for site-specific field-measured BAFs and BSAFs.

3. Use of Biota-Sediment Accumulation Factors (BSAFs)

Comments—Several commenters stated that the use of the BSAF approach for deriving a BAF is inappropriate. Some comments centered around the perceived lack of validation and peer review of the BSAF approach, and others focused on the relationship between the water column concentration of a chemical and its sediment concentration, represented by the factor Π_{socw}. One commenter noted that the BSAF method is simply a means to predict a water concentration of a chemical of interest from the sediment concentration of that chemical, the water and sediment concentration of a reference chemical(s), and the ratio of K_{ow} for the chemical of interest and the reference chemical(s). A commenter indicated that loading history of a given chemical directly affects what the value of Π_{socw} would be at any given time, and that Π_{socw}/K_{ow} (disequilibrium ratio) for the chemical in question and the reference chemical has to be constant under the assumptions of the BSAF approach. The commenter stated, however, that Π_{socw}/K_{ow} will not be constant because of

25

differential loading histories, and that because the concentration of the chemical of interest cannot be measured in water, the assumptions about Π_{socw}/K_{ow} cannot be verified. In their view this made the use of BSAFs invalid.

Response—The method of predicting BAFs from BSAFs has been evaluated for certain pesticides, PCBs, chlorinated benzenes, and dioxins using two data sets from Lake Ontario (Oliver and Niimi,1988;USEPA, 1990) and one from Green Bay (USEPA, 1992b). EPA has also recently completed further evaluation of this method for certain PCB congeners, pesticides, and chlorinated benzenes in Lakes Ontario, Green Bay, and the Hudson River. This additional evaluation and validation work is included in the Bioaccumulation TSD. The evaluations show that in the vast majority of situations, the BSAFs predict field-measured BAFs very well.

EPA agrees with the commenter who noted that the BSAF method is structured to predict water concentrations for chemicals that cannot be measured for the purpose of directly measuring a field BAF. However, the BSAF method is more important for its ability to capture the net effect of biomagnification, food web structure, hydrophobicity, bioavailability factors, and metabolism on a specific chemical's net potential for bioaccumulation. The BSAF method is needed to predict BAFs for chemicals with nondetectable and difficult-to-predict concentrations in water (*e.g.*, dioxins). No alternative methods to predict BAFs for such chemicals were identified by either public commenters or peer reviewers. The BSAF method equation has been modified (see below) in the Bioaccumulation TSD to clarify the essential data components of the method. The revised BSAF equation shows that measured concentrations in water and surface sediment, not a complete BSAF, are needed for the reference chemical. The equation also shows that a measured BSAF for the chemical of interest is the most important component for determination of a BAF when the concentration in water cannot be measured.

EPA agrees with commenters that the BSAF method should not be used for all organic chemicals that may be addressed through the 2000 Human Health Methodology, and accordingly have restricted application of the method to nonionic organic chemicals with log K_{ow}s ≥ 4.0. We have also provided more specific guidance on selection of reference chemicals and use of multiple reference chemicals to secure the most accurate estimate of a chemical's BAF.

One commenter contended that the BSAF approach for deriving BAFs is seriously flawed. The concern is that the approach is valid only if a reference chemical (chemical r) can be found with a sediment-water fugacity ratio (which represents the differential partitioning of a chemical between water and sediment) equal to that of the chemical for which the BAF is being determined (chemical of interest). The commenter contends that the BSAF approach could validly be used only if it could be shown that the fugacity ratio is a constant for the chemical of interest and the reference chemical. The commenter submitted figures to demonstrate conceptually that two chemicals with radically different loading histories will have dissimilar fugacity ratios. EPA disagrees that in order for the BSAF to work, the fugacity ratio has to be constant, but does agree that in order to best use the BSAF approach, a general knowledge of chemical loading histories to an ecosystem is needed to help provide a basis for choosing appropriate reference chemicals. Such information may be obtained from chemical production records, historical fish residue monitoring data, or dated sediment core analysis. We recognize that due to various factors (loading histories, microbial degradation, etc.) fugacity ratios for both chemical (i) and (r) may shift over time, leading to the potential for temporal variability of sediment-water distributions of nonpolar organic chemicals. Although it was not shown explicitly in the 1998 draft TSD, an important benefit of the BSAF approach is that it can account precisely for such differences in sediment-water distributions of nonpolar organic chemicals. The BSAF method is robust to the extent that the choice of reference chemicals is based on meeting the sediment-to-water fugacity ratio condition: That the ratios be similar—they do not have to be constant. The extent that these ratios for chemicals with log K_{ow}s ≥ 4 may change with chemical loading over long periods of time after sediments become contaminated, and thereby contribute to small shifts in BSAFs and larger shifts in BAFs, is an issue of possible concern that EPA recognized in the 1998 draft TSD. EPA noted on page 188 of the TSD (USEPA, 1998d) that "BSAFs measured for systems with new chemical loadings or rapid increases in loadings may be unreliable due to underestimation of steady-state C_{soc}s."

To better address the water-to-sediment relationship issue, EPA has revised the equations that serve as the basis for deriving a BSAF. In the revised equations, a factor $D_{i/r}$ has been added, which is defined as the ratio of the fugacity gradient (modeled as Π_{socw}/K_{ow}) between sediment and water for chemical (i) in comparison to that of a reference chemical (r). The revised equations are as follows:

$$\frac{(\Pi_{socw})_i}{(K_{ow})_i} = (D_{i/r})\frac{(\Pi_{socw})_r}{(K_{ow})_r} \qquad (1)$$

$$\text{thus, } (\Pi_{socw})_i = \frac{(D_{i/r})(\Pi_{socw})_r(K_{ow})_i}{(K_{ow})_r}$$

By definition, Π_{socw} can be used to relate chemical i's BSAF to its BAF_{ℓ}^{fd}:

26

$$\left(\prod_{socw}\right)_i = \frac{(C_{soc})_i}{\left(C_w^{fd}\right)_i} = \frac{\left(BAF_l^{fd}\right)_i}{(BSAF)_i} \qquad (2)$$

$$\text{thus, } \left(BAF_l^{fd}\right)_i = (BSAF)_i\left(\prod_{socw}\right)_i$$

By substituting rearranged Equation 1 into rearranged Equation 2:

$$\left(BAF_l^{fd}\right)_i = (BSAF)_i \frac{(D_{i/r})\left(\prod_{socw}\right)_r (K_{ow})_i}{(K_{ow})_r} \qquad (3)$$

where:

$(BAF_\ell^{fd})_i$ = BAF expressed on a freely dissolved and lipid-normalized basis for chemical of interest "i".

$(BSAF)_i$ = Biota-sediment accumulation factor for chemical of interest "i".

$(C_{soc})_i$ = Concentration of chemical of interest "i" in sediment normalized to sediment organic carbon.

$(C_{soc})_r$ = Concentration of a reference chemical in sediment normalized to sediment organic carbon.

$(C_w^{fd})_i$ = Concentration of chemical of interest "i" freely dissolved in water.

$(C_w^{fd})_r$ = Concentration of the reference chemical freely dissolved in water.

$D_{i/r}$ = ratio between Π_{socw}/K_{ow} for chemicals "i" and "r" (normally chosen so $D_{i/r} = 1$).

$(K_{ow})_i$ = octanol-water partition coefficient for chemical of interest "i".

$(K_{ow})_r$ = octanol-water partition coefficient for the reference chemical "r".

$(\Pi_{socw})_i$ = sediment organic carbon to water freely dissolved concentration ratio of chemical of interest "i".

$(\Pi_{socw})_r$ = sediment organic carbon to water freely dissolved concentration ratio of reference chemical "r".

Equation 3 is intended to provide an improved representation of how the BSAF method/model works. By using $D_{i/r}$, the new equation accounts for differences in sediment to water column concentrations that might exist between the chemical of interest and the reference chemical because of factors such as loading histories or degradation. Unlike one commenter's analysis, in which an equation was derived without the BAF or BSAF, equation 3 shows these quantities as central to the model; that is, the BSAF is measured and then transformed into a BAF by estimating the chemical's Π_{socw}/K_{ow}. This model could alternatively be described as a determination of $(C_w^{fd})_i$ from a measured value of $(C_{soc})_i$ combined with a measured value of $(C_\ell)_i$ to give an accurate measure of $(BAF_\ell^{fd})_i$. However, we believe that equation 3 best describes the BSAF method as allowing measured BSAFs to be transformed into BAF_ℓ^{fd}s for the specific purpose of developing either national or a site-specific water quality criteria when directly measured BAF_ℓ^{fd}s cannot be obtained.

When good-quality data are available for reference chemicals (r) that should have equal or similar sediment-water fugacity ratios as a chemical (i) whose $(BAF_\ell^{fd})_s$ cannot be measured directly, then $D_{i/r} = 1$. When $D_{i/r} \leq 1$, it may be estimated based on properties of the chemicals and knowledge of their loading histories to the ecosystem. Equation 3 provides a greater degree of flexibility for use of the BSAF method than the original equation. This flexibility highlights a logical stepwise transition from measured to fully modeled site-specific BAFs that can incorporate estimates of $D_{i/r}$ through fate modeling, should interested parties choose to do so. In such a situation, if the uncertainty associated with choice of $D_{i/r}$ is perceived to be too great, a determination of a site-specific $(BAF_\ell^{fd})_i$, which still takes advantage of measured values of $(C_\ell)_i$ and $(C_{soc})_i$, could be accomplished if a mass balance model, specifically calibrated with $(C_\ell)_i$ and $(C_{soc})_i$, is used to predict $(C_w^{fd})_i$. Such an approach would be time consuming and expensive but would allow prediction of $(BAF_\ell^{fd})_i$ over time as a function of changes in $(\Pi_{socw})_i$ associated with anticipated changes in mass loading of the chemical into an ecosystem. In cases where the intended use of the site-specific criterion is to determine permit conditions or establish a TMDL, a mass balance model presumably would have to be developed, and thus use of the model for providing a $(BAF_\ell^{fd})_i$ would not require an extraordinary effort. However, as with the BSAF method, it should be noted that mass balance model predictions of $C_w^{fd}{}_i$ also cannot be directly validated through measurements. EPA's appreciation for the value of hybrid models comes from recognition that incorporation of measured bioaccumulation potentials, including those provided by the BSAF method, are especially advantageous for those chemicals with transformation rates, such as metabolism throughout the food chain, that are presently not accurately known or incorporated into mechanistic bioaccumulation models.

Finally, we disagree with the circular argument that the BSAF approach has "extremely limited utility" because "it will not be possible to demonstrate that Π_{socw}/K_{ow} is a constant" because Π_{socw}/K_{ow} cannot be measured directly for one chemical. The inherent limitation for validation of a predicted BAF because of the inability to measure the concentration of freely dissolved chemical in water (C_w^{fd}) applies to any approach/model available and is not a just criterion for rejection of a BAF method. Validation may be based on the ability of the BAF to predict concentrations in fish from predicted values of C_w^{fd}. Data from the Great Lakes clearly show that such predictions are possible, and accurate (USEPA, 1998d). It should also be noted that during the external peer review of the BSAF approach, the peer reviewers stated "for the chemicals examined (persistent and bioaccumulative), extrapolation to other circumstances may be reasonable," thereby disagreeing with public commenters. EPA believes that restricting the use of the BSAF method to highly hydrophobic chemicals, clarifying the use of reference chemicals, elaborating on the primacy of the sediment-water fugacity equivalence

27

condition for use of the method, and validation with additional data sets alleviates concerns about using this new method.

4. Dissolved Organic Carbon (DOC) and Particulate Organic Carbon (POC)

Comments—Two comments were received on the DOC/POC approach used to determine the bioavailable fraction of organic chemicals in surface water and sediments. Rather than solely use default organic carbon values, commenters wanted to the ability to select DOC/POC values they believe are more representative of their waterbody type or site-specific conditions.

Response—In the 2000 Human Health Methodology, EPA allows use of site-specific DOC and POC data when normalizing the BAF to organic carbon content. One can either conduct studies to generate the necessary site-specific data or modify the national organic carbon database to their particular site and conditions. To facilitate the latter, we have updated and expanded the organic carbon database used to develop the national default POC/DOC values to enable the regulated community to choose which values best represent their site conditions and will provide defensible site-specific DOC and POC estimates. The national DOC/POC database will be made available for use by all States, Tribes, and other members of the regulated community.

5. Fish Lipid Content

Comments—A commenter stated that lipid content can affect the results of the Gobas model used to derive national default FCMs. The commenter noted that the model is relatively insensitive to fish lipid content but more sensitive to benthic invertebrate lipid content. They believed this should be considered in the development of FCMs.

Response—EPA agrees that lipid content can affect the results of the Gobas model and is only using the Gobas model with default lipid values to derive national BAFs when there are no data to derive a field-measured BAF. In cases where a State or authorized Tribe has site-specific data on fish lipid content, the revised methodology allows input of those site-specific data to estimate bioaccumulation. Furthermore, to facilitate the generation of site-specific lipid values, we have updated and expanded the lipid database used to develop the national default values based on a whole range of organisms commonly consumed by persons in the United States. We will include additional guidance for States and authorized Tribes on how to adapt the national default lipid values to reflect State and local consumption patterns. To enable such adaptions, EPA will make the raw data available to States and authorized Tribes.

6. Use of Food Chain Multipliers (FCMs)

Comments—Several commenters stated that the use of model-derived FCMs (Gobas 1993) to calculate a BAF from either a BCF or a K_{ow} (Methods 3 and 4) is inappropriate. The commenters noted issues with several of the default input parameters (*e.g.*, food web, lipid, Π_{socw}, temperature). The primary concern of commentors is that Gobas model-based national default FCMs do not account for site-specific factors that influence bioaccumulation, such as food web structure, nor does the current use of the model account for metabolism. Commenters expressed concern that use of default FCMs in predictive approaches may lead to overestimates of bioaccumulation. Some commenters preferred the use of field-based FCMs or direct use of the Gobas model, which allows for input of site-specific data and metabolism rates if available, rather than uses of model-derived default FCMs.

Response—EPA is using a state-of-the-art food web model for deriving FCMs, which incorporates the latest thinking and knowledge on the processes occurring in aquatic food webs. Commenters suggested that the assumptions used in constructing these models are not appropriate. We recognize that any modeling formulation of contaminant behavior in aquatic food webs requires simplification of a very complex biological system in order to assemble a tractable model. These simplifications do not imply or mean that our scientific understanding of all processes occurring in food webs is complete. As documented in the scientific literature, these simplifications provide reasonable model formulations with good predictive power. The suggestion that every modeling assumption has to be completely understood and validated under all circumstances before using or constructing a useful modeling tool is unreasonable. EPA has performed a detailed analysis of the importance and sensitivities of individual input parameters for food web models and of the overall uncertainties associated with predictions from food web models (Burkhard 1998). We have provided a discussion in the Bioaccumulation TSD of the Gobas model and implications that uncertainties in their respective input parameters have on derived FCMs. EPA has retained the use of Gobas model to derive default FCMs.

To address national versus site-specific concerns expressed by some commenters, the methodology has been revised to separate the BAF methodology into national and site-specific guidance. The national methodology for deriving national BAFs retains the use of default FCMs based on a mixed benthic/pelagic food web and national averages of various model input values. We believe this food web is the most broadly applicable food web encountered in nature; its use results in FCMs that are midway between pure benthic and pure pelagic structures. The revised guidance includes a brief discussion of the uncertainties associated with our selection of the mixed benthic/pelagic food web. In the site-specific guidance, the 2000 Human Health Methodology provides guidance on which of EPA's recommended FCMs to use depending on the situation. In addition, we encourage direct use of the Gobas model by stakeholders so that changes could be made to the default food web inputs to reflect site-specific factors that influence bioaccumulation, and also encourage derivation of field-based FCMs. States and authorized Tribes have the option to generate site-specific FCMs by conducting site-specific field studies, reviewing published literature, or using other scientifically defensible models.

Although several commenters criticized the national application of the Gobas model because metabolism rate is set equal to zero, the peer review panel acknowledged EPA's position that there are currently no acceptable methods available to adequately determine species and chemical-specific metabolism rates for use in the Gobas model. Because EPA agrees that for certain chemicals metabolism can be an important factor in bioaccumulation, the revised methodology does not use FCM-based predictions for chemicals that are expected to be metabolized substantially. To assist users of the 2000 Human Health Methodology in determining for which chemicals or groups of chemicals metabolism should be of little concern, we have developed a table of chemicals that are not substantially metabolized or are likely very slowly metabolized. This table has been put in the Bioaccumulation TSD. The table is not all inclusive because there are numerous chemicals (*e.g.*, hundreds of thousands in use commercially today) for which few or no metabolism data exist, but is representative of chemicals or groups of chemicals that are likely to be commonly encountered in aquatic systems. When metabolism is suspected, users of the 2000 Human Health Methodology might be more inclined to use or develop field data and/or measure a BCF in the laboratory in these situations. It should also be noted that in the future, should appropriate chemical and species-specific metabolism data become available, the Gobas model can incorporate it with little effort.

Finally, EPA partially agrees with commenters that certain procedures of the 1998 draft Methodology revisions (*e.g.*, K_{ow} and FCM-predicted BAFs) might lead to overestimates of BAFs for certain types of pollutants, such as those that are metabolized substantially to chemical forms not addressed by the AWQC. In response to this issue, and as discussed previously, additional guidance and limitations have been placed on several of the procedures in the revised methodology. However, EPA does not agree with the notion that our methodology would lead to a general over prediction for all BAFs. We use central tendencies where possible for all inputs in the Gobas model, and a geometric mean BCF for chemicals that have more than one BCF for a given trophic level. Thus, we know of no reason why laboratory-measured BCFs multiplied by a FCM would always result in overestimates of BAFs, or why the BSAF and K_{ow} * FCM-predicted BAFs applied to highly hydrophobic contaminants that do not metabolize substantially would be biased a priori toward overestimating BAFs. These views are supported by information in the 1998 TSD (Exhibits 2.4.1, 2.4.3, and 2.4.6 for BSAFs), Burkhard *et al.* (1997) for the K_{ow}*FCM method, and information presented in the Bioaccumulation TSD.

7. Fish Tissue Criteria

Comments—A few commenters suggested that for selected highly bioaccumulative chemicals that are difficult to measure in water, criteria based on fish tissue concentration may be more appropriate than ambient water column concentration criteria.

Response—Regarding fish tissue criteria, EPA agrees that the development of human health criteria for highly bioaccumulative chemicals which are expressed in terms of tissue residues in aquatic organisms is worthy of consideration. However, such tissue residue criteria would still require a mechanism to relate chemical loads and concentrations in water and sediments to concentrations in tissues of appropriate aquatic organisms (*i.e.*, bioaccumulation factors or bioaccumulation models). EPA is presently exploring the feasibility of developing tissue-based criteria and is evaluating numerous issues associated with implementation of tissue-based criteria. At an appropriate in the future, EPA will consider development of additional guidance on tissue residue criteria pending the outcome of this evaluation.

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Outline for Human Health Focus Group Final Report

I. Executive Summary

II. Overview of Human Health Focus Group

a) Purpose – why was the group formed?

b) How was it formed?
   i) Selection criteria
   ii) Nominations from Core Team
   iii) Planning team decides

c) Who is in the Group
   i) List of people with reference to an Appendix with full biographies
   ii) List of staff supporting the group

d) Questions addressed by group
   i) How we came up with the questions
   ii) Clearly explain that we were interested in their scientific opinions
      (1) Not seeking consensus
      (2) Not seeking recommendations on which rate Oregon should choose
      (3) Not seeking any policy advice

III. Questions addressed by the Group

a) Considering the available local, regional and national information on fish consumption, what is the scientific evidence Oregon should rely on in selecting a fish consumption rate to use in setting water quality standards?
   i) List of studies reviewed
   ii) Summary of group deliberations (divided by study?)\
      (1) Includes areas of consensus (if any) and areas of dissent (if any)
      (2) Highlight "hot topics"
   iii) Conclusions, trends, summary statements…

b) How should anadromous fish be considered in selecting a fish consumption rate and/or calculating criteria?
   i) Summary of group deliberations
   ii) Conclusions and summary statements

c) To what extent are populations who consume more than the current fish consumption rate of 17.5 grams/day at a greater risk for health impacts? What are the assumptions and uncertainties around this risk?
   i) Summary of group deliberations