

## **SECTION 1**

### **INTRODUCTION**

#### **1.1 OVERVIEW**

Toxic chemicals released to the environment from point sources such as industrial and municipal discharges and from nonpoint sources such as agricultural runoff and atmospheric deposition have contaminated surface waters and their sediments across the United States. In some areas, contamination arises from one or more related chemicals. For example, in the Hudson River in New York, attention has focused on high concentrations of a group of related chemicals called polychlorinated biphenyls, or PCBs. In other areas, a complex mixture of chemicals is present. For example, over 900 different synthetic organic compounds have been found in Puget Sound in Washington State, while nearly 1,000 chemical contaminants have reportedly been found in the Great Lakes.

Many chemical pollutants concentrate in fish and shellfish by accumulating in fatty tissues or selectively binding to fish muscle tissue (the fillet). Even extremely low concentrations of bioaccumulative pollutants detected in water or bottom sediments may result in fish or shellfish tissue concentrations high enough to pose health risks to fish consumers. Lipophilic contaminants, particularly certain organochlorine compounds, tend to accumulate in the fatty tissues of fish. Consequently, fish species with a higher fat content, such as carp, bluefish, some species of salmon, and catfish, may pose greater risks from some contaminants than leaner fish such as bass, sunfish, and yellow perch. Although exposure to some contaminants may be reduced by removing the fat, skin, and viscera before the fish is eaten, other contaminants, such as methylmercury, accumulate in the muscle tissue of the fillet and therefore cannot be removed by trimming. In addition, some fish are consumed whole or are used whole in the preparation of fish stock for soups and other foods. Under these conditions, the entire body burden of bioaccumulative contaminants contained in the fish would be ingested by the consumer (U.S. EPA, 1991b).

Results of a 1989 survey of methods to estimate risks to human health from consumption of chemically contaminated fish (Cunningham et al., 1990), funded by the U.S. Environmental Protection Agency (EPA) and conducted by the American Fisheries Society, identified the need for standardizing the approaches to assessing risks and for developing advisories for contaminated fish and shellfish. Four key components were identified as critical to the development of a consistent risk-based approach to developing consumption advisories: standard

practices for sampling and analyzing fish and shellfish, standardized risk assessment methods, standardized procedures for making risk management decisions, and standardized approaches to risk communication.

**Note: Throughout this document series, the term "fish" refers to sport- and subsistence-caught freshwater, estuarine, and marine fish and shellfish, unless otherwise noted.**

To address concerns raised by the survey, EPA developed a series of four documents designed to provide guidance to state, local, regional, and tribal environmental health officials who are responsible for issuing fish consumption advisories for noncommercially caught fish. The documents are meant to provide guidance only and do not constitute a regulatory requirement. The documents are: *Guidance for Assessing Chemical Contamination Data for Use in Fish Advisories, Volume 1: Fish Sampling and Analysis* (released 1993, revised in 1995 and 2000), *Volume 2: Risk Assessment and Fish Consumption Limits* (released in 1994 and revised in 1997 and 2000), *Volume 3: Risk Management* (released in 1996), and *Volume 4: Risk Communication* (released in 1995). EPA recommends that the four volumes of this guidance series be used together, since no one volume provides all the necessary information to make decisions regarding the issuance of fish consumption advisories.

This volume (Volume 2) provides guidance on risk assessment procedures to use in the development of risk-based consumption limits for the 25 high-priority chemical contaminants identified in Volume 1 (see Table 1-1).

The target analytes listed in Table 1-1 were selected by EPA's Office of Water as particularly significant fish contaminants, based on their occurrence in fish and shellfish (as evidenced by their detection in regional or national fish monitoring programs or by state issuance of a fish advisory), their persistence in the environment (half-life >30 days), their potential for bioaccumulation (BCF values >300), and their oral toxicity to humans.

### 1.2 OBJECTIVES

It should be noted that the EPA methodology described in both Volumes 1 and 2 of this guidance series offers great flexibility to the state users. These documents are designed to meet the objectives of state monitoring and risk assessment programs by providing options to meet specific state or study needs within state budgetary constraints. The users of this fish advisory guidance document should recognize that it is the consistent application of the EPA methodology and processes rather than individual elements of the program sampling design that are of major importance in improving consistency among state fish advisory

Table 1-1. Target Analytes Recommended for Fish Sampling Programs <sup>a</sup>

<b>Metals</b>	<b>Organophosphate Pesticides</b>
Arsenic (inorganic)	Chlorpyrifos
Cadmium	Diazinon
Mercury (methylmercury)	Disulfoton
Selenium	Ethion
Tributyltin	Terbufos
<b>Organochlorine Pesticides</b>	<b>Chlorophenoxy Herbicides</b>
Chlordane, total ( <i>cis</i> - and <i>trans</i> -chlordane, <i>cis</i> - and <i>trans</i> -nonachlor, oxychlordane)	Oxyfluorfen
DDT, total (2,4'-DDD, 4,4'-DDD, 2,4'-DDE, 4,4'-DDE, 2,4'-DDT, 4,4'-DDT)	<b>PAHs<sup>e</sup></b>
Dicofol	<b>PCBs</b>
Dieldrin	Total PCBs (sum of PCB congeners or Aroclors) <sup>f</sup>
Endosulfan (I and II)	<b>Dioxins/furans<sup>g</sup></b>
Endrin	
Heptachlor epoxide <sup>b</sup>	
Hexachlorobenzene	
Lindane ( $\gamma$ -hexachlorocyclohexane; $\gamma$ -HCH) <sup>c</sup>	
Mirex <sup>d</sup>	
Toxaphene	

DDD = p,p' - dichlorodiphenyldichloroethane.

DDE = p,p' - dichlorodiphenyldichloroethylene.

DDT = p,p' - dichlorodiphenyltrichloroethane.

PAHs = Polycyclic aromatic hydrocarbons.

PCBs = Polychlorinated biphenyls.

<sup>a</sup> The reader should note that carbophenothion was included on the original list of target analytes. Because the registrant did not support reregistration of this chemical, all registered uses were canceled after December 1989. For this reason and because of its use profile, carbophenothion was removed from the recommended list of target analytes.

<sup>b</sup> Heptachlor epoxide is not a pesticide but is a metabolite of the pesticide heptachlor.

<sup>c</sup> Also known as  $\gamma$ -benzene hexachloride ( $\gamma$ -BHC).

<sup>d</sup> Mirex should be regarded primarily as a regional target analyte in the southeast and Great Lakes states, unless historic tissue, sediment, or discharge data indicate the likelihood of its presence in other areas.

<sup>e</sup> It is recommended that tissue samples be analyzed for benzo[a]pyrene and 14 other PAHs and that the order-of-magnitude relative potencies given for these PAHs be used to calculate a potency equivalency concentration (PEC) for each sample (see Section 5 of Volume 1).

<sup>f</sup> Analysis of total PCBs (as the sum of Aroclors or PCB congeners) is recommended for conducting human health risk assessments for total PCBs (see Sections 4.3.6 and 5.3.2.6 of Volume 1). A standard method for Aroclor analysis is available (EPA Method 608). A standard method for congener analyses is under development by EPA; however, it has not been finalized. States that currently do congener-specific PCB analyses should continue to do so and other states are encouraged to develop the capability to conduct PCB congener analyses. When standard methods for congener analysis have been verified and peer-reviewed, the Office of Water will evaluate the use of these methods.

<sup>g</sup> It is recommended that the 17 2,3,7,8-substituted tetra- through octa-chlorinated dibenzo-p-dioxins (PCDDs) and dibenzofurans (PCDFs) and the 12 dioxin-like PCBs be determined and a toxicity-weighted total concentration calculated for each sample (Van den Berg et al., 1998) (see Sections 4.3.7 and 5.3.2.6 of Volume 1).

programs. For example, this document presents consumption limits that were calculated using a risk level of 1 in 100,000 ( $10^{-5}$ ); however, states may choose to calculate consumption limits based on other risk levels.

One major factor currently affecting the comparability of fish advisory information nationwide is the fact that the states employ different methodologies to determine the necessity for issuing an advisory. For example, some states currently do not use the EPA methodology at all or use it only in their assessment of health risks for certain chemical contaminants. Often these states rely instead on exceedances of U.S. Food and Drug Administration (FDA) action levels or tolerances to determine the need to issue an advisory. FDA's mission is to protect the public health with respect to levels of chemical contaminants in all foods, including fish and shellfish.

FDA has developed both action levels and tolerances to address levels of contamination in foods. FDA may establish an action level when food contains a chemical from sources of contamination that cannot be avoided even by adherence to good agricultural or manufacturing practices, such as contamination by a pesticide that persists in the environment. An action level is an administrative guideline or instruction to the agency field unit that defines the extent of contamination at which FDA may regard food as adulterated. An action level represents the limit at or above which FDA may take legal action to remove products from the marketplace. Under the Food, Drug, and Cosmetic Act, FDA also may set tolerances for unavoidably added poisonous or deleterious substances, that is, substances that are either required in the production of food or are otherwise unavoidable by good manufacturing practices. A tolerance is a regulation that is established following formal, rulemaking procedures; an action level is a guideline or "instruction" and is not a formal regulation (Boyer et al., 1991).

FDA's jurisdiction in setting action levels or tolerances is limited to contaminants in food shipped and marketed in interstate commerce. Thus, the methodology used by FDA in establishing action levels or tolerances is to determine the health risks of chemical contaminants in fish and shellfish that are bought and sold in interstate commerce rather than in locally harvested fish and shellfish (Bolger et al., 1990). FDA action levels and tolerances are indicators of chemical residue levels in fish and shellfish that should not be exceeded for the general population who consume fish and shellfish typically purchased in supermarkets or fish markets that sell products that are harvested from a wide geographic area, including imported fish and shellfish products. However, the underlying assumptions used in the FDA methodology were never intended to be protective of recreational, tribal, ethnic, and subsistence fishers who typically consume larger quantities of fish than the general population and often harvest the fish and shellfish they consume from the same local waterbodies repeatedly over many years. If these local fishing and harvesting areas contain fish and shellfish with elevated tissue levels of chemical contaminants, these individuals potentially

could have increased health risks associated with their consumption of fish and shellfish.

The following chemical contaminants discussed in this volume have FDA action levels for their concentration in the edible portion of fish and shellfish: chlordane, DDT, DDE, DDD, dieldrin, heptachlor epoxide, mercury, and mirex. FDA has not set an action level for PCBs in fish, but has established a tolerance in fish for this chemical. FDA also has set action levels in fish for two chemical contaminants that are not discussed in this volume: chlordecone (Kepone) and ethylene dibromide. FDA had set an action level for toxaphene; however, this level was revoked in 1993 because FDA determined that toxaphene residues were no longer occurring as unavoidable contaminants in food (57 FR 60859). In addition, in 1981, FDA set an advisory level for dioxin in fish, in response to requests from the governors of the Great Lake states. This advisory level was nonenforceable federal advice and was provided with the intention that state and local authorities use it to develop their own control policies (Boyer et al., 1990).

Table 1-2 compares the FDA action levels and tolerances for these seven chemical contaminants with EPA's recommended screening values (SVs) for recreational and subsistence fishers calculated for these target analytes using the EPA methodology.

The EPA SV for each chemical contaminant is defined as the concentration of the chemical in fish tissue that is of potential public health concern and that is used as a threshold value against which tissue residue levels of the contaminant in fish and shellfish can be compared. The SV is calculated based on both the noncarcinogenic and carcinogenic effects of the chemical contaminant, which are discussed in detail in Volume 1 of this series (EPA, 2000a). EPA recommends that the more conservative of the calculated values derived from the noncarcinogenic rather than the carcinogenic effects be used because it is more protective of the consumer population (either recreational or subsistence fishers). As can be seen in Table 1-2, for the recreational fisher, the EPA-recommended values typically range from 2 to 120 times lower and thus are more protective than the corresponding FDA action or tolerance level. This difference is even more striking for subsistence fishers for whom the SVs are 20 to 977 times lower than the FDA values.

EPA and FDA have agreed that the use of FDA action levels for the purposes of making local advisory determinations is inappropriate. In letters to all states, guidance documents, and annual conferences, this practice has been discouraged by EPA and FDA in favor of EPA's risk-based approach to derive local fish consumption advisories.

**Table 1-2. Comparison of FDA Action Levels and Tolerances with EPA Screening Values**

<b>Chemical Contaminant</b>	<b>FDA Action Level (ppm)</b>	<b>EPA SV for Recreational Fishers (ppm)</b>	<b>EPA SV for Subsistence Fishers (ppm)</b>
Chlordane	0.3	0.114	0.014
Total DDT	5.0	0.117	0.014
Dieldrin	0.3	$2.5 \times 10^{-3}$	$3.07 \times 10^{-4}$
Heptachlor epoxide	0.3	$4.39 \times 10^{-3}$	$5.40 \times 10^{-4}$
Mercury	1.0	0.40	0.049
Mirex	0.1	0.80	0.098
	<b>FDA Tolerance Level (ppm)</b>		
PCBs	2.0	0.02	$2.45 \times 10^{-3}$

Source: U.S. FDA, 1998.

### 1.3 SENSITIVE SUBPOPULATIONS

In addition to the risks borne by the general population as a result of consuming contaminated fish, various populations eating higher-than-average quantities of fish are at greater risk of having higher body burdens of bioaccumulative contaminants. Those at greatest risk include sport and subsistence fishers. In this document, subsistence fishers are defined as fishers who rely on noncommercially caught fish and shellfish as a major source of protein in their diets. In addition to these populations, pregnant women and children may be at greater risk of incurring adverse effects than other members of the populations because of their proportionally higher consumption rates and/or increased susceptibility to adverse toxicological effects.

EPA has provided this guidance to be especially protective of recreational fishers and subsistence fishers within the general U.S. population. EPA recognizes, however, that Native American subsistence fishers are a unique subsistence fisher population that needs to be considered separately. For Native American subsistence fishers, eating fish is not simply a dietary choice that can be completely eliminated if chemical contamination reaches unacceptable levels; rather eating fish is an integral part of their lifestyle and culture. This traditional lifestyle is a living religion that includes values about environmental responsibility and community health as taught by elders and tribal religious leaders (Harris and Harper, 1997). Therefore, methods for balancing benefits and risks from eating

contaminated fish must be evaluated differently than for the general fisher population.

For any given population, there can be a sensitive subpopulation comprising individuals who may be at higher than average risk due to their increased exposure or their increased sensitivity to a contaminant or both. For Native American subsistence fishers, exposure issues of concern that should be addressed as part of a comprehensive exposure assessment include the following:

- **Consumption rates and dietary preferences.** Harris and Harper (1997) surveyed traditional tribal members in Oregon with a subsistence lifestyle and determined a consumption rate of 540 g/d that included fresh, dried, and smoked fish. They also confirmed that the parts of the fish (heads, fins, skeleton, and eggs) that were eaten by this group were not typically eaten by other groups. Another study conducted of four tribes in the Northwest that also surveyed tribal members in Oregon, but did not target subsistence fishers, reported a 99<sup>th</sup> percentile ingestion rate of 390 g/d for tribal members (CRITFC, 1994). These consumption rates are much higher than the default consumption rates provided in this document for subsistence fishers, which emphasizes the need to identify the consumption rate of the Native American subsistence population of concern.
- **Community characteristics.** It is important to consider family-specific fishing patterns in any exposure scenario, and attention should be paid to the role of the fishing family with respect to the tribal distribution of fish, the sharing ethic, and providing fish for ceremonial/religious events. Entire communities are exposed if fish are contaminated, and the community contaminant burden as a whole must be considered, not just the maximally exposed individual.
- **Multiple contaminant exposures.** Multiple contaminant exposure is significant for Native American subsistence fishers. A large number of contaminants are often detected in fish tissues and their combined risk associated with the higher consumption rates and dietary preferences for certain fish parts could be very high even if individual contaminants do not exceed the EPA reference dose (Harper and Harris, 1999).
- **Other exposure pathways.** For Native American subsistence fishers, overall exposure to a contaminant may be underestimated if it fails to take into account nonfood uses of fish and other animal parts that may contribute to overall exposure, such as using teeth and bones for decorations and whistles, animal skins for clothing, and rendered fish belly fat for body paint (Harper and Harris, 1999). If other wildlife species (e.g., feral mammals, turtles, waterfowl) that also live in or drink from the contaminated waterbody are eaten, or if the contaminated water is used for irrigation of crops or for livestock watering or human drinking water, the relative source contribution

of these other pathways of exposure also must be considered. As with fish and wild game, plants are used by Native Americans for more than just nutrition. Daily cleaning, preparation, and consumption of plants and crafting of plant materials into household goods occurs throughout the year (Harris and Harper, 1997).

As in the general population, increased sensitivity to a chemical contaminant for Native Americans can result from factors such as an individual's underlying health status and medications, baseline dietary composition and quality, genetics, socioeconomic status, access to health care, quality of replacement protein, age, gender, pregnancy, and lactation. These factors are only partially considered in the uncertainty factor(s) used to develop an RfD (Harper and Harris, 1999).

Other important issues that need to be considered concern risk characterization and risk management. For Native American subsistence fishers, the use of an acceptable risk level of 1 in 100,000 ( $10^{-5}$ ) may not be acceptable to all tribes. Each tribe has the right to decide for themselves what an acceptable level of risk is, and, in some cases, it may be zero risk to protect cultural resources. Ecological well-being or health is another key issue. Human health and ecological health are connected in many ways, and the ripple effects are often not recognized. For example, human health may be affected by injury to the environment, which affects the economy and the culture (Harper and Harris, 1999).

Native American subsistence fishers should be treated as a special high-risk group of fish consumers distinct from fishers in the general population and distinct even from other Native American fish consumers living in more suburbanized communities. Table 1-3 compares fish consumption rates for various fisher populations within the general population and specific Native American tribal populations. EPA currently recommends default fish consumption rates of 17.5 g/d for recreational fishers and 142.4 g/d for subsistence fishers. However, the tribal population fish consumption studies show that some Native American tribal members living in river-based communities (CRITFC, 1994) eat from 3 to 22 times more fish (from 59 g/d up to 390 g/d) than recreational fishers, and that traditional Native American subsistence fishing families may eat up to 30 times more fish, almost 1.2 lb/d (540 g/d) (Harris and Harper 1997). The fish consumption rate from Harris and Harper (1997) for Native American subsistence fishers (540 g/d) is also 3.8 times higher than the EPA default consumption rate for subsistence fishers (142.4 g/d) in the general population. The difference in fish consumption is due to the fact that the Native American subsistence fisher's lifestyle is not the same as a recreational fisher's lifestyle with additional fish consumption added, nor is it the same as the "average" Native American tribal member living in a fairly suburbanized tribal community. In addition to exposures from direct consumption of contaminated fish, Native American subsistence fishers also receive more exposure to the water and sediments associated with catching and preparing fish,



Table 1-3. Fish Consumption Rates for Various Fisher Populations

Source	Recreational fishers (g/d)	Subsistence Fishers (g/d)	Native American Subsistence fishers (g/d)	Native Americans (g/d)	Basis for Consumption Rate
U.S. EPA	17.5 <sup>a</sup>	142.4 <sup>a</sup>	70 (mean) <sup>b</sup> 170 (95 <sup>th</sup> percentile) <sup>b</sup>	NA	Fish consumption rate from 1994 and 1996 Continuing Survey of Food Intake by Individuals (CSFII) (USDA/ARS, 1998)
Harris and Harper (1997)	NA	NA	540 (fresh, smoked, and dried)	NA	Surveyed members of the Confederated Tribes of the Umatilla Indian Reservation
CRITFC (1994)	NA	NA	NA	59 (mean) 170 (95 <sup>th</sup> percentile) 390 (99 <sup>th</sup> percentile)	Surveyed members of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribes
Toy et al. (1996)	NA	NA	NA	53 (median, males) 34 (median, females)	Surveyed members of the Tulalip Tribe
				66 (median, males) 25 (median, females)	Surveyed members of the Squaxin Island Tribe

NA = Not available.

<sup>a</sup> These values were revised in the 3<sup>rd</sup> edition of Volume 1 of this series (U.S. EPA, 2000a)

<sup>b</sup> These values are from EPA's Exposure Factors Handbook (U.S. EPA, 1997f)

and possibly from drinking more unfiltered river water than more suburbanized tribal community members as well. The Native American subsistence fishing population should be treated as a separate group with a very unique lifestyle, distinct from recreational and subsistence fishers in the general U.S. population and even distinct from other Native American fisher populations.

#### **1.4 CONTENTS OF VOLUME 2**

Figure 1-1 shows how Volume 2 fits into the overall guidance series and lists the major categories of information provided. This volume covers topics necessary for conducting risk assessments related to consumption of chemically contaminated fish. The first four sections follow the anticipated sequence of activities to conduct a risk assessment, develop risk-based consumption limits, and prepare consumption limit tables for a range of fish contaminant levels, meal sizes, and consumer groups. The last two sections provide summary information on the toxicological properties of the 25 target analytes and geographic information system (GIS) mapping tools for risk assessment and risk management.

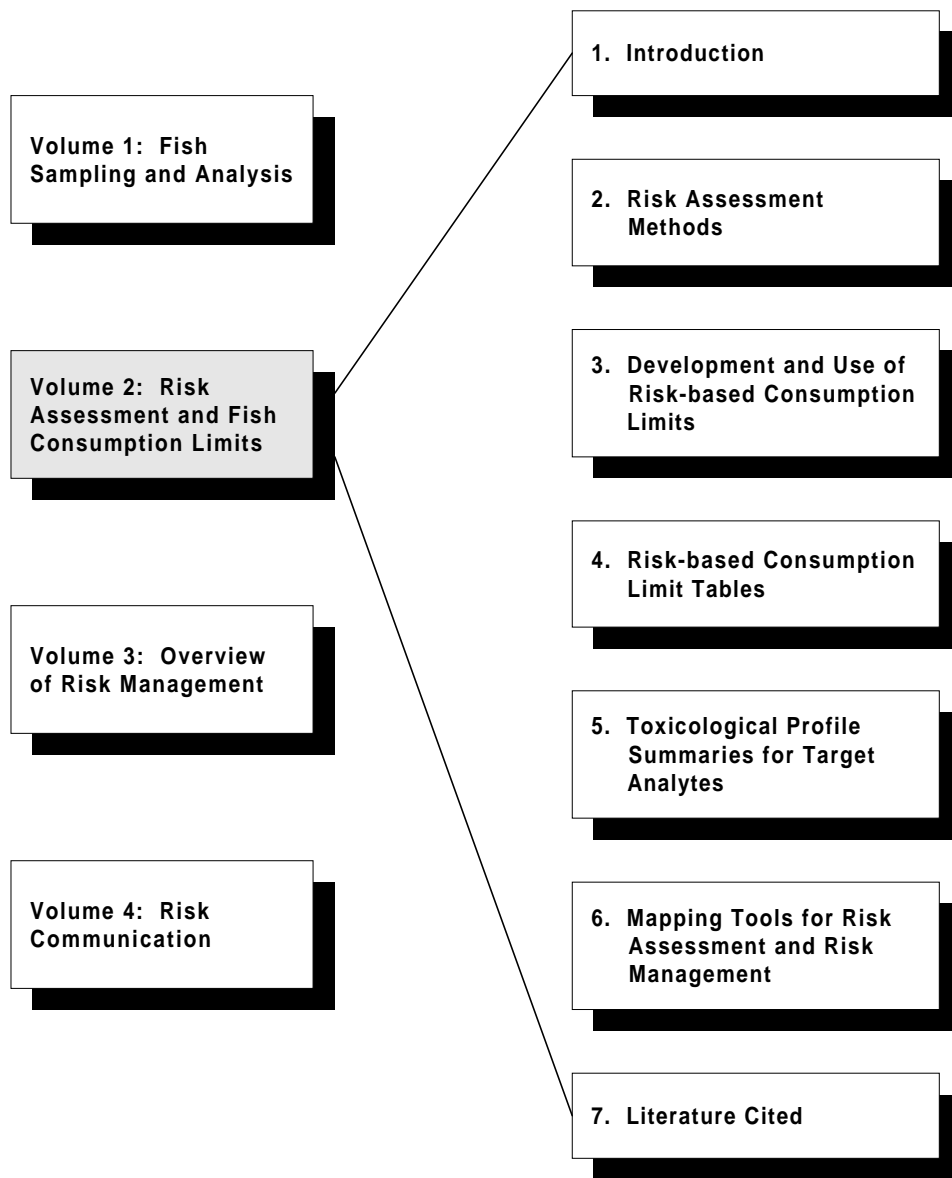
Section 1 of this document reviews the development of this guidance document series, lists the 25 target analytes of concern with respect to chemical contamination of fish and shellfish, summarizes additions and revisions to this third edition, and references information used in the development of this document.

Section 2 introduces the EPA four-step risk assessment process: hazard identification, dose-response assessment, exposure assessment, and risk characterization. Details on each of these steps are provided, along with a discussion of the major uncertainties and assumptions.

Section 3 of this document presents the information needed to calculate or modify the consumption limit tables provided for the 25 target analytes in Section 4. The reader is guided through calculations of risk-based consumption limits for carcinogenic and noncarcinogenic effects using the appropriate cancer slope factor (CSF) and reference dose (RfD). The reader is shown how selection of various input parameters such as the maximum acceptable risk level, consumer body weight, meal size, and time-averaging period influence fish consumption limits for single species diets. In addition, information is provided on methods for calculating consumption limits for single-species diets with multiple contaminants and multiple-species diets contaminated with a single or multiple contaminants.

The monthly consumption limits for each of the 25 target analytes are provided in Section 4.

Section 5 presents a toxicological profile summary for each of the 25 target analytes. Each profile summary contains a discussion of the pharmacokinetics, acute toxicity, chronic toxicity, reproductive and developmental toxicity,



**Figure 1-1. Series Summary: Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories.**

mutagenicity, carcinogenicity, populations with special susceptibilities, interactive effects of the target analytes with other chemical contaminants, and critical data gaps with respect to toxicity. The most current EPA risk values (CSFs and RfDs) from sources such as EPA's Integrated Risk Information System (IRIS) and the Office of Pesticide Programs are provided, with a discussion of supporting dose-response data.

Section 6 has been added to provide readers with an overview of GIS mapping tools for use in risk assessment and risk management. Mapping can be used to display information germane to all aspects of fish advisory programs. Maps may focus on fish contaminant levels, waterbodies where fish advisories are in effect, sport and subsistence fishing locations, or consumption levels of target populations of fishers. The reader is provided with instructions to access EPA websites on the Internet to obtain additional GIS datasets and coverages.

In keeping with current EPA recommendations, discussions of uncertainty and assumptions are included in each section of the document. Although information was sought from a variety of sources to provide the best available data concerning the development of fish consumption advisories, limited data exist for some critical parameters (e.g., toxicological properties of certain chemicals and susceptibilities of specific populations such as the elderly, children, and pregnant or nursing women). Although substantial toxicological information is available for all target analytes discussed in this document, readers are cautioned to always consider the methods and values presented in the context of the uncertainty inherent in the application of science to policies for safeguarding the general public from environmental hazards.

The focus of this document is primarily on the risk due to consumption of non-commercially caught fish and shellfish from freshwater, estuarine, and marine waters. This document provides guidance on the evaluation of the overall risk associated with multimedia exposure to chemical contaminants found in fish (e.g., exposure resulting from other food sources, consumer products, air, water, and soil). EPA recommends that a comprehensive risk assessment be considered for all confirmed fish contaminants, including an evaluation of all significant exposure pathways (e.g., inhalation, dermal, and oral exposures).

Risk assessment and risk management of chemically contaminated fish are complex processes because of the many considerations involved in setting fish consumption advisories, including both the health risks and benefits of fish consumption, the roles of state and federal agencies, and the potential impact of advisories on economic and societal factors. These topics are discussed in Volume 3 of this guidance series (*Overview of Risk Management*). The final volume in the series deals with how risk managers can best communicate the health risks and benefits of fish consumption to the general public as well as recreational and subsistence fishers. These topics are detailed in Volume 4 (*Risk Communication*).

## **1.5 CHANGES TO VOLUME 2**

The following changes were made to this edition:

### Section 1:

- Included discussion of Native American subsistence fishers.
- Included new information on the development of FDA action levels and tolerances and provided rationale as to why states should adopt the EPA risk-based approach.

### Section 2:

- Revised table on uncertainty factors to be consistent with new information.
- Revised developmental toxicity section: removed repetitive material and put detailed information from this section in Appendix E.
- Included information from recent EPA guidelines for the health risk assessment of chemical mixtures (1999).

### Section 3:

- Revised consumption limit tables in Section 4 to be calculated as fish meals per month, at various fish tissue concentrations, for noncancer and cancer health endpoints.
- Assumed an acceptable risk of 1 in 100,000 in meal consumption limits; the second edition used an acceptable risk of 1 in 10,000, 1 in 100,000, and 1 in a million.
- Updated risk values used in consumption limit tables based on IRIS (1999) and new information from EPA's Office of Pesticide Programs.
- Assumed an 8-oz (0.227-kg) meal size for calculation consumption limits; the second edition assumed four meal sizes of 4, 8, 12, and 16 oz.
- Recommended a default value for meal size of shellfish.
- Assumed a monthly time-averaging period; the second edition assumed biweekly, 10-day, weekly, and monthly time-averaging periods.
- Updated discussion of multiple chemical interactions to be consistent with EPA's recent guidance on chemical mixtures.
- Revised examples using updated risk values from IRIS (1999).

**Section 4:**

- Prepared reformatted, streamlined consumption limit tables for each chemical, using assumptions outlined above (Section 3).
- The definition of "safe fish consumption" was changed from 30 fish meals per month to 16 fish meals per month.

**Section 5:**

- Updated chemical-specific information based on IRIS (1999) and other recent toxicological information on data sources.
- Included additional information on PCBs and dioxin analysis.

**Section 6:**

- Included new information on georeferencing of fish advisories in the new Internet version of the National Listing of Fish and Wildlife Advisories (NLFWA).

**Section 7:**

- Updated references.

**1.6 SOURCES**

Information from a wide range of government and academic sources was used in the development of this document. Current approaches developed by states, regional groups such as the Great Lakes Sport Fish Advisory Task Force, and federal agencies including EPA and FDA were reviewed. Section 7 contains a complete listing of literature sources cited in this document.

In addition, to review the first edition of this document, EPA assembled an Expert Review Group consisting of officials from several EPA offices, FDA, regional groups, and the following states: California, Florida, Michigan, Delaware, Illinois, Minnesota, Missouri, North Dakota, New Jersey, and Wisconsin. A list of the experts and their affiliations is provided in Appendix A. The Expert Review Group contributed significant technical information and guidance in the development of the first edition of this document. Written recommendations made by the experts were incorporated into the final document. Some members were also consulted further on specific issues related to their expertise. In a second round of reviews, this document was circulated to all states, several Native American tribes, and various federal agencies for comment, and additional modifications were made. Participation in the review process does not imply concurrence by these individuals with all concepts and methods described in this document. The Expert Review Group did not review the current edition of the document because the

basic risk assessment procedures had already been approved. This third edition was issued primarily to update new toxicological information for several analytes and to revise and streamline the consumption limit tables using updated exposure factors.