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GUIDANCE FOR ASSESSING CHEMICAL CONTAMINATION DATA FOR USE IN FISH ADVISORIES

VOLUME III: OVERVIEW OF RISK MANAGEMENT

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Office of Water
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Washington, DC

EXECUTIVE SUMMARY

State, local, and federal agencies currently use various methods to estimate risks to human health from the consumption of chemically-contaminated, non-commercial fish. A 1988 survey, funded by the U.S. Environmental Protection Agency (EPA) and conducted by the American Fisheries Society, identified the need for a standardized approach to evaluating risks and developing fish consumption advisories to provide comparable advisories across different jurisdictions (RTI, 1990). Four key components were identified as critical to the development of a consistent risk-based approach: standardized practices for sampling and analyzing fish, standardized risk assessment methods, standardized procedures for making risk management decisions, and standardized approaches to risk communication (RTI, 1990).

To address concerns raised by the survey respondents, EPA has developed a series of four documents designed to provide guidance to state, local, regional, and tribal environmental health officials responsible for issuing fish advisories. The documents are designed as guidance only and do not constitute a regulatory requirement. The documents are:

Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories
Volume I: Fish Sampling and Analysis
Volume II: Risk Assessment and Fish Consumption Limits
Volume III: Risk Management
Volume IV: Risk Communication

It is essential that all four documents be used together, since no single volume addresses all of the topics involved in the development of risk-based fish consumption advisories.

Fish contamination has become a recognized health hazard in some areas in recent

years. While most fish provide an excellent source of nutrition, some fish are sufficiently contaminated to generate health risks (e.g., Minamata disease in Japan). The responsibility for safeguarding the public from contaminated fish is shared by different agencies in the United States. Federal agencies such as the United States Food and Drug Administration (FDA)[1] have responsibility for advisories regarding commercial fish. EPA, the Department of Energy, and the United States Fish and Wildlife Service, are also involved in managing and monitoring waterbodies, controlling pollutant releases, and managing clean up and remediation efforts that impact fish contaminant concentrations. Responsibility for safeguarding the public against effects of contaminants in non-commercial fish falls to state, local, and tribal agencies and groups. The overall objective of this series is to provide guidance to these agencies and groups regarding the development of fish advisories for non-commercial fish.

The field of risk management, as it deals with fish advisories, is a relatively new and evolving area. A few states have long-standing advisory programs; however, written evaluations of these programs were not available for the most part. Consequently, there is limited information available from which to draw conclusions or guidance regarding management strategies. Examples of types of advisories were obtained from ongoing advisory programs. Advisory program staff were consulted regarding their experiences with various management approaches. Due to the information constraints, this document provides an overview of risk management rather than detailed and highly specific guidance. Numerous state and local advisory programs have recently been developed, and it is anticipated that additional information will be available in future editions of this volume.

A variety of options exist for managing health risks through fish advisories. Options for limiting consumption of contaminated fish range from approaches requiring limited resources to resource-intensive approaches such as the development of quantitative health-based advisories. This document presents various options that may be used in fish advisory programs, with a discussion of the types of information and resources required and their advantages and disadvantages. A discussion is included of specific characteristics that may be considered when developing a fish advisory program, including: contaminant and risk levels, resources available for program development, the feasibility and efficacy of the options, and the anticipated impacts of various options on target populations (e.g., on nutrition, economics, traditional activities, communities, risk). A structure for organizing information on options and characteristics is provided and a tiered approach to developing fish advisories is discussed. Templates are included to enable risk managers to organize their information to evaluate needs and to identify the optimal group of options and consumption limits for their area.

[1] See the Glossary for definitions of abbreviations and selected terms.

The risk management approach discussed in this volume includes a discussion of critical decisions required to carry out sampling and analysis, risk assessment, and advisory program development. This highlights for the risk manager those decisions that may have a significant impact on risk estimates and the corresponding advisories. The uncertainties inherent in these decisions are also discussed.

Environmental justice is discussed in this volume because contaminated fish may be consumed in greater quantities by minorities and low-income populations in many areas of the United States. These groups are often subsistence fishers (fishers who rely substantially on fish they catch as a food source) and may be simultaneously exposed to the pollutant found in their fish via other sources as well (in other foods, air, and water). Subsistence fishers live in urban environments, where high pollution levels often have obvious industrial or other sources, as well as in rural areas, where water or soil contamination may occur via long-range transport or from non-point sources.

While health concerns are often the focus of fish advisory development this document also provides information on health benefits of fish consumption and the economic and social impacts of various advisory strategies. Information on the benefits of fishing and fish consumption are provided to enable risk managers to evaluate the potential impacts of advisories; however, information on these topics is limited, often location-specific, and dependent on local characteristics. Quantitative cost-benefit analysis is not discussed in this volume; however, qualitative information on health benefits of fish and limited fishing revenue data are included. Information is also provided on potential societal impacts meriting consideration, such as traditional dietary patterns and religious and social traditions that rely on fishing and fish consumption. Although these types of impacts cannot be quantified or adapted to a balance sheet approach, they merit consideration in the development of advisories. The social, economic, and health impacts of advisories will vary depending upon the characteristics of the local population, and use of local information is encouraged.

A theme carried through this document is to utilize local information and participation where possible and to involve all potentially impacted parties in the decision-making process. It is hoped that the evaluation of potential impacts of fish advisories and broader public participation in decision-making will provide all affected parties access to policy making, and result in well-founded and widely accepted fish advisories.

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ACKNOWLEDGEMENTS

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GLOSSARY & ABBREVIATIONS

acute exposure	exposure at a relatively high level over a short period of time (minutes to a few days). (This is defined in IRIS as 24 hours or less; however, sources consulted utilized exposure periods of up to a few days. Consequently, the more encompassing definition is appropriate in reading this document.)
acceptable risk level	the maximum level of individual lifetime carcinogenic risk considered "acceptable" by risk managers.
agency	state, local, and tribal agencies and groups who have responsibility for managing risks associated with fish contamination are referred to as agencies in this text. These may include departments of environmental protection or health, tribal councils, and other types of regulatory and governing groups.
ATSDR	Agency for Toxic Substances and Disease Registry, U.S. Dept. of Health and Human Services, Public Health Service.
BW	body weight of an individual, expressed in kilograms (kg).
cancer potency	(often used interchangeably with slope factor) the slope of the dose-response curve in the low-dose region used with exposure to calculate the estimated lifetime cancer risk. Often expressed as risk per one milligram of exposure to the toxic chemical per kilogram body weight per day (mg/kg-d). Usually is calculated using the upper 95% confidence limit on the linear term in the linearized multistage (LMS) model.
chronic exposure	multiple exposures occurring over an extended period of time, or a significant fraction of the lifetime

developmental toxicity	adverse effects on the developing organism resulting from exposure prior to conception, during prenatal development, or postnatally up to the time of sexual maturation.
dose-response relationship	relationship between the exposure to an agent and changes in aspects of the biological system, apparently in response to that agent.
efficacy	refers to the degree to which a fish advisory program obtains compliance with advisories on the part of fish consumers.
endpoint	response measure in a toxicity study (e.g., liver damage, developmental toxicity, cancer).
EPA	United States Environmental Protection Agency.
exposure limits	a daily limit on exposure based upon health and toxicity data, which the reader may calculate, using the study data provided in this or other sources (mg/kg-day).
feasibility	refers to the match between the human, material, and financial resources required by an agency to carry out a program and the requirements of the program.
FDA	United States Food and Drug Administration.
fish	refers in this document to non-commercial fish from estuarine and fresh water sources, unless otherwise noted.
incidence	number of new cases of a disease within a specified time.
kg	kilogram, one thousand grams (10^3), equivalent to 2.205 pounds (avoirdupois).
mg	milligrams, one thousandth (10^{-3}) of a gram.
mg/kg-day	milligrams exposure per kilogram body weight of the exposed individual per day.

mutagenic	capable of inducing changes in genetic material (e.g., DNA).
recreational fishers	non-commercial and non-subsistence fishers. Synonymous with sport fishers in this document.
Reference Dose (RfD)	estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of adverse non-carcinogenic effects during a lifetime. Units are mg/kg-day.
risk	the probability of injury, disease, or death under specific circumstances.
SF	see cancer potency. (Not to be confused with safety factor approaches used in non-cancer analyses.)
sport fishers	non-commercial and non-subsistence fishers. Synonymous with recreational fishers in this document.
subsistence fishers	refers in this document to be people who rely on non-commercial fish as a major source of protein.
threshold	dose or exposure below which a significant adverse effect is not expected.

Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories

SECTION 1

INTRODUCTION

1.1 Overview and Objectives

The objective of this volume is to provide state, local, and tribal agencies with risk management guidance for developing fish advisories. Fish contamination has been recognized as a potential health hazard in recent years. While most fish provide an excellent source of nutrition, some fish are sufficiently contaminated to cause health problems (e.g., Minamata disease in Japan).

The field of risk management, as it deals with fish advisories, is a relatively new and evolving area. Although a few states have long-standing advisory programs, written evaluations of these programs are generally not available. Consequently, limited information is available from which to draw conclusions or guidance regarding management strategies. Examples of types of advisories were obtained from ongoing advisory programs. Advisory program staff were consulted regarding their experiences with various management approaches. This document therefore provides an overview of risk management rather than detailed and highly specific guidance. EPA will provide more detail on the experiences and recommendations of state and local programs in future editions of this volume.

This risk management volume is part of a series that provides information on:

- identifying and quantifying fish contamination,
- evaluating risks associated with contamination,
- managing those risks, and
- communicating risk information and protective strategies to the public.

Various agencies have responsibility for issuing fish advisories and preventing fish contamination. State, local, and tribal agencies have primary responsibility for safeguarding the public against effects of contaminants in non-commercial fish.[1]

[1] State, local, and tribal agencies are referred to as "agencies" in this document and include groups responsible for managing risks associated with fish contamination. These may include departments of environmental protection or health, tribal councils, and other types of regulatory and governing groups.

Federal agencies are responsible for commercial fish and for activities related to preventing fish contamination. The United States Food and Drug Administration (FDA)[2] is responsible primarily for developing advisories regarding commercial fish. The United States Environmental Protection Agency (EPA), the Department of Energy (DOE), and the United States Fish and Wildlife Service are also involved in managing and monitoring waterbodies, controlling pollutant releases, and clean-up and remediation efforts that impact fish contaminant concentrations (see Section 2.5).

This volume addresses factors to be considered in both the development of advisory programs and the establishment of health-based fish advisories. This process is complex due to the variety of factors involved:

- the type of contamination,
- the level of contamination,
- local fish consumption practices,
- local population characteristics, and
- resources available for an advisory program.

The various options for limiting consumption of contaminated fish can be tailored to fit local characteristics and needs. These options range from approaches that require limited resources and have limited effectiveness (e.g., general advisories), to more resource-intensive and effective approaches (e.g., quantitative advisories). This document presents various options that may be used in fish advisory programs and discusses their strengths and weaknesses. Other relevant characteristics like resources available for program development, risk levels, and economic and cultural impacts, are also discussed. Templates for organizing information on options and characteristics are included.

Agencies currently employ a range of methods to estimate risks to human health from consumption of chemically-contaminated fish. Results of a 1988 survey of such methods, funded by the U.S. Environmental Protection Agency (EPA)[3] and conducted by the American Fisheries Society, indicated the need for a more consistent approach to assessing risks from contaminated fish.[4] The four key components identified as critical in a risk-based approach to developing fish

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[2] See the Glossary for definitions of abbreviations and selected terms.

[3] Throughout this document the abbreviation EPA will be used to represent the U.S. Environmental Protection Agency.

[4] In this document, fish refers to non-commercial fish from estuarine and fresh water sources.

consumption advisories were:

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

To address concerns raised by the survey, EPA is developing a series of four documents to provide guidance to agencies issuing fish advisories for non-commercial fish (i.e., self-caught fresh water and estuarine fish). These four volumes comprise the *Guidance for Assessing Chemical Contamination Data for Use in Fish Advisories:*

Volume I: Fish Sampling and Analysis (EPA, 1993a),

Volume II: Development of Risk-Based Intake Limits (EPA, 1994a),

Volume III: Overview of Risk Management, and

Volume IV: Risk Communication (EPA, 1994c).

Supplements to Volume II have also recently been released. These provide information regarding exposure assessment, including fish consumption patterns, risk characterization, and mapping. The four volumes and the supplements should be used together, since no one volume provides all the necessary information to evaluate and make decisions regarding the issuance of fish consumption advisories. While these volumes are designed to provide guidance to agencies developing fish advisory programs, **they do not constitute a regulatory requirement.** To provide further information, EPA recently developed the National Listing of Fish Consumption Advisories data base, available from the Office of Water on five disks in a PC format.

1.2 Series Summary

To provide guidance on using a human health risk-based approach to determine both the level of the advisory and the most appropriate type of advisory, this series presents the following features:

- methods to assess contaminant levels in fish tissues,

- methods to evaluate population risks for specific groups, waterbodies, and geographic areas;

- discussion on identifying target populations, with information on especially susceptible subpopulations;
- descriptions of various risk management options for fish advisory programs, with the experiences of agencies that have utilized the options;
- factors that may be considered in selecting program options and protection levels, including organizational factors such as feasibility and efficacy, and the impacts of various options on target populations (e.g., on nutrition, economics, traditional activities, communities, and risk);
  and
- methods for organizing information on risk, options impacts, and target populations' characteristics.
- methods of risk communication

Table 1.1 provides more specific information on the major activities covered in the documents in this series. All the activities carried out in the process of developing fish advisories and managing risks associated with contaminated fish are listed in the table. Volume I provides guidance on developing a sampling and analysis program to characterize the nature of the fish contamination distribution in waterbodies throughout an area. Volume II provides an overview of risk assessment, chemical-specific risk values, and methods for calculating meal intake limits. It also provides the groundwork for a population risk evaluation. Volume III, this document, provides information on selecting and implementing various options for reducing risks associated with contaminated fish consumption. This document focuses on fish advisories, although other related activities are discussed. Volume IV provides guidance on methods for communicating risk information and for evaluating the target audience for risk advisories to determine the best approach for communicating risk.

Table 1.1. Activities Related to the Development of Fish Advisories and Risk Management and Volumes in the Series Containing Discussions of These Activities

ACTIVITY	Sampling and Analysis	Risk Assessment	Calculate Health-Based Intake Limits	Evaluate Options	Select Appropriate Risk Management Options[5]
DATA GENERATED	1.concentration in fish tissue (V. I) 2.geographic distribution of contaminant (V. I)	1. individual risks (V. 2) 2. population and subgroup risks (V. 3) 3. identify groups at highest risk (V. 3)	1. health-based consumption limits (V. 2 & 3) 2. maximum acceptable contamination levels (V. 2 & 3)	1. potential options and administrative requirements (V. 3) 2. benefits and adverse impacts of options (V. 3) 3. other mechanisms for reducing contamination and risk (V. 3)	1. identify options that are optimal for a specific locality (V. 3)
RELATED ACTIVITIES **NOT** COVERED IN THIS SERIES	evaluate sources of contamination and transit pathways	determine if medical monitoring or intervention is warranted (primarily relevant to high exposures)	determine what actions are needed to lower contamination to minimal risk levels	work with remediation and enforcement agencies to reduce contamination	integrate programs with relevant local activities ongoing through other agencies or groups

[5] Risk communication activities related to fish advisories are discussed in Volume IV of this series.

Major functions are listed in the first row. The data or conclusions generated by each step are listed below the activities, along with the volume in which the activities are discussed. Some related activities relevant to fish advisories but beyond the scope of this series are listed in the final row. As Table 1.1 shows, the development of advisories depends on the collection of appropriate data in the early stages of program development and proceeds through analysis (risk assessment) to decision-making (risk management).

1.3 Volume III Contents

Figure 1.1 shows how Volume III fits into the overall series and lists the major categories of information provided. This volume covers topics necessary for decision-making to manage risks related to chemically contaminated fish. The sequential order of the sections follow the anticipated sequence of activities to be carried out in developing a risk management program.

Section 2 contains a discussion of various options for limiting contaminated fish consumption. Federal roles and activities are identified. Regulatory and other options for state, local, and tribal governments are presented with discussions of the organizational features of each option. Some anecdotal information is provided on the experiences of various agencies in implementing different program options.

Section 3 provides information on the potential impacts of limiting consumption, including social, economic, cultural, and nutritional impacts, costs, feasibility, legislative and political constraints, and other factors. The impacts vary depending on the specific circumstances of an area and the population of concern.

Section 4 contains a discussion of methods for comparing health risks associated with consumption to impacts of limiting consumption. It provides schematics for organizing information on a site-specific basis regarding various risk management options, their applicability to an area, and attributes and requirements for their implementation. A tiered approach to developing fish advisories is discussed. Templates are included to help risk managers organize their information to evaluate needs and to identify the optimal group of options and consumption limits.

Section 5 contains a list of references consulted and cited.

Figure 1.1 Series Summary: Guidance for Assessing Chemical Contamination Data for Use in Fish Advisories

1.4 Methods and Sources

This document was developed using information from a variety of sources:

- State documents related to the development and implementation of fish advisories were consulted. These sources provided data on existing programs and, in some cases, comments on their efficacy.

- Staff members of some agencies and tribal groups with long-standing programs were consulted regarding their experiences and recommendations. Due to the recent development in many states of extensive advisory programs, limited information on management strategies exists. Future editions of this volume are expected to contain additional information on program development processes and strategies.

- Government publications and journal articles were consulted for information on scientific issues including nutrition and economics.

- Government documents and programs were consulted for information on mapping methods (e.g., GIS mapping), regulatory roles of various agencies, and information on existing programs designed to address pollution prevention and waterbody remediation.

- Workgroup members[6] and other experts from state, local, tribal, and federal governments, academic institutions, and advocacy groups were contacted by phone, and provided both information about their current programs and experiences and ideas for future activities.

1.5 Underlying Assumptions

Risk management for any environmental program requires numerous staff and management decisions. The decision-making process is aided by comprehensive information on both the nature of the problem to be addressed and the

[6] Work on this document was guided by a workgroup of experts on fish contamination issues. Their names and affiliations are listed in the Acknowledgements section in the front of this volume. This group reviewed the outline and drafts of the document, and made numerous comments and recommendations on the content.

characteristics and implications of options for remediation. The approach to risk management described in this volume is based upon underlying assumptions regarding decision-making in the public sector:

Chemical contamination of fish may pose health risks. These risks are dependent on the nature and severity of the contamination and the characteristics of the exposed population. Risk estimation is a developing science that cannot predict precise effects in individuals or populations. Consequently, uncertainty exists regarding the type and extent of health risks. Risk estimates can be used, however, with other relevant information, to make decisions regarding fish advisory programs.

The goal of developing fish advisories is to minimize the health risks to fish consumers as well as minimize any negative effects of restricting consumption. When fish contamination levels pose sufficiently elevated health risks (determined on a local basis), agencies may elect to take restrictive action to protect public health. Because many risk reduction options are associated with some negative impacts, decision-makers must also consider potential impacts on all affected parties.[7] These impacts include social, cultural, economic, health, and any other impacts associated with options for reducing risks.

Most options for reducing risks will require trade-offs between risk reduction and social, economic, and other costs. Decision-making to select options is primarily a policy activity rather than a scientific one. Consequently, it is beneficial to make such decisions with input from all affected parties.

Each agency and exposed population has unique characteristics, resources, strengths, goals, and constraints. Consequently, there is no one best approach to developing and implementing fish advisory programs. Each agency should design a program based upon the unique characteristics of its contamination problem, populations at risk, and affected parties. EPA does not recommend specific target intake limits or risk levels for contaminants. It also does not recommend using FDA action levels for site-specific fish consumption advisories.

*The **ultimate** goal of a fish contamination risk reduction program is to return waterbodies to a condition in which fish are no longer contaminated at a level that will pose unacceptable risks to human health.* While remediation of contaminated water is beyond the scope of this document, it is briefly discussed

[7] Affected parties may include fish consumers, individuals whose livelihood or lifestyle are dependent on non-commercial fishing, and individuals whose land use or value are related to non-commercial fishing.

in Section 2.5, which contains a listing of federal programs that may provide assistance.

1.6 Critical Decisions

Both science and policy are components of a fish advisory program. In the policy arena, decisions are required to establish and achieve policies and goals. Decisions are also required to conduct risk assessments and determine how science will be used in establishing policies. Many elements of risk assessment involve significant uncertainty (e.g., animal to human extrapolations, differences in susceptibility over a lifespan, the effects of exposure to a mixture of contaminants). Although some scientific data on these topics exist, they are rarely definitive. Under these circumstances, the decisions that transcend current scientific knowledge may be considered policy decisions, and both policy and scientific experts should participate in the decision-making process to arrive at the best choice. Scientists may be able to best describe the uncertainties and some alternatives, while policy makers may bring non-scientific issues to bear and consider potential impacts of decisions on a broader level.

In this document (and in others in the series) many issues that are decision points can be found in phrases like "readers may wish to...," where the reader may determine the best course of action. Minor decisions may be related to the use of specific resources (e.g., a particular laboratory method, a set of toxicological information sources). These decisions are expected to have a relatively minor impact on overall program activities and efficacy. Alternatively, critical decisions (or groups of decisions) are those that may have a significant impact on the target population, their level of risk or protection, and program efficacy.

Table 1-2 lists critical decisions in risk management for a fish advisory program, along with the section in which they are addressed. As stated above, the four volumes in the series *Guidance for Assessing Chemical Contamination Data for Use in Fish Advisories* are designed to be used together, although they address different topics regarding fish advisory development. Volume III, addressing risk management, provides an overview of the critical decisions made throughout the fish advisory development process. Relevant discussions also appear in other volumes in the series (e.g., decisions regarding sampling and analysis [Volume I], risk assessment [Volume II], and risk communication [Volume IV]). The critical decisions listed in Table 1-2 are discussed briefly in this section, and in more depth in subsequent sections of this volume.

Table 1-2. Critical Decisions

Nature of Decision (Category)	Section of Volume III or Volume Number
1. sampling and analysis	Vol. I
2. population risk estimation (risk assessment) including: consumption rates - subpopulation selection non-fish exposure - air, water, soil, occupational, non-fish food sources risk values - RfDs, cancer potency values, other values	Vol.II Supplement A
3. selection of target populations or risk levels	Vol.II Supplement A
4. risk management options under consideration	2.2
5. consideration of positive and negative impacts	3, 4.2
6. selection of most appropriate risk management options	4.3
7. level of protection afforded by advisories including: carcinogenic effects - acceptable risk level non-cancer effects - value selected as benchmark	4.4 and Vol. II Supplement A
8. level of program effort and funding	4.5
9. program evaluation and modification	4.6

Category 1. Sampling and Analysis

Decisions regarding sampling and analysis are discussed in Volume I. These decisions include sampling location, frequency, the chemicals analyzed, and those levels and frequency of occurrence that trigger the decisions to issue advisories. In most cases, it is neither economically feasible nor necessary to sample and analyze all waterbodies. When sampling has not been conducted previously, no scientific information is available on which to base sampling decisions. Consequently, sampling and analysis decisions may be based on policy or on the likelihood of contamination (e.g., using TRI data, the presence of Superfund sites, or clusters of environmentally-related disease).

Category 2. Population Risk Estimation.

Methods for calculating population risk require risk assessors to combine information on consumption patterns, contaminant levels, and risk values (e.g., RfDs) to obtain an overall estimate of risk for various population subgroups.[8] These methods are described in Supplements A and B to Volume II. Risk assessment used to establish risk-based fish advisories incorporates many decisions that involve policy considerations because they transcend current scientific knowledge. Examples of these decisions include choosing a health endpoint among many credible endpoints, and the degree of safety incorporated in risk values and subsequent risk estimates.

A range of values for the inputs used in risk calculations are discussed in Volume II. The exposure and toxicity values used affect the outcome of risk estimates. Risk estimates, in turn, are often used to determine the appropriate course of action, the population groups or geographic areas requiring action, and the fish advisory levels.

Critical decisions include the type of consumption data used (e.g., survey data collected locally, "average" consumption values from various studies, "high-end" estimates from studies), the location and nature of contaminant sampling (which may depend on available resources), the sources of concurrent exposure to the same contaminants considered, the risk values used to estimate risk, and the level of protection afforded by the advisory. Decisions on these factors involve policy rather than science and should be considered by risk managers in developing an overall fish advisory program.

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[8] EPA is currently reviewing risk assessment methods for carcinogens and non-carcinogens. Information will be provided on any new recommended approaches (e.g., the benchmark dose approach, non-linear cancer extrapolation, categorical regression) in future editions of this series.

Category 3. Target Populations and Risk Levels.

Identifying target populations is a critical decision, because it may determine which groups will be the focus of risk reduction activities. This decision may be linked to those regarding sampling locations and groups to be considered in selecting consumption data (either through surveys or based on previous studies in the literature). If a risk-based approach is taken to population selection, targeted populations will be those groups identified following a risk assessment as having unacceptably high risk levels.

Decisions are also required to determine the breadth of the population to protect through advisories. Choosing members of the fish consuming population who eat an average (50th percentile) amount of fish versus those who consume larger amounts (i.e., at the 80, 90, or 99th percentiles) is a policy rather than a scientific decision.

The selection of unacceptable and acceptable risk levels are significant policy decisions and may involve evaluating various assumptions underlying the risk estimates. Risk managers may choose to focus on a particular risk level for carcinogens (e.g., one in one million) or specific types of risks (e.g., developmental, cancer, organ-specific toxicity to susceptible subpopulations) as being of critical importance. Others may focus on particular communities or population groups at risk. These decisions are very important because they may determine levels of protection, who is protected, and the scope and nature of fish advisory programs.

Considerable trade-offs exist in many cases between maximizing public protection and minimizing an advisory's negative impacts. If the goal is to protect 99% of the population, including the highest consuming individuals in a high-consumption population group, advisories will be much more prevalent (and any negative impacts more pronounced) than if a program were to target the average consumer's behavior. However, focusing on average exposure and risk levels may not protect the high-risk populations who need to obtain information that they can use to protect their health.

Category 4. Options Under Consideration

Risk managers determine which program options are under consideration in a fish advisory program (e.g., posting notices, catch and release, restricting waterbody access). From this set of options a subset is usually identified that will actually be employed. The decision to consider all possible strategies for risk reduction is important because it provides wide latitude in addressing the needs of target populations. Very restrictive options, such as restricting

waterbody access, are rarely employed in practice.

In many areas, risk managers may choose options to reduce fish-related risks under a specific set of constraints. For example, agencies responsible for tracking contaminant levels in fish may not have the regulatory authority to restrict fishing access. In most areas, however, the health department has authority to restrict access in cases where a clear and present danger to the public exists. In many cases, budgetary constraints may curtail significantly the number and types of risk management options available. Because the options have differing potentials for reducing risk, limiting the types of available program options may affect the risk reduction potential of a program significantly.

Category 5. Consideration of Positive and Negative Impacts

Recommending limitations in fish consumption involves tradeoffs with respect to health, recreation, economics, community and traditional activities, personal interests, and other perceived benefits of fish consumption. Although risk managers are encouraged to consider all risks and impacts in some way, managers may elect to focus on one or a few of the potential risks or impacts. The types of options and the strength of the advisories recommended will depend on how various population groups and their risks are evaluated and upon the impacts that are considered most important. Deciding how to prioritize and balance the risks and impacts involved will have a pronounced effect on fish advisory programs.

Category 6. Selection of Most Appropriate Options

Selecting appropriate fish advisory program options from those that have been considered is obviously a critical decision in developing a program. Although this decision appears to be the most important one, it generally corresponds to individual or community risk levels and characteristics. The various decisions that have been made up to this point regarding consumption rates, sampling and analysis, selection of risk values, treatment of non-fish exposures, and consideration of impacts, all contribute significantly to the basis for selection and the ultimate choice of appropriate options, target populations, and protection levels.

Category 7. Level of Protection

Risk managers may choose from various risk values (RfDs and cancer potencies) to establish consumption limits. These values may generate consumption limits that vary by orders of magnitude for a single contaminant, especially when cancer-based and non-cancer-based values are compared. In

addition, targeted acceptable risk levels are used in setting limits for carcinogens. Decisions regarding risk values can have a substantial impact on consumption advisories and on potential risks to the population.

Carcinogenic Effects - Acceptable Risk Levels

Cancer risks are evaluated based upon an assumed relationship between exposure and lifetime risk as defined in the cancer potency values for each target analyte. Risk managers determine the level of risk (e.g., one in one million) that is acceptable. This decision enables them to select appropriate exposure level. The acceptable level of risk can be determined by the needs and goals of the target population, the decision-makers, or, under ideal circumstances, by joint discussions between the two groups. Meal consumption limits provided for the carcinogenic target analytes in Volume II are listed for three cancer risk levels: one in ten thousand, one in one hundred thousand, and one in one million. The method used to calculate the values is presented in Volume II so that alternative risk levels can be calculated.

Non-cancer Effects - Value Selected as Benchmark

The potential for non-carcinogenic effects can be evaluated by comparing exposures to a Reference Dose (RfD) or some other benchmark of a "safe" exposure level. Volume II presents the RfDs developed by EPA, along with a summary of toxicological information for the 23 target analytes. In the summary data, recent study results are presented for some analytes regarding developmental, neurological, and other types of toxicity. Risk managers may choose which benchmark value they consider most appropriate for their target population of concern. In some cases, more than one value may be selected for various population subgroups (e.g., children, women of reproductive age).

Category 8. Level of Program Effort and Funding

As noted above under Section 4 (Selection of Most Appropriate Options), financial constraints may affect the choice of options for developing a fish advisory program. Financial and other resource factors (e.g., staff, materials, access to information) also affect the methods used to implement options, how extensively they are implemented throughout an area, and ultimately how effective the programs are.

Category 9. Program Evaluation and Modification.

Program evaluation and modification are important activities to be considered even in the initial planning of a program. Reviews of a program's design are

necessary to determine how effective it is: who it is reaching, whether their behavior has changed, and whether the target population requires additional information. Program evaluation also enables the risk manager to determine how the program might be altered to better address its goals. Accordingly, flexibility is vital so that necessary modifications can be made both in the initial design and over time as needs change. The decision to include these elements in a program design will help provide for the long-range success of a fish advisory program.

This document provides an overview of a wide variety of risk management options and their potential utility and impacts. State, local, and tribal risk managers are urged to review the various options and to include all interested parties in the decision-making process in order to develop the best possible programs for their areas.

1.7 Environmental Justice

This document reflects EPA's policy regarding environmental equity and justice. The President's Executive Order (Feb 11, 1994), *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*, specifically directs federal agencies to identify and address disproportionately high adverse human health or environmental effects on minority and low-income populations and workers.[9]

Environmental justice is particularly relevant to the work discussed in this document because contaminated fish may be consumed in greater quantities by minorities and low-income populations in many areas of the United States. These groups often comprise subsistence fishers and may be simultaneously exposed to the same or similar acting contaminants in air, water, and other foods. This exposure may occur both in an urban environment, where high pollution levels often have obvious industrial or other sources, and in less developed areas, where water or soil contamination may occur via long-range transport or from non-point sources.

Many specific recommendations of the executive order address program coordination and activities tracking at the federal level. Additional recommendations may be useful to state, local, and tribal governments for better addressing environmental justice issues. These include the following:

- promote the enforcement of all health and environmental statutes in areas with

[9] Readers are encouraged to review Executive Order 12898 in its entirety.

minority populations and low-income populations;

- ensure greater public participation;
- improve research and data collection relating to the health and environment of minority populations and low-income populations;
- identify differential patterns of natural resources consumption among minority populations and low-income populations; and
- identify multiple and cumulative exposures.

The executive order contains some specific recommendations regarding subsistence consumption of fish and wildlife that may also be relevant for state, local, and tribal governments:

- collect, maintain, and analyze information on the consumption patterns of populations who rely principally on fish and/or wildlife for subsistence (urban and rural);
- communicate to the public the risks of those consumption patterns;
- provide guidance reflecting the latest scientific information available concerning methods for evaluating the human health risks associated with consuming pollutant-bearing fish or wildlife. Consider such guidance in developing policies and rules;
- translate crucial public documents, notices, and hearings relating to human health or the environment for limited English-speaking populations; and
- ensure that public documents, notices, and hearings relating to human health or the environment are concise, understandable, and readily accessible to the public.

These recommendations to federal offices are generally covered by the caveat that such activities should be carried out whenever practicable and appropriate. While these are potentially useful and necessary activities, this information does not constitute a requirement for state, local, and tribal governments, although the values espoused are useful for consideration. If additional assistance is needed on environmental justice issues and strategies, readers may wish to contact:

U.S. EPA Office of Environmental Justice
401 M. St. S.W.

Washington, D.C.
20460
phone: (202) 260-6357

This guidance document addresses concerns regarding environmental justice through the variety of mechanisms discussed below. A major focus of risk management is to evaluate and reduce risks to the most highly exposed individuals or population groups. With respect to fish contaminants, these people are often subsistence fishers, although in some areas they may be primarily sport fishers.

Highest consuming **or** most susceptible subgroups of concern include subsistence fishers, pregnant women, children, groups with poor nutritional status, and individuals with certain pre-existing health problems. Volume II provides substantial toxicological information regarding susceptible subgroups on a chemical-specific and chemical class-specific basis. Information is also provided on characteristics of population subgroups that may cause them to be generally more susceptible to chemical exposures. These subgroups, such as women of reproductive age and children, may be targeted for special efforts in advisory programs (discussed in this volume). Specific methods for calculating advisories tailored to children of various ages and other subgroups are presented in Volume II and discussed further in this document.

The discussions of exposure assessment in Volume II and its Supplements include information regarding fish consumption patterns of highly exposed minority groups such as Asian and Native American communities. The results of numerous recently completed studies show higher consumption rates among these groups than among the general fisher population.

Studies have indicated that highly polluted areas contain disproportionate numbers of minority and low-income populations. To avoid an unsafe exposure level, groups exposed to the same or similar-acting contaminants in media other than fish may require lower consumption limits than if their exposure occurred only through fish. To address this concern, this volume contains information regarding methods for estimating total exposure including air, water, soil, food, and workplace exposures. This information, important for any groups exposed through multiple media, is particularly relevant for groups who reside in highly polluted areas, such as industrialized urban areas and near hazardous waste sites.

Throughout this text, readers are reminded of aspects of the risk management process that may involve public participation. Encouraging participation by traditionally-disenfranchised groups may improve fish advisory program implementation and efficacy. Decisions on the type of risk reduction programs to be established in a community, the pursuit of remediation efforts, and the level of

acceptable risk for a community requires community participation to be the most effective. Discussions of critical decisions in this volume emphasize the value of community member participation and the need for information regarding affected communities.

The potential community, societal, and economic impacts of risk management fish advisory options are discussed in this volume. Subsistence fishers and some other fisher groups consume higher quantities of non-commercial fish; Consequently, they are at greater risk of negative nutritional, economic, or community impacts if their fish consumption is reduced. The negative impacts of consumption reductions are discussed in Section 3. Numerous representatives of Native American, Asian American, urban fishers, rural fishers, and other groups were contacted to obtain their ideas regarding the various options for reducing risks associated with contaminated fish consumption (see the expert source list under Acknowledgements in the front of this document).

Many individuals consulted from community and tribal groups requested information regarding environmental remediation and pollution prevention be included in this volume. These groups frequently expressed the sentiment that the ultimate goal should be to improve environmental quality so that fish advisories are no longer necessary. This has been EPA's goal since its inception and has been shared by many state, local, and tribal programs. In response to these requests, information was collected from a variety of federal, state, tribal, and other sources regarding rights and responsibilities in environmental remediation and pollution prevention. The information summarized in Section 2 provides a road map through various offices at the federal level responsible for remedial action and pollution prevention. Information on federal activities and responsibilities may provide both risk managers and affected groups with the ability to evaluate ongoing efforts, obtain additional information, and participate in determining future activities where necessary. Because state, regional, local, and tribal programs vary considerably, a summary of their activities was beyond the scope of this document.

The environmental justice activities at the federal level are being accelerated as the need to evaluate and address inequities in environmental contamination and health risks is recognized. The approach outlined in this series is designed to assist state, local, and tribal governments in evaluating risks for both the general population and subgroups, allocating resources based on risk levels, and providing more healthful alternatives for all their citizens. EPA welcomes recommendations regarding these issues and approaches to addressing environmental justice.

SECTION 4.

DECISION-MAKING REGARDING FISH ADVISORY OPTIONS

4.1. Overview

This section contains a discussion of methods for comparing the characteristics of various management options to select the most appropriate options and levels of protection based on program goals, available resources, and local conditions. A discussion of both data organization and decision-making, as well as one of qualitative comparisons of risk, organizational features, and impacts are presented. Also addressed are decisions required for program design. The focus of this section is on qualitative comparisons among options, although the use of quantitative information is encouraged. Many factors, such as cultural and other social impacts, cannot be quantified, or easily compared to quantitative risk or economic data.

Templates are provided that can be used by risk managers to organize information on option characteristics. These templates utilize information discussed in other sections of this volume (e.g., risk levels, options). Issues related to prioritizing impacts are discussed along with methods for program evaluation and modification.

4.2. Qualitative Comparisons of Health Risks and Options Impacts

The information discussed in other sections and volumes should be used to evaluate overall advantages and disadvantages of various program options. The information includes:

- organizational impacts including feasibility and efficacy (Section 2),
- societal impacts including nutritional, cultural, and economic impacts (Section 3), and
- population risk characterization (Supplement B in Volume II).

The information can also be used to prioritize activities. It is suggested that the planning and evaluations for fish advisories be carried out on a site-specific basis whenever feasible. As discussed previously, local population characteristics and impacts on local traditions and economies may vary considerably from one area to another.

Various types of information are required for decision-making. Some may be of a quantitative nature (e.g., risks associated with current consumption patterns, the estimated costs of various program activities, staffing requirements, impacts on property values). The quantitative values may be best estimates; however, this type of predictive information often contains significant uncertainty and should be considered accordingly. Most information collected for a fish advisory program will likely be of a qualitative nature (e.g., potential cultural impacts on targeted populations, nutritional impacts).

Some form of risk characterization is also assumed to have been generated, although it may not be precise and should be considered a rough estimate even when detailed analyses have been carried out. (Risk characterization is discussed in Supplement B.) Federal risk assessment methods were designed primarily to provide a means to establish exposure limits (e.g., for drinking water standards) and generate protective rather than predictive estimates. Consequently, the risk estimates should be considered an indication of maximum risk rather than a precise predictor of actual risk. As discussed previously, risk reduction through implementation of fish advisory programs are characterized as "benefits" for purposes of discussing advantages and disadvantages of various options. Benefits are those cases or people who would have been affected that were not affected as a result of reductions in their consumption of contaminated fish.

A wide variety of risk management options have been considered in this document. The selection of which options to consider for inclusion in a fish advisory program is a critical decision. Risk managers may have wide latitude in establishing fish advisory programs or they may be operating under a specific set of constraints regarding their options for reducing fish-related risks. Restricting access to waterbodies or banning fishing may not be an option in areas where no regulatory authority is held by the overseeing fish contamination problems. (In most areas, however, the health department will have authority to restrict access in cases where a clear and present danger to the public exists.)

Significant constraints on program options may also be imposed by budgetary or other conditions. Because the options have differing potentials for reducing risk, restricting options may affect a program's risk reduction potential significantly. The full spectrum of risk management options should be considered prior to selecting

a particular subset of activities. This approach enables risk managers to review the advantages and disadvantages of all possibilities with other interested parties, so that the final decisions may be considered objective and fully thought through.

Table 4-1 provides a template for organizing information on the various impacts, resource needs, and benefits of program options. This template provides only a small amount of space for information entry in any category. Indicators of effect may be used instead of long narrative descriptions; alternatively, risk managers may use this template as a model to modify according to their needs. Information should be organized by water body and/or targeted population. One set of data could be generated for each subpopulation, allowing decisions to be made more easily on a site-specific basis. This method is recommended because the characteristics of each group may differ.

Restriction of fish consumption involves tradeoffs with respect to health, recreation, economics, community and traditional activities, and personal interests and other perceived benefits of fish consumption. Risk managers are encouraged to consider all risks and impacts in some way; however, managers may elect to focus on one or a few of the potential risks or impacts. The types of options and the degree of restrictiveness than a fish advisory program recommends will depend, in part, on the way in which various population groups and their risks are evaluated and upon the impacts considered most important. Decisions regarding how risks and impacts are prioritized and balanced will have a pronounced effect on fish advisory programs. Involvement of all affected parties in the evaluation and decision-making process is highly recommended.

4.3. Selection of Options

Risk managers, in concert with other policy makers, scientific and health advisors, and community members, will recommend the most appropriate options for dealing with fish contamination. In large programs, such as state programs, an array of options may be chosen corresponding to specific

Table 4-1. Information Summary on Organizational Factors, Impacts and Benefits: Template[1]

Risk Management Options	Feasibility			Efficacy		Nutrition	Cultural Impacts		Economic Impacts	Health Benefits	
	Staff	Funds	Reg. Auth.	Education	Risk Reduction		Traditional Activities	Diet		Non-Cancer	Cancer
No action											
Fish advisories											
General											
Quantitative											
Catch and release											
Voluntary											
Mandatory											
Fish ban											
Voluntary											
Mandatory											

[1] This template is for entry of information in any form which is useful to risk managers. This may be descriptive or quantal information, such as high, medium and low, or quantitative information such as number of staff required, costs of programs, etc. It is not anticipated that governing bodies will have detailed information on all categories included; however, this template may be used to organize the inforamtion which has been collected.

contamination characteristics, risk, targeted populations, and resources. It is assumed in this document that most decisions will involve the use of general or quantitative fish advisories in areas where contamination is known to exist at levels posing significant population risks. As discussed in Section 2, however, determining what level of risk is significant is an agency decision, and will affect the scope and nature of fish advisory programs.

The selection of appropriate fish advisory options is obviously a critical decision (as defined in Section 1) in program development. While this appears to be the most important decision, it usually will be based upon information gathered regarding individual or community risk levels and characteristics. This information, in turn is dependent on previous decisions regarding consumption rates, sampling and analysis, risk value selection, target population identification, evaluation of non-fish exposures, and consideration of impacts. These factors have been discussed in previous sections of this document and are summarized in Table 1-1. Because all previous decisions contribute to the basis for option selection and determination of protection levels, it is suggested that risk managers review these initial decisions prior to making the final decisions discussed in this chapter.

It is useful to evaluate whether previous decisions were health conservative or not; whether they took into account all or some of the population; whether they focused on average, high end, or bounding exposure and risk values; and other factors. Such information can be used when evaluating options and advisory levels to arrive at appropriate choices. If conservative assumptions were used in previous decisions, there may be less concern that compliance with advisories be strictly adhered to. Alternatively, if average values were used and sensitive populations were not targeted, non-compliance with advisories could have significantly greater adverse effects.

In selecting specific fish advisory options, risk managers may want to consider carefully which strategies are likely to be most effective for the populations which are to be served. This group is typically made up of several populations near various waterbodies and may require separate evaluation of each case. Information on the likelihood that a group will benefit from a particular approach can be inferred from the data collected on cultural, economic, and nutritional impacts. In addition, any other anecdotal or local information with a bearing on this type of decision should be considered. Such decisions are not necessarily based solely on objective data, and may require a familiarity with and sensitivity to the targeted population.

Practical considerations regarding sample quantitation limits are also relevant. Some contaminants may not be quantifiable at levels which are as low as those

indicated as optimal by health risk data. For example, quantifying the concentrations may not be possible at levels yielding a cancer risk of one in one million. This practical constraint may be important in establishing a realistic advisory. In some cases it may necessitate the acceptance of a higher level of risk than would be chosen based solely on health considerations. Flexibility in the program design will allow for modifications in advisories over time in keeping with more sensitive assays likely to be developed in the future.

Risk managers may elect to base option selection largely on risk. An example of this type of approach follows:

- A governing body could elect to take no action when cancer risks were less than one in one million and the concentrations were significantly less than the RfDs for non-carcinogens.

- General advisories could be developed when cancer risk levels were in the range of one in one hundred thousand to one in one million and the RfDs were not exceeded but were approached.

- Quantitative advisories could be developed for carcinogens with risk levels greater than one in ten thousand but less than one in one thousand and when the RfDs were exceeded by a factor of up to ten.

- Fishing bans and/or catch and release programs (either voluntary or involuntary) could be used when cancer risks exceeded on in one thousand and RfDs were exceeded by a factor greater than 10.

This tiered approach provides a spectrum of activities to deal with negligible to serious risks. This is only an example; risk managers may decide to structure their programs quite differently. Decisions should be made in the context of previous decisions and include considerations of whether previous decisions were sufficiently health conservative. As discussed throughout this document, decisions should also take into consideration the characteristics and needs of local affected communities.

The tiered approach is an overall strategy that may be applicable to all areas within a governing body's jurisdiction. It is risk-based and its application to specific waterbodies and populations requires risk information. Consequently, risk calculations may be carried out (see Supplement B in Volume II) requiring contamination data, consumption patterns, risk values, and body weight data. Table 4-2 provides a template that risk managers may use to organize

Table 4-2. Tiered Approach to Fish Advisories	
Risk Level	Option
Cancer	
Non-Cancer	
Other Considerations	

information for a tiered approach to risk reduction. Note that both cancer risk and non-cancer risk entry cells are provided. The advantages and disadvantages of selecting various values for the parameters used in this table are discussed throughout this text.

This approach is especially sensitive to decisions regarding consumption patterns and risk values. Contamination data are obtained through sampling and so not subject to alterations. Body weight data, while important, will usually not alter final results significantly. For example, the use of a 60 kg body weight for women will result in an "allowable" level of contamination which is only 15 percent lower than that for a 70 kg man. Approaches based on children's body weights may have a more substantial impact. Consumption patterns may vary widely within and among populations. The rate of 6.5 g per day is less than one tenth that observed in many studies of subsistence fishers, some of whom consume considerably more than 100 grams per day. For example, a recently completed study in the Great Lakes found that the average fisher consumed 360 grams per day (GLIFWC, 1994). Selecting a consumption rate is therefore a critical factor in establishing where fish advisories are needed and the nature of the advisory programs. It may be advisable to develop criteria based on different consumption rates for populations with widely varying consumption patterns.

Risk values are also a critical parameter in making decisions regarding advisory programs. Supplement B discusses the importance of selecting an appropriate health endpoint (e.g., developmental, systemic, non-carcinogenic) and its potentially significant impact on the level of contamination considered to pose unacceptable risks. As the discussions of individual chemical contaminants in Volume II demonstrate, many contaminants are associated with numerous different types of toxicity that may be exhibited at different levels of exposure. Recent developmental toxicity, neurotoxicity, or immunotoxicity data may indicate that risk occurs at lower levels of exposure than those indicated by previous liver and kidney toxicity studies. (The organ that is most sensitive will vary by chemical.) The use of the most sensitive endpoint will result in a more conservative approach to health protection.

Carcinogenic toxicity has in the past often yielded the most health-conservative exposure limits, especially when coupled with a low level of "acceptable" risk such as one in one million. Decision-makers may elect to choose a non-cancer health endpoint or a less stringent level of acceptable risk. For some chemicals there may be alternatives to choose from regarding risk endpoints and values varying by

orders of magnitude. The decisions will affect the scope and nature of a fish advisory program and the level of protection afforded the public substantially. Careful consideration of the advantages and disadvantages of the decisions regarding risk parameters is strongly encouraged.

Table 4-2 contains separate entry areas for other considerations that decision-makers may feel are important. These may include specific concerns regarding special sensitivities or types of effects that risk managers may feel justify an alternative approach. An example of this might be when new toxicity data become available. Under these circumstances, risk assessors may provide a new analysis that is used in developing fish advisories. An example is provided by mercury, which has been carefully evaluated by some states and subsequently stringent guidance was developed. Evidence of mercury toxicity is provided in human studies and causes serious effects in offspring of exposed women and exposed infants, as discussed in Volume II. These factors have led some risk managers to approach this chemical more aggressively than other contaminants. Risk managers may also elect to address other developmental toxins with greater conservatism due to concerns regarding exposures of pregnant women. Significant toxicity data gaps, the existence of known highly sensitive individuals in a population, or other predisposing factors such as poor nutritional status may lead risk managers to vary their options selections.

4.4. Levels of Protection

When fish advisories are considered necessary, risk managers will determine the level of protection in a fish advisory to be afforded targeted populations. Risk managers may choose from various risk values (e.g., RfDs and cancer potencies, locally generated values) to establish consumption limits. These values will result in consumption limits varying by orders of magnitude, especially when cancer-based and non-cancer-based values are compared. In addition, targeted "acceptable" risk levels are used in setting limits for carcinogens. Decisions regarding risk values can have a substantial impact on consumption limitation policies and on potential risks to the population.
This is discussed in some detail in Supplement B of Volume II.

The consumption limits, listed in Volume II, provide different levels of protection from carcinogenic risk, ranging from one in ten thousand to one in one million upper bound lifetime likelihood of cancer. Consumption limits corresponding to these different risk levels in risk multiples of 10 are provided; however, the methodology to calculate consumption limits for other risk levels is also described, and can be used when appropriate. Cancer risks are evaluated based upon an assumed

relationship between exposure and lifetime risk as defined in the cancer potency values for each target analyte. Risk managers determine what level of risk is acceptable (e.g., one in ten thousand, one in one million), which enables them to identify a particular exposure level as acceptable. The acceptable level of risk can be determined by the needs and goals of the target population, the decision-makers, other affected parties, or, under ideal circumstances, by joint discussions between the various impacted groups and agency staff.

Consumption limits based on non-carcinogenic effects typically use an RfD or other benchmark approach to determine a "safe" exposure level. The potential for non-carcinogenic effects can be evaluated by comparing exposures quantitatively to a Reference Dose (RfD) or some other benchmark of a "safe" exposure level (Supplement B in Volume II). Volume II provides the RfDs developed by EPA, along with a summary of toxicological information for the 23 target analytes. It also includes discussions of recent study results for most analytes regarding developmental, neurological and other types of toxicity. As discussed in Volume II, risk assessors may elect to use the EPA RfDs or review of the toxicological literature and develop their own exposure limits, based upon which values they consider most appropriate for their target populations. In some cases, more than one value may be selected for various subgroups of the population (e.g., children, women of reproductive age).

Table 4-3 provides a template to be used to list the selected values for contaminants in a particular waterbody, or which are of concern to a particular population. If a population fishes from more than one waterbody it may be advisable to include all chemical exposures in one evaluation so that similarly acting chemicals can be identified. The template includes entry areas for a variety of population subgroups and for various body weights of children. Risk managers may decide to refine their advisories to this level, or may determine that one general advisory is sufficient.

Consumption limits are provided in Volume II and offer various options from which to choose. Consumption limits for children are based on one body weight in Volume II; however, methods for calculating consumption limits for other body weights are also provided in that volume. Adult consumption limits are based on a 70 kilogram body weight for the general population and for women. Risk assessors and managers may determine that their female population of reproductive age has a different average body weight, or that a lower than average body weight should be used to provide a more health conservative values. Methods for calculating new consumption limits (or modifying the limits provided in the tables listed in Volume II) are also provided.

Table 4-3. Template for the Summary of Advisory Levels

Contaminant	General Advisory	Basis	Women's Advisory	Basis	Children's Advisory			Basis	Other	Basis
					Body Weight	Body Weight	Body Weight			

Decisions regarding the establishment of fish intake limit levels are at the discretion of the agency issuing fish advisories. The federal agencies, including EPA and FDA, who provide information and support in this area, do not have regulatory authority over non-commercial fish. Agencies are encouraged to establish limits which are most appropriate for their target populations in the context of local needs and characteristics.

4.5. Level of Program Effort and Funding

As discussed in Section 2, programs utilizing similar options (e.g. quantitative fish advisories) may differ substantially due to differing levels of effort and funding. Financial constraints may be moderate or severe, depending on the financial circumstances of the agency. These constraints affect the manner in which options can be implemented and may be a consideration in selection of an option as discussed in Section 2. The level of program effort and funding is a critical decision which is often beyond the scope of the risk manager. Risk managers may wish to maximize the available resources through cooperative activities with other agencies carrying out similar work, community groups with similar goals, or health or environmental organizations having similar interests (this is briefly discussed in Section 3).

Discussions of organizational structures and staffing for fish advisory programs are beyond the scope of this document. There are numerous public management guidebooks, however, providing information on effective and efficient management structures and program design that could maximize the effectiveness of a fish advisory program regardless of its size (Gawthrop,1984; Koteen, 1989; Bryson, 1988 and 1992; Frederickson, 1980; Vasu, 1990; Campbell, 1988; Gilbert, 1983; Association for Public Policy Analysis and Management, 1982; Carr, 1990). Readers are urged to consult these sources, as well as states and other groups that have set up fish advisory programs, to identify approaches that can be used to meet their goals using available resources.

A significant consideration in evaluating the type of fish advisory program that can be set up using a particular resource allocation is the overall population to be served. This population is typically made up of several sub-populations near various waterbodies, that may have different consumption patterns, risks, and likelihood of compliance with advisories. Within the constraints imposed by available resources, risk managers must determine which groups are in the greatest need of services and how those groups will best be served. Moderate services may be provided to a larger number of groups, or especially high-risk groups may be targeted for intensive efforts. The utilization of all types of information previously

discussed in this document may be helpful in determining the best approach to this type of resource allocation problem. Consultation with affected parties is also encouraged, because they may have strategies for accessing other resources to address program goals.

4.6. Program Evaluation and Modification

When a fish advisory program is being designed or modified, risk managers may want to consider inclusion of a component that involves program evaluation and modification. These activities are often not considered in the initial planning of a program, but an efficacy review in a program can help managers determine how effective it is (who it is reaching, whether their behavior has changed, whether the target population wants additional information, etc) and how the program might be altered to better address its goals. This type of activity can be carried out informally through contacting local participants and members of the targeted population routinely, or may be more formally designed to sample effectiveness randomly through surveys or some other means.

Incorporating flexibility into fish advisory programs is important so that necessary modifications can be made both in the initial design and over time as needs change. The decision to include these elements in a program design is one the risk managers should consider carefully to provide for the long-range success of a fish advisory program. The decision to include these components in a fish advisory program is considered critical because it may have a substantial impact on a program's long-term success.

4.7. Summary

This section has provided methods for organizing and considering information regarding risk, organizational issues, and impacts of fish advisory options. Risk managers and others involved in the decision-making process may need to utilize information from a variety of sources to gain an overall sense of who needs to be served by fish advisory programs and how to best design a program. As with any public undertaking, all problems and issues cannot be anticipated. Consequently, program flexibility is necessary to ensure long-term effectiveness. By broadly considering the characteristics of the target populations, however, risk managers will be better able to design programs appropriately (this is also addressed in

Volume IV: Risk Communication). When decisions are made and programs are designed with participation from representatives of targeted populations, valuable insights into the community are gained and the opportunities for a successful program are increased.

The Agency recognizes that there is much valuable information that can be obtained through the experiences of people in the field who are working on the development of fish advisory programs. EPA welcomes contributions from these people. Future versions of this document will benefit from information which readers submit.