SECTION 2

MONITORING STRATEGY

The objective of this section is to describe the strategy recommended by the EPA Office of Water for use by states in their fish and shellfish contaminant monitoring programs. A two-tiered strategy is recommended as the most cost-effective approach for State contaminant monitoring programs to obtain data necessary to evaluate the need to issue fish or shellfish consumption advisories. This monitoring strategy is shown schematically in Figure 2-1 and consists of

- **Tier 1—Screening studies** of a large number of sites for chemical contamination where sport, subsistence, and/or commercial fishing is conducted. This screening will help states identify those sites where concentrations of chemical contaminants in edible portions of commonly consumed fish and shellfish indicate the potential for significant health risks to human consumers.

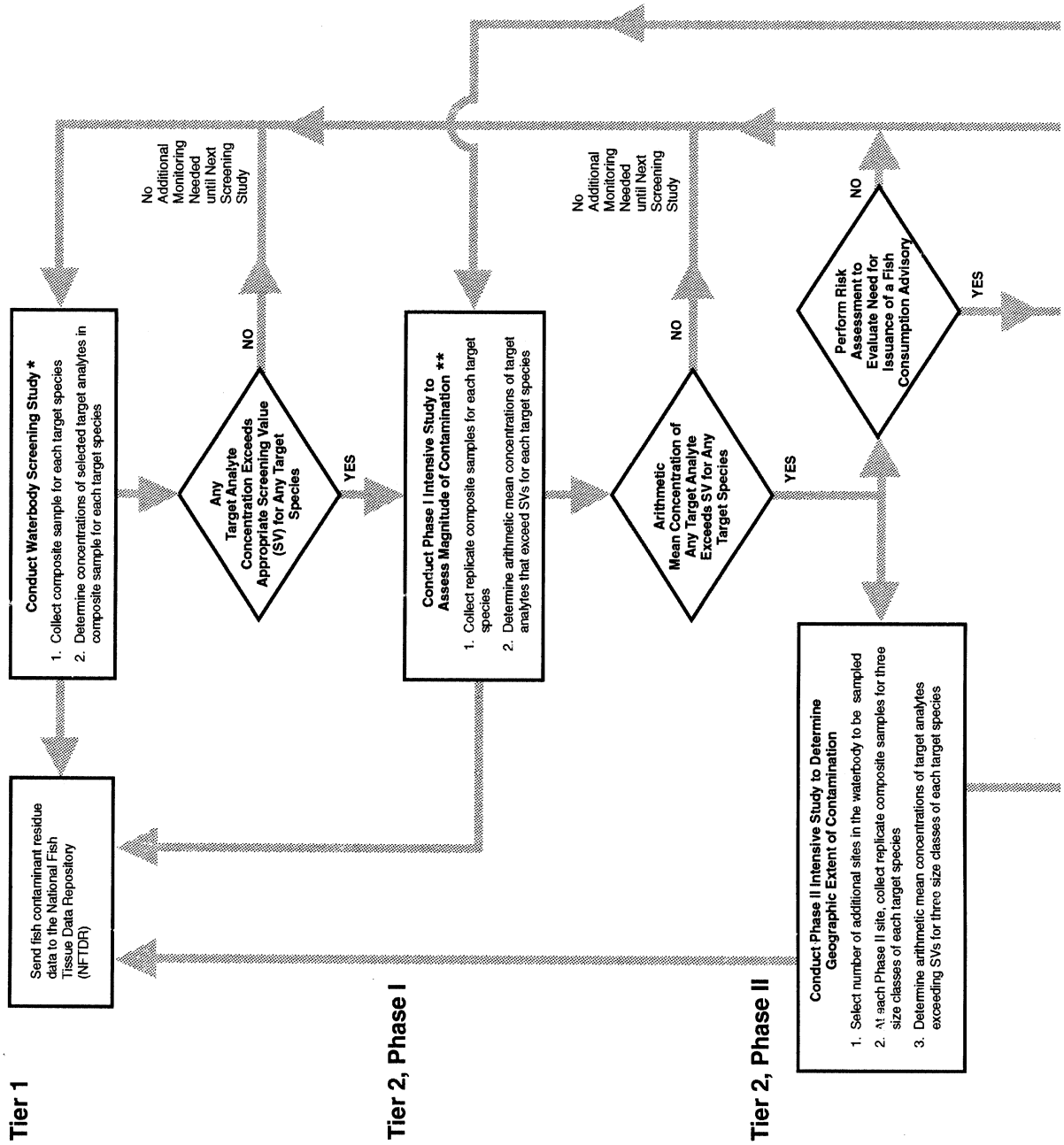
- **Tier 2—Two-phase intensive studies** of problem areas identified in screening studies to determine the magnitude of contamination in edible portions of commonly consumed fish and shellfish species (**Phase I**), to determine size-specific levels of contamination, and to assess the geographic extent of the contamination (**Phase II**).

One key objective in the recommendation of this approach is to improve the data used by states for issuing fish and shellfish consumption advisories. Other specific aims of the recommended strategy are

- To ensure that resources for fish contaminant monitoring programs are allocated in the most cost-effective way. By limiting the number of sites targeted for intensive studies, as well as the number of target analytes at each intensive sampling site, screening studies help to reduce overall program costs while still allowing public health protection objectives to be met.

- To ensure that sampling data are appropriate for developing risk-based consumption advisories.

- To ensure that sampling data are appropriate for determining contaminant concentrations in various size (age) classes of each target species so that states can give size-specific advice on contaminant concentrations (as appropriate).


Tier 1
Tier 2, Phase I
Tier 2, Phase II
Conduct Waterbody Screening Study *
1. Collect composite sample for each target species
2. Determine concentrations of selected target analytes in composite sample for each target species
Any Target Analyte Concentration Exceeds Appropriate Screening Value (SV) for Any Target Species
NO
YES
No Additional Monitoring Needed until Next Screening Study
Conduct Phase I Intensive Study to Assess Magnitude of Contamination **
1. Collect replicate composite samples for each target species
2. Determine arithmetic mean concentrations of target analytes that exceed SVs for each target species
Arithmetic Mean Concentration of Any Target Analyte Exceeds SV for Any Target Species
NO
YES
No Additional Monitoring Needed until Next Screening Study
Perform Risk Assessment to Evaluate Need for Issuance of a Fish Consumption Advisory
NO
YES
Send fish contaminant residue data to the National Fish Tissue Data Repository (NFTDR)
Conduct Phase II Intensive Study to Determine Geographic Extent of Contamination
1. Select number of additional sites in the waterbody to be sampled
2. At each Phase II site, collect replicate composite samples for three size classes of each target species
3. Determine arithmetic mean concentrations of target analytes exceeding SVs for three size classes of each target species

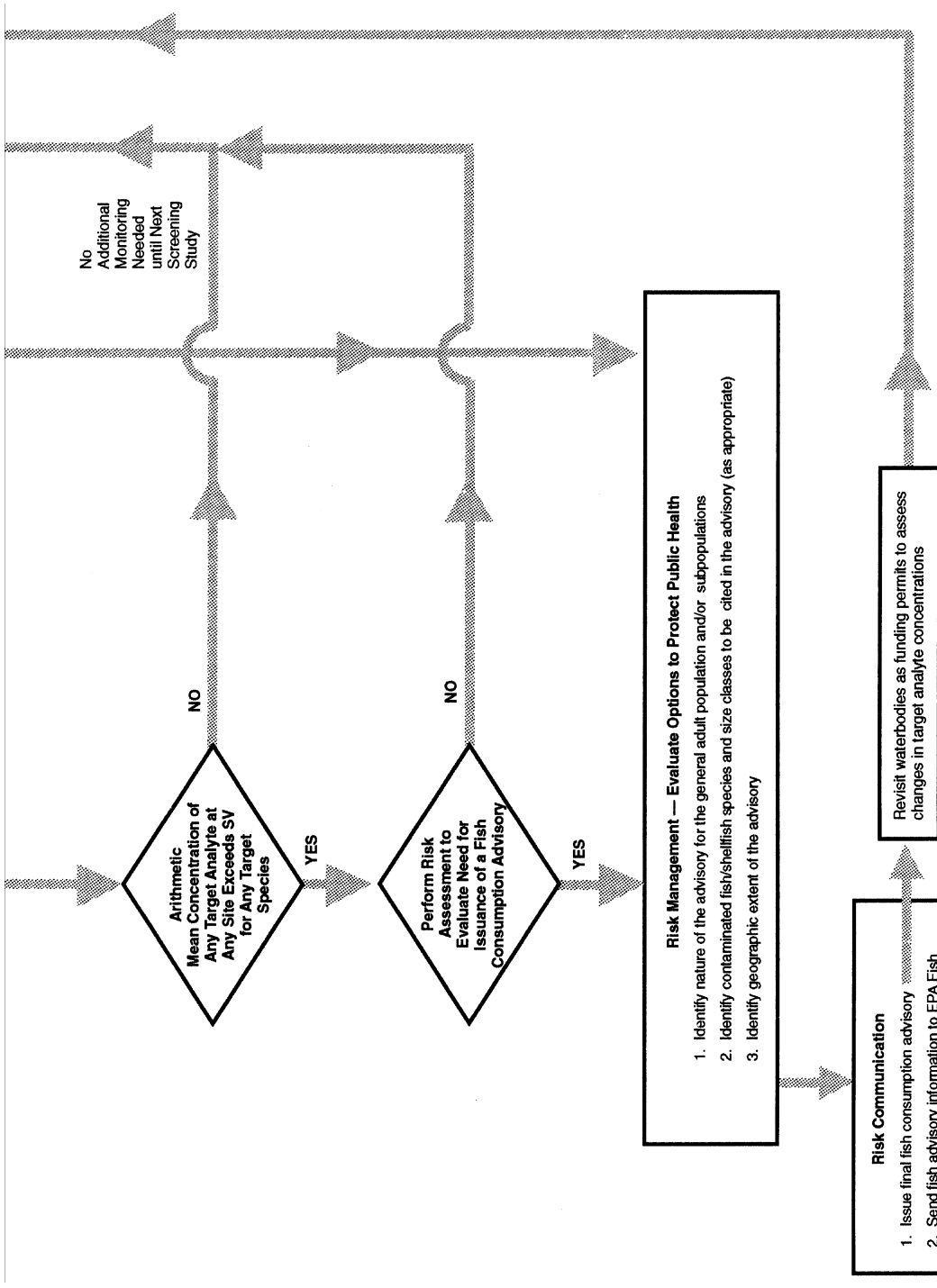


Figure 2-1. Recommended strategy for state fish and shellfish contaminant monitoring programs.

- To ensure that sampling designs are appropriate to allow statistical hypothesis testing. Such sampling designs permit the use of statistical tests to detect a difference between the average tissue contaminant concentration at a site and the human health screening value for any analyte.

The following elements must be considered when planning either screening studies or more intensive followup sampling studies:

- Study objective
- Target species (and size classes)
- Target analytes
- Target analyte screening values
- Sampling locations
- Sampling times
- Sample type
- Sample replicates
- Sample analysis
- Data analysis and reporting.

Detailed guidance for each of these elements, for screening studies (**Tier 1**) and for both Phase I and Phase II of intensive studies (**Tier 2**), is provided in this document. The key elements of the monitoring strategy are summarized in Table 2-1, with reference to the section number of this document where each element is discussed.

2.1 SCREENING STUDIES (TIER 1)

The primary aim of screening studies is to identify frequently fished sites where concentrations of chemical contaminants in edible fish and shellfish composite samples exceed specified human health screening values and thus require more intensive followup sampling. Ideally, screening studies should include all water-bodies where commercial, recreational, or subsistence fishing is practiced; specific sampling sites should include areas where various types of fishing are conducted routinely (e.g., from a pier, from shore, or from private and commercial boats), thereby exposing a significant number of individuals to potentially adverse health effects. Composites of skin-on fillets (except for catfish and other scaleless species, which are usually prepared as skin-off fillets) and edible portions of shellfish are recommended for contaminant analyses in screening studies to provide conservative estimates of typical exposures for the general population. If consumers remove the skin and fatty areas from a fish before preparing it for eating, exposures to some contaminants can be reduced (see U.S. EPA, 2000a, Appendix C of Volume 2 of this guidance document series).

Note: If the target population of consumers includes primarily ethnic or subsistence fishers who consume the whole fish or tissues of the fish not typically consumed by the general population, state monitoring programs should include the fish sample type associated with the target consumers' dietary and/or culinary preference (see Section 6.1.1.6, Sample Type, for additional information.)

Table 2-1. Recommended Strategy for State Fish and Shellfish Contaminant Monitoring Programs

Program element	Tier 1 Screening study	Tier 2 Intensive study (Phase I)	Tier 2 Intensive study (Phase II)
Objective (see Section 2)	Identify frequently fished sites where commonly consumed fish and shellfish target species are contaminated and may pose potential human health risk.	Assess and verify magnitude of tissue contamination at screening site for commonly consumed target species.	Assess geographic extent of contamination in selected size classes of commonly consumed target species.
Target species and size classes (see Sections 3 and 6)	Select target species from commonly consumed species using the following additional criteria: known to bioaccumulate high concentrations of contaminants and distributed over a wide geographic area. Recommended types of target species: Inland fresh waters: 1 bottom-feeder, 1 predator Great Lakes: 1 bottom-feeder, 1 predator Estuarine/ marine: 1 shellfish and 1 fish species, or 2 fish species (one species should be bottom-feeder).	Resample target species at sites where they were found to be contaminated in screening study.	Resample at additional sites in the waterbody 3 size classes of the target species found to be contaminated in Phase I study.
	OPTIONAL: If resources are limited and a state cannot conduct Tier 2 intensive studies, the state may find it more cost-effective to collect additional samples during the Tier 1 screening study. States **may** collect (1) one composite sample of each of three size classes for each target species, (2) replicate composite samples for each target species, or (3) replicate composite samples of each of three size classes for each target species.	OPTIONAL: If resources are limited and a state cannot conduct Tier 2, Phase II, intensive studies, the state may find it more cost-effective to collect additional samples during the Tier 2, Phase I, intensive study. States **may** collect replicate composite samples of three size classes of the target species found to be contaminated to assess size-specific contaminant concentrations. Other commonly consumed target species may also be sampled if resources allow.	OPTIONAL: If resources allow, select additional commonly consumed target species using same criteria as in Phase I study.

See notes at end of table.

(continued)

Table 2-1. (continued)

Program element	Tier 1 Screening study	Tier 2 Intensive study (Phase I)	Tier 2 Intensive study (Phase II)
Target analytes (see Section 4)	Consider all target analytes listed in Table 4-1 for analysis but prioritize the 25 target analytes based on water and sediment sampling results, land use within the watershed, geographic characteristics, regional and national advisory trends and analytical costs. Include additional site-specific target analytes as appropriate based on current or historic data.	Analyze only for those target analytes from Tier 1 screening study that exceeded SVs.	Analyze only for those target analytes from Tier 2, Phase I, study that exceeded SVs.
Screening values (see Section 5)	Calculate SVs using oral RfDs for noncarcinogens and using oral slope factors and an appropriate risk level (10^{-4} to 10^{-7}) for carcinogens, for adults consuming 17.5 g/d and 142.4 g/d of fish and shellfish (default values) or based on site-specific dietary data. **Note:** In this guidance document, EPA's Office of Water used 17.5 g/d (for recreational fishers) and 142.4 g/d (for subsistence fishers) consumption rates, 70-kg adult body weight, and, for carcinogens, used a 10^{-5} risk level, 70-year exposure, and assumed no loss of contaminants during preparation or cooking. States may use other SVs for site-specific exposure scenarios by adjusting values for consumption rate, body weight, risk level, exposure period, and contaminant loss during preparation or cooking.	Use same SVs as in screening study.	Use same SVs as in screening study.
Sampling sites (see Section 6)	Sample target species at sites in each harvest area that have a high probability of contamination and at presumed clean sites or given areas as resources allow (see Appendix A).	Sample target species at each site identified in the screening study where fish/shellfish tissue concentrations exceed SVs to assess the magnitude of contamination.	Sample at additional sites in the harvest area 3 size classes of the target species found to be contaminated in Phase I study to assess the geographic extent of the contamination in the waterbody.

See notes at end of table.

(continued)

Table 2-1. (continued)

Program element	Tier 1 Screening study	Tier 2 Intensive study (Phase I)	Tier 2 Intensive study (Phase II)
Sampling times (see Section 6)	Sample during legal harvest season when target species are most available to consumers. Ideally, sampling time should not include the spawning period for target species unless the target species can be legally harvested during this period.	Same as screening study.	Same as screening study.
Sample type (see Sections 6 and 7)	Collect composite fillet samples (skin on, belly flap included) for each target fish species and composite samples of edible portions of target shellfish species. The exceptions to the "skin on, belly flap included" recommendation is to use skin-off fillets for catfish and other scaleless species.	Same as screening study.	Same as screening study but collect composite samples for three size classes of each target species as appropriate.
	OPTIONAL: States **may** use individual fish samples, whole fish, or other sample types, if necessary, to improve exposure estimates of local fish-, shellfish-, or turtle-consuming populations. Sample type should reflect dietary and fish preparation methods of the target population of concern.	Same as screening study.	Same as screening study.
Sample replicates (see Section 6)	Collect one composite sample for each target species. **Collection of replicate composite samples is encouraged but is optional**. If resources allow, collect a minimum of one replicate composite sample for each target species at 10% of the screening sites for QC.	Collect replicate composites for each target species at each Phase I site.	Collect replicate composites of three size classes for each target species at each Phase II site.
Sample analysis (see Section 8)	Use standardized and quantitative analytical methods with limits of detection adequate to allow reliable quantitation of selected target analytes at or below SVs.	Use same analytical methods as in screening study.	Use same analytical methods as in screening study.

See notes at end of table.

(continued)

Table 2-1. (continued)

Program element	Tier 1 Screening study	Tier 2 Intensive study (Phase I)	Tier 2 Intensive study (Phase II)
Data analysis and reporting (see Sections 6, 7, 8, and 9)	For each target species, compare target analyte concentrations of composite sample with SVs to determine which sites require Tier 2, Phase I, intensive study.	For each target species, compare target analyte arithmetic mean concentrations of replicate composite samples with SVs to determine which sites require Phase II intensive study. If resources are insufficient to conduct Phase II intensive study, conduct a risk assessment and assess the need for issuing a preliminary fish or shellfish consumption advisory.	For each of three size classes within each target species, compare target analyte arithmetic mean concentrations of replicate composite samples at each Phase II site with SVs to determine geographic extent of fish or shellfish contamination. Assess the need for issuing a final fish or shellfish consumption advisory.
Data analysis and reporting (see Sections 6, 7, 8, and 9) (continued)	The following information should be reported for each target species at each site:	The following information should be reported for each target species at each site:	The following information should be reported for each of three size classes within each target species at each site:
	• Site location (e.g., sample site name, water-body name, type of waterbody, and latitude/longitude)	• Same as screening study.	• Same as screening study.
	• Scientific and common name of target species	• Same as screening study	• Same as screening study
	• Sampling date and time	• Same as screening study	• Same as screening study
	• Sampling gear type used	• Same as screening study	• Same as screening study
	• Sampling depth	• Sampling depth	• Sampling depth
	• Number of QC replicates (optional)	• Number of replicates	• Same as Phase I study
	• Number of individual organisms used in the composite sample and in the QC replicate composite sample if applicable	• Number of individual organisms used in each replicate composite sample	• Same as Phase I study

See notes at end of table.

(continued)

Table 2-1. (continued)

Program element	Tier 1 Screening study	Tier 2 Intensive study (Phase I)	Tier 2 Intensive study (Phase II)
	• Predominant characteristics of specimens used in the composite sample and in the QC replicate if applicable (e.g., life stage, age, sex, total length or body size) and description of fish fillet or edible parts of shellfish (tissue type) used	• Predominant characteristics of specimens used in each replicate composite sample (e.g., life stage, age, sex, total length or body size) and description of fish fillet or edible parts of shellfish (tissue type) used	• Same as Phase I study
	• Analytical methods used (including a method for lipid analysis) and method detection and quantitation limits for each target analyte.	• Same as screening study	• Same as screening study
Data analysis and reporting (see Sections 6, 7, 8, and 9) (continued)	• Sample cleanup procedures	• Same as screening study.	• Same as screening study.
	• Data qualifiers	• Same as screening study.	• Same as screening study.
	• Percent lipid in each composite sample.	• Same as screening study.	• Same as screening study.
	• For each target analyte:	• For each target analyte:	• For each target analyte:
	– Total wet weight of composite sample (g) used in analysis	– Total wet weight of each replicate composite sample (g) used in analysis	– Same as Phase I study
	– Measured concentration (wet weight) in composite sample including units of measurement for target analyte	– Measured concentration (wet weight) in each replicate composite sample and units of measurement for target analyte	– Same as Phase I study
	– Measured concentration (wet weight) in the QC replicate, if applicable	– Range of concentrations (wet weight) for each set of replicate composite samples	– Same as Phase I study
		– Mean (arithmetic) concentration (wet weight) for each set of replicate composite samples	– Same as Phase I study
		– Standard deviation of mean concentration (wet weight)	– Same as Phase I study

See notes at end of table.

(continued)

Table 2-1. (continued)

Program element	Tier 1 Screening study	Tier 2 Intensive study (Phase I)	Tier 2 Intensive study (Phase II)
	– Evaluation of laboratory performance (i.e., description of all QA and QC samples associated with the sample(s) and results of all QA and QC analyses)	– Same as screening study	– Same as screening study
	– Comparison of measured concentration of composite sample with SV and clear indication of whether SV was exceeded	– Comparison of target analyte arithmetic mean concentration of replicate composite samples with SV using hypothesis testing and clear indication of whether the SV was exceeded	– Same as Phase I study

QA = Quality assurance.
QC = Quality control.
RfDs = Reference doses.
SVs = Screening values.

Because the sampling sites in screening studies are focused primarily on the most likely problem areas and the numbers of commonly consumed target species and samples collected are limited, relatively little detailed information is obtained on the magnitude and geographic extent of contamination in a wide variety of harvestable fish and shellfish species of concern to consumers. More information is obtained through additional intensive followup studies (**Tier 2, Phases I and II**) conducted at potentially contaminated sites identified in screening studies.

Although the EPA Office of Water recommends that screening study results not be used as the sole basis for conducting a risk assessment, EPA recognizes that this practice may be unavoidable if monitoring resources are limited or if the state must issue an advisory based on detection of elevated concentrations in one composite sample. States have several options for collecting samples during the **Tier 1** screening study (see Figure 2-1), which can provide additional information on contamination without necessitating additional field monitoring expenditures as part of the **Tier 2** intensive studies.

The following assumptions are made in this guidance document for sampling fish and shellfish and for calculating human health SVs for recreational and subsistence fishers:

- Use of commonly consumed target species that are dominant in the catch and have high bioaccumulation potential (see Section 3, Target Species)

- Use of fish fillets (with skin on and belly flap tissue included) for scaled finfish species, use of skinless fillets for scaleless finfish species, and use of edible portions of shellfish (see Section 6.1.1.6, Sample Type)

- Use of fish and shellfish above legal size to maximum size in the target species

- Use of a 10^{-5} risk level, a human body weight of 70 kg (average adult), a consumption rate of 17.5 g/d for recreational fishers and 142.4 g/d for subsistence fishers, and a 70-yr lifetime exposure period to calculate SVs for carcinogens.

- Use of a human body weight of 70 kg (average adult) and a consumption rate of 17.5 g/d for recreational fishers and 142.4 g/d for subsistence fishers to calculate SVs for noncarcinogens (see Section 5, Screening Values for Target Analytes).

- Use of no contaminant loss during preparation and cooking or from incomplete absorption in the intestines.

For certain site-specific situations, states may wish to use one or more of the following exposure assumptions to protect the health of high-end fish consumers such as subsistence fishers at potentially greater risk:

- Use of commonly consumed target species that are dominant in the catch and have the highest bioaccumulation potential

- Use of whole fish or whole body of shellfish (excluding shell of bivalves), which may provide a better estimate of contaminant exposures in ethnic or Native American subsistence populations that consume whole fish or shellfish

- Use of the largest (oldest) individuals in the target species to represent the highest likely exposure levels

- Use of a 10^{-6} or 10^{-7} risk level, body weights less than 70 kg for women and children, site-specific consumption rates for sport fishers or for subsistence fishers or other consumption rates based on dietary studies of local fish-consuming populations, and a 70-yr exposure period to calculate SVs for carcinogens. **Note:** EPA has reviewed national data on the consumption rate for sport and subsistence fishers and the recommended default values for these populations are 17.5 and 142.4 g/d, respectively (USDA/ARS, 1998; U.S. EPA, 2000c).

- Use of body weights less than 70 kg for women and children and site-specific consumption rates for sport fishers or for subsistence fishers or other consumption rates based on dietary studies of local fish-consuming populations to calculate SVs for noncarcinogens. **Note:** EPA has reviewed national data on the consumption rate for sport and subsistence fishers and the recommended default values for these populations are 17.5 and 142.4 g/d, respectively (USDA/ARS, 1998; U.S. EPA, 2000c).

There are additional aspects of the screening study design that states should review because they affect the statistical analysis and interpretation of the data. These include

- Use of composite samples, which results in loss of information on the distribution of contaminant concentrations in the individual sampled fish and shellfish. Maximum contaminant concentrations in individual sampled fish, which can be used as an indicator of potentially harmful levels of contamination (U.S. EPA, 1989d), are not available when composite sampling is used.

- Use of a single sample per screening site for each target species, which precludes estimating the variability of the contamination level at that site and, consequently, of conducting valid statistical comparisons to the target analyte SVs.

- Uncertainty factors affecting the numerical calculation of quantitative health risk information (i.e., references doses and cancer slope factors) as well as human health SVs.

The use of composite samples is often the most cost-effective method for estimating average tissue concentrations of analytes in target species populations to assess chronic human health risks. However, there are some situations in which individual sampling can be more appropriate from both ecological and risk assessment perspectives. Individual sampling provides a direct measure of the range and variability of contaminant levels in target fish populations. Information on maximum contaminant concentrations in individual fish is useful in evaluating acute human health risks. Estimates of the variability of contaminant levels among individual fish can be used to ensure that studies meet desired statistical objectives. For example, the population variance of a contaminant can be used to estimate the sample size needed to detect statistically significant differences in contaminant screening values compared to the mean contaminant concentration. Finally, the analysis of individual samples may be desirable, or necessary, when the objective is to minimize the impacts of sampling on certain vulnerable target populations, such as predators in headwater streams and aquatic turtles, and in cases where the cost of collecting enough individuals for a composite sample is excessive. For states that wish to consider use of individual sampling during either the screening or intensive studies, additional information on collecting and analyzing individual samples is provided in Appendix C. States should consider the potential effects of these study design features when evaluating screening study results.

Note: As part of screening studies, states may wish to issue information not only on restricting or avoiding consumption of certain species from certain waterbodies, but on promoting unrestricted fish consumption in those waterbodies where the levels of contamination are below the SVs for all 25 of the target analytes. Waterbodies in which target analyte concentrations (see Section 5) are below the selected target analyte SVs are known as “green areas” where states can promote fish consumption to specified fisher populations. Guidance to assist states in designating these safe or green areas is provided in detail in Appendix B.

2.2 INTENSIVE STUDIES (TIER 2)

The primary aims of intensive studies are to assess the magnitude of tissue contamination at screening sites, to determine the size class or classes of fish within a target species whose contaminant concentrations exceed the SVs, and to assess the geographic extent of the contamination for the target species in the waterbody under investigation. With respect to the design of intensive studies, EPA recommends a sampling strategy that may not be feasible for some site-specific environments. Specifically, EPA recognizes that some waterbodies cannot sustain the same intensity of sampling (i.e., number of replicate composite samples per site and number of individuals per composite sample) that others (i.e., those used for commercial harvesting) can sustain. In such cases, state fisheries personnel may consider modifying the sampling strategy (e.g., analyzing individual fish) for intensive studies to protect the fishery resource. Although one strategy cannot cover all situations, these sampling guidelines are reasonable for the majority of environmental conditions, are scientifically defensible, and provide

information that can be used to assess the risk to public health. Regardless of the final study design and protocol chosen for a fish contaminant monitoring program, state fisheries, environmental, and health personnel should always evaluate and document the procedures used to ensure that results obtained meet state objectives for protecting human health.

The allocation of limited funds to screening studies or to intensive studies should always be guided by the goal of conducting adequate sampling of state fish and shellfish resources to ensure the protection of public health. The amount of sampling that can be performed by a state will be determined by available economic resources. Ideally, state agencies will allocate funds for screening as many sites as is deemed necessary while reserving adequate resources to conduct subsequent intensive studies at sites where excessive fish tissue contamination is detected. State environmental and health personnel should use all information collected in both screening and intensive studies to (1) conduct a risk assessment to determine whether the issuance of an advisory is warranted, (2) use risk management to determine the nature and extent of the advisory, and then (3) effectively communicate this risk to the fish-consuming public. Additional information on risk assessment, risk management, and risk communication procedures will be provided in subsequent volumes in this series.