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Development of Management Strategies for Contaminated Fish and Shellfish in New Jersey

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Division of Science and Research

DEVELOPMENT OF MANAGEMENT STRATEGIES FOR CONTAMINATED FISH AND SHELLFISH IN NEW JERSEY

Final Report

by

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Introduction

Contamination of seafood (fish and shellfish of both marine and fresh water origin) with toxic substances has been a critical and widespread environmental, economic and human health problem in New Jersey and throughout the U.S. The National Academy of Sciences-Institute of Medicine study on seafood safety concludes that most seafood available in the U.S. is wholesome and unlikely to cause illness (IOM 1991). However, the report states that one-fifth of the fish and shellfish eaten in the U.S. is derived from recreational or subsistence fishing, and these products are not subject to health-based control. Further, the report rates the risk of consumption of chemically contaminated finfish and shellfish as high for "recreational fishers in certain areas, pregnant women, and children." Risk is enhanced for subsistence fish consumers and for recreational anglers in areas of high contamination. The report calls for corrective measures for chemically contaminated fish and shellfish that include reductions in discharges of chemicals that cause contamination, harvest restrictions by site and species, improved risk assessment for cancer and non-cancer endpoints, and improved consumption advisories for contaminated sport fish.

This goal of this project is the development of recommendations, directed to the State of New Jersey, on how the State should utilize monitoring data to issue consumption advisories and to take future regulatory actions for contaminated fish and shellfish. The project objectives are: 1) To review and evaluate selected Federal, State, and other programs designed to regulate or manage fish and shellfish contamination and that

issue consumption advice for sport-caught fish based on contaminant monitoring programs, and; 2) To develop a structure for a scientifically supportable procedure to interpret the results of monitoring programs to make risk management decisions.

Methods

Censuses of all states in the U.S. (RTI 1990) and of thirty coastal and Great Lakes states (NOAA 1990) were conducted to examine programs that address consumption advisories for fish and shellfish. Sample collection, analysis, and data interpretation techniques used by states were examined as part of these surveys. The results are useful in assessing the number of fish consumption advisories, the species for which they are issued, and in assessing how advisories are developed and used in the United States.

Most states in the U.S., as well as the Province of Ontario, Canada, develop and issue consumption advisories for contaminated fish or shellfish. A variety of methods are used to develop consumption advisories, including application of U.S. FDA and EPA action levels, use of quantitative risk assessment procedures, and combinations of each method. Sixty eight percent of states in the U.S. frequently use FDA action levels to derive levels of concern for contaminants while twenty percent derive a level of concern from risk assessment procedures using U.S. EPA's cancer potency factor or reference dose (RTI 1990, NOAA 1990). Many states also use combinations of FDA action levels and risk assessment procedures to derive consumption advisories. Twenty-two states analyze more than 100 fish/shellfish tissue samples annually while nineteen states analyze between 25 and 100 samples.

(RTI 1990). Further, five states (California, Wisconsin, Michigan, Illinois, and Missouri) survey more than fifty water bodies annually for fish and shellfish contamination while eight states (Minnesota, Wisconsin, New York, Florida, Michigan, California, Missouri, and Pennsylvania) issue consumption advisories for more than ten water bodies.

Several jurisdictions were chosen for detailed analysis of their monitoring, data interpretation, and advisory development procedures. These jurisdictions utilize a variety of methods to collect, analyze, interpret, and manage fish tissue contaminant data. Included in the analysis are procedures utilized by Ontario, California, Delaware, Illinois, Maryland, Michigan, Missouri, Minnesota, New York, Pennsylvania, and Wisconsin.

Four major methodologic proposals for development of fish consumption advisories, presented since the mid 1980s, were examined (Clark et al. 1987, National Wildlife Federation 1989, Dourson and Clark 1990, U.S. EPA 1989). Each of these proposals are based on the application of quantitative risk assessment proced[illegible]. Other factors critical for the development of consumption advisories were examined also. These include the potential reduction of tissue contaminant levels through preparation and cooking techniques, sampling protocols for contaminated sport fish, and quality assurance/quality control procedures for sampling and analysis of contaminated sport fish tissues.

Recommendations

General Procedures

Despite the widespread use of FDA action levels to trigger consumption advice, both the U.S. EPA and the U.S. FDA recommend against the use of action levels to develop advice for local or regional fish and shellfish contamination problems. In place of the tolerance/action level-based approach, a more scientifically justifiable approach is recommended which is based on quantitative risk assessment procedures to trigger consumption advice as well as to make regulatory decisions associated with contaminated fish and shellfish.

A risk-based approach to advisory development and regulatory programs for contaminated fish and shellfish is recommended for the State of New Jersey. This recommendation is made for several reasons: First, it is technically and scientifically better justified than an action level approach; it will more adequately protect human health, and; the approach is receiving increasing acceptance in many state advisory programs.

A risk-based approach in its simplest form would follow U.S. EPA guidelines for quantitative risk assessment. State agencies with substantial resources available for chemical hazard assessment may prefer to conduct four-step risk assessments (hazard evaluation, dose-response evaluation, exposure evaluation, and risk characterization) for each contaminant in fish and shellfish. Such assessments would then serve as the basis for consumption advisories and regulatory actions. An alternative to this approach is reliance on U.S. EPA established potency derivations for common contaminants in fish and shellfish. The U.S. EPA has established potency (slope) factors

for common carcinogens and estimates of allowable daily intakes (reference doses) for common systemic toxicants (non-carcinogens). The values are available through U.S. EPA's computerized Integrated Risk Information System (IRIS), which may be accessed via the National Library of Medicine's TOXNET database.

Some limitations apply to potency estimates for chemicals available through IRIS, the most important of which is that some of these values do not reflect recent advances in toxicologic knowledge. For example, a reference dose for PCBs available through IRIS does not reflect recent data derived from epidemiologic studies that address the developmental effects associated with PCB exposure. However, use of EPA derived potency or reference values available through IRIS, combined with incorporation of very recent toxicologic information, should provide an adequate basis for justifiable and protective trigger levels for contaminants in fish and shellfish.

Use of the slope or potency factor to issue consumption advisories for fish and shellfish contaminated with one or more carcinogens requires several assumptions. First, a state must choose one or more acceptable cancer risk levels around which advice will be generated. As no single risk level is considered the most appropriate, it is recommended that New Jersey choose a cancer risk level within the range of 10^{-4} to 10^{-6} to generate consumption advice for contaminated fish and shellfish. It is recommended further that advice be generated for only one risk level rather than offering different advice associated with different risk levels and allowing the consumer to choose which risk level and associated advice is appropriate.

Advice based on acceptable risk levels should be accompanied by information showing comparable risks for other activities. Comparable risk information should only be derived for similar activities (e.g. from consumption of other contaminated or non-contaminated foods), not from activities where risk estimates have been derived with different methods (e.g. risks associated with automobile accidents derived from actuarial data).

A choice of meal size is also necessary to develop risk-based advice for contaminated fish and shellfish (for both carcinogens and systemic toxicants). Common meal sizes range from 113 grams to 227 grams (one quarter to one half pound). Information on meal frequency is not necessary since it is recommended that consumption advice be issued on a meal frequency basis. Finally, assumptions regarding the standard individual to be protected (size and exposure period/life span) must be articulated. The standard assumptions for human weight and exposure period/life span are 70 kg and seventy years respectively. Other choices for standard weight and exposure periods may be appropriate, for example where children may be highly exposed.

Advice should be generated to restrict consumption of contaminated fish and shellfish to limit contaminant intake (exposure) to levels that do not pose unacceptable cancer risks or exceed the appropriate reference dose. Such advice should be issued on a meal-per-week or meal-per-month basis. For example, advice should state that consumers should restrict consumption of species X to no more than once per week (or month). Further refinement of consumption advice (e.g. consume no more than two

meals per week or 3.5 meals per month) is likely to result in overly complex advice which is subsequently ignored by the consumer, and is not recommended.

Quantitative Procedures

Advice for consumption frequency and regulatory decisions for contaminated fish and shellfish should be determined as follows for individual carcinogens:

$$\text{Fish intake (kg/day)} = \frac{\text{RAI (mg/kg/day) X 70 kg}}{\text{TC (mg/kg)}} \quad \text{(Eq. 7)},$$

where RAI = Risk Associated Intake, defined as the intake in kg/day that would not result in exceedence of the acceptable cancer risk level for individual contaminants, and TC = fish tissue concentration. The RAI is calculated as:

$$\text{RAI} = 1/q_1^* \text{ X ARL} \quad \text{(Eq. 8)},$$

where ARL = Acceptable Risk Level (e.g. $1 \text{ X } 10^{-5}$). The fish intake rate can then be converted to a meal frequency (no. meals per week or month) based on a determination of average meal size following Dourson and Clark (1990). It is recommended that consumption advisories be based on the meal frequency derived from the fish intake rate. For example, if the fish intake rate calculated from Equation 7 is 1 g/day, the corresponding meal frequency is much less than one meal per month (for either 1/4 or 1/2 pound meal sizes). Thus, consumption advice for this species should be "do-not-eat." Further, where the calculated consumption rate is less than one meal per month, regulatory

decisions to ban or prohibit the sale or distribution of contaminated fish or shellfish may be appropriate.

A similar procedure is recommended to derive consumption advisories and to take regulatory actions for fish and shellfish contaminated with systemic toxicants (non-carcinogens). Equation 3 (see text), based on the reference dose for individual toxicants should be used to determine the fish intake rate. Meal frequencies would then be determined as described above.

The approaches to advisory development recommended here are similar to the approaches utilized by Minnesota and proposed for utilization by scientists in the Great Lakes basin. The approach is simplified only in that it utilizes a single tissue contaminant level instead of a range of levels as utilized by Minnesota.

Since the tissues of many fish species will contain combinations of two or more contaminants, it is recommended that consumption advice and regulatory actions for contaminated fish and shellfish reflect the health risks associated with exposure to combinations of contaminants. Intake rates for fish contaminated with combinations of non-carcinogens would be developed after (Dourson and Clark 1990) such that:

$$\text{Fish intake (kg/day)} = \frac{RfD_m \text{ (mg/kg/day) X 70 kg}}{\text{TC (mg/kg)}} \qquad \text{(Eq. 6)}$$

where,

$$RfD_m = TC/\sum E_i/RfD_i \qquad \text{(Eq. 5)}$$

where TC is total contaminant load in fish flesh, RfD_m is the mixtures reference dose for the same target organ, E_i is the fish tissue concentration (mg/kg) for contaminant i and RfD_i is the

reference dose for contaminant i for the same target organ. The fish intake value can then be converted to a meal frequency based again on assumptions of average meal size as described above.

These equations can be modified to calculate the intake rate for combinations of carcinogens as follows:

$$\text{Fish intake (kg/day)} = \frac{RAI_m \text{ (mg/kg/day) X 70 kg}}{\text{TC (mg/kg)}} \qquad \text{(Eq. 10)}$$

where RAI_m = Risk Associated Intake for the mixture of carcinogens, defined as the intake in kg/day that would not result in exceedence of the acceptable cancer risk level for a combination of contaminants, assuming risk additivity, and calculated as:

$$RAI_m = TC/\Sigma E_i/RAI_i \qquad \text{(Eq. 11)}$$

where TC is total contaminant load in fish flesh, RAI_m is the risk associated intake for the mixture, E_i is the fish tissue concentration (mg/kg) for contaminant i and RAI_i is the risk associated intake for contaminant i from Equation 8. The fish intake value can then be converted to a meal frequency based again on assumptions of average meal size as described above.

Sampling Procedures

Only the edible tissues of finfish should be used for analysis of contaminant levels. Samples should be analyzed as skin-on fillets, and sampling conducted where possible for specific size-classes and species. These procedures are utilized most frequently in states with comprehensive monitoring programs and they result in monitoring of those portions of contaminated

finfish most likely to be consumed by the public. It has been the experience in the Great Lakes basin that, even though advice to remove skin from fish prior to cooking is offered, many individuals do not follow this advice; thus, analysis of skin-on fillets may provide the best estimate of potential human exposure to contaminants in sport fish.

Analysis of whole fish may be necessary where a particular species is consumed whole by a sub-population or where wildlife exposure is of concern. In this case, a monitoring program should incorporate collection of additional samples of fish species for whole sample analysis.

Composite sampling should generally be avoided. Analysis of individual fish allows assessment of the variation that may occur in tissue contaminant levels between species, within a species, and size classes of species. Analysis of variation is necessary to determine whether species- or size class-specific statistical differences exist between contaminant types and levels. However, the U.S. EPA in its draft guidance document on fish sampling and analysis recommends analysis of composite samples from fillets of ten fish, although separate composite samples are recommended for all subgroups (e.g. size or age classes, sex, etc.). The choice for composite or individual sample analysis will depend upon the available resources to conduct the analysis. Composite analysis, although it eliminates some information, may be desirable as it reduces the number of samples that must be analyzed, thus reducing costs associated with analysis. Regardless of whether individual or composite analysis is conducted, it is recommended that replicate samples be collected as part of the field QA/QC program. The U.S. EPA

has developed recommendations on the number of replicate samples that should be collected.

The average tissue concentration of contaminants should be utilized to determine whether to issue a consumption advisory for a species or size-class of sport fish species. It is recommended that the mean tissue concentration for a species or size-class be used to determine consumption advisories in equations 3 - 7, 10, and 11 of this report. The U.S. EPA has developed recommendations for statistical analysis of tissue concentrations associated with specific consumption advice (or trigger levels) in its draft guidance document on fish sampling and analysis. These recommendations should be followed as advisories and regulatory actions are developed for contaminated fish and shellfish.

Where a of range of size classes of a particular species of finfish may be consumed, analysis of the relationship between size class and contaminant level is necessary. Such analysis should be conducted with using linear regression models. Where the mean tissue concentration is significantly different between size classes, consumption advice can then be issued on a size-class specific basis.

Removing an Advisory and Retesting Contaminant Species

It should be useful to determine where and how often to retest sites for fish and shellfish contamination, particularly where all sites cannot be retested yearly or more frequently. Areas where contaminant levels for pollutants are elevated or change substantially should be retested every one to three years. Areas which show no signs of substantial changes in contaminant

levels but are popular finfish or shell fish harvesting sites should be retested at least every five years. All other areas, including relatively remote locations with no major sources of pollution nearby and no indication of changing contaminant levels in fish or shellfish should be retested at least every ten years.

The State of New Jersey should adopt a mechanism to remove a consumption advisory or remove bans on sale or distribution of fish and shellfish as contaminant levels warrant. This mechanism should require consistent reduction in contaminants over time to levels that can be confirmed statistically to be below concentrations of concern. For example, advice for no-consumption may be lifted after two subsequent years where tissue levels are such that a consumption advisory is not necessary (fish are safe for unlimited consumption). Lifting of less stringent advisories may require one year of subsequent no-consumption advice.

Advice for Preparation and Cooking

Some preparation techniques reduce the contaminant burden in finfish by a considerable amount (up to 50%), although not all contaminant concentrations are reduced by all preparation techniques. Cooking techniques, however, do not appear to significantly reduce potential exposure levels. Therefore, it is recommended that consumption advisories in New Jersey be accompanied by advice to prepare finfish appropriately to remove the greatest number and amounts of chemicals possible.

Such advice should be stated as follows:

> You can significantly reduce the level of PCBs and most pesticides (but not mercury) by properly cleaning, trimming and skinning your catch. Therefore, you should

trim all the fat from four key areas: the belly flap, lateral line, along the backbone, and adjacent to the skin. Also, remove the skin from your fish prior to cooking it.

Advice on cooking to remove contaminants is likely not appropriate for shellfish, although data are not available to address whether any preparation or cooking techniques reduce chemical contaminant levels in shellfish.

Other Recommendations

PCBs are one of the most common contaminants in fish and shellfish. Traditionally, PCB contamination has been assessed through analysis of the technical PCB formulations Aroclor 1242, 1254, and 1260. These formulations consist of multiple PCB congeners which contribute differentially to the toxicity of the mixture. Unfortunately, the toxicity of PCB has been determined from the toxicity of the Aroclor mixtures, particularly for the induction of cancer. Thus, analysis of tissue contaminant levels in fish and shellfish, and consumption advice based on that analysis, will require Aroclor specific monitoring. However, work has begun to focus on the toxicity of individual PCB congeners; thus, some states, particularly in the Great Lakes basin, are monitoring PCBs in fish and shellfish on a congener-specific basis. However, consumption advice has not been generated from congener-specific analyses as the toxicologic information available for PCB congeners is not sufficient to develop conclusions on the human health impacts of specific PCB congeners.

New Jersey toxicologists should follow developments in congener-specific PCB toxicology. Appropriate modifications to

fish and shellfish monitoring programs, and development of consumption advice based on these modifications should be developed as understanding of the human health impacts of exposure to specific PCB congeners increases.

INTRODUCTION

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Contamination of seafood (fish and shellfish of both marine and fresh water origin) with toxic substances has been a critical and widespread environmental, economic and human health problem in New Jersey and throughout the U.S. The National Academy of Sciences-Institute of Medicine study on seafood safety concludes that most seafood available in the U.S. is wholesome and unlikely to cause illness (IOM 1991). However, the report states that one-fifth of the fish and shellfish eaten in the U.S. is derived from recreational or subsistence fishing, and these products are not subject to health-based control. Further, the report rates the risk of consumption of chemically contaminated finfish and shellfish as high for "recreational fishers in certain areas, pregnant women, and children." Risk is enhanced for subsistence fish consumers and for recreational anglers in areas of high contamination. The report calls for corrective measures for chemically contaminated fish and shellfish that include reductions in discharges of chemicals that cause contamination, harvest restrictions by site and species, improved risk assessment for cancer and non-cancer endpoints, and improved consumption advisories for contaminated sport fish.

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contaminant monitoring programs, and; 2) To develop a structure for a scientifically supportable procedure to interpret the results of monitoring programs to make risk management decisions The report is presented in five sections: Section I - Review of Federal activities and guidance for the development of fish consumption advisories; Section II - Review of State activities for the development of fish consumption advisories; Section III - Review of consumption advisory methods developed by individuals or organizations other than State or Federal agencies; Section IV - Other considerations in consumption advisory development such as sampling and preparation methods, and; Section V - Recommendations to the State of New Jersey for the development of consumption advisories for contaminated fish and shellfish.

SECTION I

FEDERAL ACTIVITIES

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Federal Guidance for Development of Fish Consumption Advisories

Over half of the states in the U.S. rely on Food and Drug Administration (FDA) tolerance or action levels to determine when a consumption advisory should be issued for fish and shellfish. Tolerance and action levels are derived under the Federal Food, Drug, and Cosmetic Act (FFDCA), which is intended to ensure a safe and wholesome food supply (Bolger, et al. 1990). In essence, the FFDCA prohibits added substances in foods (including fish and shellfish) that are shipped in interstate commerce, if they may be injurious to human health. A substance is considered added when it does not occur naturally in foods.

The FDA is responsible for administration and enforcement of most portions of the FFDCA; that is, FDA is the agency primarily responsible for regulating fish and shellfish contaminated with toxic substances. One exception to FDA primacy in administering and enforcing that Act occurs in Sections 408 and 409. The U.S. EPA was granted authority to administer these sections which address pesticide residues in food, including fish and shellfish.

As part of the process to regulate toxic substances in food, the FDA establishes formal tolerances that address the extent of allowable contamination. FDA may also develop guidelines or regulatory limits for toxicants in food, which

usually happens when data on the toxicity of a substance are limited or when conditions are rapidly changing. When fish or shellfish that are shipped in interstate commerce contain an added contaminant above tolerance or action levels or guidelines, FDA may undertake regulatory steps to minimize exposure to that contaminant. These steps include seizure of the affected product. If a toxic substance for which a tolerance or regulatory guideline has not been developed occurs in food, the FDA may seize that food if it determines that the substance poses a threat to human health, or the agency may conduct a formal rule making to establish a limit for that substance.

The U.S. FDA establishes tolerances or regulatory limits for toxic substances (other than pesticides) in foods, including fish and shellfish, under Sections 406 and 408 of the FFDCA. The U.S. EPA establishes tolerances or regulatory limits for pesticides under Section 409. Both FDA and EPA utilize risk assessment procedures to establish tolerances for toxic substances in fish and shellfish. However, the process of tolerance establishment also includes considerations of economic impacts that may be experienced by society and food industries in complying with regulatory levels. Tolerances are also established at levels that would avoid removing large amounts of valuable food from the market place. For example, FDA developed tolerance levels for contaminants in fish and other foods "to ensure that consumers would not be needlessly deprived of individual foods in the effort to limit the overall PCB intake"

(Bolger et al. 1990). Finally, tolerance levels are set by considering the extent to which the contaminant is unavoidable under good manufacturing practice, and by considering the analytical and sampling capabilities available to measure the contaminant to ensure proper enforcement of a regulatory level.

When establishment of a tolerance level for a contaminant is impractical (e.g. when conditions are rapidly changing), the FDA and EPA may establish action levels for toxic contaminants. Action levels are administrative instructions to FDA field units and define the extent of contamination at which a food is considered adulterated. FDA now considers action levels to be prosecutorial guidance levels which are not binding on the courts, the public, or the FDA but that provide for establishment of regulatory limits (Bolger et al. 1990). Regulatory limits are contaminant levels that are used to classify a food as adulterated (similar to tolerance levels) but that are set by means of informal notice and comment rather than by formal notice and comment. Informal notice and comment rule-making occurs more quickly than formal rule-making and provides for quicker changes in regulatory limits than are possible for formal tolerances.

Finally, FDA may issue an advisory opinion which is non-enforceable advice on contaminant levels in foods for which there is no tolerance level. The advisory opinion can be used by states or other jurisdictions to set their own specific policies. An advisory opinion was issued by FDA for dioxin (2,3,7,8-TCDD) in fish at the request of Governors of some of the Great Lakes states in 1981.

Development of FDA/EPA Tolerance and Action Levels for Toxic Contaminants

Tolerance and action levels are developed when a national contamination problem exists for a particular contaminant. Levels are then developed and used to protect the average national consumer of fish sold in interstate commerce. Sport fish, by definition, are not transported in interstate commerce and, therefore, are not regulated by the FDA under the Federal Food, Drug, and Cosmetic Act. However, a majority of the states utilize FDA tolerance and action levels (and EPA tolerance and action levels for pesticides) to develop at least some portion of the consumption advisories for contaminated sport fish.

As part of the tolerance setting process, EPA and FDA make assumptions about the national average fish consumption rate, the average weight and lifespan of a human, as well as the total dietary exposure of a contaminant from all sources in the national food supply. Unfortunately, tolerance and action levels have been developed for only a few chemicals, and FDA has not established regulatory limits for some of the most important human toxicants (e.g. TCDD, lead, polynuclear aromatic hydrocarbons). Further, as described above, factors other than health impacts (e.g. economic impacts, analytical detection levels) are considered in the tolerance development process. Therefore, FDA and EPA have recognized that tolerance and action levels may not be appropriate for use in the development of

consumption advisories for locally or regionally contaminated sport fisheries.

EPA and FDA tolerance and action levels for pesticide and non-pesticide contaminants in fish are listed in Table 1. Most of the action levels for pesticides were established prior to the creation of the U.S. EPA in 1970; thus, the basis for these numbers is largely unknown yet their use to regulate contaminants in fish and shellfish is extensive.

Quantitative Risk Assessment, Risk Management, and Fish Consumption Advisories

The U.S. EPA (1989) states that:

> Risk assessment may be applied to data on chemical residues in fish and shellfish for the following purposes: To identify and rank toxic chemical problems in specific locations, to develop environmental criteria or guidelines at the national, state, regional, or local level, and to develop public information and advisories.

The purpose of this section is discuss the risk assessment process as it may be used in the development of public information and advisories regarding contaminated fish and shellfish.

Approximately 20% of states issuing fish consumption advisories rely primarily on a risk assessment-based approach to advisory development. Several other states utilize risk assessment processes in at least a portion of their advisory development programs. Risk assessment procedures have been established and are utilized frequently in federal regulatory

Table 1. Tolerance and action levels for common contaminants in fish and shellfish.

CONTAMINANT	ACTION LEVEL (ppm or mg/kg)
Aldrin/Dieldrin	0.3
Chlordane	0.3
DDT, DDE, TDE	5.0
Endrin	0.3
Heptachlor and Heptachlor Epoxide	0.3
Mirex	0.1
Toxaphene	5.0
Kepone	0.3
Mercury	1.0
Dioxin (2,3,7,8-TCDD)	25.0 ppt*
PCB	2.0

* The dioxin level is advisory

programs that address contaminants in fish and shellfish. The U.S. EPA utilizes quantitative risk assessment under the Clean Water Act and several other statutes that address fish and shellfish contamination (however, these programs do not address advisories for contaminated sport fish). The U.S. EPA and FDA utilize quantitative risk assessment procedures, along with other considerations, to establish tolerance and action levels for pesticides and non-pesticide contaminants.

Quantitative risk assessment procedures have been described thoroughly, and examined frequently by regulatory agencies and in the technical literature. The risk assessment process, which is conducted for carcinogenic and non-carcinogenic toxicants, consists of four stages - hazard evaluation, dose-response evaluation, exposure evaluation, and risk characterization (NAS 1983, and see U.S. EPA 1989 for a description of each step).

Traditionally, the hazard of a compound has been determined by its toxicity and the potential for and extent of human exposure. Toxicity is determined by the potency of a compound, usually derived from the dose-response relationship. Potency for carcinogens is reflected in the slope factor (q_1^*) and in the No-Observed-Adverse-Effect-Level (NOAEL) for threshold toxicants (non-carcinogens). Derivation and use of the q_1^* and the NOAEL have been described by the U.S. EPA (1989), Anderson et al. (1983), and by Barnes and Dourson (1988).

The q_1^* represents the 95% upper confidence limit of the slope of the potency or dose-response curve and addresses the

carcinogenic potency of a chemical derived from the multistage model assuming a non-threshold or linearized response at low doses. An estimate of cancer risk is derived by multiplying the q_1^* by the level of exposure. The reference dose (RfD) is derived by dividing the No-Observed-Adverse-Effect-Level (NOAEL) by an uncertainty factor. The uncertainty factor addresses the source, nature, and quality of data used to generate the NOAEL and the degree of uncertainty associated with extrapolating toxicity effects observed in surrogate laboratory animals to humans. The RfD is considered a dose, within approximately one order of magnitude, that should not pose an appreciable risk of adverse effects in exposed humans.

Much of the discussion and criticism of traditional risk assessment methodologies, particularly for carcinogens (see for example Ames and Gold 1987, Ames and Gold 1990, and Finkel 1990) transcend the use of the process to develop tolerance and action levels. At the center of the controversy for predicting human risk and effects associated with exposure to toxic chemicals is the lack of human epidemiologic evidence for those effects. In lieu of epidemiologic evidence, a human dose-response relationship is usually derived from studies conducted at high doses on surrogate laboratory animals, primarily rodents. The dose-response relationship determined from rodent studies is then used to develop estimates of potency for carcinogens (q_1^*) and for non-carcinogens (RfD) at low human doses or exposures.

Relatively small differences exist between FDA and EPA procedures to conduct risk assessments in the development of

tolerance and action levels. Further, only minor differences exist between EPA and FDA in the performance of risk assessments under different statutes and programmatic requirements. These differences include methods of scaling dose or exposure data between rodents and humans, development of an acceptable risk level, choice of model to extrapolate cancer risk or potency at low doses, and differences in exposure assumptions.

The FDA has chosen to scale between doses in humans and surrogate laboratory animals on the basis of body weight while the U.S. EPA has chosen to scale doses on the basis of surface area for carcinogenic substances. This choice may result in a risk estimate that differs by as much as six fold (6X), which is less than the degree of uncertainty of one order of magnitude usually associated with a cancer risk estimate. Model choice for low dose extrapolation for carcinogens varies between and within agencies. Both EPA and FDA assume that the dose-response curve for carcinogens is linear at low doses. Further, both agencies accept the linearized multistage model as the model of choice to estimate potency at low doses. However, both agencies will adopt other models where evidence supports such adoption. For example, the U.S. EPA uses the one-hit model to estimate the cancer potency of benzene at low doses.

Both agencies also recognize similar acceptable risk levels for carcinogens which range from 1×10^{-4} to 1×10^{-6}. The choice of a cancer risk level is a purely non-scientific issue. The basis for the choice may be public opinion, economic

impact, or political expediency but a scientific basis cannot be invoked to support such a choice. Cancer risk levels generally deemed acceptable range between 1 X 10^{-5} to 1 X 10^{-6} (Bailar 1990). The U.S. EPA takes regulatory action (e.g. for Superfund cleanups) when cancer risks are greater than 1 X 10^{-4} and usually does not take regulatory action when risks are less than 1 X 10^{-6} (Travis, et al 1987). In many cases, the U.S. EPA will not choose an acceptable risk level but, rather, will leave the choice up to a state agency or other non-federal entity. For example, EPA allows states to choose an acceptable cancer risk level in the derivation of numeric Water Quality Criteria for carcinogenic substances in surface waters.

The U.S. EPA and the U.S. FDA use fundamentally similar methods to calculate allowable daily intakes for non-carcinogens. However, the U.S. EPA has substituted the term reference dose (RfD) for allowable daily intake (ADI) even though the two are almost identical in their derivation. The U.S. EPA also uses the term uncertainty factor rather than safety factor to derive the RfD; yet, there is little difference in how safety or uncertainty factors are chosen and utilized by FDA and EPA.

The U.S. EPA provides information to states on cancer potency and reference doses or allowable daily intakes through the Integrated Risk Information System (IRIS). EPA provides documentation and support for the choice of appropriate studies for hazard evaluation, the choice of appropriate extrapolation model, choice of uncertainty factors, and other important

components of the risk assessment process. EPA provides exposure information for several risk levels for carcinogens in IRIS rather than developing information based on a single acceptable cancer risk level.

Perhaps one of the most important, yet often the weakest components of the risk assessment process is the exposure evaluation. Risk assessments for both carcinogens and non-carcinogens require information about the route and levels of exposure to toxic substances. For the purpose of this report, the exposure route of concern is through consumption of contaminated fish.

The exposure evaluation should provide information on the concentration of a contaminant in the species of concern, the potential transfer of contaminants from the environment to important aquatic species to humans, the fisheries harvest activities, diet and other characteristics of exposed humans, fish consumption rates, contaminant absorption efficiency, and dose of contaminant delivered to the target organ. Consideration should also be given to concurrent exposure to combinations of more than one toxicant. Issues associated with contaminant concentrations in species of concern and the potential transfer of contaminants to fish and ultimately to humans will be discussed in another section of this report.

For risk assessment purposes, both EPA and FDA assume that the average, national fish consumption rate of a 70 Kg male is 6.5 g/day for a 70 year lifetime. Absorption efficiency and

delivered dose are generally considered to be 100% of the exposure dose since information that addresses these phenomena is not usually available. Exposure to children, adults weighing less than 70 kilograms, and exposure associated with consumption rates greater than 6.5 g/day (approximately one, half pound meal of fish every five weeks) are not usually considered in formal risk assessment processes, particularly where those processes are intended to be applied nationally such as in the development and implementation of Water Quality Criteria or tolerance and action levels for toxic substances.

The U.S. EPA chose the 6.5 g/day fish consumption rate based on a survey of the average fish consumption in the U.S. population in the 1970s (Rupp et al. 1980). During the 1980s the popularity of fish as an important, healthy source of protein has increased substantially. However, a new fish consumption rate for the U.S. population has not been adopted by the U.S. EPA to reflect the increased popularity of fish and shellfish. The EPA does recognize that some individuals may consume significantly greater quantities of fish than the general U.S. population (EPA 1989). For example, residents of the Great Lakes basin may consume several meals of fish weekly due to the availability of a vibrant sport fishery in the Great Lakes basin. Few data are available to accurately estimate the quantities of fish consumed by Great Lakes residents. However, some states in the Great Lakes basin have adopted consumption rates as high as 30 g/day (slightly less than one, half pound meal per week) to calculate

Water Quality Criteria to reflect the potential for increased consumption of Great Lakes sport fish (Foran 1990).

It is conceivable that some subpopulations (local populations near sources of major recreational fisheries, Native American populations, etc.) consume fish on as much as a daily basis. The U.S. EPA (1989) recommends consideration of fish consumption rates as high as 180 g/day (approximately six half pound meals per week) as the "reasonable worst case" consumption rate for local populations that may substitute fish for other protein sources.

The use of a 70 kilogram human weight in the risk assessment process is designed to represent an average adult weight. Thus, advisories or other risk assessment activities based on these levels are developed to be protective of adults. Children also ingest fish from surface water systems although the U.S. EPA does not suggest incorporation of weights for children in the calculation of risk.

Risk assessment for exposure to combinations of toxicants is particularly difficult as information on synergistic or antagonistic effects is not usually available for most contaminant combinations. Therefore, EPA (1989) recommends that risk-additivity be assumed; that is, the total risk for a chemical mixture is estimated as the sum of upper-limit risks for carcinogens or the sum of hazard indices for non-carcinogens (where the same target organ is affected by all non-carcinogenic toxicants in the combination).

The full structure of a quantitative risk assessment model is presented in U.S. EPA (1989, Figure 6, page 64).

SECTION II

STATE ACTIVITIES

STATE ACTIVITIES

Introduction

Censuses of all states in the U.S. (RTI 1990) and of thirty coastal and Great Lakes states (NOAA 1990) were conducted to examine programs that address consumption advisories for fish and shellfish. Sample collection, analysis, and data interpretation techniques used by states were examined as part of these surveys. The results are useful in assessing the number of fish consumption advisories, the species for which they are issued, and in assessing how advisories are developed and used in the United States.

Most states in the U.S., as well as the Province of Ontario, Canada, develop and issue consumption advisories for contaminated fish or shellfish. A variety of methods are used to develop consumption advisories, including application of U.S. FDA and EPA action levels, use of quantitative risk assessment procedures, and combinations of each method. Sixty eight percent of states in the U.S. frequently use FDA action levels to derive levels of concern for contaminants while twenty percent derive a level of concern from risk assessment procedures using U.S. EPA's cancer potency factor or reference dose (RTI 1990, NOAA 1990). Many states also use combinations of FDA action levels and risk assessment procedures to derive consumption advisories.

The RTI and NOAA studies also indicated that consumption advisories are issued for between sixty and seventy species of fish and shellfish throughout the U.S. Approximately 21% of

advisories in the NOAA study were issued for species of the Percidae, 16% for salmonids, 13% for centrachids, 12% for pike, and 11% for carp. The RTI study suggested that consumption advisories are most often issued for carp, catfish, sunfish, and salmon and trout (finfish), and for blue crab, American oyster, soft-shell clam, and blue mussel.

Twenty-four contaminants have been detected in fish and shellfish nationally at levels that have prompted states to issue consumption advisories. The most common contaminants for which consumption advisories are issued are PCBs, mercury, chlordane, and dioxins/furans. Ten states issue consumption advisories in 10 or more water bodies, and five of these states are located in the Great Lakes basin. Only two states in the U.S. did not issue any consumption advisories (Idaho and S. Dakota).

A variety of state agencies are involved in the process of consumption advisory development and issuance. State health departments are the sole agency responsible for interpreting fish/shellfish tissue data for human health impacts in 24 of 50 states (48%) while, in 92% of all states, health agencies are at least involved in interpretation. State health departments are solely responsible for issuance of consumption advisories in 22 of 50 states (44%), and play a lead or frequent role in another 18 states (38%). Environmental and fisheries agencies play a major role in 16 (32%) and 13 (26%) states respectively. State environmental agencies play a major role in collection of fish and shellfish data in sixty percent of states, while health

departments and fisheries agencies played a role in collection activities in 50% and in 42% of the states respectively.

Most states rely either on FDA action or tolerance levels, or on a risk assessment process to interpret monitoring data and to develop consumption advisories. Thirty-four of 50 states (68%) frequently use the FDA action level to derive levels of concern for contaminants. Ten states (20%) derive a level of concern from risk assessment pr dures using U.S. EPA's cancer potency factor or reference dose. Many states use combinations of FDA action levels and risk assessment procedures to derive consumption advisories. And nine states suggested that a protocol for developing fish consumption advisories based on risk assessment was under development.

As part of these studies, states were asked what problems they were having with consumption advisory development and what guidance they desired in the process. Many states suggested that guidance was needed in setting appropriate restrictions on the number of meals of contaminated sport fish, in identifying human populations at risk from exposure to toxicants in contaminated sport fish, in determining the number of samples required to trigger advisories, and in development of methods to determine when to set or lift an advisory. Finally, states suggested they needed assistance and guidance in advisory communication.

Substantial methodologic differences in sample collection, analysis, and data interpretation also exist between jurisdictions. Twenty-nine of fifty states (58%) conduct residue

analysis and issue consumption advisories for size classes of fish and shellfish rather than just for an entire species. Most often, states focus tissue analysis and advisory development on size classes that are most likely to be consumed, that are most abundant, or that are most contaminated. Approximately half of the states analyze the edible portion of a fish with the skin on, while sixteen states analyze the whole fish. Sixty-eight percent of the states frequently analyze fish tissue for metals, PCBs, and pesticides, while thirteen states (26%) analyze for the priority pollutants and eleven states (22%) analyze tissues for volatile organic compounds (VOCs).

In this section, the methods of several jurisdictions that have vast experience in the development of consumption advisories for contaminated sport fish are reviewed and analyzed. Twenty-two states analyze more than 100 fish/shellfish tissue samples annually while nineteen states analyze between 25 and 100 samples (RTI 1990). Further, five states (California, Wisconsin, Michigan, Illinois, and Missouri) survey more than fifty water bodies annually for fish and shellfish contamination while eight states (Minnesota, Wisconsin, New York, Florida, Michigan, California, Missouri, and Pennsylvania) issue consumption advisories for more than ten water bodies.

These and other jurisdictions were chosen for detailed analysis of their monitoring, data interpretation, and advisory development procedures. These jurisdictions utilize a variety of

methods to collect, analyze, interpret, and manage fish tissue contaminant data. Included in this analysis are procedures utilized by the following jurisdictions: Ontario, California, Delaware, Illinois, Maryland, Michigan, Missouri, Minnesota, New York, Pennsylvania, and Wisconsin.

Mechanisms Used by States to Trigger Consumption Advisories

California

California does not have a comprehensive, statewide program to monitor contaminants in fish and shellfish and to develop consumption advisories based on the results of monitoring programs. However, an extensive fish and shellfish monitoring program has been conducted along the southern California coast for several contaminants including DDT and PCBs.

The California Environmental Protection Agency, Office of Environmental Health Hazard Assessment surveyed fish and shellfish from "representative locations" in southern California (California EPA 1991). Fish were collected from 24 sites representing areas frequently fished by pier, private boat and party boat anglers. A pilot study was conducted to determine which chemicals occurred in fish tissues at concentrations that may pose risks to human health. A comprehensive study, based on the results of the pilot, was then conducted where fifteen species of fish were collected, although not all species were collected from each site. Normally, from five to ten species were sampled, and twenty fish from a single species collected

from each site. Approximately four thousand fish were sampled during the comprehensive study and one thousand chemical analyses were conducted. DDT, PCB, mercury, chlordane, and tributyltin (TBT) were monitored in tissues of fish collected from each site.

The California EPA determined the concentrations of the chemical contaminants in edible tissues, and evaluated the health significance of contaminant levels in order to develop guidelines for safe consumption of fish taken from the coastal regions in southern California. Composite samples for chemical analysis were prepared by combining edible tissue from four individual fish. Five composites were then analyzed from twenty fish collected from each species. Correlation analyses were conducted between each contaminant concentration and fish size at a few sites.

Concentrations of DDT in composites ranged from non-detect (ND) to 8.05 mg/kg (ppm), wet weight. Chlordane concentrations ranged from ND to 65 ug/kg (ppb), PCB concentrations (Aroclors 1254 and 1260) ranged from ND to 3.5 mg/kg (ppm), mercury concentrations ranged from less than 50 ug/kg to 724 ug/kg (ppb), and TBT concentrations ranged from 52 ug/kg to 105 ug/kg (ppb).

The California EPA estimated theoretical excess cancer risks from consumption of fish with DDT, PCB, and chlordane for all samples with mean concentrations above chemical-specific, method detection limits (38 ppb for DDT, 50 ppb for PCB, 3 ppb for chlordane). Cancer risks were calculated assuming a lifetime

exposure, consumption of one meal per week of individual species from each site (this is a consumption rate of 23 grams/day or one, 5.75 ounce meal per week). The excess cancer risks calculated for fish contaminated with DDT, PCB, or chlordane ranged from 4.4×10^{-6} to 3.0×10^{-3}.

Adverse health effects were not expected associated with consumption of fish contaminated with mercury (neurotoxicity and developmental toxicity) and TBT (immunological effects) at levels observed at all monitoring sites. Comparison of tissue concentrations with the allowable daily intake (ADI) or the reference dose (RfD) for mercury (0.4 ug/kg-day) and TBT (0.03 ug/kg-day) resulted in a conclusion of no likely adverse effect associated with consumption of fish from southern California waters.

The California EPA developed contaminant levels to trigger consumption advisories for fish contaminated with DDT, PCB, or chlordane. Consumption advice was issued in categories that included "do-not-eat", "restrict consumption to no more than one meal per week," "restrict consumption to no more than one meal every two weeks," and "restrict consumption to no more than one meal per month." Advice categories were based on consumption rate/tissue concentration relationships that would not result in excess cancer risks greater than 10^{-5}.

Tissue concentrations of PCB that would result in a consumption advisory were below the method detection limit (MDL) for PCB. Therefore, a multiple (2X) of the MDL was used as the

trigger level for PCP consumption advice since this level was between the analytical level of detection (50 ppb) and the level of quantitation (120 ppb). This trigger level was associated with an excess cancer risk of 1 X 10^{-4}. Excess cancer risk estimates for DDT and chlordane, and the PCB method detection limit resulted in the following trigger levels for these contaminants - 100 ppb for PCBs, 100 ppb for DDT, and 23 ppb for chlordane. California did not invoke a statistical basis for its consumption advice triggers.

Consumption advice based on these trigger levels was provided for individual species and for each specific geographic site. Consideration was given in the report of how to trigger advice based on risk estimates for individuals who consume combinations of fish species. California chose to set contaminant levels of concern, or trigger levels, via chemical-specific, health or risk assessment-based criteria. Guidance was then provided to reduce exposure to acceptable levels for individual species with tissue concentrations that exceeded individual trigger levels.

The overall consumption recommendations issued by California EPA were designed to reduce exposures to levels that result in overall risks of less than 10^{-4}. Consumption recommendations are intended for individuals who frequently consume fish taken from sites within the study area. California recommends that, in addition to following site and species specific risk information, individuals should include several

different fish species and consume fish caught at several different sites. The following, more general advice is also issued by California:

> Eat a variety of different fish species. In this way, exposure to chemical contaminants is reduced in comparison to consumption of only a highly contaminated species.
>
> Consume fish caught from several different fishing locations. In this way, overall exposure to chemical contaminants is reduced in comparison to exposure to highly contaminated fish species from highly contaminated sites. In addition, avoid exclusively fishing in the more highly contaminated areas.
>
> Trim fat from fish fillets and cook fish by baking or broiling on a rack to reduce DDT and PCB in edible portions. This method of preparation will not reduce concentrations of all chemical contaminants (e.g. metals).

Delaware

Delaware does not have a comprehensive fish monitoring program nor does Delaware generate consumption advice on a widespread, comprehensive basis. Delaware has made site specific management decisions based on fish tissue contamination. For example, the state discontinued stocking a stream (Red Clay Creek) with trout because of chemical contamination and resultant fish consumption advisories. Such a decision is relatively unique. The state has also used a combination of risk assessment and reliance on FDA action levels to generate consumption advice. For example, an approach that relied on the allowable daily intake (ADI) was used to generate consumption advice for fish contaminated with chlorinated benzene in Red Lion Creek.

Alternatively, FDA action levels were used to trigger advice for fish in Red Clay Creek and the St. Jones River.

Some consideration has been given to implementation of a risk-based approach to advisory development although the approach has not been adopted. Concern has been expressed, however, about the potential adverse economic impacts associated with development of advisories based on risk assessment. Other on-going activities in Delaware include a state-wide consumption patterns survey, collection and analysis of contaminants in striped bass, and pursuit of mechanisms to reconcile the objectives of fisheries managers and concerns based on potential health hazards of consuming contaminated sport fish (Rick Greene, Dept. of Natural Resources and Environmental Control - personal communication).

Maryland

Maryland conducted an extensive fish tissue monitoring program as part of a state-wide monitoring program for water quality from 1977 to 1985. Since 1985, more site specific analyses have been conducted for fish tissue contamination. The purpose of this monitoring program was to determine the "health of state waters," not necessarily to determine the levels of contaminants in fish that pose health risks to humans.

As part of this program fish collections have been performed during the fall months by electroshock and other collection methods. Monitoring has occurred at thirty three

locations throughout the state and the number of stations sampled each year ranged from ten to thirty three. Thirty one different species from nine families were analyzed for contaminants between 1977 to 1985. Contaminants analyzed during the study included arsenic, mercury, cadmium, lead, chromium, copper, zinc PCBs, lindane, DDT (and metabolites), dieldrin, endrin, aldrin, dacthal, mirex, toxaphene, methoxychlor, endosulfan, hexachlorobenzene, heptachlor epoxide, heptachlor, and chlordane. Substantial analysis of contaminant trend data has been conducted throughout state.

Generally, two species have been targeted for collection from each monitoring station - a high trophic level predator and a bottom feeder. Fish of individual species were grouped into composite samples (from 5 similarly sized individuals), and whole fish samples collected for tissue analysis. Fish length, weight, total number of each species, and the number of individuals were noted at each sampling site.

Despite extensive sampling of fish tissue in this program, Maryland provides relatively little information on the nature and extent of consumption advice issued for contaminated sport fish. Where consumption advice has been issued, it appears to have been based on comparison of tissue concentrations of contaminants with FDA action levels for those contaminants.

A 1986 report "Intensive survey for chlordane contamination in finfish in Lake Roland, Back River, and Patapsco River" presented results of efforts to monitor chlordane in

several species of fish. In several species collected from these sites, including black crappie, carp, channel catfish, and American eel, mean and median chlordane levels were above the FDA action level of 0.3 ppm. A recommendation was made to Maryland Dept. of Health and Mental Hygiene to issue a consumption advisory for these rivers.

A fish tissue network was developed in 1991 for three large geographic areas in the state. Three samples (one game species and two of "accumulator" or bottom dwelling species) were to be sampled at each site in the network. Samples were to be composed of five fish of target species and sizes collected from each site. Composites of five whole fish and fish fillets were intended to be analyzed. The results of this monitoring effort, and the methods proposed to develop consumption advice based on it, were not available at the writing or this report.

Missouri

Missouri has conducted extensive fish tissue monitoring and generates consumption advice for contaminated sport fish. Tissue monitoring programs were initiated in 1984 and an average of ninety five sites are sampled annually. Thirty four areas are presently under advisories for chlordane contamination (chlordane drives most of the consumption advisories in Missouri).

Advisories that are generated from monitoring activities are based on composite samples of fillets of at least three similarly sized fish of a species and are representative of what

individuals would catch from a site. The Missouri Dept. of Health conducts risk assessments for contaminated sport fish and issues consumption advisories. Generally, advisories are triggered for a species based on the concentration of contaminants and the percentage of samples from a collection site that are at or above an appropriate trigger level. Triggers are calculated using the most current risk assessment methodology of U.S. EPA (as discussed in Section I), consumption data from the area of concern where it is available, and a 1×10^{-5} risk level for cancer, or appropriate margin of safety for non-carcinogens. Missouri uses a level of concern (trigger level) for chlordane of 100 ppb (John Crellin, personal communication). FDA action levels may also be used when they are similar to numbers obtained using EPA risk assessment methods.

Missouri uses three levels of advisories:

Level 1 - safe for unlimited consumption;
Level 2 - limit consumption to specified monthly or weekly amount (as of 1991 chlordane health advisory - 1 meal/month);
Level 3 - do not eat.

Level 1 advice is issued when concentrations of fewer than 10% of composite samples for all species sampled at site are above chemical-specific trigger levels. Level 2 advice results when a composite sample for a species is at or above the trigger level or when 10 to 49% of samples from all species from the site are at or above the trigger level. Level 3 advice results when a composite sample for a species is at or above the trigger level or when 50% or more of the samples from all appropriate species from the site are at or above the trigger level.

If a site has Level 3 advice for two or more years, and if the affected species is commercially harvested, Missouri recommends that detention and embargo of fish from the affected area "should be strongly considered." Missouri also recommends that a random survey of fish from area fish markets and commercial fishermen should be conducted before regulatory action is taken.

A site-specific Level 3 advisory can be lifted after two subsequent years of a Level 1 advisory that is issued at that site or after one year of a Level 2 advisory followed by one year of a Level 1 advisory. A Level 2 advisory can be lifted after one year's data show that requirements have been met for a Level 1 advisory.

The Great Lakes States and Provinces

Great Lakes jurisdictions have worked cooperatively to develop and issue fish consumption advisories. The mandate for cooperation derives from the Great Lakes Toxic Substances Control Agreement of 1986 in which the Great Lakes Governors committed to achieve uniform fish consumption advisories throughout the basin. Such uniform advisories have not been achieved (as of the writing of this report) although some progress has been made toward that goal. For example, the health agencies of all jurisdictions are designated as the lead agencies for advisory development. All jurisdictions except Minnesota apply FDA action levels to trigger consumption advisories for contaminated sport fish. All

jurisdictions issue special, more restrictive, consumption advice to women of child bearing age, pregnant women, and children. All but one jurisdiction uses skin-on fillets as the standard sample. All states issue cooking and cleaning advice as part of their consumption advisories. And all state laboratories have QA/QC programs for contaminant analysis although interstate QA/QC has not been coordinated.

Some substantial differences also exist between consumption advisory programs in the Great Lakes basin (Foran and VanderPloeg 1989). There are substantial differences in specific triggers used to place fish in various consumption advisory categories. Differences also exist in the number of advisory categories used by individual jurisdictions, in how and when to use risk assessment procedures to trigger advice, in how to address combinations of contaminants, in the selection of contaminants to be monitored, and in how and when to follow the U.S. EPA guidance manual on risk assessment for contaminated sport fish. Examined below are the advisory development programs used by each of the jurisdictions in the Great Lakes basin.

Ontario

The Province of Ontario has a massive, provincial-wide monitoring and advisory development program for contaminated sport fish (Ontario MOE 1990). The Province issues consumption advice for over 1,600 locations. Fish tissue collections are made by the staff of the Ministry of Natural Resources, and

samples are sent to Ministry of Environment laboratories for analysis. Ontario conducts analyses of mercury, PCBs, mirex, DDT, toxaphene, lindane, heptachlor, aldrin, chlordane, TCDD, chlorinated phenols, chlorinated benzenes, and PAHs in fish tissue. Monitoring locations are selected by determination of popular angling areas, areas with known or suspected sources of pollution, areas that provide major sources of food for local inhabitants (near Indian reserves), areas that are being opened for recreational development, and as part of monitoring programs for long-term studies of contaminants in fish.

Species are selected for monitoring based on their ability to accumulate specific contaminants as a function, for example, of size, lipid content, or feeding behavior. Ontario collects a minimum of ten to twenty fish of each species (50 - 100 preferred) at a site, with lengths and weights representative of the size range of that species at that site. Tissue analysis is conducted for contaminants in lean, dorsal, skinless, boneless muscle tissue. The Province analyzes individual fish samples rather than sample composites.

Ontario has also developed a retesting protocol: Areas where contaminant levels for pollutants are elevated or change substantially are retested every one to three years; areas which show no signs of substantial changes in contaminant levels but are popular sport fishing sites are retested at least every five years; all other areas, including relatively remote locations with no major sources of pollution nearby and no indication of

changing contaminant levels in fish are retested at least every ten years.

Ontario utilizes federal (Canadian) action levels which are quite similar to FDA action levels to trigger consumption advice for contaminated sport fish. Advice to restrict consumption to not more than once or twice per month for long term consumers, or to not more than once or twice per week for persons eating fish only one to three weeks per year is issued for organic contaminants. Do-not-eat advice is not issued for organic contaminants. Restrict consumption advice as well as do-not-eat advice is issued for fish with elevated mercury concentrations. Ontario advises that women and children should not eat any fish with contaminants exceeding federal action levels.

Ontario uses the following trigger levels for contaminants in sport fish: PCB - 2.0 ppm (based on TDI = 1 ug/kg/d), TCDD - 20ppt (TDI = 10 pg/kg/day), Mirex - 0.1 ppm (TDI = 0.28 ug/kg/day), DDT - 5.0 ppm (TDI = 20 ug/kg/day). These levels are developed from a risk assessment procedure, including risk assessment for carcinogens. However, Ontario does not use linearized, low dose extrapolation procedures for carcinogens. Rather, the Province uses a NOAEL/ADI approach for all effects. For example, the action level for PCB is calculated from a LOAEL derived from a rat carcinogenicity study. The LOAEL from the study is 100 ppm or 5 mg/kg/day. A safety factor of 5000 is then applied to derive a Tolerable Daily Intake (TDI) of

1 ug/kg/day for humans. Exposure assumptions used in development of the calculation of the trigger level include intake of 30 g/day of fish for a 60 kilogram adult with 50% of total PCB intake occurring from fish. A maximum PCB intake of 210 ug/week (based on TDI of 1 ug/kg/day) is provided by consumption of fish with tissue concentrations of PCBs of 1.86 ppm. This level is rounded to 2.0 ppm to derive the action level. Advice to restrict consumption for fish with PCB tissue concentrations greater than 2.0 ppm is then issued for individual species and size classes of species.

A similar risk assessment process has been used to derive the action level for mercury 0.5 ppm (TDI = 0.47 ug/kg/day). However, Ontario issues consumption advice for fish contaminated with mercury as follows.

Tissue concentration:

< 0.5 ppm - no restriction on consumption;
> 0.5 ppm - women and children - do not eat;
0.5 - 1.0 ppm - consume no more than 1/2 pound per week;
1.0 - 1.5 ppm - consume no more than 0.3 pounds per week;
> 1.5 ppm - do not eat (all other consumers).

Ontario uses regression analysis to generate size specific advice for contaminated sport fish species. Size and tissue concentration of individual contaminants are plotted and regression analysis applied to determine the statistical relationship between size and contaminant concentration. All fish sizes for which the contaminant concentration is greater

than the action level are then included in the restrict consumption category.

Michigan, Wisconsin, Illinois, Indiana

All four states use FDA action levels to generate consumption advice for organic contaminants. These states utilize different trigger levels for mercury (WI and MI - 0.5 ppm, Illinois and Indiana - 1.0 ppm). These states also use the following advice categories and triggering mechanisms for organic contaminants:

Category 1. Fish for which 0 to 10% of the samples exceed any FDA action level. (Unrestricted Consumption - MI, IL, IN; no specific consumption advice by WI for this category)

Category 2. Fish for which 11 - 49% of samples exceed the FDA action level. (Restrict to no more than one meal per week, no consumption for women and children - MI, IL, IN; Consumption rate advice not used by WI except "no consumption" for women and children")

Category 3. Fish for which 50% or more exceed any FDA action level. (No Consumption - all).

The states use the following advice categories and triggering mechanisms for mercury:

Michigan - 0.5 - 1.5 ppm - no more than one meal per week (no consumption for women and children);
> 1.5 ppm - no consumption;

Wisconsin - up to 0.5 ppm - no restrictions (women and children - no more than one meal per month);

0.5 - 0.75 ppm - No more than 26 meals per year and no more than 13 meals in any one month (women and children - do not eat);

0.75 - 1.0 ppm - No more than 13 meals per year and no more than 7 meals in any month, space remaining 6 meals over rest of year at a rate of one meal per month (women and children - do not eat);

> 1.0 ppm - do not eat.

Illinois, Indiana - >1.0 ppm - do not eat

Michigan and Wisconsin have also issued a general advisory for all inland lakes to eat no more than one meal per week of several top predator species (e.g. pike, bass, large perch, crappie, walleye).

Wisconsin, Indiana, and Michigan collect skin-on fillets analyzed as individual fish while Illinois collects skin-on fillets and composites the samples within a defined size range. Generally, these states collect 10 samples of each size class although they will use five samples if necessary.

Ohio, Pennsylvania

Ohio and Pennsylvania compare the average tissue concentration of mercury (trigger level - 1 ppm) and organic contaminants with the FDA action level to trigger consumption advice. Do-not-eat advice is issued where the average tissue concentration is greater than the action level and unrestricted consumption advice is issued when the average tissue concentration is less than the action level.

These states collect skin-on fillets from five fish and composite the samples within a defined size range (10 samples per composite).

New York

New York follows the procedures of most Great Lakes states to trigger consumption advice but also considers concurrent exposure to multiple contaminants. Thus, New York utilizes FDA action levels and an additivity formula for organic contaminants (see Foran and VanderPloeg 1989 for further description of this procedure). The state utilizes the sums of ratios of individual contaminant concentrations and their corresponding action levels. If the sum of the ratio is greater than 1, New York advises that those fish be consumed no more than once per month (no consumption for women and children). If the sum of the ratios is greater than 3, the state recommends no consumption.

New York also issues a general advisory to restrict consumption to no more than one meal (1/2 pound) per week for fish from any of New York fresh waters.

New York uses the following procedures to trigger consumption advice for mercury. If the fish tissue concentration is:

> 1.0 ppm - restrict consumption to no more than one meal per month (no consumption for women and children);

> 2.0 ppm - no consumption.

Minnesota

Minnesota, which has traditionally used a complex risk assessment-based procedure to generate consumption advice for

contaminated sport fish, is the only state in the Great Lakes basin which uses techniques to generate consumption advisories that are consistent with the techniques used in its environmental regulatory programs. The state does not rely on FDA action levels to trigger consumption advisories for contaminated sport fish.

Presently, Minnesota develops consumption advice for fish contaminated with PCBs, dioxin and mercury. Consumption advice is based on the limit of detection for PCBs (0.05 ppm) and for TCDD (0.6 ppt). If any fish of a particular species has detectable amounts of PCBs or TCDD, Minnesota advises consumers to eat no more than one meal per month for that species (do-not-eat advice is issued for women and children). Minnesota has temporarily moved away from the use of risk assessment to generate advisories. This may be due, in part, to a desire to incorporate congener-specific toxicity information for PCBs and TCDD into consumption advisory development mechanisms.

Historically, Minnesota has relied on risk assessment-based procedures to calculate consumption advisories. Minnesota has relied on the EPA reference dose for mercury to trigger consumption advisories for long term consumers of sport fish contaminated with mercury. The following advice has been issued based on tissue levels in a species or size class of species:

<0.16 ppm - no restriction;
0.16 - 0.65 ppm - eat no more than 1 meal/week;
> 0.65 ppm - no consumption for women and children;
0.66 to 2.81 ppm - eat no more than 1 meal/month;
> 2.81 ppm - no consumption.

These advice categories are calculated from the following equation drawing on EPA's RfD for mercury (0.3 ug/kg/day):

$$\frac{0.3 \text{ ug/kg/day} \times 70 \text{ kg} \times 30.42 \text{ days/month}}{[\text{Hg}] \text{ ug/g fish} \times 227 \text{ g fish/meal}} = \frac{2.81}{[\text{Hg}] \text{ ug/g}} \quad \text{(Eq. 1)}$$

This equation allows calculation of the number of meals per month that can be consumed without exceeding the RfD for a fish with any tissue concentration of mercury. The following table shows the number of meals per month for fish contaminated with mercury ranging from 0.16 ug/g (ppm) to 4.5 ppm.

Tissue Conc. (ug/g)	< 0.16	0.16 - 0.65	0.65 - 2.8	2.81 - 4.5
Meal Rate #/month	>18	18 - 4	4 - 1	1 - 0.7

Minnesota has chosen a conservative approach for advisory development such that the minimum number of meals which can be consumed safely is the lowest meal frequency which is then chosen in each category such that advice is to eat 18, 4, 1, and 0 meals per month for each contaminant range.

Minnesota has also generated consumption advice for short term consumers of fish contaminated with mercury and organic compounds. For mercury, Minnesota uses parathesia (decreased sensation, numbness, tingling) as the effect of interest. Parathesia occurs at a blood concentration of approximately 200 ng/ml. Assuming exposure is based on a meal size of 0.5 lb (227 grams) and a 70 kilogram body weight,

and assuming fish provide the only source of mercury, and that short term consumption occurs over 52 days (less than 5-6 half lives where one mercury half life = 52 days), the number of meals per week that can be consumed, based on various mercury tissue concentrations, for a short term consumer, is shown below.

	Tissue Concentration (ug/g)			
	< 0.16	0.16 - 0.65	0.65 - 2.8	2.81 - 4.5
Consumption Period	# Meals/Week			
1 week	> 50	12	3	2
2 weeks	> 26	6	2	1
3 weeks	> 18	4	1	1

Consumption after 260 days is considered chronic and the meal frequency is calculated from the U.S. EPA reference dose as above. Advice, based on various tissue concentrations, is then issued as follows:

	Tissue Concentration (ug/g)			
	<0.16	0.16 - 0.65	0.65 - 2.8	2.81 - 4.5
Vacation	unlimited	unlimited	1 meal/wk	1 meal/year
Season	unlimited	2 meals/wk	2 meal/mo	1 meal/mo
Annual	unlimited	1 meal/wk	1 meal/mo	do not eat

Minnesota issues separate advice for women of child bearing age, pregnant women, and children. Minnesota recommends that consumption of fish contaminated with mercury should be monitored for 10 months (5-6 half lives) prior to pregnancy to ensure that pregnancy is not begun with harmful levels of

mercury. Consumption advice for women and children is to eat one-quarter the amount of fish that non-pregnant adults are advised is safe as above such that:

	Tissue Concentration (ug/g)			
	<0.16	0.16 - 0.65	0.65 - 2.8	2.8 - 4.5
Consumption Period	# Meals/Week			
vacation	unlimited	1 meal/wk	1 meal/yr	do not eat
2 mo vac	2 meal/wk	2 meal/mo	0.5 meal/mo	do not eat
chronic	1 meal/wk	1 meal/mo	do not eat	do not eat

Minnesota has developed consumption advisories for PCBs based on a reference dose of 5×10^{-5} mg/kg/day. This reference dose is developed for reproductive toxicity and is derived from a LOAEL calculated from the studies of Fein et al. (1984) of 0.5 ug/kg/day divided by an uncertainty factor (UF) of 10 to reach the RfD of 0.05 ug/kg/day or 5×10^{-5} mg/kg/day. The reference dose does not address carcinogenecity. Calculation of the no adverse effect consumption rate follows the calculation methods for mercury where the number of meals per month is calculated by:

$$\frac{5 \times 10^{-5} \text{ mg/kg/day} \times 70 \text{ kg} \times 30.42 \text{ days/month}}{[\text{PCB}] \text{ ug/g} \times 227 \text{ g fish/meal}} = \frac{0.47}{[\text{PCB}] \text{ ug/g}} \quad \text{(Eq. 2)}$$

Thus, meal frequency advice based on the PCB tissue concentration is shown in the following table:

	Tissue Concentration (ug/g)			
	< 0.027	0.027 - 0.11	0.12 - 0.5	> 0.5
Meal Rate #/month	> 18	18 - 4.3	4.3 - 1	< 1
Advice	unlimited consumption	1 meal/wk	1 meal/mo	none

The upper bound estimate of cancer risk based on a cancer potency factor of 7.7/mg/kg/day and intake of 5 X 10^{-5} mg/kg/day (the reference dose) is 3.8 X 10^{-4}. Minnesota also states in its consumption advisory that: "Currently, cancer will affect about one in every two people in Minnesota; primarily due to smoking, diet, and hereditary risk factors. If you follow this advisory for PCB-contaminated fish over your lifetime, the PCBs in the fish you eat may not increase your cancer risk. At worst, EPA estimates are that one additional cancer case may develop in 1 of 2,500 to 10,000 people eating PCB-contaminated fish for 70 years."

As stated earlier, Minnesota has recently moved away from the risk-based approach to develop consumption advisories for PCB and TCDD since these contaminants can't be detected in fish at concentrations less than 0.05 ppm (50 ug/kg). Therefore, for Minnesota's 1992 advisory, the state has proposed to allow unlimited consumption of PCB-contaminated fish when the tissue concentration is less than the detection level. Restrict consumption advice (one meal per month) will be issued when the concentration is greater than the LOD (pregnant women, children,

nursing mothers, and women who may become pregnant in next several years are advised to eat none of fish with detectable concentrations of PCBs).

Proposed Regression Approach

Scientists from the Great Lakes states have recently agreed in principle to adopt a risk-based approach to advisory development for contaminated sport fish. This approach has not been approved by administrators in the Great Lakes states. Should it be approved and should all states agree to its use, states in the Great Lakes basin will have achieved uniformity in advisory development for the first time. They will also have agreed as a group to a risk-based advisory development procedure.

The proposed approach has several components. First, the following general statement would be issued:

> All fish may absorb and concentrate some toxic chemicals if present in their environment. It is common sense to minimize your exposure to these chemicals. This advisory identifies fish with the highest contamination and assuming you follow the cleaning and cooking advice, suggests how often they can be eaten. This information is intended to assist you in minimizing your toxic chemical exposure, while continuing to eat sport fish and enjoying its health benefit.

A general cancer risk statement would also be issued:

> Some chemical contaminants found in fish cause tumors in animals and are probable human cancer agents. Individual cancer risk cannot be predicted with

certainty. Enforcement agencies often use different assumptions and mathematical models to estimate human cancer risk. If you consistently follow this advisory, the contaminants in the fish you eat may not increase your cancer risk at all.

General benefit and cleaning and cooking statements would be issued such that:

When properly prepared, fish provide a high protein diet which is low in saturated fats. Many researchers suggest that a half-pound of fish a week in the diet is beneficial in preventing heart disease. The health benefits of fatty fish rich in omega-3 fatty acids are not clear. What is clear, is that fish of almost any species may have substantial health benefits when they replace a high saturated fat source of protein in the diet. This includes lean as well as fatty fish. You can get the health benefits of a diet rich in fish without the high levels of chemicals which contaminate some fish. Choose fish carefully to minimize your exposure to chemical contaminants.

You can significantly reduce the level of PCBs and most pesticides (but not mercury) by properly cleaning, trimming and skinning your catch. It is important to trim all the fat from four key areas: the belly flap, lateral lines, along the backbone, and adjacent to the skin. Cooking does not destroy PCBs; the heat from cooking melts the fat in the fish, thus removing some of these contaminants. It is not advisable to deep-fry your Great Lakes trout or salmon. It is best to broil or bake trimmed, skinned fish on an elevated rack so any additional fat melted out of the fish drops off. Do not use the drippings for sauces.

The states would all assume a uniform meal size of 1/2 Lb (227 grams) and a 70Kg body mass for risk assessment purposes. Advice categories would include:

No consumption restrictions;
Consume no more than 1 meal per week;
Consume no more than 1 meal per month;
Vacation consumption - consume no more than 6 meals per year;
No consumption.

A risk assessment procedure would be based on impairment of infant-neurological development and would be used to assess PCB exposures as it incorporates data from both human epidemiologic studies and laboratory animal assays. The state scientists proposed a RfD of 5 X 10^{-5} mg/kg/day for PCB (identical to Minnesota's RfD for PCBs) although they did not select a single study from which to derive the reference dose. Rather, they chose a value that "was consistent with multiple studies." Thus, according to the scientists, the RfD is a composite and "may not be appropriate for use in regulatory programs." The scientists also proposed that PCBs will be used as a surrogate for total toxic residues and suggest that this approach is rationalized by the fact that women examined in the PCB neurological studies were exposed to combinations of contaminants while effects were attributed only to PCBs.

The proposed approach to trigger advisories is similar to the procedure utilized by Minnesota. However, the approach incorporates a 50% reduction factor associated with cooking and cleaning; that is, trigger levels are increased by 50% over Minnesota's due to the assumption that cooking and cleaning activities reduce tissue contaminant levels. (This issue is discussed in the Section IV of this report.)

Trigger levels and associated advice categories for PCBs are developed for long term consumers as follows:

Tissue Conc.	Consumption Rate
0 - 0.05 ppm	unrestricted consumption
0.06 - 0.2 ppm	up to 1 meal/week
0.21 - 1.0 ppm	up to 1 meal per month
>2.0 ppm	do not eat

The present proposal contains an advice gap for tissue concentrations between 1.0 - 2.0 ppm. The approach also considers a short term, or vacation consumer. When PCB tissue concentrations are between 1.1 - 2.0 ppm, consumption should be restricted to fewer than six meals per year. When concentrations are greater than 2.0 ppm, consumption of those fish should be avoided.

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SECTION III

OTHER ADVISORY DEVELOPMENT METHODS

CONSUMPTION ADVISORY DEVELOPMENT METHODS

Introduction

Three major methodologic proposals for development of fish consumption advisories have been presented since the mid 1980s (Clark et al. 1987, National Wildlife Federation 1989, Dourson and Clark 1990). All of these proposals, discussed below, have been based on the application of quantitative risk assessment procedures. The U.S. EPA has also developed a guidance document for the assessment of health risks for consuming contaminated fish and shellfish which is discussed below.

Point System - Carcinogens

Clark et al. (1987) proposed a risk-based point system to develop and issue consumption advisories for contaminated sport fish. The approach was presented only for carcinogens but may be equally applicable for non-carcinogenic substances (through use and application of a reference dose - RfD). The approach was developed for four contaminants - PCBs, DDT, dieldrin, and chlordane - which had adequate tissue contaminant data in fish. The approach relies on the calculation of the upper bound cancer risk via use of EPA's cancer potency (slope) factor (q_1^*), an assumption that an average fish meal size is 114 g (1/4 pound), exposure over a 70 year lifetime, and an average body weight of an individual consuming contaminated fish of 70 kilograms. The approach also relied on an assumption of risk-additivity for

concurrent exposure to more than one carcinogen. An estimate was then derived of the lifetime cancer risk associated with consumption of one meal per year of various Lake Michigan sport fish species. Lifetime excess cancer risks for consumption of various sized lake trout, coho salmon, chinook salmon, and bloater chubs ranged from 2.8×10^{-4} to 5×10^{-6}.

The authors suggested that direct communication of cancer risk estimates was not the most effective means of communicating health risk information or consumption advice. Rather, they proposed a point system analogous to point systems used for duck hunting in Michigan and Wisconsin. (Each duck species carries a point score, with more common ducks carrying lower scores. A hunter may shoot up to a predetermined number of points worth of ducks, e.g. 100, during a daily hunting trip.) The authors assigned arbitrarily a value of 100 points to a cancer risk of 1×10^{-4}; thus, yearly consumption of one meal of contaminated sport fish which resulted in a lifetime cancer risk of 2.8×10^{-4} would result in a point total of 280. Yearly consumption of one meal of contaminated sport fish which resulted in a lifetime excess cancer risk of 5×10^{-6} would result in a point total of 5. If an individual wished to maintain an excess cancer risk at 1×10^{-4} or 1×10^{-5}, the individual would restrict the yearly number of meals of contaminated sport fish species so that the point total did not exceed 100 or 10 respectively. The yearly consumption rate that limited the point total to 100 (or 10) points could be multiplied by 70 to calculate a lifetime meal

total. The yearly meal associated point total could then be exceeded as long as the lifetime meal total was not exceeded. However, the study did not address non-cancer effects that may result from consumption of a large number of contaminated fish meals in a short period of time.

The authors suggest that advisory information on the risks of consuming contaminated sport fish should be provided to the public and the public then permitted to make their own decisions on which and how much fish to consume. To facilitate dissemination of risk information, the authors suggest that information on risks of other activities be presented along with the risks of consuming contaminated sport fish to put several voluntary risks, including sport fish consumption, into perspective. They suggest, however, that great care must be taken in developing information on comparable risks so that risk information is not selected to minimize or elevate the public's perception of risks associated with consumption of contaminated fish. For example, if Lake Michigan fish were consumed at the same rate as a charcoal broiled steak (114 g/wk), the lifetime cancer risk of fish consumption would be 5.8×10^{-3}, or a risk of from 100 to 500 times that from consumption of the steak.

The method utilized in this study is simply a risk-based approach for consumption advisory development. As such, it is scientifically more defensible than an approach that utilizes FDA action or tolerance levels to trigger (or communicate) advice. However, use of a point total rather than a risk estimate is

proposed to simplify communication of risk information. As such, the consumer must still determine what is an acceptable risk and understand the nature of acceptable risk as such information is conveyed in the context of other voluntary risks. An understanding of the nature of quantitative risk estimates is required for the consumer to make a choice of which and how many fish to consume regardless of whether that information is conveyed as a risk estimate or as a point total. Calculation of a point total associated with an acceptable risk level appears only to add another layer of complexity to an already highly complex methodology. Restricting point totals based on risk levels as proposed in this study, rather than restricting risk levels themselves may not provide the simplicity necessary to enhance the widespread use of such a process.

Rf[illegible] Approach

This approach has been proposed by Dourson and Clark (1990) and relies on a standard risk assessment methodology for non-carcinogenic substances. The approach is relatively unique, however, in that it is proposed for use with combinations of toxicants as well as single toxicants. The approach is based on the U.S. EPA's oral reference dose (RfD), which is a dose of a toxicant, similar to an allowable daily intake (ADI), that should not pose adverse effects when ingested daily by a 70 kilogram individual over a lifetime. The RfD does not necessarily define a safe dose; rather, the uncertainty about the number may be as

much as an order of magnitude.

The intake rate (kg/day) of a fish contaminated with a single toxicant would be expressed as:

$$\text{Fish intake (kg/day)} = \frac{\text{RfD (mg/kg/day) X 70 kg}}{\text{tissue concentration (mg/kg)}} \qquad \text{(Eq. 3)}$$

where RfD is the reference dose for that toxicant and tissue concentration is the average fish tissue concentration (for a species or size class of species). The fish intake rate can then be interpreted as a meal frequency (no. meals per week or month) based on a determination of average meal size. For example, if the average meal size is 1/2 pound (230 grams), a fish intake rate of 10 g/day is derived, and the corresponding meal frequency would be one meal per month.

Dourson and Clark suggest that a consumption advisory could then be based on the meal frequency derived from the fish intake rate. For example, if the fish intake rate calculated from the equation is 1 g/day, the corresponding meal frequency is much less than one meal per month (for either 1/4 or 1/2 pound meal sizes). Thus, consumption advice for this species may be "do-not-eat." Consumption advice based on a fish intake rate of 3 - 7 g/day may be "eat no more than once per month."

Intake rates for fish contaminated with combinations of contaminants would be developed as follows:

$$TC/RfD_m = E_1/RfD_1 + E_2/RfD_2 + \ldots . E_i/RfD_i \qquad \text{(Eq. 4)}$$

where TC is total contaminant load in fish flesh, RfD_m is the mixtures reference dose for the same target organ, E_i is the fish tissue concentration (mg/kg) for contaminant i and RfD_i is the reference dose for contaminant i for the same target organ. The RfD_m is calculated as

$$RfD_m = TC/\sum E_i/RfD_i. \qquad \text{(Eq. 5)}$$

The fish intake rate can then be calculated from:

$$\text{Fish intake (kg/day)} = \frac{RfD_m \text{ (mg/kg/day)} \times 70 \text{ kg}}{TC \text{ (mg/kg)}} \qquad \text{(Eq. 6)}$$

The fish intake value can then be converted to a meal frequency based again on assumptions of average meal size as described above.

This approach, applied to single chemicals, is useful only for substances for which a RfD has been calculated. Use of the approach to develop consumption advice for multiple contaminants is only appropriate where RfDs for individual contaminants in the combination have been developed and where individual RfDs are based on the same target organ. Finally, this approach is not useful for carcinogens as the RfD does not address the potency of carcinogenic compounds. However, the equations used to calculate fish intake rate for single (Eq. 3)

and multiple contaminants (Eq. 6) may be used to determine fish intake rates for carcinogens by substituting the risk specific dose, calculated from the EPA's cancer slope factor, for the RfD.

NWF Approach

The National Wildlife Federation (NWF 1989) developed a model fish consumption advisory for Great Lakes sport fish in 1989. NWF utilized standard risk assessment practices to calculate the cancer and non-cancer health risks associated with consumption of contaminated sport fish from Lake Michigan. NWF utilized fish tissue contaminant data collected by the four states surrounding Lake Michigan to assess potential human exposure to contaminants through consumption of sport fish. Contaminant data were gathered from skin-on fillets of several fish species and expressed for individual species and individual size classes of species. Four contaminants were commonly found in the edible tissue of Lake Michigan sport fish - DDT, PCB, dieldrin, and chlordane.

NWF calculated cancer risks for fish contaminated with one or more of the four toxicants through use of the standard U.S. EPA approach to cancer risk assessment. The organization did not rely directly on U.S. EPA's cancer slope factor (q_1^*) to determine the potency of individual carcinogens. Rather, NWF researchers reviewed all pertinent cancer bioassays and chose the most appropriate study for utilization in prediction of human cancer risk. The linearized multistage model was utilized to

calculate an excess cancer risk for low dose exposures in humans from high dose exposures in laboratory rodent assays. Risk additivity was assumed when individual species or size classes of species contained more than one contaminant.

NWF also calculated the non-cancer risks associated with consumption of sport fish contaminated with DDT, PCB, dieldrin, and chlordane. Reference dose (RfD) and hazard index (HI) approaches were utilized, following U.S. EPA procedures for calculation of these indices, to determine the non-cancer risks associated with exposure to the four contaminants (described in the previous section).

NWF determined the cancer and non-cancer risks associated with consumption of contaminated sport fish at various meal frequencies. Meal frequencies (number of meals over a lifetime) were determined for three cancer risk levels - 1×10^{-4}, 1×10^{-5}, and 1×10^{-6} - based on the concentrations of the four contaminants in tissues of individual size classes of Lake Michigan sport fish. Consumption information was then issued through communication of the cancer risks associated with consumption of various lifetime meal frequencies for each species or size class of species. Communication was based on offering individuals a choice of acceptable cancer risks. For example, eleven meals of Lake Michigan lake trout greater than thirty inches could be consumed over a lifetime without exceeding a 1×10^{-4} cancer risk; one meal of lake trout greater than thirty inches could be consumed over a lifetime without exceeding a

1×10^{-5} cancer risk, and no meals of lake trout could be consumed without exceeding a lifetime risk of 1×10^{-6}. Further, for the 1×10^{-4} risk level (eleven meals over a lifetime), advice was included to not consume more than one meal per year to avoid non-cancer risks (in this case associated with liver damage). This advice was based on a hazard index derived for the four contaminants that was greater than one. Again, the cancer and non-cancer risk estimates were based on risks associated with concurrent exposure to the four contaminants.

NWF also recommended more restrictive consumption advice for women of child bearing age, pregnant women, nursing mothers, and children fifteen years of age or younger. This advice recommended that these individuals should not eat any of the Lake Michigan sport fish species examined during the study. The more restrictive advice for women and children was based on information derived from a number of human epidemiologic studies and studies of laboratory animals that demonstrated reproductive and developmental impairment with exposure to halogenated organic compounds, specifically polychlorinated biphenyls.

NWF issued risk-specific consumption advice for ten species or size classes of Lake Michigan sport fish. It was assumed that most individuals reading the advice pamphlet did not have a thorough grasp of the nature or meaning of cancer risk estimates. Therefore, information on the derivation of cancer and non-cancer risk estimates was included with consumption advice. Also included was information on comparative risks

associated with consumption of other foods (red meat, cod and haddock, tuna, chicken, and fish and seafood from other locations with contaminant problems such as Puget Sound and Quincy Bay) contaminated with similar toxicants. Data on chemical contamination of other foods were derived from U.S. FDA market basket surveys and from state and federal agency reports for Puget Sound and Quincy Bay. Cancer risk estimates were developed for each food type and shown on a risk continuum along with Lake Michigan sport fish.

Discussion of cleaning and preparation techniques that could potentially reduce contaminants in sport fish prior to consumption, as well as discussion of the benefits of consuming fish were included in the risk communication document. Also included in the document was information on sources of the contaminants in Great Lakes sport fish and information on how these sources might be controlled to reduce contamination of Lake Michigan and of Lake Michigan sport fish.

U.S. EPA Guidance

The U.S. Environmental Protection Agency has developed a guidance manual on assessing the health risks from contaminated fish and shellfish (U.S.EPA 1989). The document is primarily a reiteration of U.S. EPA guidance for standard risk assessment practice. The document is intended to describe the steps of a health risk assessment procedure for consumption of contaminated fish and shellfish; to define the conceptual basis for standard

toxicological variables and criteria (e.g. q_1^*, RfD) related to risk assessment, to provide guidance on the presentation of risk assessment results, and to summarize assumptions and uncertainties of the recommended procedure for risk assessment.

Many of the components of a comprehensive risk assessment process for carcinogens and non-carcinogens that are presented in the EPA guidance manual were discussed in Section I of this report. Unfortunately, the EPA guidance document does not offer proposals for mechanisms to incorporate cancer and non-cancer risk information into development of consumption advice for contaminated fish and shellfish. In fact, EPA offers only a few examples of formats for presenting the results of risk assessments to risk managers and technical audiences, not to the consumers of contaminated sport fish. EPA states clearly that guidance on interpretation of risk estimates to support decision making is beyond the scope of the manual. As such, the document is only useful for quantitative risk assessment and not for conducting comprehensive risk management activities such as developing and communicating risk-based consumption advice for contaminated sport fish.

However, EPA does offer a few recommendations for communication of risk assessment information (although it is likely that this information will be more useful to a technically trained audience). For example, the guidance document recommends that plots of estimated risk vs. consumption rate be used as the primary means of presenting risk assessment results for

contaminated fish and shellfish since actual consumption rates for a population or portions of a population are usually unknown. EPA also suggests that risk information may be presented by comparison of risk estimates for the study area (or species) with risk estimates for consumption of fish from a reference area, or for risks associated with consumption of alternative foods. Finally, EPA recommends that the assumptions and uncertainties underlying the risk assessment model along with estimates of the model variables should be summarized in a concise format (e.g. table). Assumptions and uncertainties may include those associated with the exposure evaluation (estimates of fish consumption in a population), with adsorption of an ingested contaminant (EPA assumes 100%), with the exposure period for humans (70 years), with low dose extrapolation for carcinogens, with risk additivity, with determination of the weight of evidence, and others. All of these recommendations have been utilized in several fora that have involved development of quantitative risk information and communication of that information to the lay public.

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SECTION IV

OTHER CONSIDERATIONS IN CONSUMPTION ADVISORY DEVELOPMENT

OTHER CONSIDERATIONS IN CONSUMPTION ADVISORY DEVELOPMENT

Introduction

The analyses presented in Sections I - III addressed only briefly several important factors in the development of consumption advisories for contaminated sport fish. These factors include the potential reduction of tissue contaminant levels through preparation and cooking techniques, sampling protocols for contaminated sport fish, and quality assurance/quality control procedures for sampling and analysis of contaminated sport fish tissues. These issues are addressed below.

Preparation and Cooking of Potentially Contaminated Sport Fish

Several states have included with their consumption advisories advice on preparation (cleaning) and cooking techniques to reduce contaminants in sport fish. Relatively little research has been conducted, however, to determine whether various preparation and cooking procedures significantly reduce tissue contaminant levels. Yet, information on the potential reduction of tissue contaminant levels by various preparation and cooking activities is crucial where assumptions of contaminant reductions are incorporated into risk-based consumption advice. For example, the states in the Great Lakes basin have assumed that proper preparation and cooking of contaminated sport fish reduces contaminant levels by fifty percent in the proposed regression approach (discussed in Section II). This approach

incorporates a 50% reduction factor associated with cooking and cleaning; that is, trigger levels are increased by 50% due to the assumption that cooking and cleaning activities reduce tissue contaminant levels by this amount. Existing research on the effects of various cooking and preparation practices is reviewed in this section.

Several studies have examined reductions in tissue concentrations of PCBs, DDT, mirex, and a few other lipophilic pesticides associated with removal of skin and fatty tissue prior to cooking and consumption. Reinert et al (1972) reported that DDT concentrations were seven to 12 times higher in the dorsal, medial, and ventral (fatty) areas of whole (eviscerated) steaks of coho salmon than in the loin, and four to eight times more concentrated in the dorsal, medial, and ventral areas of whole steaks of lake trout than in the loin. The DDT concentration in whole steaks ranged from 14 to 17 ppm. Reinert reported also that filleting of yellow perch removed more than 90% of DDT in that species. The DDT concentration in whole yellow perch in this study was approximately 4 ppm.

Skea et al. (1979) evaluated the effect of trimming (removal of skin, belly fat, fat in the dorsal area, and fat along the lateral line) on reduction of mirex, DDE, and PCBs in brown trout and smallmouth bass from Lake Ontario. The average concentrations of these contaminants ranged from 0.03 - 0.17 ppm mirex, 2.85 - 5.18 ppm PCB, and; 0.35 - 0.92 ppm DDE. Skea reported reductions of mirex, PCBs, and DDE of between 43% and

64% in trimmed fish compared with untrimmed fish, along with a fat reduction of over 50%.

Voiland et al. (1991) evaluated the effect of trimming on reduction of PCBs and mirex in Lake Ontario brown trout. These fish had an average PCB tissue concentration of 1.05 ppm (untrimmed fillet) and an average mirex concentration of 0.05 ppm (untrimmed fillet). A 44% reduction in the concentration of mirex, and a 46% reduction in the concentration of PCBs were observed in trimmed fillets compared with untrimmed fillets. Fat content in trimmed brown trout was reduced by over 60% compared with untrimmed fillets.

These reductions have been replicated in other studies. White et al. (1985) demonstrated a 57% reduction in PCB concentration (45% reduction in lipid content) in trimmed fillets of striped bass taken from the Hudson River in 1981 compared with untrimmed striped bass. Sanders and Haynes (1988) reported a 27% reduction in PCB concentration in trimmed bluefish purchased from commercial sources on the North Carolina coast compared with untrimmed bluefish. (Contaminant reductions lower than those observed in other studies may have been due to trimming techniques that did not remove fat along the lateral.) Armbruster et al (1989) examined the effects of trimming on PCB concentrations in blue fish in the Atlantic Ocean near Long Island. The mean concentration of PCBs in raw untrimmed fillets was 1.76 ppm. Trimming the fillets of these fish resulted in an average reduction in PCB concentrations of nearly 60%.

Most of the fish species examined in these studies have relatively high lipid concentrations. Thus, removal of fatty areas in the fillet appears effective in reducing the concentrations of lipophilic contaminants. However, one common contaminant of sport fish, mercury (in its organic, methylated form), is not highly lipophilic; thus, its concentration in fish tissue is not likely to be reduced by trimming away the skin and fatty portions of a fillet. Results of research have not been located to document reductions (or lack of reductions) of mercury in fish tissue associated with trimming techniques. However, the Great Lakes states advise that trimming techniques do not reduce mercury contamination in Great Lakes sport fish as part of their fish consumption advisories. Research is being conducted presently through the Michigan Department of Public Health to determine the effects of trimming on mercury as well as other contaminant concentrations in sport fish.

Various cooking techniques have been promoted, along with trimming techniques, to reduce the levels of contaminants in sport fish. Cooking techniques that have been recommended include methods that allow fats to drain away such as baking, broiling, and grilling on a rack. Advice also is issued to avoid pan frying which may concentrate contaminants in the frying fluids. Data to support these recommendations are not as strong as data that address contaminant reductions associated with trimming techniques.

Reinert et al (1972) reported that smoked bloaters contained 36% less DDT than brined fish. However, the percent of

weight loss during cooking was similar (35%) and the concentration of DDT in smoked fish (9.0 ppm) changed little from the concentration in brined fish (9.2 ppm). Other studies have reported inconsistent reductions (or no reductions) associated with various cooking techniques. Puffer and Gossett (1983) reported weight normalized reductions in DDT and PCB concentrations in pan fried fish although actual concentrations in pan fried fish increased compared with uncooked samples. Skea et al (1979) reported minor reductions in mirex, PCB, and DDE in smoked or deep fried fish compared with raw fish, while increases in the same contaminants were observed in baked and broiled fish compared with raw fish. Armbruster et al (1987) suggested that, although PCB concentrations in striped bass were reduced approximately 10% by cooking, there were no significant differences in reduction between six cooking methods (baking, boiling, broiling, frying, microwaving, poaching). Other studies (Smith et al 1973, Zabik et al 1982) have also reported highly variable effects of cooking techniques on tissue contaminant levels, dependent upon contaminant type and species. Generally, most studies conclude that some reduction in contaminant levels may result from cooking but that the cooking method may have relatively little influence comparatively on the amount of contaminant reduction.

Sampling Protocols

The U.S. EPA is in the process of developing guidance for sample collection and preparation for contaminated sport fish.

The draft guidance document addresses six subjects associated with collection and analysis of contaminated sport fish: Monitoring strategy (screening and intensive), selection of target species, selection of target contaminants, field procedures (sample design, collection, processing, etc., including QA/QC), laboratory procedures (including QA/QC), and analysis and reporting. The guidance document is presently in draft form and is likely to be modified before it is finalized. Only a brief overview of the document's important components are presented below.

The draft guidance document recommends a two-tiered monitoring strategy. Tier one is designed to identify waterbodies, through a screening process, where chemical contaminants in fish tissues exceed defined trigger values. Tier two is designed to conduct intensive monitoring of potentially contaminated sport fish, as indicated from tier one screening analysis, to determine the magnitude of contaminant residues in fish and shellfish and to determine the geographic extent of contamination. The draft guidance document suggests that results of tier one screening are not intended to be used to generate consumption advisories for contaminated sport fish and shellfish.

A target species approach is recommended for use in both the screening (tier one) and intensive (tier two) study phases of fish and shellfish monitoring programs. Criteria for selection of target fish and shellfish species include the potential for a species to accumulate high concentrations of contaminants,

geographic ubiquity of the species, pollutant tolerance of the species, ease in identification and abundance of the species, and recreational, commercial, or subsistence fishing value of the species. The draft guidance document offers a list of species that possess one or more of these characteristics.

A target contaminant approach is also recommended for use in both the tier one and tier two study phases. Characteristics of target contaminants include their prevalence and persistence in the environment, their potential to accumulate in tissues of fish and shellfish, their potential to persist in fish and shellfish tissues, their potential to pose human health risks upon exposure through consumption of contaminated fish and shellfish, and their analytical feasibility. A list of potential target contaminants is presented in the draft guidance document.

EPA also proposes use of a value to trigger consumption advisories for contaminated fish and shellfish. This trigger value is derived via a standard risk assessment-based approach that incorporates consideration of chemical potency and exposure. Trigger values for non-carcinogens are developed through use of the reference dose (RfD) and trigger values for carcinogens are developed through use of the cancer potency (slope) factor. Trigger values are offered in the proposed guidance document for a number of contaminants for both tier one and tier two studies.

The draft guidance document offers guidance on field sampling design for tier one and tier two monitoring studies, on collection, processing, preservation, and shipping of field

samples, and a comprehensive quality assurance program for field sampling. The document also presents guidance on laboratory procedures to be followed from the time a sample is received, through analysis, to final archiving. The document presents extensive quality assurance/quality control recommendations for all laboratory activities as well as procedures for chain-of-custody, sample processing, sample distribution, and sample analysis.

Finally, the draft document provides guidance on data analysis and evaluation to determine the necessity for issuance of consumption advisories for contaminated fish and shellfish. Included in this guidance are recommendations for statistical analysis of data and recommendations for issuing various types of fish and shellfish consumption advisories. Recommendations for interpretation of monitoring data and use in consumption advisory development are most pertinent to the present analysis. Unfortunately, only two pages of the draft guidance document are devoted to data interpretation and advisory development. Recommendations presented in these two pages mirror those discussed in earlier sections of this report.

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SECTION V

ANALYSIS AND RECOMMENDATIONS

ANALYSIS AND RECOMMENDATIONS

Introduction

The management programs for contaminated fish and shellfish of twelve jurisdictions were examined in detail for this study (Table 2). Most of these programs rely on the use of FDA action or tolerance levels to generate consumption advice although several of the jurisdictions either rely in part on risk assessment procedures to manage contaminated fish and shellfish or incorporate risk assessment procedures into the development of action levels. Several of these jurisdictions are considering moving away from reliance on action levels to an entirely risk-based approach to the management of contaminants in fish and shellfish. Such an approach is recommended by the U.S. EPA.

The States in the Great Lakes basin have made perhaps the greatest progress toward development and adoption of a risk-based approach to consumption advisory development. However, only Minnesota has adopted and relies exclusively on such an approach to manage contaminants in sport fish. California has also utilized a risk-based approach to consumption advisory development although California has not adopted a state-wide methodology to monitor and manage contaminants in fish and shellfish.

Mechanisms to develop a technically sound, scientifically supportable approach to manage contaminants in fish and shellfish have been developed by several entities. Clark et al. (1987), Dourson and Clark (1990), and the National Wildlife Federation

Table 2. Methods used to develop fish consumption advisories in nine States and by the U.S. EPA.
(See text for details on each jurisdictional program)

JURISDICTION	Develops Risk-based FCAs	Risk Level Meal Size	Develops Action Level-based FCAs	Guidelines Available for Retesting and FCA Removal	Preparation and Cooking Advice
U.S.EPA	recommended	Variable NI	not recommended	NO	NO
Ontario	NO	NI 227 grams	YES*	YES	YES
California	YES	1×10^{-5} 227 grams	NO	NO	YES
Delaware	YES	NI NI	YES	NO	NO
Maryland	NO	NI NI	YES	NO	NO
Missouri	YES	1×10^{-5} SS	YES	YES	YES
L. Mich.[1]	YES - HG	NI NI	YES	NO	YES
L. Erie[2]	NO	NI NI	YES	NO	YES
New York	YES	NI 227 grams	YES	NO	YES
Minnesota	YES^	NI 227 grams	NO	NO	YES

1. Michigan, Wisconsin, Illinois, Indiana
2. Ohio, Pennsylvania

NI - Not indicated or not used

SS - Site Specific

^ - Does not develop FCAs based on carcinogenesis

* - States that Canadian action levels are risk-based

(1989) have each proposed risk-based mechanisms to develop consumption advise for contaminated sport fish. Portions of these mechanisms have been utilized by some jurisdictions although no jurisdiction has adopted any of these approaches in its entirety as part of a comprehensive, risk-based approach to manage contaminants in fish and shellfish. Yet, these approaches are the most scientifically defensible and will provide the greatest protection to human health if utilized comprehensively in State programs to manage contaminated fish and shellfish.

Recommendations are made below for the development and adoption of a risk-based approach to manage contaminants in fish and shellfish in New Jersey.

Existing Contaminant Management Activities in New Jersey

The State of New Jersey took aggressive action in 1983 to protect humans from exposure to contaminants (specifically PCBs) in fish in shellfish. This action resulted in the closure of striped bass and American eel fisheries and prohibition of sale of these species in designated New Jersey waters. The action also resulted in issuance of consumption advisories for striped bass, American eel, bluefish, white perch, and white catfish taken from the northeast region. Advice to restrict consumption to not more than one meal per week as well as instructions for cleaning and preparation was also issued by the state. This advice resulted from the analysis of fish and shellfish that indicated occurrence of detectable levels of PCBs (Aroclor 1254)

in 75% of finfish and 50% of shellfish monitored as part of the study. Eleven percent of finfish exceeded the FDA action level for PCBs of 2.0 ppm (mg/kg). None of the shellfish had tissue concentrations that exceeded the FDA action level.

A document published by the New Jersey Department of Environmental Protection (NJDEP 1990) summarizes fish and shellfish prohibitions issued by, and in effect for New Jersey. The state has prohibited the sale of all striped bass statewide and recommended limitations of consumption (not more than once per week for general population, no consumption for pregnant women, children, nursing mothers, or women of child bearing age) of large bluefish statewide.

Expansion of advisories and sale prohibitions from a regional to a state-wide basis occurred in 1988. Halgren et al. (1988) concluded that PCB concentrations in bluefish larger than 60 centimeters had the highest probability of exceeding the FDA action level of 2 ppm, and there were no regional differences identified in PCB levels for large bluefish (> 60 cm) collected throughout the state. Regional actions were also taken ranging from prohibitions on the sale and consumption of all species of fish, shellfish, and crustaceans, to limitations on the consumption of selected species.

These actions appear to have been triggered by widespread contamination of fish and blue crabs with PCBs, although there is some indication that dioxin and chlordane have contaminated blue crabs from selected sites. Comparison of tissue contaminant

levels with FDA action levels for PCBs and chlordane appears to provide the basis for prohibitions on sale and consumption, and for issuance of advice to restrict consumption of contaminated species.

A risk assessment was conducted for dioxin contamination of blue crabs from Newark Bay (Belton, 1987) and recommendations were made for prohibition on the sale and consumption of this species based on unacceptable risks to consumers of blue crabs. Lobsters were also analyzed but data were classified as insufficient to characterize the health risks associated with consumption of lobster. Further analysis indicated that 50% of blue crab samples taken from Raritan Bay contained TCDD levels greater than the FDA recommended level for no consumption (50 ppt). Mean TCDD concentrations in lobster were between 25 and 50 ppt.

In 1989, the New Jersey DEP issued a consumption advisory for bluefish longer than 24 inches and greater than six pounds. DEP recommended that these fish should be consumed no more than once per week, and that women of child bearing age, pregnant women, nursing mothers, and children should not consume any of these fish. The basis for this advice was the recognition that PCB concentrations in bluefish were greater than the FDA action level for PCBs of 2 ppm. It appears, then, that New Jersey has relied, like many states in the U.S., on FDA action, tolerance, or other guideline levels as well as risk assessment procedures to issue consumption advice and to take regulatory actions for contaminated fish and shellfish.

The purpose of this project is the development of recommendations on how New Jersey should utilize contaminant monitoring data for fish and shellfish to issue consumption advisories and to take regulatory actions. These recommendations are offered below and are based on the analyses presented in previous sections of this report.

Recommendations

A Risk-based Approach to Advisory Development

Sixty eight percent of states surveyed in the late 1980s relied predominantly on the use of FDA action levels to trigger consumption advice for contaminated fish and shellfish. Only 20% of states utilized a risk-based approach to advisory development, although many states used some combination of FDA action levels and risk assessment. Despite the widespread use of FDA action levels to trigger consumption advice, both the U.S. EPA and the U.S. FDA recommend against the use of action levels to develop advice for local or regional fish and shellfish contamination problems. In place of the tolerance/action level-based approach, a more scientifically justifiable approach is recommended which is based on quantitative risk assessment procedures to trigger consumption advice as well as to make regulatory decisions associated with contaminated fish and shellfish.

Although a majority of states rely on FDA action levels to trigger consumption advice for contaminated fish and shellfish, several states, including those in the Great Lakes

basin, have recognized that a risk-based approach is more appropriate and more protective of human health. These states are in the process of developing risk-based approaches to trigger consumption advice (and in some cases to take regulatory actions) for contaminated fish and shellfish.

A risk-based approach to advisory development and regulatory programs for contaminated fish and shellfish is recommended for the State of New Jersey. This recommendation is made for several reasons: First, it is technically and scientifically better justified than an action level approach; it will more adequately protect human health, and; the approach is receiving increasing acceptance in many state advisory programs. The approach is described in detail below.

A risk-based approach in its simplest form would follow U.S. EPA guidelines for quantitative risk assessment. State agencies with substantial resources available for chemical hazard assessment may prefer to conduct four-step risk assessments (hazard evaluation, dose-response evaluation, exposure evaluation, and risk characterization) for each contaminant in fish and shellfish. Such assessments would then serve as the basis for consumption advisories and regulatory actions. An alternative to this approach is reliance on U.S. EPA established potency derivations for common contaminants in fish and shellfish. The U.S. EPA has established potency (slope) factors for common carcinogens and estimates of allowable daily intakes (reference doses) for common systemic toxicants (non-

carcinogens). The values are available through U.S. EPA's computerized Integrated Risk Information System (IRIS), which may be accessed via the National Library of Medicine's TOXNET database.

Some limitations apply to potency estimates for chemicals available through IRIS, the most important of which is the inability for some of these values to reflect very recent advances in toxicologic knowledge. For example, a reference dose for PCBs available through IRIS does not reflect recent data derived from epidemiologic studies that address the developmental effects associated with PCB exposure. However, use of EPA derived potency or reference values available through IRIS, combined with incorporation of very recent toxicologic information, should provide an adequate basis for justifiable and protective trigger levels for contaminants in fish and shellfish.

Use of the slope or potency factor to issue consumption advisories for fish and shellfish contaminated with one or more carcinogens requires several assumptions. First, a state must choose one or more acceptable cancer risk levels around which advice will be generated. Levels of additional or extra risk ranging from 1×10^{-4} to 1×10^{-6} are most commonly recognized as "acceptable" for exposed human populations (acceptable risk levels were discussed earlier in this report). As no single risk level is considered the most appropriate, it is recommended that New Jersey choose a cancer risk level within the range of 10^{-4} to 10^{-6} to generate consumption advice for contaminated fish and

shellfish. It is recommended further that advice be generated for only one risk level rather than offering different advice associated with different risk levels and allowing the consumer to choose which risk level and associated advice is appropriate. This recommendation is derived from experience gained in former risk assessment, risk management, and risk communication activities. Communication of risk assessment information to lay persons is particularly difficult and generally confusing. Rather than offering an array of advice associated with different risk levels, advice associated with a single risk level reduces the amount of information that needs to be communicated and absorbed by the public.

Advice based on acceptable risk levels should be accompanied by information showing comparable risks for other activities. Comparable risk information should only be derived for similar activities (e.g. from consumption of other contaminated or non-contaminated foods) not from activities where risk estimates have been derived with different methods (e.g. risks associated with automobile accidents derived from actuarial data). For example, the NWF advisory procedure (copy enclosed) included information on comparative risks associated with consumption of other foods contaminated with similar toxicants. Foods included red meat, cod and haddock, tuna, chicken, as well as fish and seafood from other locations with contaminant problems such as Puget Sound and Quincy Bay. These data were obtained from the U.S. FDA market basket surveys and from state

and federal agency reports for Puget Sound and Quincy Bay. Further information on mechanisms to communicate risk-based consumption advice can be obtained from individuals with specific expertise in this area (e.g. Dr. Barbara Knuth, Cornell University).

A choice of meal size is also necessary to develop risk-based advice for contaminated fish and shellfish (for both carcinogens and systemic toxicants). Common meal sizes range from 113 grams to 227 grams (one quarter to one half pound). Information on meal frequency is not necessary since it is recommended that consumption advice be issued on a meal frequency basis (described further below). Finally, assumptions regarding the standard individual to be protected (size and exposure period/life span) must be articulated. The standard assumptions for human weight and exposure period/life span are 70 kilograms and seventy years respectively. Other choices for standard weight and exposure periods may be appropriate, for example where children may be highly exposed.

Advice should be generated to restrict consumption of contaminated fish and shellfish to limit contaminant intake (exposure) to levels that do not pose unacceptable cancer risks or exceed the appropriate reference dose. Such advice should be issued on a meal-per-week or meal-per-month basis. For example, advice should state that consumers should restrict consumption of species X to no more than once per week (or month). Further refinement of consumption advice (e.g. consume no more than two

meals per week or 3.5 meals per month) is likely to result in overly complex advice which is subsequently ignored by the consumer, and is not recommended.

Procedures

Advice for consumption frequency and regulatory decisions for contaminated fish and shellfish should be determined as follows for individual carcinogens:

$$\text{Fish intake (kg/day)} = \frac{\text{RAI (mg/kg/day) X 70 kg}}{\text{TC (mg/kg)}} \quad \text{(Eq. 7)},$$

where RAI = Risk Associated Intake, defined as the intake in kg/day that would not result in exceedence of the acceptable cancer risk level for individual contaminants, and TC = fish tissue concentration. The RAI is calculated as:

$$\text{RAI} = 1/q_1^* \text{ X ARL} \quad \text{(Eq. 8)},$$

where ARL = Acceptable Risk Level (e.g. $1 \text{ X } 10^{-5}$). The fish intake rate can then be converted to a meal frequency (no. meals per week or month) based on a determination of average meal size following Dourson and Clark (1990). For example, if a fish intake rate of 10 g/day is derived from Equation 7, and if the average meal size is assumed to be 227 grams (1/2 pound), the corresponding meal frequency would calculated as follows:

$$\frac{\text{10 g/day X 30 days/mo}}{\text{227 g/meal}} = \text{1.32 meals/mo} \quad \text{(Eq. 9)}.$$

Rounding 1.32 meals/mo yields a meal frequency of one meal per month to avoid exceeding an acceptable cancer risk level of 1×10^{-5}. Dourson and Clark (1990) have suggested, and it is recommended here that consumption advisories be based on the meal frequency derived from the fish intake rate. For example, if the fish intake rate calculated from Equation 7 is 1 g/day, the corresponding meal frequency is much less than one meal per month (for either 1/4 or 1/2 pound meal sizes). Thus, consumption advice for this species should be "do-not-eat." Further, where the calculated consumption rate is less than one meal per month, regulatory decisions to ban or prohibit the sale or distribution of contaminated fish or shellfish may be appropriate.

This procedure (Equation 7) is also recommended to derive consumption advisories and to take regulatory actions for fish and shellfish contaminated with systemic toxicants (non-carcinogens). In this case, Equation 3, based on the reference dose for individual toxicants should be used to determine the fish intake rate. Meal frequency advice is then generated as in Equation 9. The approaches to advisory development recommended here are similar to the approaches utilized by Minnesota and proposed for utilization by scientists in the Great Lakes basin (regression approach). The approach is simplified only in that it utilizes a single tissue contaminant level instead of a range of levels as utilized by Minnesota. Further discussion of appropriate tissue contaminant concentrations to be utilized in Equations 7 and 3 is presented below.

Since the tissues of many fish species will contain combinations of two or more contaminants, it is recommended that consumption advice and regulatory actions for contaminated fish and shellfish reflect the health risks associated with exposure to combinations of contaminants. Intake rates for fish contaminated with combinations of non-carcinogens would be developed after Equation 6 (Dourson and Clark 1990) such that:

$$\text{Fish intake (kg/day)} = \frac{RfD_m \text{ (mg/kg/day) X 70 kg}}{TC \text{ (mg/kg)}} \qquad \text{(Eq. 6)}$$

where,

$$RfD_m = TC/\sum E_i/RfD_i \qquad \text{(Eq. 5)}$$

where TC is total contaminant load in fish flesh, RfD_m is the mixtures reference dose for the same target organ, E_i is the fish tissue concentration (mg/kg) for contaminant i and RfD_i is the reference dose for contaminant i for the same target organ. The fish intake value can then be converted to a meal frequency based again on assumptions of average meal size as described above.

These equations can be modified to calculate the intake rate for combinations of carcinogens as follows:

$$\text{Fish intake (kg/day)} = \frac{RAI_m \text{ (mg/kg/day) X 70 kg}}{TC \text{ (mg/kg)}} \qquad \text{(Eq. 10)}$$

where RAI_m = Risk Associated Intake for the mixture of carcinogens, defined as the intake in kg/day that would not result in exceedence of the acceptable cancer risk level for a

combination of contaminants, assuming risk additivity, and calculated as:

$$RAI_m = TC/\sum E_i/RAI_i \qquad \text{(Eq. 11)}$$

where TC is total contaminant load in fish flesh, RAI_m is the risk associated intake for the mixture, E_i is the fish tissue concentration (mg/kg) for contaminant i and RAI_i is the risk associated intake for contaminant i from Equation 8. The fish intake value can then be converted to a meal frequency based again on assumptions of average meal size as described above.

Sampling Procedures

Perhaps the most important recommendation for sampling fish and shellfish to generate consumption advice or to take regulatory actions is to apply consistent sampling mechanisms throughout the monitoring program. Consistency allows comparisons of data to establish trend information over time with confounding problems associated with different sampling procedures.

The U.S. EPA has proposed guidance for sampling procedures in its draft document on sample collection and preparation for contaminated sport fish. Therefore, only a few recommendations for sample collection and preparation are offered here. First, it is advised that only the edible tissues of finfish be used for analysis of contaminant levels. Samples should be analyzed as skin-on fillets, and sampling conducted

where possible for specific size-classes and species. These procedures are utilized most frequently in states with comprehensive monitoring programs and they result in monitoring of those portions of contaminated finfish most likely to be consumed by the public. It has been the experience in the Great Lakes basin that, even though advice to remove skin from fish prior to cooking is offered, many individuals do not follow this advice; thus, analysis of skin-on fillets may provide the best estimate of potential human exposure to contaminants in sport fish.

Analysis of whole fish may be necessary where a particular species is consumed whole by a sub-population or where wildlife exposure is of concern. In this case, a monitoring program should incorporate collection of additional samples of fish species for whole sample analysis.

It is generally recommended that composite sampling be avoided and that samples from individual fish and shellfish be analyzed. Such analysis allows assessment of the variation that may occur in tissue contaminant levels between species, within a species, and size classes of species. Analysis of variation is necessary to determine whether species- or size class-specific statistical differences exist between contaminant types and levels. However, the U.S. EPA in its draft guidance document on fish sampling and analysis recommends analysis of composite samples from fillets of ten fish, although separate composite samples are recommended for all subgroups (e.g. size or age

classes, sex, etc.). The choice for composite or individual sample analysis will depend upon the available resources to conduct the analysis. Composite analysis, although it eliminates some information, may be desirable as it reduces the number of samples that must be analyzed, thus reducing costs associated with analysis. Regardless of whether individual or composite analysis is conducted, it is recommended that replicate samples be collected as part of the field QA/QC program. The U.S. EPA has developed recommendations on the number of replicate samples that should be collected.

The average tissue concentration of contaminants should be utilized to determine whether to issue a consumption advisory for a species or size-class of sport fish species. It is recommended that the mean tissue concentration for a species or size-class be used to determine consumption advisories in equations 3 - 7, 10, and 11 of this report. The U.S. EPA has developed recommendations for statistical analysis of tissue concentrations associated with specific consumption advice (or trigger levels) in its draft guidance document on fish sampling and analysis. These recommendations should be followed as advisories and regulatory actions are developed for contaminated fish and shellfish.

Where a of range of size classes of a particular species of finfish may be consumed, analysis of the relationship between size class and contaminant level is necessary. Such analysis should be conducted with appropriate statistical procedures,

usually linear regression models. Where the mean tissue concentration is significantly different between size classes, consumption advice can then be issued on a size-class specific basis.

Removing an Advisory and Retesting Contaminant Species

It will be useful to New Jersey to determine where and how often to retest sites for fish and shellfish contamination, particularly where all sites cannot be retested yearly or more frequently. The procedures of Ontario appear adequate to determine retesting protocols. Areas where contaminant levels for pollutants are elevated or change substantially should be retested every one to three years. Areas which show no signs of substantial changes in contaminant levels but are popular finfish or shell fish harvesting sites should be retested at least every five years. All other areas, including relatively remote locations with no major sources of pollution nearby and no indication of changing contaminant levels in fish or shellfish should be retested at least every ten years.

The State of New Jersey should also consider mechanisms to remove a consumption advisory or remove bans on sale or distribution of fish and shellfish as contaminant levels warrant. The procedures of Missouri appear useful to determine where and when to remove consumption advisories. Generally, this mechanism requires consistent reduction in contaminants over time to levels that can be confirmed statistically to be below concentrations of

concern. For example, advice for no-consumption may be lifted after two subsequent years where tissue levels are such that a consumption advisory is not necessary (fish are safe for unlimited consumption). Lifting of less stringent advisories may require one year of subsequent no-consumption advice.

Advice for Preparation and Cooking

Some preparation techniques reduce the contaminant burden in finfish by a considerable amount (up to 50%), although not all contaminant concentrations are reduced by all preparation techniques. Cooking techniques, however, do not appear to significantly reduce potential exposure levels. Therefore, it is recommended that consumption advisories in New Jersey be accompanied by advice to prepare finfish appropriately to remove the greatest number and amounts of chemicals possible.

Such advice may be stated as follows:

> You can significantly reduce the level of PCBs and most pesticides (but not mercury) by properly cleaning, trimming and skinning your catch. Therefore, you should trim all the fat from four key areas: the belly flap, lateral line, along the backbone, and adjacent to the skin. Also, remove the skin from your fish prior to cooking it.

This language is derived from a statement prepared and utilized by the Great Lakes states. It should accompany any consumption advisory and should also include a picture demonstrating the four key areas and appropriate removal techniques. Advice on cooking to remove contaminants is likely

not appropriate for shellfish, although data are not available to address whether any preparation or cooking techniques reduce chemical contaminant levels in shellfish.

Other Recommendations

PCBs are one of the most common contaminants in fish and shellfish. Traditionally, PCB contamination has been assessed through analysis of the technical PCB formulations Aroclor 1242, 1254, and 1260. These formulations consist of multiple PCB congeners which contribute differentially to the toxicity of the mixture. Unfortunately, the toxicity of PCB has been determined from the toxicity of the Aroclor mixtures, particularly for carcinogenecity. Thus, analysis of tissue contaminant levels in fish and shellfish, and consumption advice based on that analysis, will require Aroclor specific monitoring. However, work has begun to focus on the toxicity of individual PCB congeners; thus, some states, particularly in the Great Lakes basin, are monitoring PCBs in fish and shellfish on a congener-specific basis. However, consumption advice is not yet generated from congener-specific analyses as the toxicologic information available for PCB congeners is not sufficient to develop conclusions on the human health impacts of specific PCB congeners.

New Jersey toxicologists should follow developments in congener-specific PCB toxicology. Appropriate modifications to fish and shellfish monitoring programs, and development of

consumption advice based on these modifications should be developed as understanding of the human health impacts of exposure to specific PCB congeners increases.

SECTION VI

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