8 Conclusions and Research Needs

8.1 Overall Conclusions and Research Needs

This document has outlined an approach to evaluate the potential health benefits of consuming fish against the potential health risks of eating contaminated fish. Some evidence exists for an association between decreased risk of CHD or MI, and consumption of small amounts of fish, including mainly lean (non-fatty) fish. Additional studies have seen some association between eating fish and reduced risk of stroke and arthritis, and enhanced immunological and nervous system development. These data, along with the superior nutritional value of fish, are strong enough that public health officials routinely encourage the public to eat more fish.

Consuming uncontaminated fish (or at least fish that are smaller, younger, or in general less contaminated) may provide health benefits as mentioned above, but without the potential health risks associated with contamination. Before eating any contaminated fish, consumers should consider fish supplies from cleaner water bodies, eating smaller, less contaminated fish, and cooking and cleaning methods that reduce contaminants. The eating of such “cleaner” fish rather than more contaminated fish would maximize the net benefit of fish consumption. This is shown specifically in Figures 6-6 to 6-16 for low versus high concentrations of chemicals in fish, for those chemicals that bioaccumulate, or for fish contaminated with more that one chemical.

When alternatives to the eating of contaminated fish are not available or desired, it may be appropriate to weigh the risks of eating less of these contaminated fish with the benefits gained from eating more of these same fish. The framework developed here can crudely compare these risks and benefits. However, this framework has a number of significant data gaps. These gaps are sufficiently large so as to prevent any definitive conclusions from this study or any overall recommendations regarding existing fish consumption advisory programs of the U.S. or other countries. Further study is needed to confirm and extend these preliminary findings.

This framework is an initial attempt to evaluate risks and benefits (both qualitatively and quantitatively) on a common scale. Constructing this framework has identified numerous areas that need further research and development. Two needs seem paramount. First, better estimations of benefits are needed for the general population and its sensitive subgroups. Although information in this text is highly suggestive of the protective effects of eating fish and allows some quantification, more definitive work is needed to support the quantitative values shown in Table 6-1. Second, better risk information is needed on the chemicals that commonly contaminate fish. Indeed, we already have sufficient knowledge on the toxicity of most of these pollutants that quantifying risks above the RfD can be done. This information is essential for this framework, or any other construct, to be effective.

Specific conclusions and research needs on each technical chapter are summarized below.

8.2 Chapter 2

Some evidence exists for an association between decreased risk of CHD or MI, reduced risk of stroke and arthritis, enhanced immunological and nervous system development, and consumption of small amounts of fish, including mainly lean (non-fatty) fish. However, it seems unlikely that decades-long intake of small amounts of fish protect, if fish is indeed etiologically protective, via the very small amounts of omega-3 long-chain polyunsaturated fatty acids so ingested. The resolution of this issue has important implications for public health and nutritional recommendations. Thus, further studies -- observational and interventions, particularly clinical trials -- are needed to resolve whether there is an etiologically significant protection against CHD or MI afforded by regular ingestion of modest amounts of fish. Similarly, more research is needed on the relationship of fish intake and health endpoints other than CHD or MI.

Data gaps and research needed on the benefits of fish consumption include:

- More understanding is needed on the benefits of consuming fish and why consuming fish provides these benefits. For example, is it the n-3 FAs? Selenium or some other mineral? Substitution for other less healthful foods? Or another mechanism or combination of factors yet to be determined?

- Numerous epidemiological studies have been conducted which provide some evidence for an association between consuming fish and reduced risk of coronary heart disease, stroke and arthritis. More research is needed in this area and on the other possible beneficial effects of fish consumption. More long-term studies and randomized controlled clinical trials are needed.

- Studies are needed on groups of people who consume more fish than the national average. These people are at most risk due to their high consumption, but the existing epidemiology studies have not included groups with high rates of consumption. Do the potential benefits increase with increases in consumption, or is there a point at which benefits plateau at some consumption rate? Are there health detriments to even higher consumption of fish?

- The information used in this report on the change in specific health effects with consuming fish was limited to studies primarily in adults and for only three health endpoints. Additional studies on the benefits of fish consumption should be encouraged. Every effort should be made to ascertain quantitative information on the benefits of fish consumption to pregnant women, infants and young children, as well as health impacts of larger consumption rates.

8.3 Chapter 3

Fish is high-quality protein that the public should be encouraged to eat. There are many nutritional benefits associated with eating fish, regardless of the species type. Unlike red meats, eggs and dairy products, fish provides very high quality protein *and* a "heart healthy" combination of fatty acids. Further, fish (both lean and fatty) is one of the few foods that contain n-3 (omega-3) fatty acids, a class of fatty acids that are essential for the development of the nervous system and that may have other beneficial health effects. Calcium, iron, zinc, vitamin A, niacin, vitamin B6, and vitamin D tend to be low in U.S. diets; fish supplies all of these vitamins and minerals, in addition to others.

Data gaps and research needed on the nutritional aspects of fish consumption include:

- Fish is known to be a good dietary source of selenium, but few reference data are published; more research into the role of selenium in human health is also needed.

- Nutrient databases contain a wide range of fish species, but samples used to obtain nutrient values are composites of cooked fish from various unknown locations.

- Nutrient values are generally expressed on the basis of a 100 gram cooked fish portion. This limits the extent to which comparisons can be made with contaminant data, which are usually based on raw tissue samples of wild fish gathered from specific geographic areas, and expressed as concentrations rather than on a weight basis.

- Different methods of preparing and cooking fish will alter some of the organochlorine contaminant levels. Ideally, the same samples of prepared and cooked fish would be sent for both contaminant and nutrient analysis, and weighed records of amounts of the fish consumed would be kept to enable researchers to better assess the physiological risks and benefits to humans.

- A comparison of the nutritional and contaminant contents of protein sources other than fish would be ideal, since it would give information on the benefits and risks of other protein sources. This would allow one to make risk to risk comparisons with fish substitutions. See Figure 6-3 for a hypothetical discussion of this issue.

8.4 Chapter 4

The risks of consuming fish with chemical contaminants are not completely understood. However, information for the six chemicals selected for this document was available on EPA's IRIS (U.S. EPA, 1999). The majority of this information was of medium confidence, which means that additional toxicity data may change the resulting risk values somewhat. For most compounds, this risk information was based on data from laboratory animal studies (methylmercury and chlorpyrifos were the exceptions). These results must be extrapolated to humans with considerable uncertainties involved, but the methods used for this extrapolation are widely accepted as health protective.

This framework requires an understanding of potential health risks at doses above those that are considered "safe" or at a threshold for toxicity. Traditional cancer risk methods have provided risk assessors with extrapolation to levels of environmental concern. While these estimates are uncertain, they are generally regarded as falling on the side of being health protective. The method that was chosen to estimate risks above the RfD is more recently developed and while is designed to also be health protective, it has not been widely tested. It has the advantage of ease of use with existing EPA information from IRIS.

Concordance of effects between laboratory animals and humans is not generally known. Therefore, the critical effects driving the risk estimates derived from laboratory animal data may not necessarily be the effects one would see in humans. However, the framework is flexible and could be used with information on the non-critical effects of these same chemicals to further refine the overall risk estimates.

Data gaps and research needed on the potential risks from fish consumption include:

- One of EPA's methods for calculating risk above the RfD was used here (Price et al., 1997). This method is new and needs further exploration. It has the advantages of being more generally applicable than categorical regression or benchmark dose, and is less resource intensive. It can be used directly from the existing data as on EPA's IRIS. However, it is not the only approach to the problem of risk above the RfD, and as demonstrated, the method does not work for all chemicals.

- For the framework to be most useful, noncancer risks above the RfD must be estimated for all significant critical effects of chemicals that contaminate fish, in particular, for the contaminant PCBs. For example, the case study of the Vietnamese immigrant women consuming Lake Ontario sportfish was severely hampered by the inability to estimate the risks above the RfD for PCBs (Figure 6-24). Some exceedances of the PCB RfD were as much as 40-fold. Other chemicals need similar investigation.

- RfDs are designed to be protective for all adverse effects based on the data for the critical effect. When doses exceed the RfD, as the framework assumes they could, then the critical effect may begin to manifest itself in the exposed population. The framework uses dose-response information on the critical effect to predict the increased incidence of the critical effect. But in addition to the critical effect, other effects may also be seen at higher doses. Some of these *non-critical effects* may be more severe than the critical effect (e.g., reduced body weight versus liver toxicity). At present, EPA has not developed dose-response relationships for non-critical effects in humans. For the framework to fully characterize potential risks, and the net health benefit of eating contaminated fish, dose-response relationships for non-critical effects should also be developed.

8.5 Chapter 5

The benefits of catching and eating fish can go beyond the nutritional value and potential reduced risk of certain diseases. For some subgroups such as tribes it may be important to consider the social, religious and cultural importance of fish to that society. Economic impacts might also be considered for this and other groups. Among isolated and/or lower-income groups, fish may represent an important economic resource, and a source of needed high-quality protein, that is not easily replaced. In such communities, advisories designed to limit consumption of fish may have unforeseen detrimental socio-cultural impacts. These potential consequences need to be considered when assessing the risk and benefits of fish consumption.

Data gaps and research needed on the cultural aspects of fish consumption include:

- A scale to measure these impacts and benefits should be developed which can be directly compared to those used to measure health risk and benefits. Several approaches might be considered, including normalized scales being developed for use with tribal communities (e.g., Harper, 1999). The affected individual or group should determine the magnitude of the modification.

- More quantitative information needs to be amassed on specific consumption behaviors of population groups for whom fish is important, with the aim of more productively combining socio-cultural data with biological data in developing risk assessments and consequent risk management strategies.

- More research is needed on environmental justice with fish consumption, and on the relationship between fish consumption and group sovereignty, especially in regard to Native American communities.

8.6 Chapter 6

The current version of the framework represents a significant step forward over the way risks and benefits of eating fish have been addressed in the past. However, future work should further explore several important aspects of the framework. A number of conclusions and recommendations for additional work are listed below.

- Incorporate full range of benefits data. The examples of benefits that are presented in the framework are representative based on the available data. However, they do not incorporate the entire quantitative benefits data (see Table 2-1). At a minimum, all the data sets supporting, or contradicting, the existence of a particular health benefit should be further summarized and discussed, and data should be presented for any endpoint having quantitative benefits information. A meta-analysis might be considered for each endpoint supported by more than one data set. This might allow the development of a single dose-response curve for each health endpoint. Such single dose-response benefit curves would make the framework easier to use.

- Severity Schemes. For this framework, the severity approach of EPA and ATSDR for estimating RfDs/RfCs and MRLs (Table 6-2) was used to modify the health risks associated with chemical exposure. This approach has the advantages of simplicity, familiarity and consistency with the use of information from EPA's IRIS, and of ATSDR information found in its toxicological profiles. One shortcoming of this approach is the implied equal spacing between levels. There is no scientific or mathematical justification proposed for a FEL being considered three times as "severe" as a less serious LOAEL. Other caveats were discussed in chapter 6 (see Table 6-3).

  In like fashion, a modifier to the magnitude of health benefits accrued from eating fish was used to roughly compare with the risk of different health endpoints. This modifier of health benefits (e.g., coronary heart disease avoided) was ranked as none, minimal, moderate or maximum. This modifier has the advantages of simplicity and consistency with the use of information for health risks. As for health risks, however, the scheme for health benefits is being used in a quantitative fashion in the framework, and this results in several shortcomings which were discussed in Chapter 6 (see Table 6-3).

Other severity schemes should be explored for comparing the health risks and benefits of fish consumption. The results are likely to be more complex, however. Several of these schemes will necessitate additional judgment regarding the appropriate severity level of both the critical effect and benefit. At least one of these schemes (i.e., Ponce et al., 1998) also incorporates the concept of duration of the effect or benefit through the use of QALYs. Every attempt should be made to see if these more complex severity schemes add value when compared to the simpler one, which was used here.

- Explicitly incorporate uncertainty. It is important to recognize that with the exception of noncancer risks (see Figures 4-1 and 4-2), uncertainty in health benefits and risks is not dealt with explicitly by the framework in its current version. Moreover, the uncertainty surrounding the estimates of the different benefits and risks associated with eating fish are unlikely to be the same. For example, the uncertainty surrounding estimated cancer risks based on animal toxicity data is likely much greater than the uncertainty surrounding estimated coronary heart disease benefits based on human data.

  An important future refinement of the framework would be explicit consideration and quantification of uncertainty surrounding estimates of potential health risk and benefit, because both have the potential to alter the interpretation of the framework and the resulting FCI.

- Conduct a sensitivity analysis. The current version of the framework uses fixed inputs for most of the variables that determine potential risk, potential benefits and the FCI. Such fixed information helped develop the framework and also allowed for exploration of a number of issues associated with its use. However, many of these fixed parameters can and do vary, and additional work is needed to investigate how the FCI changes when these parameters are changed. Such a sensitivity analysis would greatly improve interpretation of the framework results and perhaps help focus future work on the input variables that have the greatest potential to affect the FCI.

- Evaluation of additional mixtures of chemicals. The framework and case studies used only a few chemicals and concentrations to examine the relationship between potential risks and benefits of eating contaminated fish. While the choice of these chemicals reflected the frequency of residues and number of fish consumption advisories (Table 4-1), other chemicals are also found in fish. While the analysis of a limited number of chemicals is useful for the development of the framework and its application, the choice of concentrations could perhaps better reflect those typically observed in waters of the U.S (the example concentrations presented here were much higher than average). Based upon comments from the Advisory Committee, methylmercury, PCBs and dioxin are the chemicals for which advisories are most commonly needed and typical high concentrations might vary between 0.2 and 1 mg/kg for methylmercury and PCBs, and be around 1 ng/kg for dioxin toxic equivalents.

- Risk curves for non-sensitive groups. For health risks, specific risk curves for non-sensitive members of the population could also be developed. This would avoid matching the health risk for the sensitive individual with the health benefit to the average individual. For example, with methylmercury the risk curve is based on risk to the infant and fetus, whereas the benefit curve was for the adult. Use of an adult risk curve would have changed the conclusions of the Florida Everglades case study.

8.7 Chapter 7

A strong communication program is needed to best implement use of the framework and approach outlined in this document. This approach can provide individuals and groups (communities, states or tribes) the ability to describe and analyze tradeoffs between benefits and risks. Ultimately, however, no approach will be successful if it cannot be understood and applied by the audiences for which it is intended. Therefore research is needed with at-risk populations (e.g., tribes with potentially heavy fish consumption, women of childbearing age, fish-eating families with children), to identify their information needs. This is an iterative development of communication approaches and content, with communicators and target audiences working in partnership.

A key to the approach proposed in this document is research-based evaluation. Since no approach will be successful if it cannot be understood and applied by the audiences for which it is intended, both formative and summative evaluation research efforts are needed.

- Formative evaluation research would include working with the target audiences to identify their information needs. Ideally, formative evaluation begins with in-depth, qualitative analysis of information needs and the range of potential responses to and concerns about various types of information. Focus groups and other interactive forums often provide the best mechanism for this stage of research. Formative evaluation continues with iterative development of communication approaches and content, with communicators and target audiences working in partnership.

- Summative evaluation, an empirical assessment of the impact of the communication process, is a critical research need to assess the efficacy of the FCI approach. Summative evaluation is often hypothesis-based. For example, possible hypotheses related to use of the FCI include:

  H_1: Availability of health benefit/risk comparison information via the FCI will be related to increased confidence of fish consumers that they are making an informed decision about fish consumption;

  H_2: Increased information provided to fish consumers through the FCI will lead to improved compliance with health advisory recommendations.

Summative evaluation assesses the extent to which program objectives were achieved. Thus, achievement of the objectives of health advisory programs using the FCI should be evaluated systematically, both before implementing FCI, and after. Collecting baseline data is critical to evaluating the impact of new risk management and communication programs.

8.8 Final Comment

The need to consider the health and nutritional benefits of fish consumption has long been recognized when crafting public policy regarding people eating fish contaminated with low levels of chemicals. Due in part to this well-defined need, the purpose of this research was to develop an understanding and framework by which to evaluate the comparative risks posed by dietary changes as a result of fish consumption advisories. We have been partially successful in this endeavor. This research should lead to a better understanding of the health benefits and health risks of fish consumption, although further work is needed before the framework that we suggest can be generally useful. We anticipate that public health officials and consumers will use this increased understanding to evaluate a broader range of dietary information before making decisions about this important resource.

8.9 References

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