Comparative Dietary Risks:
Balancing the Risks and Benefits of Fish Consumption

Results of a Cooperative Agreement between

The U.S. Environmental Protection Agency

and

Toxicology Excellence for Risk Assessment (*TERA*)

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List of Abbreviations

AA	Arachidonic Acid
ADI	Allowable Daily Intake
AFS	American Fisheries Society
AOC	Areas of Concern
ARIC	Arteriosclerosis Risk in Communities
AR	Attributable Risk
ATSDR	Agency for Toxic Substances and Disease Registry
ChE	Cholinesterase
CSF	Cancer Slope Factor
B_i	Background incidence of health endpoint i
BMD	Benchmark Dose
BMDL	Lower confidence limit on a benchmark dose
$BMDL_{10}$	Lower bound on dose corresponding to 10% risk (used to be explicit that the lower bound and not the maximum likelihood estimate is being used)
BMI	Body Mass Index
BMR	Benchmark Response
BW	Body Weight
CHD	Coronary Heart Disease
CNS	Central Nervous System
COPD	Chronic Obstructive Pulmonary Disease
CSF	Cancer Slope Factor
CSFII	Continuing Survey of Food Intakes by Individuals
DHA	Docosahexanoic Acid
DL	Detection Limit
ECG	Electrocardiogram
ED	Effective Dose
EPA	Eicosapentanoic Acid
EPA	Environmental Protection Agency
FA	Fatty Acid
Trans-FA	Trans-fatty Acid
FCI	Fish Consumption Index
FDA	Food and Drug Administration
FEL	Frank Effect Level
FEV	Forced Expiratory Volume
FVC	Forced Vital Capacity
HDL	High Density Lipoprotein
HHP	Honolulu Heart Program
HI	Hazard Index
IRIS	Integrated Risk Information System
LDL	Low Density Lipoprotein
LOAEL	Lowest Observed Adverse Effect Level
MeHg	Methylmercury
MI	Myocardial Infarction
MOE	Margin of Exposure

MRL	Minimal Risk Level
NEJM	New England Journal of Medicine
NIDDM	Non-insulin-dependent diabetes mellitus
NTP	National Toxicology Program
NOAEL	No Observed Adverse Effect Level
NOEL	No Observed Effect Level
PAH(s)	Polyaromatic Hydrocarbon(s)
PCB(s)	Polychlorinated Biphenyl(s)
PCDD(s)	Polychlorinated dibenzodioxin(s)
PCDF(s)	Polychlorinated dibenzofurans(s)
ppm	Parts Per Million
PUFA	Polyunsaturated Fatty Acid
QALY	Quality Adjusted Life Years
R	Risk
RQ	Reportable Quantity
RR	Relative Risk
RR_i	Relative Risk of health endpoint i at a given consumption rate
RfC	Reference Concentration
RfD	Reference Dose
RSD	Risk Specific Dose
S	Severity
S_i	Severity of health endpoint i
SFA	Saturated Fatty Acid
UF	Uncertainty factor
WHO	World Health Organization

Foreword

This document is the result of a cooperative agreement between Toxicology Excellence for Risk Assessment (*TERA*) and the U.S. Environmental Protection Agency (U.S. EPA), Office of Water. *TERA* formed a Research Team of scientists to collectively develop knowledge of problems regarding assessing health risks and benefits posed by consumption of chemically contaminated fish and determine a method to evaluate both risks and benefits together. The final outcome of this cooperative agreement is this report, which summarizes what is known about health risks from consumption of contaminated fish, health benefits from consuming fish, and general problems associated with comparisons of these risks and benefits. Moreover, this report proposes a framework for comparing the health benefits and health risks in a quantitative fashion.

The results of this research are intended to lead to a better understanding of the relative health risks and benefits of consumption of contaminated fish. The authors of this report anticipate that the proposed framework will be used by local risk managers and fish consumers to further evaluate health benefits, health risks and other dietary information on contaminated fish. Furthermore, states and tribes may use the results of this or subsequent work in assessing local conditions and developing policies towards site-specific fish consumption advisories. An Advisory Committee of state, local, tribal, industry and environmental scientists provided input during the course of this research on the design and use of the framework. This Advisory Committee reviewed a draft of this document and suggested improvements.

Funding for this work was provided by the U.S. EPA under Cooperative Agreement number CX825499-01-0 and by *TERA*. Mr. Jeffrey Bigler of the U.S. EPA Office of Water was the Project Officer. Although the information in this document has been funded in large part by the United States Environmental Protection Agency, it does not necessarily reflect the views of the Agency and no official endorsement should be inferred.

We would welcome your comments on this document. Please contact Toxicology Excellence for Risk Assessment (*TERA*) at 513-542-7475 (RISK), or tera@tera.org (e-mail).

Authors and Contributors

To conduct this research and write this document, Toxicology Excellence for Risk Assessment (*TERA*) formed a Research Team of scientists from a number of key disciplines, including risk assessment, nutrition science, environmental anthropology, medicine and public health, risk communication and toxicology. The Research Team members each contributed knowledge and inspiration from their respective fields to write or contribute to specific chapters, as well as collaborate on the quantitative framework outline.

Authors and Research Team

Paul D. Anderson, Ph.D. (Chapter 6)
Ogden Environmental and Energy Services, Westford, MA

Daniel Cartledge, Ph.D. (Chapter 5)
Monmouth College, Department of Sociology and Anthropology, Monmouth, IL

Martha Daviglus, M.D. (Chapter 2)
Northwestern University Medical School, Department of Preventive Medicine, Chicago, IL

Michael Dourson, Ph.D. (Chapters 4, 6 and 8)
Toxicology Excellence for Risk Assessment, Cincinnati, OH

Barbara A. Knuth, Ph.D. (Chapter 7)
Cornell University, Department of Natural Resources, Ithaca, NY

Elaine Murkin, M.Sc., (Chapters 2, 3 and 6)
University of Guelph, Division of Applied Human Nutrition, Guelph, Ontario, Canada

Jacqueline Patterson, M.En. (Chapters 1 and 8)
Toxicology Excellence for Risk Assessment, Cincinnati, OH

Paul Price, M.S. (Chapter 4)
Ogden Environmental and Energy Services, Portland, ME

Judy Sheeshka, Ph.D. (Chapters 2, 3 and 6)
University of Guelph, Division of Applied Human Nutrition, Guelph, Ontario, Canada

Jerry Stober, Ph.D.
U.S. Environmental Protection Agency EPA, Athens, GA

Jason Unrine, B.S. (Chapter 4 and 6)
Toxicology Excellence for Risk Assessment, Cincinnati, OH

Contributors (Advisory Committee)

An Advisory Committee was formed in 1997 at the beginning of this project to provide advice and assistance to *TERA* and the Research Team by identifying target and countervailing risks, suggesting case study ideas and providing comments on the practicality and usefulness of the framework. The Advisory Committee met in February 1999 to review a draft of this document. The Committee members provided many helpful and constructive suggestions for revisions; many of which are reflected in the final document. *TERA* and the Research Team greatly appreciated the input and suggestions of the Advisory Committee. Their comments have significantly strengthened this document.

Henry Anderson, M.D.
Bureau of Public Health, State of Wisconsin, Madison, Wisconsin

Michael Bolger, Ph.D.
Food and Drug Administration, Washington, D.C.

J. Milton Clark, Ph.D.
U.S. Environmental Protection Agency, Region 5, Chicago, Illinois

John Festa, Ph.D.
American Forestry Products Association, Washington, D.C.

Kory Groetsch, M.S.
Great Lakes Indian Fish & Wildlife Commission, Odanah, Wisconsin

Neil Kmiecik, M.S.
Great Lakes Indian Fish & Wildlife Commission, Odanah, Wisconsin

Amy Kyle, Ph.D.
School of Public Health, University of California
& Natural Resources Defense Council, San Francisco, California

Randall Manning, Ph.D.
Department of Natural Resources, State of Georgia, Athens, Georgia

Gerald Pollock, Ph.D.
California Environmental Protection Agency, Sacramento, California

Edward Ohanian, Ph.D.
U.S. Environmental Protection Agency, Washington, D.C.

Andy Smith, Ph.D.
Bureau of Health, State of Maine, Augusta, Maine

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Executive Summary

A comparative dietary risk framework (hereafter referred to as the framework) has been developed under this Cooperative Agreement for comparing the possible health risks of consuming contaminated fish, while considering the potential health benefits lost by not eating fish. The result of using the framework is a crude quantitative representation of the risk and benefit associated with eating contaminated fish. The output of the framework is referred to as the fish consumption index (FCI).

The FCI is an estimate of relative risk. It is not an estimate of absolute risk. In other words, it does not provide users of the framework with an estimate of their increased or decreased incidence of a particular health outcome. It simply provides a mechanism by which users can weigh the possible health risks versus the possible health benefits of eating contaminated fish. Cultural benefits of catching and eating fish (or detriments of not being able to fish or consume fish) may also be considered, however the current version of the framework does not attempt to quantify these benefits.

Before considering risks and benefits, a determination should be made that alternatives to contaminated fish are not available. Perhaps lower contaminated fish sources are available sufficient to maintain the individual's desired level of fish consumption. Situations where the weighing of benefits and risks may be necessary may include subsistence populations where alternatives to contaminated locally caught fish are limited.

The framework is designed to provide information for a range of fish consumption rates, allowing a user to roughly estimate the range of consumption rates at which people may have a net benefit, a net risk, and the consumption rate at which no net change in the health index would be likely. However, the suggested framework has a number of significant data gaps. These gaps are sufficiently large so as to prevent any definitive conclusions. Moreover, these gaps prevent making any overall recommendations on the existing fish consumption advisory programs of the U.S. or other countries. Further study is needed to confirm and extend the preliminary findings discussed in this document.

Use of the framework and FCI does not imply the proper choice is simply achieving a situation in which the net risks and benefits are zero. Nor is it a justification for accepting fish consumption risks as long as there is a net benefit. Rather, the framework helps make the risks and benefits transparent. Decisions about acceptable risks and distribution of risks and benefits throughout society should be made collectively by the communities affected, and are not a focus of this text. That the FCI may demonstrate cases in which fish consumption benefits may outweigh the risks is not a license to pollute. Rather, society must determine policy about long-term goals for minimizing environmental pollution based on a range of ethical, economic, social, and other criteria. Again, the purpose of this text is to discuss the underlying scientific issues associated with comparing the risks and benefits of fish consumption. It does not address the social, economic or ethical considerations.

There is some evidence for an association between decreased risk of coronary heart disease (CHD) or myocardial infarction (MI) and consumption of small amounts of fish, including

mainly lean (non-fatty) fish. In addition, other health endpoints have been examined and some research suggests that eating fish may be associated with reduced incidences or severity of a number of other endpoints. This evidence, along with the superior nutritional value of fish, is 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. The eating of such "cleaner" fish rather than more contaminated fish, would maximize the net benefit of fish consumption, as we show specifically for low versus high concentrations of chemicals in fish, for those chemicals that either bioaccumulate or not, or for fish contaminated with more that one chemical.

This framework is an initial attempt to evaluate risks and benefits (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 or modify our chosen quantitative values. Second, better risk information is needed on the chemicals that commonly contaminate fish. Sufficient knowledge on the toxicity of most of these pollutants exists, on which noncancer risks could be quantified. Both sets of information are essential for this framework to be most effective.