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Health Risk From Chemically Contaminated Seafood

"Briefing Paper" & Proceedings from Narragansett Bay

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Narragansett Bay Estuary Program

Current Report

The Narragansett Bay Project

HEALTH RISK FROM CHEMICALLY CONTAMINATED SEAFOOD "BRIEFING PAPER" AND PROCEEDINGS FROM NARRAGANSETT BAY PROJECT MANAGEMENT COMMITTEE

Katrina V. Kipp
EPA Region I

and the staff of the
Narragansett Bay Project

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Recommendations included in this briefing paper represent preliminary decisions reached by the Management Committee and are subject to amendment prior to their incorporation into the Comprehensive Conservation and Management Plan (CCMP).

The Narragansett Bay Project is sponsored by the U.S. Environmental Protection Agency and the R.I. Department of Environmental Management.

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FOREWORD

The United States Congress created the National Estuary Program in 1984, citing its concern for the "health and ecological integrity" of the nation's estuaries and estuarine resources. Narragansett Bay was selected for inclusion in the National Estuary Program in 1984, and the Narragansett Bay Project (NBP) was established in 1985. Narragansett Bay was designated an "estuary of national significance" in 1988. Under the joint sponsorship of the U.S. Environmental Protection Agency and the Rhode Island Department of Environmental Management, the NBP's mandate is to direct a program of research and planning focussed on managing Narragansett Bay and its resources for future generations.

The NBP will develop a draft Comprehensive Conservation and Management Plan (CCMP) by December, 1991, which will recommend actions to improve and protect the Bay and its natural resources.

The NBP has established the following seven priority issues for Narragansett Bay:

- management of fisheries
- nutrients and potential for eutrophication
- impacts of toxic contaminants
- health and abundance of living resources
- health risk to consumers of contaminated seafood
- land-based impacts on water quality
- recreational uses

The NBP is taking an ecosystem/watershed approach to address these problems and has funded research that will help to improve our understanding of various aspects of these priority problems. The Project is also working to expand and coordinate existing programs among federal, state and local agencies, as well as with academic researchers, in order to apply research findings to the practical needs of managing the Bay and improving the environmental quality of its watershed.

The attached report includes a "briefing paper" prepared for consideration by the Management Committee of the Narragansett Bay Project (Section I) and Management Committee Proceedings (Section II). Section II includes a) minutes of the Management Committee meeting(s) where the issues identified in the "briefing paper" were discussed (Appendix A); b) preliminary recommendations endorsed by the Management Committee (Appendix B); and c) Management Committee attendance (Appendix C). The Narragansett Bay Project will subsequently estimate the cost of each preliminary recommendation made by the Management Committee and identify possible funding sources. This information will enable the Management Committee to develop the draft CCMP including priorities for implementation over a five year planning horizon. Upon completion, the draft CCMP will be available for public review and comment.

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HEALTH RISK FROM CHEMICALLY CONTAMINATED SEAFOOD " BRIEFING PAPER "

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"To eat or not to eat, that is the question."

Anonymous

SYNOPSIS

BACKGROUND

Like most urban estuaries, Narragansett Bay has serious problems with contamination of its waters and sediments with toxic pollutants, including metals and organics. A major issue of concern for the Narragansett Bay Project (NBP) is the potential risk to human health from consumption of contaminated seafood. Research has shown that organisms such as fish and shellfish that are exposed to toxics tend to accumulate the compounds in their tissues. In high enough levels, the toxics then pose a threat not only to the fish themselves but also to humans who may catch and eat fish from contaminated areas.

Risk assessment is a scientific tool used by regulatory agencies to evaluate risks from certain activities and to make regulatory risk management decisions to protect human health. A series of risk assessment analyses were conducted using chemical levels measured in Narragansett Bay quahaugs (Mercenaria mercenaria) and winter flounder (Pseudopleuronectes americanus). This assessment provides a measure of the potential risks to humans from exposure to various chemicals through consumption of Narragansett Bay quahaugs and winter flounder.

The results of the risk assessment for quahaugs indicate that the highest potential risks of adverse health effects are associated with Providence River quahaugs and high levels of consumption, due primarily to the organic, oil-based petroleum aromatic hydrocarbons (PAHs) and polychlorinated biphenyls (PCBs), and the metal cadmium. The findings for winter flounder show the highest risks associated with high consumption levels, and due primarily to PCBs and mercury. Risks were similar regardless of where the flounder were harvested, although Providence River flounder exhibited slightly higher risks. In summary, consumption of quahaugs or flounder in very large quantities, or from contaminated areas, results in a greater risk of cancer.

Although estimated risks associated with consumption of Narragansett Bay quahaugs and winter flounder are not high enough to be an immediate health threat, in some cases, estimated risks may be unacceptable. However, these results are not directly applicable to other species due to a variety of factors including different routes and rates of bioaccumulation and varying levels of exposure (consumption).

Currently, bluefish and striped bass are subject to consumption advisories due to PCB levels. This advisory is not limited to Rhode Island; similar advisories have been issued by several states due in part to the migratory nature of bluefish and striped bass. Therefore, this advisory is not reflective of conditions within Narragansett Bay and will not be discussed in detail in this paper.

Chemical contaminants that appear in measurable quantities in foods should always be a concern. The presence of toxics in fish tissue are indicative of contamination of water, sediments, and/or the food source. Until this is addressed through source reduction and other pollution abatement strategies, seafood contamination and the associated potential health threats will remain a problem.

INITIAL DECISIONS NEEDED:

1. Source Control/Source Reduction

ISSUE A: Should the states of Rhode Island and Massachusetts undertake additional activities to reduce the levels of toxics in the tissues of Narragansett Bay and RI fish and shellfish?

2. Risk Assessment/Risk Management

ISSUE A: Should any immediate risk management action be taken to protect human health from consumption of Narragansett Bay and RI seafood based on current information?

ISSUE B: Should the Federal government develop a consistent, coherent national policy on risk assessment and risk management of contaminated seafood and provide guidance to states?

ISSUE C: Should the State of Rhode Island adopt a standard risk assessment protocol, risk management policy, and risk communication program for both commercial and recreational fisheries, and work cooperatively with Massachusetts to ensure a consistent approach to interstate waters?

ISSUE D: Should Massachusetts work cooperatively with Rhode Island to ensure a consistent risk assessment protocol, risk management policy, and risk communication program for fisheries in the Narragansett Bay watershed?

BRIEFING PAPER

HEALTH RISK FROM CHEMICALLY CONTAMINATED SEAFOOD

1. STATEMENT OF THE PROBLEM

A. INTRODUCTION

A major issue of concern for Narragansett Bay and for other coastal areas throughout the United States is the safety of seafood for human consumers. Reports and studies documenting high levels of contamination in seafood, such as EPA's Quincy Bay Study (USEPA, 1988) and the Coast Alliance report (Simon and Hague, 1987), have served to underscore the magnitude of the chemical contamination of coastal waters and the living resources inhabiting them. Accompanying the increasing awareness of the contamination problem is the growing concern by seafood consumers about potential health risks from eating fish and shellfish that may contain toxic chemicals.

A previous briefing paper dealt with the health threats associated with pathogens including bacteria and viruses in shellfish. It should be pointed out that pathogen contamination poses a much more immediate health threat to human consumers. Diseases resulting from these pathogens, such as gastroenteritis, can cause immediate, serious health problems including death. However, adverse health effects associated with toxic contamination of seafood are generally long-term, such as cancer. Cancer risk estimates are generally based on a cumulative lifetime exposure (consumption), while pathogen-related illnesses are caused by a one-time exposure. It is difficult enough to link pathogen-related illness to consumption of shellfish; it is nearly impossible to link health effects that may show up years later to consumption of shellfish or fish that may be chemically contaminated.

Urban estuaries and coastal areas have serious problems with chemically contaminated waters and sediments associated with chronic point and non-point source discharges. Municipal and industrial effluents, combined sewer overflows and stormwater runoff, as well as atmospheric deposition, contribute toxic chemicals to coastal waters. These toxics tend to adsorb to particles that eventually settle to the bottom, resulting in accumulation of the toxics in the sediments. Because bottom-dwelling marine organisms accumulate chemicals from the sediments and water to which they are exposed, and by consuming food that contains toxics, tissue concentrations of contaminants in these organisms tend also to be high. Studies conducted for the Narragansett Bay Project have demonstrated that Narragansett Bay is a typical urban estuary with significant toxic contamination concentrated in the upper Bay in proximity to centers of population. There are also identified, and possibly some as yet unidentified, toxic "hot spots" such as Allen Harbor and Blackstone River impoundments. These areas of highly contaminated sediments may be associated with hazardous waste sites or historical toxic discharges.

In addition, catastrophic or episodic events such as the World Prodigy oil spill are also a concern due to the potential for extensive contamination of local fisheries. Lack of Federal criteria for human consumption for petroleum hydrocarbons in seafood made it difficult for state regulators to determine the necessity for closing fisheries or limiting consumption as a result of the World Prodigy spill.

Commercial fishing is a major industry in Rhode Island. Landings of quahaugs, the most important commercial molluscan shellfish in the state, were 2.5 million pounds in 1989, with a value of $14 million. Flounder (all species) landings in 1988 totalled 10.0 million pounds with a value of $11.5 million. Rhode Islanders' fondness for seafood was substantiated by a survey conducted by Brown University (Brown et al., 1987) for the Narragansett Bay Project. The study found that 84% of Rhode Islanders surveyed regularly consume seafood.

Because of the importance of seafood to the state, early in the Narragansett Bay Project, the Management Committee identified potentially contaminated seafood and associated possible health risks as a priority issue. Specific management questions related to seafood contamination were developed and research was designed to answer these questions. The answers to these questions will allow resource managers and public health officials to most effectively manage the fisheries and reduce potential health risks. The questions posed by the Narragansett Bay Project regarding chemically contaminated seafood were as follows:

- Does Narragansett Bay seafood from approved harvest areas pose a risk to human consumers if consumed in moderate amounts? In large quantities?

- In the event that shellfish beds currently closed due to pathogens may be considered for reopening for harvest, are there areas that should remain closed due to unacceptable risks from chemical contaminants in the quahaugs?

- Are improvements in water quality due to implementation of pollution abatement strategies likely to result in a reduction of tissue contaminant levels and an accompanying reduction in health risk?

- Are current government regulatory programs and risk management efforts effective in protecting consumers from risks associated with contaminated seafood?

To help answer these and other questions, the Narragansett Bay Project funded a number of studies to measure chemical levels in tissues of important commercial and recreational species. Assessments of the potential health risks to consumers of Narragansett Bay quahaugs and winter flounder were conducted using these tissue levels as well as other available data. The purpose of the risk assessment was to provide a framework for evaluating the potential hazards to human health from eating Narragansett Bay seafood. The next step will be to determine the necessary regulatory risk management activities to reduce any unacceptable hazards to protect human health.

The purpose of this briefing paper is to summarize the risk assessment analyses conducted using Narragansett Bay data and present the findings and their implications. Three different studies (Brown et al., 1988 and 1990; Hoffman, 1990; Kipp, in preparation) will be discussed and compared.

Project efforts have focussed on the quahaug and winter flounder, the two most important commercial species in Narragansett Bay, but where available, data on other species were evaluated. The magnitude of health risks to humans from consuming quahaugs and winter flounder from Narragansett Bay were quantified. The effectiveness of current regulatory programs, and the roles of state and federal agencies, in protecting consumers were also evaluated. Finally, alternative risk management strategies for reducing fish contamination and health risk are identified.

B. RESEARCH RESULTS

The Narragansett Bay Project funded several projects to measure the levels of chemical contaminants in important Narragansett Bay species. These projects and the chemicals and species studied are listed in Table 1, along with other studies used in the risk assessment. Thibault/Bubly Associates (1989) and Cullen and King (draft) measured metal levels in the quahaug, Pruell et al. (1988) and Quinn et al. (draft) evaluated levels of organic compounds in quahaugs, and Lee et al. (draft) measured metals and organics in winter flounder. In addition, there exists a variety of data from other studies and other estuaries and for other species.

Analyses of tissue residues of fish and shellfish from Narragansett Bay generally show some correlation between tissue levels and water and sediment levels, with organics and copper more closely correlated with sediment concentrations and other metals more closely correlated with water column concentrations (Quinn et al., draft; Cullen and King, draft). Tissue levels of metals (Thibault/Bubly Associates, 1989; RIDOH, unpublished; Cullen, 1984; Cullen and King, draft) and organics (Pruell et al., 1988; Quinn et al., draft) are highest in the contaminated Providence River, located in the most urbanized area of the watershed. The water, sediment, and tissue concentrations tend to follow a decreasing down-bay gradient with concentrations lowest in the lower bay. Figure 1 shows this down-bay gradient for several metals. This type of pattern is similar to other urban estuaries such as New

Bedford Harbor. More information on these relationships can be found in the Narragansett Bay Project characterization reports on metals (Bender et al., 1989), organics (Quinn, 1989), and PCBs (Latimer, 1989), and the two reports on metals in Narragansett Bay by Nixon (1990a; 1990b).

C. RISK ASSESSMENT METHODOLOGY

Risk assessment is a tool used to determine the magnitude and probability of potential harm to human health by exposure to toxic substances. Risk assessment is based on scientific information combined with certain assumptions.
Although a number of uncertainties exist in this approach, it can be an effective tool for quantifying risks and providing estimates of potential health risks from various sources, in this case from consumption of seafood containing toxic contaminants. It also is used in making regulatory risk management decisions on the appropriate course of action to protect human health. The objective of the risk analysis described in this paper was to evaluate the magnitude of and any health implications of contamination of quahaugs and winter flounder in Narragansett Bay.

The U.S. Environmental Protection Agency (EPA) has developed guidelines for performing risk assessments and has issued a guidance manual, "Assessing Human Health Risks from Chemically Contaminated Fish and Shellfish" (USEPA, 1989), specifically for seafood risk assessment. This manual was the basis for most of the risk assessment analyses for Narragansett Bay. Basically, the risk assessment procedure for seafood consists of determining the dose of a chemical a human would be exposed to during a lifetime based on a certain consumption rate of seafood with observed tissue levels, and predicting the likelihood of adverse health effects from this dose based on EPA toxicity values.

A risk assessment usually consists of the following steps:

1) **hazard identification**

This step involves the identification of the chemicals of concern and the potential health effects that could occur as a result of exposure to those chemicals. Key data sets are identified and the chemicals of concern are selected based on their presence in significant quantities and their known health effects.

2) **exposure assessment**

This step consists of identifying the human populations that may be exposed to the chemicals of concern and estimating the rate of exposure. Both the average (mean exposure level) and maximally exposed (usually the upper 1% or 0.1% of the population representing those persons who would receive the highest exposure) individual are identified and exposure (consumption) rates are determined.

TABLE 1: Data Sets Used in Narragansett Bay Risk Assessment

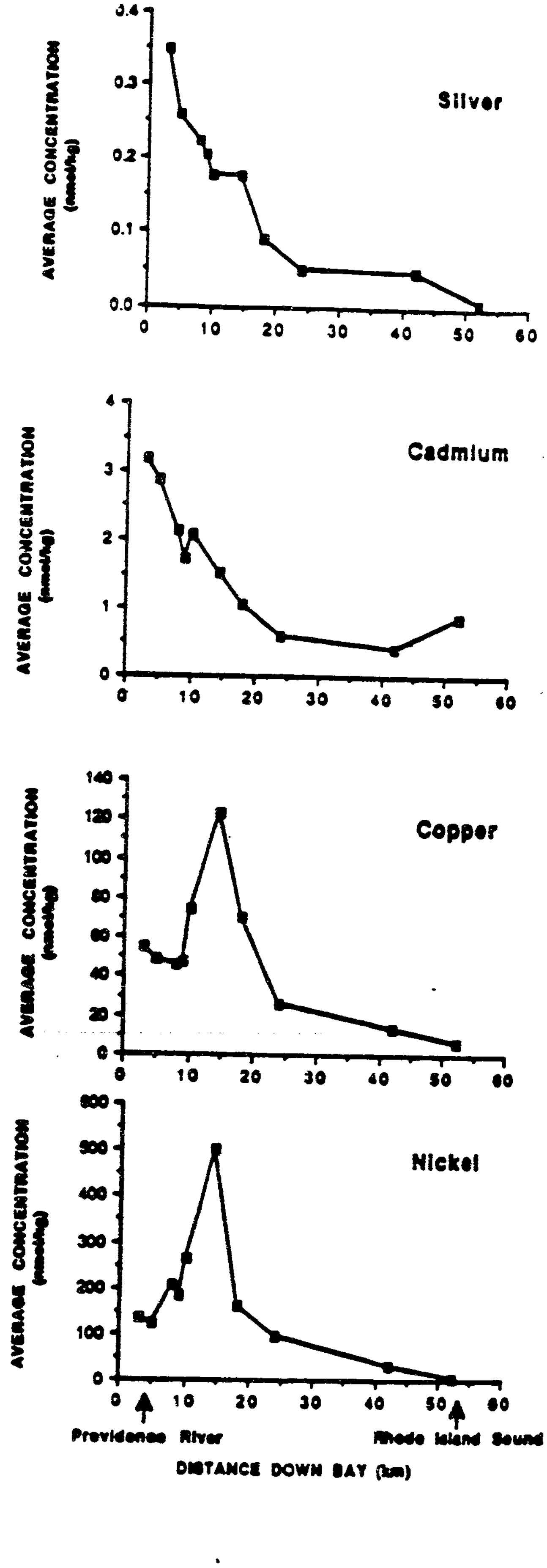
Data Set*	Species	Metals	Organics**
Pruell et al., 1984	Quahaug		PAHs
Pruell et al., 1988***	Quahaug		PAHs; PCBs; Pesticides: HCB, a-HCH,Chlordane, g-HCH (Lindane), DDT, DDD, DDE
Quinn et al., 1989***	Quahaug		PAHs; PCBs; DDE
Cullen, 1984	Quahaug	Copper, Nickel	
Cullen/King, 1990***	Quahaug	Cadmium, Chromium, Copper, Lead, Nickel	
Thibault/Bubly Ass., 1989***	Quahaug	Cadmium, Chromium, Copper, Lead, Mercury, Nickel, Zinc	
RIDOH, unpublished	Quahaug	Cadmium, Chromium, Copper, Lead, Zinc	
Lee et al., 1988***	Winter Flounder	Arsenic, Cadmium, Lead, Mercury	PCBs

* See references for full citation.

** Other chemicals may have been analyzed but were not included in the Narragansett Bay risk analyses.

*** Project funded by the Narragansett Bay Project.

FIGURE 1: BAY DISSOLVED TRACE METAL CONCENTRATIONS
(Bender, et al., 1987)



3) **dose-response assessment**

This is an assessment of the potential toxicological response to various doses of the chemicals of concern, usually based on laboratory animal toxicological tests. The likelihood of adverse human health effects are extrapolated from the animal tests. This information is usually obtained through IRIS, EPA's Integrated Risk Information System, and other sources.

4) **risk characterization**

This is the estimation of the potential risks of adverse health effects based on dose-response data and exposure data. The dose is estimated based on contaminant levels and exposure rate. The dose estimates are combined in the risk assessment model with the dose-response toxicity values to generate upper-bound estimates of the likelihood of potential health effects.

The dose is calculated using the following equation:

$$\frac{C \times CR}{BW} = DOSE$$

Where: C = concentration of contaminant in the fish tissue

CR = consumption rate of human population

BW = average human body weight (70 kg)

Standard assumptions that are made include 1) exposure over a 70 year lifetime, 2) average human body weight of 70kg during the lifetime exposure, and 3) 100% of all chemicals (10% for mercury) ingested are absorbed.

The dose is then combined with dose-response toxicity values (from EPA) to estimate risks. Risk characterization for humans is conducted separately for carcinogens (cancer-causing) and non-carcinogens (non-cancer health effects such as neurological disorders). Generally, organic chemicals such as PAHs, PCBs, and pesticides fall into the carcinogen category and metals into the non-cancer category for oral exposure. Some chemicals are in both categories and therefore, are included in both types of risk assessment.

The risk assessment calculations for carcinogens are based on a linearized multistage model. It is assumed that there is no threshold below which no toxic effects occur. Therefore, any exposure to a carcinogen is associated with some risk. The toxicity value or CPF is a statistically-derived value that attempts to quantify the finite risk of cancer at various doses. The cancer risk estimates are generated using the following equation:

DOSE x CPF = INCREASED CANCER RISK

Where: CPF = cancer potency factor (from EPA)

Increased cancer risks are calculated for each chemical. Carcinogenic risk estimates can then be summed across all chemicals and all species to provide a probability of increased cancer risk from exposure to the chemicals of concern. This approach to additivity does not account for possible antagonistic or synergistic effects of the chemicals.

The carcinogenic risks are expressed in terms of predicted additional cases of cancer in an exposed population over a lifetime as a result of exposure to the chemical(s) of concern (example: 2.7 additional cancer cases in 100,000 individuals = 2.7×10^{-5}).

There is no single level of risk that is considered acceptable. Various EPA regulatory programs define acceptable risk differently, with levels of acceptable risk ranging from a higher level of risk of 1 in 10,000 (10^{-4}) to the more conservative and protective level of 1 in 10,000,000 (10^{-7}), depending on the particular program. Generally, risk estimates less than 10^{-5} are considered acceptable. Determination of an acceptable risk is a risk management decision to made by the responsible regulatory agency (e.g., a state health department). The Rhode Island Department of Health (RIDOH) generally uses 10^{-5} or 10^{-6} as an acceptable risk level for carcinogens. The Massachusetts Department of Public Health (MADPH) has established as policy, an acceptable risk level of 10^{-6}. Any reference to an "acceptable" level of risk in this paper is purely arbitrary; the final determination of what is an acceptable level of risk rests with the state. This is a risk management decision that is made after careful evaluation of the risk assessment results and consideration of economic impacts and social aspects.

Non-carcinogens are assumed to have a threshold below which health effects are not initiated and therefore, individuals can tolerate a low level of exposure with no increased risk of adverse health effects. The estimated highest average daily exposure to humans over a lifetime unlikely to cause adverse health effects is the Reference Dose or RfD. The non-cancer risks are evaluated using the following equation:

$$\frac{\text{DOSE}}{\text{RfD}} = \text{HAZARD RATIO}$$

Where: RfD = reference dose (from EPA)

Because the RfD reflects the "acceptable dose" below which no adverse health effects would be expected, any observed dose below the RfD would be considered acceptable. This means that if the Hazard Ratio is less than 1, the dose is safe. If the Hazard Ratio is 1 or greater, then adverse health effects may be likely, with the likelihood increasing as the Hazard Ratio increases. Similarly to cancer risks, non-cancer risks are considered additive, but only when the chemicals affect the same target organ. The significance of the Hazard Index, the sum of additive Hazard Ratios, is also evaluated by comparison to 1.

A number of conclusions can be made based on the results of a risk assessment. However, the risk assessment methodology has numerous assumptions and uncertainties associated with it and therefore, it should be kept in mind that the risk numbers should be considered estimates of plausible, upper-bound risks that can be used to evaluate the relative hazard associated with exposure to various toxics and routes of exposure. These risks are not to be considered indicative of the actual risks one might experience but are most likely much higher because safety and uncertainty factors are incorporated into the development of toxicity values. The risk assessment methodology used by EPA is purposefully very conservative and this must be kept in mind when evaluating risk management alternatives. On the other hand, the risk estimates are based on consumption rates that may not necessarily represent the population at greatest risk. Rather than the maximum consumer, pregnant and nursing women and children under 12 years may actually be the most sensitive group due to non-carcinogenic reproductive and developmental effects; the risk calculations may not be conservative enough in this case. Studies conducted on women that regularly consumed Great Lakes fish contaminated with PCBs found that their children had significant reproductive and developmental problems (Jacobson et al., 1984).

Some of the assumptions and uncertainties associated with risk assessment may contribute to this potential overestimation of actual risk. These uncertainties may include 1) the validity of the toxicity values; 2) the quality and representativeness of the tissue data; 3) the extrapolation of animal toxicological tests to humans; 4) the assumption that cooking does not change the chemical concentrations; 5) other sources of exposure to the chemicals of concern; 6) variability of the population of human consumers; 7) appropriateness of selected consumption rates; 8) the assumption that all chemicals ingested are absorbed; and 9) that chemical effects are additive. Assuming that chemical effects are additive does not account for possible synergistic or antagonistic effects of chemicals. The assumption that cooking does not change the chemicals may not be accurate for organic compounds.

The risks associated with Narragansett Bay quahaugs and winter flounder have been evaluated for the Narragansett Bay Project to different degrees by Brown et al. (1990 and draft), Hoffman (1990), and Kipp (in preparation). The following sections of this paper will discuss the methodologies used by each investigator and present the results of their studies.

D. RISK ASSESSMENT BY KIPP (IN PREPARATION)

This section will examine the risk assessment analyses recently completed by Kipp (in preparation) for Narragansett Bay quahaugs and winter flounder. This work has been coordinated closely with the RIDOH to ensure that the results are the most useful for their needs. These analyses were based on the EPA guidance for performing risk assessments for contaminated seafood and were the most extensive conducted in terms of number of data sets, chemicals and species included in the evaluation. This work is still in progress and has not yet been peer-reviewed by outside experts; the results should be considered preliminary.

For the hazard identification, eight data sets were identified (Table 1) and compiled into a data base for use in the risk assessment process. Most available data was tissue contaminant levels for quahaugs; only one data set was found for Narragansett Bay winter flounder. The range of tissue concentrations measured in quahaugs and winter flounder from Narragansett Bay, and used in the risk analyses, is shown in Table 2. Also shown in Table 2 for comparison are average metal concentrations in quahaugs from 11 states (Capar, 1986); data for Narragansett Bay quahaugs are not significantly different. The winter flounder tissue concentrations for Narragansett Bay are similar to values obtained for other coastal locations (e.g., coastal Massachusetts, Salem Harbor, Quincy Bay, Buzzards Bay), slightly lower than Boston Harbor, and much lower than New Bedford Harbor (Schwartz, 1987 and 1988; USEPA, 1988). Figure 2 shows the sampling stations for the eight data sets. Some miscellaneous data on soft clams, mussels, oysters and lobster, as well as data from other areas, are also being examined; this tissue data was not included in the risk analysis but these tissue levels can, in a general sense, be compared to the levels used in the risk assessment. Caution must be used in making generalizations about potential risks.

Eight data sets may seem like an excellent data base but there are a number of limitations with the data. Most importantly, as can be seen from Table 1, not all data sets include the same species and chemicals. Four data sets contain data on metals in quahogs, but not all the same chemicals; three data sets contain organic data for quahogs, but not all the same ones; one data set has data for metals and one organic for winter flounder. Only one flounder data set exists which makes it difficult to generalize from the risk assessment results. Clearly, additional sampling of winter flounder is needed. Similarly, not much organic chemical data exists for any species in Narragansett Bay. Secondly, although there were numerous sampling locations throughout the bay, there are still gaps in the coverage and many areas of the bay were not sampled. Outfalls and hot spots were not targeted, and Mount Hope Bay was not sampled near pollution sources. No winter flounder were collected from Mount Hope Bay, but would likely be similar to the rest of Narragansett Bay due to the mobile nature of finfish. The data for each chemical were compared between data sets where possible and most were statistically similar, however, there is some variability between and within data sets. It is impossible to tell if it is due to sampling variability (e.g., seasonal), different analytical techniques or some other factor.

TABLE 2: Range of Mean Concentrations in Edible Tissue from Data Sets Used in Narragansett Bay Risk Assessment (ppm, wet weight).

METALS

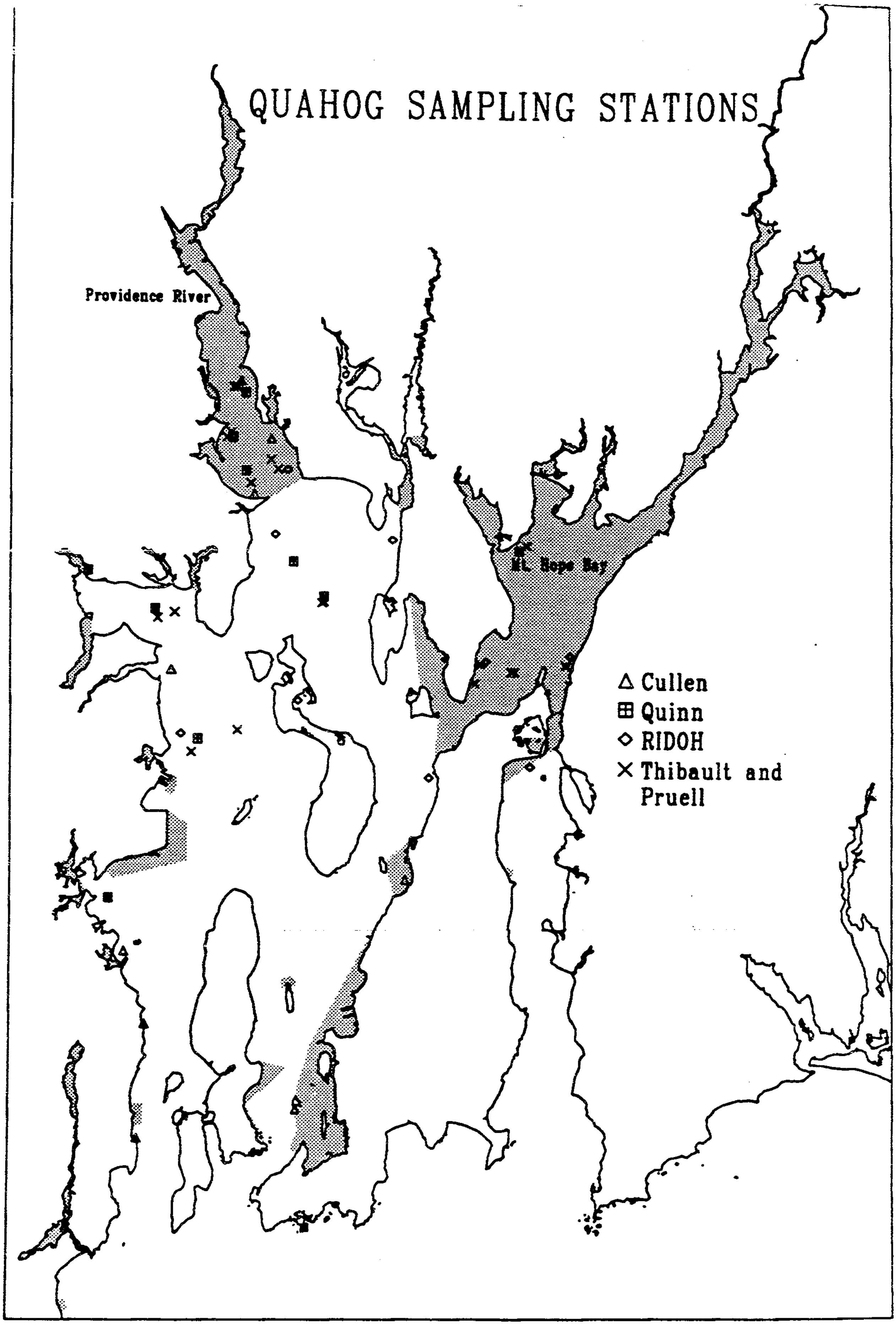
	Arsenic	Cadmium	Chromium	Copper	Lead	Mercury	Nickel	Zinc
QUAHAUGS								
Open areas	-	.096-.223	.107-.508	2.23-4.53	.205-1.48	.023	.902-2.63	18.65-20.99
Providence R.	-	.126-.201	.178-.759	3.26-9.49	.352-1.07	.024	1.39-2.94	23.34-23.57
Mt. Hope Bay	-	.137-.211	.507-.558	2.08-4.27	.407-.822	.055	1.95	18.84-23.96
WINTER FLOUNDER*	.020	.192	-	-	.604	.154	-	-
FDA LEVELS**	-	-	-	-	-	1.00	-	-
11-State Averages***	-	.086	0.40	3.70	0.24	-	1.40	18.00

ORGANICS

	PAHs	PCBs	a-HCH	g-HCH	Chlordane	DDD	DDE	DDT	HCB
QUAHAUGS									
Open areas	.0017-.0235	.0136-.0240	.000066	.000032	.00060	.00035	.00037-.00064	.000020	.000089
Providence R.	.0305-.0438	.0368-.0400	.000054	.000017	.00187	.00047	.00070-.00108	.000023	.000115
Mt. Hope Bay	.0244-.0282	.0159-.0176	.000063	.000030	.00043	.00025	.00053-.00072	.000000	.000083
WINTER FLOUNDER*	-	.183	-	-	-	-	-	-	-
FDA LEVELS**	-	2.0	-	-	0.3	5.0	5.0	5.0	-

* Only legal size flounder (11.5" or longer) included.
** FDA Action Levels or Tolerances for fish tissues.
*** 11-State Averages for metals in quahaugs from Caspar, 1986.

FIGURE 2:


QUAHOG SAMPLING STATIONS
Providence River
Mt. Hope Bay
△ Cullen
⊞ Quinn
◇ RIDOH
× Thibault and Pruell

Of the numerous chemicals measured in species of interest (i.e., quahaugs or winter flounder), several were identified as chemicals of concern (Table 3) and were included in the risk analyses. These chemicals were selected based on their presence in significant quantities in the water column and in sediments in Narragansett Bay and because they are known to cause health effects. Some chemicals were not included because they were either found in extremely low concentrations or no toxicological information was available.

<u>TABLE 3:</u> Chemicals of concern for Narragansett Bay

METALS:	Arsenic
	Cadmium
	Chromium
	Copper
	Lead
	Mercury
	Nickel
	Zinc
ORGANICS:	PAHs (polycyclic aromatic hydrocarbons)
	PCBs (polychlorinated biphenyls)
PESTICIDES:	HCB (hexachlorobenzene)
	alpha-HCH (hexachlorocyclohexane)
	gamma-HCH (Lindane)
	Chlordane
	DDT
	DDD
	DDE

Before the risk analyses were begun, the data were examined and compared to existing FDA alert limits (see p. 28 for discussion of FDA limits) for contaminants in fish. For the chemicals of concern, FDA levels exist for mercury, PCBs, Chlordane, DDT, DDE, and DDD. No sample measured in Narragansett Bay quahaugs exceeded the FDA levels for any chemical. This provides an initial screening that indicates contamination levels are not high enough be an immediate health threat or to cause a fishery advisory or closure for seafood in interstate commerce.

In the exposure assessment, the magnitude and duration of the exposure of humans to the chemicals of concern in Narragansett Bay was determined. Dose estimates were calculated based on site-specific consumption rates and observed tissue concentrations of the chemicals for each species. Consumption rates for Rhode Island were developed based on four national seafood consumption surveys summarized by Hu (1985), EPA suggested rates (USEPA, 1989), and preliminary results of a Rhode Island consumption survey currently being conducted by investigators at the University of Rhode Island (Morrissey and Anderson, in preparation). Once this consumption survey is completed, the consumption rates will be adjusted if necessary.

Consumption rates were developed for two populations, average consumers and maximum consumers. The average consumer represents the "typical" Rhode Island consumer who eats about 3 meals per month of a variety of seafood from various sources, some of which may come from Narragansett Bay. It should be noted that for the average consumer, surveys indicate that canned tuna accounts for most of the seafood eaten. The maximum consumer (in this case, assumed to be 0.1% or less of the population) represents the worst case scenario and was assumed to be a recreational or subsistence fisherman who would consume large quantities of seafood harvested from the bay. The estimated consumption rates for these two populations is given in Table 4. The meal size in this case (1/3 lb.) is based on USEPA (1989) but can be varied without changing the results of the risk analyses. It may be likely that a flounder meal is 1/2 lb. or greater; the annual consumption rate remains the same.

Exposure (= dose) was calculated from the consumption rates and the actual measured concentrations of chemicals in the fish tissues. For the average consumer, the mean tissue concentration and the average consumption rate was used to calculate the dose. The dose for the maximum consumer was calculated using the highest observed values of the chemicals and the maximum consumption rate.

TABLE 4: Estimated seafood consumption rates for Rhode Island[a]

SEAFOOD	SERVING SIZE	CONSUMPTION RATES	#SERVINGS/YEAR
QUAHAUGS	150g (1/3 lb.)	Average: 1.2 g/day	2.9
		Maximum: 15.0 g/day	36.5
WINTER FLOUNDER	150g (1/3 lb.)	Average: 1.0 g/day	2.4
		Maximum:165.0 g/day	401.5

[a] Based on 70 kg human over 70 year lifetime

The dose estimates were combined in the risk assessment model with the dose-response toxicity values to generate upper-bound estimates of the risk of potential health effects associated with the consumption of Narragansett Bay seafood contaminated with specific chemicals.

Risk estimates for Narragansett Bay were calculated for several scenarios. Estimates were made for both average and maximum consumers. Data for quahaugs were segregated and analyzed by the geographic area from which the clams were collected. Separate risk calculations were done for clams from the following areas:

1) open areas (includes seasonal and conditional closure areas)
2) Mount Hope Bay (closed)
3) Providence River (closed)
4) seafood stores

Figure 2 shows Mount Hope Bay and the Providence River as shaded areas. Data collected at stations within these areas were included in that particular risk scenario. All unshaded areas were included in the open areas category.

A summary of the cancer risk analyses for quahaugs from Narragansett Bay is contained in Table 5. Cancer risk is calculated using organic chemical data only since metals are not known carcinogens by oral exposure. The results indicate that for average consumers, quahaugs from any area are within generally acceptable levels (10^{-5} to 10^{-6}). Although consumers of average quantities of quahaugs from any area have little increased risk, consumers of maximum quantities of quahaugs may have one or two orders of magnitude (10 to 100 times) more risk (10^{-4}) than average consumers. These risk values are at the margin of acceptable risk and should be evaluated closely by state regulators, particularly if RIDOH has reason to believe that the population is exposed to elevated levels from other sources (e.g., lead from paint or pesticides from produce). The highest risks for both groups of consumers are associated with quahaugs from the Providence River, however, Providence River quahaugs have less than two times more risk than open areas. Risks associated with quahaugs from Mount Hope Bay are similar and possibly slightly lower than open areas. Risk estimates for maximum consumers were about 20-25 times higher than for average consumers.

The cancer risks attributable to the various chemicals for the different scenarios were determined; 59-72% was due to PAHs and 27-41% to PCBs. The various other organic chemicals contributed less than 1% of the total cancer risk.

TABLE 5: Estimated total upper bound lifetime cancer risk from Narragansett Bay quahaugs

Average Consumption (1.2 g/day quahog meat)

Site:	Cancer Risk:
Open Areas	7.8 in 1,000,000
Providence River	13.0 in 1,000,000
Mount Hope Bay	7.7 in 1,000,000

Maximum Consumption (15 g/day quahog meat)

Open Areas	1.9 in 10,000
Providence River	3.0 in 10,000
Mount Hope Bay	1.6 in 10,000

Table 6 presents data on quahaugs collected from seafood stores; these clams were found to fall within generally acceptable levels of risk. Levels of contaminants in clams from stores were about 10 times higher than clams collected from a control location on Dutch Island in the lower Bay (see Figure 2 for location). This may reflect the fact that more shellfishing activity occurs in the upper Bay which is in closer proximity to sources of toxics.

TABLE 6: Risk estimates for quahaugs from Rhode Island seafood stores.

Consumption Rate	Seafood Stores	Control Location
Average consumer	1.2 in 1,000,000	3.4 in 10,000,000
Maximum consumer	4.2 in 100,000	4.4 in 1,000,000

The results of the risk assessment for non-carcinogens are presented in Table 7. Any Hazard Ratio greater that 1 represents a potential for adverse health effects. For Narragansett Bay metals in quahaugs, cadmium is the only metal with a Hazard Ratio greater than one, in open areas and the Providence River; Mount Hope Bay is less than 1. This is probably a result of the methodology for calculating the Hazard Ratio for the maximum consumer. The maximum cadmium concentration observed was used to calculate the dose, however, a close examination of the data reveals that the cadmium maximums for both open areas and the Providence River are probably outliers. Recalculating the Hazard Ratio using next lowest value for each data set results in a Hazard Ratio of 0.39 for open areas (instead of 1.5) and 0.20 for the Providence River (instead of 5.0). Further work on identifying and excluding outliers through a statistical process will be undertake for the technical report.

As with cancer risks, non-cancer risk estimates can be summed across all chemicals and all species to provide a probability of increased cancer risk from exposure to the chemicals of concern. However, risk additivity only applies when the chemicals affect the same target organ. This type of analysis was not possible for the non-cancer risk because none of the chemicals were additive by oral exposure.

Lead is not included in the above table. Because of the severity of health effects associated with lead and the numerous sources of exposure, EPA no longer recommends using the simplistic method of calculating a Hazard Ratio for lead. EPA has developed an uptake/biokinetic computer model that allows all routes of exposure to be evaluated at once. Lead concentrations in seafood tissue and local consumption rates can be input and the model can predict increased blood lead levels based on the specified exposure. Preliminary work with this model indicates that dietary exposure from Narragansett Bay quahogs and winter flounder probably would result in minimal increases in blood lead levels, especially considering other major sources such as dust and air. Further work with this model using Rhode Island specific lead data is in progress.

Winter flounder data were evaluated on a bay-wide basis and also segregated into two geographic areas, the Providence River and lower Bay/salt ponds, based on widely separate sampling locations. The division of the data into these two areas was arbitrary considering that flounder migrate around the bay, but any differences observed could possibly be attributed to proximity to pollution sources. The flounder data was also sorted by size with only data for legal size (11.5" or greater) flounder included in the risk analysis.

Analyses using Narragansett Bay winter flounder data show a similar pattern to quahaugs. The risk calculations are presented in Table 8. Consumers of average quantities of winter flounder have little increased risk while consumers of maximum quantities are exposed to increased risks above an acceptable risk level. The maximum consumption rate of 165 g/day for winter flounder may be overly high for Rhode Island. Although some Rhode Islanders may actually consume fish at this rate, most people probably eat a variety of types and not exclusively flounder.

However, in the absence of site-specific data, this is the EPA recommended worst-case scenario rate. This rate was chosen, based on local interviews, as a valid maximum for Quincy Bay, Massachusetts, another coastal New England area, but Quincy Bay is considered "the flounder fishing capital of the world" (USEPA, 1988).

The risks are primarily from PCBs (cancer) and mercury (non-cancer). Although there is a slight increased risk associated with flounder from the Providence River compared to flounder from the lower bay/salt ponds, this difference appears minimal. since flounder migrate, one would not expect to see large differences within the bay.

TABLE 7: Hazard ratios for metals in Narragansett Bay quahaugs.

Area	Ave/Max	Cadmium	Chromium	Copper	Mercury	Nickel	Zinc
Open Areas	Average	.0038	.0018	.0021	.0013	.0023	.0018
	Maximum	1.5	.34	.15	.19	.12	.062
Prov. River	Average	.0034	.0026	.0044	.0014	.0025	.0020
	Maximum	5.0	.48	.20	.057	.065	.065
Mount Hope Bay	Average	.0036	.0019	.0020	.0031	.0017	.0021
	Maximum	.21	.24	.15	.11	.049	.088

a HAZARD RATIO = $\frac{\text{DOSE}}{\text{REFERENCE DOSE}}$

TABLE 8: Risk estimates for winter flounder from Narragansett Bay

HAZARD RATIOS:	Cadmium	Mercury	Arsenic
Lower bay/salt ponds			
Average	.0025	.0073	.00028
Maximum	.073	4.1	.1
Providence River			
Average	.0033	.0073	.00032
Maximum	.067	2.7	.09

CANCER RISK (from PCBs):

Lower bay/salt ponds	
Average	1.8 in 100,000
Maximum	9.9 in 1,000
Providence River	
Average	2.6 in 100,000
Maximum	8.3 in 1,000

To put risk estimates in perspective, it is helpful to present the results in a format that is easier to understand than lists of risk numbers. It is also useful to compare the results to other similar activities and to results from other areas. Figure 3 shows the estimated cancer risk for various levels of quahaug consumption. A person can determine their rate of consumption in meals per year and see what additional risk is associated with it. This figure also clearly shows the difference in risk between clams from different areas. At low consumption rates, the differences are minimal but they become more significant at higher rates. Figure 4 shows a similar pattern for winter flounder, however, the difference between areas is less pronounced.

Table 9 compares the results of the risk assessment for Narragansett Bay quahaugs to risks from other eating and drinking activities, including consumption of seafood from highly contaminated areas. Quahaugs from Narragansett Bay are relatively much safer than fish from New York Harbor or Lake Michigan, or clams, lobster and flounder from Quincy Bay (note: there are no quahaugs in Quincy Bay). Comparison of average tissue concentrations in Narragansett Bay quahaugs to national averages for various chemicals and to levels measured in other areas show that Narragansett Bay levels are similar to and are not elevated to the rest of the country (Bender et al., 1989; Capar, 1988; Hoffman, 1990).

It may be tempting to extrapolate these results for quahaugs and winter flounder to all Narragansett Bay fish species. It should be noted that each species has different routes and rates of bioaccumulation of toxics and different human consumption rates associated with them. Little data exists for other species in Narragansett Bay. The limited data for soft clams, Mya arenaria appears similar to levels measured for quahaugs, however, additional monitoring and a formal risk assessment should be performed before any conclusions can be drawn.

It should also be noted that this risk assessment is subject to the same uncertainties, assumptions, and limitations previously discussed (p. 12). In particular, it does not account for interactive effects of chemical mixtures, sensitive populations, effects of cooking, or other sources of the same chemicals. Limitations of the data have also been discussed. Site-specific consumption information is needed to validate the consumption rates used in this analysis. Despite these limitations, the results of the risk assessment can be used to make some preliminary judgments about the risks associated with consumption of Narragansett Bay quahaugs and winter flounder, and to identify areas where additional monitoring and analyses are needed.

E. RISK ASSESSMENT BY BROWN ET AL. (1990)

In 1986, prior to the issuance of EPA guidance for fish risk assessment, the Narragansett Bay Project and the Rhode Island Department of Environmental Management (RIDEM) jointly funded the development of a risk assessment methodology by Brown et al. (1988; 1988; 1990). At that time, the Rhode Island regulatory agencies did not have the technical expertise to conduct risk assessments that RIDOH currently has. Because fish and shellfish contamination was a priority issue, the Narragansett Bay Project and RIDEM felt that it would be helpful to the state to fund development of a methodology that the state could implement. Since then, RIDOH established the Office of Environmental Health Risk Assessment (OEHRA) with the responsibility to perform risk analyses for a variety of risk exposures including contaminated fish. A major drawback to the Brown methodology is that the methodology itself, as well as the preliminary analyses conducted by Brown, have not been acceptable to the OEHRA, which has favored the EPA procedure followed by Kipp (in preparation). Brown et al. (1988) states that the Brown methodology "is currently used by the Rhode Island Department of Environmental Management"; this statement is incorrect. Although the Brown methodology generally followed current EPA guidelines, it is already outdated and has some important deviations and drawbacks that will be noted at the appropriate place in this discussion.

FIGURE 3:

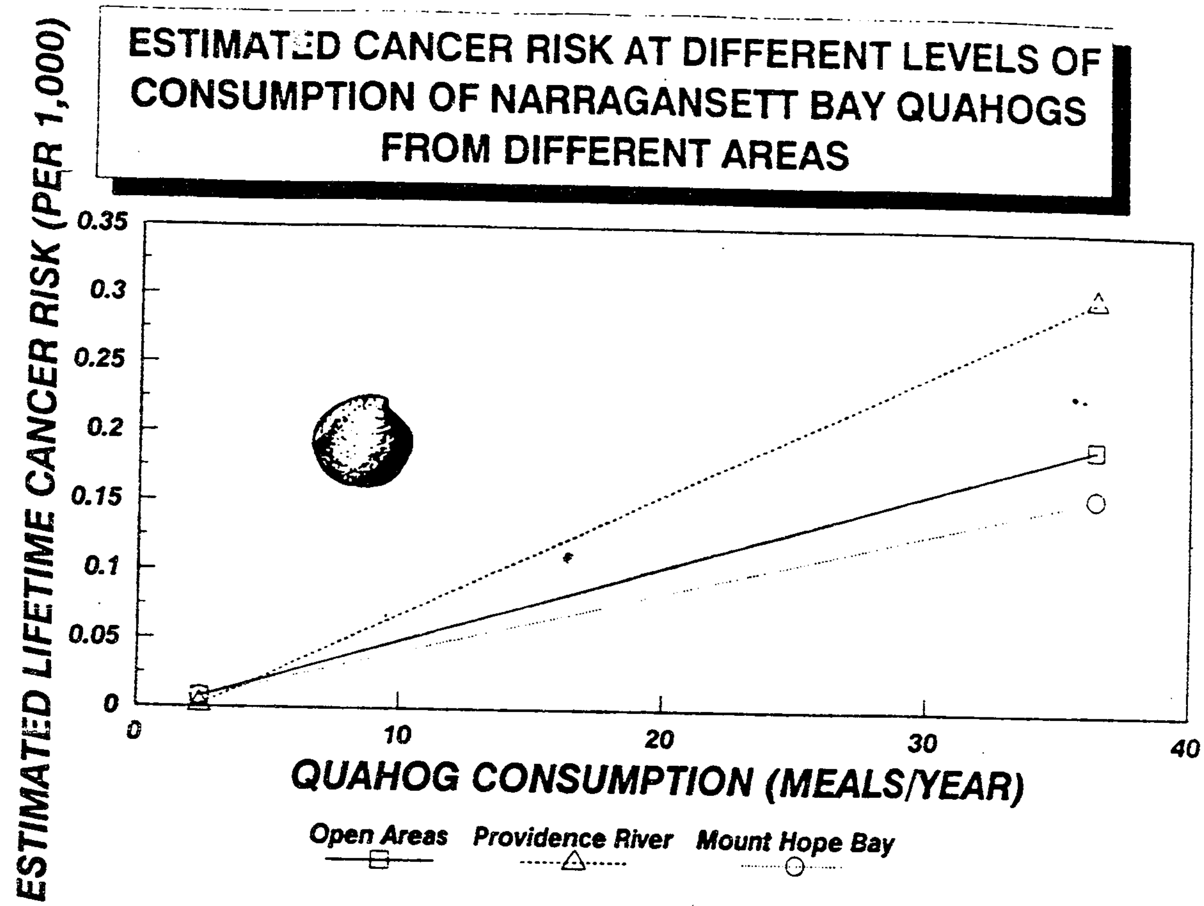


FIGURE 4:

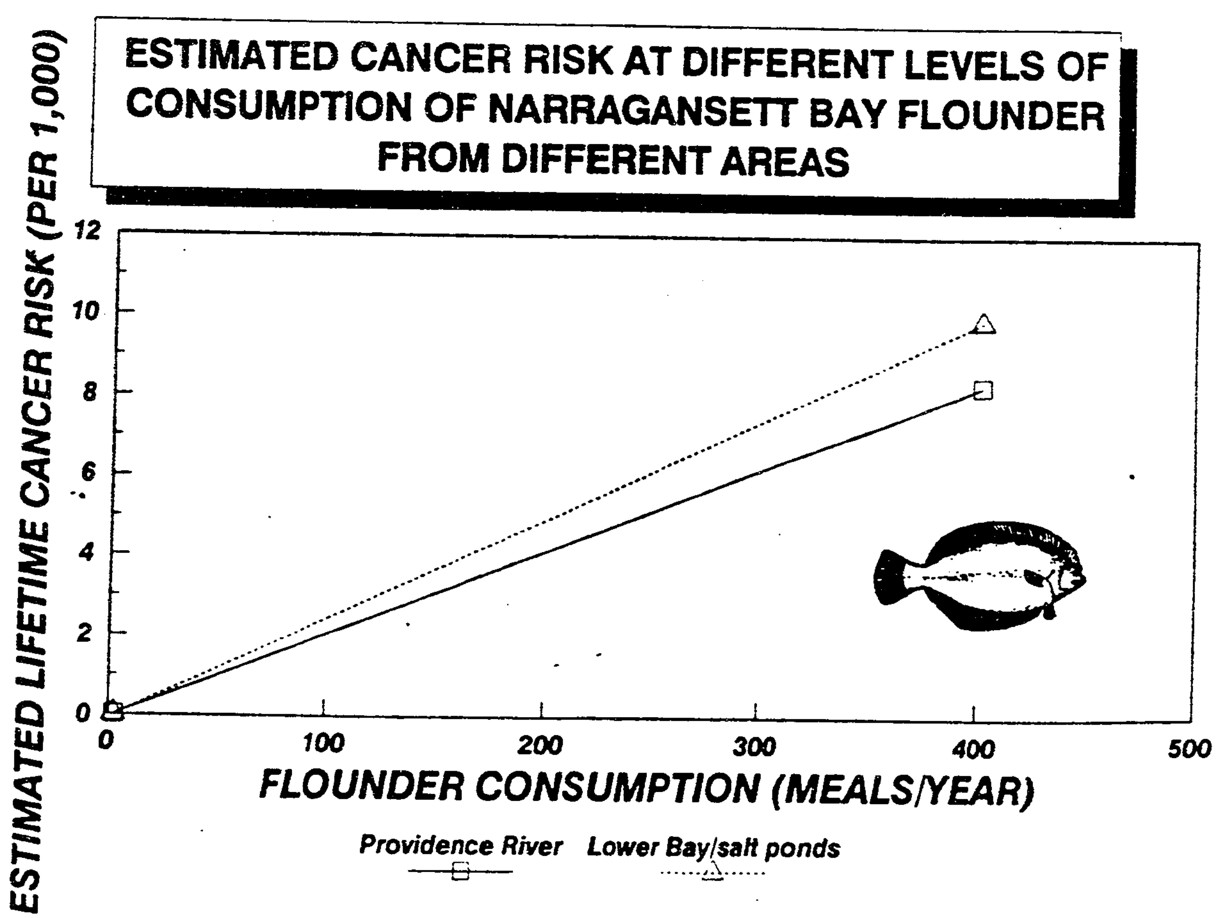


TABLE 9: Estimated average lifetime cancer risks from oral exposure for various eating and drinking activities.

Source of Risk	Average Lifetime Risk
New York Harbor fish: average (30 lb/yr)	9 in 1000
Lake Michigan fish: average (13 lb/yr)	6 in 1000
Quincy Bay seafood: average (2.5 lb/yr) (including tomalley)	1 in 1000
Diet soda (saccharin): 12.5 oz/day	7 in 10,000
Peanut butter (aflatoxins): 4 tbsp/day	6 in 10,000
Puget Sound seafood: average (10 lb/yr)	2 in 10,000
Milk (aflatoxins): 1 pt/day	1 in 10,000
Quincy Bay seafood: average (2.5 lb/yr) (excluding tomalley)	8 in 100,000
Miami/New Orleans drinking water: 2 lb/day	7 in 100,000
Narragansett Bay Providence River quahogs: average (1 lb/yr)	1 in 100,000
Narragansett Bay Open Areas: average (1 lb/yr)	8 in 1,000,000
Narragansett Bay Mount Hope Bay: average (1 lb/yr)	8 in 1,000,000

The Brown methodology consisted of a two phase process. Phase I involved generating toxicity profiles and screening chemicals of concern into High and Low Hazard categories. In many cases, rather than using existing EPA values, Brown independently developed toxicity profiles and toxicity values for the chemicals under consideration. Because most of these values were significantly different from accepted EPA numbers, the validity of Brown's analyses were reduced. However, for some of the chemicals of concern, EPA had not developed toxicity values. A strong point of Brown's work was the consideration of reproductive and developmental effects in evaluating toxicity. At that time, EPA values were limited in their inclusion of these effects.

Chemicals which were included in the High Hazard category were then subject to further screening to identify those associated with the most serious potential health effects. Those chemicals identified as a high priority for assessment then were considered for Phase II. Phase II involved the determination of an allowable daily oral intake of a chemical from seafood for each health effect, corresponding to an acceptable risk level. This allowable intake was then converted to a corresponding "safe" concentration of that chemical in seafood. Basically, the method consisted of estimating background levels (from other sources) of the chemical of concern and calculating from that what level of chemical could be allowed in seafood without an incremental increase in risk exceeding an acceptable risk. The benefit to this method is that a series of alert levels for chemicals in seafood could be generated.

A drawback to the Phase II assessment is that the focus of the assessment was only on those health effect categories which contribute the most to the health hazard. This may lead to underestimating the importance of other health effects. Also, this method does not account for additivity of chemical effects because each chemical is treated in isolation. For metals, this is not such an important concern since metals are not generally additive for oral exposure, but it is important for organics.

Some preliminary risk analyses were conducted using the quahaug tissue levels measured by Thibault/Bubly Associates (1989) and Pruell et al. (1988). These analyses were limited to one data set each of metals and organics tissue levels. Phase I screening was conducted for a variety of chemicals; preliminary assessments were conducted for cadmium, lead, nickel, mercury, PAHs, and PCBs.

Consumption rates used by Brown differ from those used by Kipp. Brown assumed an average consumption rate for quahaugs of 20 g/day (about 36 meals of 1/2 lb. per year or 50 meals of 1/3 lb. per year). 20 g/day is the national average rate for all seafood species combined. Brown's value may be high for Rhode Island. On the other hand, Brown did not use a maximum consumption rate for any analyses; this value may better represent a worst-case situation.

Brown's findings are similar to the results obtained by Kipp discussed in the previous section. Based on the Phase II assessments, Brown concluded that cadmium, nickel, mercury, PCBs, and PAHs are present in levels at the margin of concern but do not seriously exceed acceptable levels. Only lead was found to be a serious concern; this is because other sources of lead are so significant that exposure to even low levels from seafood may result in an unacceptable increase in risk. As discussed earlier, preliminary analyses by Kipp using EPA's lead model support this conclusion, although the lead contribution from quahaugs may be less of a concern than indicated by Brown.

In conclusion, Brown's methodology has several drawbacks that make it of limited usefulness to RIDOH. These include, but are not limited to, an unnecessarily complex risk assessment process, outdated and possibly inaccurate toxicity values, inappropriate incorporation of risk management into the risk assessment process, use of only one consumption rate, and the inability to consider additive effects of chemicals. In defence of Brown's work, at the time it was undertaken, the EPA guidance manual had not been finalized, little tissue data was available, and the number of EPA toxicity values were limited. The substantial effort and hard work that went into developing Brown's methodology should be recognized.

F. RISK ANALYSIS BY HOFFMAN (1990)

In writing a summary of the first year research funded by the Narragansett Bay Project, Hoffman (1990) proposed marine water quality guidelines or criteria for human health protection for quahaug growing areas, designed to protect quahaug meats from unacceptable metal content. Hoffman also developed quahaug tissue criteria or "seawater guideline for quahaug consumer protection". These "alert levels" were derived from Brown's (1990) preliminary risk analyses and proposed maximum acceptable metal contents of quahaugs.

The quahaug alert levels were derived from Brown's risk analyses by dividing Brown's acceptable dose by Hoffman's consumption rates for Rhode Islanders (similar to Brown's). This immediately makes the alert levels subject to the same limitations described for Brown's methodology and results.

The marine water quality criteria developed by Hoffman were derived two ways; 1) from EPA drinking water standards, based on the theory that fish consumers should not be exposed to metals in any greater amount than that allowed in drinking water, and 2) by dividing the Hoffman quahaug alert levels by bioconcentration factors, which were also developed by Hoffman. From an EPA perspective, this is an inappropriate use of drinking water criteria, especially considering the different consumption patterns involved with fish consumption compared to drinking water. In addition, EPA has already established water quality criteria for the protection of human health from consumption of fish for 108 chemicals. These criteria are based on risk assessment analyses to determine acceptable levels of chemicals in fish based on a 10^{-6} risk level, and then a translation of these levels to water concentrations through the use of bioaccumulation factors. Problems with Hoffman's criteria include 1) EPA water quality criteria already have been developed, 2) different bioaccumulation factors than currently accepted values were used in Hoffman's method of criteria development, 3) Hoffman's consumption values were similar to those used by Brown and are subject to the same concerns, 4) the data base used as a basis for criteria development was very limited, and 5) use of Brown's methodology makes Hoffman's conclusions subject to the same limitations as Brown.

Based on these water quality and quahaug criteria compared to data from monitoring studies, Hoffman concluded that the Seekonk River and Providence River are likely problem areas, especially for nickel, cadmium and lead. Other conclusions targeted mercury as a possible problem in Mount Hope Bay and lead in Allen Harbor. More recent data from Mount Hope Bay and Allen Harbor do not support these concerns.

G. REGULATORY FRAMEWORK

After the risk assessment is completed, the next step is for the responsible regulatory agencies to decide the appropriate risk management response. The risk assessment provides the scientific basis for regulatory decision-making. In risk management, risks are interpreted in the context of economics, politics, law and social factors, and the appropriate actions (e.g., consumption advisory) are determined. The regulatory agency must weigh the risks associated with an activity such as eating contaminated fish against the potential benefits associated with that activity (e.g., decreased heart disease), and then identify acceptable risks and implement control strategies.

There are several Federal and state agencies with jurisdiction to regulate contaminated seafood. These agencies have differing regulatory mandates and therefore often have different risk management responses to incidences of seafood contamination.

The U.S. Food and Drug Administration (FDA) is responsible for establishing and enforcing safe levels (tolerances and action levels) for contaminants in fish and shellfish in interstate commerce for which a national market exists and for which use of a national average consumption rate of about 19 g/day is appropriate. Seafood in interstate commerce is a mix of fish from many areas and as such, in theory, any contaminated seafood will be diluted by uncontaminated seafood. FDA does not have jurisdiction over recreational fisheries and FDA tolerances or action levels are not designed for the protection of local consumers of recreationally caught seafood who may ingest substantial quantities of seafood caught from a limited geographic area over a long period of time.

The use of FDA levels for regulating recreational fisheries has several limitations. As discussed above, these levels are based on national consumption rates and may not be protective of consumers who catch and eat large quantities. Although a risk assessment similar to the EPA approach is used in deriving levels, the FDA also factors economic considerations (e.g., potential impacts of fisheries closures) into the process of setting levels. As a result, the levels have risk management built into them and may not be as protective as a straight risk assessment based level. Another limitation is that only a few FDA levels exist and so there often are no levels for many chemicals of concern. These tolerances and action levels are listed in Table 10.

TABLE 10: FDA legal limits (parts per million (ppm), wet weight) for fish contaminant levels in the U.S.

Chemical	Action Level
Mercury (methyl)	1.0
PCBs[a]	2.0
Aldrin/Dieldrin	0.3
Chlordane	0.3
DDT, DDE, DDD, DDIs	5.0
Endrin	0.3
Heptachlor	0.3
Kepone	0.3-0.4
Mirex	0.1
Toxaphene	5.0

[a] FDA Tolerance; all other FDA Action Levels

The U.S. Environmental Protection Agency (EPA) does not have the authority to regulate consumption of contaminated fish, but it can conduct site-specific risk assessments, using local consumption rates (usually much higher than the national average rates used by FDA in setting levels), and can recommend that states take action to protect public health. The responsibility for regulation of sport fisheries belongs to the state, which may take regulatory action such as an advisory, based on an assessment of the level of contaminant found locally and on local fish consumption rates.

In Rhode Island, the Department of Health and the Department of Environmental Management (RIDEM) participate in the management of contaminated fish and shellfish through an Interagency Committee under Rhode Island Health Laws. Decisions about fish advisories and opening and closing fishing areas are jointly made by the two agencies, however, the RIDOH Office of Environmental Health Risk Assessment performs risk assessments and issues the advisories.

Currently an advisory against consumption of bluefish and a ban on sales of striped bass are in effect in Rhode Island due to unacceptable PCB levels. This advisory was not based on a risk assessment performed by RIDOH but rather was based on a comparison of tissue levels to the FDA tolerance for PCBs of 2 ppm (parts per million). Advisories or bans for these two species have been issued separately by several coastal states, although this is a regional problem, due to the migratory nature of these fish. The PCB levels in bluefish and striped bass do not reflect conditions within Narragansett Bay; the PCBs are bioaccumulated by these predators at the top of the marine food chain by eating smaller fish containing PCBs along their migratory routes.

Risk assessment is also beginning to be incorporated into RIDEM activities. As required by EPA, RIDEM is presently reviewing the chemicals on EPA's 304(a)(1) list, and will be adopting water quality criteria for protection of human health for the State of Rhode Island. Criteria must be adopted for "... all toxic pollutants..., the discharge or presence of which in the affected waters could reasonably be expected to interfere with those designated uses adopted by the State, as necessary to support such designated uses." Numerical criteria for 129 chemicals have been developed by EPA. However, if EPA approves, the state can elect to develop some or all of their own criteria based on site-specific conditions such as different consumption rates or acceptable risk levels. These criteria are concentration levels of contaminants in surface water that provide protection to human consumers of fish from the effects of toxic chemicals. The criteria are developed by translating acceptable levels in fish tissue based on risk assessment to a level in water in which the fish resides. Bioconcentration factors (BCF), measures of the potential of a chemical to accumulate in tissues, are used to determine the safe level in water to protect human health. The EPA criteria are derived based on a 10^{-6} acceptable risk level for carcinogens.

Massachusetts has a somewhat different program from Rhode Island (Zeitlin, 1990). The Massachusetts Department of Public Health's (DPH) Division of Food and Drugs is responsible for performing risk assessments, conducting epidemiology studies and for determining the need to issue consumption advisories. The advisories are disseminated by the Department of Fisheries, Wildlife, and Environmental Law Enforcement, which also does public outreach and education. The Department of Environmental Protection (DEP) and the Division of Marine Fisheries (for marine waters) collect and analyze fish tissue and assist in enforcing advisories. Unlike in Rhode Island, the DPH does not routinely analyze samples but rather evaluates data collected by other agencies. Massachusetts advisories are usually based on FDA action/tolerance levels but occasionally are based on risk assessment. Massachusetts has adopted as policy, an acceptable risk level of 10^{-6} for carcinogens. The state has already adopted, by reference, all 129 water quality criteria for the protection of human health on the 304(a)(1) list.

Currently, no mechanism exists for states to address interstate or regional fish contamination problems, except on a state by state basis. States usually act independently; rarely do states coordinate risk management activities. The Federal government does not provide much guidance or assistance in dealing with regional issues.

H. CONCLUSIONS

As previously discussed, the Narragansett Bay Project posed a series of management questions related to chemically contaminated seafood. The risk analyses discussed above were designed with the purpose of answering these questions to the best degree possible. The results of these risk analyses, regarding the safety of Narragansett Bay seafood, allow us to at least draw some preliminary conclusions regarding the answers to the questions, which are discussed below. Based on these preliminary answers, some decisions about risk management strategies, or the need for further monitoring and analyses, can be made.

Does Narragansett Bay seafood from approved harvest areas pose a risk to human consumers if consumed in moderate amounts? In large amounts?

Generally, results indicate that, at least for quahaugs and winter flounder, there is no immediate health threat associated with an average level of consumption of these species from any area. This is based on the assumption that cancer risks in the 10^{-5} to 10^{-6} or lower range are "acceptable", the range usually considered acceptable by EPA and Rhode Island regulatory agencies. 10^{-6} is the level of acceptable risk in Massachusetts. For persons that eat average or moderate amounts of these two species, there is little increased risk of adverse health effects, however, persons that eat very large quantities of either or both species harvested from open areas face probable increased risks in the 10^{-4} range for quahaugs and 10^{-3} range for winter flounder. These risks are above acceptable risk levels.

It should be noted that the tissue contaminant levels for both quahaugs and winter flounder from Narragansett Bay are similar to levels found in other urban estuaries in the northeast. Many of these contaminants are ubiquitous and concerns regarding the safety of seafood have been raised in other states. Because this problem is so widespread, a regional or Federal solution is essential.

It is necessary to closely examine the maximum consumers, especially when the risks are above acceptable levels as in this case. Consumption rates should be closely evaluated to ensure appropriateness. It is also important to consider certain subpopulations when evaluating the need for regulatory action. Some groups may be at relatively greater risk. Sensitive populations, usually pregnant or nursing women and children under 12 years, are often targeted for special protection due to possible reproductive or developmental effects of chemicals. Subsistence fishermen, often ethnic groups in urban areas, may consume large quantities of seafood. This seafood may be routinely harvested from contaminated, closed areas. In addition, these groups may have cultural differences in food preparation resulting in higher exposure if fish livers are eaten.

Other sources of the same chemicals should also be examined to determine if seafood is the major route of exposure, in which case, regulatory action may be appropriate. If seafood is a minor source, then regulatory action should focus on those other sources to achieve the maximum benefit.

In the event that shellfish beds currently closed due to pathogens may be considered for reopening for harvest, are there areas that should remain closed due to unacceptable risks from chemical contaminants in the quahaugs?

The two currently closed areas considered in the risk assessment for quahaugs were the Providence River and Mount Hope Bay. Major contamination problems in these areas from pathogens will have to be addressed before these areas can be considered for reopening. Only then will the toxic contamination of quahaugs from these areas become important issue, except in the case of subsistence fishing. Strategies for eliminating pathogens may reduce toxics inputs to some degree.

Based on the limited data available, there appears to be no difference in risks associated with quahaugs between Mount Hope Bay and currently open areas. However, no sampling stations in Mount Hope Bay were located in likely areas of high toxics contamination, (e.g., near major sources such as Fall River and the Taunton River). Metals concentrations in Mount Hope Bay quahaugs may have actually increased in recent years (Leigh Bridges, pers. comm.). It would be necessary to collect and analyze quahaugs from this area before any decision could be made about reopening all of Mount Hope Bay.

Quahaugs collected from the Providence River have a slightly higher risk associated with them than quahaugs from open areas. This risk is less than twice as large. However, similarly to Mount Hope Bay, sampling locations were not close to major sources of toxics in the upper Providence River. Limited data on flounder indicate a slight increase in risk associated with the Providence River; this may not represent exposure to toxics in the Providence River since flounder are mobile.

Are improvements in water quality due to implementation of pollution abatement strategies likely to result in a reduction of tissue contaminant levels and an accompanying reduction in health risk?

This question cannot be answered based on the risk analyses or available data. It is impossible to discern any long term trends in tissue contaminant levels because levels of toxics in fish tissues from Narragansett Bay have only been measured during recent years, not much data exists, and analytical procedures have improved, making it difficult to compare data sets. Examination of existing data has not shown any long-term trends (Bender et al., 1989; Quinn, 1989; Latimer, 1989).

The toxics in the tissues most likely result from either absorption through the skin from contact with contaminated sediments, or bioaccumulation through the food chain. Either way, the only way these levels will be reduced in the long term is through reducing or removing the contamination sources. Because water quality improvements will eventually translate into reduced toxics in the sediment, it can be expected that pollution abatement strategies will be likely to result in reduced tissue contamination. This process will be slow and improvements will not be immediately evident.

Are current government regulatory programs and risk management efforts effective in protecting consumers from risks associated with contaminated seafood?

At this time, it is impossible to determine if current government regulatory risk management activities have been effective in protecting consumers from potential risks associated with quahaugs and winter flounder. Regulatory agencies have essentially taken little action to protect consumer from contaminated seafood, with the exception of bluefish and striped bass. Fortunately, levels of risk for quahaugs and winter flounder are relatively low, regardless of the area harvested, except for maximum consumers. This should not be a reason for complacency, as the presence of any toxics in fish tissue is cause for concern. There always exists the potential for discovering higher tissue levels, especially if sampling is focused near known sources or contaminated hot spots. These areas have not been monitored adequately or at all. Additionally, current programs may not be protective enough of certain sensitive populations (e.g., pregnant women) or maximum consuming populations (e.g., subsistence fishermen).

One additional point that should be mentioned is that there are several documented benefits to eating seafood. The risks of some diseases (e.g., heart disease, diabetes, some cancers) may actually be reduced by regular consumption of fish and shellfish. This report did not attempt to quantify these benefits or to weigh them against potential risks. However, individual decisions regarding seafood consumption should take these important benefits into consideration.

PROGRAM GOAL

PROPOSED GOAL: To protect human health by ensuring the safety of seafood harvested from Narragansett Bay and RI for human consumers.

The proposed strategy for achieving this goal is as follows:

1) identify the potential risks associated with consumption of potentially contaminated seafood from Narragansett Bay and RI;

2) identify unacceptable risks, if any, associated with specific seafood products; and

3) reduce risks by
   - a) reducing contaminant levels in target species and
   - b) implementing risk management activities (e.g., consumption advisories/fishery ciosures) as needed.

ISSUES AND OPTIONS TO BE CONSIDERED

1. SOURCE CONTROL/SOURCE REDUCTION

ISSUE A: Should the states of Rhode Island and Massachusetts undertake activities to reduce the levels of toxics in the tissues of Narragansett Bay and RI fish and shellfish?

PROBLEM DESCRIPTION

Municipal and industrial effluents, stormwater runoff, combined sewer overflow discharges, atmospheric deposition, and episodic events such as oil spills contribute toxic chemicals to Narragansett Bay. The risk assessment results indicate that these toxics accumulate in fish tissue in levels high enough to be a potentially serious concern. Although the risk estimates for quahaugs and flounder from the bay do not, in most cases, indicate an immediate health threat, any toxics in detectable levels in seafood are grounds for concern. The only way to reduce these levels in fish tissue is to reduce the toxics to which the fish are being exposed. Studies have shown that some toxics in fish tissue show a correlation to water concentrations and some to sediment concentrations. Therefore, both sources of exposure need to be controlled.

As discussed in the "Sewage Contamination/Pathogens" briefing paper, source reduction and control strategies will be discussed in detail at a later time in the "CSO" and other briefing papers. At this time, the only decision needed is whether source control and reduction is a viable strategy to pursue for reducing human health risk from toxic contamination in Narragansett Bay and RI seafood.

ALTERNATIVES CONSIDERED

A-1. No change in current toxic control activities.

A-2. The states of Rhode Island and Massachusetts should undertake additional activities to reduce the levels of toxics in the tissues of Narragansett Bay and RI fish and shellfish.

RECOMMENDED ALTERNATIVE: A-2

The states of Rhode Island and Massachusetts should undertake additional control and abatement activities to reduce the levels of toxics in the tissues of Narragansett Bay and RI fish and shellfish. This can only be accomplished by reducing the exposure of the organisms to toxics. Reduction of loadings of toxics to the water column will ultimately result in reduced levels of toxics in the sediment and in prey species. Toxics loadings have already been significantly reduced through improved wastewater treatment, industrial pretreatment, pollution prevention and other programs. Various control and reduction strategies should be evaluated and implemented to further reduce toxics input to Narragansett Bay. Pollution prevention and source reduction strategies will be relatively inexpensive, however, if capital improvements to treatment plants are required, they will likely be costly. The costs of recommended strategies will be discussed in later briefing papers.

2. RISK ASSESSMENT/RISK MANAGEMENT POLICIES FOR SEAFOOD

ISSUE A: **Should any immediate risk management actions be taken to protect human health from consumption of Narragansett Bay and RI seafood based on data and findings described in this paper?**

PROBLEM DESCRIPTION

As discussed earlier in this paper, there is little increased risk of adverse health effects associated average rates of consumption of quahaugs, and somewhat higher risks associated average consumption of winter flounder from Narragansett Bay. These risks appear to be at unacceptable levels for consumers of very large quantities of these species.

ALTERNATIVES CONSIDERED

A-1. No action should be undertaken.

A-2. Some risk management actions should be undertaken.

PREFERRED ALTERNATIVE: A-2

Issuance of consumption advisories or bans by the Rhode Island and Massachusetts regulatory agencies at this time is not warranted due to the lack of conclusive evidence that there is an immediate health threat. Further examination of the data and findings, and especially identification of the populations most at risk, needs to be conducted before any risk management decisions are made. Then, if warranted, the appropriate advisory(s) should be issued. The two states should work closely together to coordinate these risk assessment and risk management activities. Some activities which should be undertaken immediately, prior to decisions on appropriate risk management actions, include:

1. The regulatory agencies of Rhode Island and Massachusetts should begin coordination meetings.

2. Additional data on tissue contaminant levels of winter flounder should be collected and evaluated. It would be premature to take action based on one data set.

3. Data on quahaugs from inadequately sampled areas such as Mount Hope Bay should be collected and evaluated.

4. Consumption rates should be re-examined once the results of the consumption survey currently underway are available.

ISSUE B: **Should the Federal government develop a consistent, coherent national policy on risk assessment and risk management of contaminated seafood and provide guidance to the states?**

PROBLEM DESCRIPTION

Currently, little guidance exists to help states deal with the issue of contaminated seafood. Few FDA action or tolerance levels have been established and states have little guidance by which to evaluate levels of toxics in fish and shellfish. In addition, a Federal role is needed to effectively deal with interstate issues such as migratory species (e.g., bluefish), waterbodies within different state jurisdictions, and interstate commerce of seafood products. States acting unilaterally to deal with any of these interstate issues may face a competitive disadvantage compared to states that regulate less stringently. Consumers are confused by conflicting messages when differing advisories are issued for the same waterbody. An example of this is the Great Lakes, where previously each bordering state has issued different advisories for several fish species. Efforts are underway to standardize these advisories.

Because of differing jurisdictions regarding contaminated seafood, and differing opinions on how to resolve these differences, EPA and FDA have not been able to develop a consistent national policy on contaminated seafood. The agencies are working together through the Joint EPA/FDA Contaminated Fish Committee to address these problems. It is essential that the Federal agencies accomplish this and then progress to developing a consistent policy for risk assessment and risk management.

EPA has made fish contamination a priority issue and is working with FDA towards developing a cooperative, consistent approach to risk assessment and management. EPA sponsored a survey of states regarding fish consumption advisories and which solicited suggestions from states on how EPA, FDA, or other Federal agencies could assist states. The results have been summarized in a report (Cunningham, 1990). The states identified the following areas where the Federal government could assist them:

1) reach agreement on safe levels of consumption;
2) provide consistent risk assessment/advisory methods;
3) improve information transfer;
4) provide more funding and technical support; and
5) prepare guidance and/or workshops on risk assessment methodology, advisory development and risk communication, and various analytical issues such as quality assurance for sample collection and residue analysis procedures.

EPA recently followed up this survey by holding a workshop for state health and fisheries agencies to discuss these issues and to set priorities for Federal assistance to states.

In summary, the states are demanding that the Federal government address the issue of seafood safety and provide leadership in all aspects of risk assessment and risk management. The Narragansett Bay Project should support this call for action.

ALTERNATIVES CONSIDERED

B-1. No change from current approach.

B-2. The Federal government should develop a consistent, coherent national policy on risk assessment and risk management of contaminated seafood and provide guidance to the states.

RECOMMENDED ALTERNATIVE: B-2

The Federal government should develop a consistent, coherent national policy on risk assessment and risk management of contaminated seafood at the state, regional and national levels. A consistent approach is critically needed to 1) reduce current confusion at all levels; 2) eliminate inconsistencies between states in risk assessment and risk management; 3) avoid potential negative economic impacts to states unilaterally adopting stricter standards than other states; 4) provide a greater degree of protection of human health; and 5) increase consumer confidence in seafood. This national policy should include the following:

1. FDA and EPA, as well as other Federal agencies, should provide leadership and guidance for a consistent approach for risk assessment, advisories, monitoring, risk management, and risk communicaton. The Federal government should assume responsibility for interstate risk management issues. This can be accomplished by:

a) **establishment of an interagency Fish Contamination Taskforce to coordinate and implement Federal activities and to provide support and guidance to the states** - the current EPA/FDA Fish Contamination Committee should be expanded to become this Taskforce; other Federal agencies and state representatives should participate; the National Marine Fisheries Service

(NMFS) would be especially important because it collects fisheries survey and contaminant data; regional subcommittees could be formed

b) **resolution of disagreements between EPA and FDA regarding risk assessment methodologies** - EPA and FDA risk assessment methodologies are basically the same. Differences between agency approaches include animal to human scaling factors and toxicity values (e.g., Cancer Potency Factors); these should be made consistent.

c) **development and implementation of strategies to address interstate and regional issues** - the interagency Taskforce should be the decision-making body for interstate risk assessment and risk management issues

d) **development by FDA and EPA of more and better regulatory guidance limits and safe consumption levels for chemical contaminants in seafood, for application to local consumption situations as well as cases of seafood in interstate commerce**

- guidance limits for local and national application should be developed
- action levels or tolerances should be developed for many additional chemicals including PAHs, metals, and organic compounds
- guidance should be provided on determining appropriate local consumption rates for seafood, including identification of sensitive populations
- guidelines on selecting acceptable risk levels should be developed

e) **development of guidance for risk management strategies** - includes criteria for advisories

f) **development of guidance for sampling and monitoring of fish and shellfish for risk evaluation**, including standard methods for contaminant analysis

2. EPA and FDA should provide technical support and assistance to states on fish contamination issues. This technical assistance should consist of guidance manuals, workshops, technical support, and funding for, but not limited to, the following topics:

a) monitoring and sampling
b) conducting risk assessments
c) establishing appropriate consumption rates
d) criteria for issuing advisories/bans
e) educational programs

EPA is planning on establishing a clearinghouse for information on advisories issued by all states.

3. Funding should be provided for scientific research needed to support risk assessment and risk management efforts. This research agenda should include:

a) applicability of findings relative to one species to other species (e.g., quahaugs to oysters)
b) relationship of concentrations of toxics in the water and sediment to fish tissue levels
c) relationship of fish tissue contaminants to fish pathology
d) toxicological testing to improve toxicity values
e) human epidemiological studies
f) consumption surveys at local and national levels

4. The Federal government should establish a laboratory intercomparison and certification program for analysis of fish and shellfish, as well as water and sediment quality parameters. This should include development of standard methods for conducting the analyses. All that is available presently are reference tissues from the National Bureau of Standards and the EPA National Performance Evaluation Program for water contaminant analysis.

5. The Federal government should establish a national seafood inspection program that inspects for chemical contaminants as well as handling procedures related to bacterial contamination. FDA and the National Marine Fisheries Service currently maintain limited inspection activities. NMFS is testing a new voluntary inspection program. There is currently a food safety bill being considered by the U.S. Congress. Regardless of which agency is identified as lead, the activities of all agencies involved in issues of seafood safety should be coordinated through the interagency Fish Contamination Taskforce. The Taskforce should be responsible, in an advisory capacity, for national consumption advisories, and should be the lead group in the development and implementation of regional advisories (e.g., Marine Fisheries Council recommended advisory for bluefish).

ISSUE C: **Should the State of Rhode Island adopt a standard risk assessment protocol, risk management policy, and risk communication program for both commercial and recreational fisheries, and work cooperatively with Massachusetts to ensure a consistent approach to interstate waters?**

PROBLEM DESCRIPTION

The RIDOH currently does not have a standard risk assessment protocol and risk management policy for regulating contaminated seafood and ensuring seafood safety, although a advisory protocol has been drafted (Appendix 1). Rhode Island, like most states, uses the FDA Action Levels or Tolerances as guidelines for judging seafood contamination. The limitations with this approach as discussed previously are that 1) the FDA levels are based on national, rather than site-specific, consumption rates; 2) economic considerations were incorporated during development of the FDA levels; and 3) very few FDA levels have been promulgated. This means that states have little by which to interpret and regulate chemical levels in fish.

ALTERNATIVES CONSIDERED

C-1. No change from current approach.

Currently, RIDOH issues advisories or fishery closures based solely on FDA Action Levels or Tolerances. An example is the current ban on sales of striped bass due to levels of PCBs, which exceed the FDA Tolerance of 2 ppm. This approach may be protective of human health, since there has not been evidence of health problems traceable to seafood toxic contamination. However, the lack of medical records positively linking cancer to contaminated seafood, and the long latency period for health effects due to toxics likely results in an underestimation of the true effects. Also, the results from the risk analyses conducted with Narragansett Bay data indicate that there is not an immediate health threat from consumption of Narragansett Bay quahaugs and winter flounder.

C-2. RIDOH and RIDEM should develop a standard coordinated approach to ensuring the safety of Narragansett Bay and RI seafood through a program of risk assessment, risk management, and risk communication until the Federal government develops a consistent risk assessment/risk management/risk communication policy including standards for fish safety; the state should then adopt the Federal approach and standards.

RECOMMENDED ALTERNATIVE: C-2

Although a Federal solution is needed, until the Federal government provides the necessary leadership to address issues of seafood safety, RIDOH and RIDEM should develop a standard coordinated approach to ensuring the safety of Narragansett Bay seafood and RI through a program of risk assessment,risk management, and risk communication. Although levels of contaminants in Narragansett Bay quahaugs and winter flounder are generally low and corresponding health risks are also relatively low, any levels should be a cause for concern. Winter flounder should be targeted for additional monitoring and analysis since risks are elevated. RIDOH is already beginning to implement this type of program and the NBP should encourage and support this effort. These efforts should target pathogens as well as toxics.

The Rhode Island regulatory agencies should be progressive and proceed with this approach regardless of the activities of the Federal government to address this issue. The Federal agencies are likely to be very slow in developing and implementing a national policy with standards for seafood safety. Provided that eventually the Federal government successfully develops and implements a policy for seafood, Rhode Island should then adopt these Federal standards.

Although more protective of human health, unilateral implementation of state standards prior to Federal standards would put the state at a competitive disadvantage. By adopting more protective and restrictive standards for seafood safety, Rhode Island fishermen would be competing against products from other states with no state standards. On the other hand, strict state standards would provide an excellent guarantee of quality and could be a useful marketing tool; the risk analysis indicates that the quahaugs and flounder are relatively safe and so harvest restrictions are unlikely. Also, the situation may arise where Rhode Island would be forced to restrict imports of seafood from other states that do not meet the state standards. This could also cause some economic difficulties. However, economic considerations must be balanced against the need to protect human health.

Note that the preferred alternative recommends that RIDOH and RIDEM adopt provisional standards in the absence of Federal action. The regional nature of some contamination problems, such as PCB contamination of bluefish and striped bass, and the migratory behaviour of many species, dictate the need for a Federal solution. In addition, potential barriers to interstate commerce created by inconsistent advisories between states for the same species argue for a Federal solution.

In lieu of Federal action, Rhode Island should begin coordinating with Massachusetts regulatory agencies to address the interstate nature of the Narragansett Bay watershed. This is especially important for Mount Hope Bay. The states need to develop a cooperative, consistent approach to fish and shellfish contamination problems across state lines.

This coordinated state approach to seafood safety should include the following:

1. RIDOH and RIDEM should work with Massachusetts on the Narragansett Bay watershed, and with other states and Federal agencies on a regional and national basis, to develop a consistent approach to risk assessment, management, and communication.

2. RIDOH should establish as policy, an acceptable risk level for carcinogens to use as a basis for evaluating risks from fish and shellfish, and should then develop and adopt state "action levels" that identify unacceptable levels of chemicals in fish tissues. (see #2). RIDOH has generally used 10^{-5} to 10^{-6} as an acceptable risk for carcinogens. An approach should be developed for evaluating non-carcinogenic risks. The decision on an acceptable risk level must be made after considering the economic and social implications. RIDOH is examining the development of "action levels" based on the results of the risk assessment conducted by Kipp. Tissue reference concentrations (action levels) would be developed for a series of quahaug consumption rates and eventually action levels would be developed for other species based on monitoring data.

3. RIDOH should develop and implement a fish and shellfish advisory protocol for protecting human consumers from seafood contaminated with toxics. This protocol has been drafted (Appendix 1) and tested in evaluating striped bass data for the existing advisory.

4. RIDEM's and RIDOH's shellfish monitoring program should be expanded to include:

a) **coordination with Massachusetts to develop a comprehensive and consistent monitoring strategy for interstate waters**

b) **sampling of additional chemicals, stations, and species -**

- tissue analysis should be expanded to include organic chemicals including PCBs and PAHs and priority pollutant scans should be performed on occasion
- station locations should be reevaluated to target problem areas, areas not previously sampled adequately (e.g., Mount Hope Bay and the upper Providence River), discharges, and hot spots
- species monitored should be expanded to include finfish and both molluscan and crustacean shellfish
- sampling should also include water and sediment sampling

c) **routine sampling of seafood markets** - spot checks of seafood products purchased randomly at markets should be conducted whether or not an inspection program is implemented

d) **monitoring levels of toxics in quahaugs collected for the quahaug transplant program and for evaluating the feasibility of reopening shellfishing areas**

e) **coordination with other RIDEM monitoring programs and with the NBP long-term monitoring plan** - The NBP long-term monitoring program is currently being developed by investigators at the University of Rhode Island; the plan will incorporate fish tissue sampling and will be evaluating current RIDOH and RIDEM monitoring programs; recommendations on improving and expanding these programs will be made and should be implemented

5. RIDEM and RIDOH laboratory capabilities for monitoring should be expanded. RIDEM currently does not have any laboratory facilities and relies completely on RIDOH and contract labs. RIDEM and RIDOH should work together to improve the existing RIDOH facility for expanded analytical capabilities for fish and shellfish. The agencies should provide adequate resources (funding and personnel) to maintain a high quality analytical facility. The current contract between RIDEM and RIDOH is attempting to accomplish this objective. Alternatively, RIDEM could develop its own laboratory capabilities.

Laboratory improvements should include:

a) **updated analytical procedures** - existing procedures should be evaluated and updated as new methods are developed

b) **computerization of the database** - RIDOH should continue current efforts to computerize food inspection data including shellfish monitoring data

c) **adequate staff, equipment and financial support**

6. RIDOH and RIDEM should institute a laboratory intercomparison and certification program for state, federal, university, and private laboratories - A major problem with evaluating data is that data quality varies greatly and analytical techniques often differ from lab to lab and over time as techniques improve. A Federal/state certification/intercomparison program would be way to overcome these problems, as well as helping to ensure good quality data.

7. RIDOH and RIDEM Division of Enforcement, in conjunction with Federal agencies, should institute a state seafood testing and inspection program. Efforts are currently underway to pass federal legislation instituting a testing and inspection program on a national scale. Rhode Island's limited testing program should be expanded regardless of federal activities. The inspection program would include monitoring for toxics, pathogens, and quality (freshness). RIDOH and RIDEM should investigate delegation of administration of inspection and enforcement powers to the RIDEM Division of Enforcement. Rhode Island commercial fishermen would benefit from the consumer confidence such a program would generate. Rhode Island should also consider implementing some Massachusetts programs such as the traceability program that requires tagging of all fishery products with source information.

8. RIDOH and RIDEM should develop an educational program regarding seafood safety, and seafood contamination issues - This is especially important when advisories are issued. This would also be an excellent opportunity to reassure consumers about the high quality of Narragansett Bay seafood relative to other urban estuarine areas.

The costs of the several components to this program would vary for each component and for each agency. #1-3, 8 and 9 have some minimal personnel costs associated with them; however, #4-7 could conceivably be rather costly. Most costs would be associated with expanding analytical capabilities, especially if RIDEM were to build its own laboratory. Major costs would also be associated with sample collection and analyses for a large-scale monitoring and inspection program. Chemical analyses, especially organics, are expensive.

ISSUE D: **Should Massachusetts work cooperatively with Rhode Island to ensure a consistent risk assessment protocol,risk management policy, and risk communication program for fisheries in the Narragansett Bay watershed?**

PROBLEM DESCRIPTION

Basically, the same discussion applies for Massachusetts as for Rhode Island regarding the need for a consistent approach for risk assessment,risk management, and risk communication. Due to the interstate nature of the Narragansett Bay watershed, Massachusetts and Rhode Island need to work cooperatively to address problems of fish contamination.

ALTERNATIVES CONSIDERED

D-1. No change from current approach.

D-2. Massachusetts should adopt a risk assessment protocol, risk management policy, and risk communication program consistent with Rhode Island, until the Federal government develops a consistent risk assessment/risk management/risk communication policy including standards for fish safety; the state should then adopt the Federal approach and standards.

RECOMMENDED ALTERNATIVE: D-2

Rhode Island and Massachusetts should work together to develop a consistent and cooperative approach to monitoring, assessing and managing contaminated fish and shellfish in the Narragansett Bay basin. The two states, and other New England states if feasible, should coordinate policies for seafood safety to ensure a consistent approach to interstate waterbodies such as Mount Hope Bay, and to prevent with inequities in seafood marketing between states. Massachusetts should coordinate Rhode Island to develop a consistent approach. Similar to recommendations for Rhode Island, this approach should include:

1. Massachusetts should work with Rhode Island on the Narragansett Bay watershed, and with other states and Federal agencies on a regional and national basis, to develop a consistent approach to risk assessment, management, and communication.

2. Massachusetts should develop and adopt state "action levels" that identify unacceptable levels of chemicals in fish tissues, based on an acceptable risk level. Massachusetts uses 10^{-6} as an acceptable risk level; the appropriateness of this level for protection from contaminated seafood should be evaluated. Massachusetts should consider developing "action levels" similarly to Rhode Island.

3. Massachusetts should implement a fish and shellfish advisory protocol for protecting human consumers from seafood contaminated with toxics consistent with the RIDOH draft protocol.

4. Massachusetts DMF should coordinate with Rhode Island to develop a comprehensive, cooperative monitoring strategy for interstate waters within the Narragansett Bay watershed. DMF already monitors several species including quahaugs, winter flounder, and lobster on a regular basis. Chemical analyses are performed for metals and organics. However, most sampling occurs in the coastal area and little occurs in Mount Hope Bay.

5. Massachusetts laboratory capabilities should be evaluated and expanded if necessary. Analytical procedures should be updated as new methods become available.

6. Massachusetts should participate with Rhode Island (and other states) in a laboratory intercomparison program. Massachusetts frequently participates in lab intercomparison studies; this activities should be expanded to include Rhode Island and Federal labs.

7. Massachusetts DPH and DMF should institute a state seafood testing and inspection program. Legislation instituting a seafood testing program was proposed to the state Legislature in 1989 and 1990, however, lack of funds prevented passage of the bill. Massachusetts currently has a much more extensive testing program than Rhode Island; thousands of analyses are performed yearly on seafood from commercial sources.

8. Massachusetts should expand educational efforts regarding seafood safety which were initiated after the Quincy Bay Study. Coordination with Rhode Island could avoid duplication of effort and provide cost savings.

REFERENCES

Bender, M., D. Kester, D. Cullen, W. King, S. Bricker, and W. Miller. 1989. Distribution of trace metals in the water column, sediments and shellfish of Narragansett Bay. Report to the Narragansett Bay Project.

Brown, M., L. Kossin and H. Ward. 1987. Narragansett Bay issue assessment: public perceptions. Report to the Narragansett Bay Project.

Brown, H. S., R. Goble and C. C. Mao. 1988. Assessment of hazards of contaminants in seafood. DRAFT report to the Narragansett Bay Project.

Brown, H. S., R. Goble and L. Tatelbaum. 1988. Methodology for assessing hazards of contaminants in seafood. Regul. Toxicol. Pharmacol. 8: 76-101.

Brown, H. S., R. Goble and L. Tatelbaum. 1990. Methodology for assessing hazards of contaminants in seafood. Report to the Narragansett Bay Project.

Capar, S. G. 1988. Lead, cadmium, and other elements in domestic shellfish. FDA report.

Capuzzo, J. M., A. McElroy, and G. Wallace. 1987. Fish and shellfish contamination in New England waters: an evaluation and review of available data on the distribution of chemical contaminants. Report for Coast Alliance.

Cullen, J. D. 1984. A biogeochemical survey: copper and nickel in Mercenaria mercenaria, relative to concentrations in the water column in a New England estuary. M. S. Thesis, University of Rhode Island.

Cullen, D. and J. King. 1990. Relationships between Cu, Ni, Cd, Cr and Pb levels in soft tissues of Narragansett Bay Mercenaria and sediments. DRAFT report to the Narragansett Bay Project.

Cunningham, P. A., J. M. McCarthy and D. Zeitlin. 1990. Results of the 1989 census of state fish/shellfish consumption advisory programs. Research Triangle Institute report for EPA.

Hoffman, E. J. 1990. The first year of the Narragansett Bay Project: results and recommendations. Report to the Narragansett Bay Project.

Hu, T. 1985. Analysis of seafood consumption in the U.S.: 1970, 1974, 1078, 1981. Pennsylvania State University report to NMFS.

Jacobson, J. L., S. W. Jacobson, G.G. Fein, P. M. Schwartz, and J. K. Dowler. 1984. Prenatal exposure to an environmental toxin: a test of the multiple effects model. Development Psychology 20: 523-532.

Kipp, K. 1990. Health risks associated with chemically contaminated seafood from Narragansett Bay. In preparation.

Latimer, J. S. 1989. A review of the major research done in Rhode Island on polychlorinated biphenyls in water, atmosphere, sediment, and biota. Report to the Narragansett Bay Project.

Lee. T. C., S. B. Saila and R. E. Wolke. 1988. Winter flounder contaminant and pathological survey - Narragansett Bay and vicinity. DRAFT report to the Narragansett Bay Project.

Nixon, S. W. 1990a. A history of metal inputs to Narragansett Bay. DRAFT report to the Narragansett Bay Project.

Nixon, S. W. 1990b. Recent inputs of metals to Narragansett Bay. DRAFT report to the Narragansett Bay Project.

Pruell, R. J., E. J. Hoffman and J. G. Quinn. 1984. Total hydrocarbons, polycyclic aromatic hydrocarbons and synthetic organic compounds in the hard shell clam, Mercenaria mercenaria, purchased at commercial seafood stores. Mar. Envir. Res. 11: 163-181.

Pruell, R. J., C. B. Norwood, R. D. Bowen, R. E. Palmquist, and S. J. Fluck. 1988. Organic contaminants in quahogs, Mercenaria mercenaria, collected from Narragansett Bay. Report to the Narragansett Bay Project.

Quinn, J. G. 1989. A review of the major research studies on petroleum hydrocarbons and polycyclic aromatic hydrocarbons in Narragansett Bay. Report to the Narragansett Bay Project.

Quinn, J. G., J. S. Latimer, L. A. LeBlanc and J. T. Ellis. 1989. Assessment of organic contaminants in Narragansett Bay sediments and hard shell clams. DRAFT report to the Narragansett Bay Project.

Schwartz, J. P. 1987. PCB concentrations in marine fish and shellfish from Boston and Salem Harbors, and coastal Massachusetts. Division of Marine Fisheries Publication #14,997-36-110-8-87-CR.

Schwartz, J. P. 1988. Distribution and concentration of polychlorinated biphenyls in lobster, winter flounder, and quahogs from Buzzards Bay, Massachusetts. Report to the Buzzards Bay Project.

Simon, A. W. and P. Hague. 1987. Contamination of New England's fish and shellfish: a report to the governors and the public. Coast Alliance, Washington, D.C.

Thibault/Bubly Associates. 1989. Trace metals in quahog clams from Narragansett Bay. Report to the Narragansett Bay Project.

U.S. Environmental Protection Agency. 1988. Analysis of risks from consumption of Quincy Bay fish and shellfish. Metcalf & Eddy report to EPA.

U.S. Environmental Protection Agency. 1989. Assessing human health risks from chemically contaminated fish and shellfish. EPA Report # EPA-503/8-89-002.

Zeitlin, D. 1990. State-issued fish consumption advisories: a national perspective. NOAA Report.

V. APPENDIX 1

PROTOCOL FOR ISSUING HEALTH ADVISORIES ON CONSUMPTION OF FISH AND SHELLFISH

OFFICE OF ENVIRONMENTAL HEALTH RISK ASSESSMENT, RHODE ISLAND DEPARTMENT OF HEALTH

JANUARY 18, 1990

LEVEL	CRITERIA	ACTION
0	Less than 10% of the samples of a valid sampling exceed the U.S. FDA Tolerance Limit or the State of Rhode Island Action Level for any contaminant, and The Hazard Index* of that valid sampling does not exceed unity (1)	No Health Advisory
1	10 to <30% of the samples of a valid sampling exceed the U.S. FDA Tolerance Limit or the State of Rhode Island Action Level for any contaminant, and The Hazard Index* of that valid sampling does not exceed Two (2); or The Hazard Index* of a valid sampling exceeds unity (1) but does not exceed Two (2);	Health Advisory recommending that this species of fish or shellfish not be consumed by "sensitive" populations, such as pregnant women, women who may become pregnant, nursing mothers, children, and other persons determined to be in a high risk group (sensitive populations to be determined on a case-by-case basis), and recommending that all others limit consumption of this species of fish or shellfish to one meal per week; in addition, if the contaminant is a fat soluble agent, provide recommendations for food preparation to minimize exposure to the contaminant (e.g. removing skin, trimming off fat, avoiding dark meat, cooking so as to allow removal of fat)

2	<u>30 to 50%</u> of the samples of a valid sampling exceed the U.S. FDA Tolerance Limit or the State of Rhode Island Action Level for any contaminant, and The <u>Hazard Index</u>* of that valid sampling does not exceed <u>Five (5)</u>; or The <u>Hazard Index</u>* of a valid sampling exceeds <u>Two (2)</u> but does not exceed <u>Five (5)</u>	<u>Health Advisory</u> recommending that this species of fish or shellfish not be consumed by "sensitive" populations, such as pregnant women, women who may become pregnant, nursing mothers, children, and other persons determined to be in a high risk group (sensitive populations to be determined on a case-by-case basis), and recommending that all others limit consumption of this species of fish or shellfish to <u>one meal per month</u>; in addition, if the contaminant is a fat soluble agent, provide recommendations for food preparation to minimize exposure to the contaminant (e.g. removing skin, trimming off fat, avoiding dark meat, cooking so as to allow removal of fat) and <u>Ban on the Sale</u> of this species of fish or shellfish (covering those populations of the affected species meeting these contamination criteria; e.g. all fish of the given species caught in Rhode Island waters) and/or <u>Closure of Applicable Shellfish Beds</u> to harvesting

3	≥50% of the samples of a valid sampling exceed the U.S. FDA Tolerance Limit or the State of Rhode Island Action Level for any contaminant; or The Hazard Index* of a valid sampling exceeds Five (5)	Health Advisory recommending that no one consume this species of fish or shellfish, and Ban on the Sale of this species of fish or shellfish (covering those populations of the affected species meeting these contamination criteria; e.g. all fish of the given species caught in Rhode Island waters) and/or Closure of Applicable Shellfish Beds to harvesting

U.S. FDA = United States Food and Drug Administration

* The Hazard Index of a sample is calculated as follows:

For one or more contaminants, the Hazard Index (HI) is the sum of the ratios of the measured concentration of each contaminant to its respective Tolerance Limit or Action Level.
A separate HI is calculated for each toxic endpoint of concern, for example cancer, kidney damage, nervous system damage, liver damage, etc. All detected contaminants capable of inducing (as determined from animal or human data) the given toxic endpoint are included in the calculation of that HI. For purposes of conservatively biasing toward overprotection of human health in situations where necessary information is incomplete, all contaminants known or suspected of being carcinogenic (EPA Cancer Categories A, B1, B2; IARC Classification 1 or 2) are included in the calculation of a cancer HI.
The HI for any toxic endpoint is calculated as follows:

$$HI_{endpoint} = \sum_{i=1}^{n} \frac{C_i}{L_i} = \frac{C_1}{L_1} + \frac{C_2}{L_2} + \ldots + \frac{C_n}{L_n}$$

where i (1,2,...,n) = contaminant detected,
C = mean measured concentration of contaminant, and
L = U.S. FDA Tolerance Level or State of Rhode Island Action Limit for the contaminant.

SECTION II:

PROCEEDINGS FROM NARRAGANSETT BAY PROJECT MANAGEMENT COMMITTEE

OCTOBER 24, 1990

APPENDIX A:

MANAGEMENT COMMITTEE MEETING MINUTES

OCTOBER 24, 1990

TRANSCRIPT HAS BEEN RESTRICTED TO HEALTH RISK DISCUSSION FOR THE PURPOSES OF THIS DOCUMENT

NARRAGANSETT BAY PROJECT
NBP MANAGEMENT COMMITTEE MEETING
October 24, 1990
1:00 p.m. - 5:00 p.m.

Meeting Minutes

HEALTH RISK FROM CHEMICALLY CONTAMINATED SEAFOOD

Mr. Arthur Johnson (MA DEP) said that Table 10 on page 29 needed a technical correction. The FDA "action level" listed for total mercury actually refers to methyl mercury only.

I. SOURCE CONTROL/ SOURCE REDUCTION

ISSUE A: Should the states of Rhode Island and Massachusetts undertake additional activities to reduce the levels of toxics in the tissues of Narragansett Bay fish and shellfish?

Mr. Grant suggested that the group return to this issue last because of its comprehensive nature.

II. RISK ASSESSMENT/RISK MANAGEMENT

ISSUE A: Should any immediate risk management actions be taken to protect human health from consumption of Narragansett Bay seafood based on data and findings described in this paper?

Mr. Grant summarized this issue before turning to the four steps recommended for immediate activity under alternative A-2. Alternative A-1 recommended that no action be undertaken.

Ms. Kipp said that the first of the recommended coordination meetings between RI and MA regulatory agencies took place that morning. (Step # 1)

Mr. Dave Borden (RIDEM Fish and Wildlife) stated for the record that his agency supports this concept.

Ms. Karp suggested that additional research be conducted on other species as well as on flounders. (Step # 2)

Mr. Dick Sisson (RIDEM Fish and Wildlife) agreed with the recommendation for additional quahog research, and added that regularly scheduled sampling of permanently closed (uncertified) areas should be reestablished. (Step # 3)

Ms. Kipp explained that Dr. Michael Morrisey of URI was conducting a telephone seafood consumption survey of 300 households, after which consumption rates should be reexamined. (Step # 4) She noted that RI and MA agencies agree on the need for a more substantial survey.

Mr. Sisson noted that NOAA is currently conducting a wider "live feeding" study.

Ms. Kipp said that the NOAA study addresses pathogens only.

Mr. Beck commented that since health risk is such an important and controversial issue, the data collected in these studies needs to be credible to all parties.

Dr. Deacutis asked if there were current programs examining other components of our diet to compare their risks with the risks from seafood.

Dr. Prager noted that identifying such problems is the first step in risk analysis.

Ms. Nancy Ridley (MA Department of Public Health) said that the interstate "coordination group" would be addressing the benefits and risks of eating seafood relative to food from other sources, as well as several other issues, including non-carcinogenic effects and the role of food handling (i.e., transportation, storage, and preparation). She cited the lack of a consistent uniform policy between EPA and FDA as a major obstacle to evaluating health risks from food sources.

Mr. Grant concluded that the committee endorsed the steps recommended under alternative A-2 with the additions recorded above.

<u>ISSUE B</u>: Should the Federal government develop a consistent, coherent national policy on risk assessment and risk management of contaminated seafood and provide guidance to the states?

Ms. Kipp said that while EPA headquarters seems willing to work with FDA on this issue, FDA might not be willing to develop a cooperative policy.

Mr. Leigh Bridges (MA Division of Marine Fisheries) and Mr. Borden said that the EPA/FDA differences should be the primary issue because the states can not solve an array of problems without prior Federal, or at least regional, agreement on a consistent policy.

Dr. Prager said that the group needs to be careful in using the term "risk assessment."

Ms. Karp pointed out that the "risk assessment" was used purposely in the briefing paper in preference to "risk management."

Ms. Ridley and Ms.Ngozi Oleru (MA Dept. Public Health) observed that risk education should be emphasized also.

Recommendations B-2 (1-5) were endorsed.

<u>ISSUE C</u>: Should the State of Rhode Island adopt a standard risk assessment protocol and risk management policy for both commercial and recreational fisheries, and work cooperatively with Massachusetts to ensure a consistent approach to interstate waters?

Under this alternative, eight specific steps were listed.

Ms. Ridley suggested that "risk communication" be added wherever risk assessment or management are mentioned.

Ms. Kipp said that RI currently employs an informal policy for developing acceptable risk levels associated with carcinogens on a case by case basis. She said RIDOH has a draft advisory protocol.

Ms. Ridley said that the RIDOH draft is a protocol for management not for assessment.

Ms. Kipp said the CCMP should encourage RIDOH to adopt and implement the draft protocol.

Mr. Borden said that RIDEM Fish and Wildlife reviews the advisory process but that RIDOH issues all advisories. In regard to monitoring interstate waters, he said that both states receive the same raw data, but each issues its own advisories.

Dr. Pederson asked if the group agreed on the ranking of carcinogens.

Ms. Kipp said the recommendations do not explicitly address ranking.

Dr. Prager suggested that the recommendations should address ranking.

Mr. Johnson identified the lack of reconciliation between FDA standards and EPAs assessment model as the primary problem.

Ms. Oleru said that MA DPH has confronted this issue in the past and is trying to resolve it.

Ms. Ridley said the protocol contained in the three page appendix to the Health Risk "Briefing Paper" is an effective model used in the Great Lakes area.

Mr. Borden, addressing the measure (Step #4) calling for RIDEM and RIDOH to expand shellfish monitoring, noted that 90% of all tags on shellfish simply say "Narragansett Bay."

Ms. Ridley suggested that RI consider utilizing the MA approach to tagging and tracing shellfish. MA uses a tamper proof "credit card" like system.

Mr. Sisson stated that co-mingling of shellfish from different sources is a concern.

Mr. Borden asked if co-mingling from different states was not a bigger problem than co-mingling from within one state.

Ms. Kipp and Ms. Ridley said both types are a problem.

Mr. Borden also cautioned that agencies need to be careful how they construct sampling methods, to avoid inadvertently hurting the wrong market.

Ms. Ridley emphasized the importance of tracing, and said that MA passed regulations allowing it to embargo seafood from an entire state if necessary to protect public health.

Mr. Grant summarized the measure (Step # 5) calling for the expansion of RIDEM and RIDOH laboratory monitoring capabilities and noted the large expense associated with this measure.

Dr. Prager agreed on the expense, but emphasized that the laboratories urgently need upgrade.

Dr. Deacutis said that the group should recognize that RIDOH staffing has been reduced annually during recent years.

Ms. Ridley stated that the CCMP should encourage the Federal government to give states resources.

Ms. Kipp, underscoring the need for a laboratory intercomparison and certification program (Step # 6), noted the difficulty in comparing different data sets due to varying analytical methods and quality.

Dr. Prager suggested that, alternatively, the State could tie-in to an existing quality assurance program for standards.

Dr. Pederson said that many of these existing programs are flawed and that agreements are needed for calibrations as well.

Ms. Ridley observed that food and extraction standards differed greatly.

Mr. Borden, while noting that RIDEM Enforcement Division has done an excellent job inspecting seafood houses, said he did not think this Division should institute testing programs (Step # 7).

Ms. Karp said that the Division of Enforcement already conducts some testing and has endorsed this recommendation.

Ms. Derry Riding (RI Department of Administration, Office of Municipal Affairs) said that the measure supporting development of an educational program about seafood safety (Step # 8) should also address home storage.

Mr. Borden suggested that all references to Narragansett Bay seafood should be expanded to cover all RI seafood.

All recommendations were accepted with the revisions noted above.

ISSUE D: **Should Massachusetts work cooperatively with Rhode Island to ensure a consistent risk assessment protocol and risk management policy for fisheries in the Narragansett Bay watershed?**

Ms. Kipp said that the last clause of the preferred alternative (D-2) should be reworded as follows (changes in bold): the State should then consider adopting the Federal approach and standards.

Mr. Grant then returned the discussion to Issue A, and concluded that there was agreement on this recommendation as a general policy objective.

All recommendations were accepted, with the revisions noted above.

APPENDIX B:

SUMMARY OF MANAGEMENT COMMITTEE DECISIONS

OCTOBER 24, 1990

TRANSCRIPT HAS BEEN RESTRICTED TO HEALTH RISK DISCUSSION
FOR THE PURPOSES OF THIS DOCUMENT

SUMMARY OF MANAGEMENT COMMITTEE DECISIONS

Decisions made at the Management Committee meeting on October 24, 1990:

HEALTH RISK FROM CHEMICALLY CONTAMINATED SEAFOOD

I. SOURCE CONTROL/SOURCE REDUCTION

ISSUE A: Should the States of Rhode Island and Massachusetts undertake additional activities to reduce the levels of toxics in the tissues of Narragansett Bay and Rhode Island fish and shellfish?

DECISION: The States of Rhode Island and Massachusetts should undertake additional activities to reduce the levels of toxics in the tissues of Narragansett Bay and Rhode Island fish and shellfish.

II. RISK ASSESSMENT/RISK MANAGEMENT POLICIES FOR SEAFOOD

ISSUE A: Should any immediate risk management actions be taken to protect human health from consumption of Narragansett Bay and Rhode Island seafood based on data and findings described in this paper?

DECISIONS: Based on preliminary findings, immediate risk management should be undertaken to protect human health from consumption of Narragansett Bay and Rhode Island seafood:

- The regulatory agencies of Rhode Island and Massachusetts should hold regular coordination meetings.
- Additional data on tissue contaminant levels of winter flounder and other species should be collected.
- Additional samples of quahogs from inadequately sampled and uncertified waters should be collected and evaluated.
- Local seafood consumption rates should be examined in a broad survey and risk assessment should be reexamined using these figures.

ISSUE B: Should the Federal government develop a consistent, coherent national policy on risk assessment and risk management of contaminated seafood and provide guidance to the states?

DECISIONS: The Federal government should develop a consistent, coherent national policy on risk assessment and risk management of contaminated seafood and provide guidance to the states.

- U.S. Food and Drug Administration (FDA) and U.S. Environmental Protection Agency (EPA), as well as other Federal agencies, should provide leadership and guidance for a consistent approach for risk assessment, advisories, monitoring, and risk management. The Federal government should assume responsibility for interstate risk management issues. This can be accomplished by the:

  a) establishment of an interagency Fish Contamination Taskforce to coordinate and implement Federal activities and to provide support and guidance to the states;
  b) resolution of disagreements between EPA and FDA regarding risk assessment methodologies;
  c) development and implementation of strategies to address interstate and regional issues;
  d) development by FDA and EPA of more and better regulatory guidance limits and safe consumption levels for chemical contaminants in seafood, for application to local consumption situations as well as cases of seafood in interstate commerce;
  e) development of guidance for risk management strategies; and
  f) development of guidance for sampling and monitoring of fish and shellfish for risk evaluation.

- FDA and EPA should provide technical support and assistance to states on fish contamination issues.
- Funding should be provided for scientific research needed to support risk assessment and risk management efforts.
- The Federal government should establish a laboratory intercomparison and certification program for analysis of fish and shellfish, as well as water and sediment quality parameters.
- The Federal government should establish a national seafood inspection program that inspects for chemical contaminants.

ISSUE C: Should the State of Rhode Island adopt a standard risk assessment protocol, risk management policy, and risk communication program for both commercial and recreational fisheries, and work cooperatively with Massachusetts to ensure a consistent approach to interstate waters?

DECISIONS: Rhode Island Department of Environmental Management (RIDEM) and Rhode Island Department of Health (RIDOH) should develop and adopt a standard coordinated approach to ensure the safety of Narragansett Bay and Rhode Island seafood through a program of risk assessment, risk management, and risk communication for both commercial and recreational fisheries, until the Federal government develops a consistent risk assessment/risk management/risk communication policy including standards for fish safety. The State should then consider adopting the Federal approach and standards.

- RIDOH and RIDEM should work with Massachusetts on the Narragansett Bay watershed, and with other states and Federal agencies on a regional and national basis, to develop a consistent approach to risk assessment, management, and communication.
- RIDOH should establish as policy an acceptable risk level for carcinogens, and should develop and adopt state "action levels" that identify unacceptable levels of chemicals in fish tissues.
- RIDOH should develop and implement a fish and shellfish advisory protocol for protecting human consumers from seafood contaminated with toxics.
- RIDEM and RIDOH should expand their respective shellfish monitoring programs to include coordination with Massachusetts to develop a comprehensive and consistent monitoring strategy for interstate waters; sampling of additional chemicals, stations, and species; routine sampling of seafood markets; monitoring levels of toxics in quahaugs collected for the quahaug transplant program and for evaluating the feasibility of reopening shellfishing areas; and coordination with other RIDEM monitoring programs and with the NBP long-term monitoring plan.
- RIDEM and RIDOH should expand and improve their laboratory capabilities.
- RIDEM and RIDOH should institute a laboratory intercomparison and certification program for state, federal, university, and private laboratories.
- RIDOH and RIDEM Division of Enforcement, in conjunction with Federal agencies, should institute a state seafood testing and inspection program.
- RIDEM and RIDOH should develop an educational program regarding seafood safety, seafood contamination, and seafood handling and storage issues.

<u>ISSUE D</u>: Should Massachusetts work cooperatively with Rhode Island to ensure a consistent risk assessment protocol, risk management policy, and risk communication program for fisheries in the Narragansett Bay watershed?

<u>DECISIONS</u>: Massachusetts should adopt a program for risk assessment, risk management, and risk communication consistent with the State of Rhode Island's program, until the Federal government develops a consistent risk assessment/risk management/risk communication policy, including standards for fish safety. The State of Massachusetts should then consider adopting the Federal approach and standards.

- Massachusetts should work with Rhode Island on the Narragansett Bay watershed, and with other states and Federal agencies on a regional and national basis, to develop a consistent approach to risk assessment, risk management, and risk communication.

- Massachusetts should develop and adopt state "action levels" that identify unacceptable levels of chemicals in fish tissues, based on an acceptable risk level.
- Massachusetts should implement a fish and shellfish advisory protocol for protecting human consumers from seafood contaminated with toxics consistent with the RIDOH draft protocol.
- Massachusetts Department of Marine Fisheries (DMF) should coordinate with Rhode Island to develop a comprehensive, cooperative monitoring strategy for interstate waters within the Narragansett Bay watershed.
- Massachusetts laboratory capabilities should be evaluated and expanded if necessary.
- Massachusetts should participate with Rhode Island (and other states) in a laboratory intercomparison program.
- DMF and the Massachusetts Department of Public Health (DPH) should institute a state seafood testing and inspection program.
- Massachusetts should expand educational efforts regarding seafood safety which were initiated after the Quincy Bay Study.