Technical Support Document for Establishing Fish and Shellfish Consumption Advisories in Maryland

Maryland Department of the Environment
Water and Science Administration

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TABLE OF CONTENTS

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Note to reader: The general term "fish consumption advisory" refers to MDE recommendations regarding the number of meals of a given species of fish from a waterbody considered acceptable for consumption. Typical recommendations might include limiting consumption to 4 or 8 fish meals per month, depending upon the size of the fish or whether the person consuming the fish is an adult, a woman of child-bearing age, or a child.

ACRONYMS

ADD	average daily dose
AT	averaging time
BW	body weight
Cf	concentration of a chemical in fish
CPF	cancer potency factor
DDT	dichloro-diphenyl-trichloroethane
DNR	Department of Natural Resources
ED	exposure duration
EPA	U.S. Environmental Protection Agency
FDA	U.S. Food and Drug Administration
HQ	hazard quotient
IRIS	Integrated Risk Information System
LADD	lifetime average daily dose
LOAEL	lowest observed adverse effect level
MDE	Maryland Department o the Environment
MDH	Maryland Department of Health
MeHg	methylmercury
MF	meal frequency
MS	meal size
NCHS	National Center for Health Statistics
NOAEL	no observed adverse effect level
PCBs	polychlorinated biphenyls
ppm	parts per million
RF	reduction factor
RfD	Reference Dose
TSD	Technical Support Document
WIC	Women, Infants, and Children Program

1.0 INTRODUCTION

This Technical Support Document (TSD) describes the general procedures used by MDE in developing its fish consumption advisories. The Maryland Department of the Environment (MDE) shares the goals stated by the Great Lakes Sport Fish Advisory Task Force (1993):

1) maintaining the health benefit of fish consumption,
2) minimizing the potential for toxic chemical exposures to anglers and those who consume the anglers' catch,
3) using credible and understandable science, and
4) presenting the information in a manner conducive to maximum voluntary compliance.

Some chemicals in surface waters and sediments tend to concentrate - or bioaccumulate - in fish and shellfish. The presence of chemicals in fish and shellfish and the associated potential health risks to those individuals who consume the fish are of concern to various government agencies and the public. The U.S. Food and Drug Administration (FDA) carries the primary responsibility for regulating risks associated with fish sold in the interstate marketplace. In order to arrive at acceptable levels of chemicals in fish, the FDA considers national fish consumption habits and national fish contamination patterns. This approach is consistent with their mandate to ensure the overall safety of the nation's food supply. However, the FDA does not consider the risks to recreational fishermen nor subsistence anglers who may consume substantially greater amounts of fish from a local or regional waterway which has become contaminated (Reinert et al., 1991). Assessing and managing those risks is the responsibility of State environmental and health agencies.

1.1. History

During the early 1970s, the Maryland Department of Health and Mental Hygiene (DHMH) collected locally caught commercial fish from various fish markets in the Baltimore region. This monitoring was conducted to supplement US Food and Drug Administration (FDA) monitoring

conducted nationally and included assessments for contaminants of local concern, such as kepone. The focus of this monitoring was to evaluate the potential for human health concerns.

The Maryland Department of Natural Resources (DNR) began its environmental monitoring of fish in 1976. DNR's focus was on assessing environmental concerns and the monitoring included both lower level food web bait fish and predatory species. Initial efforts analyzed whole fish for contaminant levels. In 1980, the water monitoring program was reassigned from DNR to MDH. Thereafter, most of the monitoring focused on the assessment of edible portions of the fish. On occasion, various organ tissues and whole fish were analyzed in addition to the fillets.

MDE has monitored chemical contaminant levels in Maryland's fish since the early 1970s. Initial evaluations of the contaminant levels for possible human health effects were based on the FDA fish consumption guidelines utilized for commercially available fish. Later, Maryland decided to estimate potential risks associated with fish consumption by local subsistence fishermen.

In general, fish targeted for collection have included popular recreational fish. Eels, fallfish, and other species are collected when target species are not readily available. A secondary goal of the monitoring program is to assess temporal and geographic trends in fish tissue contamination by obtaining the same species during revisits to the sites.

2.0 METHODS

MDE is responsible for monitoring and evaluating contaminant levels in fish, shellfish and crabs in Maryland waters. The tissues of interest for human health include the edible portions of species (e.g., fish fillet). Such monitoring enables MDE to determine whether the specific contaminant levels in these species are within acceptable limits for human consumption. Results of such studies are used to issue consumption advisories for recreationally caught fish, shellfish, and crab species in Maryland. Additionally, since fish, shellfish, and crabs have the potential to accumulate inorganic and organic chemicals in their tissues (even when these materials are

present in very low concentrations in water), monitoring of these species becomes a valuable indicator of environmental pollution in a given waterbody. Chemicals typically tested in fish tissue include those found at historically high levels in water and sediments, such as polychlorinated biphenyls (PCBs), chlorinated pesticides (e.g., DDT and decomposition compounds, dieldrin) and total and/or methyl mercury (MeHg). Appendix A includes the specific chemicals screened by MDE's current and past fish tissue monitoring programs.

Fish Tissue Monitoring

The current regional sampling areas divide the State waters into five core regions:

- Western Maryland (fresh water – running streams and rivers, lakes and reservoirs) – usually screened for MeHg,
- Metro (non-tidal waters in the Baltimore/Washington metro area) – usually screen for PCBs and MeHg,
- Harbors and Bays (tidal waters) – usually screened for PCBs and MeHg,
- Western Bay Tributaries (tidal waters) – usually screened for PCBs and MeHg, and
- Eastern Shore (tidal and nontidal waters) – usually screened for PCBs, MeHg, and chlordane.

MDE routinely monitors watersheds within these five regions. When routine monitoring indicates potential hazards to the public and environment, additional monitoring of the affected area may be conducted to verify the initial findings and identify the appropriate species and size classes associated with harmful contaminant levels. Findings from such studies are the basis for the fish consumption advisories.

The types of fish sampled include important predatory game species (e.g., small mouth bass and striped bass), common recreational panfish species (e.g., white perch, bluegill, and crappie) as well as bottom dwelling, accumulator species with relatively high fat content (e.g., carp, catfish, and American eel).

Shellfish and Crab Monitoring

Since the 1960's, MDE has been surveying metal and pesticide levels in oysters and clams from the Chesapeake Bay and its tributaries. Prior to 1990, this effort was conducted as often as every one to two years. In response to low levels of contaminants found and very little change from year to year, the bay-wide monitoring is currently conducted less frequently. Between 2001-2003, blue crabs were sampled in several locations throughout Maryland.

Risk Management and Advisories

Because the issuance of a fish advisory is fundamentally a risk management action, factors in addition to the technical risk assessment are often considered prior to issuing fish consumption advisories (e.g., weighing the risks associated with exposure to contaminants with the benefits of including fish as part of a healthy diet). Fish consumption advisories are typically issued in those situations where consuming more than 8 meals of fish per month (96 meals per year) from the waterbody is associated with a lifetime cancer risk greater than 10^{-5} (i.e., 1 additional possible cancer case in a population of 100,000 people). Similarly, if the non-cancer health risk exceeds a hazard index of one, then an advisory would normally be issued.

The following subsections describe MDE's methods for determining the risk associated with consumption of locally caught fish containing contaminants and for setting fish consumption advisories.

2.1 Human Health Risk Assessment

In conducting a risk assessment for contaminants in fish, answers to the following basic questions are sought:

- What contaminants are present in the fish and at what concentrations?
- What types of health effects are associated with exposure to these contaminants?
- How toxic are the contaminants?
- Who might consume the fish and how much do they consume?
- What is the magnitude of health risks posed?

Risk assessment, as first described by the National Academy of Sciences (NAS, 1983) and refined over the past few decades, is a scientifically-based procedure used to estimate the probability of adverse health effects under particular exposure conditions. As described by the NAS, risk assessment consists of four separate steps: hazard identification, dose-response evaluation, exposure assessment, and risk characterization. These steps are discussed in greater detail below.

2.1.1 Hazard identification

Hazard identification is the qualitative determination of whether a chemical is associated with a particular health effect (NAS, 1983). Appendix B of this TSD includes background information on PCBs and methylmercury - both commonly detected in fish - including a description of the health endpoints of concern associated with each chemical.

2.1.2 Dose-response evaluation

The purpose of the dose-response evaluation is to establish the relationship between the magnitude of exposure and extent of toxic injury or disease. Chemical-specific toxicity values including non-cancer reference doses (RfD) and cancer potency factors (CPF) are identified. This process includes: (a) the extrapolation of findings in laboratory animals or in humans from epidemiological studies to potentially exposed humans by taking into account interspecies variability; and (b) extrapolation from the general population to the more sensitive individuals by incorporating the range of sensitivities among humans.

For carcinogenic chemicals, it is assumed that cancer risk is zero only if there is no exposure to that chemical (referred to as a non-threshold phenomenon). In contrast to carcinogenic hazard, non-cancer hazards assume that toxic effects only occur after exposure is greater than some threshold level that exceeds the body's natural defense mechanisms. The RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure of the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious effects during a lifetime (Dourson and Clark, 1990). The units of the RfD are the

same as the units of dose: mg of contaminant per body weight of human per day (mg/kg-day). Operationally, the RfD is obtained by dividing either the highest dose of the chemical that did not produce a toxic effect in experimental studies (the No Observed Adverse Effect Level or NOAEL) or the lowest dose that did produce a toxic effect (the Lowest Observed Adverse Effect Level or LOAEL) by the product of uncertainty and modifying factors. The uncertainty factors account for differences in sensitivity to toxic effects within and between species, as well as differences in toxic effects between chronic and subchronic exposures. The modifying factor reflects the confidence in the quality of the animal assay data in predicting health effects in humans.

The principal source of information used to obtain cancer potency factors and Reference Doses is the U.S. Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS). While other sources may be available, they have not undergone full peer review and would not be considered as reliable as values obtained from the IRIS database. Dose-response information on the toxicity of PCBs and methylmercury – the chemicals that drive most of the fish consumption advisories in Maryland - appears in Appendix B of this document; these values are used by MDE in assessing the risk to human health associated with fish consumption from a specific water body.

2.1.3 Exposure assessment

Exposure assessment is the estimation of the amount of a chemical ingested, inhaled, or absorbed by a target population. In an exposure assessment, at least two different measures of intake are necessary, depending on the nature of the effect being evaluated. When evaluating exposure to non-carcinogenic chemicals, intake is calculated by averaging the intake over the period of exposure, which is referred to as the averaging time (AT) (EPA, 1989a). The averaging time is applied to the calculation of non-cancer exposure resulting in an average daily dose (ADD). The equation to calculate the ADD from exposure via the consumption of fish is given in Eq. 2.1. The parameters included here are discussed in detail in the sections below.

$$ADD = \frac{Cf \times MS \times MF \times ((100 - RF)/100) \times ED}{BW \times AT} \qquad \text{Eq 2.1}$$

where:

ADD = average daily dose (mg/kg-day)

Cf = measured concentration of the contaminant in the edible portion of the fish (mg/kg or parts per million [ppm])

MS = meal size in ounces x conversion factor of 0.02835 = kg/meal

MF = meal frequency, or number of meals consumed per day (meals/day)

RF = reduction factor, or percent reduction in contaminant concentration in the fish due to trimming and cooking losses (%)

ED = exposure duration (days)

BW = body weight (kg)

AT = averaging time (days)

For carcinogens, intakes are calculated by averaging the total cumulative dose over a lifetime and are referred to as the lifetime average daily dose (LADD) (EPA, 1989a). The equation to calculate the lifetime average daily dose from exposure via the consumption of fish is as follows:

$$LADD = \frac{Cf \times MS \times MF \times ((100 - RF)/100) \times ED}{BW \times AT} \qquad \text{Eq 2.2}$$

where:

LADD = Lifetime Average daily dose (mg/kg-day)

Cf = measured concentration of the contaminant in the edible portion of the fish (mg/kg or ppm)

MS = meal size in ounces x conversion factor of 0.02835 = kg/meal

MF = meal frequency, or number of meals consumed per day (meals/day)

RF = reduction factor, or percent reduction in contaminant concentration in the fish due to trimming and cooking losses (%)

ED = exposure duration (days)

BW = body weight (kg)

AT = averaging time (days) (lifetime for carcinogens)

Parameters included in Equations 2.1 and 2.2 are discussed in the following subsections.

Concentration of the contaminant in the fish (Cf):

Fish tissue concentration data are gathered and managed by MDE's fish tissue monitoring program. For each waterbody of interest, there may be chemical-specific data from several fish (analyzed either as individuals or as composites). An estimate of central tendency is used to represent the measured concentration of the contaminant in the edible portion of the fish tissue (Cf in Equations 2.1 and 2.2 above). MDE considered the use of the median or the weighted mean as the estimate of central tendency. As a matter of policy**, the median fish tissue value will be used by MDE to generate fish consumption advisories**. The advantages of using the median value are: (i) the value will be less influenced by extreme values in the dataset, and (ii) use of the median is concordant with the methodology used by Delaware. In general, fish tissue concentration data for a specific waterbody will be drawn from the most recent year of fish sampling. However, in some cases, additional data from sampling up to 4 years prior may be included in the determination of the median value for the waterbody.

In some cases, fish tissue levels of a particular contaminant may be below the laboratory limit of detection. In this situation, MDE assigns a value of zero to those measurements.

Meal frequency (MF):

In the case of fish consumption advisories, MDE is interested is using fish tissue concentrations to determine the number of meals per month for a specific fish species that an angler may consume without appreciable risk. For this situation, Equations 2.1 and 2.2 can be rearranged such that the dependant variable is the meal frequency. In Equations 2.5 and 2.6 below, the units of MF are meals/day. These can be converted to meals/month or meals per year as desired by multiplying MF by 30.44 day/month or 365.25 day/year, respectively (see Appendix C).
In general, if fish tissue levels correspond to meal frequency of less than or equal to 8 meals per month, then an advisory is issued. If more than 8 meals per month are acceptable, then guidance of "No Restrictions" is given.

Meal size (MS):

If actual fish consumption data are available for a particular waterbody, those data could be used to estimate site-specific ingestion rates. In general, however, this type of information is not available. Consequently, reasonable assumptions must be made concerning meal size. As a default, a meal size of 8 ounces (equivalent to 227 g) is assumed for the general adult population and women of child-bearing age, while 3 ounces (equivalent to 85 g) is assumed for children under 6 years of age. According to a study of anglers around the Chesapeake Bay area, "Most anglers who provided fish to their families reported that the women in the household eat about the same serving size as the angler, and 8 ounces was the most commonly reported serving size" (Gibson and McClafferty, 2005). The value of 8 oz is also used by 20 states (WV, 2005). The value of 3 oz/day for children is consistent with Gibson and McClafferty (2005) and EPA (2000a).

In the absence of specific crab consumption data, MDE currently analyses crab meat and crab hepatopancreas separately and issues separate advisories for crab meat and crab hepatopancreas based on data for each tissue and assuming 8 oz or 3 oz consumption of each tissue. An 8-oz meal is assumed to be equivalent to 9 medium crabs.

Exposure duration (ED):

Exposure duration reflects the length of time an individual is expected to be exposed to a particular chemical from a given source. Information on exposure duration is typically derived from population mobility data. Because the population is quite mobile, exposure duration will vary from individual to individual and from household to household. However, for purposes of risk assessment, exposure duration is typically assigned a value which reflects a reasonable worst-case residence time. According to EPA (1989a), "National statistics are available on the upper-bound (90^{th} percentile) and average (50th percentile) number of years spent by individuals at one residence… Because of the data on which they are based, these values may underestimate the actual time that someone might live in one residence. Nevertheless, the upper-bound value of 30 years can be used for exposure duration when calculating reasonable maximum residential

exposures. In some cases, however, lifetime exposure (70 years by convention) may be a more appropriate assumption." The procedures presented in this TSD use a 30-year exposure duration for adult receptors. Although this may seem unreasonably conservative, this value will underestimate exposure for those people who spend their entire lives fishing and consuming recreationally caught fish from the same region, even if they do change their principal place of residence.

For chemicals with hazards principally affecting young children (e.g., neurodevelopmental effects), a separate exposure duration of 6 years, representing exposure during the first 6 years of life, is used.

Averaging time (AT):

According to EPA (1989a), the selected averaging time "depends on the type of toxic effect being assessed. When evaluating exposures to developmental toxicants, intakes are calculated by averaging over the exposure event. When evaluating longer-term exposure to non-carcinogenic toxicants, intakes are calculated by averaging intakes over the period of exposure (i.e., subchronic or chronic daily intakes). For carcinogens, intakes are calculated by prorating the total cumulative dose over a lifetime (i.e., chronic daily intakes, also called lifetime average daily intake). This distinction relates to the currently held scientific opinion that the mechanism of action for each category is different…The approach for carcinogens is based on the assumption that a high dose received over a short period of time is equivalent to a corresponding low dose spread over a lifetime…"

Thus, AT for carcinogens is based on lifetime. Based upon current data, the average life expectancy of the entire U.S. population is 74.7 years (EPA, 1989b). MDE assumes a life expectancy of 70 years. This value aggregates males and females, blacks, whites, and others.

For non-carcinogens, AT is set at 30 years for adults. For cases where early life exposures are deemed to be the critical effect, the averaging time for children's exposures is set to 6 years.

Percent reduction of chemical due to cooking and trimming – reduction factor (RF):

Based on recent studies conducted on Great Lakes fish, typical losses of PCBs and chlorinated pesticides resulting from proper trimming and cooking may be roughly one-third (e.g., 33%) and in some cases, as high as 50% (Zabik et al., 1993). These figures, however, assume that the angler has followed trimming advice carefully and that the oils in the fish are allowed to drip away during cooking. MDE uses a value of 30% for chemicals such as lipophilic organics that preferentially reside in the fatty tissue of fish. The fish consumption advisory should include language indicating that if the fat is not removed from the fish prior to cooking, the angler should consume less fish.

Body weight (BW):

Body weight is an important factor because it influences the dose in an inverse fashion; the lighter the individual being exposed to a given amount of a toxicant, the greater the dose to that individual. This basic concept is taken into account within these procedures by specifying three separate receptor groups, each of which has its own characteristic weight. The three groups include adults of average weight (i.e., general population), women of child-bearing age, and children between the ages of 0 and 6 years.

- According to data from the USEPA (1989b), the mean body weight of all adults between the ages of 18 and 75, men and women combined, is 71.8 kilograms, or roughly 158 pounds. The National Center for Health Statistics (NCHS) provides data on body weight for males and females over the age of 20 (86 kg and 74 kg, respectively) (1999-2000 data, https://www.cdc.gov/nchs/fastats/body-measurements.htm). The average would be 80 kg. The mean of the values from EPA and NCHS give a body weight of 76 kg. The EPA Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (EPA, 2000a) cites NHANES III data; in the agency document, women of childbearing age were considered to be between the ages of 15 and 44 years old. The median body weight in this group was 63.2 kg and the mean was 67.3 kg. EPA also cites the earlier analyses of Ershow and Canter (1989); they do not state the age range but give

a median of 64.4 kg and a mean of 65.8 kg. The recommendation in the EPA Methodology was to use a body weight value of 67 kg for a pregnant woman where pregnant women are the specific population of concern and the chemical of concern exhibits reproductive and/or developmental effects.

- The average weight of boys and girls combined between the ages of 0 and 6 years old is 14.5 kilograms, or 40 pounds (EPA, 2000b). This approximates the value in EPA's Child-Specific Exposure Factors Handbook (EPA, 2002, Table 11-6) of 15.1 kg, which is the mean for boys and girls combined.

MDE assumes weights of 76 kg, 67 kg, and 14.5 kg for adults, women of child-bearing age, and children ages 0 to 6 years, respectively.

The following table summarizes the values used for the various parameters describing average daily doses of chemicals found in angler-caught fish consumed by the general population, women of child-bearing age, and children ages 0-6 years:

Table 1. Values for parameters describing average daily doses of chemicals found in angler-caught fish consumed by the general population, women of child-bearing age, and children ages 0-6 years.

Exposure Factor	General Population	Women of Child-Bearing Age	Children (0-6 years)
Meal size (oz)	8	8	3
Meal size (gr)	227	227	85
Meal frequency	calculated	calculated	calculated
Exposure duration (yr)	30	30	6
Averaging time (day)			
Carcinogens	25,567.50	25,567.50	NA
Noncarcinogens	10,957.50	10,957.50	2,191.50
Body weight (kg)	76	67	14.5
Reduction Fraction			
Metals	0%	0%	0%
Organics	30%	30%	30%

2.1.4 Risk characterization

Risk characterization is the integration of the dose-response evaluation and exposure assessment to produce an estimate of the nature and magnitude of potential human health risk. Risk characterizations typically include descriptions of major assumptions, scientific judgments, and, to the extent possible, estimates the uncertainties embodied in the assessment (EPA, 1989a). In this step of the risk assessment process, cancer risk (in the case of carcinogens) and the hazard index (in the case of non-cancer endpoints) are determined.

2.1.4.1 Carcinogenic effects

Excess lifetime cancer risk is computed as the product of the LADD (Lifetime Average Daily Dose) and the cancer potency factor (CPF) as shown in equation 2.3 below. This equation yields conservative estimates of risk, representing a plausible upper limit for the cancer risk at the assumed exposure. Consequently, it is unlikely that the actual risk associated with a given exposure is higher than the risk predicted using this model.

$$\text{Risk} = \text{LADD} \times \text{CPF} \qquad \text{Eq 2.3}$$

LADD has units of mg/kg-day and CFP has units of 1/(mg/kg-day). The product of these two values (i.e., risk) is therefore unit less. Risk, by definition, is the probability of injury, disease, or death under specific circumstances. By convention, excess lifetime cancer risks derived from the above equation are typically expressed in scientific notation. For example, a computed risk of 0.00004 is written as 4×10^{-5}. Alternatively, this same risk could be expressed as a lifetime rate. This is obtained simply by taking the reciprocal of the computed excess risk. For instance, a lifetime risk of 4×10^{-5} is the same as 1 additional cancer in 25,000 individuals over a 75 yr period (i.e., 1/0.00004 = 25,000). Similarly, 1×10^{-6} refers to a 1 in a million cancer risk.

The final point to be made about the above equation is that it is written in terms of excess risk because risks associated with exposure to environmental contaminants are added to, or are in excess of, cancer risks associated with other sources, (e.g., tobacco smoke, indoor radon, ambient air pollution).

2.1.4.2 Non-carcinogenic effects

The magnitude of non-cancer health effects is determined by taking the ratio of the estimated ADD to the RfD for the chemical of interest. This ratio is referred to as the hazard index (HI). Hazard indices greater than 1 indicate that a potential non-cancer hazard exists. Hazard indices less than 1 are expected to be without appreciable risk of adverse effects. The hazard index is computed as follows:

$$HI = ADD/RfD \qquad \text{Eq 2.4}$$

2.2 MAXIMUM NUMBER OF FISH MEALS PER UNIT TIME

The concepts introduced above can be used to answer the basic question of how many meals of fish can be consumed from a given waterbody while maintaining health risk at a defined level (a hazard index less than 1 or a cancer risk of 1 in 100,000 or less). To answer this question, we rearrange the equations presented previously, solving for meal frequency as the dependent variable. If we specify a maximum allowable cancer risk or maximum hazard index for a given set of exposure factors, then the resulting meal frequency is the maximum recommended number of meals per unit time (in this case, meals/day; in order to estimate meals per month or meals/year, the value would be multiplied by 30.44 days/month or 365.25 days/year, respectively). The method for calculating meal frequency for carcinogens is given in Equation 2.5 :

$$MF = \frac{RL \times BW \times AT}{Cf \times MS \times ((100 - RF)/100) \times ED \times CPF} \qquad \text{Eq 2.5}$$

Where:

MF = meal frequency (meal/day)

RL = risk level (unitless; 1 x 10^{-5})

BW = body weight (kg)

AT = averaging time (days) (lifetime for carcinogens)

Cf = concentration of the contaminant in the edible portion of the fish (mg/kg or ppm)

MS = meal size in ounces x conversion factor of 0.02835 = kg/meal

RF = reduction factor, or percent reduction in contaminant concentration in the fish due to trimming and cooking losses (%)

ED = exposure duration (days)

CPF = cancer potency factor (1/mg/kg-day)

In Equation 2.5, the risk level is the target cancer risk level associated with a given chemical in the fish. MDE sets this value at 1 in 100,000 (i.e., 10^{-5}).

In a similar manner, an equation can be derived that provides an estimate of the maximum number of fish meals per time at a hazard index equal to 1 (in this case, meals/day; in order to estimate meals per month or meals/year, the value would be multiplied by 365.25 days/year or 30.44 days/month, respectively). The resulting equation is as follows:

$$MF = \frac{HI \times BW \times AT \times RfD}{Cf \times MS \times ((100 - RF)/100) \times ED} \qquad \text{Eq 2.6}$$

Where:

MF = meal frequency (meals/day)

HI = hazard index (unitless)

BW = body weight (kg)

AT = averaging time (days)

RfD = Reference Dose (mg/kg-day)

Cf = concentration of the contaminant in the edible portion of the fish (mg/kg or ppm)

MS = meal size in ounces x conversion factor of 0.02835 = kg/meal)

RF = reduction factor, or percent reduction in contaminant concentration in the fish due to trimming and cooking losses (%)

ED = exposure duration (days)

Appendix C shows example Excel worksheets with sample calculations for determining meal frequencies associated a given fish tissue chemical concentration. The examples given are for PCBs and methylmercury; to use these equations to estimate meal frequency, the median fish tissue concentration for the chemical/species/waterbody of interest would be entered.

As a matter of policy, MDE uses traditional methods for rounding to the nearest whole number of meals. For example, if the median fish concentration results in an estimated meal frequency of 1.6 meals/month, MDE would advise that consumers limit consumption to 2 meals/month. In cases where fish tissue concentrations are sufficiently high such that the recommendation would be to consume less than 1 meal/month, the following method is followed: (i) for concentrations corresponding to meal frequencies of 0.5 to < 1 meal per month, MDE advises that consumers limit their consumption to 1 meal every other month; (ii) for concentrations corresponding to meal frequencies < 0.5, MDE advises that those fish not be consumed.

3.0 DISCUSSION

This TSD provides the background information necessary for understanding the methodologies used by MDE for determining whether fish consumption advisories are needed for specific waterbodies in Maryland. MDE will update this document as necessary to reflect any major changes in the technical procedures or to clarify the existing approach. In addition to the technical issues described in the preceding sections, several additional topics are discussed here, including (i) chemicals of emerging concern, (ii) how the methodology used for developing fish consumption advisories comports with other programs within MDE, and (iii) MDE's approach for addressing the issues of multiple advisories for fish species in a waterbody based on the same chemical of concern, or multiple advisories in a waterbody when there is more than one chemical of concern.

3.1 Chemicals of Emerging Concern

It is well-documented that certain bioaccumulative, toxic chemicals are found in fish across the United States at levels that frequently result in the issuance of fish consumption advisories. Historically, two of these chemicals – methylmercury (mostly in fresh water) and PCBs (mostly

in tidal waters) – have been the focus of efforts within Maryland. However, MDE is aware that additional chemicals that have not been well-studied may require attention in the future. Given the limited resources available and the high cost of fish sampling and chemical analysis, compelling information is needed to justify adding new chemicals to MDE's monitoring program. In order to issue scientifically justifiable fish consumption advisories, MDE believes that there must be robust toxicity values (i.e., RfDs or CPFs) for the chemical(s), and that evidence of bioaccumulation of the chemical(s) exists.

One class of chemicals that has received increased attention over the past several years is a group of flame retardants referred to as PBDEs, or polybrominated diphenyl ethers. These compounds bioaccumulate in fish and have been measured in fish in the Delaware River (Greene, 2007). It is encouraging that a preliminary risk evaluation of the Delaware River fish found human health risks to be relatively low (Greene, 2007). This assessment was based on maximum concentrations of four PBDEs (BDE-47, 99, 153, and 209) among 149 fish samples collected within the Delaware River Basin in combination with EPA's toxicity values (RfDs for all 4 compounds and a CSF for BDE-209 only) (personal communication, R. Greene). Similar results were reported for PBDEs in southern Mississippi catfish (Staskal et al., 2008).

3.2 Relationship to other MDE Programs

Differences in the parameter values used to assess risk can exist across programs within MDE depending upon specific program goals and statutes. For example, for fish consumption advisories, MDE believes that it is important to weigh the potential risks associated with consumption of contaminants in fish with the health benefits that accrue from a diet that includes regular fish consumption.

3.3 Fish Advisories for Multiple Fish Species

The guidelines recommend that if consumption limits for a species are given by MDE, people should avoid eating other fish that contain the same contaminant. For example, if MDE recommends limiting consumption to 4 meals of largemouth bass from a lake during a single

month based on methylmercury contamination, the consumption of other fish that may contain mercury, such as canned tuna, should be avoided during the same general time period.

3.4 Instructions for Creating Fish consumption Advisory Tables

All fish consumption risk communication messages should be presented in terms of three population groups: general population (GP), women of childbearing age (WCBA), and children (CH).

PCBs meal recommendations are determined based on the following:

GP: conduct both cancer-based and non-cancer-based calculations (using GP body weight, meal size, etc.) → the most restrictive results are selected for the table.

WCBA: non-cancer-based (using WCBA body weight, meal size, etc.) calculations

CH: non-cancer-based (using CH body weight, meal size, etc.)

Mercury meal recommendations are determined based on the following:

GP: non-cancer-based calculation (using GP body weight, meal size, etc.).

WCBA: non-cancer-based calculation (using WCBA body weight, meal size, etc.).

CH: non-cancer-based calculation (using CH body weight, meal size, etc.).

The cancer and non-cancer-based calculations are presented in Appendix C.
If more than one contaminant has been detected, the final recommendation is based on the most restrictive result (i.e., risk driver: Hg vs. PCB).

Species	**Waterbody**	**Recommended Meals per Month**			**Contaminant**
		GP* (8 oz meal)	**Women**** (8 oz meal)	**Children***** (3 oz meal)	
Fish 1	Stream 1	5	4	2	Mercury
	Stream 2	6	6	5	PCBs
Fish 2	Stream 1	9	9	8	PCBs, Mercury

* **GP** general population (men, women above childbearing age, children above 6-years-old)

** **Women** women of childbearing age (women who are pregnant or may become pregnant, or are nursing)

*** **Children** children 0-6 years-old.

4.0 FISH CONSUMPTION ADVISORY OUTREACH PLAN AND RISK/BENEFIT COMMUNICATION

In developing an outreach plan for fish consumption advisories, it is important to recall that "Understanding the [anglers'] perception of risk is important to fisheries and health planners because successful advisory dissemination depends on the ability to target information to the correct audience in the most appropriate manner" (Gibson and McClafferty, 2005). MDE benefits in this regard from the Chesapeake Bay Angler Interview study (Gibson and McClafferty, 2005) which provides information on fish consumption advisory outreach to a widely used waterbody in the State. The study found that:

- The majority of local fishermen interviewed were aware of the existence of fish consumption advisories. Such awareness however did not necessary result in any significant change in their behavior.
- The anglers desired advisories in different languages and posters that include graphics (e.g., pictures of the fish types).
- While television, signs at fishing locations, and newspapers were identified as the most common sources for this type of information, interpersonal communication and signs at fishing locations were considered to be the best way of disseminating advisories and the most effective modes for changing consumption behavior.

MDE has developed procedures for notifying the public about existing consumption advisories for recreationally-caught fish in Maryland waters. In the past, MDE has notified the public about fish consumption advisories through use of the following tools:

- Posters and signs (in English and Spanish) at fishing locations with the most restrictive fish consumption advisories
- Statewide and Baltimore Harbor brochures – distributed by Women, Infants, and Children's (WIC) clinics and MDE employees

- MDE website https://mde.maryland.gov/programs/Marylander/fishandshellfish/Pages/fishconsumptionadvisory.aspx
- Media events such as press releases and interviews.

MDE https://mdewin64.mde.state.md.us/WSA/FCA/index.htmlMDE will continue using these methods and will place special emphasis on ensuring that advisories are posted in areas of highest concern. Additionally, MDE plans to continue issuing and distributing a Spanish version of its statewide brochure as well as involve local watershed groups and local health departments in its future outreach activities.

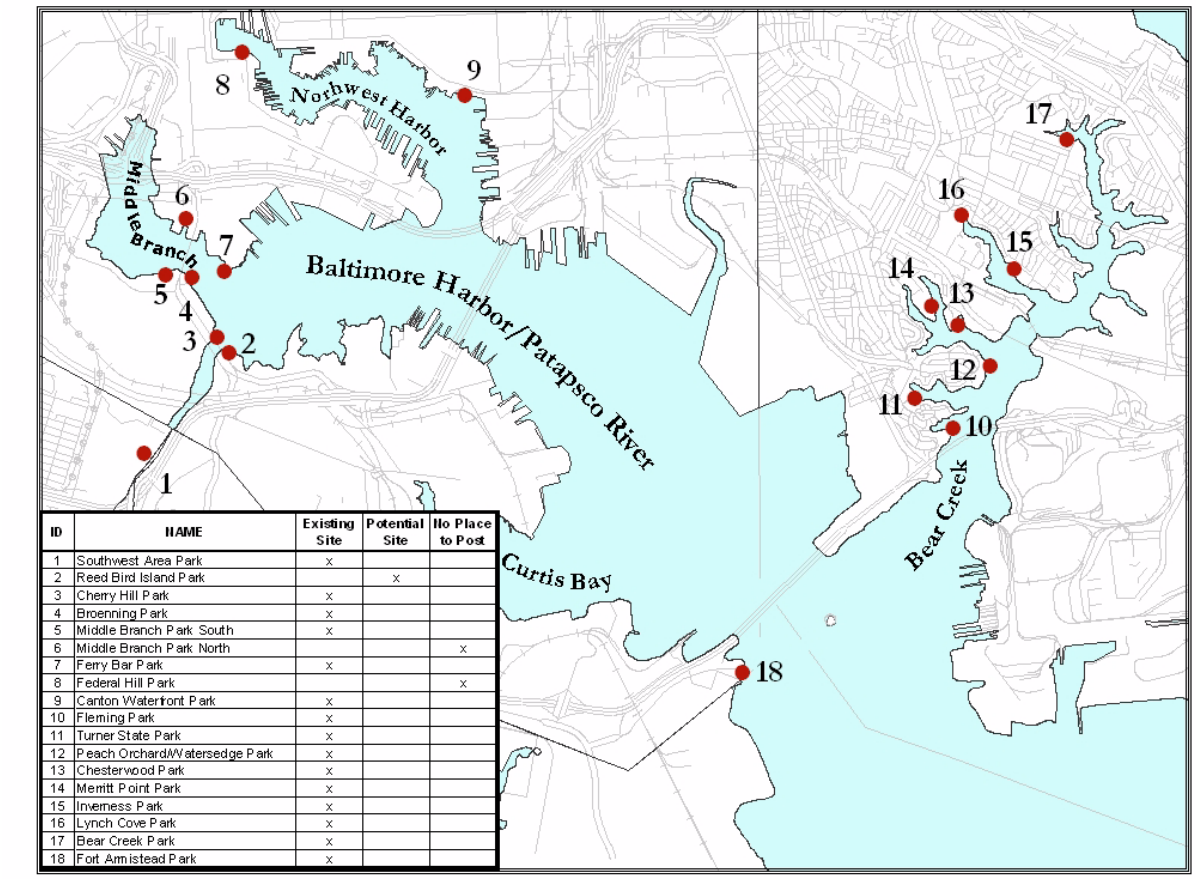
4.1 Components of MDE's Outreach Plan

At the beginning of every fishing season, MDE posts advisory signs at fishing locations with the most restrictive fish consumption advisories. On a regular basis, MDE updates its fish advisory website, and, when possible, includes fish advisory information in Maryland Department of Natural Resources-issued fishing guidebooks. MDE now provides an interactive map that provides modernized, user-friendly information on fish consumption advisories. The map, which can be opened on web browsers, allows anglers to see what advisories are in effect in specific waterways. The map is optimized for mobile devices, with a widget that allows users to zoom to their exact location on the map with the press of a button. Additionally, MDE works to involve local governments and watershed groups in its outreach effort.

Sign Posting at Fishing Locations

The results of surveys and meetings with the regional stakeholders indicate that communicating with the public regarding Maryland's fish consumption advisories should be a continuous process. As signs are relatively cost-effective and valuable communication tools, MDE will continue posting signs at sites around Baltimore Harbor area (see Figure 1 for possible locations) and other areas of highest concern. MDE will also provide signs (in English and Spanish) to counties upon request. These signs will be customized for each specific county, and include a link to the MDE interactive map, or, for smaller bodies of water, a customized online brochure.

MDE will continue working with local jurisdictions to help post signs and distribute brochures.



ID	NAME	Existing Site	Potential Site	No Place to Post
1	Southwest Area Park	x		
2	Reed Bird Island Park		x	
3	Cherry Hill Park	x		
4	Broenning Park	x		
5	Middle Branch Park South	x		
6	Middle Branch Park North			x
7	Ferry Bar Park	x		
8	Federal Hill Park			x
9	Canton Waterfront Park	x		
10	Fleming Park	x		
11	Turner State Park	x		
12	Peach Orchard/Watersedge Park	x		
13	Chesterwood Park	x		
14	Merritt Point Park	x		
15	Inverness Park	x		
16	Lynch Cove Park	x		
17	Bear Creek Park	x		
18	Fort Armistead Park	x		

Figure 1: Example Fish Consumption Advisory Poster Sites

Fish Consumption Brochures

In past years, MDE has distributed the following fish consumption advisory brochures:

- Guide to Safer Fish Consumption for Women and Children in Maryland,
- Patapsco River and Baltimore Harbor – Guide to Safer Eating for Fisherman and Their Families.

These have been distributed to fishermen at Baltimore Harbor fishing locations (Figure 1), to new or expecting mothers visiting WIC clinics throughout Maryland, and to the general public inquiring about Maryland fish consumption advisories.

Fish Consumption Advisory Website

MDE maintains a website (https://mde.maryland.gov/programs/Marylander/fishandshellfish/Pages/fishconsumptionadvisory.aspx) that informs the public about current recreational fish consumption advisories. This website provides the most up-to-date information about fish consumption advisories throughout Maryland, answers the most often asked questions, and gives links to related websites for EPA, FDA, and other states. The website also contains an electronic version of MDE's informational brochures and local fish consumption advisories broken down by a specific water body and fish species as well as an interactive map that provides modernized, user-friendly information on fish consumption advisories. The map, which can be opened on web browsers, allows anglers to see what advisories are in effect in specific waterways. The map is optimized for mobile devices, with a widget that allows users to zoom to their exact location on the map with the press of a button.

DNR Fishing Guide

MDE maintains a website (https://mde.maryland.gov/programs/Marylander/fishandshellfish/Pages/fishconsumptionadvisory.aspx) that informs the public about current recreational fish consumption advisories. This website provides the most up-to-date information about fish consumption advisories throughout Maryland, answers the most often asked questions, and gives links to related websites for EPA, FDA, and other states. The website also contains an electronic version of MDE's informational brochures and local fish consumption advisories broken down by a specific water body and fish species as well as an interactive map that provides modernized, user-friendly information on fish consumption advisories. The map, which can be opened on web browsers, allows anglers to see what advisories are in effect in specific waterways. The map is optimized for mobile devices, with a widget that allows users to zoom to their exact location on the map with the press of a button.

An example timeline for an annual outreach program is shown in Table 2:

Table 2: Generic Outreach Program Timeline

Task	Months after laboratory data are received				
	4	**5**	**6**	**7**	**8**
Update English version of the statewide brochure in cooperation with DHMH	✓				
Work with DNR on text for Fishing Guide	✓				
Translate and print statewide brochure in Spanish	✓				
Print Health Advisory signs	✓				
Distribute brochures to WIC clinics	✓	✓	✓		✓
Post Health Advisory signs	✓		✓		
Distribute brochures to fishermen at Baltimore Harbor locations	✓		✓		✓
Establish working relations with local watershed groups: posting signs, brochure distribution, word of mouth	Continuous effort				

4.2 Benefits of Fish Consumption

This TSD describes the procedures used by MDE to determine where, and for which fish and shellfish species, consumption advisories are needed. However, it is also important to note that consumption of fish is generally thought to confer health benefits including enhanced cardiovascular health and neurological benefits to the developing fetus. At the same time, contaminants in fish may be associated with certain types of adverse effects, such as cancer or neurodevelopment effects. Information on both the risks and the benefits of fish and shellfish consumption are important parts of communication associated with fish consumption advisories. Some example language from West Virginia's Sport Fish Consumption Advisory Guide (WV, 2005) is given here:

Benefits of Eating Fish

Fish are nutritious and good to eat. Eating fish is part of a healthy diet. Fish is high in quality protein, low in saturated fats, and provides valuable vitamins and minerals. Fish contain omega-3 fatty acids which reduce blood clotting and plaque from forming in your arteries. Recent studies have shown eating as little as one meal of fish a week can

significantly reduce the risk of a fatal heart attack. Many doctors suggest that eating 8 ounces of fish each week helps to prevent heart disease. When properly prepared, fish provide numerous health benefits. The American Heart Association recommends eating two to three fish meals each week. Another study linked a significantly lower risk of stroke for those who ate more than one meal of fish a week. Fish contain nutrients essential for proper development of infants. Eating fish may also lower lung disease in smokers and may help relieve symptoms of arthritis. Other benefits of eating fish include:

• Fish offer high-quality protein with fewer calories than a similar-sized portion of meat. For example, both catfish and ground beef are about 18 percent protein. But for an eight-ounce meal, catfish has 232 calories while the ground beef has 640 calories.

• Fish are low in sodium and are a good source of potassium, vitamins, and other minerals.

• Fish are generally low in cholesterol and saturated fats which have been associated with heart disease.

• While the health benefits of fish are still being studied, much of the current research is focused on various kinds of beneficial fats in fish, particularly omega- 3 fatty acids. Some studies have indicated that these fatty acids have favorable effects on health conditions such as hardening of the arteries and high cholesterol.

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APPENDIX A: Example chemicals in MDE's current and past fish tissue monitoring programs

Organics

2,4,5,6-Tetrachloro-*m*-xylene
Aldrin
Arochlor
Benfluralin (benefin)
Chlordane
Chlorpyrifos
DDD
DDE
DDT
Diazinon
Dieldrin
Endosulfan I, II
Endrin
Ethion
HCB
Heptachlor
Heptachlor epoxide
Hexachlorocyclohexane
Kepone
Methoxychlor
Nonachlor
Oxychlordane
Oxyfluoren
PBDEs
PCBs
Pendamethalin
Polycyclic aromatic hydrocarbons
Toxaphene
Trifluralin

Metals and organometals

Aluminum
Arsenic
Cadmium
Chromium
Cobalt
Copper
Iron
Lead
Manganese
Mercury
Methylmercury
Nickel
Selenium
Silver
Tin
Zinc

APPENDIX B: Chemical Summaries for Selected Contaminants

In Maryland, fish consumption advisories tend to be issued based on fish tissue levels of one chemical – mercury – and one group of chemicals – polychlorinated biphenyls, or PCBs. Summary information for these chemicals was extracted from EPA's Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories (2000b), Section 5: Toxicological Profile Summaries for Target Analytes (https://www.epa.gov/sites/production/files/2015-06/documents/volume2.pdf) and EPA's Integrated Risk Information System. References shown in the information in this Appendix may be found in the original citations.

Mercury

(Excerpts are given here. For complete information and citations given in this section, see http://www.epa.gov/iris/subst/0073.htm, https://www.epa.gov/sites/production/files/2019-02/documents/guidance-implement-methylmercury-2001.pdf, and www.epa.gov/ost/fishadvice/volume2/index.html)

Background

Mercury is widely distributed in the environment due to both natural and anthropogenic processes. It is released generally as elemental mercury (Hg0) or divalent mercury (Hg2+). It can be converted between these forms and may form mercury compounds by chemical processes in air, water, and soil. Biological processes in other media, primarily soil and sediment, can convert inorganic mercury into organic, mostly methylmercury. In fish tissue, the majority of mercury is methylmercury. Generally, the amount of mercury in fish tissue increases with the age and the size of the fish. The accumulation of mercury in fish varies among species; for the most part, the fish-eating species of fish accumulate higher concentrations of mercury than do nonpiscivorousfish. Mercury is found in highest concentrations in organs and muscle.

Data on mercury toxicity have been reviewed for inclusion in IRIS. Currently there are both RfDs and cancer assessments in IRIS for elemental mercury, inorganic mercury (mercuric chloride), and methylmercury (interim RfD). EPA, in response to a mandate of the Clean Air Act Amendments of 1990, has prepared a multivolume *Mercury Study Report to Congress*. This has been peer reviewed extensively including a recent review by the Science Advisory Board (SAB). (U.S. EPA, 1997d). Methylmercury has also been the subject of evaluation by numerous states. Detailed analyses have been conducted in some specific areas, including evaluation of data regarding blood and hair mercury levels, toxic effects, and biological half-life values to estimate safe consumption levels of contaminated fish (Shubat, 1991, 1993; Stern, 1993). As discussed in previous sections, a total exposure assessment is beyond the scope of this document. Readers may wish to consult other sources to obtain information on background levels of methylmercury in the environment. Additional information on dietary sources of mercury is available in the FDA *Adult Total Diet Study*, conducted from October 1977 through September 1978, which contains information on total mercury content (not restricted to methylmercury), in a number of foods (Podrebarac, 1984). Readers are also referred to Volume III, *An Assessment of Exposure from Anthropogenic Mercury Emissions in the United States* of the *Mercury Study Report to Congress* (U.S. EPA, 1997d).

Pharmacokinetics

Methylmercury is rapidly and nearly completely absorbed from the gastrointestinal tract; 90 to 100 percent absorption is estimated (WHO, 1990). Methylmercury is somewhat lipophilic, allowing it to pass through lipid membranes of cells and facilitating its distribution to all tissues, and it binds readily to proteins. Methylmercury in fish binds to amino acids in fish muscle tissue. The highest methylmercury levels in humans are generally found in the kidneys. Methylmercury

in the body is considered to be relatively stable and is only slowly transformed to form other forms of mercury. Methylmercury readily crosses the placental and blood/ brain barriers.

Chronic Toxicity

Although both elemental and methylmercury produce a variety of health effects at relatively high exposures, neurotoxicity is the effect of greatest concern. This is true whether exposure occurs to the developing embryo or fetus during pregnancy or to adults and children. Human exposure to methylmercury has generally been through consumption of contaminated food.

Recent studies have examined populations that are exposed to lower levels of methylmercury as a consequence of routine consumption of fish and marine mammals, including studies of populations around the Great Lakes and in New Zealand (Kjellstrom et al., 1986a, 1986b), the Amazon basin (e.g., Lebel et al., 1996; Marsh et al., 1995b), the Seychelles Islands (Marsh et al., 1995a), and the Faroe Islands (Dahl et al., 1996). The last two studies are of large populations of children presumably exposed to methylmercury in utero. Very sensitive measures of developmental neurotoxicity in these populations are still being analyzed and published. A 1998 workshop discussed these studies and concluded that they have provided valuable new information on the potential health effects of methylmercury. Significant uncertainties remain, however, because of issues related to exposure, neurobehavioral end points, confounders and statistics, and study design.

Reproductive and Developmental Toxicity

Data are available on reproductive and developmental effects in rats, mice, guinea pigs, hamsters, and monkeys. Convincing data from a number of human studies (i.e., Minamata Japan) also indicate that methylmercury causes subtle to severe neurologic effects depending on dose and individual susceptibility. EPA considers methylmercury to have sufficient human and animal data to be classified as a developmental toxicant.

Methylmercury accumulates in body tissue; consequently, maternal exposure occurring prior to pregnancy can contribute to the overall maternal body burden and result in exposure to the developing fetus. In addition, infants may be exposed to methlymercury through breast milk. Therefore, it is advisable to reduce methylmercury exposure to women with childbearing potential to reduce overall body burden.

Special Susceptibilities

The developing fetus is at greater risk from methylmercury exposure than are adults. Data on children exposed only after birth are insufficient to determine if this group has increased susceptibility to central nervous system effects of methlymercury. In addition, children are considered to be at increased risk of methylmercury exposure by virtue of their greater food consumption (mg food/kg body weight) by comparison to adult exposures. Additional risk from higher mercury ingestion rates may also result from the apparently decreased ability of children’s bodies to eliminate mercury.

Summary of EPA Health Benchmarks

Oral RfD Summary

Critical Effect	Experimental Doses*	UF	MF	RfD
Developmental neuropsychological impairment Human epidemiological studies (Grandjean et al., 1997; Budtz-Jørgensen et al., 1999a)	Benchmark Dose: $BMDL_{05}$ range of 46-79 ppb in maternal blood for different neuropsychological effects in the offspring at 7 years of age, corresponding to a range of maternal daily intakes of 0.857-1.472 µg/kg-day	10	1	$1E^{-4}$ mg/kg-day (0.0001 mg/kg-day)

*Conversion Factors and Assumptions —Maternal daily dietary intake levels were used as the dose surrogate for the observed developmental effects in the children exposed in utero. The daily dietary intake levels were calculated from blood concentrations measured in the mothers with supporting additional values based on their hair concentrations. A benchmark dose approach (BMD) was used rather than a no-observed-adverse-effect level/lowest-observed-adverse-effect level (NOAEL/LOAEL) approach to analyze the neurological effects in children as the response variable.

This assessment updates the 1995 RfD assessment on IRIS and is the same as the RfD that was based on the study of a poisoning episode in Iraq in which developmental neurotoxicity was observed following ingestion of methylmercury-treated grain (Marsh et al., 1987).

Polychlorinated Biphenyls (PCBs)

(Excerpts are given here. For complete information and citations given in this section, see www.epa.gov/ost/fishadvice/volume2/index.html)

Polychlorinated biphenyls (PCBs) are a mixture of chlorinated biphenyl chemicals comprised of various chlorine substitution patterns. There are 209 possible PCB congeners. Mixtures of PCBs were marketed in the United States under the trade name Aroclor, with a numeric designation that indicated their chlorine content. Although production and use of PCBs were banned in 1979, this chemical group is extremely persistent in the environment and bioaccumulates through the food chain. However, environmental mixtures of PCBs differ from the commercial mixtures because of partitioning, transformation, and bioaccumulation. There is evidence that some of the more toxic PCB congeners preferentially accumulate in higher organisms (Aulerich et al., 1986). Consequently, the aggregate toxicity of a PCB mixture may increase as it moves up the food chain (U.S. EPA, 1993a). PCB exposure is associated with a wide array of adverse health effects in experimental animals, but the effects of PCB exposure in humans are less clear. Many effects have only recently been investigated (e.g., endocrine effects), and the implications of newer studies are not fully known. The health effects of PCBs are still under active evaluation and currently there is not sufficient information on the specific congeners to develop congener-specific quantitative estimates of health risk (ATSDR, 1998c; U.S. EPA, 1993a). Aroclor mixtures, rather than environmental mixtures or bioconcentrated PCB mixtures, have been used in laboratory animal studies to determine toxicity. The preferable studies would be those that utilize human dose-response data from populations who have consumed PCBs via fish or who have been exposed to PCBs in occupational settings. Because sufficient human data are lacking, animal data were used to develop RfDs and CSFs for PCBs. The Office of Water recommends that total PCBs, calculated as the sum of the concentrations of the congeners or homologue groups, be reported. Aroclor analysis is not recommended, except for screening studies, because environmental PCB mixtures cannot be characterized by any commercial Aroclor mixture (Cogliano, 1998).

Pharmacokinetics

PCBs are absorbed through the GI tract and distributed throughout the body. Studies of individual chlorobiphenyl congeners indicate, in general, that PCBs are readily absorbed, with an oral absorption efficiency of 75 percent to greater than 90 percent (ATSDR, 1998b). Because of their lipophilic nature, PCBs, especially the more highly chlorinated congeners (tetra- through hexachlorobiphenyl), tend to accumulate in lipid-rich tissues. Greater relative amounts of PCBs are usually found in the liver, adipose tissue, skin, and breast milk. It has been shown that absorption of tetra- and higher chlorinated congeners from breast milk by nursing infants ranges from 90 to 100 percent of the dose (ATSDR, 1998b). Offspring can also be exposed to PCBs through placental transfer. PCBs have also been measured in other body fluids including plasma, follicular fluid, and sperm fluid. The retention of PCBs in fatty tissues is linked to the degree of chlorination and also to the position of the chlorine atoms in the biphenyl ring. In general, higher chlorinated PCBs persist for longer periods of time. Pharmacokinetics modeling of PCB disposition indicates that PCB movement in the body is a dynamic process, with exchanges between various tissues that depend on fluctuating exposure levels to specific congeners. The

result is elimination of congeners that are more easily metabolized and retention of those that resist metabolism (ATSDR, 1998c).

Chronic Toxicity

In animal studies, numerous effects have been documented, including hepatic, gastrointestinal, hematological, dermal, body weight changes, endocrine, immunological, neurological, and reproductive effects (ATSDR, 1998b). Most of the studies have involved oral exposure. Despite the variety of adverse effects observed in animals exposed to PCBs, overt adverse effects in humans have been difficult to document. This has been attributed to the fact that, in most cases, the dosages tested in animals were considerably higher than those found in occupational exposures and to the difficulties with interpreting epidemiological studies (James et al., 1993; Kimbrough, 1995). These include multiple confounding factors, uncertain exposure estimates, and statistical limitations. Skin rashes and a persistent and severe form of acne (chloracne) have been reported following exposures to PCBs. Occupational and accidental exposures have indicated that PCBs may affect many organs including the gastrointestinal, respiratory, immune, central nervous, and cardiovascular systems.

EPA has derived an RfD of 2×10^{-5} mg/kg-d for Aroclor 1254 (IRIS, 1999). The RfD was based on a LOAEL of 0.005 mg/kg-d for ocular and immunological effects in monkeys. The study reported ocular exudate and inflamed Meibomian glands, distorted growth of finger and toenails, and decreased antibody response (IgM and IgG) to injected sheep red blood cells at the lowest dose tested. Uncertainty factors of 10 for sensitive individuals, 3 for extrapolation from monkeys to humans, 3 for extrapolation from a subchronic exposure to a chronic RfD, and 3 for use of a minimal LOAEL were applied, resulting in a total uncertainty factor of 300. An uncertainty factory of 3 (rather than 10) for extrapolation from subchronic to chronic exposure was used, because the duration of the critical study continued for approximately 25 percent of the lifespan of monkeys, and the immunologic and clinical changes observed did not appear to be dependent upon duration.

EPA has medium confidence in the study used as the basis for the RfD for Aroclor 1254, in the database, and in the RfD. EPA based this rating on the fact that the database consisted of a large number of laboratory animal and human studies; however, there were some inconsistencies in the effect levels for reproductive toxicity and the results of an unpublished study were considered (IRIS, 1999).

Developmental Toxicity

PCB mixtures have been shown to cause adverse developmental effects in experimental animals (ATSDR, 1998c). Some human studies have also suggested that PCB exposure may cause adverse effects in children and in developing fetuses while other studies have not shown effects (U.S. EPA, 1999a). Reported effects include lower IQ scores (Jacobson and Jacobson, 1996), low birth weight (Rylander et al., 1998), and lower behavior assessment scores (Lonky et al., 1996). However, study limitations, including lack of control for confounding variables, and deficiencies in the general areas of exposure assessment, selection of exposed and control

subjects, and the comparability of exposed and control samples. Different findings from different studies provide inconclusive evidence that PCBs cause developmental effects in humans (ATSDR, 1998b).

The RfD for Aroclor 1016 is based on reduced birth weights observed in monkeys in a 22-month study (discussed below under longer-term developmental studies). This study established a NOAEL of 0.007 mg/kg-d. Applying an uncertainty factor of 100 (3 for sensitive individuals [infants exposed transplacentally], 3 for interspecies extrapolation, 3 for database limitations [male reproductive effects are not directly addressed and two-generation reproductive studies are not available], and 3 for extrapolation from subchronic to chronic) to the NOAEL yields an RfD of 7×10^{-5} mg/kg-d (IRIS, 1999). However, since the RfD for Aroclor 1254 is more conservative (2×10^{-5} mg/kg-d) and protects against adult toxicity concerns as well as the risk to the fetus and children, this RfD will be used to calculate the consumption limits for all populations (adults, women of reproductive age, and children).

EPA has medium confidence in the study, in the database, and in the RfD for Aroclor 1016. EPA based this rating on the fact that the critical study was well conducted in a sensitive animal species and the database for PCBs in general is extensive; however, since mixtures of PCBs found in the environment do not match the pattern of congeners found in Aroclor 1016, EPA felt that only a medium confidence ranking could be given. For those particular environmental applications where it is known that Aroclor 1016 is the only form of PCB contamination, EPA stated that the RfD could be considered to have a high confidence rating (IRIS, 1999).

A study was conducted of pregnancy outcomes in women who had consumed PCB-contaminated fish from Lake Michigan over an average of 16 years (exposure both prior to and during pregnancy). Consumption of contaminated fish and levels of total PCBs in cord serum correlated with lower birth weight, smaller head circumference, and shorter gestational age. Fish consumption, however, was correlated with delayed neuromuscular maturity, and, at 7 months, the children had subnormal visual recognition memory. Children from this cohort were examined at age 4 and 11 years. At age 4, cord serum PCB levels were associated with impaired short-term memory. Activity level was inversely related to 4-year serum PCB level and also to maternal milk PCB level. At age 11, prenatal exposure to PCBs was associated with lower full-scale and verbal IQ scores after controlling for potential confounding variables, such as Socioeconomic status. The results from this series of studies were confounded by possible maternal exposure to other chemicals and by the fact that the exposed group, on average, drank more alcohol and caffeine, prior to and during pregnancy, weighed more, and took more cold medications during pregnancy, than the nonexposed group (Fein et al., 1984a, 1984b). Other relevant studies generally found no significant differences between control groups and exposed groups concerning stillbirths, multiple births, preterm births, congenital anomalies, and low birth weight. Information on chronic developmental toxicity is available from studies in Rhesus monkeys (ATSDR, 1998b). Exposure periods ranged from 12 to 72 months. Inflammation of tarsal glands, nail lesions, and gum recession were noted in offspring of monkeys exposed to Aroclor 1254. Adverse neurobehavioral effects were reported following exposure to Aroclor 1016 and Aroclor 1248. Other observed effects included reduction in birth weight and increased infant death for Aroclor 1248.

Exposure via lactation is a significant concern for neonates because PCBs concentrate in milk fat. Animal studies indicate that lactational exposure, in some cases, can be more significant than transplacental transfer. In monkeys, signs of intoxication have been observed in offspring exposed to PCBs in maternal milk (ATSDR, 1998b).

In summary, the results from some studies in humans suggest that exposure to PCBs may cause developmental effects. However, limitations of these studies diminished the validity of the results. Animal studies indicate that PCBs can cause some developmental effects following prenatal or postnatal exposure.

Mutagenicity

The majority of mutagenicity assays of PCBs have been negative (IRIS, 1999). However, an increase in the percentage of chromosomal aberrations in peripheral lymphocytes and an increase in the sister chromatid exchange rate were reported in a study of workers manufacturing PCBs for 10 to 25 years. Although workers and controls were matched for smoking and drinking, concurrent exposure to other known human genotoxic chemicals occurred (ATSDR, 1998b). Another study found an increased incidence of chromatid exchanges in lymphocytes from workers exposed to PCBs in an electric power substation fire compared to unexposed controls. It is possible that toxic chlorinated dioxins and/or furans generated during the fire may have been responsible for the effects. The weight of evidence from the in vitro and in vivo genotoxicity studies suggests that PCBs are not likely to be genotoxic to humans. However, exposure to PCBs may enhance the genotoxic activity of other chemicals (ATSDR, 1998b).

Carcinogenicity

PCBs are classified by EPA as Group B2; probable human carcinogens . This is based on studies that have found liver tumors in rats exposed to Aroclors 1260, 1254, 1242, and 1016. Evaluation of the animal data indicates that PCBs with 54 percent chlorine content induces a higher yield of liver tumors in rats than other PCB mixtures.

Human epidemiological studies of PCBs have not yielded conclusive results (Silberhorn et al.,1990). There is some suggestive evidence that xenoestrogens, including PCBs, may play a role in breast cancer induction (ATSDR, 1998c). Some studies have indicated an excess risk of several cancers, including: liver, biliary tract, gallbladder, gastrointestinal tract, pancreas, melanoma, and non-Hodgkin's lymphoma (IRIS, 1999, ATSDR, 1998c). As with all epidemiological studies, it is very difficult to obtain unequivocal results because of the long latency period required for cancer induction and the multiple confounders arising from concurrent exposures, lifestyle differences, and other factors. The currently available human evidence is considered inadequate but suggestive that PCBs may cause cancer in humans (IRIS, 1999).

The Agency's recent peer-reviewed reassessment published in a final report, *PCBs: Cancer Dose-Response Assessment and Application to Environmental Mixtures* (U.S. EPA, 1996c), adopts an innovative approach that distinguishes among PCB mixtures by using information on

environmental processes. It considers all cancer studies (which used commercial mixtures only) to develop a range of cancer slope factors, then uses information on environmental processes to provide guidance on choosing an appropriate slope factor for representative classes of environmental mixtures and different pathways. Depending on the specific application, either central estimates or upper bound estimates can be appropriate. Central estimates describe a typical individual's risk, while upper bounds provide greater assurance that the true risk is not likely to be underestimated. Central estimates are used for comparing or ranking environmental hazards, while upper bounds provide information about the precision of the comparison or ranking. In this reassessment, the use of the upper bound values was found to increase cancer potency estimates by only two or threefold over those using central tendency. Upper bounds are useful for estimating risks or setting exposure-related standards to protect public health and are used by EPA in quantitative cancer risk assessment. Thus, the cancer potency of PCB mixtures is determined using a tiered approach based on environmental exposure routes with upper-bound slope factors ranging from 0.07 to 2 per mg/kg-d for average lifetime exposures to PCBs. It is noteworthy that bioaccumulated PCBs appear to be more toxic than commercial PCBs and appear to be more persistent in the body (IRIS, 1999). In addition, there is evidence that early-life exposures may result in an increased risk (U.S. EPA, 1996c). Therefore, the highest cancer slope factor is recommended for the following conditions: food chain exposure; sediment and soil ingestion; inhalation of dust or aerosols; dermal exposure (if an absorption factor has been applied); presence of dioxin-like, tumor- promoting, or persistent congeners; and early-life exposure. Alternatively, if site-specific congener concentrations are available, the risk assessment can be supplemented by determining the dioxin-like toxicity (U.S. EPA, 1996c; Cogliano, 1998).

Special Susceptibilities

There is evidence that embryos, fetuses, and neonates are more susceptible to PCBs due to their underdeveloped enzymatic systems, which may lead to increased PCB accumulation in the body. Breast-fed infants may have an increased risk because of bioconcentration of PCBs in breast milk and high intake rates relative to body weights. In addition, there is evidence that a steroid present in human milk inhibits glucuronyl transferase activity, which could, in turn, inhibit glucuronidation and excretion of PCB metabolites. Other individuals with potentially greater risk include those with liver and blood diseases or those with syndromes associated with impairment to the metabolic systems that help eliminate PCBs from the body.

Summary of EPA Health Benchmarks

Chronic Toxicity: 2×10^{-5} mg/kg-d based on Aroclor 1254

Carcinogenicity: 2.0 per mg/kg-d based on mixed PCBs

APPENDIX C: SPREADSHEET INSTRUCTIONS FOR CALCULATING MEAL FREQUENCIES

1. Instructions

FISH CONSUMPTION ADVISORY WORKSHEETS

PLEASE READ CAREFULLY BEFORE PROCEEDING!!

The following worksheets contain equations for calculating fish meal frequencies on a monthly or yearly basis.
Each worksheet pertains to an individual chemical for either cancer of non-cancer endpoints
For carcinogens, meal frequencies are assessed for general population only unless otherwise indicated.
For non-carcinogens, 3 separate meal frequencies are estimated: general population, children ages 0-6 yr, and women of child-bearing age

INSTRUCTIONS

1. The inputs for parameters (body weight, meal size, exposure duration, cooking reduction, averaging time) are given in the TSD.
2. A cancer risk level of 10-5 and a hazard index of 1 are set by MDE policy.
3. **The above inputs should not be altered without permission.**
4. With each successive fish sampling and analysis program, new fish tissue levels will be made available for waterways in MD.
5. The parameter "Cf" represents the fish tissue level for a waterbody where an advisory is under consideration.
6. "Cf" is the median value for that waterbody.
7. **"Cf" may be adjusted as new data become available to estimate the recommended maximum meal frequency using the following procedure:**
8. Insert a new Worksheet
9. Label new worksheet with chemical name, endpoint (cancer or non-cancer), and year.
10. Copy relevant existing worksheet into new worksheet and modify **new worksheet only**.
11. Enter new data for Cf to estimate new meal frequency.
12. This new Worksheet should contain information for all waterbodies being assessed for the given chemical and endpoint.
13. Each worksheet may also contain fish/crab-specific estimates

2. Methylmercury calculations for the general population, children, and women of child bearing age

General population – MeHg

MF = HIxBWxATxRfD/CfxMSx(100-RF/100)xED

MF	HI	BW	AT	RfD	Cf	MS	RF	ED
0.14	1	76	10957.5	0.0001	0.235	0.227	1	10957.5

MF	= meal frequency (meal/day)		
HI	= hazard index (unit less; 1)		
BW	= body weight (kg)		
AT	= averaging time (days)		
RfD	= Reference Dose (mg/kg-day)		
C_f	= median concentration of the contaminant in the edible portion of the fish (mg/kg or ppm)		
MS	= meal size in ounces x 0.02835 (kg/meal)	8 oz meal = 0.226796 kg	3 oz meal = 0.085049 kg
RF	= percent reduction in contaminant concentration in the fish due to trimming and cooking losses (%) given as 100-RF/100		
ED	= exposure duration (days)		

****Meals per month = 4**

**Fractional numbers of MF are treated as follows:
1. Use traditional method for rounding to the nearest whole number of meals (e.g., 1.0 to 1.4 = 1; 1.5 to 2.0 = 2).
2. For MF < 1 meal/month, but ≥ 0.5 meal/month, recommendation is to limit consumption to 1 meal every other month.
3. For MF < 0.5 meal/month, recommendation is to NOT consume those fish.

Children ages 0-6 (separate calc for children due to neurodevelopmental effects) MeHg

MF = HIxBWxATxRfD/CfxMSx(100-RF/100)xED

MF	HI	BW	AT	RfD	Cf	MS	RF	ED
0.07	1	14.5	2191.5	0.0001	0.235	0.085049	1	2191.5

MF = meal frequency (meal/day)
HI = hazard index (unitless; 1)
BW = body weight (kg)
AT = averaging time (days)
RfD = Reference Dose (mg/kg-day)
C_f = concentration of the contaminant in the edible portion of the fish (mg/kg or ppm)
MS = meal size in ounces x 0.02835 (kg/meal) 8 oz meal = 0.226796 kg 3 oz meal = 0.085049 kg
RF = percent reduction in contaminant concentration in the fish due to trimming and cooking losses (%) given as 100-RF/100
ED = exposure duration (days)

Meals per month = 2

**Fractional numbers of MF are treated as follows:
1. Use traditional method for rounding to the nearest whole number of meals (e.g., 1.0 to 1.4 = 1; 1.5 to 2.0 = 2).
2. For MF < 1 meal/month, but ≥ 0.5 meal/month, recommendation is to limit consumption to 1 meal every other month.
3. For MF < 0.5 meal/month, recommendation is to NOT consume those fish.

Women of child-bearing age - MeHg

MF = HIxBWxATxRfD/CfxMSx(100-RF/100)xED

MF	HI	BW	AT	RfD	Cf	MS	RF	ED
0.13	1	67	10957.5	0.0001	0.235	0.227	1	10957.5

MF	= meal frequency (meal/day)		
HI	= hazard index (unitless; 1)		
BW	= body weight (kg)		
AT	= averaging time (days)		
RfD	= Reference Dose (mg/kg-day)		
C_f	= median concentration of the contaminant in the edible portion of the fish (mg/kg or ppm)		
MS	= meal size in ounces x 0.02835 (kg/meal)	8 oz meal = 0.226796 kg	3 oz meal = 0.085049 kg
RF	= percent reduction in contaminant concentration in the fish due to trimming and cooking losses (%) given as 100-RF/100		
ED	= exposure duration (days)		

****Meals per month = 4**

**Fractional numbers of MF are treated as follows:

1. Use traditional method for rounding to the nearest whole number of meals (e.g., 1.0 to 1.4 = 1; 1.5 to 2.0 = 2).
2. For MF < 1 meal/month, but ≥ 0.5 meal/month, recommendation is to limit consumption to 1 meal every other month.
3. For MF < 0.5 meal/month, recommendation is to NOT consume those fish.

3. PCBs calculations (non-cancer) for the general population, children, and women of child bearing age

General population – PCBs - non-cancer

MF = HIxBWxATxRfD/CfxMSx(100-RF/100)xED

MF	HI	BW	AT	RfD	Cf	MS	RF	ED
0.25	1	76	10957.5	0.00002	0.039	0.227	0.7	10957.5

MF	= meal frequency (meal/day)		
HI	= hazard index (unitless; 1)		
BW	= body weight (kg)		
AT	= averaging time (days)		
RfD	= Reference Dose (mg/kg-day)		
C_{fish}	= median concentration of the contaminant in the edible portion of the fish (mg/kg or ppm)		
MS	= meal size in ounces x 0.02835 (kg/meal)	8 oz meal = 0.226796 kg	3 oz meal = 0.085049 kg
RF	= percent reduction in contaminant concentration in the fish due to trimming and cooking losses (%) given as 100-RF/100		
ED	= exposure duration (days)		

****Meals per month = 7**

**Fractional numbers of MF are treated as follows:
1. Use traditional method for rounding to the nearest whole number of meals (e.g., 1.0 to 1.4 = 1; 1.5 to 2.0 = 2).
2. For MF < 1 meal/month, but ≥ 0.5 meal/month, recommendation is to limit consumption to 1 meal every other month.
3. For MF < 0.5 meal/month, recommendation is to NOT consume those fish.

Children ages 0-6 (although the RfD is not based on neurodevelopmental effects, many scientists believe this effect to be important – thus a separate calculation for children is included here) - PCBs

MF = HIxBWxATxRfD/CfxMSx(100-RF/100)xED

MF	HI	BW	AT	RfD	Cf	MS	RF	ED
0.12	1	14.5	2191.5	0.00002	0.039	0.085049	0.7	2191.5

MF	= meal frequency (meal/day)		
HI	= hazard index (unitless; 1)		
BW	= body weight (kg)		
AT	= averaging time (days)		
RfD	= Reference Dose (mg/kg-day)		
C_{fish}	= median concentration of the contaminant in the edible portion of the fish (mg/kg or ppm)		
MS	= meal size in ounces x 0.02835 (kg/meal)	8 oz meal = 0.226796 kg	3 oz meal = 0.085049 kg
RF	= percent reduction in contaminant concentration in the fish due to trimming and cooking losses (%) given as 100-RF/100		
ED	= exposure duration (days)		

****Meals per month = 4**

**Fractional numbers of MF are treated as follows:

1. Use traditional method for rounding to the nearest whole number of meals (e.g., 1.0 to 1.4 = 1; 1.5 to 2.0 = 2).
2. For MF < 1 meal/month, but ≥ 0.5 meal/month, recommendation is to limit consumption to 1 meal every other month.
3. For MF < 0.5 meal/month, recommendation is to NOT consume those fish.

Women of child-bearing age – PCBs – non-cancer								
MF =	HIxBWxATxRfD/CfxMSx(100-RF/100)xED							
MF	HI	BW	AT	RfD	Cf	MS	RF	ED
0.22	1	67	10957.5	0.00002	0.039	0.227	0.7	10957.5

MF	= meal frequency (meal/day)		
HI	= hazard index (unitless; 1)		
BW	= body weight (kg)		
AT	= averaging time (days)		
RfD	= Reference Dose (mg/kg-day)		
C_{fish}	= median concentration of the contaminant in the edible portion of the fish (mg/kg or ppm)		
MS	= meal size in ounces x 0.02835 (kg/meal)	8 oz meal = 0.226796 kg	3 oz meal = 0.085049 kg
RF	= percent reduction in contaminant concentration in the fish due to trimming and cooking losses (%) given as 100-RF/100		
ED	= exposure duration (days)		

****Meals per month =**	**7**

**Fractional numbers of MF are treated as follows:
1. Use traditional method for rounding to the nearest whole number of meals (e.g., 1.0 to 1.4 = 1; 1.5 to 2.0 = 2).
2. For MF < 1 meal/month, but ≥ 0.5 meal/month, recommendation is to limit consumption to 1 meal every other month.
3. For MF < 0.5 meal/month, recommendation is to NOT consume those fish.

4. PCBs calculations (cancer) for the general population

General population – PCBs - cancer

MF = RLxBWxAT/CfxMSx(100-RF/100)xEDxCPF

MF	RL	BW	AT	Cf	MS	RF	ED	CPF
0.14	0.00001	76	25567.5	0.039	0.227	0.7	10957.5	2

MF = meal frequency (meal/day)

RL = risk level (unitless; 1 x 10^{-5})

BW = body weight (kg)

AT = averaging time (days) (lifetime for carcinogens)

C_{fish} = median concentration of the contaminant in the edible portion of the fish (mg/kg or ppm)

MS = meal size (kg/meal) — 8 oz meal = 0.226796 kg

RF = percent reduction in contaminant concentration in the fish due to trimming and cooking losses (%) given as 100-RF/100

ED = exposure duration (days)

CPF = cancer potency factor (1/mg/kg-day)

****Meals per month = 4**

**Fractional numbers of MF are treated as follows:

1. Use traditional method for rounding to the nearest whole number of meals (e.g., 1.0 to 1.4 = 1; 1.5 to 2.0 = 2).
2. For MF < 1 meal/month, but ≥ 0.5 meal/month, recommendation is to limit consumption to 1 meal every other month.
3. For MF < 0.5 meal/month, recommendation is to NOT consume those fish.