Human Health Water Quality Criteria: Introduction to Relative Source Contribution

US Environmental Protection Agency

September 2015

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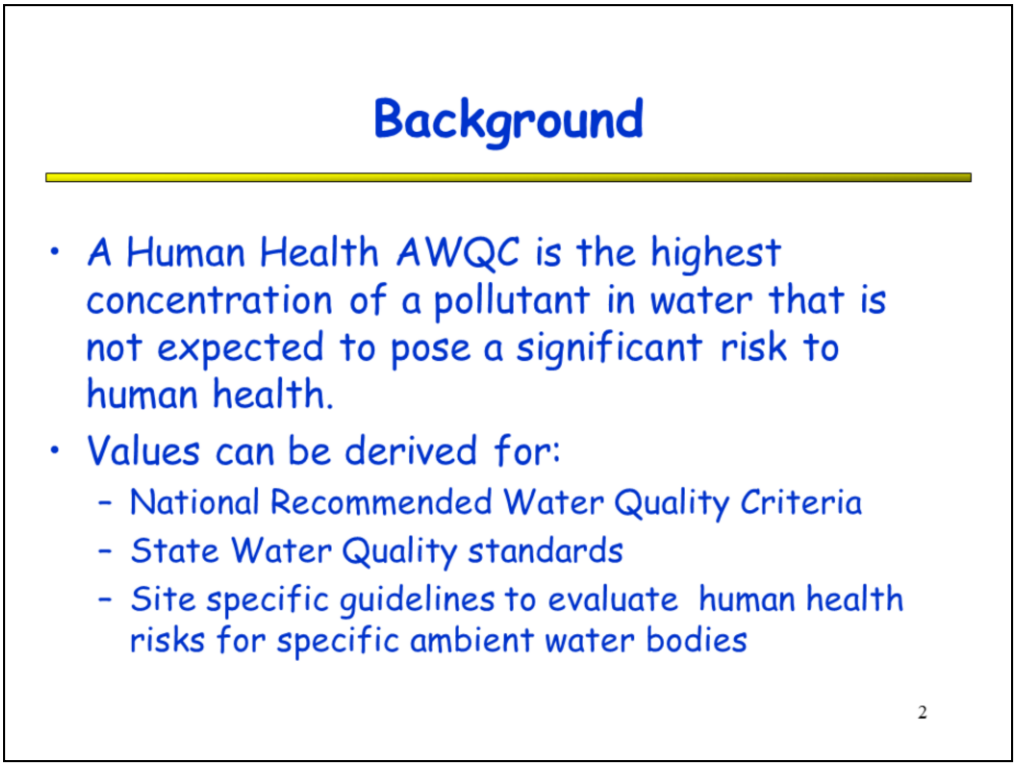
The following presentation is an introduction to the process for calculating a Relative Source Contribution for use in the derivation of an Ambient Water Quality Criterion for the protection of human health.



The human health criteria are estimates of concentrations of pollutants in ambient water that are not likely to pose a significant risk to the exposed human population. *(Ambient refers to open waters such as rivers, lakes and streams, as opposed to closed water supply systems that distribute treated water or wastewater).* Section 304(a)(1) of the Clean Water Act requires EPA periodically to review and publish criteria for water quality that accurately reflect the latest scientific knowledge on the kind and extent of all identifiable effects on human health and welfare. These criteria are not Federal regulations; however, they are sometimes used by the States and authorized Indian Tribes to establish standards. They present scientific data and guidance on the effects of pollutants that can be used to derive regulatory requirements, including the promulgation of water quality-based effluent standards *(the Clean Water Act, section 302)*, water quality standards *(the Clean Water Act, section 303)*, or toxic pollutant effluent standards *(the Clean Water Act, section 307)*.

States have a requirement to develop standards for the ambient water bodies within their boundaries. Some adopt the national standards where they exist while other develop their own standards for chemicals of concern within their states. This module will introduce the basic concepts used in the development of the relative source contribution (RSC) term that is needed to calculate the AWQC for noncarcinogens and tumorigenic chemicals that show a non-linear response to dose. The RSC is not used in the calculation of the AWQC for carcinogens with a linear response to dose.

RSC

- An RSC is used in the calculation of the HH AWQC for chemicals that are for noncarcinogens and carcinogens with a nonlinear response to dose.
- The RSC is the relative contribution of the contaminant as found in drinking water and/or fish/shellfish from a water body or water bodies of concern to total daily exposure.

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The RSC is the relative contribution of the contaminant from a water body or water bodies of concern to total daily human exposure through its use as drinking water or through ingestion of fish from that source. When the water body of concern is an estuary, which is not a source of drinking water, the value calculated is one that applies to fish/shellfish only and is identified as an "organisms only" value.

If the water body is a source water for a drinking water treatment plant and the chemicals is unregulated, it is assumed that it will not be removed by the treatment process. Accordingly water intake is included in the derivation of the AWQC to provide protection for both direct consumption and home use of treated water from the water source.

Equations for Deriving AWQC

- Noncancer Effects:

$$AWQC = RfD \cdot RSC \cdot \left(\frac{BW}{DI + \sum_{i=2}^{4} \left(FI_i \cdot BAF_i \right)} \right)$$

- Cancer Effects:
  - Nonlinear

$$AWQC = \frac{POD}{UF} \cdot RSC \cdot \left(\frac{BW}{DI + \sum_{i=2}^{4} \left(FI_i \cdot BAF_i \right)} \right)$$

- Note the RSC Term in each equation
- An RSC is not used in calculating the HH AWQC for a carcinogen considered to have a linear response to dose

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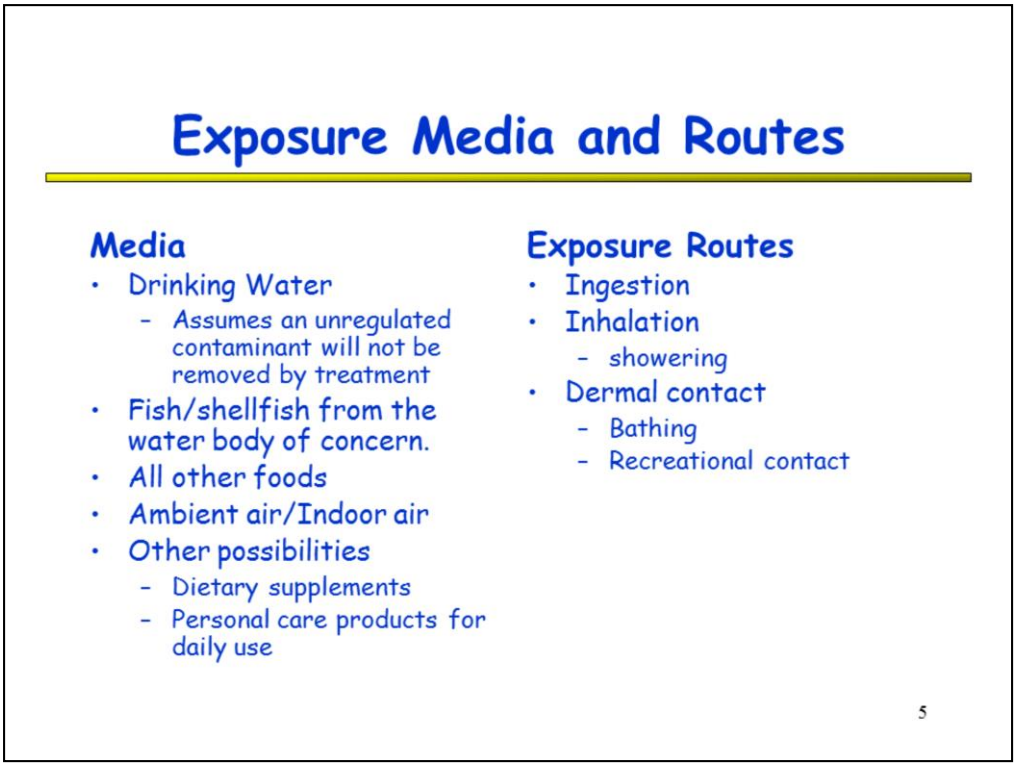
This slide presents the two equations used to calculate human health (HH) Ambient Water Quality Criteria (AWQC) that include the RSC term. No RSC value is used in calculating a guidelines for a carcinogen with a linear response to dose. The equation selected will differ depending on the chemical contaminant and the type of adverse health effect associated with that chemical.

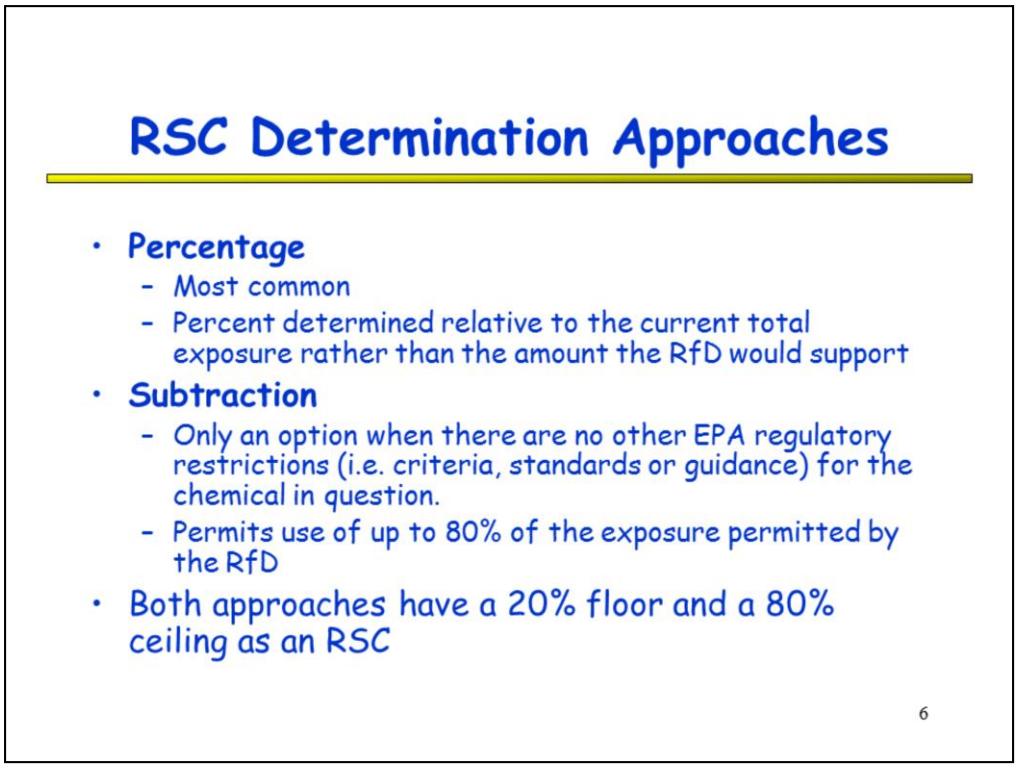


When determining the RSC, one must consider the various sources of environmental exposure to the chemical. Of primary concern are the sources directly related to the water body of concern, i.e. the water from that source that is ingested and fish that are caught an used as a source of food by sport fishermen, groups for which the fish are a major portion of their dies (subsistence tribes) or caught and sold commercially within the area.

Data on the concentrations of the contaminant in the fish are most often collected locally by the state for the fish species used by the populations of concern through periodic analysis of the amounts of chemical in the water and (on occasion) by doing a fish survey where representative fish are caught and their tissues analyzed for the presence of the contaminant. Worst case assumptions can be derived using the water concentration and trophic-level specific bioaccumulation values (BAF) for the fish species involved.

Calculation of an RSC also requires estimation of the exposure to the contaminant from all other sources of exposure. This means the State must attempt to identify the amounts in all dietary foods not including the fish/shellfish from the water body of concern; ambient air, indoor air, and other exposure sources. These data are often difficult to identify, especially for a specific locality and make calculation of a data-driven RSC a challenge.

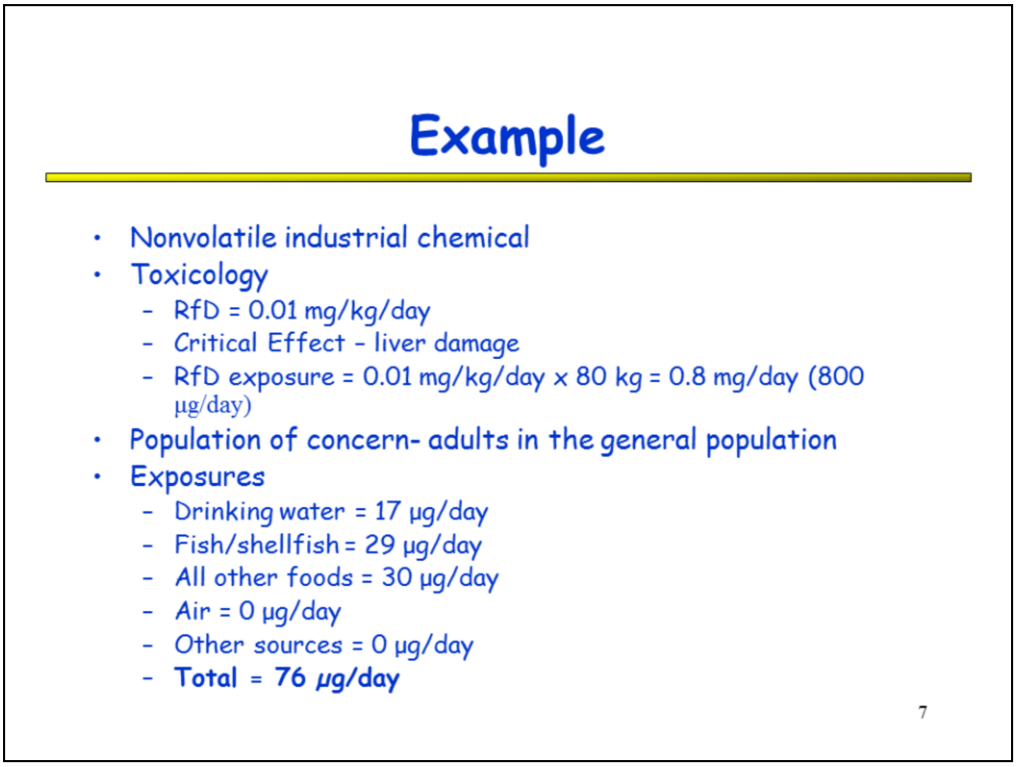
Consideration must also be given to exposure routes other than direct ingestion, such as inhalation of a chemical that volatilizes during showering and inhaled or is taken up through the skin during bathing or dishwashing. The HH Methodology presents information related to oral and inhalation exposures. Procedures for including dermal uptake in the RSC calculation are not presently available. It is very difficult to accurately and precisely identify all potential sources of exposure and quantify uptake from non-oral routes. For that reason, the RSC is always capped at 80%.



There are two approaches to derivation of an RSC, percentage and subtraction. In most cases, the percentage is the more conservative of the two because the denominator for the RSC derivation is the estimate for current total exposure and not the exposure that the reference dose (RfD) or adjusted point of departure (POD) for the cancer effect considers to be safe. The percentage approach is designed to restrict exposures to environmental contaminants to those associated with current use patterns.

The subtraction approach can only be applied in cases where there are no other EPA regulatory restrictions (criteria, standards, or guidance) for environmental releases of the contaminant to the environment. It allows up to 80% of the exposure that is considered to be safe based on the RfD or adjusted POD and is not restricted by the levels caused by current use patterns.

As mentioned previously, the 80% upper bound on the RSC is justified by the difficulties an evaluator has in identifying all sources of exposure. There is also a rationale for the 20% floor. HH AWQC guidelines are designed to protect the user against environmental contaminants that are found in in their source of drinking water and in fish/shellfish from that drinking water source. In cases where the chemical accounts for less than 20% of the total exposure the framers of the HH methodology questioned the value of establishing a HH AWQC for such a chemical since beyond a certain point it is more appropriate to reduce other exposure sources rather than developing criteria that will have a minimal impact on reducing total exposure of the population at large. Accordingly, 20% was selected as a floor for the process. The indirect impact of that floor is to discourage development of a guideline for a chemical that is a minor contributor to total exposure.



The following three slides illustrate the differences between the percentage and subtraction approach using the same data set.

The hypothetical chemical is a nonvolatile substance that is used to make plastic food packaging materials and is minimally bioaccumulative. The ambient water body of concern has been contaminated through low level industrial discharge. The chemical does not have any data that suggest it can cause cancer. The noncancer effect against which the RfD is protective is chronic centrilobular hypertrophy of the liver, a relative mild effect. The RfD equivalent exposure for an adult is 800 µg/day and is derived by multiplying the RfD (mg/kg/day) by 80 kg and multiplying the product by 1000 µg/mg to convert from mg/day to µg/day. The body weight for this conversion was selected because it is the 2015 updated body weight used by EPA for lifetime adult exposures and there are no data to suggest sensitivity by any particular age group.

A study was conducted to measure the contaminant in the water and in a homogeneous sample of fish species from that water consumed by sports fishermen. The ambient air concentration was assumed based on the low vapor pressure of the chemical at ambient air temperatures. The amount from other dietary foods came from a regional FDA total diet study (TDS) market basket. The FDA conducted their survey to monitor leaching from packaging materials into the food supply. The FDA considers the chemical to be an indirect food additive.

Note that in many cases this type of data will not be available to the risk assessor.

All values have been converted from concentrations in the media to amounts per day for the RSC calculation. Those conversions will be covered later in this presentation (slide 13).

Percentage Approach (Drinking Water and Organism)

$$RSC = \frac{DW + fish/shellfish}{DW + fish/shellfish + other} \times 100$$

$$RSC = \frac{(17 + 29\ \mu g/day)}{76\ \mu g/day} \times 100 = 61\%\ (rounded)$$

DW = drinking water, other = other exposures

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In the percentage approach the sum of the exposure from drinking water and the fish/shellfish from the ambient water body of concern is divided by the total of all known exposures and converted to a percent by multiplying by 100. when this value is used in the human health equation it is actually applied as the decimal value (0.61)

Subtraction Approach (Drinking Water and Organism)

- Calculate the RfD-supported exposure for the population of interest
  - 0.01 mg/kg/day x 80 kg (adult) = 0.8 mg/day (800 µg/day)
- Subtract the exposures for DW + fish/shellfish
  - 800 µg/day – (17 + 29 µg/day) = 754 µg/day
- Determine the percentage of the RfD-supported exposure represented by the remainder
  - 754 µg/day ÷ 800 µg/day x 100 = 94%
- Apply the upper bound limitation if necessary
  - Since the % of the RfD-supported exposure is > 80%, the RSC is restricted by the 80% upper bound

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When using the subtraction approach one subtracts the exposures from the drinking water and fish/shellfish from the RfD-equivalent exposure for an adult and then divides the remainder by the RfD-exposure equivalent converting it to a percent.

The RfD-exposure is sometimes described as the risk cup or the amount that can be released to the environment before there is a risk to the target population. The percent calculated is the percent of the risk cup that currently remains after subtracting what has been contributed from the ambient water source. In this case, the percent is greater than 80% limiting the RSC to the 80% upper bound in order to allow room in the risk cup from unanticipated exposures.

Percentage Approach (Organism Only) Example

- Used for estuarine fish/shellfish
- Will need to identify level of contaminant in the population's public drinking water supply since estuary water is not used for drinking
  - Contribution from the local public water (PW) supply was determined to be 4 µg/day (1.5 µg/L x 2.4 L/day)

$$RSC = \frac{\text{Fish/shellfish}}{\text{PW + fish/shellfish + other}} \times 100$$

$$RSC = \frac{29\ \mu g/day}{(4 + 29 + 30\ \mu g/day)} \times 100 = 46\%$$

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The following example applies to the same data set as that for the earlier examples except that in this case the fish come from an estuary where the water is not used as a drinking water source. A sample of water is collected from the local drinking water plant and is found to contribute 3 µg/day to human exposure. In this case only the fish/shellfish is used in the numerator for the equation. The total exposure is 28 µg/day (fsh/sh-fsh) + 4 µg/day (DW rounded) + 30 µg/day (oth foods) = 63 µg/day

Differences in Approaches

- Percentage approach will generally be more conservative and will minimize environmental distribution of a contaminant.
- The subtraction approach generally allows for a higher HHAWQC.
- Subtraction approach is not appropriate for chemicals with EPA ambient air standards, permitted pesticide residues, and drinking water standards.

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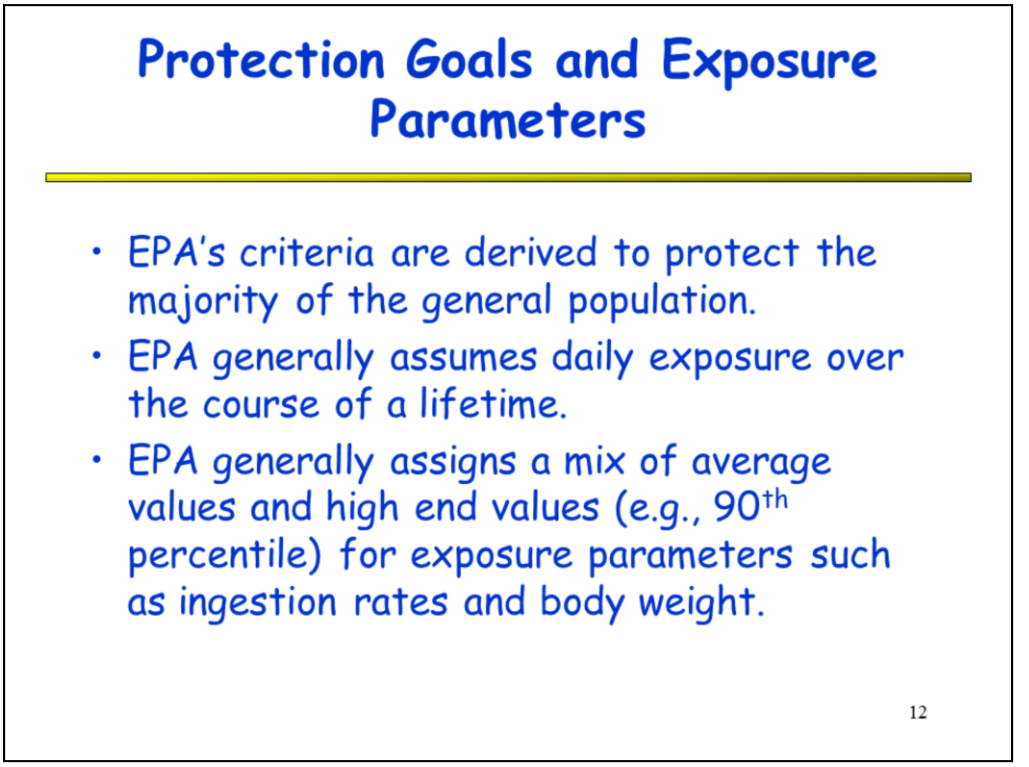

Derivation of the RSC requires converting concentrations in environmental media into daily exposure values. In most cases EPA calculates HH AWQC to protect the majority of adults in the general population for lifetime exposures. Some values are expressed as averages. Values that apply to the exposure-medium of interest are most often 90th percentile values. For example concentration of the contaminant in fish would be an average value but intake of fish would be an 90th percentile value. Both the concentration and intakes for the contaminant in the remainder of the diet would be average values.

In most cases the Human Health AWQC apply to the general adult population and assumes a lifetime exposure. However, there are some circumstances where pregnant women or children may be the population of interest. These would be situations where the critical effect on which the RfD is based applies to developmental effects that would impact the fetus during pregnancy or children during a critical period of growth or maturation.

Default Exposure Parameters

- BW = 80 kg (average adult body weight)
- DW Intake = 2.4 L/day (90th percentile)
- Fish intake = 22 g/day (90th percentile)
- Inhalation of air = 20 m^3/day
- These values are used by EPA for the national recommended water quality criteria when chronic effects are of concern.
- They are needed to convert concentration in a media to an exposure from that media.
- Conventions for the dermal exposure route are not yet available.

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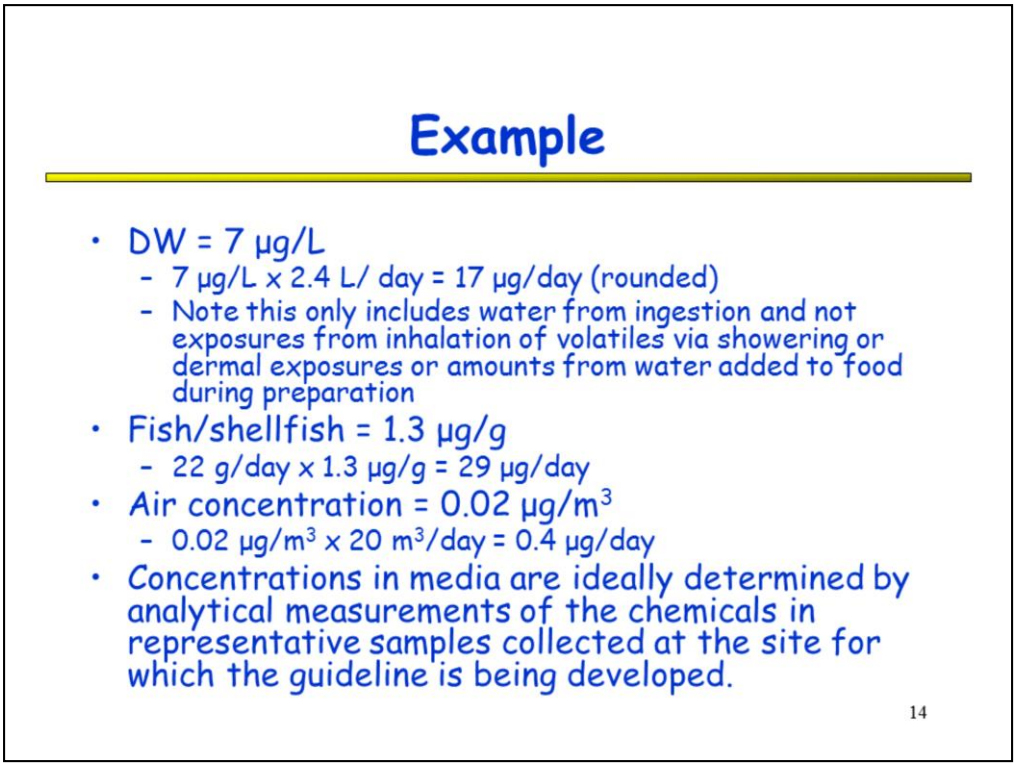
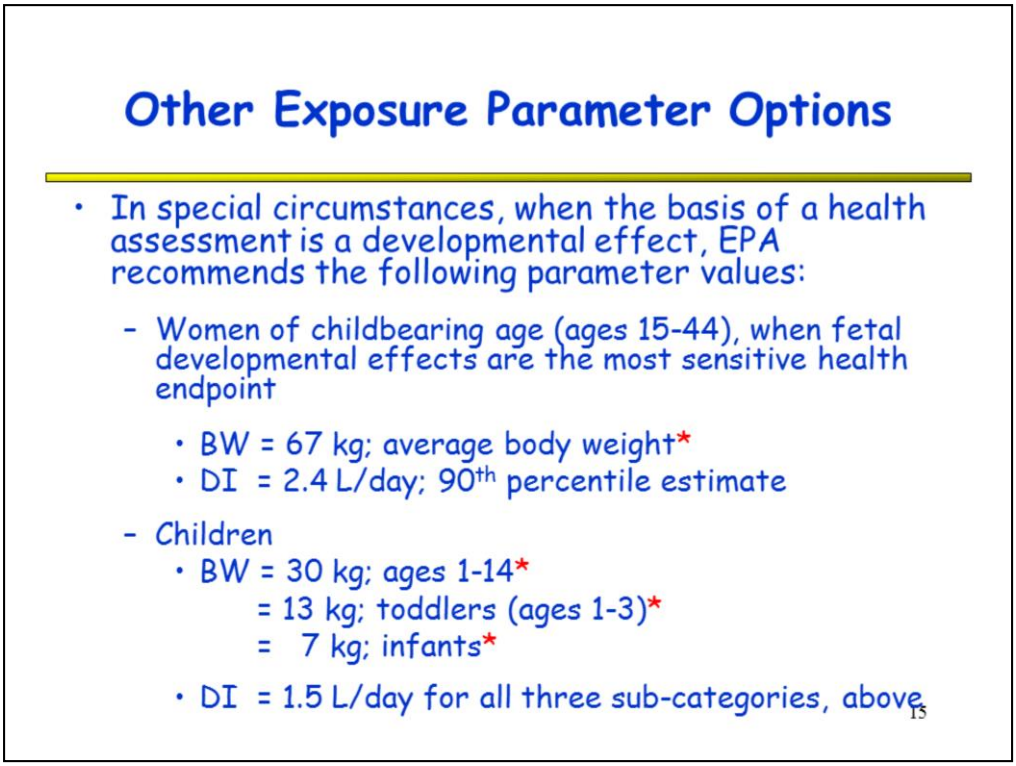
This slide presents the exposure the parameters used in cases where the HH AQWC is designed to protect adults in the general population. The values are calculated using the 2015 exposure factors.



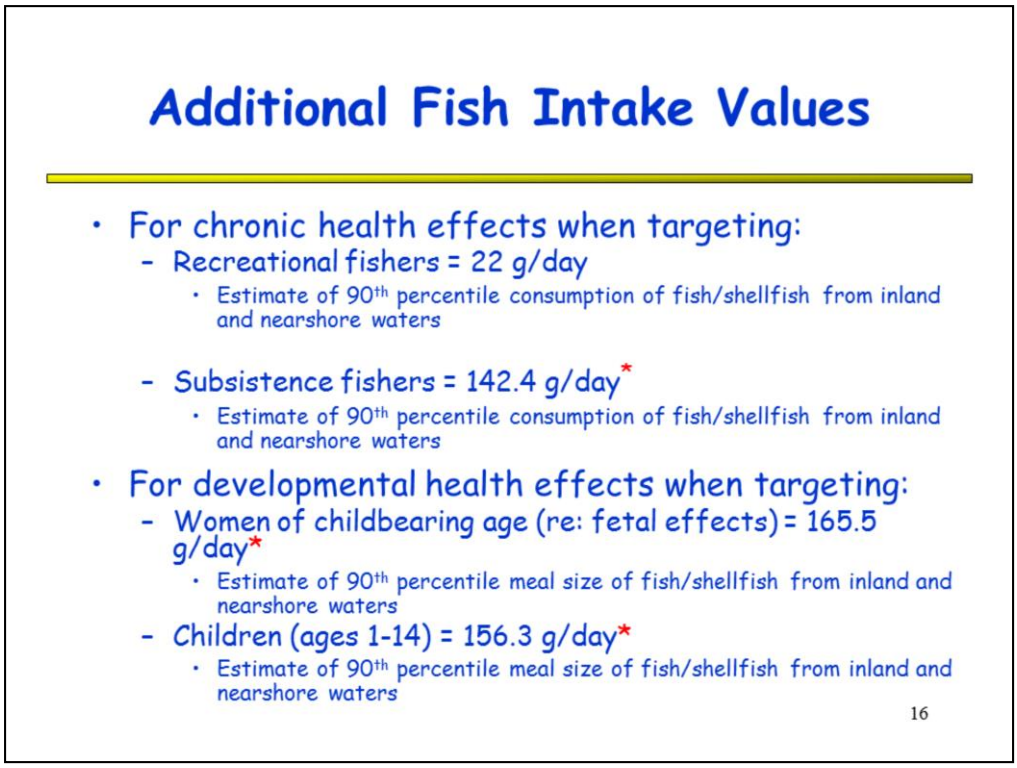
This slide illustrates how concentration in the media of concern are converted to daily exposure values using default values. The 2000 methodology identifies the analytical criteria that must be met for an assay to be considered representative. Assessors always have the option of doing a study to collect alternative values for populations of concern but to do so would be resource intensive.



EPA has also determined body weight and drinking water intake parameters that apply to pregnant women and children in critical age groups since they can be populations of concern in some instances. These values were derived from a national study (the Continuing Survey of Food Intake by Individuals: CSFII) conducted by the U. S. Department of Agriculture.

As was the case for adults, the body weights used for women of childbearing age and children are averages for the population of concern while the drinking water intakes are 90 percentile values. Fish intake options for select populations are presented on the next slide.

* Values identified with the superscript are those from the 2000 Methodology and have not yet been updated.

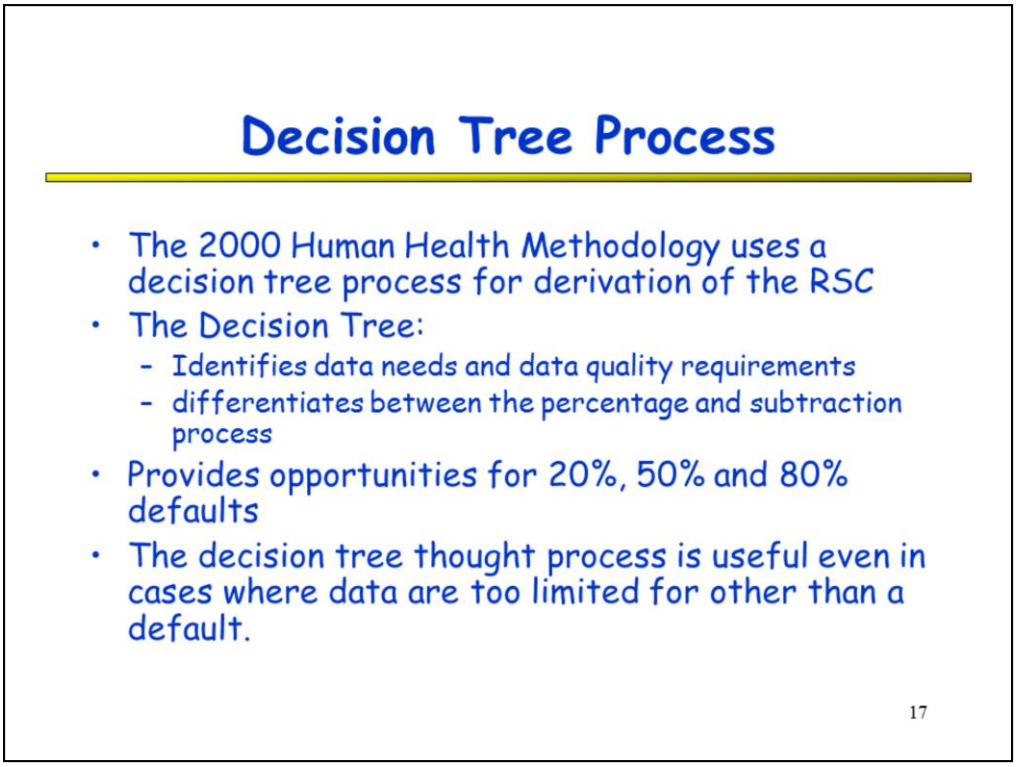


* Values identified with the superscript are those from the 2000 Methodology and have not yet been updated.

The national fresh-water fish/shellfish defaults for specific populations were also derived from the CSFII.

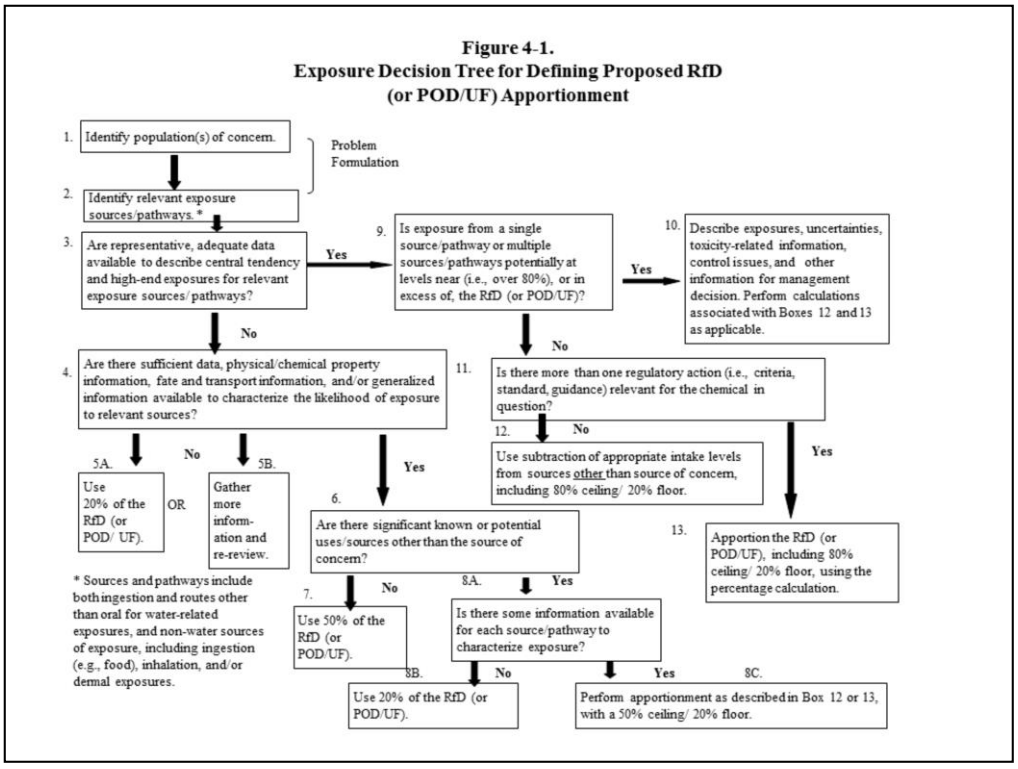
- 22 g/day is an estimate of the 90th percentile consumption of fish and shellfish from estuarine and fresh waters for adults in the general population. This value is also recommended as an estimate of consumption of fish and shellfish from estuarine and fresh waters for recreational fishers.
- 142.4 g/day is an 90th estimate of consumption of fish and shellfish from estuarine and fresh waters for subsistence fishers.
- 165.5 g/day is an estimate of the 90th percentile consumption of fish and shellfish from estuarine and fresh waters for women of childbearing age (i.e., ages 15 to 44). This value represents the consumers-only data from the survey for this particular group; specifically, the survey respondents who actually consumed fish on any of the survey days (i.e., the non-zero values only). The point of considering consumers-only (as defined above) is to produce an estimate of meal size for circumstances where acute or short-term exposures may result in adverse developmental health effects in the fetus.
- 156.3 g/day is an estimate of the 90th percentile consumption of fish and shellfish from estuarine and fresh waters for children (i.e., ages 14 and under). This value represents consumers-only data (again, the non-zero consumption values only) from the survey for this particular group. The point of considering consumers-only is to produce an estimate of meal size for circumstances where acute or sub-chronic exposures may result in adverse health effects in children.
- All of the default intake values recommended are based on the uncooked weights of the fish analyzed. EPA strongly encourages States and authorized Tribes to use the results from local or regional fish

intake surveys as more representative of their target population group(s).



The HH AQWC Methodology uses a decision tree approach to help the assessor determine if the data available are adequate to calculate a RSC using either the percentage or subtraction approach. If the data are not completely adequate the decision tree also provides routes to one of three default values.

The Agency is currently considering revisions to this methodology but even if changes are made, the thought process illustrated by the decision tree is useful to the evaluator. It relies on a combination of exposure data, use and chemical/physical property data in making an RSC decisions.



A detailed discussion of the decision tree is beyond the scope of this class. It is presented as an illustration for the number of steps and options available for the RSC. In the past most assessments used a 20% default assumption but the agency would like to encourage greater consideration for using data to support alternative values.

Independent of the process used in determining the RSC, there is a 20% floor and a 80% ceiling to account for the difficulty in identifying all possible routes of exposure.

Starting the RSC Analysis

- Determine the target population of concern
- Evaluate the relevant routes/sources of exposure
- Identify available exposure data and its relevance to the exposure scenario
- Determine if other criteria or standards exist or are being developed by EPA

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Getting started on development of an RSC requires a plan.

Is a HH AWQC needed, given the levels of contaminant found in local ambient waters?

Are there enough data to justify an approach other than one of the default options?

Which approach (percentage or subtraction) is best suited to the contaminant?

This slide identifies the steps you should take when beginning work on a RSC derivation. EPA recommends the use of data where available rather than defaults.

Data Needs

- Data to identify potential for exposure through specific media
  - Uses for chemical
  - Chemical and physical properties
    - Volatility (vapor pressure at ambient temperatures), Henry's Law constant solubility, half life in water, Kow, Koc BAF
  - TRI release or pesticide use in area
- Data on concentrations in likely exposure media
  - Ambient air, food, water, local fish, etc
- Dietary and water consumption habits for populations of concern

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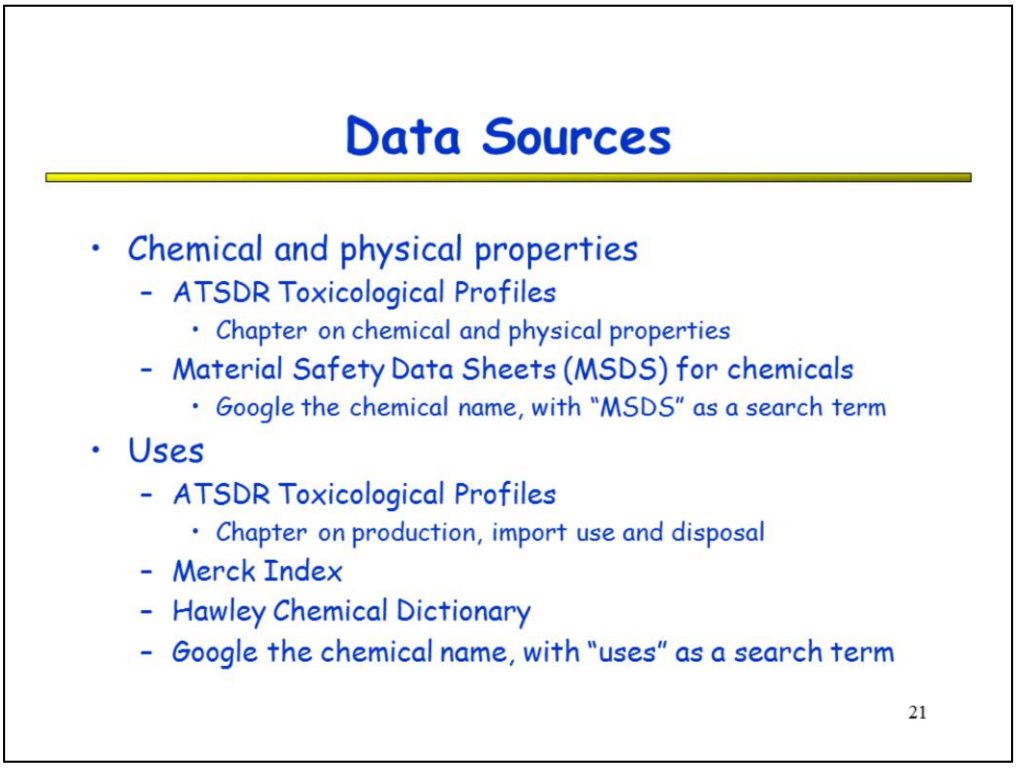
This slide lists the data should be collected for application of the decision tree approach. The three slides that follow it provide suggestions for text and on-line resources that can be used to collect the key data needs.



The notes section for Slides 21-23 provides information and internet links for the sources mentioned in the three slides. Sources are arranged alphabetically.

Agency for Toxic Substances and Disease Registry (ATSDR): ATSDR toxicological profiles" for hazardous substances found at National Priorities List (NPL) sites. These hazardous substances are ranked based on frequency of occurrence at NPL sites, toxicity, and potential for human exposure. The web site provides an alphabetical list of the Toxicological Profiles. The following Sections provide information that is useful for an RSC analysis:

Chemical and Physical Properties

Product Import, Use and Disposal

Potential for Human Exposure

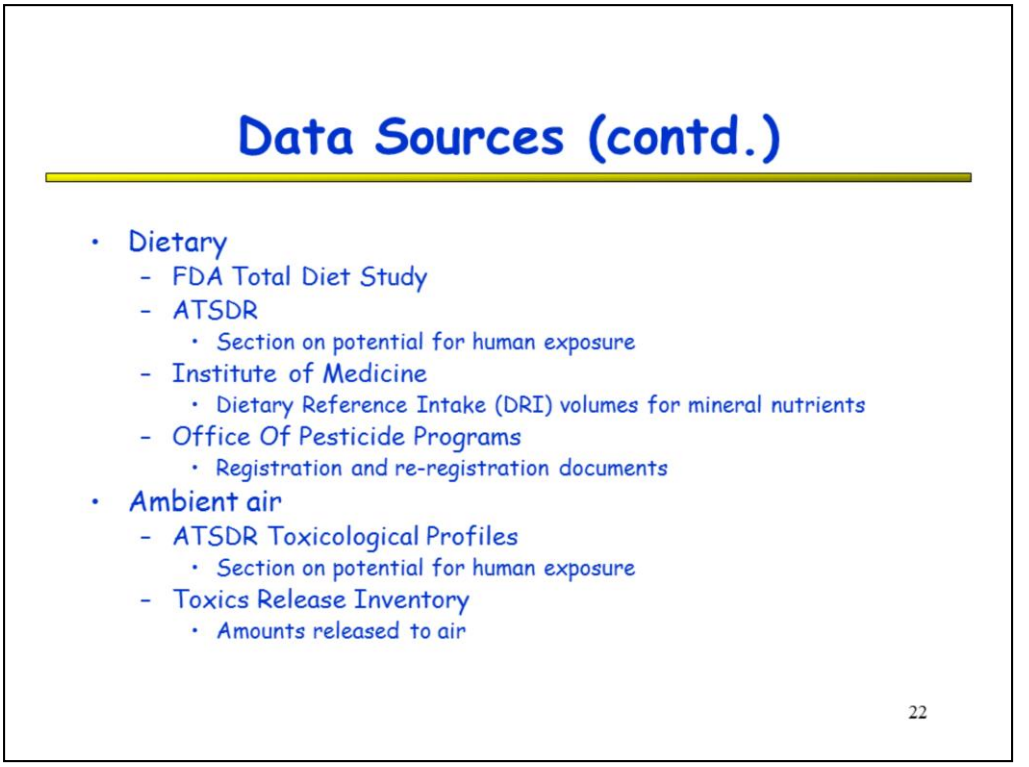
Link: http://www.atsdr.cdc.gov/toxpro2.html

Dietary Reference Intakes (DRI) from the National Academies of Sciences Institute of Medicine: Each of these following documents includes information on exposures to mineral nutrients (essential and nonessential) in the appendices at the end of the book. The books can be read on line. The following four from the series include information on inorganic elements in the diet.

Institute of Medicine IOM. (1997) Dietary reference intakes for Calcium, phosphorous, magnesium vitamin D and fluoride .Washington, DC: National Academy Press.
http://books.nap.edu/catalog.php?record_id=9810#toc

Institute of Medicine IOM. (2000) Dietary reference intakes for vitamin C, vitamin E, selenium, and carotene. Washington, DC: National Academy Press.
http://books.nap.edu/catalog.php?record_id=9810#toc

IOM. (2001) Dietary reference intakes for vitamin A, vitamin K, arsenic, boron, chromium, copper, iodine, iron, manganese, molybdenum, nickel, silicon, vanadium, and zinc. Subcommittees on Upper Reference Levels of Nutrients and of Interpretation and Uses of Dietary Reference Intakes, and the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, Food and Nutrition Board, Institute of Medicine National Academy Press: Washington, D.C.
http://books.nap.edu/catalog.php?record_id=10026#toc



DRI Contd.

Institute of Medicine IOM. (2004) Dietary reference intakes for water, potassium, sodium, chloride, and sulfate. Washington, DC: National Academy Press http://books.nap.edu/catalog.php?record_id=10925#toc

Hawley's Condensed Chemical Dictionary is a compilation of technical data and descriptive information covering thousands of chemicals and chemical phenomena, trade name products, processes, reactions, products, and related terminology. The Editor is Richard J Lewis Sr. The Publisher John Wiley and Sons. The 15th edition was published in 2007 .

Merck Index is an internationally recognized, one-volume encyclopedia of chemicals, drugs, and biologicals. Each monograph in the encyclopedia discusses a single chemical entity or a small group of very closely-related compounds. It is published by the Merck Pharmaceutical Company Whitehouse Station, N.J., USA. The records for individual chemicals include the following information:

chemical, common, generic and systematic names (including CAS® names)

trademarks and associated companies

CAS® Registry Numbers

molecular formulae, weights and percentage composition

capsule statements identifying compound classes and scientific significance

chemical, biomedical and patent literature references

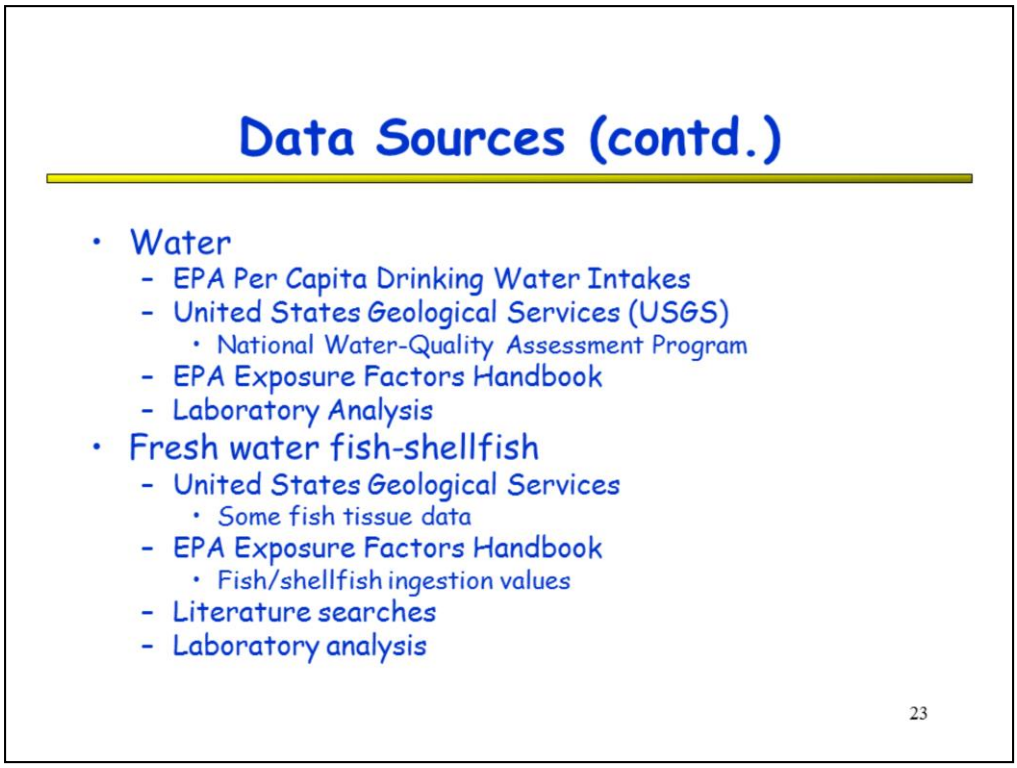
physical and toxicity data

therapeutic and commercial uses

caution and hazard information

National Water-Quality Assessment Program (NAWQA) provides an understanding of water-quality conditions and how those conditions may vary locally, regionally, and nationally; whether conditions are getting better or worse over time; and how natural features and human activities affect those conditions.

Site:http://water.usgs.gov/nawqa/



Office of Pesticide Programs (OPP) Reregistration Eligibility Decision (RED) Documents: OPP maintains a website for these documents. They include an estimate for the portion of the RfD or Population Adjusted Dose (PAD) utilized by tolerances granted to a given pesticide. Tolerance Reassessment Eligibility Decision (TRED) documents are available at this same site. Information of registration of new pesticides is published in the Federal Register and can usually be located through Google.

OPP Site:http://www.epa.gov/pesticides/reregistration/status.htm

Office of Water (OW) Estimated Per Capita Water Ingestion in the United States (2004) http://www.epa.gov/waterscience/criteria/drinking/percapita/index.html

Total Diet Study (TDS): The TDS is a program conducted by the Food and Drug Administration that measures the presence of nutrients and contaminants in the United States Diet. Analytes include nutritional elements, pesticide residues, VOCs, radionuclides, and other elements of concern (i.e. lead, mercury, arsenic). Useful web sites include the following:

http://www.foodsafety.gov/~lrd/pestadd.html

http://www.cfsan.fda.gov/~comm/tds-hist.html

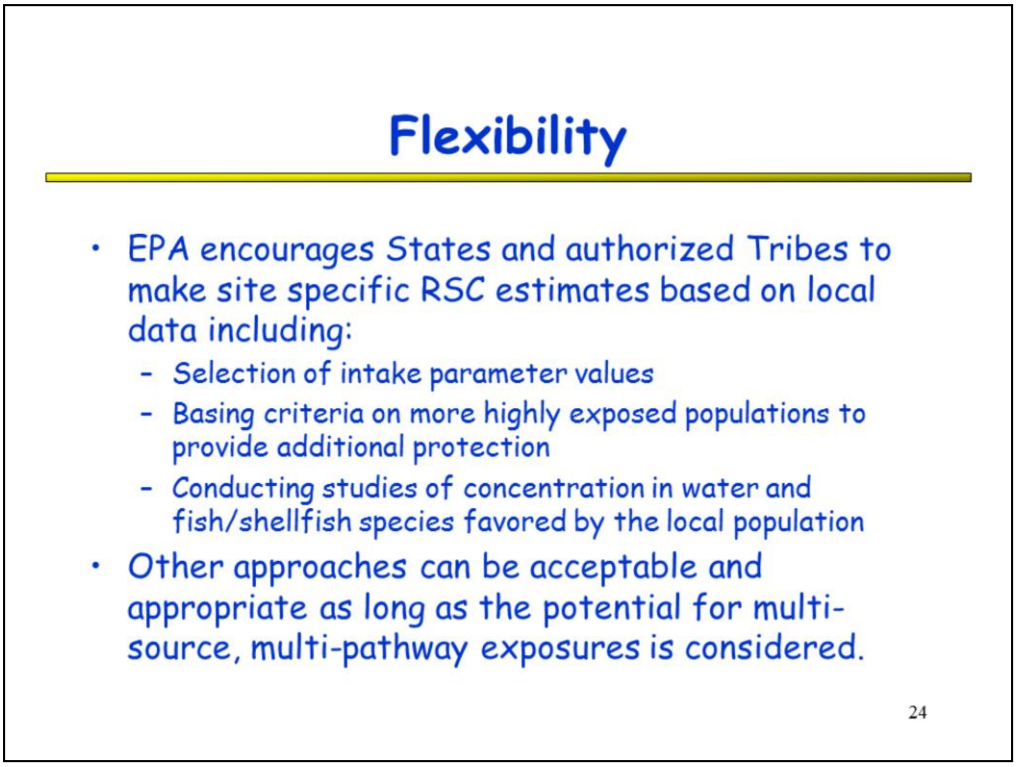
http://www.cfsan.fda.gov/~comm/tds-res.html

Toxics Release Inventory (TRI) is a publicly available EPA database that contains information on toxic chemical releases and waste management activities reported annually by certain industries as well as federal facilities.

Site: http://www.epa.gov/tri/

USEPA Exposure Factors Handbook: a useful compilation of data relevant to the assessment of human exposure to environmental pollutants. It provides quantitative inputs for exposure models, including human activity patterns, building characteristics, and physical characteristics of humans. This site also includes a link to the Child-Specific Exposure Factor's Handbook.

Site: http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=20563



There may well be approaches other than the one presented in the HH Methodology that fit your local situation. However, any approach used should be based on data, justified, and documented. It is not appropriate to merely take a RSC used in a different type of assessment and simply insert it in the HH equation. However, one may well find that other assessments pay provide some of data that are needed in your assessment such as dietary intake.