

From: Lon Kissinger [<mailto:lkiss.work@gmail.com>]

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To: Don Essig; Jeffrey Fromm

Cc: Macchio, Lisa; Chung, Angela; Mary Lou Soscia; galer.rose@epa.gov; bethel.heidi@epa.gov; fleming.sheila@epa.gov

Subject: Comments on IDEQ Conceptual Paper on Probabilistic Risk Assessment

Probabilistic Risk Assessment Methodology for Criteria Calculation Versus the Standard (Deterministic) Methodology



**State of Idaho
Department of Environmental Quality**

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Background

The equation used to develop human health water quality criteria combines chemical toxicity values developed by the United States Environmental Protection Agency (EPA) with conservative exposure parameters to calculate concentrations of chemicals in surface water associated with a given level of risk. A criterion equation for noncarcinogenic chemicals is presented as an example to understand the way in which conservative (protective) assumptions are incorporated into the calculation:

$$AWQC = RfD \times RSC \times \left(\frac{BW}{DI + (FI \times BAF)} \right)$$

Where:

AWQC = Ambient Water Quality Criterion (milligrams per liter)

RfD = Reference dose for noncancer effects (milligrams per kilogram per day)

RSC = Relative source contribution factor to account for nonwater sources of exposure (percentage)

BW = Body weight (default = 70 kilograms for adults)

DI = Drinking water intake (default = 2 liters per day for adults)

FI = Fish intake (kilograms per day)

BAF = Bioaccumulation factor (liters per kilogram)

Three of the parameters are chemical-specific: RfD, RSC, and BAF. The basis for the other parameters is considered below.

Body Weight

EPA recommends retaining the current default body weight of 70 kilograms (kg) as a representative average value for adults (EPA 2000). It is appropriate to use a mean body weight for males and females for this parameter, as opposed to an upper percentile value as is used for drinking water intake. Using an upper percentile value would be less conservative because it would result in lower intake of chemicals per unit body weight. Standard risk assessment protocol has typically used a mean value rather than a lower percentile value for body weight. The appropriateness of 70 kg is based on analysis of the NHANES III database (WESTAT 2000), as well as earlier studies: National Cancer Institute and NHANES II (EPA 1997). Taking these and more recent studies into account (EPA 2011), there appears to be an increasing trend in American body weights, and 80 kg might now be a more representative adult mean body weight. Retaining the default value of 70 kg results in a slightly more conservative calculation.

There is another reason to retain the value of 70 kg. This value is used in the derivation of cancer slope factors, and it is desirable to maintain consistency of assumptions between the dose-response relationship (slope factor) and exposure assessment (criterion derivation).

Drinking Water Intake

A water intake rate of 2 liters per day (L/day) is used in calculating EPA's national recommended water quality criteria, as well as the current Idaho criteria. Historically, EPA has assumed a drinking water intake rate of 2 L/day is representative of a majority of the population over the course of a lifetime (EPA 2000). This intake represents the 88th percentile for adults from a National Cancer Institute analysis of the 1977–1978 United States Department of Agriculture (USDA) National Food Consumption Survey (Ershow and Cantor 1989), and the 86th percentile for adults from the 1994–1996 USDA Continuing Survey of Food Intake by Individuals (CSFII). Assessment of more recent studies suggests that an intake of 2 L/day is still an appropriate upper percentile value for the general population (EPA 2011). It is also used in EPA's drinking water program. EPA notes that there is relatively little variability in water intake within the population (three-fold range) compared to fish intake (100-fold range) (EPA 2000).

Fish Intake

EPA recommends a default fish intake rate of 17.5 grams/day (g/day) to protect the general population of fish consumers. This value represents the 90th percentile of the 1994 to 1996 data from the USDA CSFII survey (USDA 2000). It represents uncooked weight of freshwater and estuarine finfish and shellfish only. EPA also recommends this value as a default intake rate for recreational fishers, along with a value of 142.4 g/day for subsistence fishers. EPA has also urged states and tribes to develop criteria to protect highly exposed population groups and to use local, state, or regional data over default fish intake values as more representative of their target population. A four preference hierarchy is recommended: (1) use of local data, (2) use of data reflecting similar geography/population groups; (3) use of data from national surveys; and (4) use of EPA's default intake rates. The main rationale for the present fish consumption rate survey effort is to collect state data to better understand fish consumption rates in Idaho.

Deterministic Risk Assessment

The criterion calculation represents a combination of conservative assumptions (the upper percentile variables for water intake and fish intake) with average or central-tendency parameters (body weight) as well as some chemical-specific parameters. For each variable, a single value from a sample distribution of values in a population is selected (for example, 2 L/day drinking water intake). For this reason, conventional deterministic risk calculation is also called the point estimate approach. The use of upper percentile exposure variables results in a reasonable maximum exposure (RME) risk estimate.

This standard calculation methodology has certain shortcomings. Rather than representing the full variability in exposure parameters present in the population of concern (Idaho residents, for example), the approach relies on conservative assumptions to ensure that an adequate level of protection for the population is achieved by the criteria. One concern with this approach is that,

by multiplying upper percentile exposure variables together, the overall conservatism is compounded. Because of this, a criterion may be based on an upper bound of exposure that may be experienced by few members of a population.

It is not possible to know with certainty what percentile of this distribution the risk estimate represents. When an attempt is made to calculate a high-end (RME) risk estimate by using upper-percentile exposure variables in combination with central tendency variables such as body weight, it cannot be known whether the risk estimate is at the 90th percentile, 95th percentile, or 98th percentile of the risk distribution.

There are methods that can be used to avoid compounded conservatism, characterize variability (the likelihood of different risk levels in a population), and also characterize the uncertainty in risk estimates. These methods are collectively referred to as probabilistic risk assessment (PRA).

Comment [KL1]: To determine the degree of conservatism in a point estimate of risk?

Do you want to describe uncertainty (i.e. lack of knowledge about something) vs. variability (i.e. the range of values a parameter could assume)?

Probabilistic Risk Assessment

PRA uses the same exposure equations as deterministic risk assessment, but it allows a better understanding of the likelihood of different risk levels in the population (variability), as well as the ability to quantitatively characterize uncertainty in risk estimates (EPA 2001). In the probabilistic approach, inputs to the risk equation are described by a probability distribution rather than a single-point estimate. Body weight is a prime example of a normally distributed continuous random variable. The distribution can be displayed as a probability density function (PDF) as well as a cumulative density function (CDF) as shown in Figure 1. The PDF shows the shape of the distribution and the relative probability of values; the CDF shows percentiles, such as the median or 90th percentile.

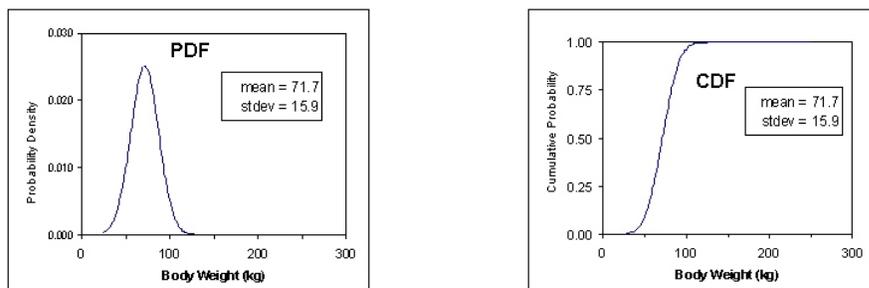


Figure 1. Normal distribution characterizing variability in body weight in adult humans (EPA 2001).

Combining Multiple Probability Distributions in a Risk Equation

The most commonly used numerical technique for PRA is Monte Carlo simulation. In this method, the variables in the exposure equation are represented by distributions rather than point estimates. A computer selects a value for each exposure variable at random from a specified PDF and calculates the corresponding risk. This process is repeated many times (10,000, for example), and each calculation is called an iteration. Each iteration can be thought of as representing a virtual individual, and the set of all iterations can be thought of as a virtual

population. Each simulation yields a set of risk estimates that can be displayed graphically using the PDF and/or-CDF for the risk distribution. The process is illustrated in Figure 2.

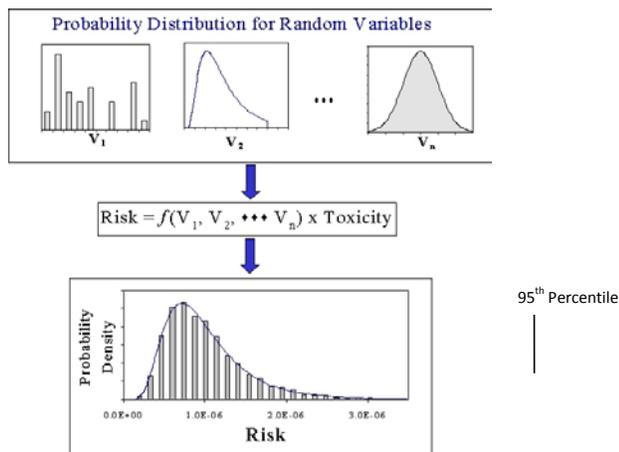


Figure 2. Conceptual model of Monte Carlo analysis (EPA 2001).

In PRA, the distributions used as inputs to the risk equations characterize the inter-individual variability inherent in each of the exposure assumptions, and the output from the Monte Carlo simulation is a distribution of risks that likely do occur in the population. Compared to deterministic risk assessment, this is a more comprehensive characterization of variability in risk estimates.

Precedent for PRA in Criteria Development

In 1994, the Florida Department of Environmental Protection (FDEP) funded the Florida Per Capita Fish and Shellfish Consumption Study, conducted by University of Florida researchers (Degner et al. 1994). Data from the study indicated that Floridians eat considerably more fish than the EPA-recommended value (at that time) of 6.5 g/day. The average consumption rate from the survey was 48 g/day; of this amount, Florida seafood species accounted for 28 g/day. The FDEP was subsequently petitioned to consider a higher fish consumption rate to recalculate human health-based criteria. A baseline risk analysis was initiated to evaluate risk at the existing criteria, and if necessary to develop new criteria. The FDEP sought stakeholder input, and the consensus was that a PRA should be conducted to more fully characterize the distribution of risks, and to consider other exposure routes such as dermal uptake from water. The FDEP contracted with the University of Florida Center for Environmental and Human Toxicology (CE&HT) to conduct the baseline risk analysis.

The FDEP approach to criteria development was built on the risk analysis work conducted by the CE&HT risk assessors. FDEP decided to use a probabilistic approach to criteria development to reduce problems such as compounded conservatism, and to evaluate risk across the entire population, rather than focusing only on the highly exposed individual. The approach directly incorporates risk assessment into the calculations.

Comment [KL2]: This discussion should also include mention the need to verify the quality of the input distributions used for analysis as well as issues of potential correlation. For example, fish consumption rate or drinking water rates might be correlated with body weight.

Comment [KL3]: You might want to include commentary on some of the weaknesses of the Degner study. For example, it did not include consumption of seafood consumed in restaurants. Further, the primary meal preparer was asked to report on consumption by other household members rather than asking them directly.

Several population variables were evaluated as distributions rather than point estimates, including fish consumption rate, drinking water consumption, and body weight. Monte-Carlo simulation was used to perform a large number (10,000 to 50,000) of iterative random samples from these distributions. The resulting values were fed into risk calculations to develop a distribution of risks representative of the characteristics of the population. The goal was to find a level for each chemical at which there would be minimal risk at an upper percentile of the exposure distribution. The chosen risk levels were a cancer risk of 1×10^{-6} for carcinogens and a hazard quotient of 1 for noncarcinogens. The human health criteria are the concentrations of each chemical at which the chosen risk level is achieved for 90% of the population. Therefore, the Monte-Carlo simulations were run iteratively until the target risk was achieved at the 90th percentile level. *Technical Support Document: Derivation of Human Health Criteria and Risk Assessment (Draft)* provides rationale for the choice of target risk level and exposure percentile; these are risk management decisions (FDEP 2012).

Comment [KL4]: Florida set the risk was set at 1 in 1,000,000 at the mean of the exposure distribution and 1 in 100,000 at the 90th percentile of the exposure distribution.

Additionally, it might be useful to identify the percentile of the Florida fish consumption distribution that resulted in the aforementioned risk targets. It is my view, that in Superfund risk assessments, that probabilistic analysis generally confirms that RME point estimates fall at the percentile of the exposure distribution.

How Idaho Might Incorporate PRA into Criteria Development

Some of the parameters in the criteria equations, such as the chemical-specific toxicity values (reference doses and slope factors), can only be represented by point estimates at the present time. The same is most likely the case with BAFs (or BCFs). The relative source contribution factor is also represented by a point estimate, typically a default percentage. Three parameters in the criteria equations are amenable to using distributions rather than point estimates: body weight, drinking water intake, and fish intake. The fish consumption rate survey effort currently underway will collect data on fish intake and body weight but not water intake. Distributions of fish intake can be developed from the survey results. For body weight, Idaho may be able use the distribution from the survey, or alternatively, follow an approach similar to that of Florida.

Comment [KL5]: However you might wish to discuss why distributions are not assigned to these parameters, as well as a CSF. I would say the major reason for not assigning distributions to the toxicity parameters is that there are not enough data to develop distributions for these parameters. It should also be noted that the toxicity parameters are upper bound estimates of potential human toxicity. This adds some health protection to the PRA. However, health protective adjustments for uncertainty are reduced as more data on a particular chemical are accumulated.

FDEP used a body weight distribution listed in the 2011 Exposure Factors Handbook, specifically body weight distribution for adults ages 18–65 from the NHANES IV survey (mean 79.96 kilograms [kg]; standard deviation 20.73) for criteria derivation and risk analysis calculations.

For water intake, FDEP followed the recommendation in EPA's 2011 Exposure Factors Handbook and used the distribution of tap water consumption from Roseberry and Burmaster (1992); these authors developed this distribution by fitting the Ershow and Cantor results to lognormal parameters. A correlation between drinking water intake and body weight of 0.29 was entered into the model to take into account that larger individuals tend to drink more water.

Comment [KL6]: Relevant to earlier comment on considering correlation between exposure parameters.

The Idaho criteria equations could be based on a PRA approach, in which three of the variables are represented by distributions, and three of the variables are represented by point estimates. The result is a hybrid of PRA and deterministic methods. This is acceptable, and actually is inescapable because all PRAs use point estimates for toxicity values, at a minimum, and often for other variables as well. The methodology should still allow a more quantitative characterization of fish consumption variability and distribution of risk to Idaho fish consumers.

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