

Risk Assessment for Chemicals in Drinking Water: Estimation of Relative Source Contribution

R.A. Howd, J.P. Brown, A.M. Fan. Office of Environmental Health Hazard Assessment (OEHHA), California Environmental Protection Agency (Cal/EPA), Oakland, CA

Presented as a poster at the 43rd annual meeting of the Society of Toxicology, Baltimore, Maryland, March 21-25, 2004 (The Toxicologist 78(1-S), March 2004)

Abstract

In estimating health-protective levels of chemicals in drinking water, one of the factors that should be considered is the proportion of the total permissible dose that is derived from water, versus other exposure routes. This is applied only for chemicals or toxic effects presumed to involve a toxicity threshold (primarily non-cancer effects), in which the combined daily dose from all exposure routes is used for calculation of allowable exposure levels. However, the calculation of the relative source contribution (RSC) is usually rather uncertain due to a lack of appropriate data, and the methods for estimation of an RSC in the absence of complete data involve a large component of "professional judgment." U.S. Environmental Protection Agency (U.S. EPA) policy provides limited guidance on calculating RSC. Values in the range of 0.2 to 0.8 (20 to 80%) are allowed, with a default value of 0.2 (20%) of total permissible exposure in the absence of data. OEHHA has generally followed this guidance, although it has also used a value of 1.0 (100%) in its derivation of Public Health Goals (PHGs) for drinking water when human data were used, which was uncontrolled for environmental exposures. Application of the principles for development of RSCs can be illustrated by examining the values and rationale used in the development of PHGs. Examples of the range of values include aluminum (1.0, acute human study), beryllium (0.2, animal study), cadmium (0.2, chronic human study), copper (0.8, acute human study), ethylbenzene (0.2, chronic animal study), fluoride (1.0, chronic human studies), Freon-11 (0.4, subchronic animal study), nickel (0.3, animal reproductive study), simazine (0.2, chronic animal study), thallium (0.2, subchronic animal study), 1,2,4-trichlorobenzene (0.2, subchronic animal study), and xylene (0.4, chronic human study). The entire set of 69 chemicals for which PHGs have so far been finalized provides a larger database for illustration of the application of RSC development principles.

Introduction

Relative source contribution, used for risk assessment of chemicals in drinking water, is the proportion of the total daily exposure to a chemical that is attributed to or allocated to tap water (accounting for multi-route exposures) in calculating acceptable levels of chemicals in water. The RSC concept has been used by U.S. EPA in drinking water risk assessments for at least 25 years, and by other agencies for almost as long. However, the concept does have significant limitations in how it has been defined and applied. This presentation summarizes current guidance on estimation and use of RSCs and how it has been applied by different risk assessment agencies for a large number of chemicals. Examination of the application of RSCs allows us to conclude with recommendations for improvements in the use of RSCs.

For clarity, some additional material has been added to this version that was omitted from the poster version, but was discussed orally.

U.S. EPA RSC Guidance

- Use values between 0.2 and 0.8
- Default = 0.2 with inadequate data
- Total exposure should not exceed the reference dose (RfD)
- Allocation to water should not be unreasonably small

As specified in Federal Register 54, 22069, 1989

Use of RSC in Calculations

$$\text{MCLG} = \frac{\text{RfD} \times \text{BW} \times \text{RSC}}{\text{L/day}}$$

$$\text{PHG} = \frac{\text{NOAEL} \times \text{BW} \times \text{RSC}}{\text{UF} \times \text{L/day}}$$

$$\text{AWQC} = \frac{\text{RfD} \times \text{BW} \times \text{RSC}}{(\text{FI} \times \text{BAF}) + \text{L/day}}$$

$$\text{MCLG} = \frac{(\text{RfD} - \text{OS}) \times \text{BW}}{\text{L/day}}$$

Acronyms: MCLG, maximum contaminant level goal; RfD, reference dose; BW, body weight; RSC, relative source contribution; L/day, liters of tap water consumed per day; PHG, public health goal; NOAEL, no observed adverse effect level; UF, uncertainty factor; AWQC, ambient water quality guidance; FI, fish intake; BAF, bioaccumulation factor; MCLG, maximum contaminant level goal; and OS, other sources.

Problems in the Use of RSC

- Guidance for estimating RSC vague
- Poor quality/limited availability of exposure data
- Default of 0.2 tends to be overused, and may be over-protective
- Should average levels in water, or target levels (MCLG, MCL, or PHG) be used in the RSC calculation?

Current U.S. EPA RSC Guidance:

The latest U.S. EPA guidance is in: Methodology for Deriving Ambient Water Criteria for the Protection of Human Health (2000), Chapter 4, as cited in personal communications with the U.S. EPA Office of Drinking Water. However, no reference to this document is currently provided on the ODW website. Critical points and an explanatory figure from the document are shown below:

“The Decision Tree allows for use of either the subtraction or percentage method to account for other exposures... The subtraction method is...acceptable when...other sources of exposure can be considered “background” and can be subtracted from the RfD (or POD/UF).” (p. 4-7)

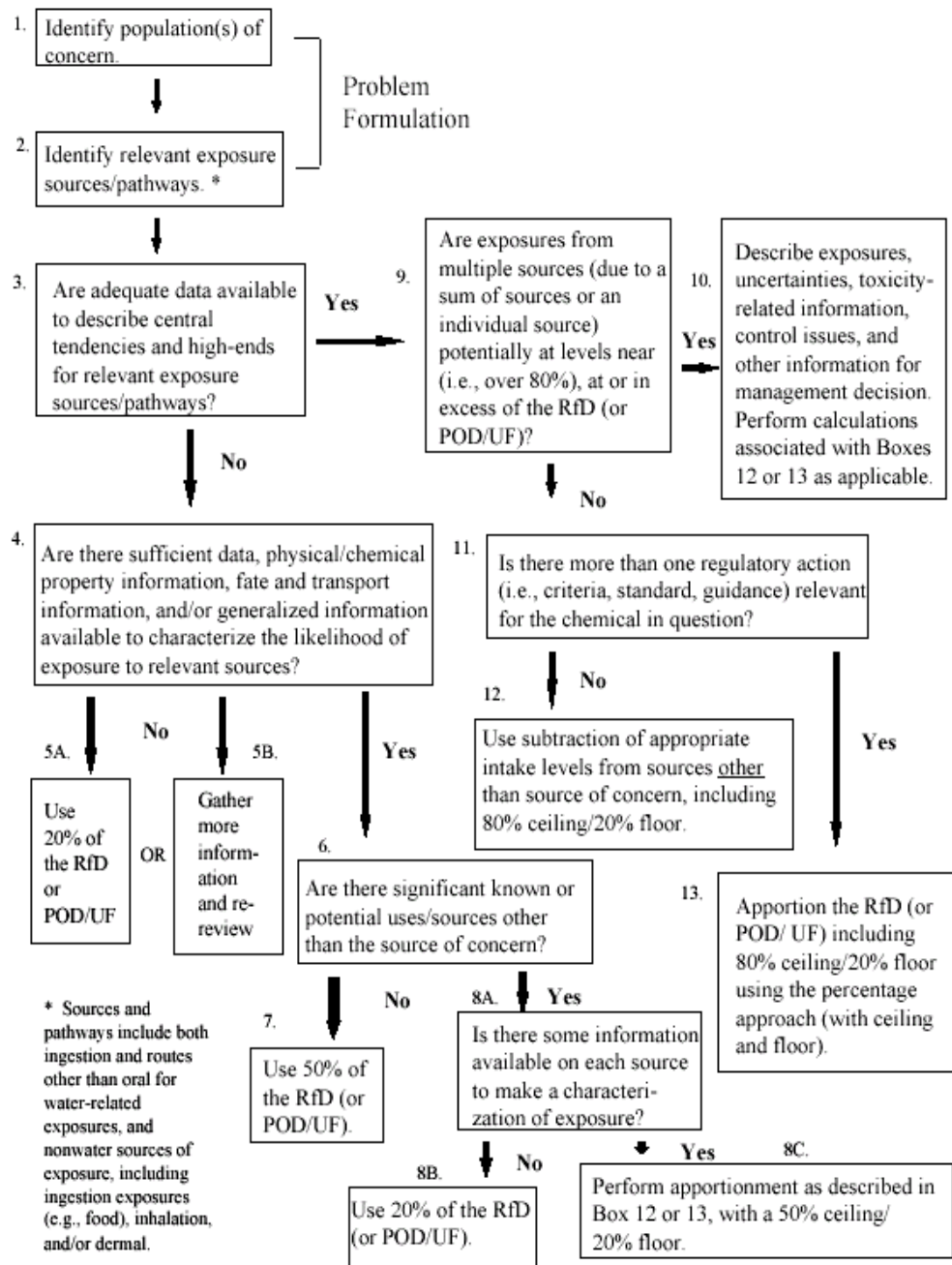
“...[I]t is necessary that adequate data exist for the relevant sources/pathways of exposure if one is to avoid using default procedures. The adequacy of data is a professional judgment for each individual chemical of concern, but EPA recommends that the minimum acceptable data...are exposure distributions that can be used to determine, with an acceptable 95% CI, the central tendency and high-end exposure levels for each source.” (p. 4-10)

“If there are some data...to make a characterization of exposure, a determination can be made as to whether there are significant known or potential uses for the chemical/sources of exposure other than the source of concern [i.e., drinking water] that would allow one to anticipate/quantify those exposures. If...not, then it is recommended that 50% of the RfD or POD/UF can be safely apportioned to the source of concern.”

“[The 20% default] is likely to be used infrequently with the Exposure Decision Tree Approach, given that the information [necessary to characterize exposure] should be available in most cases. However, EPA intends to use 20% of the RfD (or POD/UF)...as the default value.” (p. 4-12)

“If it can be demonstrated that other sources and routes of exposure are not anticipated for the pollutant in question (based on information about its known/anticipated uses and chemical/physical properties), then EPA would use the 80% ceiling. [However, as EPA’s] policy on cumulative risk assessment continues to develop, the 80% RSC may prove to be underprotective. (p. 4-15)

Figure 4.1 U.S. EPA Exposure Decision Tree for Defining Proposed RfD Apportionment.*



*From: Methodology for Deriving Ambient Water Criteria for the Protection of Human Health, Chapter 4, U.S. Environmental Protection Agency, 2000.

OEHHA's RSC policy

OEHHA has attempted to follow U.S. EPA guidance, but found few examples in U.S. EPA risk assessments of use of values other than 0.2, which we considered unreasonably conservative for most chemicals. From the beginning of the PHG program in 1996 we attempted to estimate “reasonable” values for RSC, and generally relied on professional judgment rather than hard data to derive such values. In our opinion, the U.S. EPA AWQC (2000) document, summarized above, supports this pragmatic approach. A few examples are shown below of justification statements used in our documents.

Carbon tetrachloride: RSC = 0.4 (2000)

“...volatile chemicals such as carbon tetrachloride are less likely to be found in food and soil.”

1,2-Dichlorobenzene: RSC = 0.2 (1997)

“In the absence of any specific information on the contribution of drinking water to total exposure, the default of 0.2 should be used.”

Dalapon: RSC = 0.8 (1997)

“An RSC of 80% was applied because dalapon is not currently used in agriculture and the sole source of exposure is expected to be from any residue possibly remaining in drinking water. This value is consistent with RSCs for other chemicals for which exposure comes exclusively from drinking water.”

Nickel: RSC = 0.3 (2001)

“[The RSC is] based on estimates of the amount of nickel derived from water versus diet, allowing for increased availability of nickel from the drinking water. At the PHG of 12 µg/L, assuming a water consumption rate of 2 L/day, the estimated intake dose from water would be 24 µg/day. Assuming a dietary intake dose of approximately 200 µg/day, the contribution of water to total intake of nickel would be about 11 percent. Actual mean level of nickel in California drinking water is about 20 µg/L, which would correspond to 40 µg/day, or 17 percent of total exposure. Considering that the bioavailability of soluble nickel in water is higher than the bioavailability of soluble nickel in food (Table 5), a relative source contribution of about 30 percent is determined to be a reasonable assumption for calculation of the PHG.

Perchloroethylene: RSC = 0.03 (2001)

“In this case, evidence indicated an RSC below [the default] range could be justified based on exposure to PCE from multiple sources, including air exposures associated with use of PCE in dry cleaning. The relative source contribution from drinking water was calculated as 3 percent, based on data cited in Table 3 for urban areas with 0.5 µg/L PCE in drinking water. However, this was not used for development of the PHG, since the PHG was based on carcinogenicity.”

Examples of WHO's RSC use

The basic policy of the World Health Organization, as expressed in their 2003 guidelines, is to incorporate an RSC of 0.1 (a 10% contribution from drinking water) for most chemicals. For chemicals which are highly lipophilic, a value of 0.01 (1%) is used, and in a very few instances, a data-based value has been applied. The specific wording used for two representative examples is shown below:

Barium: RSC = 1 (unstated)

“In the most sensitive epidemiological study conducted to date, there were no significant differences in blood pressure or in the prevalence of cardiovascular disease between a population drinking water containing a mean barium concentration of 7.3 mg/L and one whose water contained a concentration of 0.1 mg/L. Using the NOAEL of 7.3 mg/L ... and an uncertainty factor of 10 to account for intraspecies variation, a guideline value of 0.7 mg/L (rounded) was derived for barium in drinking water.”

Diethylhexyl adipate: RSC = 0.01

“Because of its low water solubility, DEHA released into the environment would be expected to partition to solids (biota, sediment, soil). Under ideal equilibrium conditions, it would partition mainly to the atmosphere and to terrestrial soil, and less than 1% of environmental DEHA would be found in the aquatic environment.”

Compilation of RSCs

The following table lists the major sources of information on use of RSCs that we were able to find. The basis for this list was those chemicals for which OEHHA has published Public Health Goals for the chemicals in drinking water. As of March 2004, this represents 69 of the approximately 85 chemicals that have California Maximum Contaminant Levels (MCLs) in drinking water. Cells were left blank when we could not find a value, but this should not be taken as a claim that no RSC exists for the chemical. Also, U.S. EPA and WHO have developed RSCs for other chemicals not listed here.

Some other states also develop drinking water regulatory values that may involve use of an RSC. For this purpose, New York uses a default RSC of 0.2 and North Carolina uses a default of 0.1, for example. We were not able to locate a list of chemicals from either state for which RSCs have been developed using a data-driven approach.

Relative Source Contributions for Common Chemicals

Chemical Name	Relative Source Contribution			
	California	U.S. EPA	WHO	Health Canada
aldicarb	--	0.2		0.2
aluminum	1	?		NA
antimony	0.4	0.4	0.1	0.38
atrazine	0.2	0.2		
barium	1	1	1	1
bentazon	0.2	?	?	
beryllium	0.2	0.2		
cadmium	0.2	0.25	0.1	0.12
carbofuran	0.2	0.2	0.1	0.2
carbon tetrachloride	0.4	--	0.1	
chlordane	0.2	--	0.01	
chromium	--	0.7		
copper	0.8	1?	1	
cyanide	0.2	0.2		(1)
dalapon	0.8	0.2		
DBCP	0.8	NA		
dichlorobenzene, 1,2-	0.2	0.2		0.2
dichlorobenzene, 1,4-	0.2	NA		
dichloroethane, 1,1-	0.2	NA		
dichloroethane, 1,2-	0.6	NA		0.09
dichloroethylene, 1,1-	0.2	0.2		0.1
cis/trans dichloroethylene, 1,2-		0.2/0.2		
dichloromethane	0.2	NA	0.1	
2,4-D	0.2	0.2	0.1	0.2
dichloropropane, 1,2-	0.4	NA		
dichloropropene, 1,3- (Telone)	0.2	NA		
di(2-ethylhexyl)adipate	0.2	0.2	0.01	
diethylhexyl phthalate	0.2	NA	0.01	
dinoseb	0.8	0.2		0.2
diquat	0.2	0.2	0.1	0.2
endothall	0.2	0.2		
endrin	0.2	0.2	0.1	
ethylbenzene	0.2	0.2		
ethylene dibromide	0.6	NA		

Chemical Name	Relative Source Contribution			
	California	U.S. EPA	WHO	Health Canada
fluoride	1		1	0.5
glyphosate	0.2	0.2	0.1	0.2
heptachlor and HE	0.2	NA		
hexachlorobenzene	0.2			
hexachlorocyclopentadiene	0.4	0.2	?	
lead	0.2	?		0.098
lindane	0.2	0.2	0.01	
mercury (inorganic)	0.2	0.2/subtr	0.1	0.05 (total)
methoxychlor	0.2	?	0.1	0.2
methyl tert-butyl ether	0.2	NA		
monochlorobenzene	0.2	0.2	?	0.2
nickel	0.3	0.2		
nitrate (as N)	1	(0.5)		1
nitrite (as N)	1	(0.5)		1
pentachlorophenol	0.8	0.2/--		0.2
perchlorate	0.6	NA		
picloram	0.2	0.2		0.2
selenium		subtr		0.1-0.25
simazine	0.2	0.2		0.2
2,4,5-TP (Silvex)	0.8	0.2		
tetrachloroethane, 1,1,2,2-	0.8	NA		
tetrachloroethylene (PCE)	0.03	NA		0.1
thallium	0.2	0.2		
thiobencarb	0.2			
toluene	0.4	0.2	0.1	
trichlorobenzene, 1,2,4-	0.2	0.2		
toxaphene	0.8	NA		

NA – not applicable; used above in the U.S. EPA list to refer to carcinogens, for which no RSC is developed by U.S. EPA. OEHHA develops a non-cancer PHG value for every carcinogen, so an RSC value is provided also for carcinogens in the OEHHA column.

Discussion

It may be noted in the list above that very few values are available for which a number other than the defaults has been used. OEHHA has more instances of estimation of health-protective concentrations of chemicals in drinking water using values other than 0.2, but this is partially because our drinking water risk assessment program is relatively new. The enabling legislation was passed in 1996, and the first PHG values were published in 1997. All the supporting documents are available on the OEHHA website.

The U.S. EPA values are provided in Federal Register documents that show the derivation of their MCLGs, and most of these documents are over 10 years old. U.S. EPA has not yet finalized any risk assessment using their new approach described in the Ambient Water Quality Criteria document. Chemical risk assessments currently in progress using this approach include chloroform and haloacetic acids (personal communication with U.S. EPA ODW personnel).

Overall Conclusions

- A default RSC of 0.2 is based on tradition, not data
- RSCs have been applied inconsistently
- Attempts to refine application based on physical principles, chemical usage, and occurrence data are a step in the right direction
- More work is needed to define principles and parameters for RSC calculation
- More consistency in application of basic principles is needed
- While precise exposure estimates would be useful, improvements in use of RSC can be made without precise data and calculations

For the future...

- A formal review seems appropriate to assemble and analyze the scattered data and variable usage of the RSC concept
- If/when carcinogen risk assessment can be made more accurate, should RSC be added to these calculations?
- Development of aggregate, cumulative risk assessment methods will incorporate the RSC concepts into all risk assessment programs (air, water, food, occupational)

Acknowledgments

This presentation would not have been possible without the helpful discussions and support from our OEHHA colleagues David Ting and Yi Wang as well as U.S. EPA colleagues Ed Ohanian, Joyce Donohue, and Ambika Bathija.

References

Health Canada (2003). Guidelines for Canadian drinking water quality – supporting documents. Accessed at www.hc-sc.gc.ca/hecs-sesc/water/dwgsup.htm.

OEHHA (2004). Public health goals for chemicals in drinking water. Accessed at www.oehha.ca.gov/water/phg/index.html.

U.S. EPA (1989). FR 54 (97), May 22, 1989.

U.S. EPA (1990). FR 55 (143), July 25, 1990.

U.S. EPA (1991). National primary drinking water regulations. 56 FR 3526, Jan. 30, 1991.

U.S. EPA (1992). National primary drinking water regulations. 57 FR 31776, July 17, 1992.

U.S. EPA (1994). FR 59 (145), July 29, 1994.

U.S. EPA (2000). Methodology for deriving ambient water quality criteria for the protection of human health. Office of Water, EPA-822-B-00-004, Oct., 2000.

U.S. EPA (2002). National recommended water quality criteria. Human health criteria calculation matrix. Office of Water, EPA-822-R-02-012, Nov., 2002.

U.S. EPA (2002). National primary drinking water regulations. 67 FR 19029, Apr. 17, 2002.

WHO (2003). Guidelines for drinking water quality. Accessed at www.who.int/docstore/water_sanitation_health/GDWO/draftchemicals/list.htm