VERMONT

Department of Health
Environmental Health
108 Cherry Street – PO Box 70
Burlington, VT 05402-0070
HealthVermont.gov

Agency of Human Services

[phone] 802-863-7220
[fax] 802-863-7483
[toll free] 800-439-8550

MEMORANDUM

TO: Sarah Vose, Ph.D.
DEPARTMENT: Department of Health

FROM: Razelle Hoffman-Contois, M.S. RSH
DEPARTMENT: Department of Health

SUBJECT: Department of Health Drinking Water Guidance Values - Derivation and Application
DATE: February 27, 2015

The Vermont Department of Health (Health Department) maintains a list of chemical-specific guidance values that may be used in the evaluation of drinking water supplies. This list is referred to as the Drinking Water Guidance document (Guidance). Chemicals are added at the request of other State of Vermont offices, in response to public concerns or as deemed appropriate by the Health Department.

This memo provides an overview of the source of values in the Guidance, the approach used by the Health Department to develop values and how the Guidance is currently employed by other State of Vermont programs.

The last comprehensive review and update of the Guidance occurred in 2002. Since that time:

- The Health Department developed interim guidance values for six chemicals listed in the 2002 Guidance and three additional chemicals.
- Updated toxicity information has become available for several chemicals listed in the 2002 Guidance.
- The Health Department has been asked to develop guidance values for chemicals not listed in the 2002 Guidance.
- Exposure to potentially sensitive subpopulations and/or during sensitive stages of life has gained increased attention.
- Potential exposure via inhalation of vapors due to routine household water use has gained increased attention.
- Updated information has become available regarding age-specific water ingestion rates.
- Quantitative human health risk assessment methodology has continued to evolve.

An approach that reflects the considerations noted above, as well as others, is used in the development of Health Department derived guidance values.

For the 2015 Guidance, approximately one-third of the chemicals in the 2002 Guidance were reviewed and revised as warranted. Some new chemicals were added as well. A list of chemicals reviewed since 2002 is presented in Table 1. For each chemical, a brief monograph, summarizing the information available for review, proposed guidance value and derivation thereof was prepared. On the monographs, values are generically referred to as Vermont Values (VV) during the derivation process.

For those chemicals listed in the 2002 Guidance but not yet re-reviewed, the 2002 guidance value has been carried forward. The 2015 Guidance in its entirety is included as Attachment 1.

Each guidance value is based upon the best available information at the time of derivation thus is subject to change as updated information and risk assessment methodologies become available.

SOURCE OF DRINKING WATER GUIDANCE VALUES

Three types of values are included in the Guidance. Collectively, these provide critical information for use in the evaluation of potential health implications that may be associated with exposure to chemicals in tap water.

- Primary Maximum Contaminant Levels (**MCL**s) are legally enforceable standards promulgated by the United States Environmental Protection Agency (U.S. EPA) for use in the regulation of public water systems. Each value represents the highest level of a chemical that is allowed in a public drinking water supply. An MCL reflects consideration of public health concerns due to exposure via ingestion as drinking water and potentially other factors such as cost-benefit analysis, detection limit and best available treatment technology. MCLs are derived for chemicals with carcinogenic and adverse non-carcinogenic health endpoints. For each chemical with an MCL, that value is used as the drinking water guidance value except in limited cases described below.

- Vermont Health Advisories (**VHA**s) are numeric guidelines researched and derived by the Health Department for chemicals that do not have an MCL. A VHA reflects consideration of public health concerns and analytical laboratory reporting limits. VHAs consider ingestion exposure for all chemicals as well as potential exposure via inhalation of vapors due to household water use for those chemicals that may easily volatilize. VHAs are derived for chemicals with carcinogenic and adverse non-carcinogenic health endpoints. If a VHA is exceeded, it does not necessarily follow that that adverse health effects may occur, but that exposure should be minimized while further evaluation of the water supply is conducted.

- Vermont Action Levels (**VAL**s) are numeric guidelines researched and derived by the Health Department for a small number of chemicals that have MCLs but are of specific public health interest for Vermont Public Water Systems. Thus, these few chemicals have both a U.S. EPA MCL and a Health Department derived value. The latter is always the more restrictive. The term VAL is used to distinguish these values from those derived by the Health Department for chemicals that do not have an MCL. VALs are concentrations at or above which a specific (priority) procedure will be followed in order to provide adequate protection of public health. Per a 2014 Memorandum of Agreement (MOA) (Attachment 2), the Health Department may derive VALs for benzene, carbon tetrachloride, dibromochloropropane, 1,2-dichloroethane, 1,2-dichloropropane, hexachlorobenzene, pentachlorophenol, tetrachloroethylene, trichloroethylene and vinyl chloride . The same process is used to derive VALs as VHAs.

HEALTH DEPARTMENT VHA/VAL DERIVATION PROCESS

In general, drinking water guidance values derived by the Health Department (VHAs and VALs) are generated by combining current toxicity values (*e.g.*, oral reference doses, inhalation reference concentrations, oral cancer slope factors and inhalation unit risks) with a hypothetical residential exposure scenario using standard point estimate risk assessment procedures to derive an estimate of the concentration of **each** individual chemical or in limited instances, group of chemicals, in tap water that corresponds to a fixed level of risk i.e., a Hazard Quotient of one for noncarcinogenic (systemic) effects or an incremental lifetime carcinogenic risk of one in one million. Where a chemical is known to have both noncarcinogenic and carcinogenic effects and toxicity values are available, a value is derived based on each endpoint with the most appropriate reported as the guidance.

Direct exposure via ingestion as drinking water is considered for all chemicals. In addition, inhalation of vapors due to routine household water use is considered for those chemicals with a molecular weight less than 200 grams per mole and a Henry's Law constant greater than or equal to $1E^{-5}$ atmosphere-cubic meter/mole (atm-m3/mol) as these may easily volatilize (EPA, 1991).

An upper bound volatilization factor of 0.5 Liters/m^3 (L/m^3) is assumed in the assessment of inhalation of vapors due to household water use. This constant was derived based on several assumptions including: volume of water used in a residence for a family of four is 720 L/day, volume of dwelling is 150,000 L, air exchange rate is 0.25 m^3/hour and average transfer efficiency weighted by water use is 50 percent, i.e., 50 percent of the concentration of a volatile chemical present in water will be transferred into air by all household uses (Andelman, 1990 as presented in EPA, 1991). Review of the Andelman work and extensive conversations with local water use authorities indicates the resulting factor is reasonable and appropriate for use.

Estimates of chemical-specific physical properties, such as Henry's Law constant, are primarily obtained from the Estimation Programs Interface (EPI) Suite™ which is a screening level tool developed by the U.S. EPA Office of Pollution Prevention and Toxics and Syracuse Research Corporation. In accordance with EPI Suite guidance, experimental (measured) values are used when both experimental and estimated values are available.

Each chemical is evaluated in isolation. Simultaneous exposure to more than one chemical in water, exposure via other viable pathways (e.g., dermal), and exposure to other chemicals in other environmental media are not considered. Existing background concentrations of naturally occurring inorganics are generally not taken into account. In some cases, it is possible that the Health Department derived value may be below naturally occurring levels. In the event a derived value is found to be less than a reasonable analytical laboratory reporting limit, the guidance is set equal to the reporting limit.

Toxicity

Toxicity information and oral and inhalation toxicity values are obtained and reviewed from a number of relevant and appropriate sources including:

- U.S. EPA Integrated Risk Information System
- U.S. EPA Office of Pesticide Programs
- U.S. EPA Office of Research and Development/National Center for Environmental Assessment/Superfund Health Risk Technical Support Center (STSC) Provisional Peer Reviewed Toxicity Values
- International Agency for Research on Cancer
- National Toxicology Program
- California EPA Office of Environmental Health Hazard Assessment
- California Department of Pesticide Regulation
- Agency for Toxic Substances and Disease Registry

In limited instances where no peer reviewed toxicity value is available, the open literature and/or studies provided directly to the Health Department are considered in the development of a noncancer (threshold based) oral toxicity value for use in the derivation of a guidance value.

Mutagenic Mode of Action

Consistent with U.S. EPA guidance (EPA, 2005a), multipliers termed Age Dependent Adjustment Factors (ADAFs) are used in the evaluation of carcinogens identified by U.S. EPA to operate via a

mutagenic mode of action. Per the guidance, ADAFs "…reflect the potential for early-life exposure to make a greater contribution to the cancers appearing later in life."

Chemical-specific ADAFs are used if available.

Otherwise, the following non-chemical specific, default adjustments provided by U.S. EPA are used:

- A 10 fold increase for exposures between the day of birth up until the second birthday.
- A 3 fold increase for exposures between the second birthday up until the sixteenth birthday.
- No adjustment is made for exposures occurring after turning 16 years of age.

Additional information regarding which chemicals have been identified by the U.S. EPA to operate via a mutagenic mode of action for carcinogenesis can be found at http://www.epa.gov/oswer/riskassessment/sghandbook/chemicals.htm.

Food Quality Protection Act Safety Factor

The Food Quality Protection Act (FQPA) of 1996 amended the Federal Insecticide, Fungicide and Rodenticide Act and the Federal Food, Drugs and Cosmetic Act and significantly revised the way in which pesticides are evaluated by the U.S. EPA.

The FQPA mandates that "in the case of threshold effects, an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of data with respect to exposure and toxicity to infants and children. Notwithstanding such requirement for an additional margin of safety, the Administrator [of the U.S. EPA] may use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children" (FQPA, 1996).

Drinking water guidance values derived by the Health Department for pesticides with threshold type effects may reflect incorporation of a U.S. EPA derived FQPA Safety Factor (SF). The magnitude of the FQPA SF employed is noted on the corresponding chemical-specific monograph.

Exposure

Several conservative assumptions are made in order to estimate the potential intake of a chemical in water. In reality, the magnitude and frequency of exposure will vary depending on individual circumstances. The use of such health protective assumptions, which tend to represent reasonable upper bound estimates for longer-term exposures, adds additional conservatism to the guidance values derived.

A summary of the exposure assumptions and factors employed in the development of VHAs and VALs is presented in Table 2.

A 70 year age-weighted approach (birth to age 70 years) is employed in the assessment of carcinogens while a hypothetical young child is generally the focus of noncarcinogenic evaluations. Any variances are noted on the chemical-specific monographs.

Body Weight Adjusted Water Ingestion Rate (BW_AIR)

The U.S. EPA has recommended that fine age groupings be used in the assessment of potential exposure to children (EPA, 2005b). A series of ten ranges between birth and 21 years of age is recommended for consideration as appropriate.

Consistent with this guidance, the 95th percentile per capita BW_AIR for fine age groupings based on combined direct and indirect water intake from community water supplies for consumers only (EPA, 2008) are used. As warranted, a BW_AIR commensurate with an age group of specific interest for a particular chemical is used in the development of the guidance value. Otherwise, the BW_AIR of 0.175 liters of water per kilogram of body weight per day (L/kg-d) associated with the first year of life is employed as a conservative default.

For those chemicals where reproductive toxicity is identified as the critical effect, due to small sample sizes, the BW_AIR of 0.046 L/kg-d for women between the ages of 15 and 44 years of age instead of that reported for pregnant women is used.

The 95th percentile BW_AIR of 0.044 L/kg-d for all ages for direct and indirect water ingestion from community water for consumers only (EPA, 2004) is used in the assessment of non-threshold, non-mutagenic mode of action carcinogenic effects.

Relative Source Contribution

Consistent with U.S. EPA guidance (EPA, 1990), a Relative Source Contribution (RSC) is incorporated in the development of a VHA or VAL based upon a threshold type, primarily noncarcinogenic, health effect. The RSC represents the portion of an individual's total daily exposure to a specific chemical that is attributed to or allocated to drinking water.

In keeping with the established methodology, a factor generally ranging between twenty and eighty percent is used. The exact value employed is dictated by the type and strength of information available and is noted on the chemical-specific monographs.

Additionally, the EPA Office of Pesticide Programs (OPP) has conducted extensive modeling efforts and derived conservative, age group specific, quantitative estimates of dietary exposure (and in some cases other significant sources of exposure) for many pesticides. In such instances, the chemical-specific oral toxicity value may be adjusted and an RSC employed in the development of the guidance value that reflects this consideration. Overall, use of this approach which incorporates more refined, realistic estimates of potential exposure while providing adequate protection of public health was deemed preferable to using a standard default RSC of twenty percent.

INTERAGENCY APPLICATION

As of this writing, the Vermont Agency of Natural Resources (ANR) Environmental Protection Rules (Rules) dictate that Groundwater Quality Standards be adopted. Values presented in the Health Department's Drinking Water Guidance serve as the basis of the ANR Primary Groundwater Quality Standards.

In Chapter 12 of the Rules, entitled the Groundwater Protection Rule and Strategy (GPRS)(VGPRS, 2005), it is specified that the Primary Groundwater Quality Standard (a.k.a. Primary Groundwater Quality Enforcement Standard henceforth Enforcement Standard) for a chemical will be set equal to the U.S. MCL, or if one does not exist, equal to a Health Department derived VHA.

As previously described, a small group of chemicals may have both a U.S. EPA MCL and a Health Department derived value termed a VAL. Per the December 2014 MOA (Attachment 2), in such cases, the VAL is to be used as the Enforcement Standard.

The GPRS also requires that a Preventive Action Level (PAL) be established for each chemical. A PAL is defined as "…a numerical value expressing the detectable concentration of a substance in groundwater the reaching or exceeding of which requires a response under Section 12-803 of [the GPRS]." It is specified that the PAL be set equal to one-tenth the Enforcement Standard for those chemicals deemed to possess "…carcinogenic, mutagenic, or teratogenic properties or interactive effects…" and to one-half for all other chemicals. In those instances where a calculated PAL is below the analytical laboratory reporting limit for the chemical in question, the PAL will be established as the reporting limit. The Health Department provides ANR with recommended PALs.

PALs are considered an early warning mechanism to alert ANR to potential groundwater quality degradation. Specific responses are triggered at lower levels for chemicals associated with more serious potential public health impacts. Section 12-803 details responses that may be taken when a PAL is reached or exceeded.

Enforcement Standards and corresponding PALs are listed in Appendix 1, Table 1 of the GPRS.

Per Section 12-103, provisions of the GPRS apply to all ANR "…permit and regulatory programs that control activities which may affect groundwater." These provision may also be adopted by other entities "…with authority to manage activities that may affect groundwater." This helps ensure that an adequate and consistent level of public health protection is provided across state programs.

For example, in Chapter 21 of the Rules, entitled, the Vermont Water Supply Rule (VWSR, 2010), Section 21-6.15 provides that the Secretary of ANR may adopt a Health Department derived VHA for a contaminant which may be detected in a public water system and for which no U.S. EPA MCL has been established.

Additionally, as of this writing, Section IV Vermont Agency of Agriculture, Food and Markets Regulations for Control of Pesticides in Accordance with 6 V.S.A. Chapter 87 (VAAFM, 1991) which specifies "Restrictions on the Use and Application of Pesticides" in the state of Vermont states "[a]ll pesticide applicators and licensed companies shall use pesticides ...so as not to exceed the primary groundwater quality enforcement standards identified in Appendix 1 of the Groundwater Protection Rule and Strategy in accordance with 10 V.S.A. Chapter 48 [and] shall manage the use of pesticides to reduce the concentration of pesticides in groundwater to the preventive action limits [*sic*] established by Chapter 12.702 of the Groundwater Protection Rule and Strategy when monitoring indicates the presence of pesticide concentrations in groundwater that exceed the preventive action limits [*sic*]."

REFERENCES

EPA, 1990. Seminar Publication. Risk Assessment, Management and Communication of Drinking Water Contamination. EPA/625/4-89/024. Washington, D.C. U.S. EP, Office of Drinking Water, Office of Water.

EPA, 1991. Risk Assessment Guidance for Superfund: Volume I – Human Health Evaluation Manual (Part B, Development of Risk-based Preliminary Remediation Goals). Interim. Washington, D.C. U.S. EPA, Office of Emergency and Remedial Response.

EPA, 2004. Estimated Per Capita Water Ingestion and Body Weight in the United States – An Update. EPA-822-R-00-001. Washington, D.C. U.S. EPA, Office of Water, Office of Science and Technology.

EPA, 2005a. Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens. EPA/630/R-03/003F. Washington, D.C. U.S. EPA, Risk Assessment Forum.

EPA, 2005b. Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants. EPA/630/P-03/003F. Washington, D.C. U.S. EPA, Risk Assessment Forum.

EPA, 2008. Child-Specific Exposure Factor Handbook. EPA/600/R-06/096F. Washington, D.C. U.S. EPA, Office of Research and Development, National Center for Environmental Assessment.

FQPA, 1996. Food Quality Protection Act of August 3, 1996 as amended. United States Public Law 104-170.

VAAFM, 1991. Regulations for Control of Pesticides in Accordance with 6 V.S.A. Chapter 87. State of Vermont Department [*sic*] of Agriculture, Food and Markets. Effective 8/2/91.

VGPRS, 2005. Groundwater Protection Rule and Strategy. State of Vermont Agency of Natural Resources Department of Environmental Conservation Environmental Protection Rules Chapter 12. Rule 04-P-039. Effective 2/14/05.

VWSR, 2010. Water Supply Rule. State of Vermont Agency of Natural Resources Department of Environmental Conservation Environmental Protection Rules Chapter 21. Effective 9/24/92, Revision 12/1/10.

TABLE 1
CHEMICALS REVIEWED SINCE 2002 GUIDANCE

Acetone	Chloramben
Acifluorfen, sodium	Chlorantraniliprole
Alachlor	Chlordane
Aldicarb	Chlorflurenol
Aldicarb sulfone	Chlorine
Aldicarb sulfoxide	Chlorite
Aldrin	Chlorobenzene
Ametryn	Chloromethane (Methyl chloride)
Aminoethyl ethanolamine (AEEA)	Chlorothalonil
Ammonium sulfamate	1,2-Dibromochloropropane
Anthracene	1,2-Dichloroethane
Antimony	1,2-Dichloropropane
Arsenic	Diethylene triamine (DETA)
Atrazine	Dioxane (1,4)
Azoxystrobin	Erioglaucine
Barium	Glyphosate
Bendiocarb	Gross Alpha
Benefin (Benfluralin)	Hexachlorobenzene
Benomyl	Hexahydro-1,3,5-trinitro-1,3,5-triazine (RDX)
Bensulide	Manganese
Bentazon	Methyl tertiary-Butyl Ether (MtBE)
Benzene	Monochloramine
Benzo(a)pyrene	O-Phenylphenol (OPP)
Beryllium	Octahydro-1,3,5,7-tetranitro-1,2,3,5,7terazocine (HMX)
Bis(2-chloro-1-methyl ethyl) ether	Pentachlorphenol
Bispyribac sodium	Pentaerythriol tetranitrate (PETN)
Boron	Perchlorate
Boscalid	Propoxur (Baygon)
Bromacil	$Radium^{226\ \&228}$
Bromate	Tall oil hydroxyethyl imidazoline
Bromochloromethane	Tartrazine
Bromomethane (Methyl bromide)	Tetrachloroethylene
Bromoxynil	Trichloroethylene
Butylate	Trichloropropane (1,2,3)
Cadmium	Trimethyl benzene (1,2,3)
Carbaryl	Trimethyl benzene (1,2,4)
Carbofuran	Trimethyl benzene (1,3,5)
Carbon tetrachloride	Trinitrotoluene (2,4,6) (TNT)
Carboxin	Vinyl chloride
Carfentrazone ethyl	

TABLE 2
VERMONT DEPARTMENT OF HEALTH DERIVED VALUES
EXPOSURE ASSUMPTIONS AND FACTORS

PARAMETER	DEFAULT VALUE
Exposure Time (inhalation) (hours/24 hours)	24
Exposure Frequency (days/365 days)	365
Exposure Duration (years):	
Carcinogens (nonthreshold)	70
Noncarcinogens (threshold toxicants)	Age Group Specific
Averaging Time (years):	
Carcinogens (nonthreshold)	70
Noncarcinogens (threshold toxicants)	Age Group Specific
Lifetime (years)	70
Body Weight Adjusted Water Ingestion Rate (L/kg-d)):	
All Ages	0.044
Women of Childbearing Age (15 – 44 years)	0.046
Infant (Birth -<1 year)	0.175
Age Dependent Adjustment Factors:	
Birth - < 2 years	10
2 - < 16 years	3
16 years+	1