# Health Advisory Screening Levels

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## PURPOSE

This document describes the process to select drinking water criteria used by the Florida Department of Health (DOH) for water quality clearance according to Chapter 64E-8, Florida Administrative Code which records the rules that regulate DOH drinking water systems. DOH has developed health advisory levels (HALs) to determine whether health advisories are needed. These HALs are calculated based upon guidance from Florida Statutes, 62.777. This document also provides the equations used for calculating HALs for which no standard exists and identifies the sources of input values for these equations. HALs are defined as the concentration of a chemical in potable water below which a person has little risk of toxicity when consuming two liters of water per day. HALs are developed for both cancer and non-cancer endpoints. Advisories are considered when the concentration of chemical exceeds its respective HAL.

CALCULATION OF HEALTH ADVISORY LEVELS FOR NON-CARCINOGENS

Health advisory levels are designated in the Appendix. These values are typically calculated by DOH and serve as technical guidance to assist officials.

HALs for non-carcinogenic effects are based upon the oral reference dose (RfD). The *reference dose* (RfD) is defined by the US Environmental Protection Agency (EPA) as an estimate of a daily exposure for the human population (including sensitive subpopulations) that is likely to be without an appreciable risk of deleterious effects during a lifetime (EPA, 2000). The RfD is expressed in terms of milligram of contaminant per kilogram of body weight per day (mg/kg-day). The US EPA's approach to assessing the risks associated with systemic toxicity (an effect other than carcinogenicity and mutagenicity) uses the concept of a threshold response (i.e., a set dose below which toxic effects will not occur). The threshold concept hypothesizes that a range of exposures from zero to some finite value can be tolerated by the organism with essentially no chance of expression of the toxic effect. Regulatory efforts are generally made to keep exposures below the population threshold, which is defined as the lowest of the thresholds of the individuals (i.e., sensitive individuals) within a population. Advisories are set such that total exposure from drinking on average two liters of water per day will result in a daily dose below the threshold.

DOH selected a hazard quotient of 1.0 as the target hazard quotient. A hazard quotient is a number which enables comparison of an estimated chemical intake (dose) with a reference dose level below which adverse health effects are unlikely. The hazard quotient is expressed as the ratio of the estimated intake to the reference dose. This ratio is used to evaluate the potential for non-cancer health effects, such as organ damage, from chemical exposures. The US EPA defines a hazard quotient of less than or equal to one as acceptable.

The equation for determining HALs for non-cancer effects is:

$$HAL = \frac{RfDo * BW * RSC * CF}{WC}$$

HAL = Health Advisory Level ( $\mu g / L$ )
$RfD_o$= Reference Dose (mg/kg/day)
BW=body weight (kg) (70 kg adult)
RSC= Relative Source Contribution (unitless) (20%)
CF=conversion factor (µg/mg) (1000)
WC=water consumption (L/day) (2 L/day adult)

**Body weight (BW)**

The estimated BW of the exposed individual is required in the screening value calculations since the RfD is expressed on a "per kilogram body weight" basis. The 70 kg adult general population body weight is used for all screening value calculations by FDOH, as used in U.S. EPA's *Drinking Water Standards and Health Advisories* (EPA 2012) document. This represents a lifetime exposure.

**Consumption rate (CR)**

DOH uses an average water consumption rate (WC) of two liters per day to derive HALs. The water intake value selected is at the 84$^{th}$ percentile (FDEP 2005) and is likely to be positively correlated with body weight, i.e., heavier individuals ingest more water. If so, the combined water ingestion per unit body weight value used for HAL development may be higher than the 84$^{th}$ percentile.

- The Florida Department of Environmental Protection's (FDEP) *Technical Report: Development of Cleanup Target Levels (CTLs) for Chapter 62-777, F.A.C.,* (FDEP 2005) recommends an average adult consumption rate of two liters per day.

**Relative Source Contribution (RSC)**

The RSC is not part of the exposure estimate, but it affects how the exposure estimate is used. The default RSC of 0.2 allots only 20% of an acceptable intake of a non-carcinogen to drinking water. The intent is to insure that the total intake of the contaminant, from both drinking water and non-drinking water sources, does not exceed risk based limits. For most chemicals for which HALs have been developed, it is unlikely that there will be substantial non-drinking water intake, and the default 20% RSC restriction is therefore conservative (FDEP 2005).

**CALCULATION OF SCREENING VALUES FOR CARCINOGENS**

Health advisory levels based on cancer effects are set at a level believed to represent a minimal risk of cancer from a lifetime of exposure.

A cancer slope factor (SF) is a plausible upper-bound estimate of the probability of a carcinogenic response per unit intake of a chemical over a lifetime of exposure to a particular level of a potential carcinogen. A CSF is expressed in units of risk per milligram of contaminant per kilogram of consumer body weight per day (risk/mg/kg-d). Carcinogens are assumed to act in a non-threshold manner in that any amount of exposure to a carcinogen can cause an increased risk.

DOH bases HALs on a cancer risk of $10^{-6}$. Risk assessment methods do not estimate the number of cancer cases that will actually occur, but rather estimate the incremental probability of an individual developing cancer over a lifetime as a result of exposure to the potential carcinogen (i.e., incremental or excess individual lifetime cancer risk). Therefore, a $10^{-6}$ target risk level equates to one in a 1,000,000 or one in a million probability of an individual developing cancer. The US EPA defines a cancer risk range of $10^{-6}$ to $10^{-4}$ as acceptable.

The following equation is used to calculate HALs for carcinogens:

$$HAL = \frac{TR * BW * CF}{SFo * WC}$$

HAL = Health Advisory Level ( $\mu g / L$ )
BW=body weight (kg) (70 kg adult)
CF=conversion factor (µg/mg) (1000)
WC=water consumption (L/day) (2 L/day adult)
TR=target risk (unitless )(1E-6)
SFo=oral cancer slope factor (per mg/kg/day) chemical specific

**REFERENCES**

EPA, 1992. Guidelines for Exposure Assessment. Risk Assessment Forum, EPA/600/Z-92/001. U.S. Environmental Protection Agency, Washington DC.
http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=15263

EPA, 2011. Exposure Factors Handbook. (EPA/600/R-09/052F). U.S. Environmental Protection Agency, Washington DC.
http://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=236252

EPA, 2012. 2012 Edition of the Drinking Water Standards and Health Advisories. (EPA 822-S-12-001). Office of Water. U.S. Environmental Protection Agency, Washington, DC.
http://water.epa.gov/action/advisories/drinking/upload/dwstandards2012.pdf

Technical Report: Development of Cleanup Target Levels (CTLs) for Chapter 62-777, F.A.C. Final.
http://www.dep.state.fl.us/waste/quick_topics/publications/wc/FinalGuidanceDocumentsFlowCharts_April2005/TechnicalReport2FinalFeb2005(Final3-28-05).pdf FDEP 2005.

# Health Advisory Screening Levels
# Addendum

**Last Update: 3/5/2018**

## CALCULATING HALS FOR MUTAGENS USING AGE-DEPENDENT ADJUSTMENT FACTORS (ADAF)

The Florida Department of Health (DOH) typically calculates Health Advisory Levels for carcinogens using a linear extrapolation method (FDOH 2015). However, current recommendations for carcinogens that act via a mutagenic mode of action are somewhat different (EPA 2005). The current EPA guidance states that, unless there is chemical-specific data suggesting otherwise, mutagens are assumed to have significantly higher risk when exposure is early in life. To account for the increased susceptibility, risk calculations should use Age-Dependent Adjustment Factors (EPA 2005b).

| Age Group | ADAF | Duration Adjustment |
|---|---|---|
| **0 – 2 years** | 10 | 2 years / 70 years |
| **2 – 16 years** | 3 | 14 years / 70 years |
| **≥16 years** | 1 | 54 years / 70 years |

The risk for each exposure period is calculated independently as below. The results are then added together to obtain the total unit risk (EPA 2005b).

*Unit Risk = CSF x ADAF x dose (mg/kg-day) x Exposure / 70 (years)*

Where CSF = Cancer Slope Factor

The concentration equivalent to the target risk of 1 x $10^{-6}$ (HAL) can be determined by dividing the target risk by the total unit risk (EPA 2011).

*HAL at $1x10^{-6}$ = $1x10^{-6}$ / Unit Risk*

To determine the dose, water intake and average body weight needs to be determined. The EPA Office of Water (OW) looked at two approaches:

**Approach 1:** Use independent body weight (kg) and water intake (L/day) values
**Approach 2:** Use ratio of water intake to body weight in terms of L/kg-day

The EPA OW determined that Approach 2 was preferable, because both water intake and body weight are linked at the individual level prior to performing the statistical analysis for the population (EPA 2011).

In updating our HAL listing, the DOH followed EPA OW guidance and used Approach 2 when a chemical was determined to be a carcinogen with a mutagenic mode of action.

*HAL = TR / Total Unit Risk*
*Unit Risk = CSF x ADAF x NWC x ED/70 x UC x CF*

| Age group | CSF | ADAF | NWC | ED | UC | CF | Unit Risk |
|---|---|---|---|---|---|---|---|
| **0-2 years** | Chemical Dependent | 10 | 0.104 | 2 | 1 | 1000 | $UR_1$ |
| **2-16 years** | | 3 | 0.037 | 14 | | | $UR_2$ |
| **>16 years** | | 1 | 0.032 | 54 | | | $UR_3$ |
| **Total Unit Risk** | | | | | | | $\sum_{UR1-3}$ |

HAL = Health Advisory Level (µg/L)
TR = Target Risk ($1x10^{-6}$)
CSF = Cancer Slope Factor (per mg/kg-day)
ADAF = Age-Dependent Adjustment Factor (unitless)
NWC = Normalized Water Consumption (L/kg-day)
ED = Exposure Duration (years)
$UR_x$ = Unit Risk (per µg/L)
UC = Unit Concentration (1 µg/L)
CF = Conversion Factor (1000 µg/mg)

## DATA SOURCES

The EPA has a 3-tier system for evaluating human health toxicity data sources (EPA 2003).

**Tier 1** – EPA's IRIS
**Tier 2** – EPA's Provisional Peer Reviewed Toxicity Values (PPRTV)
**Tier 3** – Other Toxicity Values (priority to sources with transparent, peer-reviewed data)

The DOH has adopted this hierarchy with some modifications.

**Tier 1** – EPA's IRIS or EPA's HHBP.
In 2004, IRIS announced that chemicals solely used as pesticides would not be reassessed and data for chemicals more recently assessed by the EPA office of Pesticide Programs (OPP) would be archived.
**Tier 2** – EPA's PPRTV.
No change from the 2003 guidance.
**Tier 3** – ATSDR or CalEPA.
These are widely-accepted data sources with transparent, publicly-available peer reviewed data.
**Tier 4** – Other Toxicity Values.
This is similar to the 2003 guidance's Tier 3. Priority should be given to sources that are the most current, provided that the data is transparent and peer-reviewed.

*Named Sources:*
IRIS = Integrated Risk Information System (US EPA)
HHBP = Human Health Benchmarks for Pesticides (US EPA)
PPRTV = Provisional Peer Reviewed Toxicity Values (US EPA)
ATSDR = Agency for Toxic Substances and Disease Registry Toxicological Profiles
CalEPA = California EPA Office of Environmental Health Hazard Assessment

*Other Sources Cited or Reviewed:*
DWSHA = Drinking Water Standards and Health Advisories (US EPA)
RSL = Regional Screening Level Resident Tapwater Tables (US EPA)
RAIS = Risk Assessment Information System (Oak Ridge National Lab)
Win-PST = Windows Pesticide Screening Tool (USDA)
HEAST = Health Effects Assessment Summary Tables for Superfund (US EPA)
EUPDB = European Union Pesticide Database (EU Directorate of Health and Food Safety)

**REFERENCES**

EPA, 1986. *Guidelines for Mutagenicity Risk Assessment.* (EPA/630/R-98/003). U.S. Environmental Protection Agency, Washington DC.
https://www.epa.gov/sites/production/files/2013-09/documents/mutagen2.pdf

EPA, 2003. *Human Health Toxicity Values in Superfund Risk Assessments.* (Memorandum to National Policy Managers). Office of Superfund Remediation and Technology Innovation. U.S. Environmental Protection Agency, Washington DC.
https://www.epa.gov/sites/production/files/2015-11/documents/hhmemo.pdf

EPA, 2005. *Guidelines for Carcinogen Risk Assessment.* (EPA/630/P-03/001B). U.S. Environmental Protection Agency, Washington DC.
https://www.epa.gov/risk/guidelines-carcinogen-risk-assessment

EPA, 2005b. *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens.* (EPA/630/R-03/003F). U.S. Environmental Protection Agency, Washington DC.
https://www3.epa.gov/airtoxics/childrens_supplement_final.pdf

EPA, 2011. *Age Dependent Adjustment Factor (ADAF) Application.* Office of Water. U.S. Environmental Protection Agency, Washington DC.
https://hero.epa.gov/hero/index.cfm/reference/details/reference_id/783747

FDOH, 2015. *Health Advisory Screening Levels*. Florida Department of Health, Tallahassee, FL.