**4717.7820 DEFINITIONS.**

Subpart 1. **Scope.** For the purposes of parts 4717.7810 to 4717.7900, the terms in this part have the meanings given them.

Subp. 2. **$AF_{lifetime}$ or lifetime adjustment factor.** "$AF_{lifetime}$" or "lifetime adjustment factor" is a numerical multiplier used to modify the adult-based cancer slope factor for lifetime exposure based on chemical-specific data.

Subp. 3. **ADAFs or age-dependent adjustment factors.** "ADAFs" or "age-dependent adjustment factors" are the default modifiers to the cancer slope factor that account for the increased susceptibility to cancer from early life exposures to linear carcinogens in the absence of chemical-specific data. For the default derivation of cancer HRLs, the following ADAFs and corresponding age groups are utilized:

$ADAF_{<2}$=10, for birth until two years of age; $ADAF_{2\ to\ <16}$=3, for two up to 16 years of age; and $ADAF_{16+}$=1, for 16 years of age and older.

Subp. 4. **Additional lifetime cancer risk.** "Additional lifetime cancer risk" means the probability that daily exposure to a carcinogen over a lifetime may induce cancer. The Department of Health uses an additional cancer risk of $1x10^{-5}$ (1 in 100,000) to derive cancer HRLs.

Subp. 5. **Carcinogen.** "Carcinogen" means a chemical:

A. classified as a human carcinogen or a probable human carcinogen according to the "EPA Classification System for Categorizing Weight of Evidence for Carcinogenicity from Human and Animal Studies," the Risk Assessment Guidelines of 1986, United States Environmental Protection Agency, Office of Health and Environmental Assessment (August 1987), which is incorporated by reference;

B. classified as "carcinogenic to humans" or "likely to be carcinogenic to humans" according to the Final Guidelines for Carcinogenic Risk Assessment, United States Environmental Protection Agency, Office of Research and Development (March 2005), which are incorporated by reference. The guidelines are not subject to frequent change. The final guidelines are available at: http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=116283 or through the public library using the Minitex interlibrary loan system; or

C. classified as a substance known to be a human carcinogen or reasonably anticipated to be a human carcinogen in the Report on Carcinogens, United States Department of Health and Human Services, Public Health Service, National Toxicology Program. This report is incorporated by reference and is subject to frequent change. The report is available at: http://ntp.niehs.nih.gov/go/roc.

Subp. 6. **Chemical.** "Chemical" includes a single chemical or a defined mixture of two or more chemicals.

Subp. 7. **Chemical abstracts service registry number or CAS number.** The "chemical abstracts service registry number" or "CAS number" means the number assigned to a chemical by the Chemical Abstracts Service, a division of the American Chemical Society, 2540 Olentangy River Road, Box 3012, Columbus, OH 43210-0012. CAS numbers function as unique identifiers for chemicals in part 4717.7860. The Chemical Abstracts Service maintains a database of all CAS numbers at http://www.cas.org.

Subp. 8. **Developmental health endpoint or developmental.** "Developmental health endpoint" or "developmental" means an adverse effect on the developing organism that may result from parental exposure prior to conception, maternal exposure during prenatal development, or direct exposure postnatally until the time of sexual maturation. Developmental toxicity may be detected at any point in the lifespan of the organism. The major manifestations of developmental toxicity include:

A. death of the developing organism;

B. structural abnormality;

C. altered growth; and

D. functional deficiency.

Subp. 9. **Duration.** "Duration" means the length of the exposure period under consideration.

A. For the default derivation of noncancer health risk limits, the following durations are utilized:

(1) acute - a period of 24 hours or less;

(2) short-term - a period of more than 24 hours, up to 30 days;

(3) subchronic - a period of more than 30 days, up to approximately ten percent of the life span in humans; or

(4) chronic - a period of more than approximately ten percent of the life span in humans.

B. For the default derivation of cancer health risk limits, the durations corresponding to the three age groups associated with the age-dependent adjustments (ADAFs) specified in subpart 3, are utilized:

(1) two-year duration for the birth to two-year age group;

(2) 14-year duration for the two- to 16-year age group; and

(3) 54-year duration for the 16 and older age group.

C. For the chemical-specific derivation of a noncancer or cancer health risk limit, the duration is based on chemical-specific information regarding the relevant length of exposure.

Subp. 10. **Endocrine or (E).** "Endocrine" or "(E)" means a change in circulating hormone levels or interactions with hormone receptors, regardless of the organ or organ system affected. Endpoints with or without the (E) designation are deemed equivalent, for example, thyroid (E)=thyroid, and shall be included in the same health risk index equation in part 4717.7880.

Subp. 11. **Health risk index.** "Health risk index" is a sum of the quotients calculated by identifying all chemicals that share a common health endpoint and dividing the measured or statistically derived concentration of each chemical by its HRL. The multiple chemical health risk index is compared to the multiple chemical health risk limit, defined in subpart 19 as one, to identify exceedances. Equations to calculate multiple chemical health risk indices are found in parts 4717.7880 and 4717.7890.

Subp. 12. **Health risk index endpoint or health endpoint.** "Health risk index endpoint" or "health endpoint" means the general description of toxic effects used to group chemicals for the purpose of calculating a health risk index. Health risk index endpoints or health endpoints for each chemical are listed in part 4717.7860.

Subp. 13. **Health risk limit or HRL.** "Health risk limit" or "HRL" has the meaning given in Minnesota Statutes, section 103H.005, subdivision 3. An HRL is expressed as µg/L.

Subp. 14. **Intake rate or IR.** "Intake rate" or "IR" means the rate of ingestion of water, or the amount of water, on a per body weight basis, ingested per day, expressed as liters per kilogram body weight per day or L/kg-day. The time-weighted average of the 95th percentile intake rate for the derivation of cancer and noncancer HRLs is calculated for the relevant duration specified in subpart 9.

Subp. 15. **Maximum contaminant level or MCL.** "Maximum contaminant level" or "MCL" means the maximum permissible level of a contaminant in water that is delivered to any user of a public water system under the Federal Drinking Water Program according to Code of Federal Regulations, title 40, section 141.2.

Subp. 16. **Maximum contaminant level-based health risk limit or MCL-based HRL.** "Maximum contaminant level-based health risk limit" or "MCL-based HRL" means an MCL that is adopted as an HRL as authorized by Laws 2007, chapter 147, article 17, section 2.

Subp. 17. **µg/L.** "µg/L" means micrograms of chemical per liter of water.

Subp. 18. **mg/kg-day.** "mg/kg-day" means milligrams of chemical per kilogram of body weight per day.

Subp. 19. **Multiple chemical health risk limit or multiple chemical HRL.** The "multiple chemical health risk limit" or "multiple chemical HRL" is equal to one. Equations to determine whether the multiple chemical health risk limit has been exceeded are in parts 4717.7880 and 4717.7890.

Subp. 20. **Nonlinear carcinogen.** "Nonlinear carcinogen" means a chemical agent for which, particularly at low doses, the associated cancer risk does not rise in direct proportion to the extent of exposure, and for which a threshold level of exposure exists below which there is no cancer risk. The HRL for a nonlinear carcinogen is based on a reference dose that is lower than the threshold for cancer risk.

Subp. 21. **Reference dose or RfD.** "Reference dose" or "RfD" means an estimate of a dose for a given duration to the human population, including susceptible subgroups such as infants, that is likely to be without an appreciable risk of adverse effects during a lifetime. It is derived from a suitable dose level at which there are few or no statistically or biologically significant increases in the frequency or severity of an adverse effect between the dosed population and its associated control group. The RfD includes one or more divisors, applied to the suitable dose level, accounting for: (i) uncertainty in extrapolating from mammalian laboratory animal data to humans; (ii) variation in toxicological sensitivity among individuals in the human population; (iii) uncertainty in extrapolating from effects observed in a short-term study to effects of long-term exposure; (iv) uncertainty in using a study in which health effects were found at all doses tested; and (v) uncertainty associated with deficiencies in the available data. An HRL is not derived if the product of the divisors exceeds 3,000. The RfD is expressed as mg/kg-day.

Subp. 22. **Relative source contribution or RSC.** "Relative source contribution" or "RSC" means the fraction of total exposure to a substance or chemical that is allocated to drinking water. The default RSC is 0.2 for highly volatile chemicals. For other chemicals, the default RSC is 0.5 for acute and short-term HRLs and 0.2 for subchronic or chronic HRLs.

Subp. 23. **Slope factor or SF.** "Slope factor" or "SF" means an upper-bound estimate of risk per increment of dose that can be used to estimate cancer risk probabilities for different exposure levels. A cancer slope factor is expressed as cancer incidence per mg/kg-day. Minnesota Statutes, section 103H.201, subdivision 1, paragraph (d), requires the Department of Health, when deriving cancer HRLs, to use cancer slope factors published by the United States Environmental Protection Agency.

Subp. 24. **Toxic effects.** "Toxic effects" means an observable or measurable adverse biological event, or the organ, tissue, or system in which the effect is manifested. The designation of endpoints does not exclude other possible observable and measurable biological events. For the purpose of grouping chemicals and creating a health risk index

when multiple chemicals are present, toxic effects may be ascribed to more general health risk index endpoints or health endpoints. Health endpoints are listed in part 4717.7860.

Subp. 25. **Volatility.** "Volatility" means having a tendency to evaporate. Using Henry's Law constants, chemicals are characterized as nonvolatile or low, moderate, or high volatility as follows:

A. nonvolatile - Henry's Law constant $<3x10^{-7}$ atm-$m^3$/mol;

B. low - Henry's Law constant $>3x10^{-7}$ to $1x10^{-5}$ atm-$m^3$/mol;

C. moderate - Henry's Law constant $>1x10^{-5}$ to $1x10^{-3}$ atm-$m^3$/mol; and

D. high - Henry's Law constant $>1x10^{-3}$ atm-$m^3$/mol.

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