**Section 620.APPENDIX A Procedures for Determining Human Threshold Toxicant Advisory Concentration for Class I: Potable Resource Groundwater**

a) Calculating the Human Threshold Toxicant Advisory Concentration

For those substances for which USEPA has not adopted a Maximum Contaminant Level Goal (MCLG), the Human Threshold Toxicant Advisory Concentration is calculated as follows:



Where:

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| --- | --- | --- |
| HTTAC  | = | Human Threshold Toxicant Advisory Concentration in milligrams per liter (mg/L); |
| RSC  | = | Relative contribution of the amount of the exposure to a chemical via drinking water when compared to the total exposure to that chemical from all sources. Valid chemical-specific data shall be used if available. If valid chemical-specific data are not available, a value of 20% (= 0.20) must be used; |
| ADE  | = | Acceptable Daily Exposure of substance in milligrams per day (mg/d) as determined pursuant to subsection (b); and |
| W  | = | Per capita daily water consumption equal to 2 liters per day (L/d). |

b) Procedures for Determining Acceptable Daily Exposures for Class I: Potable Resource Groundwater

1) The Acceptable Daily Exposure (ADE) represents the maximum amount of a threshold toxicant in milligrams per day (mg/d), which if ingested daily for a lifetime results in no adverse effects to humans. Subsections (b)(2) through (b)(6) list, in prescribed order, methods for determining the ADE in Class I: Potable Resource Groundwater.

2) For those substances for which the USEPA has derived a Verified Oral Reference Dose for humans, USEPA's Reference Dose given in milligrams per kilogram per day (mg/kg/d), as determined in accordance with methods provided in National Primary and Secondary Drinking Water Regulations, 40 CFR 136, appendix B, 40 CFR 141.80, 40 CFR 141.61, and 40 CFR 141.62, incorporated by reference at Section 620.125, must be used. The ADE equals the product of multiplying the Reference Dose by 70 kilograms (kg), which is the assumed average weight of an adult human.

3) For those substances for which a no observed adverse effect level for humans (NOAEL-H) exposed to the substance has been derived, the ADE equals the product of multiplying one-tenth of the NOAEL-H given in milligrams of toxicant per kilogram of body weight per day (mg/kg/d) by the average weight of an adult human of 70 kilograms (kg). If two or more studies are available, the lowest NOAEL-H must be used in the calculation of the ADE.

4) For those substances for which only a lowest observed adverse effect level for humans (LOAEL-H) exposed to the substance has been derived, one-tenth the LOAEL-H must be substituted for the NOAEL-H in subsection (b)(3).

5) For those substances for which a no observed adverse effect level has been derived from studies of mammalian test species (NOAEL-A) exposed to the substance, the ADE equals the product of multiplying 1/100 of the NOAEL-A given in milligrams toxicant per kilogram of test species weight per day (mg/kg/d) by the average weight of an adult human of 70 kilograms (kg). Preference will be given to animal studies having High Validity, as defined in subsection (c), in the order listed in that subsection. Studies having a Medium Validity must be considered if no studies having High Validity are available. If studies of Low Validity must be used, the ADE must be calculated using 1/1000 of the NOAEL-A having Low Validity instead of 1/100 of the NOAEL-A of High or Medium Validity, except as described in subsection (b)(6). If two or more studies among different animal species are equally valid, the lowest NOAEL-A among animal species must be used in the calculation of the ADE. Additional considerations in selecting the NOAEL-A include:

A) If the NOAEL-A is given in milligrams of toxicant per liter of water consumed (mg/L), prior to calculating the ADE the NOAEL-A must be multiplied by the average daily volume of water consumed by the mammalian test species in liters per day (L/d) and divided by the average weight of the mammalian test species in kilograms (kg).

B) If the NOAEL-A is given in milligrams of toxicant per kilogram of food consumed (mg/kg), prior to calculating the ADE, the NOAEL-A must be multiplied by the average amount in kilograms of food consumed daily by the mammalian test species (kg/d) and divided by the average weight of the mammalian test species in kilograms (kg).

C) If the mammalian test species was not exposed to the toxicant each day of the test period, the NOAEL-A must be multiplied by the ratio of days of exposure to the total days of the test period.

D) If more than one equally valid NOAEL-A is available for the same mammalian test species, the best available data must be used.

6) For those substances for which a NOAEL-A is not available but the lowest observed adverse effect level (LOAEL-A) has been derived from studies of mammalian test species exposed to the substance, one-tenth of the LOAEL-A may be substituted for the NOAEL-A in subsection (b)(5). The LOAEL-A must be selected in the same manner as that specified in subsection (b)(5). One-tenth the LOAEL-A from a study determined to have Medium Validity may be substituted for a NOAEL-A in subsection (b)(3) if the NOAEL-A is from a study determined to have Low Validity, or if the toxicity endpoint measured in the study having the LOAEL-A of Medium Validity is determined to be more biologically relevant than the toxicity endpoint measured in the study having the NOAEL-A of Low Validity.

c) Procedures for Establishing Validity of Data from Animal Studies

1) High Validity Studies

A) High validity studies use a route of exposure by ingestion or gavage, and are based upon:

i) Data from animal carcinogenicity studies with a minimum of 2 dose levels and a control group, 2 species, both sexes, with 50 animals per dose per sex, and at least 50 percent survival at 15 months in mice and 18 months in rats and at least 25 percent survival at 18 months in mice and 24 months in rats;

ii) Data from animal chronic studies with a minimum of 3 dose levels and a control group, 2 species, both sexes, with 40 animals per dose per sex, and at least 50 percent survival at 15 months in mice and 18 months in rats and at least 25 percent survival at 18 months in mice and 24 months in rats, and a well-defined NOAEL; or

iii) Data from animal subchronic studies with a minimum of 3 dose levels and control, 2 species, both sexes, 4 animals per dose per sex for non-rodent species or 10 animals per dose per sex for rodent species, a duration of at least 5% of the test species' lifespan, and a well-defined NOAEL.

B) Supporting studies which reinforce the conclusions of a study of Medium Validity may be considered to raise such a study to High Validity.

2) Medium Validity Studies

 Medium validity studies are based upon:

A) Data from animal carcinogenicity, chronic, or subchronic studies in which minor deviations from the study design elements required for a High Validity Study are found, but which otherwise satisfy the standards for a High Validity Study;

B) Data from animal carcinogenicity and chronic studies in which at least 25 percent survival is reported at 15 months in mice and 18 months in rats (a lesser survival is permitted at the conclusion of a longer duration study, but the number of surviving animals should not fall below 20 percent per dose per sex at 18 months for mice and 24 months for rats), but which otherwise satisfy the standards for a High Validity Study;

C) Data from animal subchronic or chronic studies in which a Lowest Observable Adverse Effect Level (LOAEL) is determined, but which otherwise satisfy the standards for a High Validity Study; or

D) Data from animal subchronic or chronic studies which have an inappropriate route of exposure (for example, intraperitoneal injection or inhalation) but which otherwise satisfy the standards for a High Validity Study, with correction factors for conversion to the oral route.

3) Low Validity Studies

 Low validity studies are studies not meeting the standards set forth in subsection (c)(1) or (c)(2).

(Source: Amended at 36 Ill. Reg. 15206, effective October 5, 2012)