**Section 302.585 Procedures for Determining the Lake Michigan Basin Human Health Threshold Criterion (LMHHTC) and the Lake Michigan Basin Human Health Threshold Value (LMHHTV)**

The LMHHTC or LMHHTV is derived for all toxic substances from the most sensitive endpoint for which there exists a dosage or concentration below which no adverse effect or response is likely to occur.

a) Minimum Data Requirements

1) Tier I. The minimum data set sufficient to derive a Tier I LMHHTC must include at least one epidemiological study or one animal study of greater than 90 days duration; or

2) Tier II. When the minimum data for deriving Tier I criteria are not available, a more limited database consisting of an animal study of greater than 28 days duration must be used.

b) Principles for Development of Tier I Criteria and Tier II Values

1) The experimental exposure level representing the highest level tested at which no adverse effects were demonstrated (NOAEL) must be used to calculate a criterion or value. In the absence of a NOAEL, a LOAEL must be used if it is based on relatively mild and reversible effects;

2) Uncertainty factors (UFs) must be used to account for the uncertainties in predicting acceptable dose levels for the general human population based upon experimental animal data or limited human data:

A) A UF of 10 must be used when extrapolating from experimental results of studies on prolonged exposure to average healthy humans;

B) A UF of 100 must be used when extrapolating from results of long-term studies on experimental animals;

C) A UF of up to 1000 must be used when extrapolating from animal studies for which the exposure duration is less than chronic, but greater than subchronic;

D) A UF of up to 3000 must be used when extrapolating from animal studies for which the exposure duration is less than subchronic;

E) An additional UF of between one and ten must be used when deriving a criterion from a LOAEL. The level of additional uncertainty applied will depend upon the severity and the incidence of the observed adverse effect;

F) An additional UF of between one and ten must be applied when there are limited effects data or incomplete sub-acute or chronic toxicity data;

3) The total uncertainty (∑ of the uncertainty factors) must not exceed 10,000 for Tier I criterion and 30,000 for Tier II value; and

4) All study results must be converted to the standard unit for acceptable daily exposure of milligrams of toxicant per kilogram of body weight per day (mg/kg/day). Doses must be adjusted for continuous exposure.

c) Tier I Criteria and Tier II Value Derivation

1) Determining the Acceptable Daily Exposure (ADE)

ADE = test value / ∑ of the UFs from subsection (b)(2)

Where:

acceptable daily exposure is in milligrams toxicant per kilogram body weight per day (mg/kg/day)

2) Determining the Lake Michigan Basin Human Health Threshold Criterion (LMHHTC) or the Lake Michigan Basin Human Health Threshold Value (LMHHTV)

LMHHTC or LMHHTV =

{ADE x BW x RSC } /

{WC + [(FCTL3 x BAFHHTL3) + (FCTL4 x BAFHHTL4)]}

Where:

|  |  |  |
| --- | --- | --- |
| LMHHTC or LMHHTV is in milligrams per liter (mg/L) | | |
| ADE | = | acceptable daily intake in milligrams toxicant per kilogram body weight per day (mg/kg/day) |
| RSC | = | relative source contribution factor of 0.8 |
| BW | = | weight of an average human (BW = 70 kg) |
| WC | = | per capita water consumption (both drinking and incidental exposure) for surface waters classified as public water supplies = two liters/day; or per capita incidental daily water ingestion for surface waters not used as human drinking water sources = 0.01 liters/day |
| FCTL3 | = | mean consumption of trophic level 3 fish by regional sport fishers of regionally caught freshwater fish = 0.0036 kg/day |
| FCTL4 | = | mean consumption of trophic level 4 fish by regional sport fishers of regionally caught freshwater fish = 0.0114 kg/day |
| BAFHHTL3 | = | human health bioaccumulation factor for edible portion of trophic level 3 fish, as derived using the BAF methodology in Section 302.570 |
| BAFHHTL4 | = | human health bioaccumulation factor for edible portion of trophic level 4 fish, as derived using the BAF methodology in Section 302.570 |

(Source: Amended at 47 Ill. Reg. 4437, effective March 23, 2023)