

SENATE BILL 737

SELECTION OF TRIGGER LEVELS FOR OREGON'S PRIORITY PERSISTENT POLLUTANTS



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FINAL DRAFT

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ACRONYMS

ATSDR	Agency for Toxic Substances and Disease Registry
ChV	Chronic toxicity value (for fish)
DALY	Disability-Adjusted Life-Years
DEQ	Oregon Department of Environmental Quality
DWEL	Drinking Water Equivalent Level
ECOSAR	Ecological Structure Activity Relationships {U.S. EPA model}
EQC	Environmental Quality Commission
HAL	Health Advisory Level
HBSL	Health-based Screening Level
IARC	International Agency for Research on Cancer
IRIS	Integrated Risk Information System
LOAEL	Lowest-Observed-Adverse-Effect-Level
MAC	Maximum Allowable Concentration
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
MRL	Minimal Risk Level
NOAEL	No-Observed-Adverse-Effect-Level
OPP	U.S. EPA Office of Pesticide Programs
P ² RP	Priority Pollutant Reduction Plan (also called a Toxics Reduction Plan)
P ³ L	Priority Persistent Pollutant List {required by SB 737}
PQL	Practical Quantification Limit
RED	Reregistration Eligibility Decision (document)
RfD	Oral reference dose for humans
RSC	Relative Source Contribution
SB 737	Oregon Senate Bill 737
SSD	Species Sensitivity Distribution
TT	Treatment Technique
U.S. EPA	U.S. Environmental Protection Agency
USGS	U.S. Geological Survey
WHO	World Health Organization
WPCF	Water Pollution Control Facility
WWTP	Waste Water Treatment Plant

1 INTRODUCTION

1.1 BACKGROUND

This document summarizes the Oregon Department of Environmental Quality's (DEQ) draft process to select trigger levels for pollutants on the Senate Bill 737 (SB 737) priority persistent pollutant list (P³L). A trigger level is the concentration of a pollutant in municipal Wastewater Treatment Plant (WWTP) or Water Pollution Control Facility (WPCF) effluent which, if exceeded, "triggers" the preparation, by a WWTP or WPCF, of a Persistent Pollutant Reduction Plan (P²RP) for that pollutant. This process for choosing trigger levels makes a connection between exceeding a trigger level and the potential for harm to humans or aquatic life. Trigger levels will be "selected" because DEQ is not proposing to develop them from primary toxicity data as is done for water quality standards or criteria. Selecting trigger levels also serves to emphasize that they are not, and cannot be used as, numerical water quality standards or as part of a narrative standard [per SB 737 Section 4(1)(a)(B)].

1.2 SCOPE

Where a Maximum Contaminant Level (MCL)(or Treatment Technique (TT)) exists for a listed pollutant, then that will be its trigger level [SB 737 Section 4(1)(a)(A)]. An MCL (or TT) is a legally-enforceable standard that applies to public water systems; both MCLs and TTs are set by the U.S. EPA under the Safe Drinking Water Act authorities.¹ If no MCL has been adopted for a pollutant, then the Environmental Quality Commission (EQC) may determine by rule the pollutants on the P³L that will require a P²RP [SB 737 Section 4(1)(a)(B)]. DEQ's goal is to provide the EQC with health-based trigger levels for each pollutant, values that could be used to provide a scientifically credible basis for requiring a P²RP. Because SB 737 includes a broad mandate to protect human health, fish, wildlife, and aquatic species [SB 737 Preamble, Sections 2(4) and 3(2)(a)], DEQ has determined that trigger levels for pollutants without an MCL should reflect protection of human health or aquatic life, to be consistent with the objectives of the statute.

1.3 CONCEPTUAL MODEL

Pollutants, either in effluent or from other sources, could reach humans or aquatic life in various ways and produce, or contribute to, various adverse outcomes in these receptors (Attachment 4.1). Aquatic life (e.g., fish, invertebrates, aquatic plants) may be directly and consistently exposed to effluent being discharged into the receiving waters in which they live (with the understanding that both the presence and level of any pollutants in effluent may vary over time). With respect to human receptors, DEQ recognizes that: (a) effluent is not drinking water, (b) direct human exposure to effluent is unlikely and then only briefly

¹ <http://www.epa.gov/safewater/contaminants/index.html#listmcl>

and intermittently, (c) there is no documentation indicating that SB 737's specification of an MCL signals an intent to treat effluent as drinking water, and (d) using assumptions contained in the MCL calculations will likely significantly overestimate actual human exposures (if any) to effluent. However, DEQ has determined that for consistency with the language of SB 737, human health trigger level selection will assume direct human exposure to effluent as drinking water.

DEQ thus proposes to select trigger levels based only on direct exposure scenarios (those shown with solid connecting lines in Attachment 4.1). Trigger levels selected on this basis will represent a pollutant concentration below which (a) aquatic life is not expected to experience adverse effects when directly and chronically exposed to pollutants originating in effluent or (b) humans are not expected to experience cancer or non-cancer effects when directly exposed to those same pollutants in effluent.

Direct exposure scenarios can be readily evaluated using only pollutant concentrations in effluent. The additional evaluation of indirect exposure scenarios (those shown with dotted connecting lines in Attachment 4.1) would require modeling of transport and fate processes and food web transfers to connect pollutant concentrations in effluent to those in receiving waters or aquatic species. DEQ has determined that the development, parameterization, and corroboration of such models would unduly delay trigger level selection and, ultimately, implementation of pollutant reduction actions, without necessarily increasing the level of protection beyond that afforded by considering direct exposures alone. Furthermore, SB 737 only requires an identification of which chemicals require P²RPs, making modeling for a full and quantitative exposure characterization and risk assessment unnecessary.

2 PROCESS DESCRIPTION

DEQ proposes to select trigger levels for those persistent pollutants without an MCL from one of several existing values (or from values readily calculable with existing data), using the hierarchical process outlined in Attachment 4.2 and described below. Existing values will be selected from national or international government documents or the scientific literature either of which have undergone extensive peer- and public-review, and reflect relatively current scientific information.

2.1 (1) MAXIMUM CONTAMINANT LEVEL

To protect drinking water, the U.S. Environmental Protection Agency (U.S. EPA) first sets a Maximum Contaminant Level Goal (MCLG), the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, and which allows an adequate margin of safety. MCLGs are non-enforceable public health goals. When determining an MCLG, U.S. EPA considers the risk to sensitive subpopulations (infants, children, the elderly, and those with compromised immune systems) of experiencing a variety of adverse health effects. Since MCLGs consider only public health and not the limits of detection and treatment technology, sometimes they are set at a level which water systems cannot meet.²

For chemicals that can cause non-cancer health effects, the MCLG is based on the oral reference dose (RfD), an estimate of the amount of a chemical that a person can be exposed to on a daily basis that is not anticipated to cause adverse health effects over that person's lifetime. In determining the RfD, sensitive subgroups are included, and uncertainty may span an order of magnitude. The MCLG for non-carcinogens is calculated as follows:

(1)

(2)

where: DWEL = Drinking Water Equivalent Level (mg/L); RfD = Reference dose, lifetime exposure (mg/kg/d); BW = Adult body weight (70 kg); IR_{dw} = Daily water consumption, default value (2 L/d); MCLG = Maximum Contaminant Level Goal (mg/L); RSC = Relative Source Contribution (0.2, unitless).³

If there is evidence that a chemical may cause cancer, and there is no dose below which the chemical is considered safe, the MCLG is set at zero. If a chemical is carcinogenic and a safe

² <http://www.epa.gov/safewater/standard/setting.html>

³ The RSC is the percentage of total exposure typically accounted for by drinking water. It is applied to the dose (as the RfD) to determine the maximum amount of the dose "apportioned" to drinking water. U.S. EPA's drinking water program usually takes a conservative approach to public health by applying an RSC factor of 20 percent when adequate exposure data do not exist, assuming that the major portion (80 percent) of the total exposure comes from other sources, such as diet (USEPA, 2000).

dose can be determined, the MCLG is set at a level above zero that is safe (see below).

Once the MCLG is determined, U.S. EPA sets an enforceable standard which, in most cases, is an MCL, the maximum permissible level of a contaminant in water which is delivered to any user of a public water system. The MCL is set as close to the MCLG as feasible, defined as the level that may be achieved with the use of the best available technology, treatment techniques, and other means which U.S. EPA finds are available (after examination for efficiency under field conditions and not solely under laboratory conditions), taking cost into consideration. When there is no reliable method that is economically and technically feasible to measure a contaminant at particularly low concentrations, a TT is set rather than an MCL. A TT is an enforceable procedure or level of technological performance which public water systems must follow to ensure control of a contaminant.

In almost all cases for non-carcinogens, the MCL is the same as the MCLG. For known (U.S. EPA Class A) or probable (Class B) human carcinogens, the MCLG is set at zero (i.e., no amount of chemical is considered acceptable). However, since zero cannot be measured, the MCL is based initially (prior to any economic or engineering considerations) on the practical quantification limit (PQL), the lowest concentration that can be measured on a routine basis.⁴ Thus for known or probable carcinogens, the MCL is not necessarily a “safe” level but instead is the lowest measurable level. For possible (Class C) carcinogens, a MCLG is calculated as though they were not carcinogens, then divided by a factor of ten to give the MCL. This provides an additional margin of safety in case the chemical is later determined to be a carcinogen.

After determining an MCL or TT based on affordable technology for large systems, U.S. EPA must complete an economic analysis to determine whether the benefits of that standard justify the costs. If not, U.S. EPA may adjust the MCL for a particular class or group of systems to a level that "maximizes health risk reduction benefits at a cost that is justified by the benefits." U.S. EPA may not adjust the MCL if the benefits justify the costs to large systems, and small systems unlikely to receive variances.

As required by SB 737, if an MCL is available for a pollutant, no selection process is needed and the MCL becomes the trigger level. If not, the process branches into parallel selection hierarchies for aquatic life and human health values (Attachment 4.2).

⁴ A PQL is the lowest concentration that can be reliably measured within specified limits of precision, accuracy, representativeness, completeness, and comparability during routine laboratory operating conditions, using department approved methods. Or more simply, the PQL is the minimum level of a substance for which the question “...how much of that substance is present...”, can be answered with a high degree of certainty. A PQL provides a lower bound on the technical feasibility of a trigger level.

2.2 (A) AQUATIC LIFE BRANCH

2.2.1 (A₁) U.S EPA Ambient Water Quality Criteria

Ambient Water Quality Criteria (AWQC) serve as the scientific foundation for state surface water quality standards.⁵ The target goal of the aquatic life AWQC is to protect 95% of aquatic species. Section 304(a)(1) of the Clean Water Act requires U.S. EPA to develop criteria for water accurately reflecting the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments. They do not consider economic impacts or the technological feasibility of meeting the criteria in ambient water.

Two types of criteria are available: the Criterion Maximum Concentration (CMC) and the Criterion Continuous Concentration (CCC). The CMC is an estimate of the highest concentration of a pollutant in surface water to which an aquatic community can be exposed briefly without resulting in an unacceptable effect. It is often thought of synonymously as the "acute" AWQC. The CCC is an estimate of the highest concentration of a pollutant in surface water to which an aquatic community can be exposed indefinitely without resulting in an unacceptable effect.

2.2.1.1 Trigger Level

The freshwater CCC would be selected as the trigger level, with the understanding that, regardless of the basis for its selection, a trigger level is not, and cannot be used as, a water quality standard or be part of a narrative standard [per SB 737 Section 4(1)(a)(B)].

2.2.2 (A₂) U.S EPA OPP Aquatic Life Benchmarks

These are extracted from the most recent publically available U.S. EPA Office of Pesticide Programs (OPP) risk assessments for various pesticides and are based on the most sensitive aquatic toxicity data of the distribution for each taxa.⁶ Benchmarks, developed for baseline risk assessments, are estimates of the concentrations below which pesticides are not expected to harm aquatic life. Acute and chronic criteria, for various receptor groups (fish, daphnids, algae, etc.), are available.

2.2.2.1 Trigger Level

The lowest chronic value (ChV) among all freshwater receptor groups would be selected as the trigger level.

2.2.3 (A₃) Canadian Water Quality Guidelines

Canadian water quality guidelines for the protection of aquatic life help to protect all plants and animals that live in lakes, rivers, and oceans by establishing acceptable levels for

⁵ <http://www.epa.gov/waterscience/criteria/wqctable/nrwqc-2006.pdf>

⁶ http://www.epa.gov/oppefed1/ecorisk_ders/aquatic_life_benchmark.htm

substances that affect water quality.⁷ As long as conditions are within the levels established by the guidelines, one would not expect to see negative effects in the environment. The guidelines are based on toxicity data for the most sensitive species of plants and animals found in Canadian waters and act as science-based benchmarks for the protection of 100% of the aquatic life species in Canada, 100% of the time. Generally only two values (freshwater and marine) are given for a pollutant.

In 2007, Canada updated its water quality guideline derivation protocol to allow guidelines to be determined using both statistical (Type A: Species Sensitivity Distributions (SSD)) and non-statistical (Type B: lowest endpoint) methods, with the choice of method dependent on the quantity and quality of toxicity data available (CCME, 2007). The Type A, and most preferred, method is based on the statistical distribution of all available and acceptable toxicity data. This distribution describes the variation in sensitivity of different species to a pollutant and is used to extrapolate results from single-species toxicity tests to effects in entire biotic communities. The Type B method is based on an extrapolation from the lowest available and acceptable toxicity endpoint. If toxicological or statistical requirements for the Type A method cannot be met, then the Type B (lowest endpoint) derivation method would be used.

The protocol also sets guidelines for short- and long-term exposures. Short-term guidelines are intended to estimate severe effects and protect most species against lethality during intermittent and transient events (spills, infrequent releases of short-lived or non-persistent chemicals). Long-term guidelines are meant to protect against all negative effects to aquatic ecosystem function during indefinite exposures.

Type A SSDs can be used to derive both long-term guidelines and short-term management values, the difference being that for the latter the plotted endpoints must be an LC₅₀ or equivalent. For Type B long-term guidelines, the lowest endpoint with a safety factor is used to derive a long-term guideline (B1), while the LC₅₀ (or equivalent) with a safety factor is used to derive the short-term guideline (B2).

2.2.3.1 Trigger Level

The freshwater long-term exposure guideline would be selected as the trigger level. Such guidelines derived using Type A (SSD) methods would be preferred.

2.2.4 (A₄) Peer-Reviewed Literature

There may be a few instances where a pollutant is so new (with respect to any research on it) or so unusual that no guidelines or benchmarks have yet been established for it by any other government agency or organization. In these instances, information from the: (a)

⁷ <http://ceqg-rcqe.ccme.ca/>

primary literature (peer-reviewed scientific journal articles or government documents), (b) secondary literature (review papers, reports from other jurisdictions), or (c) grey literature (unpublished documents, reports from consultants or industry archives) would be searched for any applicable toxicity information.

2.2.4.1 Trigger Level

The lowest lowest-observed-adverse-effect-level (LOAEL) or equivalent, reported for freshwater test species, would be selected as the trigger level.

2.2.5 (A5) U.S. EPA ECOSAR Model

If no previously published values can be found for a pollutant, the ECOlogical Structure Activity Relationships (ECOSAR) model would be used to estimate a toxicity value. ECOSAR is a computerized predictive model that estimates the aquatic toxicity of industrial chemicals.⁸ It uses structure activity relationships to estimate a chemical's acute (short-term) toxicity and chronic (long-term or delayed) toxicity to aquatic organisms such as fish, aquatic invertebrates, and aquatic plants. The most recent version (v1.00, 2009) of the ECOSAR has been validated as a reasonable estimator of aquatic toxicity for a variety of chemical classes.

The mode of toxic action for most neutral organic chemicals is narcosis, and many types of chemical classes present toxicity to organisms in this way (i.e., ethers, alcohols, ketones). ECOSAR refers to this as “baseline toxicity.” However, some organic chemical classes have been identified as having a more specific mode of toxicity. These are typically organics that are reactive and/or ionizable so as to exhibit excess toxicity in addition to narcosis (i.e. acrylates, epoxides, anilines). ECOSAR refers to this as “excess toxicity.” ECOSAR provides estimates of baseline toxicity and, when appropriate, estimates of excess toxicity as well.

2.2.5.1 Trigger Level

The lowest freshwater ChV across all test species (fish, daphnids, or algae) and all chemical classes to which a pollutant may belong, excluding values with solubility limit⁹ or acute-to-chronic ratio flags,¹⁰ would be selected as the trigger level.

2.3 (H) HUMAN HEALTH BRANCH

The following hierarchy of potential sources for trigger levels follows that used by the U.S. Geological Survey (USGS), following an agreement with U.S. EPA (Toccalino, 2007). USGS changed to this hierarchy once pesticides were moved from IRIS to OPP. The HBSL values come first because they incorporate both IRIS and OPP toxicity values. DEQ has determined

⁸ <http://www.epa.gov/oppt/newchems/tools/21ecosar.htm>

⁹ A chemical may not be soluble enough to measure this predicted effect.

¹⁰ Measured data were lacking within a class of chemicals, so ChV was determined from a predicted SAR using established acute-to-chronic ratios and ECOSAR regression techniques.

that for consistency with the language of SB 737, human health trigger levels for pollutants without an MCL should use the default assumptions implicit in an MCL. Thus calculations will assume an ingestion rate of 2 L/d and a RSC of 20% for non-carcinogens, and a risk level of 1 in 100,000 (1×10^{-5}) for carcinogens.¹¹ For carcinogens in drinking water, the U.S. EPA considers risk levels of 1×10^{-6} to be protective of human health, provided these levels also are protective of noncancer adverse effects (USEPA, 1988). The U.S. EPA also accepts cancer risk policies from states in the range of 10^{-4} to 10^{-6} (USEPA, 1992, 1995). A limited comparison of MCLs with other values for the same carcinogens found that MCLs generally represent an effective risk level of 1 in 100,000 (1×10^{-5}).

2.3.1 (H1) USGS Health-Based Screening Level

Health-Based Screening Levels (HBSLs) are benchmark concentrations of contaminants in water that, if exceeded, may be a potential human health concern.¹² HBSLs are non-enforceable benchmarks that were developed by the USGS in collaboration with U.S. EPA and others using U.S. EPA methodologies for establishing drinking-water guidelines and the most current, U.S. EPA peer-reviewed, publicly available human-health toxicity information (Toccalino *et al.*, 2003, 2006; USEPA, 2000). HBSLs do not consider all potential human exposure pathways (only drinking water ingestion), nor can they be used to assess ecological health. They do, however, encompass pesticide toxicity data from the OPP, which U.S.EPA's Integrated Risk Information System (IRIS) no longer does. Three different equations are used to calculate HBSLs for unregulated contaminants as determined by the U.S.EPA cancer classification for each chemical (Toccalino *et al.*, 2003).

2.3.1.1 Non-Carcinogens

Here the HBSL represents the contaminant concentration in drinking water that is not expected to cause any adverse effects over a lifetime of exposure.

(3)

where: $HBSL_{NC}$ = Health-based screening level for non-carcinogens (mg/L); RfD = Reference dose, lifetime (mg/kg/d); BW = Adult body weight (70 kg); IR_{dw} = Daily water consumption, default value (2 L/d); RSC = Relative Source Contribution (0.2, unitless).

A RSC of 20% is assumed (i.e., 20% of total contaminant exposure comes from drinking water sources and 80% comes from other sources (for example, food and air). If region-specific data are available to quantify the percentage of contaminant exposure that comes from water, then a data-derived percentage could be used instead of the 20% default.

¹¹ Carcinogens would be identified based on their U.S. EPA (1986) weight-of-evidence classification or their IARC classification. Pollutants not classified or not classifiable as carcinogens would be treated as non-carcinogens.

¹² <http://infotrek.er.usgs.gov/traverse/f?p=HBSL:HOME:0>

2.3.1.2 Carcinogens (Group C)

For possible (Group C) carcinogens or contaminants with suggestive evidence of carcinogenic potential, HBSLs are calculated as follows (Toccalino *et al.*, 2003):

(4)

where: $HBSL_{GC}$ = Health-based screening level for Group C carcinogens (mg/L); RfD = Reference dose (mg/kg/d); BW = Adult body weight (70 kg); IR_{dw} = Daily water consumption, default value (2 L/d); RSC = Relative Source Contribution (0.2, unitless); RMF = Risk Management Factor (10, unitless).

2.3.1.3 Carcinogens (Groups A, B1, B2)

For carcinogens, the HBSL range represents a contaminant concentration range in drinking water corresponding to an excess estimated lifetime cancer risk of 1 chance in 1 million (1×10^{-6}) to 1 chance in ten thousand (1×10^{-4}).

(5)

where: $HBSL_C$ = Health-based screening level for Group A, B1, B2 carcinogens (mg/L); BW = Adult body weight (70 kg); Risk = Risk level (10^{-6} - 10^{-4} , unitless); IR_{dw} = Daily water consumption (2 L/d); SF = Cancer slope factor ($[mg/kg/d]^{-1}$).

2.3.1.4 Trigger Level

For non-carcinogens, the trigger level would be the HBSL. For carcinogens it would be a HBSL calculated at a 1×10^{-5} risk level (i.e., midway between the HBSL-low and HBSL-high).

2.3.2 (H2) U.S. EPA IRIS-based Calculations

U.S. EPA's IRIS is a compilation of searchable documents that describe the health effects of individual chemicals and that contain descriptive and quantitative information on cancer and non-cancer effects.¹³ Toxicity data (reference doses and cancer slope factors) from IRIS would be used with the HBSL calculation methodology described above to calculate HBSL-equivalent values.

2.3.2.1 Trigger Level

For non-carcinogens, the trigger level would be calculated using the same default assumptions listed under H1 above.

2.3.3 (H3) U.S. EPA Health Advisory Level

The U.S. EPA's Office of Water uses Health Advisory Levels (HAL) as an estimate of acceptable drinking water levels for a chemical substance based on health effects information. A HAL is not a legally enforceable Federal standard, but serves only as

¹³ <http://cfpub.epa.gov/ncea/iris/index.cfm>

technical guidance to assist Federal, State, and local officials.¹⁴

2.3.3.1 *Non-Carcinogens, Group C Carcinogens*

For advisory levels, RfD values are updated to reflect the values in IRIS and OPP Reregistration Eligibility Decision (RED) documents. There are four types of HAL for non-carcinogens depending on the duration of the toxicity tests on which the RfD is based:

One-Day HAL: The concentration of a chemical in drinking water that is not expected to cause any adverse non-carcinogenic effects for up to one day of exposure; normally designed to protect a 10 kg child consuming 1 L/d.

Ten-Day HAL: The concentration of a chemical in drinking water that is not expected to cause any adverse non-carcinogenic effects for up to ten days of exposure; also normally designed to protect a 10 kg child consuming 1 L/d.

Long-term HAL: Covers an exposure period of approximately 7 years, or 10 percent of an individual's lifetime and can incorporate parameters for either a child (10 kg body weight consuming 1 L/d) or an adult (70 kg body weight consuming 2 L/d).

Lifetime HAL: The concentration of a chemical in drinking water that is not expected to cause any adverse non-carcinogenic effects for a lifetime of exposure, assuming a 70 kg adult consuming 2 L/d. For Group C carcinogens, its value includes an adjustment for possible carcinogenicity.

2.3.3.2 *Carcinogens (Group A, B1, B2)*

For those substances that are “known or likely to be carcinogenic to humans” (USEPA, 2005) or “carcinogenic to humans” or “probably carcinogenic to humans” (Group 1 and Group 2A, respectively; International Agency for Research on Cancer (IARC) classification categories), the development of a Lifetime HAL is not recommended. The risk manager must balance this assessment of carcinogenic potential and the quality of data against the likelihood of occurrence and significance of health effects related to non-carcinogenic toxicity. To assist the risk manager in this process, drinking water concentrations associated with estimated excess lifetime cancer risks over the range of 1 in 10,000 (1×10^{-4}) to 1 in 1,000,000 (1×10^{-6}) are calculated for a 70-kg adult drinking 2 L/d (c.f., Eq. 5 above).

2.3.3.3 *Trigger Level*

For non-carcinogens, the trigger level would be a HAL calculated using a RSC of 20% (i.e., the DWEL). For carcinogens it would be a HAL calculated with a 1×10^{-5} risk level.

2.3.4 **(H4) ATSDR Minimal Risk Levels**

The Agency for Toxic Substances and Disease Registry (ATSDR) develops Minimal Risk Levels

¹⁴ <http://www.epa.gov/waterscience/criteria/drinking/dwstandards.pdf>

(MRLs), which are estimates of the daily human exposure (over a specified duration) to a hazardous substance that is likely to be without appreciable risk of adverse non-cancer health effects should exposure occur.¹⁵ MRLs are based on non-cancer health effects only; there is no consideration of cancer effects. They are derived using the No-Observed-Adverse-Effect-Level (NOAEL)/uncertainty factor approach, for acute (1–14 days), intermediate (15–364 days), and chronic (365 days and longer) exposure durations, and for the oral and inhalation exposure routes.

MRLs are generally based on the most sensitive chemical-induced end point considered to be of relevance to humans. They are below levels that might cause adverse health effects in the people most sensitive to such chemical-induced effects. Most MRLs contain a degree of uncertainty because of the lack of precise toxicological information on the people who might be most sensitive (e.g., infants, elderly, nutritionally or immunologically compromised) to the effects of hazardous substances. ATSDR uses a conservative (i.e., protective) approach to address this uncertainty consistent with the public health principle of prevention. Thus, the resulting MRL may be as much as 100-fold below levels that have been shown to be nontoxic in laboratory animals. Exposure to a level above the MRL therefore does not mean that adverse health effects will occur.

2.3.4.1 Trigger Level

The oral intermediate MRL (or, if not available, the chronic MRL) would be used to calculate a trigger level for non-carcinogens as follows:

(6)

where: TL = Trigger level (mg/L); MRL = Minimal Risk Level (mg/kg/d); BW = Adult body weight (70 kg); RSC = Relative Source Contribution (0.2, unitless); IR_{dw} = Daily water consumption (2 L/d).

2.3.5 (H5) Health Canada Drinking Water Guidelines

Canadian drinking water guidelines are Maximum Acceptable Concentrations (MAC) for hazardous substances in drinking water.¹⁶ These guidelines are designed to protect the health of the most vulnerable members of society, such as children and the elderly.

2.3.5.1 Non-Carcinogens

For non-carcinogens, the maximum acceptable concentration is calculated as:

(6)

where: MAC = Maximum Acceptable Concentration (mg/L); ADI = Acceptable Daily Intake

¹⁵ A hazardous substance has the inherent potential to do harm, whereas risk is the probability of such harm being realized.

¹⁶ http://www.hc-sc.gc.ca/ewh-semt/pubs/water-eau/sum_guide-res_recom/index-eng.php

(mg/kg/d); UF = Uncertainty factor (10, unitless); BW = Adult body weight (70 kg); RSC = Relative Source Contribution (0.2, unitless); IR_{dw} = Daily water consumption (1.5 L/d). The uncertainty factor (UF) represents the variability seen in the human population. An ADI is essentially the same as a RfD.

2.3.5.2 Carcinogens

For carcinogens, the maximum acceptable concentration is calculated as:

(7)

where: MAC = Maximum Acceptable Concentration (mg/L); BW = Adult body weight (70 kg); Risk = Acceptable risk range (10^{-6} - 10^{-4} , unitless); SF = Cancer slope factor ($[\text{mg}/\text{kg}/\text{d}]^{-1}$); IR_{dw} = Daily water consumption (L_{eq}/d). The daily volume of water consumed by an adult (IR_{dw}) accounts for multi-route (overall) exposure, expressed in liter equivalents per day. A *de minimis* (essentially negligible) cancer risk level of 1×10^{-6} is typically assumed.

2.3.5.3 Trigger Level

For non-carcinogens, the trigger level would be the MAC. For carcinogens it would be a MAC multiplied by 10 (to equate to a 1×10^{-5} risk level).

2.3.6 (H6) WHO Drinking-water Quality Guidelines

World Health Organization (WHO) water quality targets are established for individual drinking-water constituents that represent a health risk from long-term exposure and where fluctuations in concentration are small or occur over long periods. They are typically expressed as guideline values (concentrations) of the substances or chemicals of concern.¹⁷ These health-based targets are intended to be realistic under local operating conditions and are set to protect and improve public health. The reference level of risk is 1×10^{-6} disability-adjusted life-years (DALYs)¹⁸ per person per year, which is approximately equivalent to a lifetime excess cancer risk of 1×10^{-5} (i.e., 1 excess case of cancer per 100,000 of the population ingesting drinking water containing the substance at the guideline value for a lifetime).

¹⁷ http://www.who.int/water_sanitation_health/dwq/GDWAN4rev1and2.pdf

¹⁸ The basic principle of the DALY is to weight each health effect for its severity from 0 (normal good health) to 1 (death). This weight is multiplied by the duration of the effect – the time in which disease is apparent (when the outcome is death, the “duration” is the remaining life expectancy) – and by the number of people affected by a particular outcome. It is then possible to sum the effects of all different outcomes due to a particular agent. Thus, the DALY is the sum of years of life lost by premature mortality (YLL) and years of healthy life lost in states of less than full health, i.e., years lived with a disability (YLD), which are standardized by means of severity weights, or: DALY = YLL + YLD. Key advantages of using DALYs are its “aggregation” of different effects and its combining of quality and quantity of life.

2.3.6.1 Trigger Level

For non-carcinogens and carcinogens, the trigger level would be the WHO guideline.

2.4 (S) FINAL TRIGGER LEVEL SELECTION

(S1) If both non-cancer and cancer-based trigger levels are available, the lower of the two would be selected as the human health trigger level.

(S2) If both human health- and aquatic life-based trigger levels are available, the lower of the two would be selected as the trigger level.

(S3) If neither human health- nor aquatic life-based trigger levels could be selected, no trigger level would be assigned (the PQL would not be used as a default). If no trigger level could be assigned at this time, chemical and toxicological sources would be periodically reviewed should new information become available to allow selection of a trigger level.

(S4) If a trigger level is selected, its value would be compared to its PQL. The selected trigger level would become the final trigger level if its value was greater than the PQL; otherwise the PQL would become the final trigger level.

3 REFERENCES

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4 ATTACHMENTS

- 4.1 SB 737 P³ TRIGGER LEVEL SELECTION PROCESS FLOWCHART**
- 4.2 CONCEPTUAL MODEL FOR TRIGGER LEVEL SELECTION**