



Ministry of
Environment

DIRECTOR'S INTERIM STANDARDS FOR CONTAMINATED SITES

Industrial Land Use, Human Health Protection –
Intake of Contaminated Soil Standard for Lead

Prepared pursuant to Section 63.1 of the
Environmental Management Act

Effective: From February 1, 2013 to January 31, 2014

Approved:

Michael W. Macfarlane
Director of Waste Management

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Date

1.0 Introduction and background

The [Schedule 5](#) matrix numerical soil standards for lead in the Contaminated Sites Regulation (the Regulation) [1] do not provide a “Human Health Protection – Intake of contaminated soil” standard for industrial land use sites.

Recently, as part of the [Stage 8 amendments](#) [2] to the Contaminated Sites Regulation [1], the Minister of Environment approved industrial land use “Human Health Protection – Intake of contaminated soil” standards for all Schedule 5 listed substances other than lead.

In accordance with the ministry’s Contaminated Sites Soil Task Group (CSST) [3] protocol, Human Health Protection – Intake of contaminated soil standards are derived for threshold substances¹ using CSST equations based on a toxicological reference value (TRV), i.e., a tolerable daily intake value (TDI) or reference dose (RfD) for the substance. Furthermore, for lead, the CSST Policy Decision Summary [4] and [Technical Guidance 7, “Supplemental Guidance for Risk Assessments”](#) [5], require that a Health Canada TRV be used in the derivation of human health protective soil standards.

In 2009, Health Canada [6] advised that based on its ongoing detailed review of the toxicology of lead, Health Canada’s then current TDI (3.6 ug/kg BW/day) for lead should no longer be used in conducting quantitative risk assessment at Federal contaminated sites. Prior to its retraction, Health Canada’s TDI for lead was routinely used under the Regulation in human health risk assessments performed for contaminated sites and in the derivation of human health protective soil standards.

In 2011, Health Canada [7, 8] concluded that no minimum dose exists for the chronic adverse neurodevelopmental, neurodegenerative, cardiovascular, renal and reproductive effects of lead, and that the substance should be considered a non-threshold substance.^{2,3} Health Canada’s advice was based on the finding that the adverse health effects of lead could be associated with blood lead concentrations as low as 1 – 2 ug/dL.

In November, 2012 the Canadian Council of Ministers of the Environment (CCME) [13, 14] Soil Quality Guideline Task Group posted for stakeholder/public review new [Draft CCME soil quality guidelines for lead](#).⁴ The CCME [13, 14] draft human health

¹ A threshold substance is a substance for which a defined minimal dose is required to elicit a toxicological effect.

² A non-threshold substance is a substance for which no minimal dose can be determined to elicit a toxicological effect.

³ Lead is now also considered to be a non-threshold substance by the California Environmental Protection Agency (Cal EPA) [9], US Centers for Disease Control and Prevention (US CDC) [10], US Environmental Protection Agency (US EPA) [11], and the United Nations World Health Organization (UN WHO) [12].

⁴ The comment period for the Draft CCME soil quality guidelines for lead closes March 4, 2013.

guidelines for lead were derived by Health Canada, in its role as the human health Technical Secretariat for the CCME Soil Quality Guidelines Task Group, using a novel risk-based pharmacokinetic exposure model and the following new physiologically-based TRVs:

- in children: a blood lead concentration of 1 ug/dL to prevent a cognitive decrement of 1% on a population basis,⁵ and
- in adults: a blood lead concentration of 1.4 ug/dL to prevent a cardiovascular hypertension increment of 1% on a population basis.⁶

At this time, the CCME [13, 14] draft soil quality guidelines for lead and the Health Canada proposed physiologically-based TRVs and pharmacological kinetic model used in their derivation, are under review and may be subject to additional revision and change prior to their finalization and official approval by CCME and Health Canada. In consideration of this, the Minister of Environment elected not to include lead in the recent Stage 8 amendments [2] to the Regulation [1].

However, as a temporary measure, to ensure the provision of a consistent, equitable and protective regulatory process for the management of lead under British Columbia's contaminated sites regime, the Director has established an interim "Industrial Land Use, Human Health Protection - Intake of contaminated soil" standard for lead pursuant to Section 63.1 of the *Environmental Management Act* [15].

The Director's interim industrial soil standard for lead has been developed using the soil matrix standards derivational procedures of the CSST protocol [1] as modified by the ministry to accommodate Health Canada [7, 8] advice to consider lead as a non-carcinogenic non-threshold, toxicant. The interim standard was derived for the CSST [3] defined adult receptor, using a human health industrial land use exposure term modified from the industrial exposure term used to derive the Regulation's Schedule 11 industrial vapour standards [16] and an *ad hoc* interim "TDI-equivalent" toxicity reference value for lead, developed by Wilson and Richardson [17].

Appendix 1 provides further detail on the derivation of the Director's Interim Industrial Land Use, "Human Health Protection - Intake of contaminated soil" standard for lead.

⁵ A 1% cognitive decrement, on a population basis, is equivalent to a reduction in mean IQ of 1 IQ point.

⁶ A 1% cardiovascular hypertension increment, on a population basis, is equivalent to an increase in mean systolic blood pressure of 1.1 mmHg

2.0 Director’s Interim Industrial Land Use “Human Health Protection – Intake of contaminated soil” Schedule 5, Matrix Numerical Soil Standards for Lead

MATRIX NUMERICAL SOIL STANDARDS LEAD¹

COLUMN I	COLUMN VI	Note
Site-specific Factor	Industrial (IL)	2
HUMAN HEALTH PROTECTION		
Intake of contaminated soil	4 000	3, 4

Notes

1. All values in ug/g unless otherwise stated. Substances must be analyzed using methods specified in a director’s protocol or alternate methods acceptable to a director.
2. The site-specific factor of Human Health Protection – Intake of contaminated soil specified matrix soil standard applies at all sites.
3. Director’s Interim Industrial Land Use (IL) Human Health Protection – Intake of contaminated soil standard has not been adjusted based on results of clinical studies at sites. For IL, no soil ingestion clinical study factor is available; therefore the Director’ interim IL standard was set equal to the toxicologically-derived value.
4. Intake pathway of exposure is inadvertent ingestion of soil.

The Director’s interim industrial human health soil standard for lead augments existing numerical soil quality standards and is considered to be an addendum to the Schedule 5 matrix soil standards for lead of the Regulation [1]. The Director’s interim industrial human health standard for lead has the same legal standing as any other human health protection Schedule 5 matrix numerical soil standard under the Regulation [1]. As is the case for the “Human Health Protection – Intake of contaminated soil” matrix soil standards for lead provided for other land uses in Schedule 5, the new standard for lead is mandatory and applicable at all industrial sites.

3.0 References

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For more information, contact the Environmental Management Branch at site@gov.bc.ca.

Appendix 1

Toxicological Derivation

A1. General Considerations

The Director's interim industrial land use "Human Health Protection - Intake of contaminated soil" standard for lead for use under Schedule 5 of the Regulation [1] was derived for the adult receptor, using:

1. Ministry of Environment, CSST [3] procedures, equations and assumptions for the derivation of industrial land use soil quality matrix standards for contaminated sites,
2. Ministry of Environment, CSST [3] default or modified Ministry of Environment, [12] toxicological parameter values, and
3. Wilson and Richardson, [17] interim adult receptor "TDI-equivalent" toxicity reference value for lead.⁷

A2. TDI-equivalent Toxicity Reference Value for Lead

Based primarily on their review of a recent UN World Health Organization [18] correlative study of chronic lead dose and systolic blood pressure increment in adults, Wilson and Richardson [17] determined that a daily lead intake circa 1.3 ug/kg BW/day would be associated with a corresponding 1 mmHg increase in systolic blood pressure.

Wilson and Richardson's [17] recommended "TDI-equivalent" TRV for lead in adults (1.3 ug/kg BW/day) also represents a correlative dose for lead which would be predicted to elicit a blood lead concentration circa 1.4 ug/dL. Thus, Wilson and Richardson's [17] TDI-equivalent TRV would be expected to provoke a blood lead concentration equivalent to, but not in excess of, the physiologically-based TRV to prevent a cardiovascular hypertension increment of 1% on a population basis, proposed and used by Health Canada in deriving the CCME [14, 15] draft soil quality guidelines for lead.

A3. Ministry of Environment, CSST Human Health Protection – Intake of Contaminated Soil Derivation Equation

Wilson and Richardson's, [17] TDI-equivalent TRV, although expressed as an intake dose, is directly relevant to Health Canada's critical non-threshold chronic cardiovascular hypertension toxic effect of concern related to adult lead exposure. Furthermore, since Wilson and Richardson's, [17] TRV takes the form of a TDI, it is possible to calculate a non-

⁷ For the past year, the ministry has been authorizing, under [Protocol 6, "Eligibility of Applications for Review by Approved Professionals"](#) the use of Wilson and Richardson's, [17] TDI-equivalent TRVs for lead, in contaminated site quantitative risk assessment.

threshold toxicologically relevant industrial human health protective soil standard for lead using the traditional CSST [3] derivation equation for threshold substances.

CSST Preliminary TDI-based Human Health - Intake of contaminated soil, Soil Standard (PSQS_{HH}) - Threshold Substance Equation

$$PSQS_{HH} = \frac{[SAF \times TDI] \times BW}{[(AF_I \times IR) + (AF_D \times DR) + (AF_S \times SR)] \times ET}$$

Where:

Parameter	Parameter definition	Parameter default value	Reference for default value
PSQS _{HH}	Preliminary Soil Quality Standard - Human Health	Calculated value	
TDI	Tolerable Daily Intake	1.3 x 10 ⁻³ mg/kg BW/day	Wilson & Richardson [17]
SAF	Soil Allocation Factor	0.2	CSST [3]
BW	Body Weight	70 kg (adult)	CSST [3]
AF _I	Absorption Factor Ingestion	1.0	CSST [3]
IR	Soil Ingestion Rate	2.0 x 10 ⁻⁵ kg/day (adult)	CSST [3]
AF _D	Absorption Factor Dust (Inhalation)	1.0	CSST [3]
DR	Soil Dust inhalation Rate	0 kg/day	CSST [3]
AF _S	Absorption Factor Skin (dermal)	1.0	CSST [3]
SR	Soil dermal Skin contact Rate	0 kg/d	CSST [3]
ET	Exposure Term (land use specific)	0.22 ¹	ministry derived

Notes

¹ In view of the non-threshold nature of the toxicological effects of lead, the Director elected to modify the industrial exposure term used by the ministry to establish the Schedule 11 vapour standards [16] to more conservatively model and protect possible lifetime exposure to the substance within an industrial context. Therefore, for the purposes of deriving the Director’s Interim Industrial Land Use, Human Health Protection - “Intake of contaminated soil” standard for lead the following industrial land use exposure term (ET) was used: $ET = 8hr/24hr \times 5d/7d \times 48wk/52wk \times 70yr/70yr = 0.22$

A4. Calculation of Director’s Interim Industrial Land Use, Human Health Protection – Intake of Contaminated Soil Standard for Lead

$$IL \text{ Interim } PSQS_{HH} = \frac{[0.2 \times 1.3 \times 10^{-3}] \times 70}{[(1.0 \times 20) + (1.0 \times 0) + (1.0 \times 0)] \times 0.22} = 4136.4 \text{ mg/kg (4136 ug/g)}$$

A5. Final Director’s Interim Industrial Land Use, Human Health Protection – Intake of Contaminated Soil Standard for Lead – CSST Rounded

Final Director’s Interim IL, SQS_{HH} for lead = 4 000 ug/g