

CSR Omnibus Standards Updating Supplemental Consultation Document –

Proposal to Change CSST Protocol in Respect to the Derivation of Human Health Standards for Carcinogenic Substances

Introduction

In this supplemental consultation document the ministry is proposing to change the CSST Protocol to allow using either a non-cancer or a cancer-endpoint as the basis for deriving soil ingestion standards to protect human health from carcinogenic substances.

Background

Non-carcinogenic, toxic substances are those substances which do not elicit cancer and for which a concentration (i.e. a discrete dose) can be determined below which no adverse non-cancer effects are to be expected. Most carcinogenic substances, on the other hand, can elicit both cancer and non-cancer effects. Furthermore, in respect to the cancer endpoint, it is assumed that there is some probability of eliciting cancer at any level of exposure to the carcinogenic substance (i.e. at any dose)¹.

For non-carcinogenic substances, the CSST Protocol considers:

- a) the adult to be the critical receptor for industrial land use², and
- b) the 0.6 to 4 year old child to be the critical receptor for all other land uses.

For carcinogenic contaminants, the CSST Protocol assesses cancer risk using the adult as the critical receptor for all land uses, and exposure is assumed to be continuous over 70 years (CSST, 1996)³.

Proposal to Amend the CSST Procedure

The toxicological literature and many regulatory agencies now broadly recognize that a carcinogenic substance may elicit both cancer and non-cancer effects. Furthermore, for some substances a soil

1. Under the CSST Protocol, a “**carcinogenic substance**” means any substance classified by:
 - a) UN World Health Organization, International Agency for Research on Cancer as a group 1 or group 2A carcinogen, or
 - b) US Environmental Protection Agency as a group A or group B1 carcinogen.
2. No exposure scenario for industrial land use was included in the 1996 CSST Protocol, as at that time, CSST considered human health protection on industrial sites to be the mandate and responsibility of the Workers’ Compensation Board of British Columbia. However, the 2013 Stage 8 amendment to the CSR has since established a defined exposure scenario for industrial land use which identifies the adult as the critical receptor for both non-carcinogenic and carcinogenic substances.
3. The ministry is proposing to use the 2010 Health Canada life expectancy of 80 years in the Omnibus updating of the CSR standards.

ingestion standard based on the non-cancer endpoint may be more stringent than the corresponding soil ingestion standard based on the cancer endpoint. As the CSST protocol ignores the duality of non-cancer and cancer endpoints for carcinogenic substances, it is possible that the CSST protocol may not provide the most protective standard in all circumstances (e.g. a CSST derived soil standard for a carcinogenic substance may not be adequately protective of the non-cancer endpoint that might also be elicited by that substance).

To address this potential bias, the ministry now proposes to further change the 1996 CSST Protocol for the derivation of human health soil quality standards as follows:

1. Determine if a substance is a carcinogenic or non-carcinogenic contaminant in accordance with the CSST Protocol definition of “carcinogenic substance”;
2. Where appropriate non-cancer and cancer TRVs are available for a carcinogenic substance, calculate both non-cancer and cancer endpoint-based preliminary soil ingestion standards for the substance and various land uses.
3. For each land use, adopt as the new final CSR soil ingestion standard for the carcinogenic substance, the most stringent of the cancer or non-cancer preliminary soil ingestion standards, as the CSR standard.

An example derivation for benzene is provided as Appendix 1.

Since by definition a non-carcinogenic substance cannot elicit cancer and therefore has no cancer endpoint, no change is proposed for the CSST Protocol in respect to the derivation of human health soil ingestion standards for non-carcinogenic substances.

Request for Comments

Comments on this supplemental proposal to change the manner in which the CSST Protocol derives human health soil ingestion standards for carcinogenic substances under the planned Stage 10 amendment to the CSR should be sent to Lizzy.Mos@gov.bc.ca on or before January 4, 2016.

References

CSST (1996) Overview of CSST Procedures for the Derivation of Soil Quality Matrix Standards for Contaminated Sites. Risk Assessment Unit, Environmental Protection Department, BC Environment. January 31, 1996.

Health Canada (2010) Federal Contaminated Site Risk Assessment in Canada Part I: Guidance on Human Health Preliminary Quantitative Risk Assessment (PQRA), Version 2.0. Contaminated Sites Division. Safe Environments Directorate. September 2010.

Health Canada (2004) Federal Contaminated Site Risk Assessment in Canada Part II: Health Canada Toxicological Reference Values (TRVs). Contaminated Sites Division. Safe Environments Directorate. September 2004.

Appendix 1. Example Derivation of Soil Ingestion CSR Standard for Benzene

Benzene	Land Use	Critical Receptor	Body Weight <i>kg</i>	Soil Ingestion Rate <i>kg/day</i>	Exposure Term <i>Unitless</i>	Preliminary CSR Standard	Final Rounded CSR Standard
Cancer Endpoint	W	Adult	70.7	2.00E-05	0.5	1285	1500
	A	Adult	70.7	2.00E-05	1	643	650
SFo = 5.5E-02 ≈ RsD = 1.82E-04 mg/kg/day	LDR	Adult	70.7	2.00E-05	1	643	650
	HDR	Adult	70.7	1.00E-05	1	1285	1500
	P	Adult	70.7	2.00E-05	0.5	1285	1500
	C	Adult	70.7	1.00E-05	0.33	3895	4000
	I	Adult	70.7	2.00E-05	0.1	6427	6500
Non-cancer Endpoint	W	Toddler	16.5	8.00E-05	0.5	330	350
	A	Toddler	16.5	8.00E-05	1	165	150
TDI = 4E-03 mg/kg/day	LDR	Toddler	16.5	8.00E-05	1	165	150
	HDR	Toddler	16.5	4.00E-05	1	330	350
	P	Toddler	16.5	8.00E-05	0.5	330	350
	C	Toddler	16.5	4.00E-05	0.33	1000	1000
	I	Adult	70.7	2.00E-05	0.1	28280	30000
6500	Final Standard (i.e. more stringent of the respective cancer and non-cancer endpoint preliminary CSR standards for the substance).						