BRITISH COLUMBIA | Ministry of Environment

Technical Guidance 7
"Supplemental Guidance for Risk Assessments"

CSAP Professional Development Workshop
October 26, 2011

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Risk Assessment Report
TG7, P6 Preapprovals and Minimal RA Regulatory Requirements

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Outline

Technical Guidance 7

- CSAP Review
- Finalization

Protocol 6 Preapprovals

- Joint MoE/CSAP RA meeting
  - HHRA issues
  - ERA issues

Minimal RA Regulatory requirements

- “non-prescribed” substances
- Prescribed substance with “no particular use”

Technical Guidance 7

Chronology

- Nov 2010 TG 7 ver 2 sent for CSAP Review
- Jan 2011 CSAP comment received
- May 2011 TG 7 ver 3 MoE internal review
- June 2011 Joint MoE/CSAP RA meeting
- Sept 2011 TG 7 ver 4 MoE internal review
- Oct 2011 TG 7 ver 4 finalized & approved

Current Status

- TG 7 ver 4 is being web formatted
- Issuance pending

TG 7 ver 2 CSAP Review Comment

Human Health – 4 main concerns

1. Use of Hel Can “unpublished” RA guidance
   - More recent guidance okay with rationale
2. MoE vs Hel Can “policy”
   - MoE policy takes precedence
3. Clarify carcinogenic classification
   - IARC 2A and EPA B1
4. P6 preapproval for supplemental TRVs
   - Box note added - P6 preapproval required only for *de novo* TRVs

TG 7 ver 2 CSAP Review Comment

Ecological Health – 3 main concerns

1. Expand "scope of end-points" for EcoTRVs
   - End-points now include: ECx, EDx, benchmark dose, critical tissue residue concentrations, etc.
2. Clarify cancer end-point in ERA
   - Use for rare/endangered individual organisms if data available
3. Clarify when P6 preapproval needed for EcoTRVs
   - Only for *de novo* EcoTRVs

P6 RA preapprovals

No.	Types of Applications Requiring Preapproval
5	Where the application is based on a risk assessment that includes any of the following: • probabilistic analysis; • toxicity testing of materials (soil, water, sediment,), or organisms obtained at or from the parcel; • modification of toxicity reference values; • food chain modelling; • weight-of-evidence arguments; • assessments of the aquatic receiving environment

P6 RA Preapprovals – Count to date

Type	Count
HH TRV	1
EcoTRV	2
Eco toxicity testing	2
Food chain modelling	2
Wt. of Evidence	2

Average preapproval processing time - circa 6 weeks

Joint MoE/CASP RA meeting

HHRA issues

1. Sensitive receptors - *Level of effort needed to ID?*
   - "known or reasonably inferred"
2. Trench worker assessment – *Calculations needed if have Health and Safety plan?*
   - Calculations required
3. RA for future DW use under TG 6 – *Can "inoperative future pathway" be used in RA?*
   - Yes, but expect RM controls to be included in CoC
4. Petroleum product surrogate approach - *CCME or MoE methodology?*
   - Either agency's approach okay
5. Exposure amortization - *To do or not to do?*
   - Don't

Joint MoE/CASP RA meeting

ERA issues

1. Modification of an EcoTRV – *What mods need preapproval?*
   - Clarified in TG 7 – preapproval only for *de novo E*coTRVs
2. Toxicity testing – *All components or just results?*
   - MoE looking to confirm tox tests used are relevant to site specific receptors/exposures
3. Weight of Evidence - *Must all types of WoEs be preapproved?*
   - Yes, including SAB based
4. Food chain modelling – *Is food chain modeling required for every site?*
   - No, MoE primarily concerned with bioaccumulative food chain models
5. Plant rooting depth – *How deep?*
   - P13 1 m default assumption okay
6. Vapour exposure – *Include vapour pathway in ERA?*
   - No, (unless rare and endangered and data/TRVs available)

Minimum RA Regulatory Requirements

”Unregulated Substances” in RA

1. Confusion as to if a non-prescribed substance must be included as a contaminant of concern in RA
2. Confusion as to if a prescribed substance without a particular use must be included as a contaminant of concern in RA
3. Ministry has new draft flowcharts to clarify “must include” vs. “may choose to include”
4. Draft flowcharts sent to CSAP with request for review

Definitions

”Prescribed Substance”

- A substance which is named (i.e. listed) within any of the CSR schedules is a “prescribed substance”

”Particular Use”

- A specified (i.e. listed) use for a prescribed substance for which a numerical standard is provided within a CSR schedule is a “particular use”

Definitions

Schedule 6

Generic Numerical Water Standards

COLUMN I	COLUMN II	COLUMN III	COLUMN IV	COLUMN V
Substance	Aquatic Life (AW)	Irrigation (IW)	Livestock (LW)	Drinking Water (DW)
Dichlorobenzene, 1,2-	7, 420			3
Dichlorobenzene, 1,3-	1 500			
Dichlorobenzene, 1,4-	260			1
Hexachlorobenzene			0.5	
Monochlorobenzene	13, 120			30
pentachlorobenzene	60			
Tetrachlorobenzene, 1,2,3,4-	18			
Trichlorobenzene, 1,2,3-	80			
Trichlorobenzene, 1,2,4-	240, 54			
Dichloroethane, 1,2-	1 000		5	5
Dichloroethylene, 1,1-				14
tetrachloroethylene	1 100			30
trichloroethylene	200		50	5

Contaminated Site - EMA

EMA 39 (1)

"contaminated site" means an area of the land in which the soil or any groundwater lying beneath it, or the water or the underlying sediment, contains

(a) a hazardous waste, or

(b) another prescribed substance

in quantities or concentrations exceeding prescribed risk based or numerical criteria or standards or conditions

Contaminated Site - CSR

CSR 11 Definition of contaminated site

11 (1) Subject to ... the following substances, standards and conditions are prescribed for the purposes of the definition of "contaminated site" in section 39 of the Act:

(a) ... any substance in the soil is greater than ...

(i) the applicable generic numerical soil standard, or

(ii) the lowest value of the applicable matrix numerical soil standards; ...

(b) ... any substance in the surface water or groundwater is greater than the applicable generic numerical water standard; ...

(c) ... any substance in sediment at the site is greater than the applicable generic numerical sediment criterion; ...

(c.1) ... any substance in vapour at the site is greater than the applicable generic numerical vapour standard; ...

(d) ... the concentration of any substance at the site, not specified in Schedule 4, 5, 6, 7, 9, 10 or 11, is greater than,

(i) if the substance is specified without a particular use, the concentration specified for that substance in a director's interim standard, and

(ii) if the substance is specified with a particular use, the concentration specified for that substance and use in a director's interim standard.

Contaminated Site - CSR

CSR defines a contaminated site using numerical not risk-based standards

CSR 15 Procedures for determination of contaminated site

15 (1) The numerical standards must be applied in determining whether a site is a contaminated site.

Minimum RA Regulatory Requirements

MoE Regulatory Interpretation

A site is a contaminated site if:

1. a prescribed substance is present in soil, water, sediment or vapour in excess of
2. a numerical standard specified for an applicable particular use

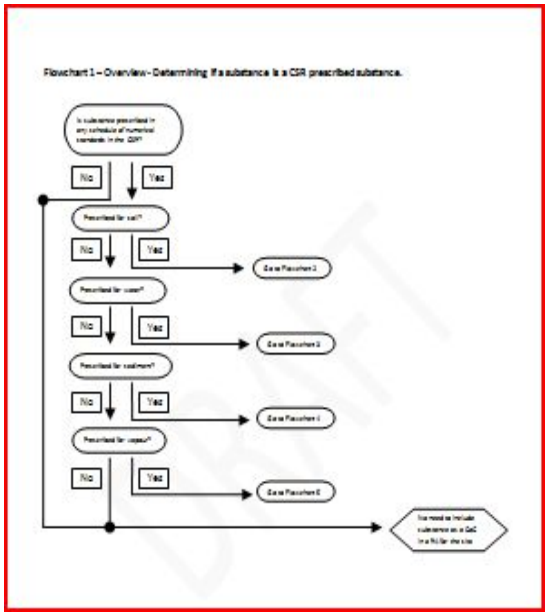
Implications for Risk Assessment

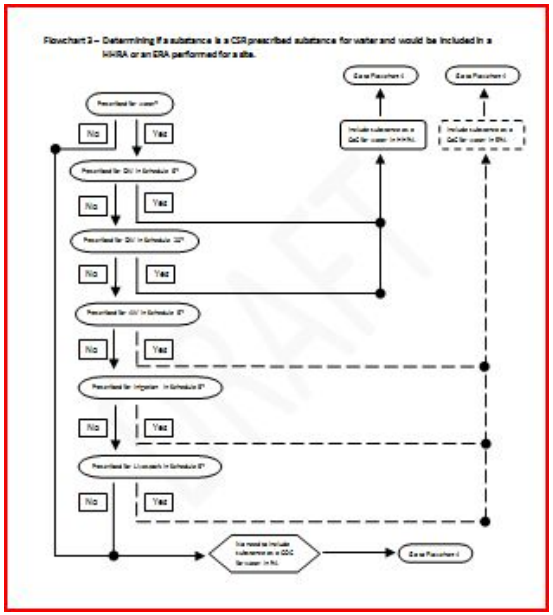
No regulatory duty to include a substance as a contaminant of concern in a RA if:

1. the substance is not a prescribed substance, or
2. is prescribed but has no specified particular use

Draft Decision Flowcharts

Ministry has drafted high level flowcharts designed to be used to determine if a substance is prescribed for a Particular environmental media, and therefore must be included as a contaminant of concern in HHRA or ERA





RA Status Report

Document	Status	Delivery Date
TG7	Finalized, preparing for web posting	ASAP
P1	Ministry proposes to revise for "intermediate level" ERA	?
P13	Being revised	2012
P20	Draft to go to CSAP for review	Dec 2011

RA Report

Questions?