Canadian Approaches to Soil Risk Assessment

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Soil Risk Assessment in Canada

- Touched upon by a number of programs and under a number of federal *Acts*, two of the main *Acts* being:

Canadian Environmental Protection Act 1999 (CEPA 1999)

- Principle federal legislative tool for assessing and managing chemical substances
- New and existing substances
- Jointly administered by Environment Canada and Health Canada

Pest Control Products Act (PCPA 2006)

- Evaluation of pest control products (pesticides and biocides)
- New and existing (re-evaluation every 15 years)
- Administered by the Pest Management Regulatory Agency (PMRA) of Health Canada

CEPA 1999

New substances program

- The Domestic Substance List (DSL) developed in 1994 for the purpose of determining substances new to Canada
- Assesses all substances introduced to Canadian commerce following the creation of the DSL before their introduction into the Canadian marketplace

Existing substances program

- Includes assessment of substances on the Domestic Substance List (DSL)
  - ~23 000 substances on the DSL
    - ~4300 substances identified in 2006 as requiring further assessment

CEPA 1999

- Substances are assessed to determine if they meet the definition of toxic as defined in Section 64 of *CEPA 1999:*

"A substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that:

a. have or may have an immediate or long-term harmful effect on the environment or its biological diversity;

b. constitute or may constitute a danger to the environment on which life depends; or

c. constitute or may constitute a danger in Canada to human life or health."

Soil Risk Assessment Under *CEPA 1999*

- Risk assessments consider:
  1. Fate in the environment
  2. Persistence and bioaccumulation potential
  3. Environmental hazard
  4. Human health hazard
  5. Exposure
  6. Risk characterization

- *CEPA 1999* prescribes use of weight-of-evidence and precautionary approaches

Soil Risk Assessment Under *CEPA 1999*

- Datasets for assessment differ between programs
  - New substances program
    - Mandatory datasets are prescribed within the New Substances Notification Regulation depending on type of substance, and the quantity, intended use and circumstances associated with its introduction
    - Mandatory datasets oriented to aquatic environment
    - Additional studies can be requested for terrestrial exposures if considered critical (e.g., biosludge application)
  - Existing substances program
    - No prescribed data generation and submission requirements, but can publish mandatory surveys (typically for use pattern data)
    - Uses publically available data or data voluntarily submitted by industry; limited funds for targeted testing
    - Often, substances are "data poor", especially for sediments and soils

Soil Risk Assessment Under *CEPA 1999*

- Soil risk assessments can consider direct and indirect exposure via soil, if warranted
  - Therefore, the risk to soil-dwelling organisms (plants, invertebrates) can be considered, but also impact on higher-organisms (birds, mammals) especially for those substances whose physico-chemical properties suggest that transfer through food webs may be important
- Data availability is typically the limiting factor for soils

Soil Risk Assessment Under *CEPA 1999*

Fate in the Environment

- Mass-balance multimedia models can determine intermedia transfer of chemicals to soil or fate in soil and biota from direct emission to soil (e.g., biosludge application)
  - Regional level (100,000 km^2)
  - Terrestrial foodwebs
- Also models for:
  - Long range transport
  - Air dispersion (local)
  - Atmospheric deposition
- If chemical is not amenable to modelling, fate is qualitatively evaluated according to its physico-chemical properties and mode of entry to environment

Soil Risk Assessment Under *CEPA 1999*

Persistence and bioaccumulation (P & B)

- The science of persistence and bioaccumulation as it affects chemical fate and distribution in organisms and the environment is an element in CEPA assessments
- Important for determining:
  - Exposure potential (e.g. residence time, long-range transport)
  - Estimating tissue residues
  - ADME properties and estimating ecotoxicity
- For P, often half-life data is only for water
  - Half-life in soil considered to be the same (Boethling et al. 1995)

Soil Risk Assessment Under *CEPA 1999*

Hazard Assessment

- Objective is to derive a predicted no effect concentration (PNEC) for organisms in direct contact with soil ($PNEC_{soil}$) or in wildlife exposed indirectly via soil and/or the foodweb ($PNEC_{wildlife}$)
- For direct contact, Environment Canada has developed several test methods for soils reflecting Canadian species and soils
- Standard test protocols required for prescribed datasets and preferred for non-prescribed data (e.g., Environment Canada, OECD, ISO, ASTM)

Soil Risk Assessment Under *CEPA 1999*

Hazard Assessment cont'd

- For indirect exposure:
  - $PNEC_{wildlife}$ derived from repeated oral dose toxicity tests on laboratory rodents that have been normalized to the body weight of the wildlife species of interest (e.g., shrew, mole, vole, fox, etc.)
  - Based on similar approaches used by USEPA for Superfund Risk Assessments

Soil Risk Assessment Under *CEPA 1999*

Hazard Assessment cont'd

- Assessment factors are used to derive PNECs from toxicity test data
- Microbial test data are examined, however, uncertainty with interpreting these data usually results in less weight given to them in assessments

Soil Risk Assessment Under *CEPA 1999*

Exposure assessment

- Aim is to derive a predicted environmental concentration (PEC)
- Scenarios are dependent on the substance, its properties, manufacture and use patterns, and life cycle stages
- Exposure scenarios may include
  - direct release to soil during manufacture, transport, and/or use;
  - removal of the substance from waste water to sludge and application of this biosludge to soils;
  - deposition from air; or
  - ingestion of contaminated soil, water and/or food by wildlife

Soil Risk Assessment Under *CEPA 1999*

Exposure assessment cont'd

- Generally PECs are for soil concentrations (PEC_{soil})
- For scenarios considering transfer in foodwebs, the $PEC_{wildlife}$ can be based on:
  - Empirical tissue residue data of prey (if available)
  - Bioenergetics modelling (soil-earthworm-shrew-fox) to estimate a total daily intake (TDI) in prey;
  - Model tissue residues in prey and predators based on BSAFs/BAFs and soil concentrations
- Tiered approach
  - Initial scenarios require less effort and are more conservative
  - Subsequent scenarios involve further refinement and increased realism

Soil Risk Assessment Under *CEPA 1999*

Risk characterization

- A weight-of-evidence approach
- Lines of evidence can include
  - Quantitative comparison of PNECs to PECs (including probabilistic methods)
  - P & B characteristics
  - Presence and distribution in environment and fate trends
  - Current and anticipated future release patterns, etc.
- Lines of evidence with higher weight contribute more to the overall conclusion

Soil Risk Assessment Under *CEPA 1999*

Regulatory Management of Substances under CEPA 1999

- Regulatory criteria for P and B in soil:
  - Half-life ≥182 days
  - No B criteria for soil, only for aquatic (BCF/BAF ≥5000 or K_{ow} ≥5)
  - Can use other indicators of bioaccumulation (BSAF, BMFs, TMFs) in the weight-of-evidence
- If a substance has been determined to meet the definition of toxic in section 64 of *CEPA 1999* and meets regulatory criteria for P and B, it may be subject to mandatory virtual elimination of releases

Soil Risk Assessment of Pest Control Products

- PMRA assesses pesticides and biocides under PCPA
  - Active ingredient
  - Formulant
  - Formulated product
  - Micro-impurity
- Unique to pesticides, they are deliberately applied. Hence, the main objectives are to characterize their risks and to determine mitigation measures to minimize their impact
- Four steps in the risk assessment
  - Data acquisition
  - Data analysis (exposure and ecological effects)
  - Risk characterisation
  - Risk mitigation

Soil Risk Assessment of Pest Control Products

Data acquisition

- Registrants required to provide comprehensive data on fate and ecotoxicity following internationally accepted guidelines (e.g., OECD, US EPA, EU):
  - Specific data include:
    - Physico-chemical properties
    - Transformation studies in soil
    - Field dissipation studies
    - Chemical transformation studies
    - Adsorption/desorption studies
    - Acute and/or chronic ecotoxicity
  - Based on intended use and chemical properties, some data requirements can be exempted
  - Data requirements for biocides are case-specific based on use pattern and potential exposure routes. Studies follow same guidelines.

Soil Risk Assessment of Pest Control Products

Data acquisition (cont'd)

- Data on transformation products are needed if they are:
  - Present at >10% of the parent compound equivalent or
  - Of concern (e.g., high toxicity, concentration increases over time)
- Other reliable sources of information are also used (literature, other regulatory bodies, monitoring data, etc.), particularly when conducting re-evaluation

Soil Risk Assessment of Pest Control Products

Data analysis

- Exposure characterization aims to:
  - Determine persistence and mobility of the active ingredients and their major transformation products:
    - considering use/ application patterns (rate, timing, interval, etc.)
    - integrating all available data (laboratory and field)
  - Determine Estimated Environmental Concentrations (EECs) for various media, including soil, surface water, groundwater and pore water (models are harmonized with US EPA)
  - EECs for drinking water are for human health risk assessment
  - For biocides, where exposure is expected (e.g., wood preservatives), analysis may use OECD scenarios

Soil Risk Assessment of Pest Control Products

Data analysis

- Ecological Effects
  - Direct exposure (soil contact)
    - Plant seedlings, earthworms, and in some cases soil arthropods
  - Indirect exposure:
    - Foliar arthropods that consume plants exposed to a systemic pesticide
    - Birds and small mammals exposed via ingestion of food (insects, plant leaves and seeds) containing pesticide residues
  - For tests with plants and invertebrates, acute and/or chronic data are considered, and if high toxicity is noted, higher-tier studies (e.g., aged residue tests, semi-field and field tests) are used, similar to EU's approach (e.g., ESCORT2)
  - For birds and mammals, both acute and reproductive tests are used

Soil Risk Assessment of Pest Control Products

Risk characterization

- Using the risk quotient method and a tiered approach
  - Screening assessment uses the most conservative assumptions to efficiently identify pesticides that are not likely to pose a risk
    - Maximum cumulative application rates, shortest application interval
    - 100% exposure
  - If a potential risk is identified, high-tiered studies (e.g., semi-field and field studies), representing more realistic exposure scenarios, are used to determine toxic effects at population level and/or community level

Soil Risk Assessment of Pest Control Products

Risk characterization (cont'd)

- Other refinements include:
  - Spray drift off-site
  - Interception of sprayed pesticide by plants
  - Revising toxic endpoint using species sensitivity distribution (SSD) analysis approach
  - Modelling or monitoring data

Soil Risk Assessment of Pest Control Products

Other considerations

- Toxic Substances Management Policy (TSMP)
  - 2 main objectives to the TSMP
    - Virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative (Track 1 substances)
    - Management of other toxic substances and substances of concern, throughout their entire life cycles (Track 2 substances)
  - Track 1 substances (persistent, bioaccumulative and toxic), POP, etc.
    - active ingredients, micro-contaminants, formulants
  - Identification - same criteria as CEPA, similar to Stockholm Convention
  - Management - virtual elimination

Soil Risk Assessment of Pest Control Products

Risk mitigation

- Risk mitigation measures for soil-dwelling organisms may include label instructions to restrict:
  - application rate
  - timing
  - number of applications
  - application intervals
  - amount of treated area
- If the risk cannot be adequately reduced by mitigation measures, a cost/benefit analysis of the proposed use may be considered and product may not be allowed for use in Canada

Thank You !

http://www.chemicalsubstanceschimiques.gc.ca

http://www.ec.gc.ca/subsnouvelles-newsubs/

http://hc-sc.gc.ca/ahc-asc/branch-dirgen/pmra-arla/index-eng.php