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
**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
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 publicly 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 km²)
  - Terrestrial foodwebs
- Also models for:
  - Long range transport
  - Atmospheric deposition
  - Air dispersion (local)
- 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\textsubscript{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
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
  - Formulated product
  - Formulant
  - 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
    - Chemical transformation studies
    - Transformation studies in soil
    - Adsorption/desorption studies
    - Field dissipation 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
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
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-newssubs/