How to bring your registration dossier in compliance with REACH

Tips and Hints - Part 5

Terrestrial toxicity

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REACH Information Requirements (1)

Terrestrial Toxicity

Annex IX	COLUMN 1 STANDARD INFORMATION REQUIREMENT	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
9.4	Effects terrestrial organisms	The study does not need to be conducted if direct and indirect exposure of the soil compartment is unlikely*. In the absence of toxicity data for soil organisms, the equilibrium partitioning method may be applied to assess the hazard to soil organisms. The choice of the appropriate tests depends on the outcome of the chemical safety assessment. In particular for substances that have a high potential to adsorb to soil or that are very persistent**, the registrant shall consider long-term toxicity testing instead of short-term.
9.4.1.	Short-term toxicity to invertebrates	
9.4.2.	Effects on micro-organisms	
9.4.3.	Short-term toxicity to plants	

*Soil exposure assumed to occur unless shown in the CSR that:

- There is no sludge application to land from exposed STPs,
- Aerial deposition is negligible, and
- Relevance of other exposure pathways such as irrigation and or contact with contaminated waste is unlikely

**Log Kow>5 and/or DT50>180 days (in absence of data this requirement assumed to be fulfilled for substances that are not readily biodegradable)

(ECHA Guidance Chapter R7c)

REACH Information Requirements (2)

Terrestrial Toxicity

Annex X	**COLUMN 1** STANDARD INFORMATION REQUIREMENT	**COLUMN 2** SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
9.4	Effects terrestrial organisms	Long-term toxicity testing shall be proposed by the registrant if the results of the chemical safety assessment according to Annex I indicates the need to investigate further the effects of the substance and/or degradation products on terrestrial organisms. The choice of the appropriate test(s) depends on the outcome of the chemical safety assessment. These studies do not need to be conducted if direct and indirect exposure of the soil compartment is unlikely*
9.4.4.	Long-term toxicity testing on invertebrates, unless already provided as part of Annex IX requirements	
9.4.6.	Long-term toxicity on plants, unless already provided as part of Annex IX requirements.	

ECHA Guidance on Terrestrial Toxicity (1)

Screening Assessment and Soil Hazard Categories

- If no soil data is available, all other available data, including that on aquatic organisms, should be used in a stepwise manner to determine whether soil data is needed

- The Equilibrium Partitioning Method (EPM)
  - May first be applied as a ”screening approach” when a PNECaquatic is available
  - It may not be sufficient for substances that are very toxic to aquatic organisms and/or have a high potential for adsorption and/or are highly persistent

- If based on the EPM the PECsoil/PNECsoil (=RCR) >1
  - Tests with soil organisms should be considered as an essential requirement for a refined hazard assessment

ECHA Guidance on Terrestrial Toxicity (2)

Screening Assessment and Soil Hazard Categories

- As part of the integrated testing strategy on terrestrial toxicity, ECHA Guidance includes advice on assigning a substance to a soil hazard category

- There are 4 soil hazard categories,
  - categories 3 and 4 are relevant for substances with highest concern

- Substance would fall into soil hazard category 3 or 4 when
  - There is indication for high adsorption OR high persistence of the substance in soil
    - High adsorption: Log Kow > 5, Log Koc > 4, Ionisable substance
    - High persistence: $DT50_{soil}$ > 180 days (default setting, unless readily biodegradable)

ECHA Guidance on Terrestrial Toxicity (3)

Soil Hazard Categories 3 and 4

- Substance would fall into
  - Soil hazard category 3 - not very toxic to aquatic organisms
  - Soil hazard category 4 - very toxic to aquatic organisms

- Substance IS very toxic to aquatic organisms when
  - EC/LC50 < 1 mg/L for algae, daphnia or fish
  - NOEC/EC10 < 0.1 mg/L for algae, daphnia or fish AND the substance is not readily biodegradable
  - NOEC/EC10 < 0.01 mg/L for algae, daphnia or fish AND the substance is readily biodegradable

- Absence of toxicity in aquatic studies should not be used to assign a substance to a soil hazard category

ECHA Guidance on terrestrial toxicity (4)

(Adopted from ECHA Guidance Chapter R7c, Table R.7.11-2)

	Hazard category 3	Hazard category 4
Approach for screening assessment	PEC * 10 / PNECscreen (based on EPM) AND conduct a confirmatory long-term soil toxicity test	Screening assessment based on EPM not recommended, intrinsic properties indicate a high hazard potential to soil organisms
Consequences from screening assessment & waiving of standard information requirements toxicity testing with soil organisms and derivation of PNECsoil	If PEC*10/PNECscreen < 1 and no indication of risk from confirmatory long-term soil toxicity testing: No further toxicity testing for soil organisms need to be done If PEC*10/PNECscreen > 1 or indication of risk from confirmatory long-term soil toxicity test: Conduct long-term toxicity tests according to the standard information requirements Annex X choose lowest value for derivation of PNECsoil	Conduct long-term toxicity tests according to the standard Information requirements Annex X, choose lowest value for derivation of PNECsoil

If risks are still shown

- Additional testing may be required
- Refinement of PEC soil also to be considered

Soil Microorganism Testing (Annex IX, 9.4.2)

- PNECaquatic does not take into consideration any toxicity data on microorganisms
  - PNECsoil based on EPM may not provide sufficient protection for terrestrial microorganisms
  - Data relating to soil microbial toxicity is required when toxicity testing on soil organisms is relevant

Long-Term Toxicity to Terrestrial Invertebrates

(Annex X 9.4.4., Annex IX 9.4. Column 2)

- There are 3 OECD guidelines that are recommended for assessing the long-term toxicity to terrestrial invertebrates:
  - OECD guideline 222 The earthworm reproduction test
  - OECD guideline 220 Enchytraeid reproduction test
  - OECD guideline 232 Collembolan reproduction test

- Each is considered capable of generating information appropriate for the fulfilment of the information requirements for this endpoint

- Appropriate test protocol to be decided based on species sensitivity (exposure route) and substance properties

Long-Term Toxicity to Terrestrial Plants

(Annex X 9.4.6. and Annex IX 9.4. Column 2)

- Recommended guidelines for long-term plant toxicity:
  - ISO 22030: Soil Quality – Biological Methods – Chronic toxicity in higher plants
  - OECD 208: Terrestrial Plant Test: Seedling Emergence and Seedling Growth
    - The guideline recommends to select the number of test species according to relevant regulatory requirements;
    - For long-term toxicity testing, ECHA considers six species as the minimum to achieve a reasonably broad selection of species to account for interspecies sensitivity

Adaptation Possibilities for Terrestrial Toxicity

- The requirements set in the relevant sections of Annexes IX, X and XI need to be fulfilled

- Exposure based adaptations (Annex XI 3)
  - adequate justification and documentation is provided, and
  - the justification is based on a thorough and rigorous exposure assessment

- Weight of evidence (Annex XI, 1.2)
  - At least 2 independent pieces of evidence
  - One study record for each piece of evidence
  - Endpoint summary: your own conclusion

- Grouping of substances and read-across approach (Annex XI, 1.5)
  - Adequate and reliable documentation
  - Scientifically sound arguments
  - Assumptions supported with (experimental) data

Adaptation – examples (1)

"The risk assessment based on EPM does not indicate a concern…"

Screening assessment based on EPM not sufficient if substance falls into soil hazard categories 2 – 4 i.e. is very toxic to aquatic organisms and/or highly adsorptive and/or very persistent.

Adaptation – examples (2)

“No effects seen in aquatic organisms…” ✗

✓ Absence of toxicity in aquatic studies may be used as part of Weight of Evidence to justify why testing is not required, but not to assign a substance to a Soil hazard category

Adaptation – examples (3)

”Substance is neither classified nor PBT…”

PNECsoil should be given also for non-classified and non PBT substances.

Adaptation – examples (4)

”Direct exposure of the soil compartment is unlikely…”

Column 2 adaptation may be possible when direct and indirect exposure of the soil compartment is unlikely, and the criteria of Annex XI section 3 are fulfilled i.e.

- adequate justification and documentation is provided, and
- the justification is based on a thorough and rigorous exposure assessment

Questions?

To the Q&A panel (between 11:00 and 13:30, Helsinki time), or

To the ECHA helpdesk (any time): http://echa.europa.eu/contact/helpdesk-contact-form