

# How to bring your registration dossier in compliance with REACH – Tips and Hints Part 4

## 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	<p>The study does not need to be conducted if <u>direct and indirect exposure</u> of the soil compartment is unlikely.</p> <p>In the absence of toxicity data for soil organisms, <u>the equilibrium partitioning method may be applied to assess the hazard to soil organisms.</u> The choice of the appropriate tests depends on the outcome of the chemical safety assessment.</p> <p>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.</p>
9.4.1.	Short-term toxicity to invertebrates	
9.4.2.	Effects on micro-organisms	
9.4.3.	Short-term toxicity to plants	

# 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	<p>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.</p> <p>These studies do not need to be conducted if <u>direct and indirect exposure</u> of the soil compartment is unlikely</p>
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)

- According to Column 2 of Annex IX registrant shall consider long-term toxicity testing according to Annex X instead of short-term in particular for substances that have a high potential to adsorb to soil or that are very persistent
  - 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)

## ECHA Guidance on terrestrial toxicity (2)

- According to Column 2 of Annex IX:

*In the absence of toxicity data for soil organisms, the equilibrium partitioning method may be applied to assess the hazard to soil organisms*

- The purpose of the EPM is to derive a PNEC<sub>soil</sub> screening
- PNEC<sub>aquatic</sub> must be available to use the EPM method
- Absence of toxicity in aquatic studies should be used as part of Weight of Evidence to justify why testing is not required, not to classify a substance to a Soil Hazard Category
  - ECHA Guidance R7c, section R.7.11.5.3. advice on deciding on terrestrial testing requirements
- PNEC<sub>soil</sub> should be given also for non-classified and non PBT substances

# Weight of Evidence for terrestrial toxicity


## Weight of Evidence (WoE)

- To assess different pieces of available information
  - *weight of evidence* has to be chosen as the *purpose flag* in IUCLID for each *endpoint study record* used for reaching the conclusion
- If both WoE and data waiving apply
  - separate IUCLID *endpoint study records* have to be created for both/all

## Soil microorganism testing (Annex IX)

- If inhibition of sewage sludge microbial activity has been observed a test on soil microbial community should be considered either by testing or by providing a specific justification
  - ECHA Guidance R7c, p. 122
- PNECaquatic does not take into consideration any toxicity data on microorganisms
  - PNECsoil based on EPM may not provide sufficient protection for terrestrial microorganisms
- Soil microorganisms test is requested if;
  - Registrant has not proved that Column 2 adaptation of *no indirect/direct exposure* is possible
  - No other specific justification why study is not required is given

## Possibilities for adaptation for terrestrial toxicity

- Chapter R7c: Column 2 adaptation may be possible when *direct and indirect exposure of the soil compartment is unlikely*
- Soil exposure assumed to occur unless shown in the CSR that
  - there is no sludge application to land from exposed STPs, and
  - aerial deposition are negligible, and
  - relevance of other exposure pathways such as irrigation and or contact with contaminated waste is unlikely
- Adaptation based on exposure considerations need to fulfil the criteria set in Annex XI section 3 
  - "adequate justification and documentation shall be provided", and
  - "the justification shall be based on a thorough and rigorous exposure assessment"
  - (see also slide 9)



## Adaptation – examples (1)

### Exposure based adaptation

*As any significant direct and indirect exposure of the soil compartment is unlikely, this study does not need to be conducted in accordance with column 2 of REACH Annex IX*



Justification for waiving terrestrial tests based on exposure considerations, but:

- no exposure assessment is submitted as part of CSR, and
- information in IUCLID section 3.5 indicates e.g. wide dispersive consumer use
  - the given adaptation is **unacceptable** and terrestrial studies according to the standard information requirements under Annex IX and X are requested as applicable
  - The Registrant still has the possibility to improve the justification

## Adaptation – examples (2)

### Adaptation based on the application of the EPM

*In accordance with Section 1 of REACH Annex XI, the study does not need to be conducted because application of the equilibrium partitioning method indicates that the substance is of low risk to soil macroorganisms*



Justification for waiving terrestrial tests based on EPM, but:

- no effects seen in aquatic studies, no PNECaquatic derived
  - not possible to use the EPM to derive PNECsoil screen
  - the given adaptation is **unacceptable** and terrestrial studies according to the standard information requirements under Annex IX and X are requested as applicable

## Adaptation – examples (3)

### Adaptation based on rapid production of degradation products

*Direct and indirect exposure of the test item to soil is unlikely due to rapid degradation of the parent compound leading to the production of degradation compounds. Thus, terrestrial tests are considered scientifically not justified*



Justification for waiving terrestrial tests based on rapid degradation of parent compound, but;

1. Registrant has the obligation to consider the toxicity of degradation products, soil ecotoxicity test on parent compound covers also the toxicity of rapidly produced degradation products
2. Soil risk assessment is based on nominal concentrations, risk assessment (RA) of parent compound covers also the RA of the degradation products
  - the given adaptation is **unacceptable** and terrestrial studies according to the standard information requirement under Annexes IX and X are requested as applicable

# **REACH Information Requirements –** Terrestrial Toxicity Guidance

Guidance on information requirements and chemical safety assessment

- Chapter R.7c: Endpoint specific guidance
- Chapter R.10: Characterisation of dose [concentration] – response for environment

Practical Guides:

<http://echa.europa.eu/web/guest/practical-guides>

Specifically the Practical guide 4: How to report data waiving

Thank you!

<http://echa.europa.eu/contact/helpdesk-contact-form>