

# Compilation of (REACH) case studies with challenges in regulatory soil risk assessment

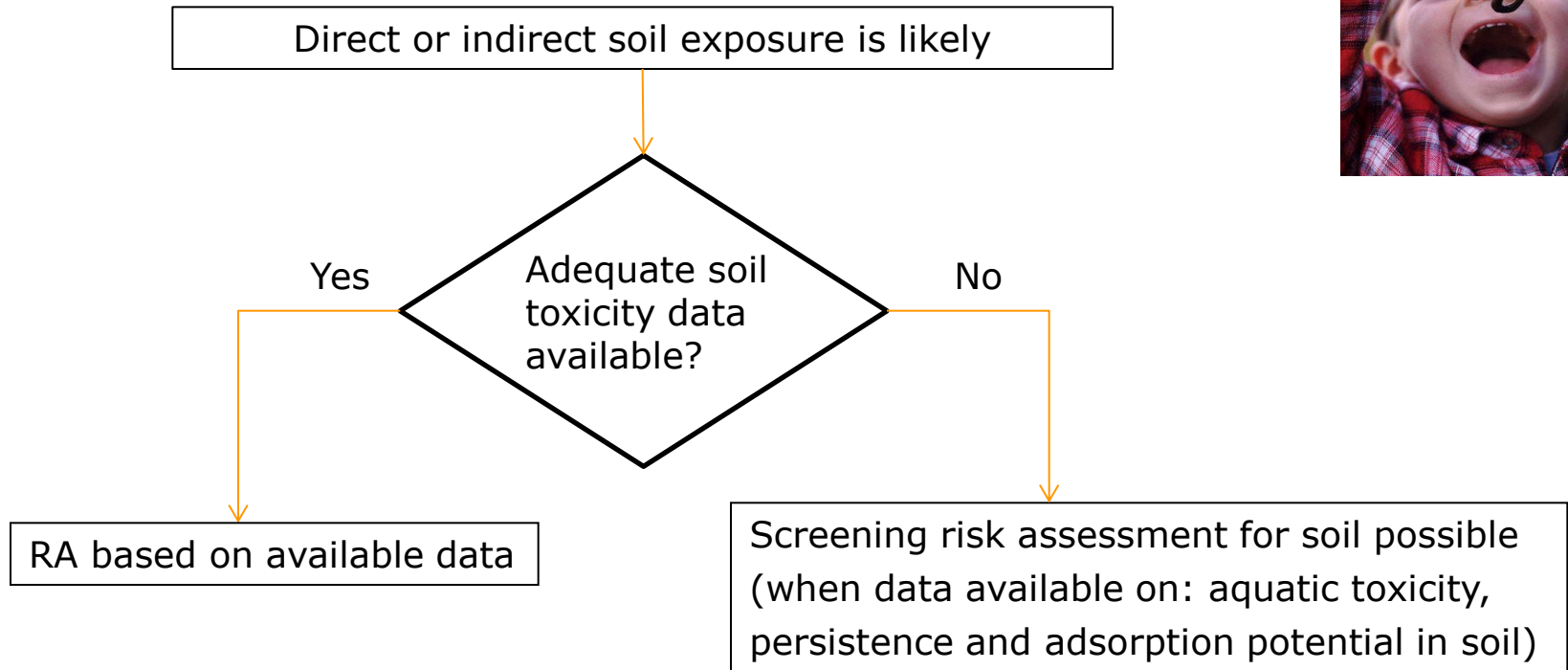
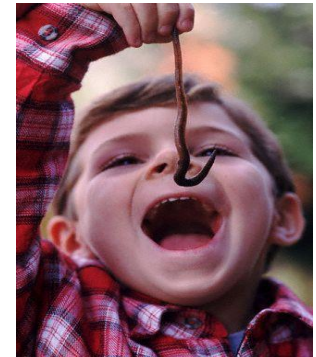
8 October 2015

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## Outline

- Soil risk assessment under REACH – further developments triggered by specific cases
- Information on soil toxicity and fate in regulatory risk management
- List of open questions/issues for further consideration



	Hazard category 1	Hazard category 2	Hazard category 3	Hazard category 4
Is there an indication for <b>high adsorption*</b> <b>OR high persistence**</b> of the substance in soil?	No	No	Yes	Yes
Is there an indication that the substance is very toxic to aquatic organisms***?	No	Yes	No	Yes
Approach for screening assessment	PEC/ PNEC <sub>screen</sub> (based on EPM)	PEC/ PNEC <sub>screen</sub> (based on EPM) AND conduct a confirmatory <b>short-term</b> soil toxicity testing  (e.g. one limit test with the most sensitive organism group as indicated from aquatic toxicity data)	PEC × 10/PNEC <sub>screen</sub> (based on EPM) AND conduct a confirmatory <b>long-term</b> soil toxicity testing  (e.g. one limit test with the most sensitive organism group as indicated from aquatic toxicity data)	Screening assessment based on EPM not recommended, intrinsic properties indicate a high hazard potential to soil organisms  <b>Long-term soil toxicity testing</b>

\*logK<sub>ow</sub> > 5 or a ionisable substance

\*\*DT50 > 180 days (default setting, unless classified as readily biodegradable)

\*\*\*EC/LC50 < 1 mg/L for algae, daphnia or fish

### **Issue 1** - (In)direct exposure of the soil is likely

#### **Case 1**

- For professional use of the substance municipal STP is indicated by the registrant → assumed that sludge from STP is applied to soil.
  - Substance is not volatile, not rapidly degradable and log K<sub>oc</sub> app. 1.4
  - EPI Suite ver. 4.1 estimation; 1.7-1.9% of the substance entering STP is adsorbed to sewage sludge.
- indirect soil exposure is likely

#### **Case 2**

- Substance used as solvent by professionals
  - Outdoor applications in open system for brushing/spraying
  - Collection/incineration of formed aerosols/gases and sealing of all surfaces is proposed for professional settings
- proposed measures are not considered adequate; thus, indirect soil exposure is likely

**Issue 2** – When the substance is considered to be very toxic to aquatic organisms (for screening RA for soil)?

- Amendment of CLP Regulation from 2011 – criteria based on chronic toxicity data for classification as hazardous to the aquatic environment introduced
- Substance is very toxic to aquatic organisms when  $EC/LC50 < 1 \text{ mg/L}$  → C&L as Cat. Chronic 1



- Equivalent level of hazard: C&L as Cat. Chronic 1 → **chronic NOEC/EC<sub>x</sub> ≤ 0.01 mg/l (rapidly degradable substances) and chronic NOEC ≤ 0.1 mg/l (non-rapidly degradable substances)**

**Terrestrial plants**

**Soil dwelling invertebrates**

**Soil microorganisms**

**DATA IN REACH REGISTRATION DATABASE RELATING TO TERRESTRIAL TOXICITY**

Comparison of the relevance of two test guidelines

Species sensitivity – what is the most appropriate species for testing long-term effects?

Can aquatic toxicity data be used for conservative screening of potential terrestrial microorganisms' toxicity?

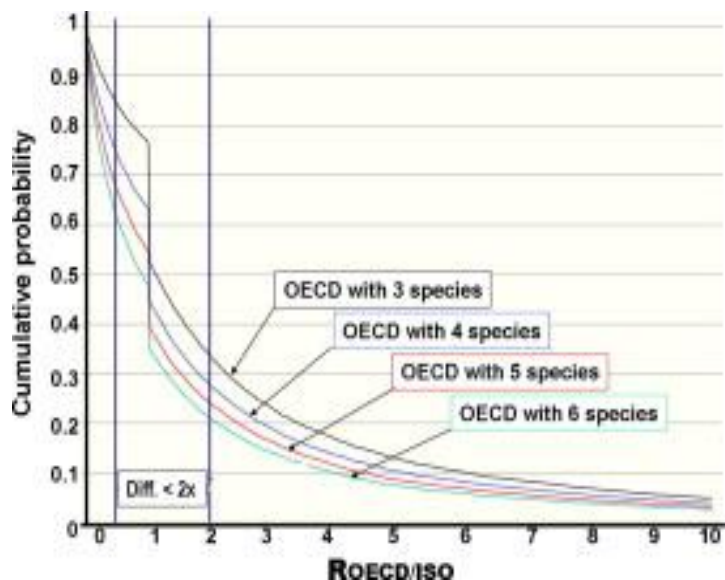
### Issue 3 - Long-term tox testing with terrestrial plants

- Two standard tests were compared
  - ISO TG 22030 versus OECD 208
- ISO covers reproductive effects but it is conducted with only two species
- OECD measures only emergence and growth, but offers a wide species coverage
- Probabilistic models were used for quantifying the expected sensitivity of each test



*Identification of chemical hazards for terrestrial plants in the regulatory context: Comparison of OECD and ISO guidelines. Tarazona, Jose V. et al., CHEMOSPHERE 93-10, p. 2578-2584, November 2013.*





- If there are no specific phytotoxicity alerts, the number of species in the OECD test (minimum of six) compensates the sensitivity of the reproductive endpoints

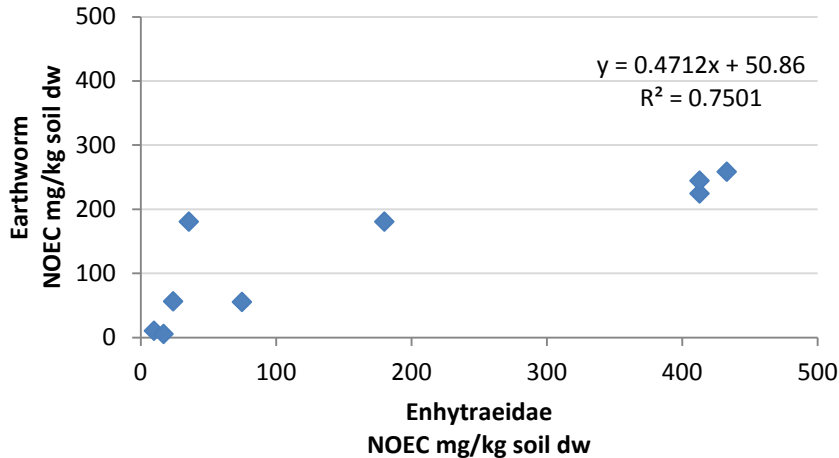
No species in the OECD Test	Equal sensitivity	OECD more sensitive	ISO more sensitive
Three species	24%	24% (18-26)	52% (58-48)
Four species	19%	36% (30-41)	45% (53-39)
Five species	16%	45% (37-50)	39% (47-34)
Six species	13%	52% (43-56)	35% (45-30)

**Issue 5** - Relevance and sensitivity of different species and applied test protocols for long-term studies on soil dwelling invertebrate organisms

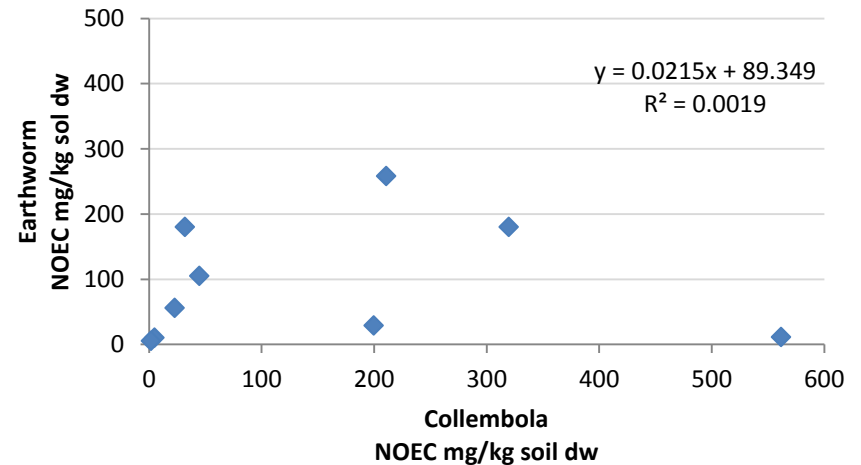
- For long-term testing ECHA proposed the following TGs:
  - Earthworm (OECD 222)
  - Enchytraeidae (OECD 220)
  - Collembola (OECD 232) (not requested for highly adsorptive substances)
- The predatory mite reproduction test in soil (OECD 226) should not be considered in isolation as a relevant test for fulfilling the REACH requirements.
- In the REACH registration database, 20 substances contained information on long-term reproduction for more than one terrestrial invertebrate.

## Information in REACH registration dossiers

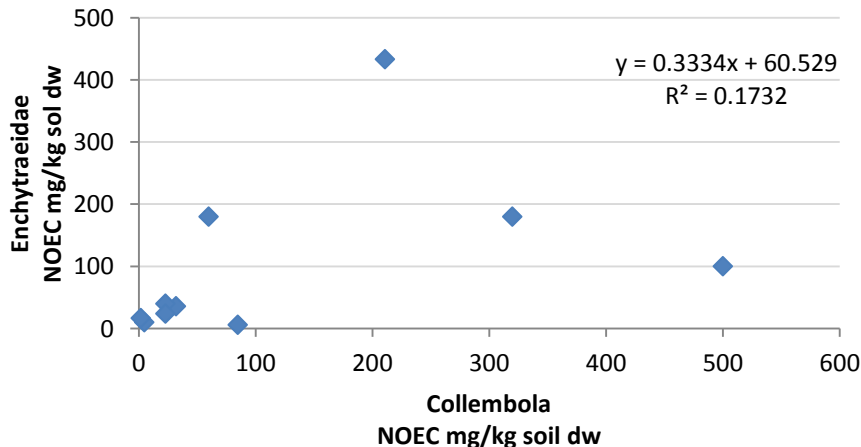
Earthworms vs Enchytraeidae without NOECs > 1000



Earthworms vs Collembola without NOECs > 1000



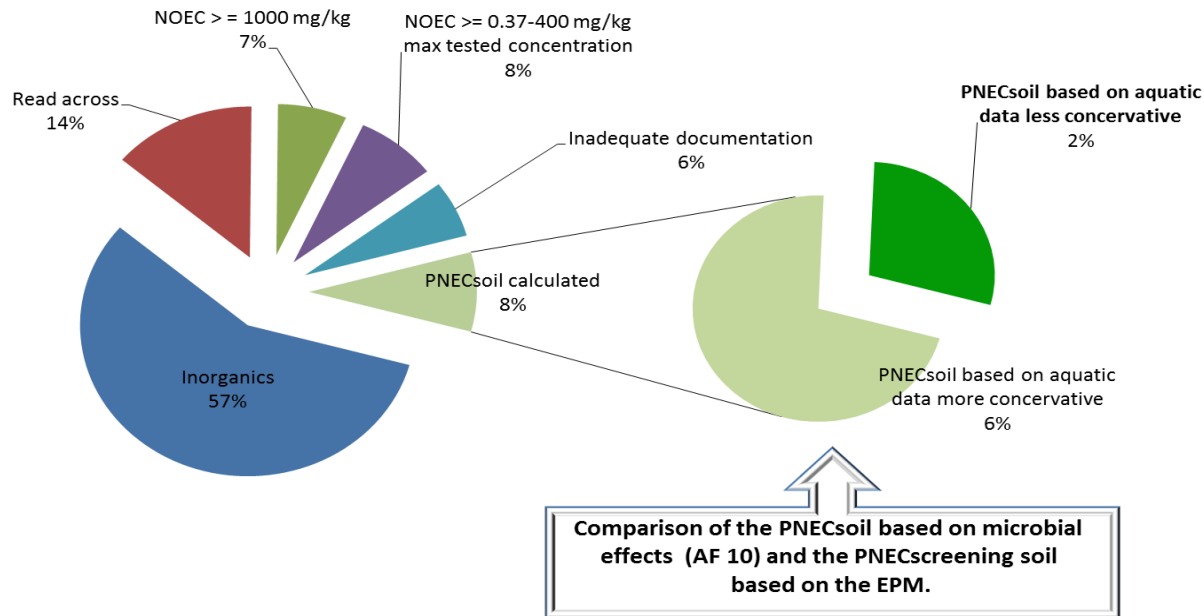
Enchytraeidae vs Collembola without NOECs > 1000



- No evidence to favour one terrestrial invertebrate species over another for being the most sensitive species in general.
- Is there a need for covering both invertebrate groups, oligochaetes (test on earthworms or *Enchytraeidae*) and arthropods (test on *Collembola*)?

## Issue 4 – Does aquatic toxicity (EPM approach) predict soil microbial toxicity?

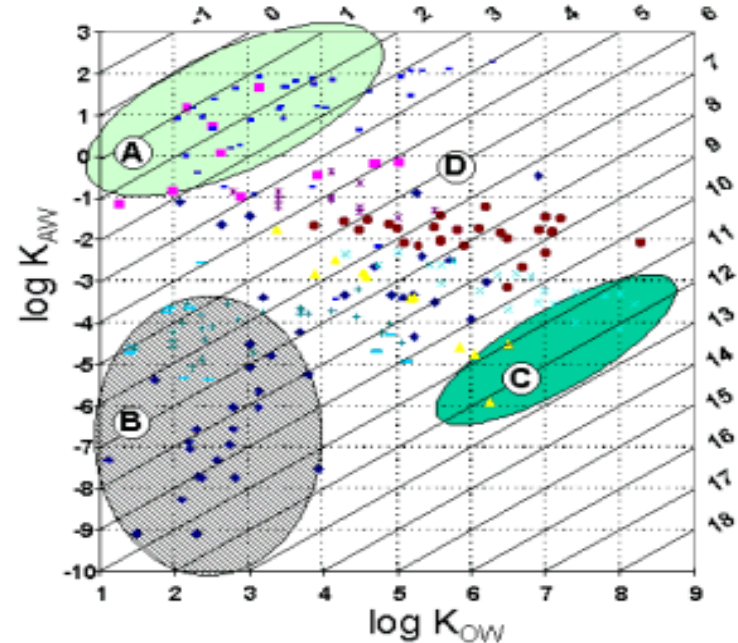
165 Dossiers contain OECD 216 and/or 217



- Uncertainty on level of protection provided by the PNECscreening for potential effects on soil microbial functions.
- ECHA recommends that information on toxicity to soil micro-organisms is included by default in all cases where a hazard is indicated for the soil compartment (hazard categories 2, 3 and 4).

## Issue 6 – When does volatility prevent testing in soil?

- Revision of thresholds to define volatile substances in the standard soil toxicity guidelines
  - Currently: volatile substance → Henry's constant or air/water partition coefficient  $>1$  or VP  $>0.0133$  Pa at 25 °C
  - Proposed: volatile substance → **air/soil partition coefficient  $>1$  or VP  $>300$  Pa at 25 °C;** analytical verification of exposure concentrations should be considered, where relevant (*proposal submitted to OECD under consultation procedure*)



A: exists predominantly in air

B: exists predominantly in water

C: exists predominantly in soil

Others: multiple media chemicals

\* *Reproduction of Figure 2.7-6 of the FOCUS AIR 2008 report based on van de Meent et al. 1998*

### **Issue 7** – Challenges in degradation simulation testing and for identification of degradation products

- Both are important and necessary:
  - Annex IX 9.2.1.3. Soil simulation testing
  - Annex IX 9.2.3 Identification of the degradation products
- Guidance, Chapter R.16 indicates 12 °C (285K) as the average environmental temperature for the EU to be used in the CSA; thus, testing at temperature of 12 °C is normally requested (if identification of degradation products is of primary interest – testing requested at higher temperatures)
- Case-by-case? Consideration of NERs when results of the testing are processed for regulatory purposes

## Issue 8 – Scope of exposure assessment and risk assessment

- When a substance meets **at least one** of REACH Article 14(4) hazard classes, categories or properties, exposure assessment is **mandatory** and should be considered for **all** standard exposure estimations
- All stages of life-cycle and all (**not only classifiable!**) identified hazards shall be considered
- Hazards identified for aquatic organisms also indicate hazard for soil and sediment organisms, i.e. exposure/risk assessment for water/sediment/soil is triggered



## Soil toxicity and fate data in regulatory risk management

- No C&L criteria based on soil toxicity data
- Half-life of degradation in soil used in PBT assessment
- Soil toxicity and bioaccumulation data can be used in WoE approach in PBT assessment
- Examples available on authorities soil risk assessment as result of work before REACH



Some open questions/issues:

- Relevance and applicability of EPM for highly adsorptive and/or very persistent substances. Relevance of application of additional AF of 10 for the soil risk assessment for those substances.
- Would indication of 'no toxicity' in aquatic toxicity testing mean that the substance is also not toxic to soil organisms? Should such an indication be considered differently for substances with good and poor solubility in water?
- Would only long-term terrestrial toxicity testing be relevant/acceptable for poorly water soluble substances?
- Use of soil toxicity and fate data in regulatory risk assessment is being further extended and there is still potential for further enhancement.

## Posters from ECHA



- Integrated testing strategy for effects on terrestrial organisms under REACH.
- Analysis of experimental terrestrial toxicity studies submitted in the framework of the REACH Regulation.
- Making use of publicly available studies within the REACH Regulation: An overview of submitted terrestrial toxicity data.

**Thank you.**

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The above represents the opinion of the authors and is not an official position of the European Chemicals Agency.