Integrated testing strategy for effects on terrestrial organisms under the REACH Regulation

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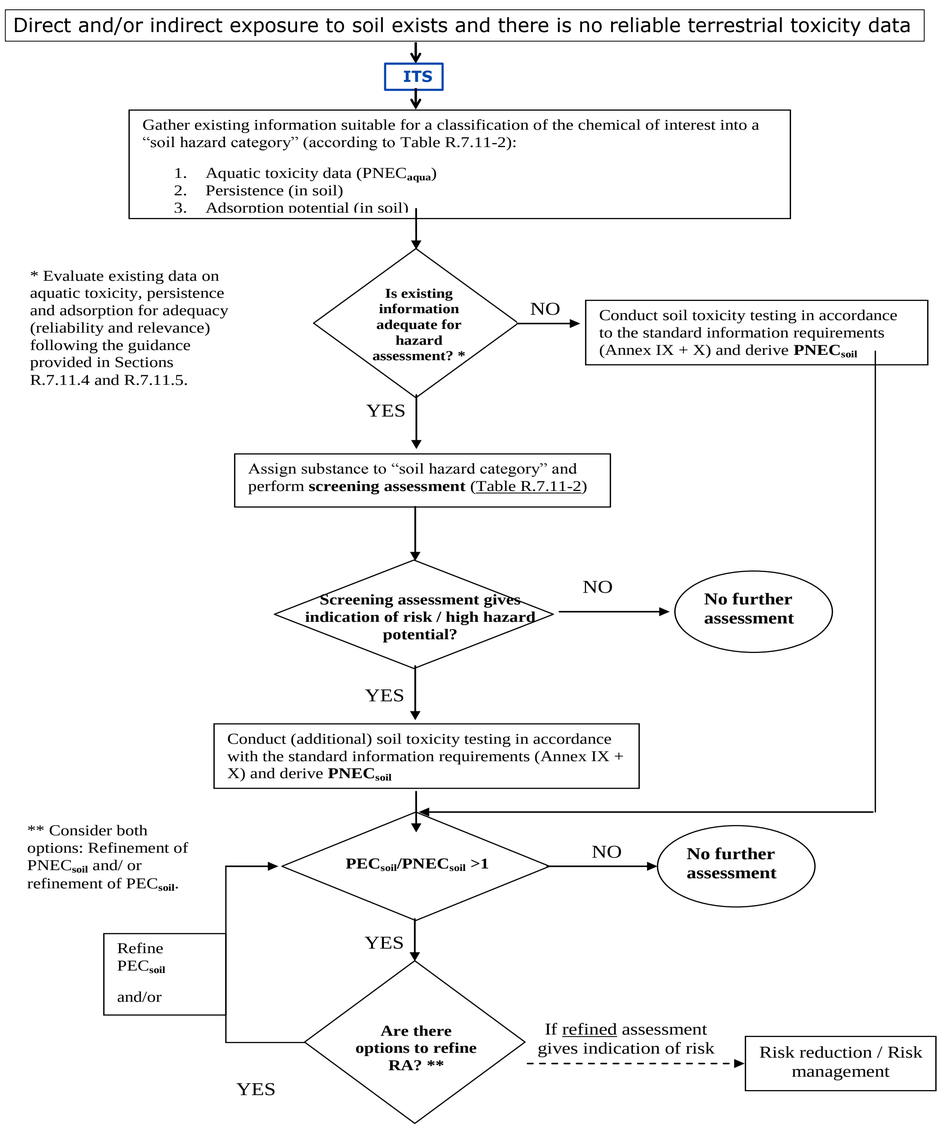
Introduction

The aim of this poster is to present the current integrated testing strategy with screening risk assessment approach for terrestrial organisms within the framework of the REACH Regulation.

Since 2009, ECHA has cooperated with other stakeholders to process a number of dossier evaluations where issues in regard of screening the risk assessment approach, summarised in the Guidance, were raised. The issues raised included discussing the acceptability of the test guidelines and relevant number of species for assessing long-term soil plants and invertebrates toxicity testing. Besides, the necessity of considering toxicity to soil microorganisms in addition to the equilibrium partitioning method-based screening risk assessment was addressed. Based on these discussions, the screening assessment approach for soil was further clarified. Furthermore, based on new regulatory knowledge, the criteria to define substances very toxic to aquatic organisms were further clarified. This poster summarises these clarifications and provides a schematic presentation of the currently applied screening risk assessment approach for soil.

INTEGRATED TESTING STRATEGY (ITS; ANNEX IX AND ANNEX X SUBSTANCES)



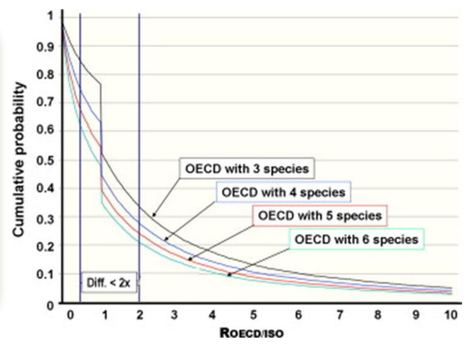
DATA IN REACH REGISTRATION DATABASE RELATING TO TERRESTRIAL TOXICITY

Long-term toxicity testing on terrestrial plants

Aim: comparison of the relevance of two guidelines measuring effects on terrestrial plants, the OECD TG 208 and the ISO TG 22030.

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

Conclusion: If there are no specific phytotoxicity alerts, both guidelines are considered suitable for assessing long-term hazards providing that a sufficient number of species is included in the OECD 208 protocol. The recommended minimum number of species is two monocots and four dicots which offers a reasonably broad selection of species to account for interspecies sensitivity.

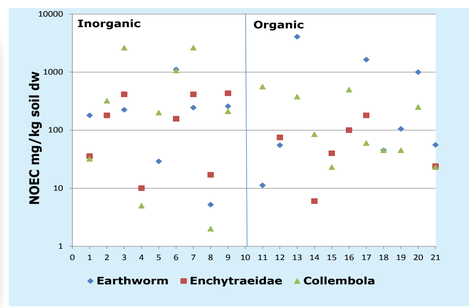


Soil dwelling invertebrates

Aim: assessment of relevance and sensitivity of different species and applied test protocols.

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.

Conclusion: Correspondence between sensitivity of earthworms and enchytraieds belonging to the same oligochaeta order seemed greater than between earthworms or enchytraieds with collembolans. The need for covering both invertebrate groups, oligochaetes (test on earthworms or Enchytraeidae) and arthropods (test on Collembola) should be considered.



Long-term toxicity to reproduction (NOEC or EC10 for effects on reproduction in mg/kg soil dw) for screened inorganic and organic substances.

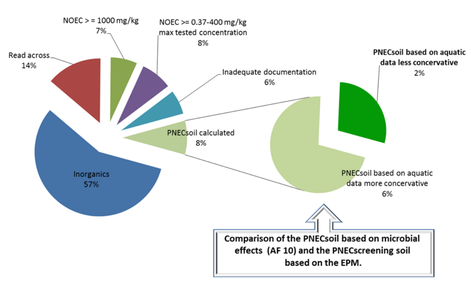
Soil microorganisms

Aim: a comparative assessment of the degree of protection offered to terrestrial microorganisms when a PNEC$_{soil}$ based on EPM is applied.

- Only 14 dossiers contained micro-organisms toxicity data enabling derivation of PNEC for soil → these PNECs were compared with PNECs for soil(EPM) → in four cases PNECmicroorganisms (in three cases AF = 10 and in one case AF >10) < PNEC (EPM).
- PNECwater does not consider toxicity data on aquatic micro-organisms.

Conclusion: 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 (i.e. substances from soil hazard categories 2, 3 and 4).

165 Dossiers contain OECD 216 and/or 217



	Hazard category 1	Hazard category 2	Hazard category 3	Hazard category 4
Is there an indication for high adsorption* OR high persistence** 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$_{screen}$ (based on EPM)	PEC/ PNEC$_{screen}$ (based on EPM) AND a confirmatory short-term soil toxicity test **AND toxicity to microorganisms test**	PEC×10 /PNEC$_{screen}$ (based on EPM) AND a confirmatory long-term soil toxicity test **AND toxicity to microorganisms test**	Screening assessment based on EPM not recommended, intrinsic properties indicate a high hazard potential to soil organisms
Consequences from screening assessment and waiving of standard information requirements Toxicity testing with soil organisms and derivation of PNEC$_{soil}$: choose lowest value for derivation of PNEC$_{soil}$	*If PEC/PNEC$_{screen}$ > 1:* Conduct short-term toxicity tests; according to Annex IX invertebrates, micro-organisms and plants	*If PEC/PNEC$_{screen}$ > 1 OR indication of risk from confirmatory short-term soil toxicity test:* Conduct short-term toxicity tests according to Annex IX (invertebrates, micro-organisms and plants)	*If PEC x 10/PNEC$_{screen}$ > 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 (invertebrates and plants) **AND conduct toxicity to microorganisms test according to Annex IX**	Conduct long-term toxicity tests according to the standard information requirements Annex X (invertebrates and plants) **AND conduct toxicity to microorganisms test according to Annex IX,**
Options for refinement of PNEC$_{soil}$ (but also consider refinement of PEC$_{soil}$)	*If PEC$_{soil}$ / PNEC$_{soil}$ > 1:* Conduct additional **long-term** OR higher tier test on soil organisms **AND/OR consider refinement of PEC soil**	*If PEC$_{soil}$ / PNEC$_{soil}$ > 1:* Conduct additional **long-term** OR higher tier test on soil organisms **AND/OR consider refinement of PEC soil**	*If PEC$_{soil}$ / PNEC$_{soil}$ > 1:* Conduct additional **long-term** OR higher tier test on soil organisms **AND/OR consider refinement of PEC soil**	*If PEC$_{soil}$ / PNEC$_{soil}$ > 1:* Conduct additional long-term OR higher tier test on soil organisms **AND/OR consider refinement of PEC soil**

* logK$_{OW}$ > 5 or a ionisable substance

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

*** default setting, unless the lowest available EC/LC50 for algae, daphnia or fish > 1 mg/L; **and/or the lowest available NOEC for algae, daphnia or fish > 0.01 mg/L (rapidly degradable substances) OR > 0.1 mg/L (non-rapidly degradable substances)**

REFERENCES: Tarazona et al., 2013, Chemosphere 93-10, p. 2578-2584
ECHA Guidance on information requirements and chemical safety assessment, Chapter R.7C , v2.0, November 2014.

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