Analysis of experimental terrestrial toxicity studies submitted in the framework of REACH Regulation

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Introduction

The minimum terrestrial dataset defined by REACH "standard information requirements" depends on the annual tonnage. However, the terrestrial toxicity studies do not need to be conducted if direct and indirect exposure of the soil compartment is unlikely. Standard REACH information requirements can be waived based on the REACH Annex XI 'general rules for adaptation', meaning weight of evidence (WoE) approaches, qualitative or quantitative structure-activity relationships ((Q)SARs), *in vitro* methods, grouping of substances and read-across, indications that testing is technically not possible, and tailored exposure-driven approaches. The current investigation analyses the availability of experimental terrestrial toxicity data and the applied test guidelines to fulfil the information requirements submitted in the framework of the REACH Regulation within two registration deadlines: 1 December 2010 and 1 June 2013.

Methodology

The data source is based on the content of the registration dossiers submitted to ECHA from 1 June 2008 until August 2015. All test methods indicated by the registrants have been analysed and grouped to understand which test guidelines and test organisms have been used to fulfil data requirements under REACH. Only experimental data from the 'regular' registrations were considered. The study was selected as experimental when the registrant chose "experimental result" or "experimental study planned" flag in the relevant field of the registration dossiers and the study was declared to be performed on the registered substance.

Reported species

Terrestrial tox. studies on invertebrates list of families and species

Non-Arthropods

Family	Genus	Species
Lumbricidae	Dendrobaena	*rubida*
	Eisenia	*Eisenia sp.*
		fetida
		andrei
	Lumbicis	*lumbricus sp.*
		terrestris
		rubellus
		variegatus
	Allolobophora	*tuberculata*
	Aporrectodea	*caliginosa*
		longa
		tuberculata
		rosea
Enchytraeidae	Cognettia	*sphagnetorum*
	Enchytraeus	*enchytraeus sp.*
		albidus
		crypticus
		luxuriosus
		bigeminus
Eudrilidae	Eudrilus	*eugeniae*
Megascolecidae	Perionyx	*excavatus*

Arthropods

Class/Order	Family
Arachnida	Camisiidae
	Laelapidae
	Lycosidae
	Phytoseiidae
	Tetranychidae
Entognatha/Collembola	Entomobryinae
	Hypogastruridae
	Isotomidae
	Onychiuridae
Insecta/Coleoptera	Bostrichidae
	Carabidae
	Curculionidae
	Dermestidae
	Elateridae
	Elateridae
	Silvanidae
	Staphylinidae
	Tenebrionidae
	Coccinellidae
Insecta/Hemiptera	Reduviidae
Insecta/Diptera	Calliphoridae
	Drosophilidae
	Culicidae
	Muscidae
	Calliphoridae
Insecta/Ephemeroptera	Baetidae
Insecta/Hymenoptera	Apidae
	Braconidae
	Trichogrammatidae
	Formicidae
Insecta/Lepidoptera	Bombycidae
	Noctuidae
Insecta/Neuroptera	Chrysopidae
Insecta/Orthoptera	Gryllidae
Malacostraca	Porcellionidae
Insecta/Isoptera	Rhinotermitidae

Other: Nematodes

Class/Order	Family
Adenophorea	Plectidae
Secernentea	Aphelenchoididae
	Ascarididae
	Heteroderidae
	Pratylenchidae
	Heterorhabditidae
	Tylenchulidae
Chromadorea	Rhabditidae

Terrestrial tox. studies on plants list of families and genus

Monocots

Family	Genus
Amaryllidaceae	Allium
Cyperaceae	Cyperus
Liliaceae	Lilium
Poaceae	Avena
	Bromus
	Echinocloa
	Hordeum
	Oryza
	Poa
	Saccharum
	Secale
	Sporobolus
	Triticum
	X. Triticosecale
	Zea
	Elymus
	Digitaria
	Lolium

Dicots

Class	Family	Genus
Magnoliopsida	Amaranthaceae	Amaranthus
		Beta
	Asteraceae	Andryala
		Chrysanthemum
		Cynara
		Helianthus
		Hypocharis
		Lactuca
		Matricaria
		Senecio
	Boraginaceae	Phacelia
		Alyssum
		Arabidopsis
	Brassicaceae	Brassica
		Lepidium
		Raphanus
		Sinapis
	Caryophyllaceae	Stellaria
	Chenopodiaceae	Chenopodium
	Cucurbitaceae	Cucumis
	Fabaceae	Glycine
		Lens
		Medicago
		Pisum
		Sesbania
		Trifolium
		Trigonella
		Vigna
		Vicia
	Fagaceae	Quercus
	Lamiaceae	Mentha
	Leguminosae	Phaseolus
	Linaceae	Linum
	Malvaceae	Gossypium
		Hibiscus
		Malva
		Tilia
	Petunioideae	Petunia
	Plumbaginaceae	Limonium
	Polygonaceae	Fallopia
		Polygonum
	Rutaceae	Boronia
		Citrus
	Solanaceae	Lycopersium
		Nicotina
		Solanum
	Vitaceae	Vitis

Reported test guidelines

Test guidelines reported for non-arthropods	Number of substances (%)	Species most commonly reported
OECD 207	36,0	Eisenia fetida
OECD 222	16,0	Eisenia fetida
SEPA (equivalent of OECD 207)	1,1	Eisenia fetida
CANADA (acute and chronic)	1,0	Eisenia andrei
EPA OPPTS 850.6200	0,3	Eisenia fetida
ISO 11268-1	1,0	Eisenia fetida
ISO 11268-2	6,0	Eisenia fetida
BBA	2,0	Eisenia fetida
OECD 220	0,6	Enchytraeus sp.
ISO 16387	0,5	Enchytraeus sp.
ISO 10872	0,5	Caenorhabditis elegans
ASTM 2001	0,1	Caenorhabditis elegans
OTHER	2,0	various
Not reported	33,0	various

Test guidelines reported for arthropods	Number of substances (%)	Species most commonly reported
OECD 232	1,2	*Folsomia candida*
ISO 11267	37,0	*Folsomia candida*
OECD 226	2,0	*Hypoaspis aculeifer*
OECD 213	2,2	*Apis mellifera*
OECD 214	2,4	*Apis mellifera*
EPPO 170	2,4	*Apis mellifera*
EPA (Acute Contact Toxicity)	2,2	*Apis mellifera*
National PPP GD	1,8	*Apis mellifera, Culex quinquefasciatus*
various IOBC and escort i&ii	4,0	various
OTHER	7,0	various
Not reported	38,2	various

Test guidelines reported for microorganisms	Number of substances (%)
OECD 216	14,0
OECD 217	5,5
ISO 14238	2,0
National PPP GD	1,5
BBA Part VI, 1-1	1,3
SETAC (PPP)	0,3
EPA OPPTS 850.5100	0,2
EPA OTS 797.3700	0,2
OTHER	1,0
Not reported	74,0

Test guidelines reported for plants	Number of substances (%)
OECD 208	20,0
ISO 11269-2	6,0
ISO 11269 -1	5,0
ISO 22030	1,0
EPA OPPTS 850	2,0
National PPP GD	1,0
other EPA	1,2
OECD 227	0,4
OTHER	0,9
Not reported	63,0

Requests for terrestrial studies under compliance check and testing proposal evaluations

ECHA performed two types of compliance check evaluations: **overall CCH** where the entire dossier had been checked and/or **targeted CCH** concentrated on evaluating selected areas of concern. The following deficiencies were targeted in compliance check of the provided information in the registered dossiers:

- *Unacceptable column 2 adaptations, e.g. screening approach based on the equilibrium partitioning method (EPM) when $PNEC_{aqua}$ has not been derived;*
- *Improperly waived toxicity testing on soil microorganisms when inhibition of sewage sludge microbial activity is observed;*
- *Unacceptable adaptations for substances falling into Hazard categories 3 and 4.*

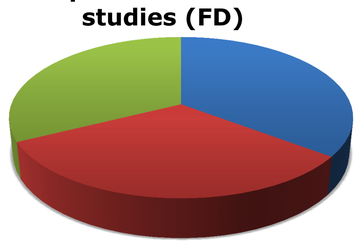
By 31 December 2014, ECHA had issued 27 compliance check final decisions that included terrestrial endpoints.

By the end of August 2015, ECHA had issued 70 final decisions following the evaluation of testing proposal requests for terrestrial testing.

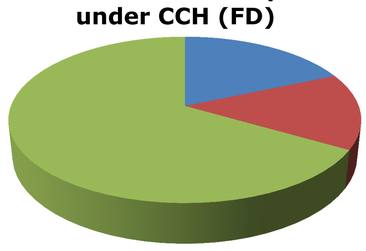
Topical Scientific Workshop on Soil Risk Assessment

7-8 October 2015 | Helsinki, Finland

TP requests for terrestrial studies (FD)



Terrestrial studies requested under CCH (FD)



Under dossier evaluation, the following tests may be requested: OECD 207, OECD 222, OECD 220, OECD 232, ISO 22033, OECD 216, OECD 217

CCH = Compliance check
TP = Testing proposal
FD = Final decisions

- For many cases, the **information on the test guideline** according to which the study was conducted, was not reported or was not reported correctly (i.e. >30 % of invertebrate studies; ~ 60 % of plant tests and >70 % of microbial tests);
- **Soil invertebrates**: there was a prevalence on testing on the species recommended by the standard test guidelines. Besides, the reporting included a large variety of species from very different families, which shows the feasibility for conducting toxicity tests on a number of relevant groups e.g. for future species sensitivity distribution approaches;
- **Terrestrial plants:** the most extensively reported test guidelines were OECD 208, ISO 11269-1 and 2;
- According to the REACH Regulation, ECHA shall check the compliance of at least 5% of registration dossiers received by the Agency for each tonnage band, and may request registrants to make their dossiers compliant by e.g. requesting further studies if considered necessary. Therefore, when interpreting the findings of the current analysis, it should be noted that in principle the current results may be affected by the outcome of the dossier evaluation work.

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