

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 structureactivity 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		Arthropods		Monocots		Dicots			
 Family	Genus	Species	Class/Order	Family	Family	Genus	Class	Family	Genus
Lumbricidae D	Dendrobaena	rubida	Arachnida	Camisiidae	Amaryllidaceae	Allium	Magnoliopsida	Amaranthaceae	Amaranthus
	Eisenia	Eisenia sp.		Laelapidae	Cyperaceae	Cyperus			Beta
		fetida		Lycosidae	Liliaceae	Lilium		Asteraceae	Andryala
	La sector de la companya de la comp	andrei		Phytoseiidae	Poaceae	Avena			Chrysanthemum
	LUMDICIS	lumbricus sp.		Tetranychidae		Bromus			Cynara
		ruhellus	Entognatha/Collembola	Entomobryinae		Echinocloa			Hellantnus
		variegatus		Hypogastruridae		Hordeum			
	Allolobophora	tuberculata		Isotomidae		Orvza			Matricaria
	Aporrectodea	caliginosa		Onychiuridae		Poa			Senecio
		longa	Insecta/Coleoptera	Bostrichidae		Saccharum		Boraginaceae	Phacelia
		tuberculata		Carabidae		Secale			Alyssum
		rosea		Curculionidae		Sporobolus			Arabidopsis
nchytraeidae	Cognettia	sphagnetorum		Dermestidae		Triticum		Brassicaceae	Brassica
	Encligitaeus	albidus		Elateridae		V. Triticosocolo			Lepidium
		crypticus		Elateridae					Raphanus
		luxuriosus		Silvanidae		Zea			Sinapis
		bigeminus		Staphylinidae		Elymus		Caryophyllaceae	Stellaria
Eudrilidae	Eudrilus	eugeniae		Tenebrionidae		Digitaria		Chenopodiaceae	Chenopodium
Megascolecidae	Perionyx	excavatus		Coccinellidae		Lollum		Eabacoao	Cucumis
			Insecta/Hemiptera	Reduviidae					lens
			Insecta/Diptera	Calliphoridae					Medicago
Other	· Nom	atodos		Drosophilidae					Pisum
other		aloues		Muscidae					Sesbania
Class/Orc	der Family			Callinhoridae					Trifolium
Adenophor	rea Plectidae	e	Insecta/Enhemeroptera	Baetidae					Trigonella
Secement	ea Apheleno	choididae	Insecta/Hymenoptera	Anidae					Vigna
beechnemed	Ascaridio	dae		Braconidae					Vicia
	Heterode	eridae		Trichogrammatidae				l agaceae	Quercus
	Pratylen	chidae		Formicidae				Lamiaceae	Phasealus
	Heterorh	abditidae	Insecta/Lepidoptera	Bombycidae				Lipaceao	Linum
	Tylench	ilidao		Noctuidae				Malvaceae	Gossynium
Chromado	roa Dhabditi	dao	Insecta/Neuroptera	Chrysopidae					Hibiscus
Chromadol			Insecta/Orthoptera	Gryllidae					Malva
			Malacostraca	Porcellionidae					Tilia
			<i>(</i>	_					

Terrestrial tox. studies on plants list of families and genus

FamilyGenusSpeciesLumbricideDendrobaen Essenia sp. (Etside antheli LumbicisEasis OrderFamilyGenusLumbricideDendrobaen (Etside antheli LumbicisEasis OrderFamilyGenusLumbricideEssenia sp. (Etside anthelicus sp. (robelus) Anisotae sp. (robelus)Cass / OrderFamilyGenusLumbricideLumbicisIntercuise (robelus) (robelus) (robelus) (robelus)FamilyGenusMaranthaceae (Cyperace) (Lillum)EnchytraeidaeAlloloophrona (robelus) (robelus) (robelus) (robelus) (robelus) (robelus)Entognatha/Collembola (Collembola (Collembola)FamilyGenus (Chrysmi (Chrysmi (Cyperace))Enchytraeidae (Congentria) (Congentria) (Congentria) (Chrysmidae) (Chrysmidae)Entognatha/Collembola (Collembola)Family (Collembola)Genus (Chrysmidae) (Chrysmidae) (Chrysmidae)Genus (Chrysmidae) (Chrysmidae)Genus (Chrysmidae) (Cyperace)Eudrilide (Congentria) (Chrysmidae) (Chrysmidae) (Chrysmidae) (Cyperace)Family (Collembola)Genus (Chrysmidae) (Concellidae) (Chrysmidae) (Chrysmidae) (Chrysmidae) (Chrysmidae)Genus (Chrysmidae) (Concellidae) (Chrysmidae) (Chrysmidae)Genus (Chrysmidae) (Chrysmidae) (Chrysmidae) (Chrysmidae)Genus (Chrysmidae) (Chrysmidae) (Chrysmidae)Genus (Chrysmidae) (Chrysmidae) (Chrysmidae)Genus (Chrysmidae) (Chrysmidae) (Chrysmidae)Genus (Chrysmidae) (Chrysmidae)Genus (Chrysmidae) (Chrysmidae)	Non-Arthropods		Arthropods		Monocots		Dicots			
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Image: second constraints I		Eisenia	Eisenia sp.		Laelapidae	Cyperaceae	Cyperus			Beta
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Malacostraca Porcellionidae Tilia	Chronadol			Insecta/Orthoptera	Gryllidae					Malva
				Malacostraca	Porcellionidae					Tilia
Insecta/Isoptera Rhinotermitidae Petunioideae Petunioideae Petunio				Insecta/Isoptera	Rhinotermitidae				Petunioideae	Petunia

Reported test guidelines

Test auidelines r	eported	Number of	Specie	es most			
for non-arthro	substances	commonly reported					
		(%)					
OECD 207		36,0	Eisenia fetida	Eisenia fetida			
OECD 222 SEDA (oquivalant of O		16,0	Elsenia fetida				
CANADA (acute and ch	ropic)	1,1					
EPA OPPTS 850.6200	in office)	0.3	0.3 Eisenia fetida				
ISO 11268-1		1.0					
ISO 11268-2		6,0	Eisenia fetida				
BBA		2,0					
OECD 220		0,6	sp.				
ISO 16387		0,5	sp.				
ISO 10872		0,5	s elegans				
ASTM 2001		0,1	s elegans				
OTHER		2,0	various				
Not reported		33,0	various				
	and a fam	Number of	C				
lest guidelines rep	orted for	substances	Species most commonly				
arthropode	5	(%)	repo	rted			
OECD 232		1,2	Folsomia candic	la			
ISO 11267		37,0	la				
OECD 226	2,0	Hypoaspis acule	eifer				
OECD 213		2,2	Apis mellifera				
OECD 214		2,4	Apis mellifera				
EPPO 170		2,4	Apis mellifera				
EPA (Acute Contact To	xicity)	2,2	Apis mellifera				
National PPP GD		1,8	Apis mellifera,	. ,			
various TOPC and acco		4.0		isciatus			
OTHER		7.0	various				
Not reported		38.2	various				
		3072	Various				
Test guidelines	Number of	f Test	quidelines	Number of			
reported for	substance	s reporte	ad for plants	substances			
microorganisms	(%)			(%)			
OECD 216	14,0	OECD 2	08	20,0			
OECD 217	5,5	ISO 112	ISO 11269-2				
ISO 14238	2,0	ISO 112	269 -1	5,0			
National PPP GD	1,5	ISO 220	030	1,0			
BBA Part VI, 1-1	ΕΡΑ ΟΡ	PTS 850	2,0				
SETAC (PPP)	0.3	Nationa	National PPP GD				
EPA OPPTS 850.5100	0.2	other E	other EPA				
EPA OTS 797 3700	0.2	OECD 2	0,4				
OTHER	1 0	OTHER		0.9			
Not reported	74 0	Not rep	orted	63.0			
	/ +,0	ποιτερ		0,0			

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



TP requests for terrestrial studies (FD)



> 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

- equilibrium partitioning method (EPM) when PNEC_{aaua} 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

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one test test on 2 trophic levels test 3 trophic levels

Terrestrial studies requested under CCH (FD)



■ one test ■ test on 2 trophic levels ■ tests on 3 trophic levels

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

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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