

Lages, 30.07.2015

Assessing the risk for soil organisms arising from the use of PPP

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Ralf Petto IBACON (DE)

structure

Assessing the risk for soil organisms at higher tiers

- I) Current regulatory situation**
- II) Soil Organisms' definition**
- III) Role of soil organisms in soils**
- IV) From lower to higher tiers in soil risk assessment
(incl. new data requirements for plant protection
products)**
- V) Open issues in effect assessment at higher tier**
- VI) Exposure assessment**
- VII) Linking exposure and effects**

I)
Regulatory background

European level

REGULATION (EC)
No 1107/2009 OF THE EUROPEAN
PARLIAMENT AND OF THE
COUNCIL
of 21 October 2009
concerning the placing of plant
protection products on the market and
repealing Council Directives
79/117/EEC and 91/414/EEC

**Member State
(MS) level, incl.
Germany**

Gesetz zum Schutz der
Kulturpflanzen
(Pflanzenschutzgesetz – PflSchG)

Ausfertigungsdatum: 06.02.2012

considered



I) regulatory background

Requirements and conditions for approval

- e) it shall have **no unacceptable effects on the environment**,
having particular regard to ..
- (i) **its fate and distribution in the environment, particularly
contamination of surface waters**, including estuarine and
coastal waters, groundwater, air and **soil** taking into account
locations distant from its use following long-range
environmental transportation;
 - (ii) **its impact on non-target species**, including on the ongoing
behaviour of those species;
 - (iii) **its impact on biodiversity and the ecosystem.**



l) regulatory background

Requirements and conditions for approval

- e) it shall have no unacceptable effects on the environment, having particular regard to its impact on biodiversity and the ecosystem.

Definitions in 1107/2009

→ **'biodiversity'** means variability among living organisms from all sources, including terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this variability may include diversity within species, between species and of ecosystems



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l) regulatory background

Requirements and conditions for approval

For pragmatically reasons, the assessment of the risk possibly posed by the use of plant protection products is performed by

- by defining 'groups' of organisms (here: soil organisms)
 - for which representative surrogates are tested
 - for which it is possible to define exposure scenarios
- by extrapolating to the overall protection goal by means of safety factors

The specific assessment of species, groups etc in the schemes should not mislead over the fact that the protection goals are understood in a broader sense



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l) regulatory background

Requirements and conditions for approval

The European Food Safety Agency has taken over the task of defining

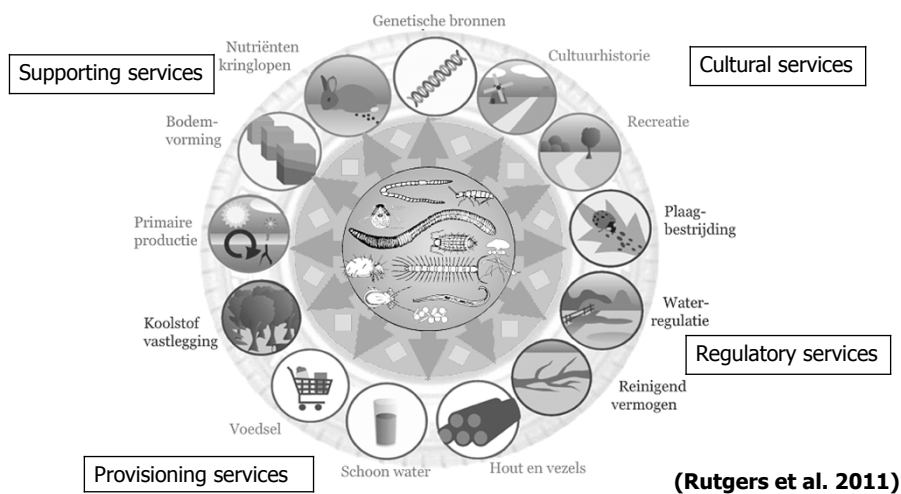
→ **Specific Protection Goals (SPG) for the traditionally assessed groups of organisms (here: soil organisms)**

The methods of defining SPG

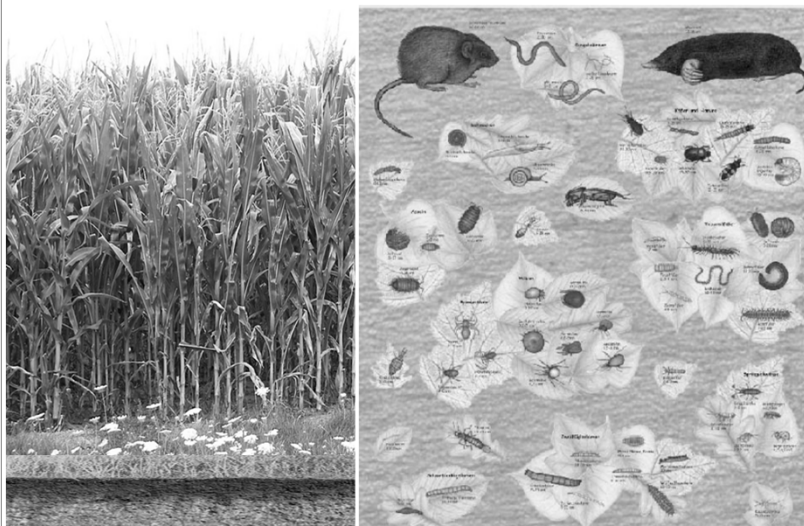
- **starts from the characterization of ecosystem services that are though to be important (in agricultural landscapes for PPP)**
- **through the identification of key organism drivers**
- **to the reasoned description of tolerable effects on these drivers**

l) regulatory background

Protection Goals for soil organisms



II) Soil Organisms' definition




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II) Soil organisms' definition

Taxa, methods, habitats, exposure?

	methods	taxa	Non-target-organisms
	aspirator scoop net (yellow)traps	<u>Hypergeic</u> e.g. Spiders Ladybeetles Bugs Wasps	<u>Non Target</u> <u>Arthropods</u> <u>(NTA)</u>
	pitfall traps photoelectors	<u>Epigeic</u> , e.g. Carabid beetles, Spiders, Collembola, Isopods	<u>NTA</u> <u>Soil Organisms</u>
	Soil cores hand sorting	<u>Endogeic</u> , e.g. Mites, Collembola, Earthworms Enchytraeids	<u>Soil Organisms</u>

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II) Soil organisms' definition

Taxa, methods, habitats, exposure?



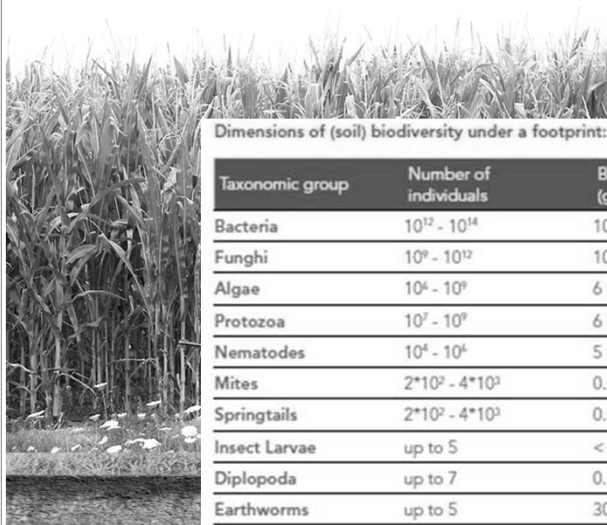
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II) Soil organisms' definition

Taxa, methods, habitats, exposure?



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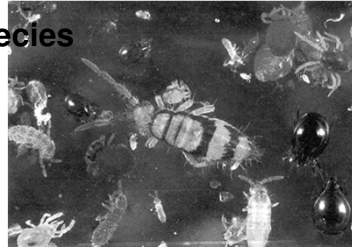
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III) Role of soil organisms in soils

Perception of importance of soil organisms' activity

a) Extremely diverse taxa

→ the role of soil organisms' species in ecosystem function is not well known. Why?



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III) Role of soil organisms in soils

Perception of importance of soil organisms' activity

a) Extremely diverse taxa

→ the role of soil organisms' species in ecosystem function is not well known. Why?

→ the soil is often seen as a 'black box'. It has to be opened to reveal the hidden structure.



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III) Role of soil organisms in soils

Perception of importance of soil organisms' activity

a) Extremely diverse taxa

→ the role of soil organisms' species in ecosystem function is not well known. Why?

→ the soil is often seen as a 'black box'. It has to be opened to reveal the hidden structure.

→ the structure does not reveal at the first glance which processes and which species have been involved at what time



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III) Role of soil organisms in soils

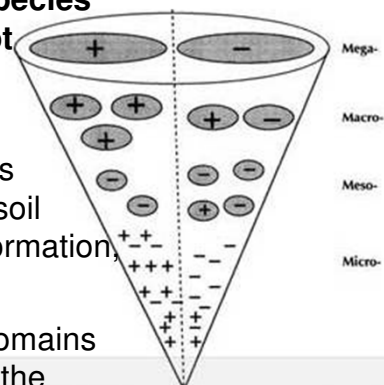
Perception of importance of soil organisms' activity

a) Extremely diverse taxa

→ the role of soil organisms' species in ecosystem function is not well known. Why?

→ Problems in the perception of the temporal and spatial scales at which processes driven by soil organisms operate (e.g. soil formation, organic matter turnover)

→ The scales of the functional domains are different and the output at the mega scale might not be apparent



(Anderson, J.M. (2000). Soil Invertebrates as webmasters in ecosystems)

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III) Role of soil organisms in soils

Perception of importance of soil organisms' activity

a) Extremely diverse taxa

→ the role of soil organisms' species in ecosystem function is not well known. Why?

→ Some species more eminently important than others



Darwin, C. R. 1881. *The formation of vegetable mould, through the action of worms*. London: John Murray.

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Applied Soil Ecology 13 (1999) 105–108

Applied
Soil Ecology

www.elsevier.com/locate/apsoil

Biodiversity and soil functioning—from black box to can of worms?

O. Andr  n^{a,*}, J. Balandreau^b

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III) Role of soil organisms in soils

Perception of importance of soil organisms' activity

a) Extremely diverse taxa

→ the role of soil organisms' species in ecosystem function is not well known. Why?

→ Functions in soils seems to be redundantly performed by several species

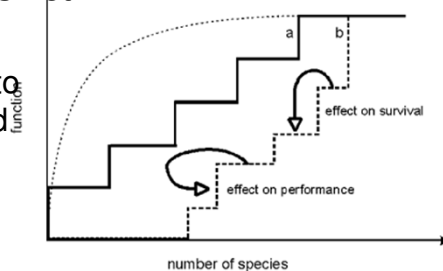


Figure 1. Average functional effect of the elimination of species from a soil biota community composed of a very rich group of redundant species and a small group of functionally important species. Graph a: no interaction between species; Graph b: effect of redundant species on survival and/or performance of functionally important species (see text for explanations).

V. Wolters et al. / Eur. J. Soil Biol. 37 (2001) 221–227

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III) Role of soil organisms in soils

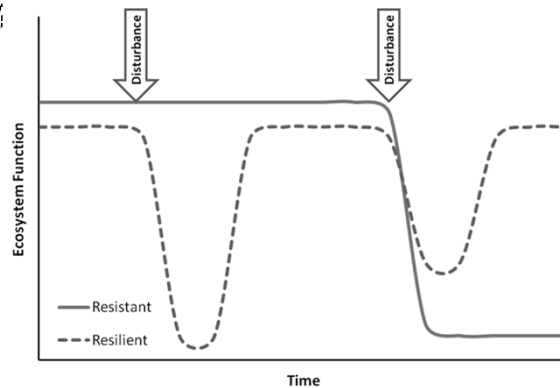
Perception of importance of soil organisms' activity

a) Extremely diverse taxa

→ the role of soil organisms' species in ecosystem function is not well known. Why?

→ Soil is rather resistant to disturbance

→ when soil fertility, soil structure is destroyed, the loss is irreversible



Stephen F. Austin State University Texas

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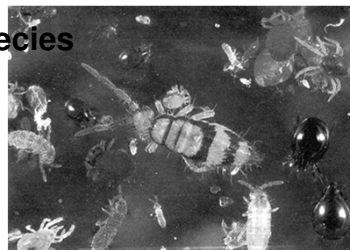
III) Role of soil organisms in soils

Perception of importance of soil organisms' activity

a) Extremely diverse taxa

→ the role of soil organisms' species in ecosystem function is not well known

→ extremely diverse ecotoxicological response



b) Diverse body structure

→ different exposure in the inhomogeneous soil medium



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I) Back to regulatory background

Protection Goals for soil organisms

SPG of each combination of key driver/ES combination: your suggestions

Earthworms as driver of nutrient cycling (in crop) (off-field)

Ecol. entity: individual – (meta)population – functional group – ecosystem
 Attribute: behaviour – survival/growth – abund./biomass – process – biodiversity
 Magnitude (??): negligible effect – small effect – medium effect – large effect
 Temp. scale: days – weeks – months – seasons – > 1 year

Ecol. entity: individual – (meta)population – functional group – ecosystem
 Attribute: behaviour – survival/growth – abund./biomass – process – biodiversity
 Magnitude (??): negligible effect – small effect – medium effect – large effect
 Temp. scale: days – weeks – months – seasons – > 1 year (NOT APPLICABLE)

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IV) From lower to higher tiers in soil risk assessment

Current data requirement and assessment

assessment endpoints

measurement endpoints

Effects on earthworms and other soil macro-organisms (KIIA 8.9, KIIIA 10.6)

Acute toxicity to earthworms	→	Acute test with <i>Eisenia fetida</i>
Sublethal effects on earthworms	→	Reproduction test with <i>Eisenia fetida</i>
Field tests (effects on earthworms)	→	Field test with local biocoenosis
Effects on other soil non-target macro-organisms ¹	→	Chronic test with <i>Folsomia candida</i> ¹ Chronic test with mit <i>Hypoaspis aculeifer</i> ¹
Effect on organic matter breakdown ¹	→	Litter bag test ¹

Effects on soil microbial activity (KIIA 8.10, KIIIA1 10.7)

Nitrogen transformation	→	Nitrogen transformation
Carbon mineralization	→	Carbon mineralization

¹ only if trigger derived from active substance persistence are exceeded

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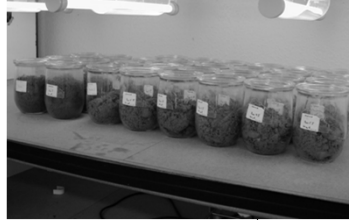
IV) From lower to higher tiers in soil risk assessment

Current data requirement and assessment

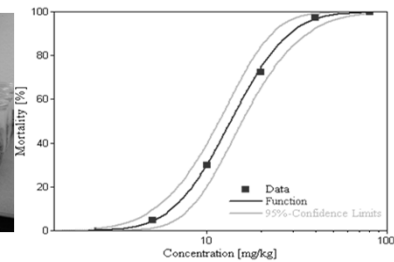
assessment endpoints

Effects on earthworms and other soil macro-organisms (KIIA 8.9, KIIIA 10.6)

Acute toxicity to earthworms



measurement endpoints



- Effect on mortality and biomass of the earthworm *Eisenia fetida/andrei*? according to OECD 207, ISO 11268-1
- Possible endpoints are LC50, NOEC for acute effects

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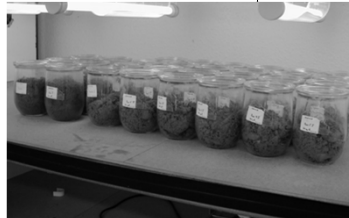
IV) From lower to higher tiers in soil risk assessment

Current data requirement and assessment

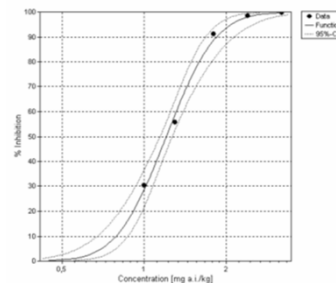
assessment endpoints

Effects on earthworms and other soil macro-organisms (KIIA 8.9, KIIIA 10.6)

Chronic toxicity to earthworms



measurement endpoints



- Effect on reproduction and biomass of the earthworm *Eisenia fetida/andrei*? according to OECD 222, ISO 11268-2
- Possible endpoints are ECx, NOEC for chronic effects

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IV) From lower to higher tiers in soil risk assessment

Current data requirement and assessment

assessment endpoints

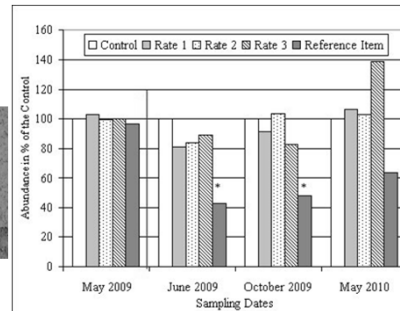
Effects on earthworms and other soil macro-organisms (KIIA 8.9, KIIIA 10.6)

Field tests (effects on earthworms)



- Effect on population structure, abundance and biomass of single earthworm species
- Possible endpoints are NOEC, NOECologically Adverse Effect Concentration after 1 y

measurement endpoints



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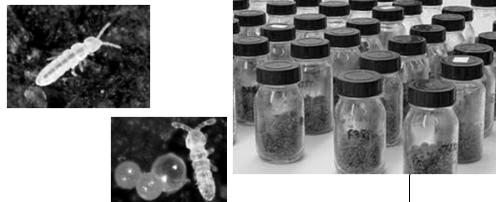
IV) From lower to higher tiers in soil risk assessment

Current data requirement and assessment

assessment endpoints

Effects on earthworms and other soil macro-organisms (KIIA 8.9, KIIIA 10.6)

Effects of other soil non-target macro-organisms



- Effect on reproduction of the collembolan *Folsomia candida* according to OECD, ISO 11267
- Possible endpoints are ECx, NOEC for chronic effects

measurement endpoints

EC₅₀ = 593.42 mg/kg (95% confidence limits not determinable)

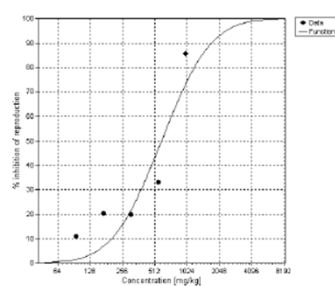


Figure 1. Concentration - Response Curve of Reproduction (28 d)

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IV) From lower to higher tiers in soil risk assessment

Current data requirement and assessment

assessment endpoints

Effects on earthworms and other soil macro-organisms (KIIA 8.9, KIIIA 10.6)

Effects of other soil non-target macro-organisms

**measurement endpoints**

EC₅₀ = 593.42 mg/kg (95% confidence limits: not determinable)

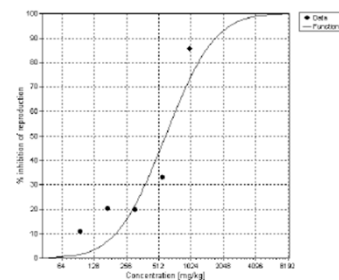


Figure 1. Concentration - Response Curve of Reproduction (28 d)

- Effect on reproduction of the collembolan *Hypoaspis aculeifer* according to OECD 226
- Possible endpoints are EC_x, NOEC for chronic effects

IV) From lower to higher tiers in soil risk assessment

Current assessment

Soil organisms groups are assessed separately

→Earthworms

→Soil mesofauna (currently only for persistent substances)

→Microorganisms

Seldom assessment of the whole community

→this does not allow to detect indirect effects

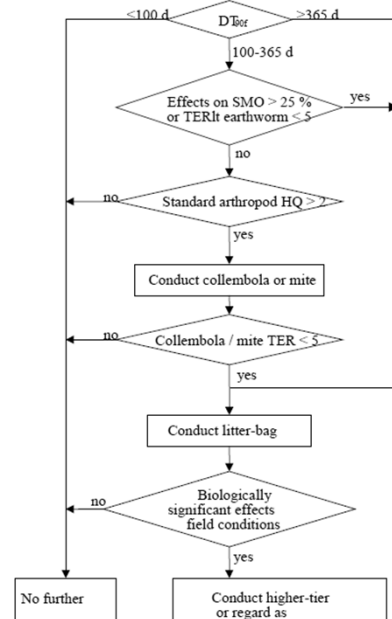
→this is not in accordance with the aquatic risk assessment



IV) From lower to higher tiers in soil risk assessment
Current assessment

MS position

- Detecting effects on a functional level is not a surrogate for detection of effects on structural level
- Up to now information required post authorization if litter bag test available



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IV) From lower to higher tiers in soil risk assessment

Future data requirement and assessment

assessment endpoints

future measurement endpoints

Effects on earthworms and other soil macro-organisms (KIIA 8.9, KIIIA 10.6)

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Effect on organic matter breakdown ¹	→	Litter bag test ¹

Effects on soil microbial activity (KIIA 8.10, KIIIA1 10.7)

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IV) From lower to higher tiers in soil risk assessment

Future data requirement and assessment

assessment endpoints

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IV) From lower to higher tiers in soil risk assessment

Future data requirement and assessment

assessment endpoints

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Higher tier tests (meso- macroorg.)	→	Mesocosms or field test with local biocoenosis

Effects on soil microbial activity (KIIA 8.10, KIIIA1 10.7)

Nitrogen transformation	→	Nitrogen transformation
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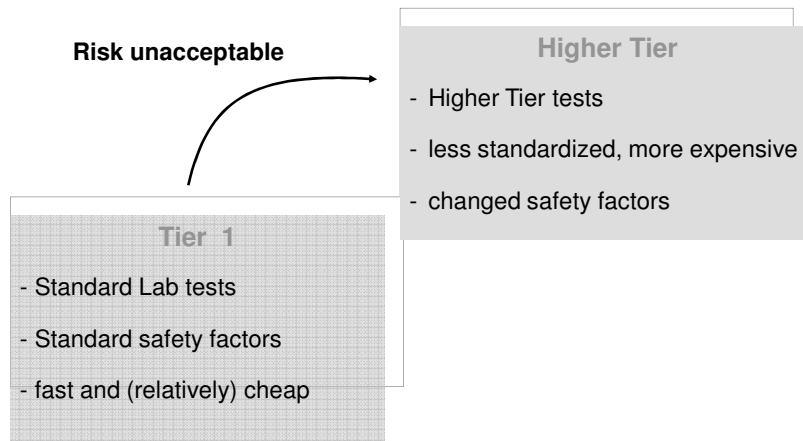
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IV) From lower to higher tiers in soil risk assessment

Higher Tier and safety factors



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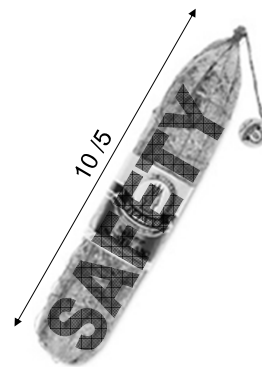
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IV) From lower to higher tiers in soil risk assessment

Uncertainties to be covered in the assessment

- (1) Intra- and inter-laboratory variation of toxicity data
- (2) Intra- and inter-species variation of toxicity data
- (3) Short-term to long-term/chronic toxicity extrapolation
- (4) Extrapolation of mono-species laboratory data to field impact on ecosystems
 - more sensitive lifestages
 - more sensitive endpoints
 - delayed effects
 - contaminated food source
 - increase in effect by co-stressors
 - exposure to mixtures
 - amplification by interspecific competition (shift in coenosis composition)
 - if recovery is considered: Species with a lower recovery potential



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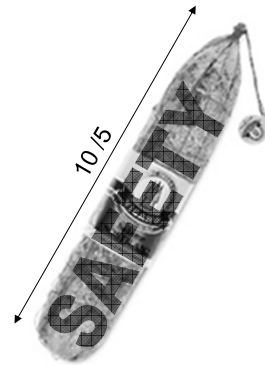
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IV) From lower to higher tiers in soil risk assessment

Uncertainties to be covered in the assessment

- (1) Intra- and inter-laboratory variation of toxicity data ☒
 - (2) Intra- and inter-species variation of toxicity data ☒
 - (3) Short-term to long-term/chronic toxicity extrapolation ☒
 - (4) Extrapolation of mono-species laboratory data to field impact on ecosystems ☐
- more sensitive lifestages
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IV) From lower to higher tiers in soil risk assessment

Types of Higher-Tier test systems

- **Field Test with local populations and biocoenoses** – full field situation, high variability, low reproducibility
- **Model ecosystems (mikro- and mesocosms)** – multispecies systems, indirect effects (e.g. predation, competition), recovery, fate and behaviour of substances, higher no. replicates
- **Test with single populations**– recovery; but: no indirect effects, isolated from the ecological context
- **Individual in simple system with changed exposure** – e.g. lower /higher bioavailability because of higher /lower sorption

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IV) From lower to higher tiers in soil risk assessment

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IV) From lower to higher tiers in soil risk assessment

Types of Higher-Tier test systems



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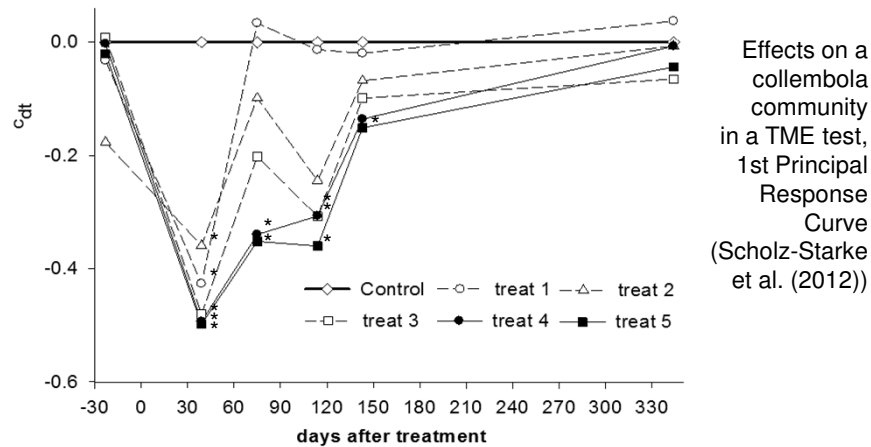
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IV) From lower to higher tiers in soil risk assessment

Examples of effects detected in soil higher tier tests



- Plausible and reliable effect description possible
- All known caveats of higher tier tests (as e.g. aquatic tests)

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V) Open questions

Multispecies Tests

Reduce the uncertainties regarding

- the sensitivity distribution of species
- the impact of indirect effects

But:

- How representative are the tested communities?
- How to define recovery? Which effects are tolerable?
- How to account for e.g. extremely declining densities in control?

The assessment of threshold values should be possible

- e.g. NOEC instead of NOEAC

High variability, low replicate number

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V) Open questions

Multispecies Tests: conclusions

- The results of **tests with soil organisms other than earthworms** will be available for (most) PPP
- For several substances **unacceptable effects** will be **indicated at lower tiers**
- For soil organisms other than earthworms, we have **no agreed guidance** for performing and evaluating higher tier multispecies tests
- Case-by-case study design is developed **according to the field test for earthworms**
- The **biocoenoses of soil meso and macrofauna do have other attributes compared to earthworms** (diversity, dynamics, life-cycle variability, aggregation) that should be reflected in e.g. endpoints, design

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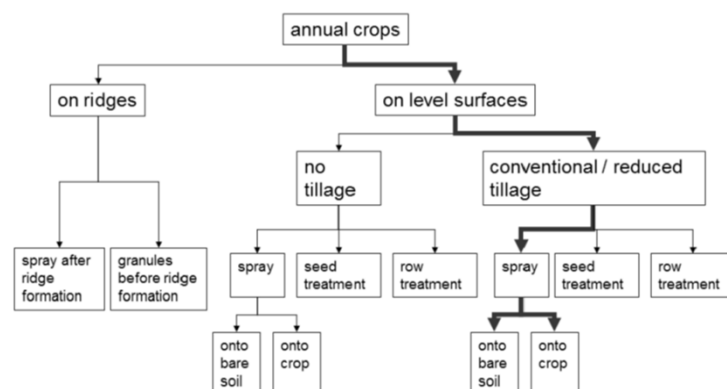
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VI Exposure assessment

Predicted Environmental Concentrations in soils

- **Scenario development and parametrization in EFSA (2015)**



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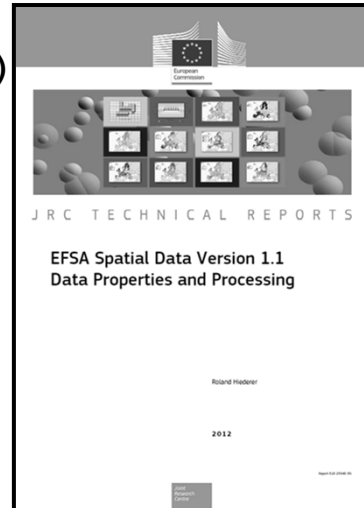
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VI Exposure assessment

Predicted Environmental Concentrations in soils

→ **Cooperation between
EU agencies (JRC and EFSA)**



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VI Exposure assessment

Predicted Environmental Concentrations in soils



CORINE Land cover

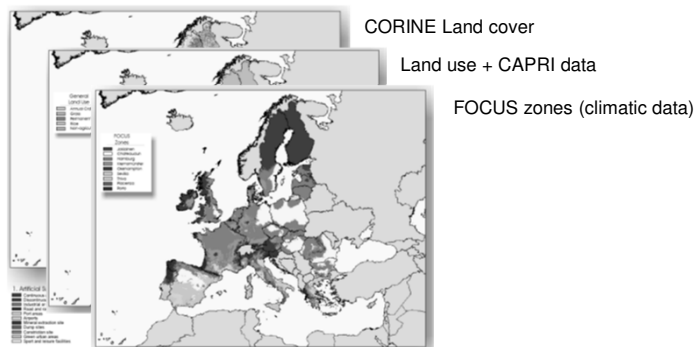
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VI Exposure assessment

Predicted Environmental Concentrations in soils



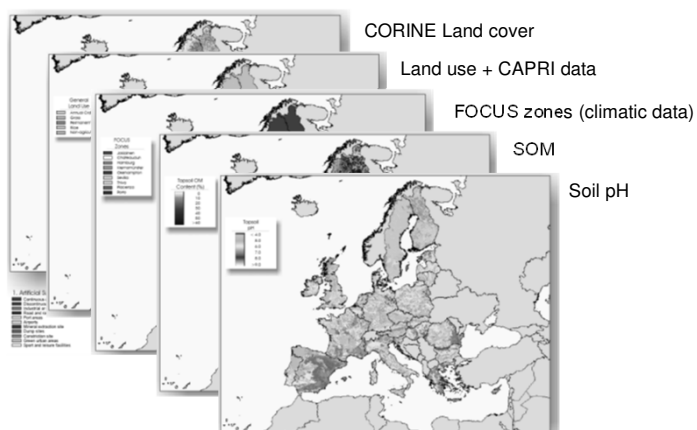
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VI Exposure assessment

Predicted Environmental Concentrations in soils



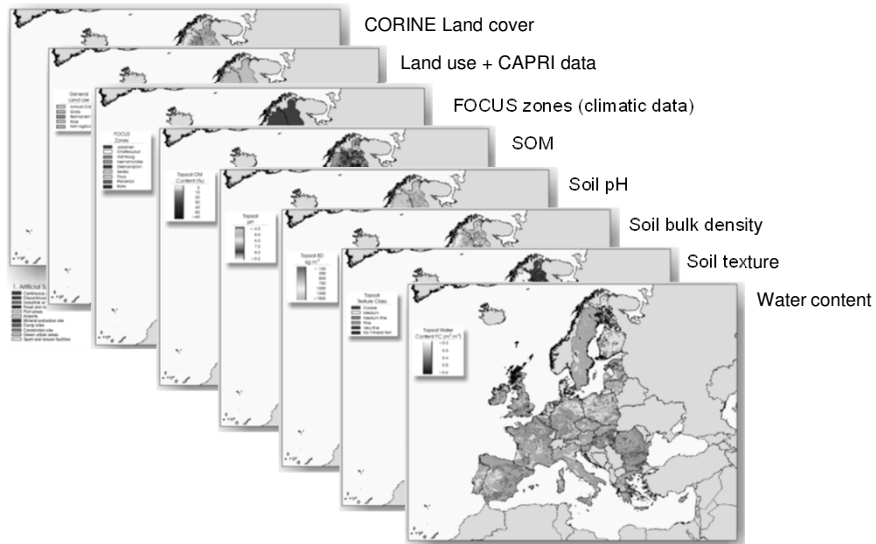
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VI Exposure assessment

Predicted Environmental Concentrations in soils



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VI Exposure assessment

Predicted Environmental Concentrations in soils

- **Scenario development for the regulatory zones**
- **95th percentile spatial distribution of concentration (total content and pore water content)**



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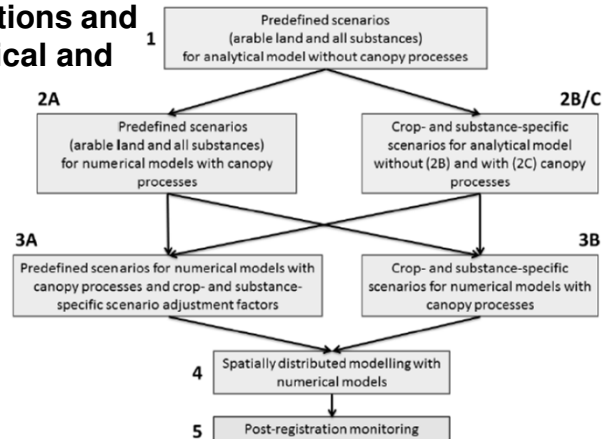
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VI Exposure assessment

Predicted Environmental Concentrations in soils

- **Tiered approach also for exposure assessment**
- **Different conditions and models (analytical and numerical)**



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VII Linking exposure and effects

Soil organisms and the 'right' PEC

- **EFSA opinion (2009): Eco(toxico)logically Relevant Concentrations are to be calculated**
- **These should results from the structure of the existing soil organisms biocoenoses**
- **Hypothesis: different biocoenoses have different exposures and therefore diverging risk**

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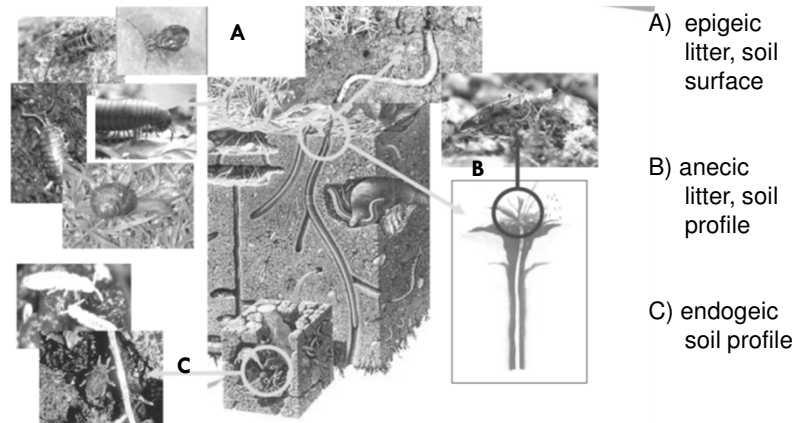
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VII Linking exposure and effects

Soil organisms and the 'right' PEC

→ **EFSA opinion (2009): Eco(toxico)logically Relevant Concentrations are to be calculated**



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VII Linking exposure and effects

Soil organisms and the 'right' PEC

→ **Is it possible to link exposure in a particular soil depth with the observed ecotoxicological effects for specific groups of organisms?**

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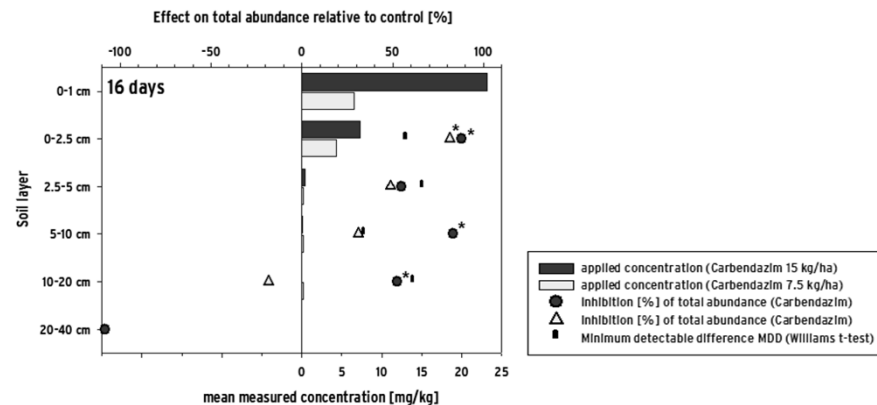
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VII Linking exposure and effects

Soil organisms and the 'right' PEC

- **Decrease of total abundance of lumbricid species in the carbendazim-treatments 7.5 kg a.s./ha and 15 kg a.s. /ha (5 replicates each) for the different soil layers in comparison to the**



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Assessing the risk for soil organisms at higher tiers

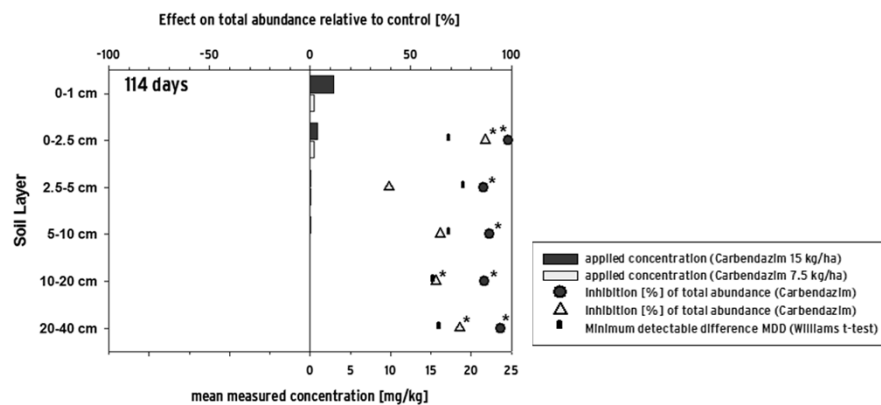
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VII Linking exposure and effects

Soil organisms and the 'right' PEC

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Assessing the risk for soil organisms at higher tiers

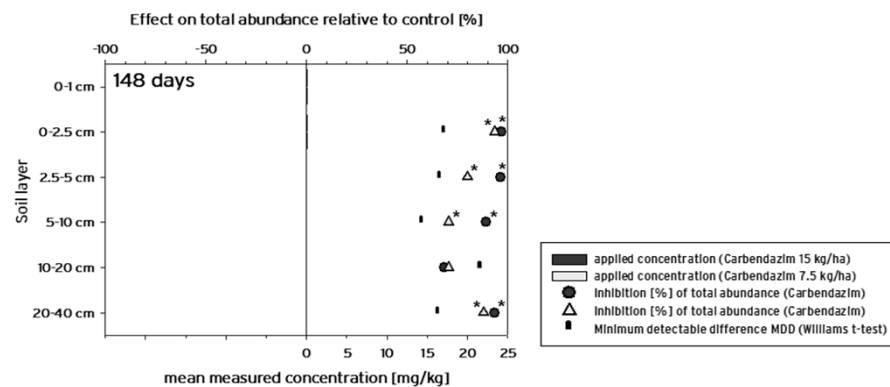
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VII Linking exposure and effects

Soil organisms and the 'right' PEC

- **Decrease of total abundance of lumbricid species in the carbendazim-treatments 7.5 kg a.s./ha and 15 kg a.s. /ha (5 replicates each) for the different soil layers in comparison to the control**



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VII Linking exposure and effects

Soil organisms and the 'right' PEC

- **Is it possible to link exposure in a particular soil depth with the observed ecotoxicological effects for specific groups of organisms?**
- **Persistence of substances and persistence of effects have to be kept in mind when addressing the long term risk for soil organisms**

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VII Linking exposure and effects

Soil organisms and the 'right' PEC

- Is it possible to link exposure in a particular soil depth with the observed ecotoxicological effects for specific groups of organisms?
- Persistence of substances and persistence of effects have to be kept in mind when addressing the long term risk for soil organisms

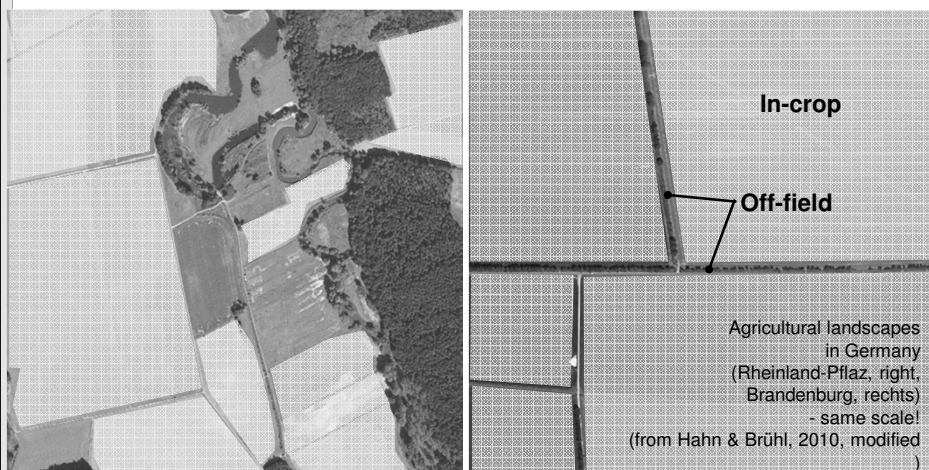
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What is important in the view of 'the regulators'?

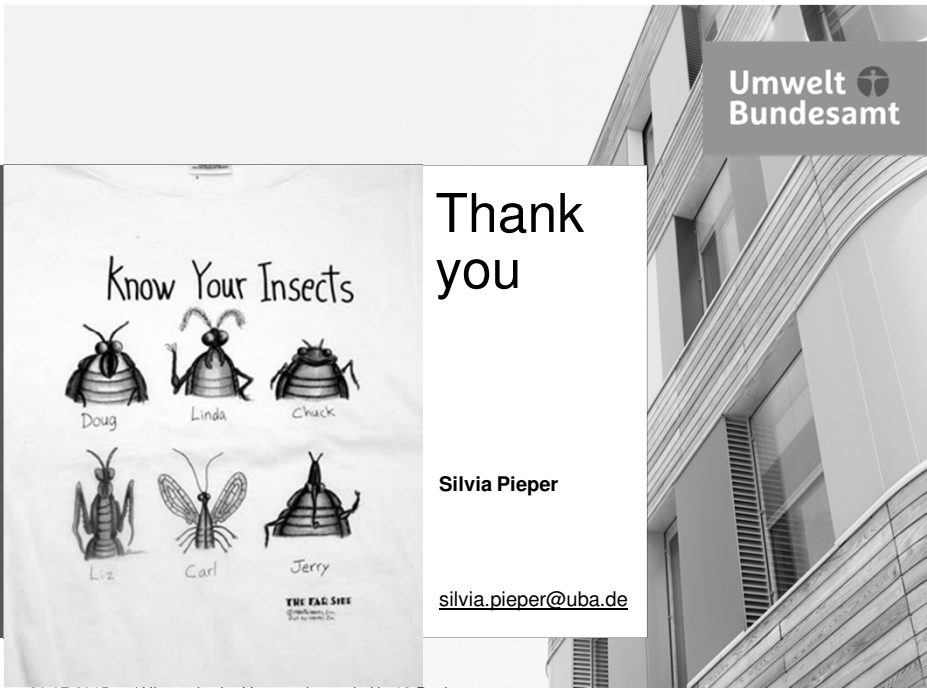
Tolerable level of effects?



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Umwelt Bundesamt

Thank you

Silvia Pieper

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30.07.2015 / Hier steht der Veranstaltungstitel in 12 Punkt 63

What is important in the view of 'the regulators'?

Assessing the risk for soil organisms at higher tiers

- Confident about the **pertinence of measurement and assessment endpoints**
- Confident about the **detectability of effects** –they should cope with the protection goal set
- Once the Specific Protection Goals are set: Confident about the **management practices** in term of application pattern (multiple applications, the summing up of effects and the disruption of recovery processes)
- Confident about the reference ecological state that is **achievable** in the field under **best conditions**
- Confident about the **predicted environmental concentrations** for lower tiers / extrapolation to other application patterns

What is important in the view of 'the regulators'?

Multispecies Tests: checklist

- **Which group of species is at risk in the field?**
- **Which life stage is at risk?**
- **Which uncertainties are to be reduced?**
- **Which proportion of the safety factor do these uncertainties account for ?**
- **Does the design allow for a statistical evaluation?**
Which effect range can be detected (e.g. 30 % mortality)? – power analysis
- **How representative are the tested species regarding their ecotoxicological sensitivity?**
- **How representative are the tested species regarding their ecological sensitivity?**