



## Environmental risk assessment in the EU – fate and ecotox (incl. dossier requirements)

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# Outline of the presentation

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- Protection goals for the environment in the EU
- Underlying documents for the environment in the EU
- Dossier requirements in the EU
- Risk assessment (including safety factors)

# Protection goals in the EU



- Environmental compartments

- Soil
- Groundwater
- Surface water
- Air



- Organisms

- Birds and other terrestrial vertebrates
- Aquatic organisms
- Honeybees and other non-target arthropods
- Earthworms and other soil macro-organisms
- Soil microbial processes
- Non-target terrestrial plants
- Others: sewage treatment micro-organisms



# Underlying documents for the environment

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## Directive 91/414/EEC

- Annex II: Fate and Ecotoxicological studies on the active ingredient (a.i.)
- Annex III: Ecotoxicological studies on the plant protection product
- Annex VI: Uniform Principles (criteria for risk assessment)

# Guidance for risk assessment (2)

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## Additional guidance:

- Guidance Document on Aquatic Ecotoxicology
- Guidance Document on Terrestrial Ecotoxicology
- Guidance Document on risk assessment for birds and mammals
- Guidance Document on Persistence in soil
- FOCUS. Soil persistence models and EU registration
- FOCUS groundwater scenarios in the EU Plant protection product review process
- Guidance document on the assessment of the relevant metabolites in groundwater
- FOCUS. Kinetic Analyses of degradation and transformation of the active substances and their metabolites in soil and water in EU registration.
- FOCUS surface water scenarios in the EU evaluation process under 91/414/EEC
- Guidance Document for environmental risk assessments of active substances used on rice in the EU for Annex I inclusion.

# Basic principle of risk assessment in EU

## TER = Toxicity Exposure Ratio

$$\text{TER} = \frac{\text{toxicity value (LD}_{50}, \text{LC}_{50}, \text{NEC})}{\text{predicted environmental concentration(PEC)}}$$

### *TER value compared to a criteria*

Registration criteria comprise a Safety factor

- Variation between individuals
- Variation between species
- Lab to field extrapolation
- Acute to long-term effects

# Environmental compartments to be protected in the EU



- Environmental compartments

- Soil
- Groundwater
- Surface water
- Air



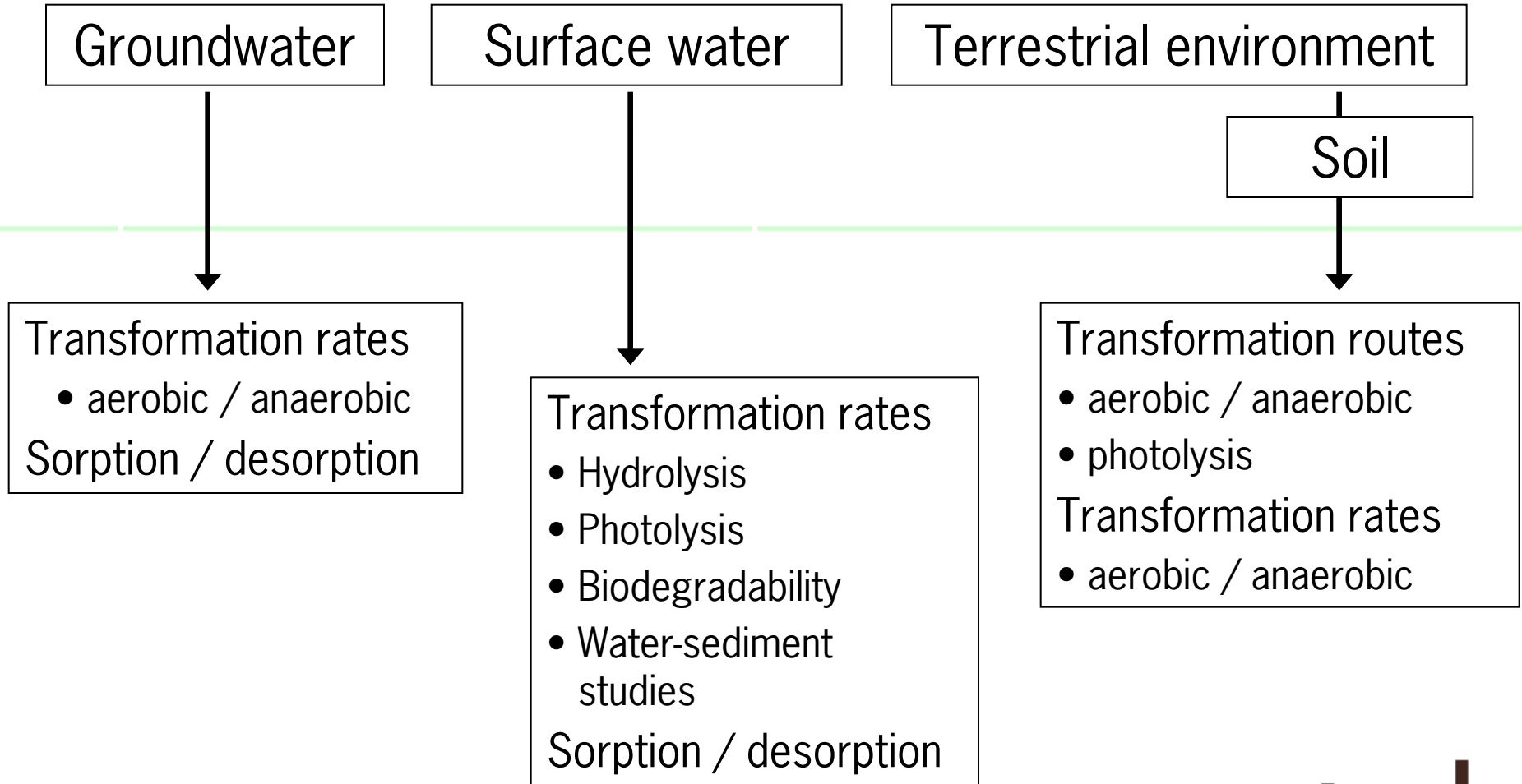
- Organisms

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# Environmental fate studies in EU

## environmental compartments





# Environmental fate studies

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## Route of degradation in soil

- Aerobic degradation (metabolites, bound residues; OECD-307)
- Anaerobic degradation (metabolites, bound residues; OECD-307)
- Soil photolysis (metabolites, bound residues; OECD draft guideline)

## Rate of degradation in soil

- Aerobic degradation of active substances and relevant metabolites (DT50 and DT90 values; OECD-307)
- Anaerobic degradation of active substances and relevant metabolites (DT50 and DT90 values; OECD-307)

# Environmental fate studies

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## Field studies in soil

- Soil dissipation studies (metabolites; DT50 and DT90-values; SETAC guidelines)
- Soil accumulation studies (DT50 and DT90-values; SETAC guidelines)

# Environmental fate studies

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## Mobility studies in the soil

- Adsorption and desorption of the active substance and relevant metabolites (K<sub>om</sub>-values; OECD-106)
- Column leaching studies with the active substance and relevant metabolites (K<sub>om</sub>-values; OECD-106)
- Aged residue column leaching (K<sub>om</sub>-values; OECD-106)
- Lysimeter studies (OECD Series on Testing and Assessment No. 22)
- Field leaching studies (SETAC-guideline)

# Environmental fate studies

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## Fate and behaviour in water

- Hydrolytic degradation (hydrolytic breakdown products, DT50-values; OECD-111)
- Photochemical degradation (breakdown products, DT50-values; OECD-309)
- Test on “Ready biodegradability” (EEC Method 4)
- Water/sediment study (metabolites formed in water and sediment, DT50 and DT90 values; OECD-308)

## Fate and behaviour in air

- Route and rate of degradation in air (guidance under development)

# Environmental fate: criteria for protection goals

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- Groundwater: concentration  $< 0.1$  ug/L
- Surface water used for drinking water: concentration  $< 0.1$  ug/L
- Soil: No DT90  $> 1$  year or DT50  $> 3$  months, unless there is no accumulation in the soil at such levels that there is an unacceptable impact on succeeding crops and the environment or unacceptable phytotoxic effects
- Air: No PEC from airborne transport in the respective environmental compartments resulting in unacceptable impact on the environment
- POP, PBT and vPvB criteria introduced in the revised Annex VI

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# Questions??????



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# Ecotoxicological protection goals



- Environmental compartments

- Soil
- Groundwater
- Surface water
- Air



- Organisms

- Birds and other terrestrial vertebrates
- Aquatic organisms
- Honeybees and other non-target arthropods
- Earthworms and other soil macro-organisms
- Soil microbial processes
- Non-target terrestrial plants
- Others: sewage treatment micro-organisms



# Information per organism to be protected

## Dossier requirements per protection goal

- First tier
- Higher tiers

## Risk assessment

- First tier
- Higher tiers





# Birds and other terrestrial vertebrates

- Birds
- Mammals



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# Birds: dossier requirements

## First tier tests

- Acute oral toxicity
- Sub-chronic toxicity and reproduction

## Higher tier tests

- Avoidance/palatability tests
- Pen/cage studies
- Field tests

No agreed standard protocols for higher tier tests!



# Birds: dossier requirements (2)

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## Acute oral toxicity

- required when exposure is possible
- one species (quail species or mallard duck)
- guideline: OECD 401
- Endpoint: LD<sub>50</sub>; NOEL

# Birds: dossier requirements (3)

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## Sub-chronic toxicity and reproduction

- required when exposure is possible during the breeding season
- one species (quail species or mallard duck)
- guideline: OECD 206
- endpoint: NOEC (reproduction)



## Effects on secondary poisoning

- in the case of rodenticides
- secondary poisoning of predators and scavengers

# Birds: Risk assessment

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## First tier:

Acute:  $TER = \text{oral } LD_{50} / PEC$

$TER > 10$

Sub-chronic or reproduction:  $TER = NOEC / PEC$

$TER > 5$

## Higher tier:

Depending on specific problems, case by case decision

# Mammals: dossier requirements

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Studies from the human toxicological data package

## Acute oral toxicity study (rat)

- endpoint: LD<sub>50</sub> (acute)

## Multigeneration study or teratogenicity study

- endpoint: NOEC (long term)



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# Mammals: Risk assessment

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## First tier:

Acute:  $TER = \text{oral } LD_{50} / PEC$

$TER > 10$

Sub-chronic or reproduction:  $TER = NOEC / PEC$

$TER > 5$

## Higher tier:

Depending on specific problems, case by case decision

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# Questions??????



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# Aquatic organisms

- Fish (including BCF)
- Aquatic invertebrates
- Algae
- Sediment dwelling organisms
- Aquatic plants



# Fish: dossier requirements

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## First tier tests

- Acute toxicity to fish
- Chronic toxicity to fish
- Bioconcentration (BCF) in fish

## Higher tier tests

- Single species tests in water/sediment systems
- Semi-realistic microcosm study
- Mesocosm study

# Fish: dossier requirements (2)

## Acute toxicity to fish

- always required
- 2 species:
  - rainbow trout (*Oncorhynchus mykiss*)
  - warm water fish species (e.g. bluegill sunfish)
- guideline: OECD 201
- Endpoint: 96 h LC<sub>50</sub>



## Chronic toxicity to fish

Always required unless:

>90% loss by hydrolysis over 24 h

3 types of chronic tests:

- chronic toxicity test on juvenile fish
- fish early life stage toxicity test
- fish full life cycle test

# Chronic toxicity tests to fish

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## Chronic toxicity test on juvenile fish (rainbow trout )

- test period: 28 days
- guideline: OECD 215
- endpoint: NOEC (survival, growth, behavior)

## Fish early life stage toxicity test

required when:

- $100 < BCF < 1000$  and acute  $LC_{50}$  (a.i.)  $< 0.1$  mg/L
- guideline: OECD 210
- endpoint: NOEC (development, growth, behavior)

## Fish full life cycle test

Required when:

- $BCF > 1000$  and elimination during the 14 day depuration phase  $< 95\%$  (bio-concentration study) and a.i. stable in water or sediment ( $DT90 > 100$  days) and acute  $LC_{50} < 0.1$  mg/L
- Endpoint: NOEC (reproduction, viability of filial generation)



# Fish: dossier requirements (3)

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## Bioconcentration factor (BCF) in fish

Required when  $\log Pow > 3$

- Not necessary when:
  - exposure not likely to occur
  - DT90 (whole system) < 10 days, unless multiple applications

# Fish: Risk assessment

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## First tier:

Acute:  $TER = LC_{50} / PEC$ :

$TER > 100$

Chronic:  $TER = NOEC / PEC$

$TER > 10$

## Higher tier:

Depending on specific problems (e.g. micro- or mesocosms), criteria to be used case by case

# Fish, BCF: Risk assessment

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## First tier:

For a.i. which are readily biodegradable

BCF < 1000

For a.i. which are not readily biodegradable

BCF < 100

## Higher tier:

- No direct or indirect effects for aquatic organisms
- Secondary poisoning birds and mammals

# Aquatic invertebrates: dossier requirements

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## First tier tests

- Acute toxicity to aquatic invertebrate
- Chronic toxicity to aquatic invertebrates

## Higher tier tests

- Single species tests in water/sediment systems
- Semi-realistic microcosm study
- Mesocosm study





# Aquatic invertebrates: dossier requirements (2)

## Acute toxicity to aquatic invertebrates

- Always required
- Test species: *Daphnia magna*
- Guideline: OECD 202
- Endpoint: 48 h EC<sub>50</sub> (immobilization)



## Chronic toxicity to aquatic invertebrates

- Always required, unless:
  - >90% loss by hydrolysis over 24 h
- Guideline: OECD 211
- Endpoint: 21 d NOEC (immobilization, reproduction)

# Aquatic invertebrates: dossier requirements (3)

## Insecticides

For insecticides *Daphnia magna* is not always the representative species:

- when toxicity of insecticide is low for *Daphnia* (48 h  $EC_{50} > 1$  mg/L; 21 d NOEC  $> 0.1$  mg/L), then acute test with *Chironomus riparius* (first instar; water only study)
- if 48 h  $EC_{50}$  (*Chironomus*)  $< 0.1 \times$  48 h  $EC_{50}$  (*Daphnia*), a chronic study with *Chironomus riparius* is required



# Aquatic invertebrates: Risk assessment

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## First tier:

Acute:  $TER = LC_{50} / PEC$

$TER > 100$

Chronic:  $TER = NOEC / PEC$ :

$TER > 10$

## Higher tier:

Depending on specific problems (e.g. micro- or mesocosms), criteria to be used case by case

# Algae: dossier requirements

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## First tier tests

- Acute toxicity to algae

## Higher tier tests

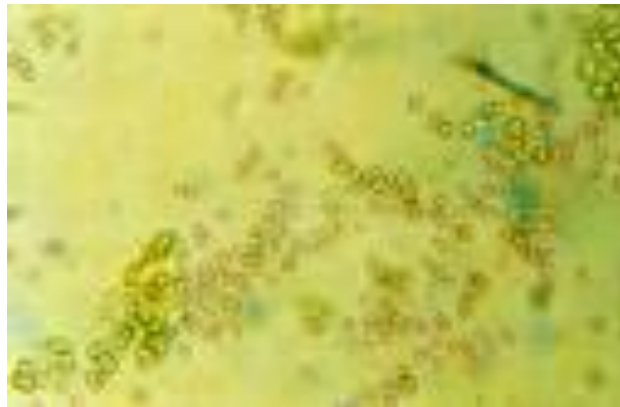
- Single species tests in water/sediment systems
- Semi-realistic microcosm study
- Mesocosm study

# Algae: dossier requirements (2)

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## Toxicity test on algal growth

- always required
- normally one species (green algae)
- herbicides and plant growth regulators: second algal species is required from different taxonomic group
- guideline: OECD 203
- endpoint: 96 h EC<sub>50</sub> (biomass, growth rate)



# Algae: Risk assessment

## First tier:

Acute:  $TER = EC_{50} / PEC$ :

$TER > 10$

## Higher tier:

Depending on specific problems (e.g. micro- or mesocosms), criteria to be used case by case



# Aquatic plants: dossier requirements

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## First tier tests

- Acute toxicity to aquatic plants

## Higher tier tests

- Single species tests in water/sediment systems
- Semi-realistic microcosm study
- Mesocosm study

# Aquatic plants: dossier requirements (2)

## Toxicity test on aquatic plants

- required for herbicides and plant growth regulators
- test species: *Lemna* sp.
- guideline: ASTM or EPA
- endpoint: 14 d EC<sub>50</sub> (number of fronds, biomass)





# Aquatic plants: Risk assessment

## First tier:

Acute:  $TER = EC_{50} / PEC$

$TER > 10$

## Higher tier:

Depending on specific problems (e.g. micro- or mesocosms), criteria to be used case by case



# Sediment dwelling organisms: dossier requirements

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## First tier tests

- Chronic toxicity to sediment dwelling organisms

## Higher tier tests

- Semi-realistic microcosm study
- Meso-cosm study

# Sediment dwelling organisms: dossier requirements (2)

## Toxicity test on sediment dwelling organisms

- Normally a chronic test is required
- Trigger:
  - when > 10% of AR (a.i.) in the sediment at or after day 14 and
  - chronic NOEC (*Daphnia*) < 0.1 mg/L
- Test species: *Chironomus riparius*
  - spiked water toxicity test (OECD 219)
  - spiked sediment toxicity test (OECD 218)
- Endpoint: 28 d NOEC (survival and development)



# Sediment dwelling organisms: Risk assessment

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## First tier:

Chronic:  $TER = NOEC / PEC$

$TER > 10$

## Higher tier:

Depending on specific problems (e.g. micro- or mesocosms), criteria to be used case by case

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# Questions??????



# Honeybees and other non-target arthropods

- Bees
- Non target arthropods



# Bees: dossier requirements

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## First tier

- Acute toxicity to bees
- Bee brood feeding test

## Higher tier

- Cage/tent/tunnel or field trial

# Bees: dossier requirements (2)

## Acute toxicity to bees

- oral toxicity test
- contact toxicity test
- required when exposure to bees is possible
- guidelines: EPPO 170, OECD 213 and 214
- endpoint: 48 h oral LD<sub>50</sub>; 48 h contact LD<sub>50</sub>



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# Bees: dossier requirements (3)

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## Bee brood feeding test

- Required when pesticide is an Insect Growth Regulator (IGR)
- Guideline: Oomen et al. (1992)

## Higher tier tests with bees

- Cage/tent/tunnel or field trials
- guideline: EPPO 170

# Bees: risk assessment

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## First tier:

Acute: oral or contact  $LD_{50}$  (ug/bee) / PEC (dose) (g/ha) **TER > 0.02**

## Higher tier:

Cage/tent/tunnel/ field trials : **no statistical difference** in effects  
between the control and treatments  
(survival and development)

# Non target arthropods: dossier requirements

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## First tier

- Effect tests on glass plates

## Higher tier tests

- Extended laboratory tests, aged-residue tests, (semi-) field studies



# Non target arthropods: dossier requirements (2)

Tests are required when exposure is possible

First tier testing: glass plate tests with:

- parasitoid (*Aphidius rhopalosiphii*) → standard species
- predatory mite (*Typhlodromus pyri*) → standard species
- Two extra species (depending on application according to SETAC)
- endpoint: LR50
- Guideline: SETAC – Guidance document on regulatory testing procedures for pesticides with non-target arthropods.



Higher tier tests

Required when risk is indicated in Tier I tests

- extended laboratory tests
- aged-residue tests
- (semi-) field studies
- Guideline: SETAC



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# Non-target arthropods: risk assessment

## First tier:

Standard species:  $TER = LR50 / PEC$

(*Aphidius rhopalosiphi* and *Typhlodromus pyri*)

$TER > 0.5$

Non standard species:

effect < 30%

## Higher tier:

All species:

effect < 50%

## Recovery

- in-field: before next season
- off-field: ecological relevant period



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# Earthworms: dossier requirements

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## First tier tests

- Acute toxicity to earthworms
- Sub-lethal toxicity to earthworms

## Higher tier tests

- Earthworm field studies



# Earthworms: dossier requirements (2)

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## Acute toxicity to earthworms

- required when exposure of soil is possible
- guidelines: OECD 207; ISO 11268-1:1993; 88/302/EC
- endpoint: 14-day  $LC_{50}$

## Sub-lethal toxicity

- triggers:
  - always when acute  $TER < 10$
  - always when  $DT_{90f} > 365$  days or when no. of applications  $> 6$
- guidelines: ISO 11268-2; forthcoming OECD 222
- endpoint: NOEC (growth, reproduction and behavior)

# Earthworms: dossier requirements (3)

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## Earthworm field studies

- Required when TER (long term) < 5
- Guideline: ISO 11268-3: 1999



# Earthworms: risk assessment

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## First tier:

Acute:  $TER = LC_{50} / PEC$  TER > 10

Chronic:  $TER = NOEC / PEC$  TER > 5

## Higher tier:

Depending on specific problems, criteria to be used case by case, expert judgment

Recovery: before next season

# Other soil non-target macro-organisms

## Test on the effects on other soil non-target macro-organisms

- When:
  - risk for arthropods (*Aphidius/ Typhlodromus*) in the first tier
  - pesticide directly applied to soil
- Possible tests
  - test on *Collembola* reproduction
  - test on gamasid mites (*Hypoaspis aculeifer*)
- Guidelines:
  - *Collembola*: ISO 11267: 1999
  - *Hypoaspis*: Løkke and Van Gestel (1998); Bakker et al. (2002)



# Other soil non-target macro-organisms: risk assessment

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First tier:

Chronic:  $TER = NOEC / PEC$        $TER < 5$

Higher tier:

Depending on specific problems, criteria to be used case by case,  
expert judgment

# Non-target terrestrial plants: dossier requirements

## Tier 1

- Available information, preferably screening data
- At least 6 species from different taxa tested at the highest nominal application rate

## Tier 2 (if potential risk in Tier 1 is identified)

- Dose-response tests on 6 – 10 plant species representing as many taxonomic groups as possible
- Guideline: OECD 208; EPA
- Endpoint:  $ER_{50}$

## Tier 3 (if still risk in Tier 2)

- Field or semi-field studies
- No standardized protocols



# Non-target terrestrial plants: risk assessment

## Tier 1:

For all of the species of the screening test: effect < 50%

## Tier 2:

TER = ER<sub>50</sub> / dose: TER > 5

or

TER = HR<sub>5</sub> / dose (probabilistic: 6 -10 species) : TER > 1

## Tier 3:

Depending on specific problems, criteria to be used case by case

# Soil microbial processes: dossier requirements

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## First tier tests

- Soil nitrification
- Carbon mineralization

## Higher tier tests

- Field studies (no protocol, expert judgment)

## Soil nitrification and soil carbon mineralization test

- required when exposure of soil is possible
- guidelines: OECD 216/217
- endpoint: Effect %

# Soil microbial processes: Risk assessment

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## First tier:

Effects on Soil nitrification < 25 % after 100 days

Effects on carbon mineralization < 25 % after 100 days

## Higher tier:

Field research (soil nitrification or carbon mineralization):

no statistical difference between the control and the treatments

## Recovery

- before next season

# Other: Sewage treatment plant (STP)

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## Effects on biological methods for STP

- Required when exposure of Sewage Treatment Plants is possible
- Guideline: OECD 209
- endpoint: L(E)C<sub>50</sub>

## Risk assessment:

No standardized criteria in 91/414





# There is more to deal with.....

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- Formulations
- Metabolites
- Etc.....

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# Questions??????



Options for Ethiopia?

# Define protection goals

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- Before environmental risk assessment procedures can be developed, national protection goals need to be defined.
  - What do we want (need) to protect?
  - Where do we want to protect it?
  - How strict do we want to protect it? What is an unacceptable effect?

# Define protection goals

- **What** do we want to protect?
- Which groups of non-target organisms (or environmental compartments) should not be affected by the pesticide at unacceptable levels?
- E.g. for the aquatic environment:
  - all aquatic organisms?
  - only all fish?
  - only all commercially harvested fish?  
[can they be separated?]



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# General protection goals in Ethiopia?

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- What are priority environmental compartments and organisms in Ethiopia?
- Should we develop hazard/risk assessment for all groups, or start with a limited number?

# Define protection goals

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- **Where** do we want to protect?
- E.g.: EU – Aquatic environment
  - Aquatic organisms in ditches adjacent to agricultural fields
- E.g.: EU – Soil environment
  - Soil organisms and processes in top 5 cm of soil
- E.g.: EU – Bees
  - Honey bees, everywhere

**Can we define where for some Ethiopian cases?**

# Define protection goals

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- **How strict** do we want to protect?
- E.g.: EU – Aquatic environment
  - No acute and chronic effects on aquatic organisms allowed

**To be defined for Ethiopia**



# Relevance for use in Ethiopia

No	Criteria	Yes/no relevant	Relevant for Ethiopia? Why?	Remarks
1	Ground-water			
2	Surface water			
3	Soil			
4	Birds and other terrestrial vertebrates			

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# Relevance for use in Ethiopia

No	Criteria	Yes/no relevant	Relevant for Ethiopia? Why?	Remarks
5	Aquatic organisms			
6	Bees			
7	Other non-target arthropods			
8	Earthworms			



# Relevance for use in Ethiopia

No	Criteria	Yes/no relevant	Relevant for Ethiopia? Why?	Remarks
9	Other soil macro-organisms			
10	Soil micro-organisms			
11	Terrestrial non-target plants			
12	Sewage systems			

