Exposure Assessments Goals to define exposure in the field and to improve the linking to effects observed in ecotoxicological experiments

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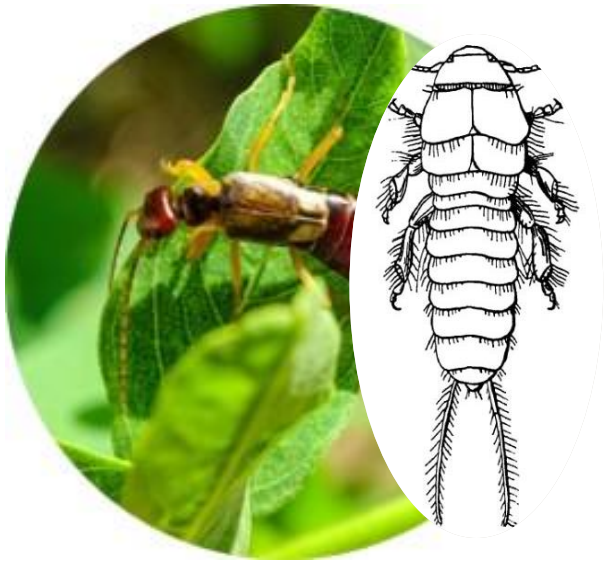
Workshop for revision of terrestrial ecotoxicology guidance

Brussels, 8 Oct 2024



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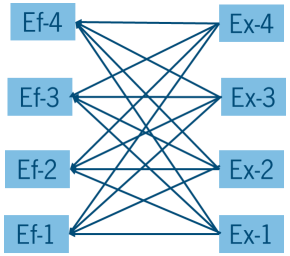
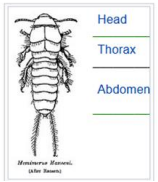
100years
1918 — 2018

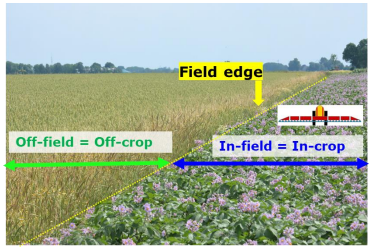
Outline

- Introduction
- Principles of risk assessment for organisms (incl. tiered approach)



- Effect and Exposure Assessment Goals (EfAGs and ExAGs)
- Definition of ExAGs
- Application to NTAs
- Linking of exposure and effects





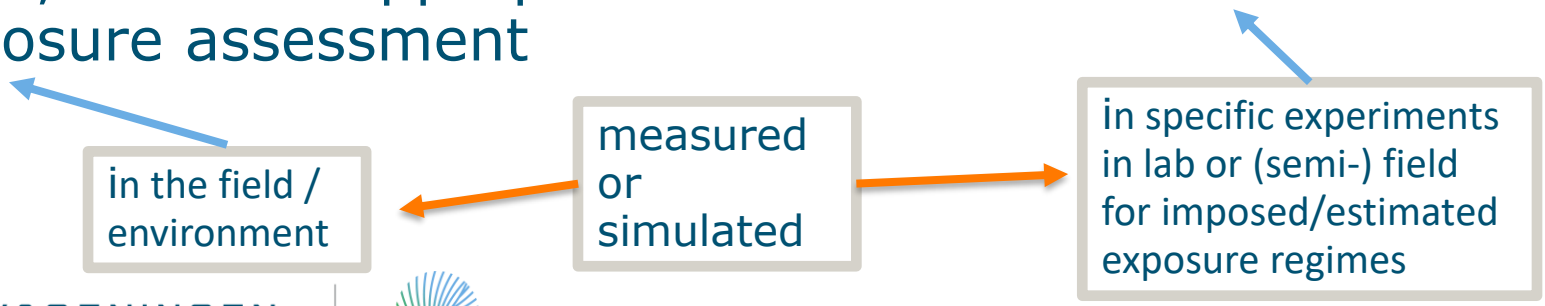
- Definition of in-field, off-field, in-crop, off-crop
- Conclusions

Principles of risk assessment for organisms (incl. tiered approach)

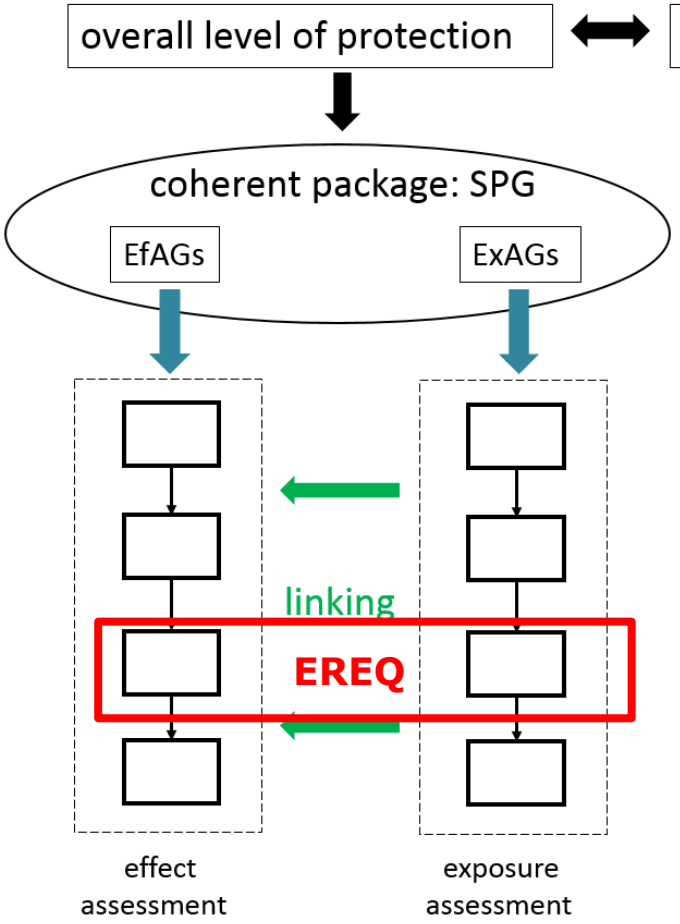
- For all organisms:
  risk assessment = exposure + effect assessment

- Overall level of protection is the most important aspect of risk assessment and is determined by the interplay of the 'exposure in the field' assessment and the eco-toxicological effects assessment in experiments

- Thus, need for appropriate combination of effect and exposure assessment



Principles for risk assessment for organisms (incl. tiered approach)



Specific Protection Goal (SPG) indicates which *Ecosystem Services* are to be protected and which *Ecological Entities* (individuals/population/groups) of non-target organisms need to be protected to reach the SPG (EFSA, 2010)

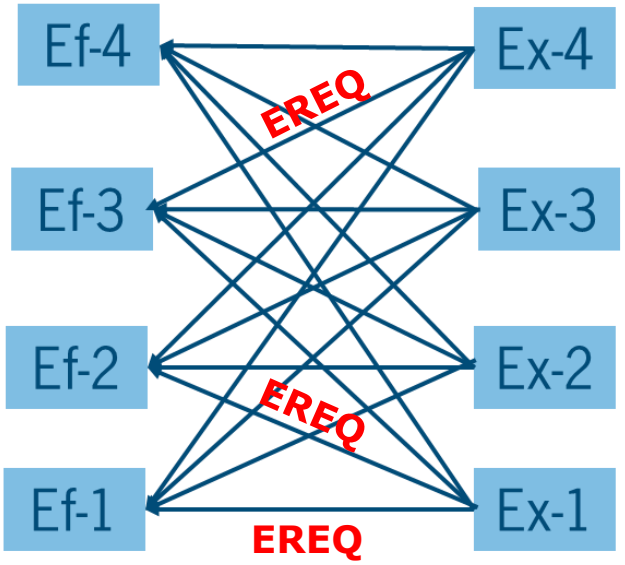
Operationalised in two assessment flow charts:
one for exposure, and
one for effects

Archetype of tiered assessment scheme
Linked by EREQ

Risk assessment for organisms (incl. tiered approach)

Linking exposure and effect tiers

- All combinations are possible, (criss-cross model):
  e.g. Ex-4 with Ef-1, but also
  Ef-3 with Ex-1
- Depends on e.g. availability data, or costs for a tier



Flow charts need to be internally consistent:

- Ex: same target quantity: same type of quantity, e.g. consumed mass
- Ef: same assessment goal: e.g. either acute or chronic endpoint,

in each step

Linking of exposure and effect tiers: highest tier

- Highest tier consists of (semi-) field tests, possibly combined with (exposure or ecological) modelling

- In field test exposure and ecotoxicological effect tiers not separated, but integrated

- Crucial question: is the exposure in the field test sufficiently 'realistic worst case' , i.e. does it represent the 90th percentile of worst case GAP ? So, the 90th percentile occurrence of agro-environmental situations in time and space ?

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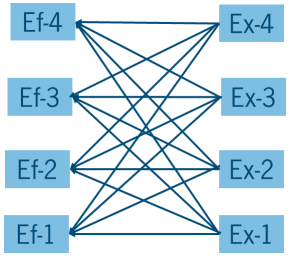

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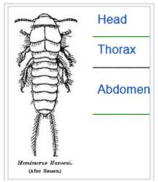

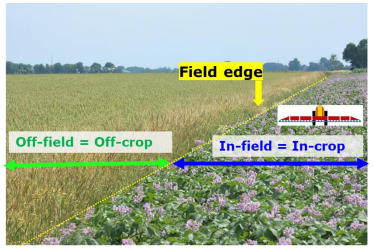

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Effect (EfAGs) and Exposure Assessment Goals (ExAGs)

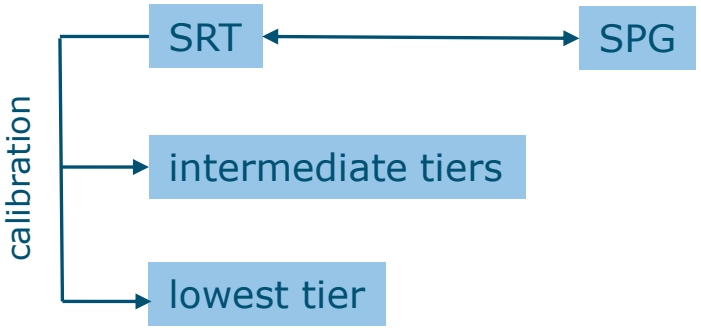
- EfAGs operationalise the SPGs in a structured way with respect to effect assessment in ecotox experiments

- Elements of EfAGs are:

- Surrogate reference tier, and desired effect percentile representing the SPG (highest tier representing reality, e.g. field study; HC_5 of SSD)
- Relevant taxa representing the Ecological Entity (colony/population) to protect (e.g. honeybee, *Osmia* spp for solitary bees; population of beneficial arthropods)
- Type of effect endpoint and toxicity endpoint quantifying it (e.g. mortality and LD_{50})
- Ecotoxicologically Relevant Exposure Quantity (EREQ) and exposure profile

Effect (EfAGs) and Exposure Assessment Goals (ExAGs)

Surrogate Reference Tier (SRT):



- Represents real situation for Ecological Entity in agricultural landscape for which the ecosystem service needs to be protected
- Highest, experimentally feasible tier of effect assessment
- Endpoints derived in lower tiers to be calibrated to higher tiers (by assessment factors), i.e. be more conservative
- Often highest tier is a field study, where exposure should not represent the 'average' exposure, but a 'realistic worst case' in the field (-> to demonstrate by comparing to the ExAG)

Definition of Exposure (ExAGs) and Effect Assessment Goals (EfAGs)

- ExAGs operationalise the SPGs in a structured way with respect to exposure assessment in the field

- Questions answered are:
  - exposure in what, where, for what timeframe
  - how conservative: what percentage of exposure situations in the field should be covered in the risk assessment

- ExAGs are defined by 6 elements

Definition of ExAGs

1. Type of exposure quantity (EREQ)
2. Temporal dimension of the exposure
3. Spatial unit
4. Statistical population of spatial units
5. Temporal population of EREQ values for one spatial unit
6. Percentile of spatio-temporal population of EREQ values

Examples ExAGs: aquatic organisms (2012,NL), bees (2013 and 2023,EFSA) soil organisms (2017,EFSA), amphibians&reptiles (2018,EFSA)




Definition of ExAGs – explanation EREQ

1. EREQ – **E**cotoxicologically **R**elevant **E**xposure **Q**uantity,

- Definition: Type of exposure that explains best in a mechanistic way the link between exposure and effects observed in an ecotoxicological experiment
- N.B. It is <u>not</u> a *value* but a *type* of quantity, i.e. a *conceptual entity*
- The EREQ is based upon ecotoxicological experiments and expertise, but used in tiered assessments of both exposure and effects

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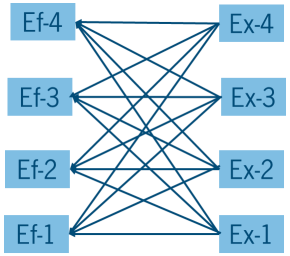

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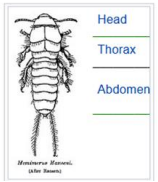

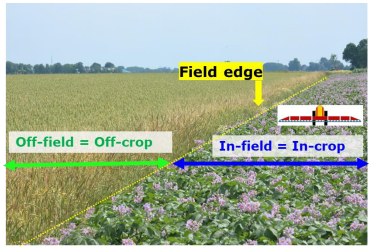

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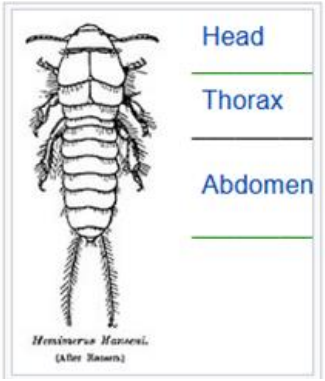
Definition of ExAGs – applied to NTAs (Adr. et al, 2022)

1. EREQ

- *Definition: type* of quantity that explains best in a mechanistic way the link between exposure and effects in an ecotoxicological experiment

Examples for above-ground NTAs:

- Current EREQ:
  - deposition rate, e.g. on soil or top of plant canopy in field (application rate corrected for BBCH, plant interception)
  - for exposure routes of contact ánd dietary intake
- Improved alternative EREQ:
  - pesticide mass sticking on the individual arthropod, or
  - pesticide mass **in** and on the individual arthropod

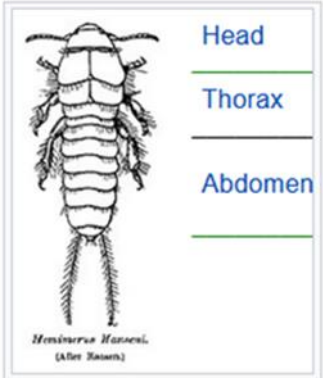


Definition of ExAGs – applied to NTAs

2. Temporal dimension of exposure

- Definition: which time period is best suited to express the toxic effect ?

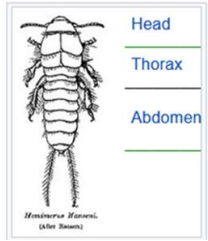
- Usually different for acute and chronic toxicity
- Options: # Peak concentration
  # Maximum of 7-d TWA residue intake



Definition of ExAGs – applied to NTAs

3. Spatial Unit (SU)

- Definition: Type of spatial unit and size/area over which exposure quantities may be averaged



Examples for above-ground NTAs living in-crop:

- Total cropped area within the field (=one unit) <-> current EREQ (dep rate)
- Population of arthropods living in the total cropped area within the field <-> improved EREQ (per arthropod)

Example for birds:

- Individual bird

Definition of ExAGs – applied to NTAs

4. Statistical population of spatial units (SU)

- Definition: Statistical population of SUs considered in exposure assessment
- Currently, for NTAs living in-crop: All treated field in the agricultural area where the compound is to be used

5. Temporal population of EREQ values for one spatial unit

- Definition: Population of EREQ values that is sufficiently long to capture the desired variability in time of the EREQs
- Often: annual maxima of time series of tens of years of EREQ values
- Example (soil organisms): 20 EREQ values (e.g. annual peak concentration, resulting from 20-year simulations in top 20 cm of EFSA PEC soil scenarios)

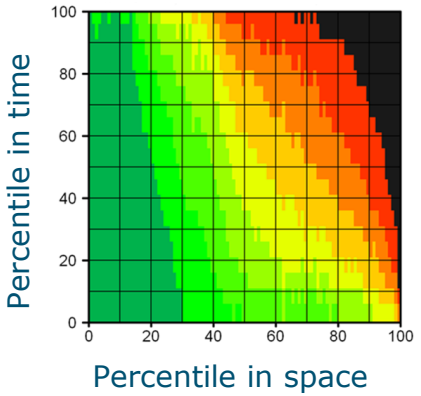
Definition of ExAGs – applied to NTAs

6. Percentile of spatio-temporal population of EREQ values

- Definition: This percentile determines which part of the spatio-temporal population of EREQ values is excluded from the effect assessment
- N.B. Effects in the excluded part depend on e.g. safety factors)

- Often:
  90^{th} percentile in time and space
  ('realistic worst case' situation)

Contour plot: overall probability of occurrence of EREQ values

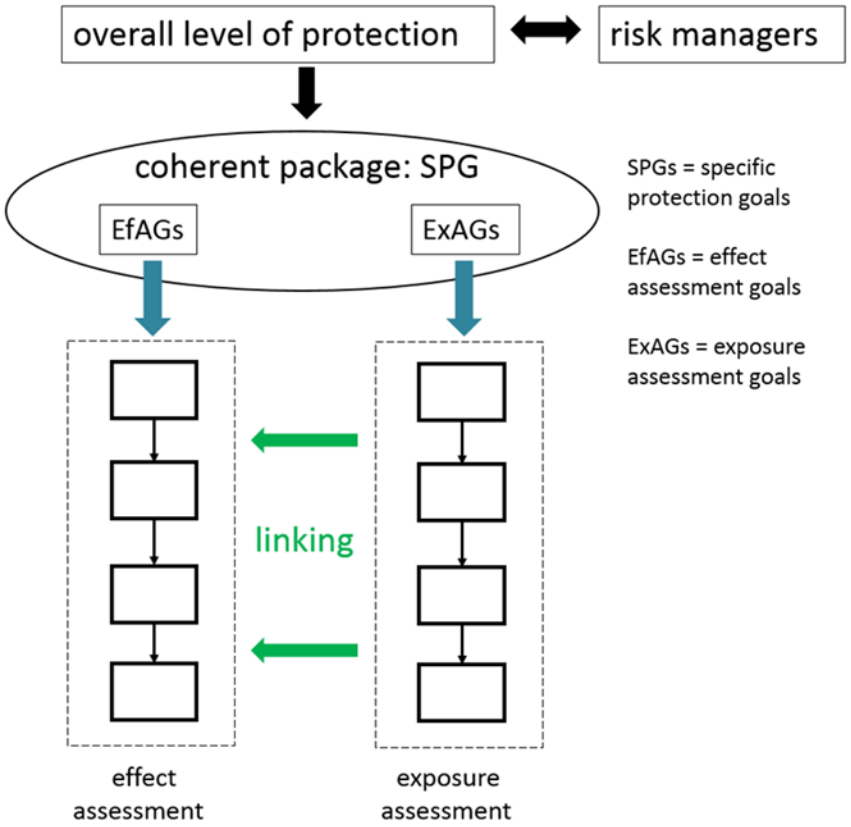


Linking of exposure and effect tiers

Linking is limited to

- Which type of EREQ
- Which temporal dimension of EREQ

These should be similar.



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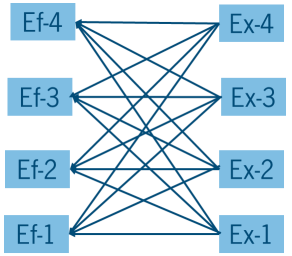

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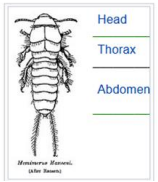

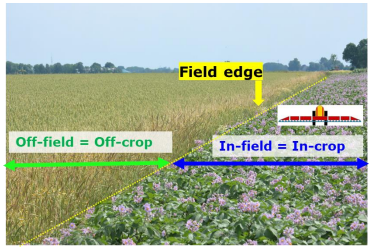

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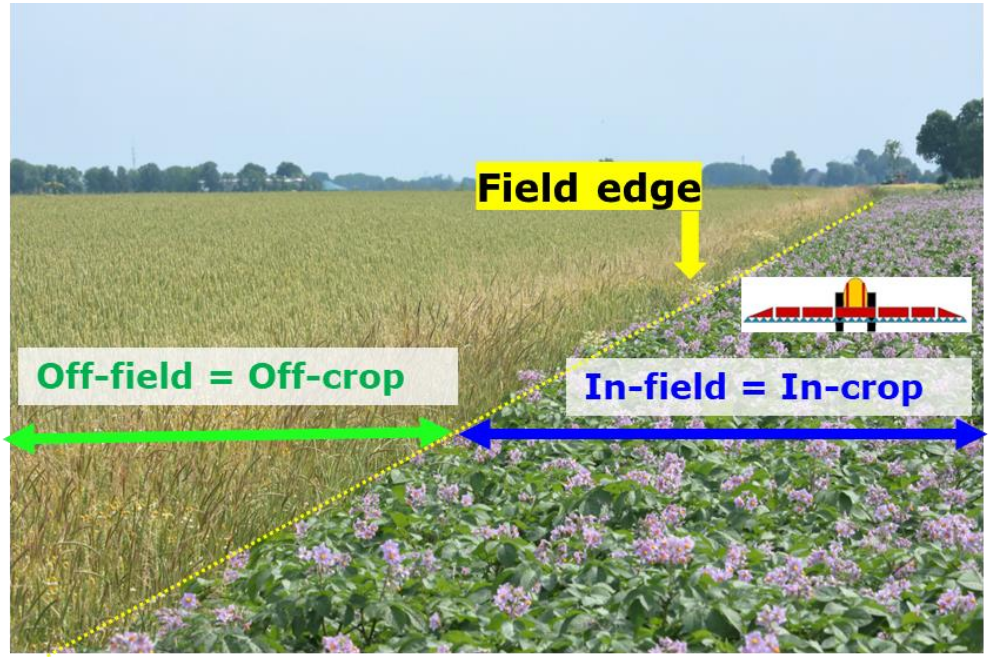
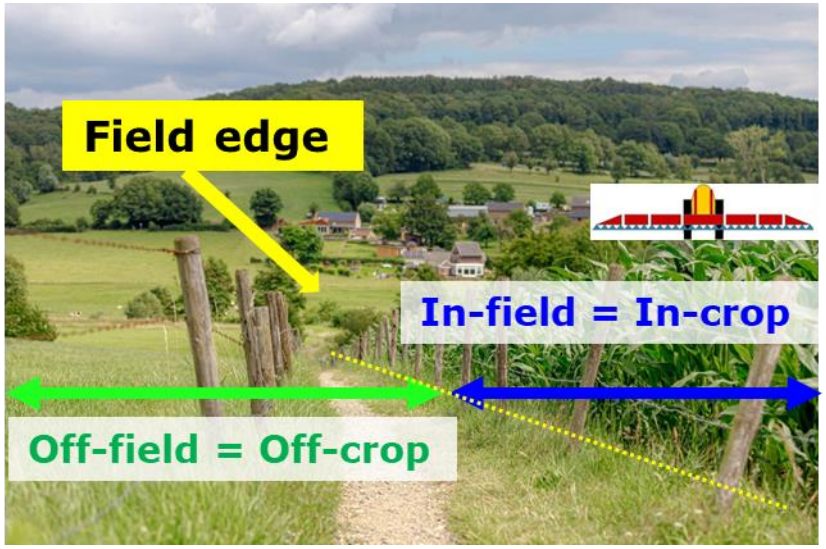


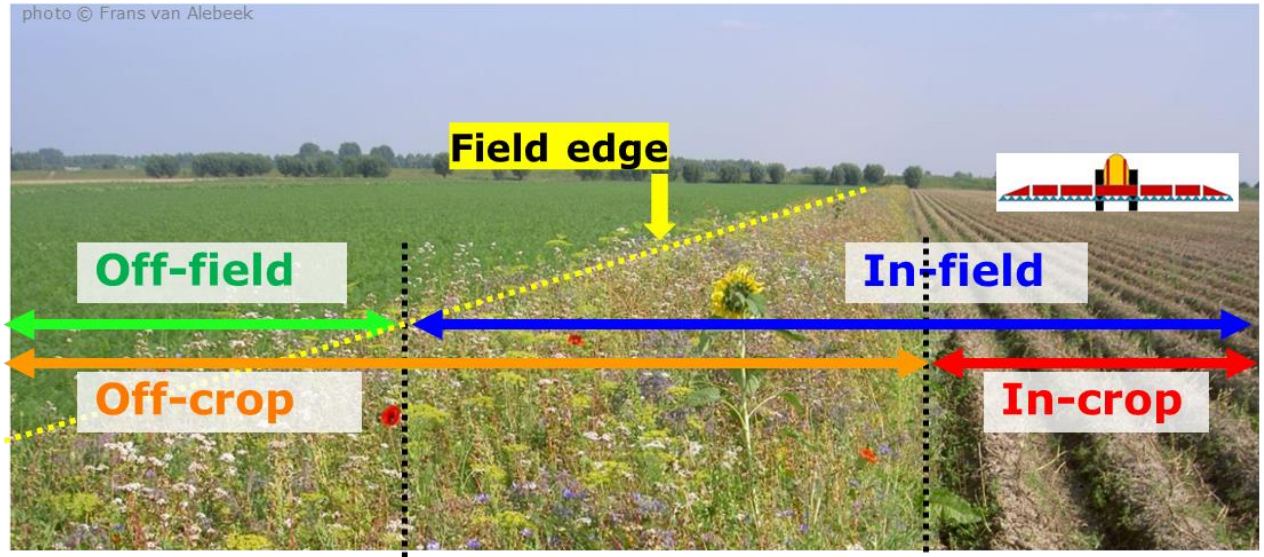


N.B.1 We reason starting from the treated crop

N.B.2 Off-crop may also consist of a crop

- Here:
  in-field = in-crop, and
  off-field = off-crop

Definition of in-field, off-field, in-crop, off-crop

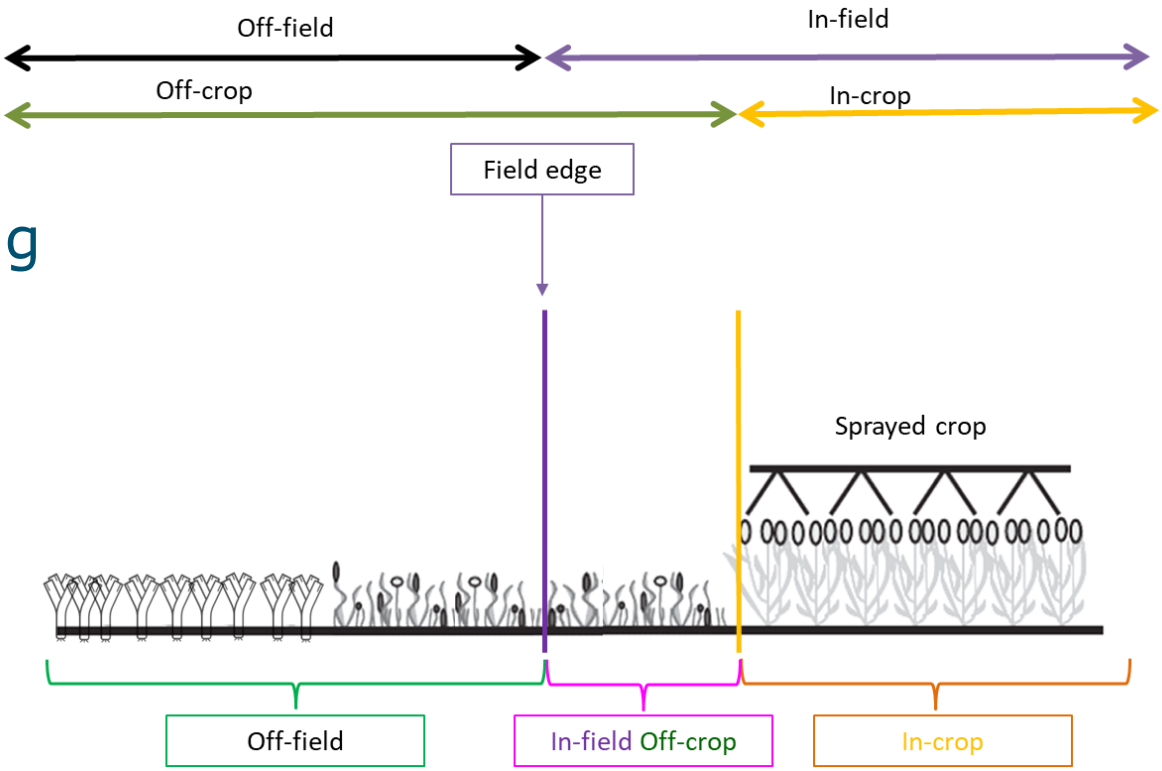


- Here:
  in-field ≠ in-crop,
  off-field ≠ off-crop

- Need for a clear definition, because the Protection Goal may not be the same in all three areas

Definition of in-field, off-field, in-crop, off-crop

- Three areas with, in theory each having its own SPG :
  1. In-crop
  2. In-field off-crop
  3. Off-field



- The two off-crop areas do not necessarily share the same protection level

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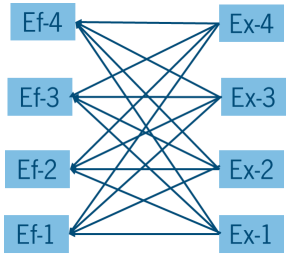

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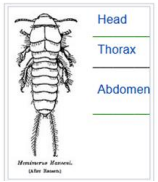

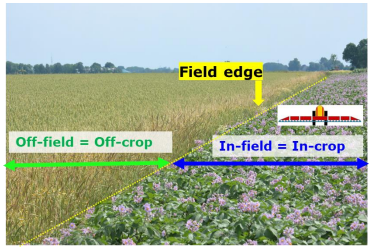

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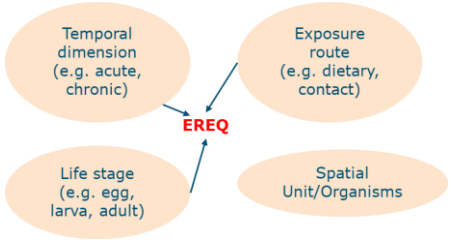
Conclusions

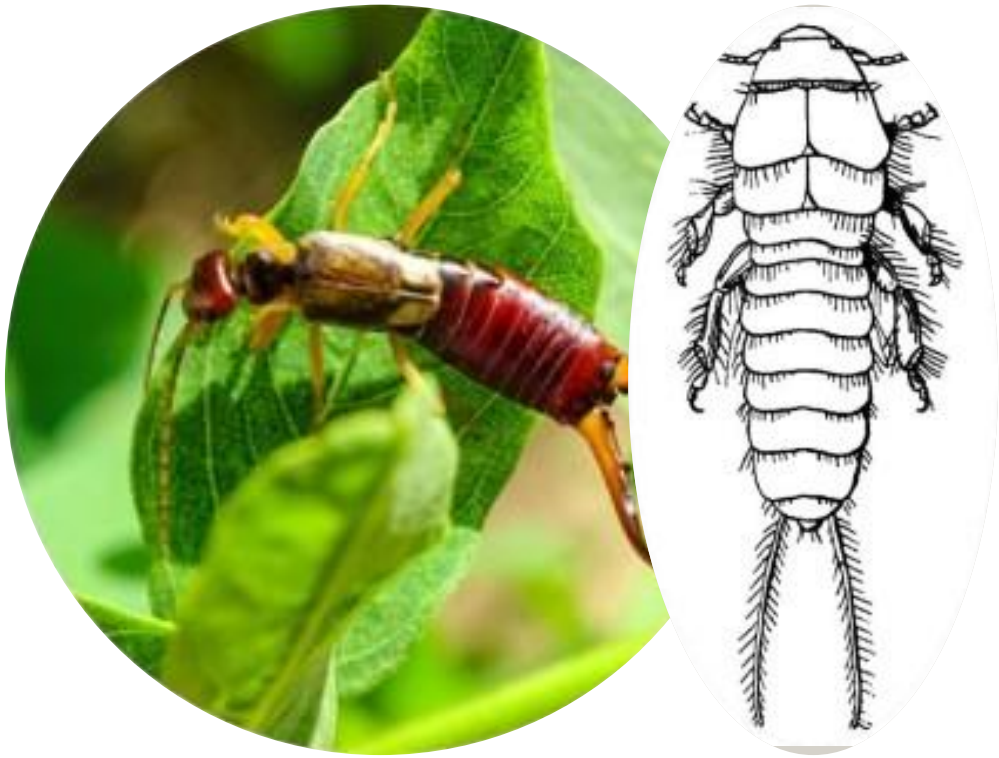
- Linking of exposure and effect tiers
  - Well established based on EREQ and its temporal dimension
  - Requires two types of exposure assessment: one for the area of use of pesticide and one for the ecotoxicological effect studies
- The EREQ concept improves communication between experts of various backgrounds, and therefore,
  it improves the quality of risk assessments
- For NTAs: much work still to be done
- Clear definition of in-field, off-field, in-crop, off-crop required



Ecotoxicologically

Relevant Exposure

Quantity for organisms



Thanks for the contributions of:

colleagues Steven Droge, Bas Buddendorf, Mechteld ter Horst

many colleagues from EFSA

Selected literature

- Boesten et al, 2007. Conceptual model for improving the link between exposure and effects in the aquatic risk assessment.
- EFSA, 2010. Scientific opinion on the development of specific protection goal options for environmental risk assessment of pesticides.
- EFSA, 2017. Guidance document for predicting environmental concentrations of a.i.’s and transformation products in soil
- Adriaanse et al, 2022. Supporting the development of exposure assessment scenarios for Non-Target Terrestrial Organisms to PPPs. Development of ExAGs.

Abbreviations

- EfAG – Effect Assessment Goal
- EFSA – European Food Safety Authority
- EREQ – Ecotoxicologically Relevant Exposure Quantity
- ExAG – Exposure Assessment Goal
- NTA – Non-Target Arthropod
- SPG – Specific Protection Goal
- SRT – Surrogate Reference Tier
- SU – Spatial Unit