

Workshop on the development of a fit-for-purpose approach for assessing the risk of low-concern active substances.

Agenda

15-16 January 2025

08:30-17:30 / 08:30-12:00



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Example of application to LCAS: case studies presentations

Inorganic substances with insecticidal activity

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INTRODUCTION... ***BACKGROUND INFORMATION...***

Previous talks covered the proposed approach, along with the conclusions and recommendations.

This approach is illustrated with case studies

Assessment is mainly conceived for toxic, synthetic chemicals not
Address Low Concern Active Substances (LCASs)

- **LCASs such as botanicals, semiochemicals, microbial metabolites, inorganics, peptides and dsRNA, exhibit specific characteristics. Their data requirements and risk assessment approaches do not always align with their use patterns or modes of action.**
- **A fit-for-purpose risk assessment scheme was developed based on the concept of problem formulation (PF) and pathways to breach the protection goals (PBPGs).**
- **Generic PBPGs and accompanying analysis plans were developed for each LCASs group**

Aim:

- To illustrate how the proposed problem formulation approach can be applied in practice for the environmental risk assessment.
- The case studies are based on existing types of substances, *but*
***THEY ARE PURELY HYPOTHETICAL AND
NOT MEANT TO SERVE AS AN ACTUAL RISK ASSESSMENT***
- For this purpose, we assume that the assessment is in the pre-submission phase. That means that the PBPGs are initially used to determine the approach and certify the first steps for informing the risk assessment. once new information becomes available, the applicant would need to update the PBPG approach to determine the next steps.

CASE STUDIES

- *Focus on only three different relevant PBPGs (to best illustrate the approach)*
- *For a complete risk assessment, all potentially relevant PBPGs for a substance must also be addressed*

The hypothetical case studies are based on three different categories:

- **an inorganic substance with insecticidal activity**
- **an oily substance (plant extract) with insecticidal activity**
- **a microbial metabolite with insecticidal activity**

INORGANIC SUBSTANCES WITH INSECTICIDAL ACTIVITY

INORGANIC SUBSTANCES WITH INSECTICIDAL ACTIVITY

- Various inorganic substances can have an insecticidal activity.
- The mode of action of inorganic substances is not based on toxicity.
- Based on the properties, the PBPGs (toxicity, desiccation, leaching) indicated in figure 1 (*next slide*) are potentially relevant.
- Although the mode of action of these substances is not based on toxicity, they may be toxic to non-target organisms.

PBPGs for toxicity should be included for these substances.

GENERIC PBPGs FOR AN INORGANIC SUBSTANCE

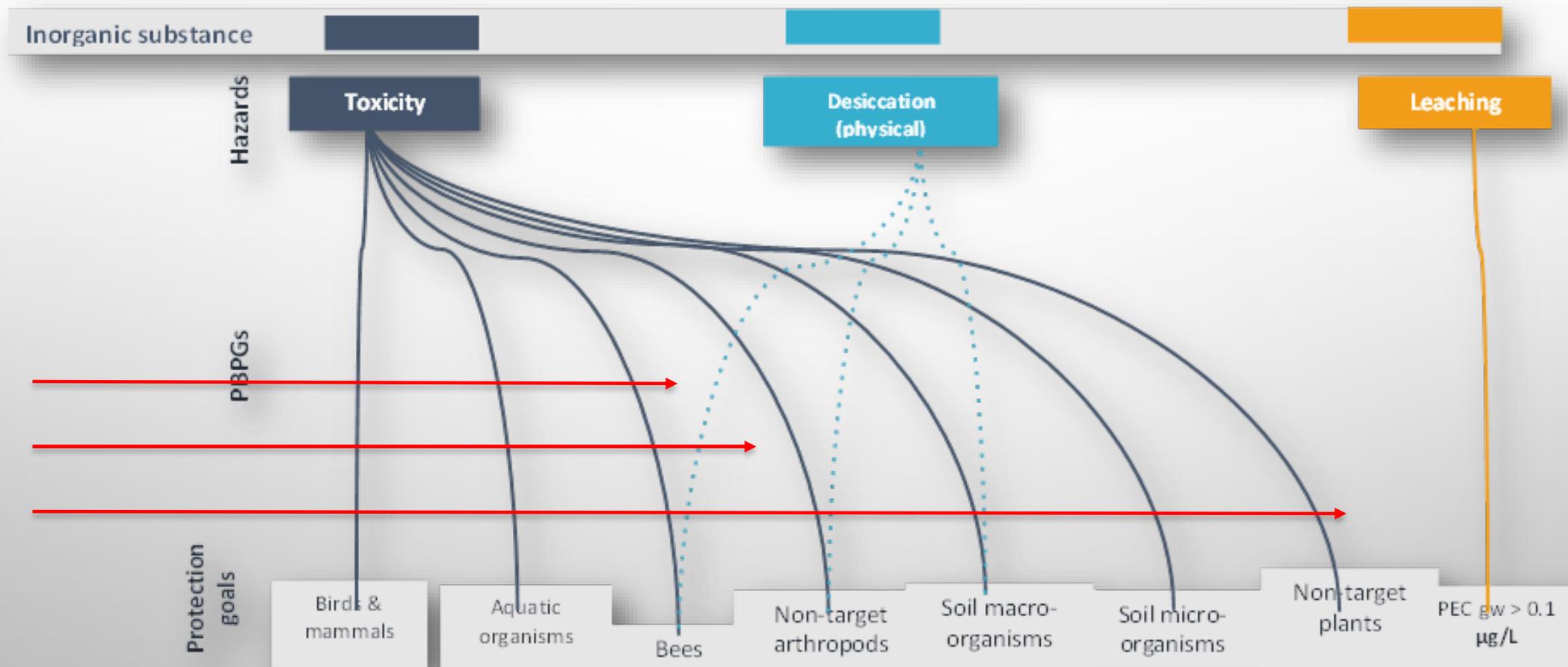


Figure 1: Overview figure of all PBPGs for NTOs and groundwater. For inorganic substances, the PBPGs as indicated in the grey bar at the top of the figure are in principle relevant. This case study focuses on the three PBPGs indicated with red arrows.

SPECIFIC CASE STUDIES FOR INORGANIC SUBSTANCES

Focus on three different PBPGs:

- PBPG for toxicity to in-field non-target arthropods
- PBPG for desiccation to in-field non-target arthropods
- PBPG for leaching to groundwater



PBPGs FOR TOXICITY TO IN-FIELD NON-TARGET ARTHROPODS

PBPG FOR TOXICITY TO IN-FIELD NON-TARGET ARTHROPODS OTHER THAN BEES

1: Use of PPP containing active substance

2: In-field NTAs are exposed to active substance

highly likely

3: Components in the active substance are toxic to NTAs at relevant concentrations

highly unlikely

4: Individual NTAs are affected by active substance/component(s) under field conditions

highly unlikely

5: Toxicity is sufficient to affect NTAs at population level

negligible

6: The potential for recolonization/recovery is affected

negligible

Harm: no potential for recolonization/recovery by non-target arthropods within a year (but preferably in a shorter period depending on the biology of the species)

negligible

Comments:

Based on

- the available information on the substance's properties,
- its natural occurrence and subsequent exposure of arthropods,
- the absence of evidence suggesting toxicity to arthropods from this natural exposure, and
- the fact that the quantities being introduced into the environment are minimal compared to those already present,

events 3 and 4 are considered highly unlikely.

- Based on the same reasoning, the likelihood of subsequent steps in the PBPG is assessed as negligible.
- Depending on the level of uncertainty in this assessment (e.g., based on the extent of the available knowledge regarding the substance and the natural exposure of arthropods), this information may be sufficient **to conclude that the likelihood of exceeding the protection goal for in-field non-target arthropods due to toxicity hazards is negligible. In this case, no further information would be needed for the assessment of this PBPG.**

PBPGS FOR DESICCATION TO IN-FIELD NON-TARGET ARTHROPODS

PBPG FOR DESICCATION (PHYSICAL EFFECT) OF IN FIELD NON-TARGET ARTHROPODS OTHER THAN BEES

1: Use of PPP containing active substance

2: Particles of the active substance cause damage to the cuticle of the NTOs

highly likely

3: Non-target arthropods are exposed to the active substance

highly likely

4: Individual arthropods are affected by the active substance under field conditions

highly likely

5: Effects of desiccation are sufficient to affect non-target arthropods at population level

likely

6. The potential for recolonization/recovery is affected

unlikely

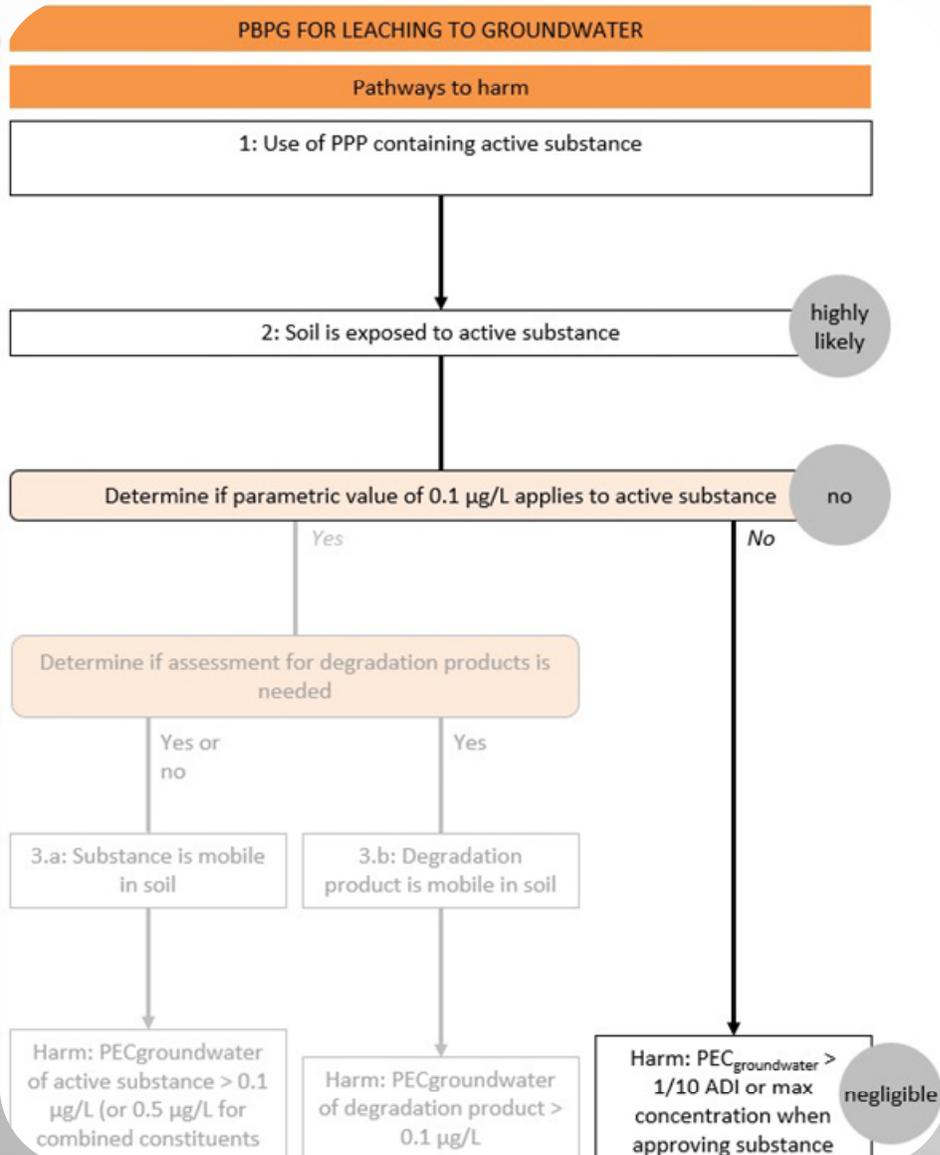
Harm: no potential for recolonization/recovery by non-target arthropods within a year (but preferably in a shorter period depending on the biology -seasonal pattern- of the species)

unknown

Comments:

- Event 2 is highly likely, as particles of this inorganic substance can be sufficiently abrasive and can absorb lipids, causing damage to the cuticle of arthropods.
- Event 3 (exposure) is also highly likely due to the proposed use.
- Event 4 (individual arthropods are affected) is assessed as highly likely based on information on the efficacy.
- Event 5 (effects of desiccation at population level) is likely to occur; the effects of this active substance are not expected to be specific and thereby not only affect the target.
- Event 6, the likelihood of being affected the inherent capacity of the population to recover or recolonize is assessed as unlikely, as for example a rain-event will cause the substance to be removed to the soil layer thereby losing its insecticidal effect. Also, not all life stages of populations are likely to be affected.
- Taken together, the available information is not yet sufficient to assess the likelihood of breaching this protection goal due to the hazard of desiccation (resulting in an 'unknown' likelihood for the last event in the PBPG).

PBPGS FOR LEACHING TO GROUNDWATER



Comments:

- The generic PBPG for leaching to groundwater is given.
- As the substance is not an organic substance, the parametric value of 0.10 µg/l is not applicable (Directive (EU) 2020/2184, Annex I Part B).
- Furthermore, as this substance consists of insoluble particles the conventional calculation models to determine predicted concentrations in groundwater are not appropriate.
- **Given these facts and the information that the substance occurs naturally in soils in relevant concentrations and there are no indications for leaching to ground water, no further information may be needed to address this pathway. Information on the physical-chemical properties of the substance and its natural occurrence - should be provided to substantiate this statement.**

CONCLUSIONS AND FUTURE PROSPECTS

- **By using the PBPG-approach, it is clear that the hazards which apply to an inorganic substance are not the same as the hazards which apply to conventional chemicals.**
- **For the hazard of desiccation, a risk assessment scheme is currently not available (in contrast to the assessment for the toxicity hazard). It is unclear if the testing approaches and the interpretation of the results used for the risk assessment scheme of toxicity are also appropriate for desiccation hazard**
- **In the absence of a risk assessment scheme, if the available body of knowledge is not sufficient to evaluate the likelihood of exceeding the protection goal, field studies are currently the only option to assess whether the effects of desiccation are acceptable.**

CONCLUSIONS AND FUTURE PROSPECTS

- **To address the hazard of desiccation, lower tier tests and a tiered risk assessment scheme (including sensitive species and acceptable effect levels) could be developed.**
- **The first step in evaluating the need for such a risk assessment scheme could involve assessing the available information on the likelihood of exceeding protection goals for non-target organisms (NTO) due to desiccation, based on prior experience with this type of substance..**



ΑΡΙΣΤΟΤΕΛΕΙΟ
ΠΑΝΕΠΙΣΤΗΜΙΟ
ΘΕΣΣΑΛΟΝΙΚΗΣ



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Thank you

