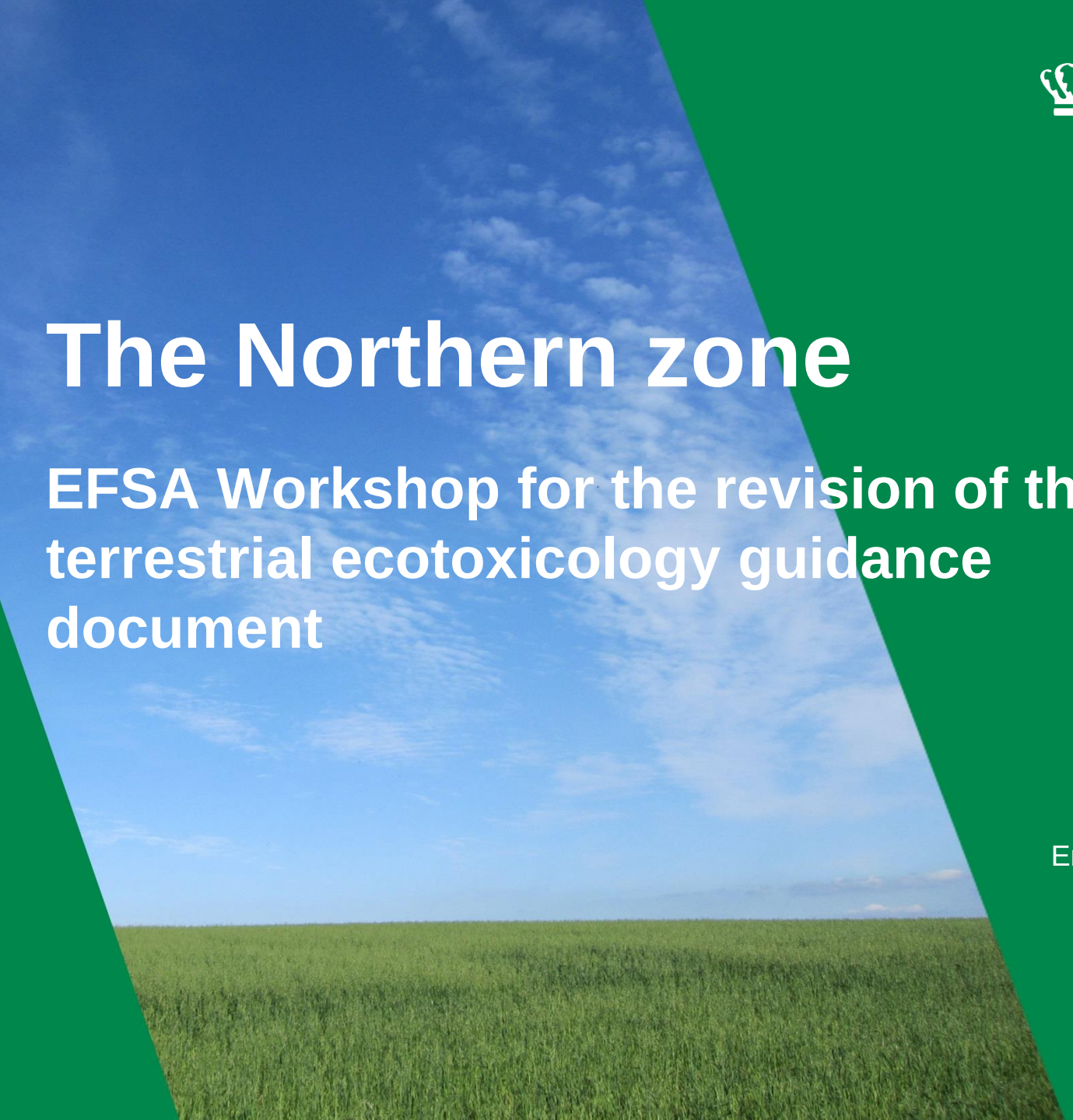

Ministry of Environment of Denmark
Environmental Protection Agency

The Northern zone

EFSA Workshop for the revision of the terrestrial ecotoxicology guidance document

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Todays contents - brief outline

- **Current state of terrestrial risk assessment in the Northern Zone**

- **Questions and expectations for the revision to the working group**
  - **general points about the future risk assessment**
  - **about test strategy and guidelines**

Terrestrial risk assessment (RA) in the Northern zone

- **In general NZ follows the EU approach with very few zonal or national specificities primarily based on climate**

- **Northern Zone cooperation (NZ guidance document updated every year) explains zonal or national specificities**

- **NZ requirements :**

  - **Use of the Nordic PECsoil calculator in risk assessments**
  - **Vegetation Distribution Factor of 5 instead of 10 for Non Target arthropods**

Terrestrial risk assessment (RA) in the Northern zone

- **Not always zonal agreement !**
  - **Sometimes there is no consensus on an endpoint (EU agreed vs refined endpoint), hence all "national" options must be included in the risk assessment**
  - **Sometimes there are issues with "tillage" refinements in PECsoil calculations (PECplateau calculated on 20 cm soil depth) now that no till farming is becoming more and more relevant in some countries. Different approaches are followed.**
  - **Issues with recolonization - when is it too late to recolonize, colder climate for the most northern countries?**

Questions and expectations to the WG and future guidance

→ general points about the future risk assessment

- **There is a wish for a tiered approach as an intermediate step between tier 1 RA and field studies**
- **In general, it would be appreciated to harmonize the risk metrics between the different risk assessment areas so that the direction is always interpreted the same (e.g., HQ vs. TER).**
- **In general, the new guidance should avoid unnecessary complexity, e.g. in exposure estimates (skip pore water concentrations?).**
- **There is a need for an updated exposure assessment (inclusion of PERSAM PECsoil calculator; Spray drift scenarios)**
- **No-till farming systems have beneficial effects for soil organisms, but less mixing of the soil means higher PECsoil values. How to incorporate no-till or reduced tillage systems (increasing in many MS in the EU) in the risk assessment?**

Questions and expectations to the WG and future guidance

→ general points about the future risk assessment

- **Testing on natural soils vs. artificial soils. How to deal with different test media and what to recommend? Natural soils as "higher tier"?**
- **A factor 2 for correction of endpoints from studies performed in artificial soil is recommended for a.s. with log Kow >2, regardless of OC content, unless it is demonstrated that toxicity is not dependent on sorption. But in EFSA recurring issues, the correction is done by default. This inconsistency should be clarified.**
- **Field studies: how to extrapolate field study results between zones with different climates? There might be guidance available already in different documents.**
- **Recolonisation when effects are shown in higher tier studies: how to evaluate it, and what should be acceptable? Different for each zone?**

Questions and expectations to the WG and future guidance

→ general points about the future risk assessment

- **How to assess the risk of soil metabolites? When and how is it covered by RA for parent compounds ?**

- **How to deal with mixture toxicity /cumulative risk assessment of products containing more than one active, and what of metabolites?**

- **Non-target terrestrial plants: no testing is required on reproductive output of plants (e.g. flowering and seed production). This should be included in future risk assessment (Strandberg *et al.*, 2019 (1)).**

  (1) Strandberg *et al.*, 2019. The Danish Environmental Protection Agency / Pesticide effects on non-target terrestrial plants at individual, population and ecosystem level (PENTA)

- **"case-specific": How to risk assess potential residues of pesticides and metabolites (e.g. plant metabolites) in plant material remaining in the fields after harvest? example of pesticides used for desiccation of potatoes - the plant is not removed from the field, hence the "intercepted" part of the applied dose remains in principle in the soil.**

Questions and expectations to the WG and future guidance

→ about test strategy and guidelines

- **Should the GD be written in a way that allows inclusion of future test methods and species?**
  - ***at the moment only OECD guideline on Eisenia fetida (reproduction) is available, and revised ISO guideline (feb 2023) including two species A. caliginosa and D. rubidus***
  - ***if/when in the future new guidelines or publications on additional species become available, it would be a good idea to have the possibility to include them e.g. give general validation criteria/ accept 'best available method'?***

- **Earthworms: indications from literature that *E.fetida / andrei* may be less sensitive to pesticides compared to other species for chronic effects (reviewed in EFSA SciOP, 2017), and is absent from the fields. Is *E. fetida* the right tier 1 species?**

- **Selection of standard species should take into account available knowledge on its sensitivity, and assessment factors (AF) should be reviewed/calibrated accordingly. Calibration is also needed so that it covers enchytraeids (also proposed in EFSA SciOP (2017).**

Questions and expectations to the WG and future guidance

→ about test strategy and guidelines

- **Correction for mortality in control (using Abbott's formula) is traditionally done just for NTAs, although the same logic could apply to other soil organisms. Discuss the inconsistencies and whether the correction is needed at all.**

- **Soil organisms: guidance is needed on whether measurements of a.s. concentrations (and metabolites) is required, and at what times. The available OECD guidelines are not always consistent about when analytical verification of the nominal dose is needed. Very different from aquatic …**

Thank you for your attention

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