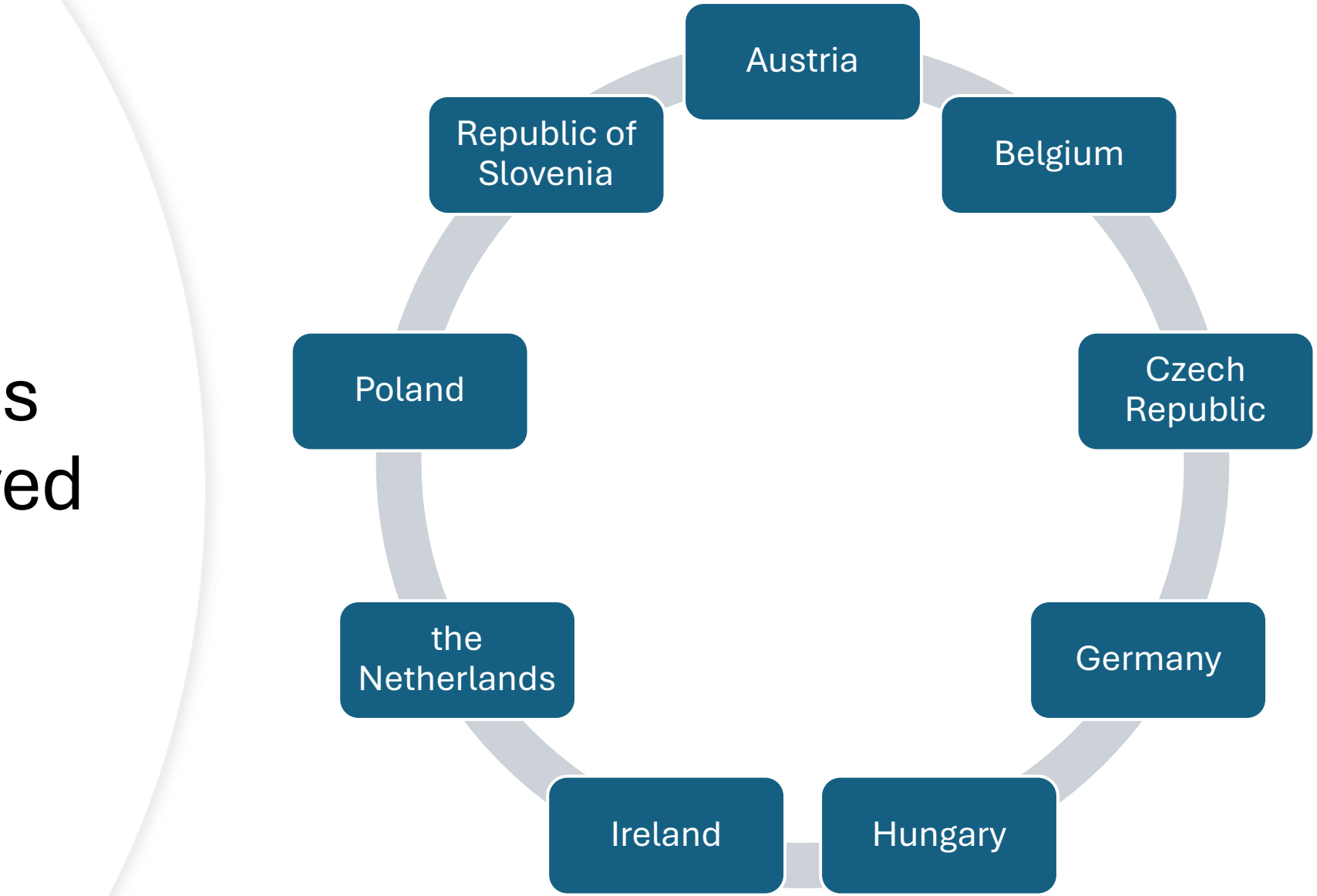
Revision of the terrestrial ecotoxicology guidance document, including indirect effects

Central zone MS Opinions and Expectations

Central zone Member states actively involved in the discussions



Scope of the revision

Incremental (brush up of SANCO/10329/2002)

- We have collected an extensive list with well-known shortcomings, which need implementation
- Suggestions for some extra points which would need to be addressed in the future

=> All details are available in an Annex to the presentation

Complete overhaul (structurally as well as conceptually)

- Holistic assessment to address direct and indirect effects in one assessment
- Combine all groups of non-target terrestrial organisms (except vertebrates and honey-bees) in one assessment
- Differentiate between exposure routes (above ground vs. below ground)
- Some czMSs would address the in-field risk as well as the off-field risk for all non-target terrestrial organisms (for NTTP only off-field is addressed)
- Consider effects of risk management options in the risk assessment

Scope of the revision

Monumental undertaking, both daunting in scale and difficulty.

czMSs emphasized the importance of maintaining an open mind and adopting pragmatic decisions and approaches to ensure the development of a workable document.

=> There is a need to make key decisions/definitions early in the development process.

Definition of the SPGs

Incremental

- Nature of the SPG needs to be defined
- SPGs for the different organism groups are the most sensitive species covered
- SPGs should consider the diverse life histories (developmental stages may differ vastly in their sensitivities)

Complete overhaul

- Nature of the SPG needs to be defined
- Calibration of SPGs to cover direct and indirect effects
- Validation of SPGs where possible (with available data during the development and after the implementation in a “phytopharmacovigilance” approach)
- Landscape level assessment addressing source sink dynamics (“sources” as part of the management options)
- In-field and off-field – in-field needs to be adequately addressed and off-field needs a high level of protection
- Temporal component (community level)

In conclusion

The czMember states urge the development of a …

- Scientifically up to date
- Scientifically sound
- Protective
- Future proof
- Workable (where necessary pragmatic; reduced complexity)

…Guidance document

Relevant Data collections

MS	Source / Type
AT	ÖPUL – Governmental monitoring schemes (biodiversity, gras development, timing of flower phenology, great bustard monitoring)
DE	Method to assess the effects on biodiversity: “Impact of pesticides on in-field non-target plants and arthropods with consequences for “food-web-support” – expanded risk assessment method for national product authorisation in Germany” 2022
DE	Assessing in-field pesticide effects under European regulation and its implications for biodiversity: a workshop report | Environmental Sciences Europe (springer.com)
DE	Preliminary Work on NTTP Guidance Revision – ongoing UBA Project (finalisation envisaged mid of 2025)
DE	Soil: Draft of an OECD field test procedure: Necessary adaptations for a harmonized fieldtesting procedure and risk assessment of earthworms (terrestrial) | Umweltbundesamt (2020)
DE	Soil: ETC HE Report 2022/6: Chemical risk indicator scoping study to develop an indicator on the risk of chemicals on ecosystems. — Eionet Portal (europa.eu)
DE	Soil: “Further development of toxicity tests with soil organisms - Sustainable protection of biodiversity in soils” (ongoing)
DE	Soil: “ERAMYC - Assessing the sensitivity of Arbuscular Mycorrhizal Fungi to chemicals in soil (finalisation envisaged mid 2025)
DE	Soil: “MICROSOIL –Investigation of Alternative Test Methods to Correctly Assess the Impact of Plant Protection Products, Biocides and Pharmaceuticals on Soil Microorganisms (finalisation envisaged mid 2025)
DE	Soil: Agricultural soil monitoring in Germany (finalisation envisaged end of 2025)
SLOV	Wild bee species monitoring program
NL	Air-filter and oak leave residue monitoring scheme
PL	Insect count initiatives

ANNEX

- **NTA**

- Active substances with a special mode of action need to be addressed:
    - Physical mode of action: tests with dried residues do not address the risk of direct overspray
    - Ovicides – in majority of currently performed studies eggs are not exposed to the test item, new guideline or modification of existing protocols needed
    - Targeted at specific species (e.g. lepidoptera)
    - Systemic mode of action
    - Pheromones, microorganism, botanicals, RNAi should be addressed.

➔ New test guidelines are needed

- Active substances with a special formulation like seed treatment and granules need to be addressed
- Use of aged residue tests in in-field risk assessment:
    - acceptable recovery time criteria needed
    - recovery time in relation to intended GAP
    - life history traits of NTAs need to be regarded
    - the concept of “recovery” should be put to the test.
- Revision of VDF
- Introduction of an intermediate tier (terrestrial mesocosms)
- Guideline to evaluate NTA field studies
- The informative value of field studies has to be evaluated.
- Natural enemies (‘beneficials’): to be included in the risk assessment or not?
- The use of ER50 in the Tier 1 of the risk assessment of NTA and in consequence an ERC10 as reproduction effects can be considered long term effects
- Penalizing persistent substances
- Incentivizing highly specific substances

- NTA wish list

- Definitions of recovery (actual or potential, via recolonisation or reproduction, taking into account landscape effects, what is an ecologically relevant period).
- Focus on in-crop effects
- Revision of current Tier 1 tests (are these sensitive enough and covering sufficient relevant taxonomic groups, feeding guilds, sensitive life stages, time scale (acute/chronic)?)
- Definition of crop specific species and off crop specific species
- Revision of current exposure routes (currently only contact, add oral and overspray route, are drift values still valid/appropriate, should volatilisation be considered as well)
- Accounting for landscape effects in the risk assessment (i.e. source-sink effects, influence of landscape on recovery, accumulative effects of PPP use, Exposure of NTAs feeding in-field and off-field (e.g. butterflies)).
- Guidance on evaluation of population models.
- Revision of current assessment factors (Tier 1 trigger still considered valid, AF for field studies)
- We should think about the effects of tank mixtures and application sequence of plant protection products.
- Species Sensitivity Distribution: guidance needed on acceptability criteria HR5 and safety factor, and the approach to follow when the HR5 does not cover the most sensitive tested species

- **Soil**

- Correction factor of 2 for organic matter in soil organism toxicity tests: revision needed
- Analytical measurements of soil concentrations in Tier 1 lab studies: further harmonised implementation via guidance needed
- Adapted laboratory and/or field studies for seed treatments or bulb dipping treatments: recommendations in GD would be welcome
- Terrestrial mesocosm studies: potential for intermediate tier?
- Evaluation of field studies (soil meso- and macrofauna) (including the use of AF in risk assessment): further guidance and harmonisation needed
- Implementation of field studies that allow to assess the impact on soil organism communities- not only earthworms or separated microarthropods - as indicated in the Scientific Opinion Soil Organisms. Alignment with ERA aquatic organisms.
- Evaluation of soil nitrification studies - use of time interval for effect calculations: implementation of CZHW-agreement via guidance needed.
- Microorganisms: is the current test still timely
- Data requirements *Folsomia* and *Hypoaspis*
- Revision of current Tier 1 tests (are these sensitive enough and covering sufficient relevant taxonomic groups, feeding guilds, sensitive life stages, time scale (acute/chronic)?)
- Insufficient data on background levels and lack of toxicity data on soil organisms
- Multiple exposure should be considered in the tests according to the intended GAP
- Effects on soil organisms occur that can only be related to high concentrations – as in the upper cm of the soil. It is questionable, if the current standard soil depth of 5 cm is sufficiently protective since active substances do not instantly distribute till 5 cm (Toschki et al 2018)
- Inclusion of tests on soil fungi
- Mixture toxicity (occurrence of multiple residues in agricultural used soils should be considered)

- Soil wish list

- Soil meso-/macrofauna: Revision of current Tier 1 tests (are these sensitive enough and covering sufficient relevant taxonomic groups, feeding guilds, sensitive life stages ?). Expected effects in the field on soil communities should be possible based on lab-results.
- Soil micro-organisms:
  - Revision of current Tier 1 tests (Is a limit test & 25% effect level still considered appropriate; consideration of a more elaborate risk assessment in addition to only considering soil nitrification process; consideration of effects on soil fungi; introduction of other relevant, sensitive microbial effect parameters and/or structural endpoints (e.g. microbial biomass).)
  - Sequencing approach
- Revision of current exposure routes (relevant concentration for risk assessment (i.e. total or bioavailable) , inclusion of oral food uptake
- Guidance on the use of PECsoil, twa.
- Accounting for landscape effects in the risk assessment (i.e. source-sink effects(?), influence of landscape on recovery, accumulative effects of PPP use)
- Guidance on evaluation of population models.
- Revision of current assessment factors (Tier 1 trigger still considered valid, AF for field studies). The evaluation presented at SETAC Rome 2018 and Helsinki 2019 show that the currently used assessment factor is not protective enough.
- Persistent substances: additional requirements/risk assessment needed, other than the use of PECsoil, accumulation?
- Combination toxicity/formulation toxicity
- Species Sensitivity Distribution: guidance needed on acceptability criteria HC5 and safety factor, and the approach to follow when the HC5 does not cover the most sensitive tested species
- Inclusion of risk mitigation measures (e.g. strip application, precision framing, reduction of AWM, for permanent cultures: inclusion of grassland stripes, application every 2nd or 3rd year, inclusion of biodiversity strips for recolonization of treated & destroyed areas) and monitoring studies (see copper: effects occur after several years. Accumulation, multiple exposure over time)

- **NTTPs**

- Use of MAF
- Species Sensitivity Distribution: guidance needed on acceptability criteria HR5 and safety factor, and the approach to follow when the HR5 does not cover the most sensitive tested species
- Visual Phytotoxicity: guidance needed
- Deviation from test conditions (temperature, humidity, no of seeds/plants/pot): guidance needed
- Duration of the toxicity tests with plants (for potential delayed effect): guidance needed
- Combination toxicity/formulation toxicity
- Consideration of metabolites
- Choice of plant species in study (crops vs. weeds/herbs), also in relation to the MoA: guidance needed
- (Semi-)field studies: guidance needed
- Testing at growth stage other than the juvenile stage (e.g. reproduction)
- Calibration of the tiered approach to the field

- NTTP wish list
- Revision of appropriateness of the ER50 endpoint (EFSA opinion (2014): ER10 values)

- Revision of appropriateness of the safety factor of 5 on the endpoint used for risk assessment
- Tests with reproduction included: guidance needed. Plus, consideration of an appropriate endpoint for this test (ER10 and ER20 might be used instead of ER50)
- Extrapolation factor in relation to extrapolation from vegetative vigour to reproduction: guidance needed
- Herbicide effects on ferns, mosses, liverworts, hornworts, horsetails, lichens, mycorrhiza, terrestrial algae or woody species: guidance needed
- Revision of current exposure routes
- Persistent substances exposure through soil
- Consideration of a population modelling
- Consideration of local applications (consider new spraying techniques besides broadcast application)