

Collaboration on Environmental Risk Assessment in the Northern Zone

By Northern Zone Ecotox Expert Group, 2016.



Northern Zone:
Denmark, Estonia,
Finland, Iceland*,
Latvia, Lithuania,
Norway and Sweden.

* Not permanent in Northern Zone Ecotox Gr.

Introduction

This poster presents work and challenges in the Northern Zone (NZ) to harmonise the zonal approach for authorisation of plant protection products (PPP) according to 1107/2009. Close collaboration is established in response to short timelines, more complicated environmental risk assessments (ERA) and limited resources. Harmonisation requires establishment of expert fora among member states (MS) and development of common guidance that are of use to both applicants and risk assessors.

Harmonising the ERA among NZ MS has many advantages:

- consistent scientific requirements among NZ MS → more of the ERA can be placed in the core RR
- the dRR is easier for applicants to make → easier for the MS to assess
- fewer mistakes, due to agreed review process by cMS
- may serve as inspiration for other MS in the CZ and SZ

The NZ guidance documents (NZ, 2016 a) cover the areas where the NZ has developed specific guidance on ERA. Some of the scientific issues that have been in focus for zonal harmonisation in the NZ are highlighted below.

Environmental exposure

PEC_{gw}

- 9 scenarios are used in the Northern Zone (2 EU FOCUS and 7 national MACRO scenarios)
- Two "groundwater projects" have been conducted (2013 and 2015) → find out if some scenarios could cover several MS's (rank scenarios and identify a worst case) and reduce the number of scenarios required for the NZ.

Results:

- Scenarios not very representative for true soil and climate conditions in the zone. Largely due to the age of the weather data and deficient soil characteristic data → But the scenarios were protective
- Not possible to rank the scenarios from best to worst since ranking depended on substance properties → No harmonisation of a worst case scenario (tier 1)
- Harmonisation after groundwater projects: NO and SE agreed on 4 scenarios (3 SE and 1 NO scenarios)

PEC_{soil}

- The "Finnish PEC_{soil} calculator" is common for all MS
- A new "Nordic PEC_{soil} calculator" which can handle both SFO, DFOP and FOMC kinetics is being developed. The calculator provides all output needed for the assessment

PEC_{sw} – risk mitigation measures

- All MS that require R-scenarios use a 10 m vegetative filter strip as risk mitigation
- Drift buffer zones are not harmonised
- Drift reducing nozzles is not an option in all MS → Projects needed to implement this measure in MS

Aquatic organisms

Harmonised higher tier refinements for NZ risk assessment, if a Tier 1 risk assessment following EFSA Aquatic GD (2013) does not address the risk.

FATE

- Refinements based on **time variable exposures** (e.g. pulse durations and/or intervals between pulses) are **not accepted**
- high uncertainty with FOCUS peaks
 - pulsed exposure highly species specific and dependent on sensitive life stages and/or different life strategies

ECOTOX

- **PECT_{wa}** not accepted in acute risk assessment
- **Geometric mean** should always be assisted by WoE approach
- **Fish, long-term:** geometric mean or median HC₅ is not accepted
- **Invertebrate, long-term:** for the geometric mean derivation only EC₁₀ from LoEP are accepted
- **Mesocosm studies:** RAC shall be based on Ecological Threshold Option (ETO); except DK (ERO)
- **Ecological modelling:** not accepted until agreed models available at EU level

Mitigation

Risk mitigation measures for each NZ MS should be presented based on country specific scenarios

Birds and Mammals

First tier risk assessment

- EFSA Guidance Document (2009)
- Maize (late BBCH): Willow Warbler should be added to the list of species
- If the first tier risk assessment indicates risk, higher tier...

Higher tier risk assessment

- Northern Zone guidance document for birds and mammals (NZ, 2016 b)
- A spreadsheet is available to facilitate calculations with agreed refinements
- Available at the Danish EPA web: <http://eng.mst.dk/media/165037/bird-mammal-scenario-template-v10-4.xlsm>

Harmonised approach considering:

- Crop and growth specific focal species, e.g. skylark, white wagtail and brown hare
- PD
- PT
- Residue levels and decline in food items
- Use of interception and dehulling data
- Non acceptance of refinements based on body burden- or ecological modelling until validated models and guidance are available at European level

Terrestrial organisms

Field studies

The acceptability/representativeness of field studies for **non-target arthropods** and **soil organisms** should be assessed for each MS

Earthworms and other soil organisms

LogK_{ow} > 2: endpoints should be divided by 2 even with study soils containing orgM <10%, unless accepted documentation is provided

QSAR

A QSAR endpoint for a metabolite can be accepted if it has been accepted at EU level

Non-target plants

- Interception as refinement for lowering the exposure not accepted
- MAF is applied according to Escort 2
- SSD: requires at least 10 species
- Deterministic risk assessment if HC₅ exceeds the EC₅₀ of the most sensitive species in the SSD

References

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