



Danish Ministry of the Environment
Environmental Protection Agency

Application and coordination of registrations in the Nordic/Baltic zone

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Northern zone cooperation

- Regular teleconference
- Yearly meetings – face to face including experts
- Good cooperation between experts in different countries.
- **Northern zone Guidance Document** on the processes and risk assessment
- **Northern zone guidance on efficacy**
- **”Common” application and Completeness check form**



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Northern zone cooperation

Harmonisation projects sponsored by the **Nordic Council of Ministers**

- **Operator exposure** workshop
- Comparison of **Groundwater models** and **Scenarios**
- **Higher tier scenarios** for the risk assessment **for birds and mammals**
- Non-professional use workshop



General Challenges

- Timelines in 1107/2009 extremely strict, difficult to keep
- Resources in authorities (and industry)
- Allocation of Zonal-RMS
- Agreement on how and when to use Guidance documents and EFSA opinions



Quality of applications

Applications received in Northern-zone have been of varying quality

- Scientific quality not sufficient
- Format: has to follow Northern zone guidance, relevant crops for this zone. Biological Assessment Dossier (BAD), lacking summaries and tables
- Lack of focus of assessment (often too extensive)

Consequence if application is not acceptable:

Rejection at completeness check stage !



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Pre-submission meetings

Pre-submission meetings can be useful if applicant is well prepared

- Discussion on GAP
- Products
- Timelines
- Acceptable refinements/strategies



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Recommendations for draft assessment report (dRR)

- Focus on the relevant information for the N-zone uses and required core evaluations
- The core dRR for NZ should only include assessments for uses that are relevant for the zone
- Summaries/tables rather than repetition of EU assessment
- Summaries with pests and effects for all trials (e.g. summary schemes/tables) often lacking (Efficacy)



Common problems encountered

- Groundwater issues not properly addressed
- Unacceptable refinements for birds/mammals and aquatics
- Unacceptable refinements/extrapolations for operator exposure assessment
- Lack of appropriate dermal adsorption study
- Inappropriate reporting of residue data
- Not sufficient efficacy data/not adequately reported



Industry requests

- More information/feed back on decisions (e.g. concerning ZRMS)
- More harmonization – guidance should be followed !
- Need for Nordic core ? YES



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Fees in Denmark

Fee system established in 2014

Zonal application fees

- 15.000 DKK up front (Completeness check)
- Main fee 200-400.000 DKK

Minor use fee

- 8630 DKK (2015) (excl. MRL)



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Staff in Denmark

Internal/Danish EPA

Expertice	Staf
Fate & behaviour	4
Ecotoxicology	6
Toxicology	9
Administrative	4
Coordinator/heads	2

External

Expertice	Staf
MRL	2
Efficacy	3



Thank you

