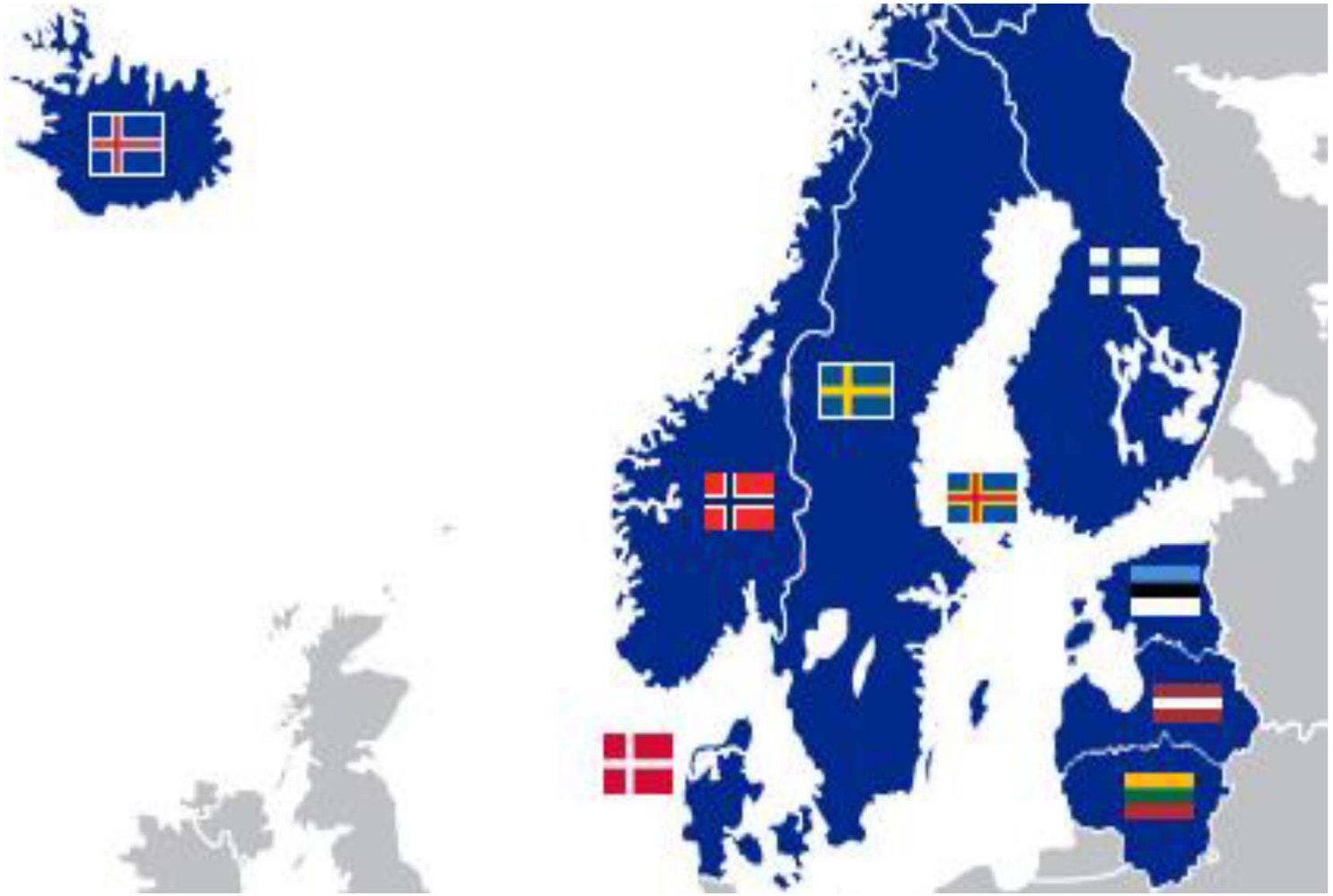
REPUBLIC OF ESTONIA
AGRICULTURE AND FOOD BOARD

Northern Zone view
update 2021

CropLife Europe Regulatory Conference

Eva Lind
Agriculture and Food Board
Head of Plant Protection and Fertilisers Department
10th March 2020

Northern Zone MS and worksharing



Calendar

- Teleconferences:
- 5-8 Steering Committee and Coordinators teleconferences per year.
- Expert group teleconferences – if needed
- Face-to-face meetings:
- Steering Committee – every year, 2020 online „face to face“ meeting
- Steering Committee and Expert group – every second year
- 2021 September (planned) - Steering Committee and Expert group meeting in Estonia

Guidance document on work-sharing in the Northern Zone (version 9.0, 2020)

- Updated every year with clear highlights of new information
- Last updates in NZ GD ver 9.0 include:
- Notifications
- Expiry dates of active substances within 12 month and following Art. 43
- Fate & behaviour: soil calculations; surface water
- Ecotox: interim approach for the risk assessment of bees pending revision of the EFSA guidance document; non-target plants
- Reporting table, national requierments, contacts

…

New version 10.0, 2021

- Currently under revision
- Amendments concerning the new version of guidance document on zonal evaluation and mutual recognition, withdrawal and amendment of authorisations (recently noted in SCPAFF)
- Other changes yet to be confirmed

Coordination of applications

- Applicant submits a preference of zRMS
- Committee decides based on:
- RMS of the active substance
- Relevance of the product in each country
- Availability of resources

Applicant is informed in due time about the appointed zRMS

All communication is directed to the appointed zRMS

- Post AIR planning: AIR IV a.s. PPPs allocated (SE). AIR V process not initiated yet

Article 43

- Different approaches in MS: assessment should be based on guidance documents at the time of dossier submission/time of application
- Assessment based on latest active substance endpoints
- Full dossier should be submitted, all exceptional cases need to be agreed with zRMS

Important to submit complete dossiers

- All FOCUS scenarios relevant to NZ MS must be submitted
- Only data relevant for the concerned countries/NZ should be presented
- Common issues: co-formulant information missing, insufficient dermal absorption studies, plant studies, bee studies, soil organism studies, mixture toxicity, efficacy: lack of split in NZ and other supporting data.

Harmonisation during Article 43

- Changes and amendments must fall within the Risk Envelope
- Must be covered by the efficacy and MRL data evaluated
- Non-significant formulation changes are accepted

We do not accept new uses that have not been previously authorised

Main challenges – EU level

- Slow decision making on approval and re-approval of actives
- ED assessment & „stop the clock“ mechanism
- Inconsistent assessment & inconsistent decisions
- Lack of agreement on scientific/EFSA level, e.g.
- Delays in adopting guidance documents (bee’s)
- Transition to using IUCLID

Main challenges – Zonal and National level

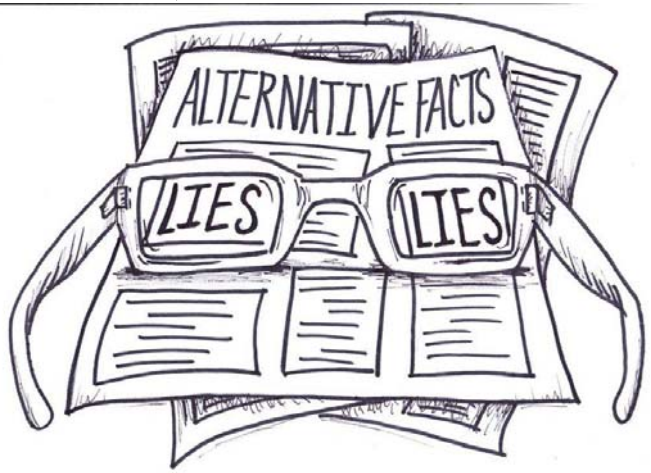
Product authorisations:

- Issues that should be resolved at EU level are transferred to zonal/national level (Confirmatory data & Cat. 4 data)
  - Classification changes - relevance of metabolites
  - Quality of dossiers
  - Work-planning (especially due to delays in a.s. decisions at EU-level)
  - Timelines, backlogs, capacity issues

Main challenges – Zonal and National level

Other issues:

- Public/political lack of trust - alternative facts/fake news
- Lack of products/restrictions
- COVID-19 – working arrangements, submission of documents



Why are we delayed?

- Workload for renewals and new applications
- Capacity in MS
- Quality of the dossier
- Communication between applicant and authority during evalua

I don't have time for new new year's resolutions, I'm still working on the backlog from 1998-2000.

Northern Zone

NZ meeting in Riga, November 2019

REPUBLIC OF ESTONIA
AGRICULTURE AND FOOD BOARD

Thank you!

Eva Lind
eva.lind@pta.agri.ee