Federal Ministry
of Food, Agriculture and
Consumer Protection

Summary of events on mutual recognition and the zonal approach in the EU

Steffen Beerbaum

Paris, 29. April 2010

Regulation 1107/09
new opportunities and new challenges

- to make this regulation work, new ways of cooperation between MS are necessary in the field of mutual recognition and autorisation in the zonal system
- two workshops were organised in Vilnius and in Braunschweig
- I will give an overview about the outcome of the workshops and try to highlight remaining challenges

Outcome of the workshops

Two guidance documents on how to organise the zonal authorisation and mutual recognition procedure and the renewal of authorisations

- Guidance document on zonal authorisations and mutual recognition under Regulation 1107/2009
- Guidance document on renewal, withdrawal and amendment of authorization under Regulation 1107/2009)

Zonal authorisations

Steering Committees

- communication within and between zones necessary
- one interzonal steering committee
- three zonal steering committees
- one zonal contact point per MS

Establish a permanent secretariat to organise meetings?

Zonal authorisations

Zonal Steering Committee - Tasks

- facilitate communication in work-sharing matters
- coordinate work sharing activities
- discuss general issues
- facilitate harmonisation of national risk assessements
- allocate evaluation work to MS (decide on ZRMS)

Zonal authorisations

Zonal Steering Committee – organisation

- each MS in the zone participates
- teleconference every 2 months
- face to face once a year
- meeting organisation on a year rotating basis by MS

Zonal authorisations

Interzonal Steering Committee – organisation

- coordination between zones
- share of evaluation work between MS, application for greenhouse use, post harvest treatment, seed treetment)
- 2 representatives from each zonal steering committee plus COM
- meet every 3 months
- once a year face to face

Zonal authorisations

Steering Committees - Challenges

- MS support fair distribution of evaluation work through steering committees – industry doesn‘t support this idea.

  Remaining question:

  What is legally possible and how to organise distribution of work?

Zonal authorisations

Database

- For managing zonal authorisations a database must be developed so that applicants and authorities can handle the authorisation work in a zonal system.
- CIRCA can only be an interim solution
- COM will provide information based on biocide database.

Zonal authorisations

industry application

- The application has to include a list of intended uses in each MS of the zone where an application has been made or is intended.
- Difficult to „control“

What happens with uses/MS that are added later?

Zonal authorisations

Regular application - timelines

- 1 year to complete the evaluation (plus 6 months if further info required)
- 8 months for ZRMS draft registration report
- 6 weeks for comments by other MS
- 2,5 months for final ZRMS reg. report + ZRMS authorisation
- 120 days for granting authorisation by other MS

Mutual recognition

- between MS belonging to the same zone
- between MS belonging to different zones
- between any MS for greenhouses, post harvest treatment and seed treetment
- MS have 120 days to decide on authorisation

Optional mutual recognition

- between MS belonging to different zones
- PPP contains a candidate for substitution
- the application contains a provisional authorisation
- the application contains a Art. 4 (7) substance

Special rules for mutual recognition

- mutual recognition authorisations must be identified and notified to the central database to avoid a „domino effect“

Harmonisation required

- The harmonisation of risk assessment was identified as very important in the context of the new regulation. Otherwise the cooperation and the trust in other MS‘s assessments might be difficult.
- Risk envelope, GAP, Efficacy, worker protection, greenhouses, national risk mitigation measures, environmental assessments were examples mentioned where harmonisation needs exist.
- English should/must be used as common language

Renewal of authorisations (1)

- Starting point: renewed approval of an active substance
- For mixed PPP the authorisation must be renewed after the renewal of each a.s.
- 3 months after renewal of a.s. renewal of PPP starts at the latest
- Authorisation holders have to apply within 3 months after renewal of a.s.
- Precondition: authorisation requirements are still met

Renewal of authorisations (2)

- At time of application for renewal of a.s., applicant shall inform ZRMS about intended PPP-authorisation renewals
- The ZRMS coordinates assessment (assessment can be done by other MS)
- The focus should be on changed critical endpoints due to new evaluated active substances
- They should be highlighted

Renewal of authorisations (3)

- The ZRMS should complete assessment after 6 months
- Focus on changed endpoints, guidance or data requirements, new conditions
- Based on assessement other MS renew (or not) within 3 months their authorisation.
- Comparative assessment has to be done on national level

Withdrawal/amendment of authorisations

- Information on withdrawal or amendment of an authorisation in one MS has to be sent to other MS, EFSA and COM
- => good information flow necessary (Email-system?)
- Before withdrawal the applicant should be informed and given the possibility to submit comments

Thank you for your attention!