Zonal Authorisation – Projects in Austria

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Introduction

- Legally binding zonal authorisation:

  For new applications after 14th June 2011

- "Pilot project":

  Voluntary for re-registrations of PPPs and new applications before 14th June 2011

Zonal authorisations - general (1)

- Legally binding by 14th June 2011 (according to Reg. 1107/2009)

- General considerations (1):

  - for applications of new PPPs (after 14th June 2011)
  - zRMS provides evaluation for the corresponding zone (exception: seed treatment, post harvest use, glasshouse use, empty store houses: only 1 zone)
  - Format: Draft Registration Report - dRR (recommended to be used by October 2010)

Zonal authorisations - general (2)

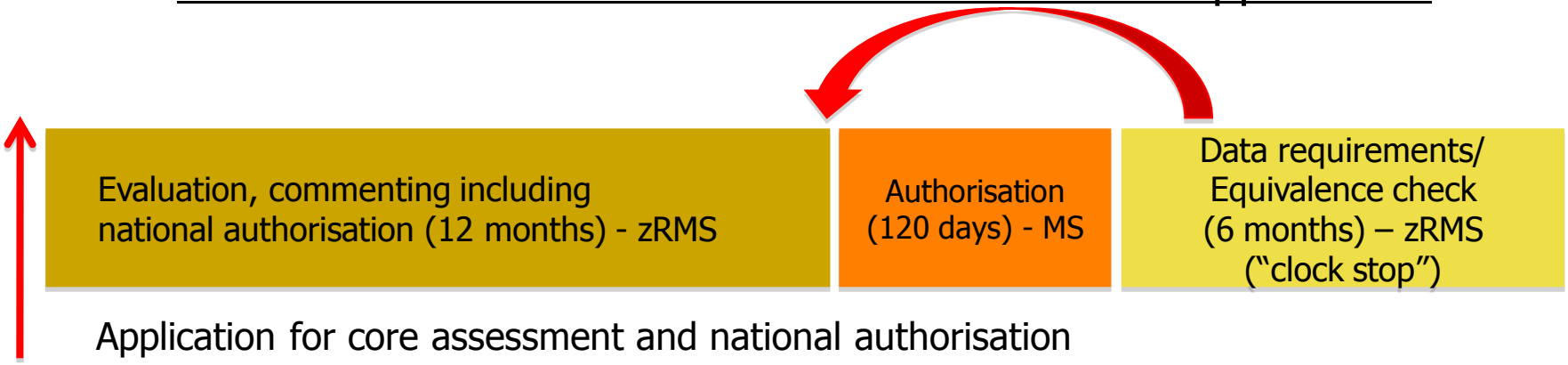
- General considerations (2):

  - "Risk envelope" to be applied – using the critical GAP (cGAP) for risk assessment (on discussion for a GD)
  - ALL intended uses within one zone to be covered
  - Commenting period: Comments from other MS including the applicant to be considered ("reporting table") – Peer Review
  - National registrations in other MS based on the assessment provided by zRMS ("Core Assessment")

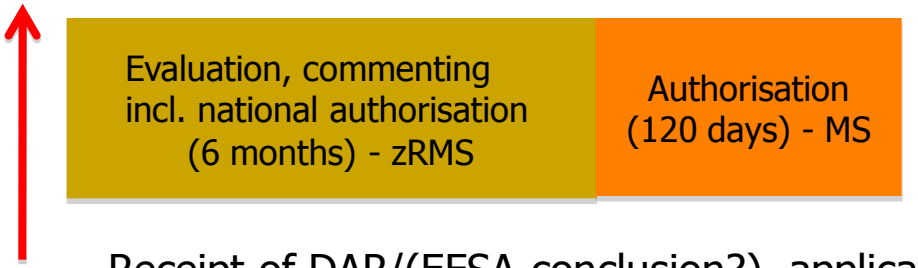
Zonal authorisations - general (3)

- Time frame (according to Reg. 1107/2009) :

  - PPPs with actives included in Annex I at time of application:



  - PPPs with actives not included in Annex I at time of application:



Zonal authorisations - general (4)

- Zonal Steering Committee:

  - Co-ordination body
  - Communication in work-sharing matters between MSs
  - general matters of risk management (not risk assesment)

  - Co-ordination of work sharing activities within and between zones
  - Role in the allocation of the Member State who will undertake the core evaluation (still under discussion!) *„competition" between MS*
  - General issues relating to the efficiency of the system
  - Facilitates the harmonisation of national risk assessments

„Pilot projects“ (1)

- Not legally binding (on voluntary basis) – but highly recommended by COM and (not all) MS
- Affected are:
  1. “new” applications before 14th June 2011
  2. All re-registrations (after 1st Annex 1 inclusion)
- Anticipation of procedures outlined in Reg. 1107/2009 (experience, see how the system works, time saving?)
- Follow timelines according to Reg. 1107/2009 as far as possible.

„Pilot projects“ (2)

- Current Austrian Projekts:

  - New applications before 14th June 2011:
    PPPs containing Cymoxanil, Metaldehyd,…

  - Re-registrations:
    PPPs containing Captan, Folpet, Pyrimethanil, Amidosulfuron, Fenoxaprop-P, Fluazinam

Lessons learned (1)

- GAPs:

  - Harmonisation of GAPs within the zone as far as possible
  - Changes of GAPs during evaluation should be avoided
  - Identification of cGAP (to be fixed at pre-submission meeting)
  - All intended uses to be adressed in Core assessment
  - Harmonised GAP table in progress (responsible MS: AT)

Lessons learned (2)

- <u>New Annex II data:</u>
  - Confirmatory data: to be evaluated by RMS (for Core assessment: await evaluation of RMS)
  - If new annex II data show more adverse risk assessment: to be evaluated by RMS (for Core assessment: await evaluation of RMS)
  - Any other new Annex II data: evaluated by RMS for re-newal of Annex I inclusion only

Lessons learned (3)

- MRLs:
  If a new MRL is necessary, a corresponding application to EFSA to be provided by zRMS as soon as possible in order to avoid delay of authorisation!

- Presubmission meeting is considered for smooth flow of evaluation (at least 2 months prior the application):
  - Solution of problems in advance of the evaluation (if any)
  - Documents to be submitted by the applicant at least 3 months prior the application

Lessons learned (4)

- Format: dRR recommended by October 2010 (for each product!)
- Setting of a reference specification is not an issue for Core assessment but for RMS
- If possible, a joint dossier should be applied (if different applicants have similar products and uses)

Challenges (1)

- Increased work load – how to handle it?

  - "External" solution: Co-operations with other MS (e.g. AT with SLOV, FRA)
  - "Internal" solution: Efficient co-ordination (primary contact point for the project, administration/management of data, transmission of information, time keeping,…)

- System is still developing: Active participation in expert meetings and in working groups!

Challenges (2)

- Commenting period:
  Already recommended and performed by AT (other MS, applicant) – system of transparency (reporting table as part of the Registration Report)

- Classification and labelling (harmonised approach):
  - Discussion paper prepared by AT in order to avoid different C & L of the same PPP in different MS
  - C & L according to 1272/2008 should be already considered now (legally binding for PPPs by 2015)

Challenges (3)

- Efficacy:
  - What is useful to be included into the Core assessment, what belongs to national addenda
  - Format: dRR or BAD (Biological Assessment Dossier)?
  - Harmonisation necessary (WG to be established, lead F)
- Harmonisation of national risk assessments
  harmonisation is necessary (see ECPA list with different national data requirements)
- Harmonisation of risk mitigation measures