Harmonisation in the zonal autorisation procedure: where do we stand and current needs

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Health and Consumers

("new") legislative framework:

Reg. 1107/2009 introduces

→ zonal authorization + mutual recognition

→ criteria for approval

→comparative assessment and substitution principle

data requirements:

Reg. 283/2013 + Communication 2013/C 95/01 (AS)

Reg. 284/2013 + Communication 2013/C 95/02 (PPP)

Zonal evaluation / mutual recognition – a policy choice

- A cornerstone of Reg 1107/2009 (*Art 40; also 41, 36)*
- Moves from 28 markets towards a common market *(→ Directive 91/414/EEC harmonised the safety standards, but not the market for PPP)*
- **Avoids duplication (multiplication) of work**
- is an intermediate solution, takes into account regulatory history in the EU

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Zonal evaluation / mutual recognition – a policy choice

3 zones *but …*

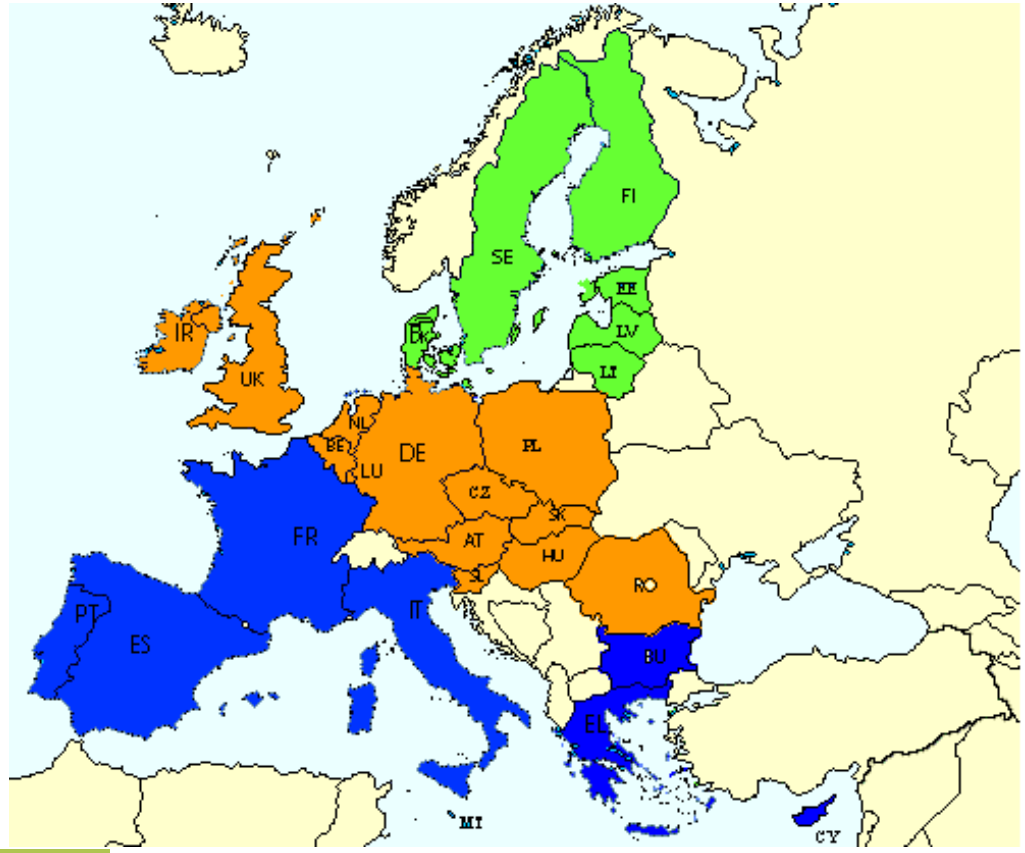
*…**one zone** for:*

greenhouse,

post-harvest,

storage and

seed treatment



Zonal evaluation / mutual recognition – a policy choice

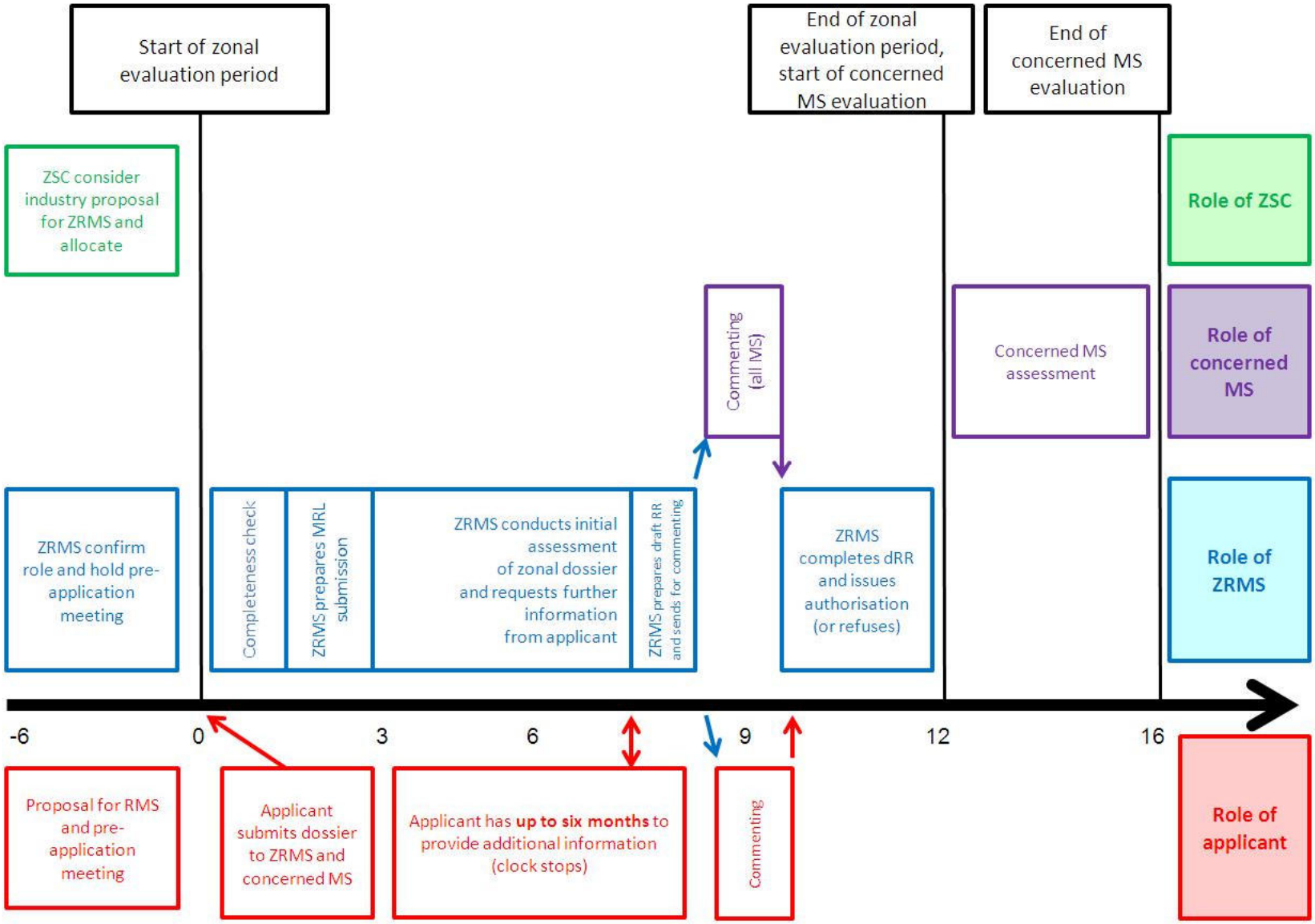
- ***Obligatory*** within a zone
- *Voluntary between zones*, for candidates for substitution, for provisional authorisations, for derogations under art. 4(7)

- Adapting risk mitigation measures is possible → addresses the specific situation in a MS
- Possibility to refuse mutual recognition if serious risk for HH or environment
- no need of consent of authorisation holder in case of a prevailing public interest

Zonal system – implementation (procedures)

- Guidance Document SANCO/13169/2010
  - Steering Committees (North, South, Center, Inter-Zonal)
  - Application and authorisation database
  - Pre-application (→ risk envelope approach), application, completeness check, evaluation
  - Harmonisation of RA medium term aim
  - Low risk products treated differently (GD will be updated)

Guidance Document SANCO/13169/2010 - overview



Zonal system – implementation (procedures)

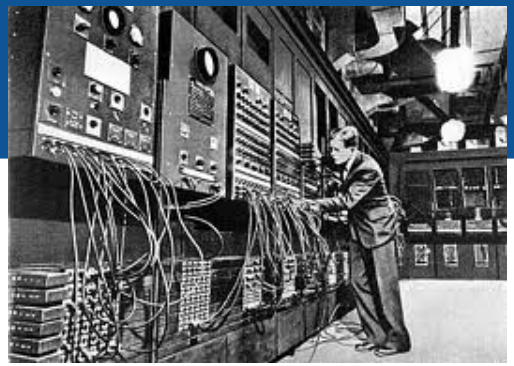
- Zonal/interzonal Steering Committees are operational
- SCs meet as foreseen by the GD (every 2nd month)
- Zonal guidance is gradually replacing national guidance
- Three expert groups streamline the zonal system:
  - Interzonal Steering Committee (izSC) – organisational
  - Post Approval Issues (PAI) – technical
  - Standing Committee (SCFCAH) - supervision
- On efficacy, cooperation with EPPO established

Zonal system – implementation (FEEDBACK)

- Recent analyses from industry and MS on the functioning → not yet working according to desire
- Yet, no thorough analysis: figures presented too divergent
- Complexity of the zonal vs. national authorisation:
  - Failure to comply with deadlines
  - Resource problems
  - Lack of streamlining in the procedure
- COM dedicated to the principle of mutual recognition and keen to enhance the functioning

Implementation: support + tools for exchange of information

- authorisation database
- CIRCA BC – cooperation / communication platform
- Harmonisation of RA: e.g. workshops like this one



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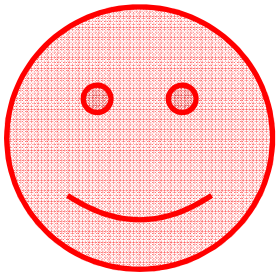
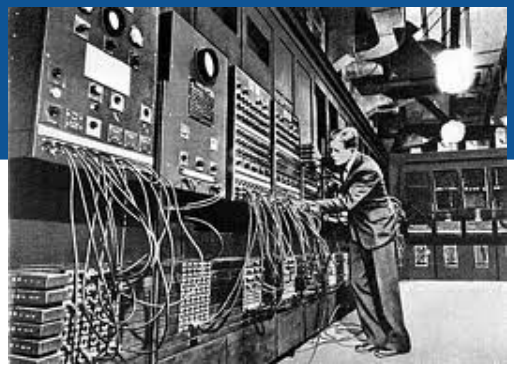
Authorisation Database

- Last testing done (June 2014)
- Publication planned September 2014





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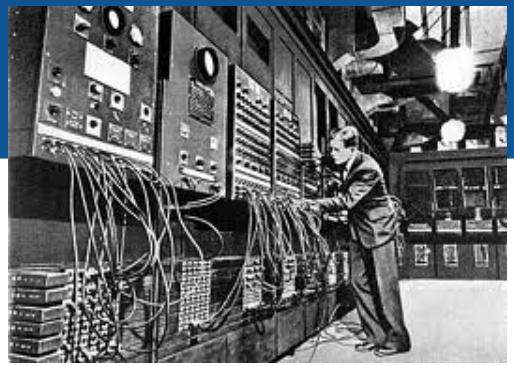
Authorisation Database

- Portal: new data entries are minimsed, links with national databases
- Modular: 1st Module (authorisation/ mutual recognition):
  - Product management
  - Follow-up of application process
  - e-mail notifications
  - User management
  - User interface
  - pre-submission phase *(added recently!)*



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Authorisation Database

- What next?
  - Training ("Train the trainer" + conferences)
  - Incorporate existing entries from MS databases
  - Expand existing EPPO codes
  - Expand pre-submission module
  - Implement other modules (amendment of authorisation, minor uses…)
  - Publish catalogue of EU authorisations

CIRCA BC

- communication / document sharing tool
- available to all registered CIRCA BC members for the PPP / Residues sectors.
- structure developed with in the SC (public / restricted areas)
- Newsgroup function: e.g. to post questions, interactions between RA

Technical issues

New data requirements (DR)

- New data requirements published in April 2013
- Communications (detailing test guidelines and guidances) to be updated regularly

  → new test guidelines and GD to be added to Communications where applicable

Technical issues

New data requirements (DR)

- Apply to all AS and PPP dossiers as from 1 January 2016

- Current transitional measures create problems for:
  - PPP dossier submissions after 1 January 2016, for PPPs containing AS which dossiers were submitted according to the old DR (and not yet renewed)
  - if new DR would be applicable to these AS dossiers, the new information would be non-EU-peer-reviewed

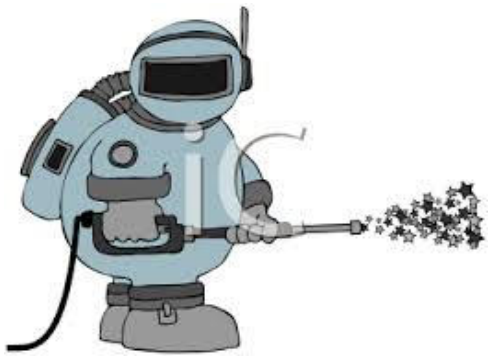
Technical issues

New data requirements (DR)

- **Amending Regulation** voted in SCFCAH in March, scrutiny of the EP on-going till Oct. 2014 (EP recess)
- **Amended GD** to be taken note once amending Regulation is published
- old DR exceptionally continue to apply to *AS dossiers in PPP submissions which were evaluated according to the old DR* (and not yet renewed)
- new data requirements ALWAYS apply for PPP dossier (as foreseen)

Further technical (content) issues

- Endocrine disruptors
- Negligible exposure
- Candidates for substitution
- Update of guidance documents



Conclusion

- harmonisation of RA is key → importance of GDs, also for "one-zone issues" like seed treatments
- communication between MS is essential
- structures to support this available → potential needs are encouraged to be raised via e.g. izSC

Thank you!

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