

Austria's experience Chair of the Central Zone - 2013

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Outline

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3. Agreements / Outcomes - 2013

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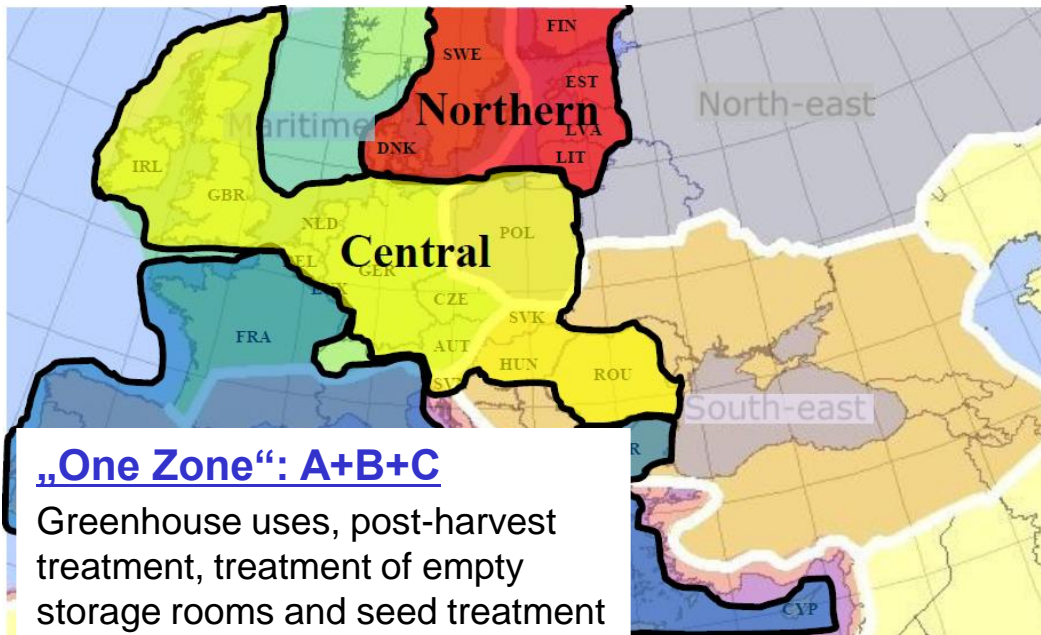
5- Challenges - 2014



Regulation (EG)1107/2009 - Zonal Evaluation

- Reg.1107/2009 in a nutshell:**
- zonal evaluation for PPP
 - fixed deadlines for evaluations

=> obligation for MSs to trust each other work, to cooperate and communicate!



Zone A- North

Denmark, Estonia, Latvia, Lithuania, Finland, Sweden

Zone B- Centre

Belgium, Czech Republic, Germany, Ireland, Luxembourg, Hungary, Netherlands, Austria, Poland, Romania, Slovenia, Slovakia, United Kingdom

Zone C- South

Bulgaria, Greece, Spain, France, Italy, Cyprus, Malta, Portugal, Croatia

1. Steering Committees - Overview



ZONAL STEERING COMMITTEE

- platform for communication and information sharing
 - contact point for questions concerning zonal procedures
 - worksharing coordination/organisation within and between the zones
 - involvement in the selection of zRMS (if the proposed zRMS by applicant is not able to act as zRMS)
 - Harmonisation (procedures, risk assessment...)
-
- phone conference (every 2 months) and face-to-face meeting (1/year)
 - 1 representative from each MS of the zone
 - Chair/co-chair: each MS for one year

INTERZONAL STEERING COMMITTEE

- platform for communication and information sharing between zones
 - contact point for general questions concerning zonal procedures in all zones
 - worksharing coordination/organisation within and between the zones
 - Harmonisation (procedures, risk assessment...)
-
- phone conference (every 2 months) and face-to-face meeting (1/year, optional)
 - 2 representatives /zone (chair+co-chair)+ COM
 - chair: COM

2. Tasks as Chair of the Zone

Annual schedule

- **Zonal:** 6 phone conferences
1 face-to-face meeting } **organized by the chair of the zone**
- **Interzonal:** 6 phone conferences
1 face-to-face meeting } **organized by COM**
(optional)

	Current chair	Incoming chair (2014)
Northern zone	Finland	Latvia
Central zone	Austria	Netherlands
Southern zone	France	Bulgaria*

*since the 1st of July 2013

2. Tasks as Chair of the Zone

Preparatory work:

- agenda public/confidential parts + supporting documents
- upload on CIRCABC, forward it to the zonal contact points in the zone
- gather the new issues raised by other MSs / update the agenda
- upload on CIRCABC / public part on CIRCABC available to the public

Meetings/Telephone conferences:

- chair the meeting/phone conferences
- prepare the minutes, identify the actions to be done/conclusions of the meeting (“bullet points”)

2. Tasks as Chair of the Zone

- **initiative** about the topics to be discussed
- **communication to interzonal Steering Committee**
- **represent the zone's position!!! at interzonal Steering Committee** (not the chair's view!)
- contact points for applicants
- coordination between MSs and applicants
- coordination of zonal independent assessments
- **update overview tables** weekly
 2013: UK / voluntary worksharing (re-reg) , AT/ new authorisation
 => overview tables will be maintained in the coming years, even if the European DB is expected soon

3. Agreements / Outcomes - 2013



Interzonal worksharing for applications submitted in more than 1 zone:

- identification of zonal independent sections: *physical chemical properties, analytical methods, confidential part and section toxicology*
- identification of projects for independent zonal worksharing
 - => Notification sheet amended indicating a proposal by applicant for a MS dealing with zonal independent assessments (to be included by the applicant)

Allocation of zRMS:

- some companies have problem finding zRMS at their intended date of submission
- always possible to identify one zRMS at central SC

3. Agreements / Outcomes - 2013



- **updates version of the notification sheet to be used**
(inclusion of the product code, applicant's contact point, kind of application (Article 33, step 2 voluntary work sharing...), possibility to name zRMS responsible for the zonal independent evaluation)
- **Art 43 renewal –notification sheet** to be elaborated
- **label extensions/amendment**: dRR should be restricted to the new information submitted
- if the zRMS evaluation indicates change of the GAP, the applicant has to adapt the national addenda when necessary before the cMSs start their national evaluation
- conclusions of the zonal steering committees (prepared by NL)

3. Agreements / Outcomes - 2013



HARMONISATION :

- harmonisation on **risk assessment** within the central zone:
 - **ecotox** – projects for 2014 organised by UK/NL
 - **fate** - projects for 2014 organised by UK/AT
 - Workshop on **operator exposure** organised by DE
- central zone harmonisation (with the exception of Germany) in using the Q10 value for fate assessment
- start of the **120 day period for cMS**: when the cMS is informed by the zRMS via e-mail that the RR is finalised and the documents (including registration certificate) is uploaded on CIRCABC (with the exception of DE, HU and SK due to national legal requirements)

4. Lessons learned

POSITIVE POINTS

- **list of agreements** (prepared by NL)
- **list of bullet points** summarizing the conclusion forwarded to the industry
- **expert meetings** with regards to risk harmonisation identified for 2014
- allocation of zRMS
- **AOB**: MSs issues sent via email in advance

TO BE IMPROVED

- update **overview tables** (information to be submitted to the chair in order to keep the list updated)
- **input from all MSs** useful and necessary

5. Challenges - 2014



2014: NL chair/ PL co-chair

Topics to be continued :

- harmonisation (expert meetings)
- MS allocations, zonal independent worksharing projects (possible problems identified will be collected and discussed)
- renewal of products according to Art. 43 of Reg. 1107/2009
- update of the list of conclusions

Face to face meeting in NL: 21st – 22nd of May 2014 :

- **representatives from industry** (2 – 3 representatives from ECPA, ECCA and IBMA each) to be invited on the 2nd day (afternoon)

Thank you for your attention

