Austria: Experiences with the Zonal evaluation procedure Applying Regulation (EC) No.1107/2009

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Rebecca Reboul
Institute for Plant Protection Products
AGES, Austrian Agency for Health and Food Safety

Austrian Agency for Health and Food Safety - AGES

- founded in 2002
- owned by the Federal Ministry of Health and by the Federal Ministry of Agriculture, Forestry, Environment, and Water Management

Bundesamt für Ernährungssicherheit

- **Institute for Plant Protection Products**
  - evaluation of active ingredients
  - evaluation and authorisation of PPP´s
  - international cooperation (within EC, OECD…)
  - MRL setting

- **Federal Office of Food Safety (BAES)**
  - authority for execution of Reg.(EG) 1107/2009
  - established to enable the execution of the official tasks
  - decision of authorisation, PPP-register
  - controls on marketing of PPPs

Outline


1- What changed on 14 June 2011?
2- Timelines
3- How to keep deadlines

1- What changed on 14 June 2011?
a) Main Objectives of the Regulation

- **shortening processing times** by defining **shorter deadlines**
- reducing administrative effort for the applicants and national regulatory authorities
- **simplification through zonal procedure :**

  - evaluation of the authorisation dossier (new authorisation, amendment and renewal) **by one Member State per zone** to avoid duplication of work

  - decision for authorisation still remains within the **competence of the Member States.**

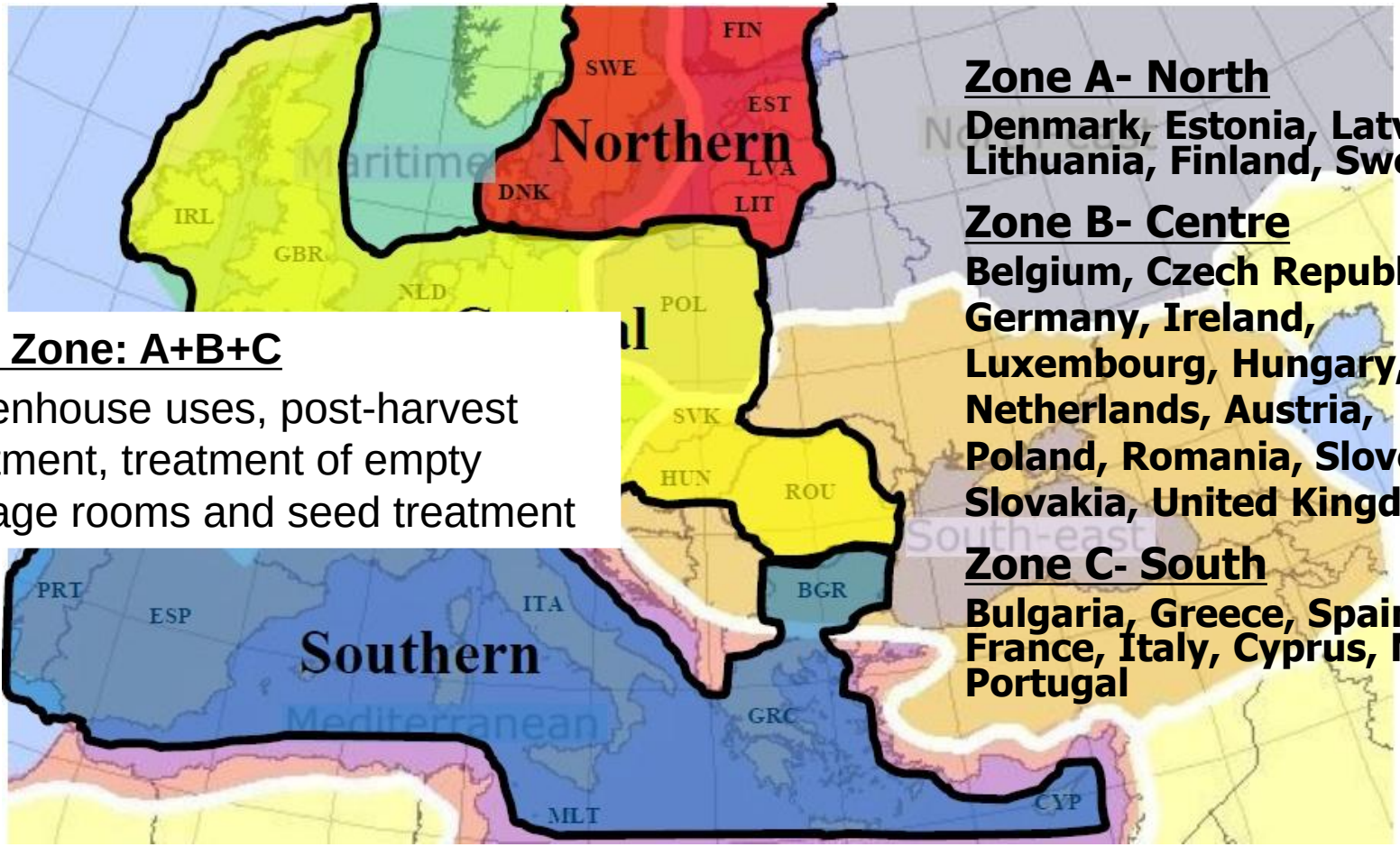
- increasing transparency in the evaluation, harmonisation of the procedures
- improving information exchange between MSs/Commission/Applicant

MS: Member state, zRMS: zonal rapporteur MS, cMS: concerned MS

1- What changed on 14 June 2011?
b) Consequences

- **for existing authorisations**
  - no direct consequences
  - decisions on a.s. at EU-level may have an impact on existing authorisations (i.e. candidates for substitutions, restrictions by renewal of a.i.)
- **for recent applications**
  - Reg(EC) 1107/2009: applications that were made **after the 14 June 2011**
  - RL 91/414/EWG, national law: applications that were made before the **14 June 2011,** re-registrations after approval of a.s. (Step 2/Post Approval)

1- What changed on 14 June 2011?
c) Zonal Evaluation (Art. 33-39)



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

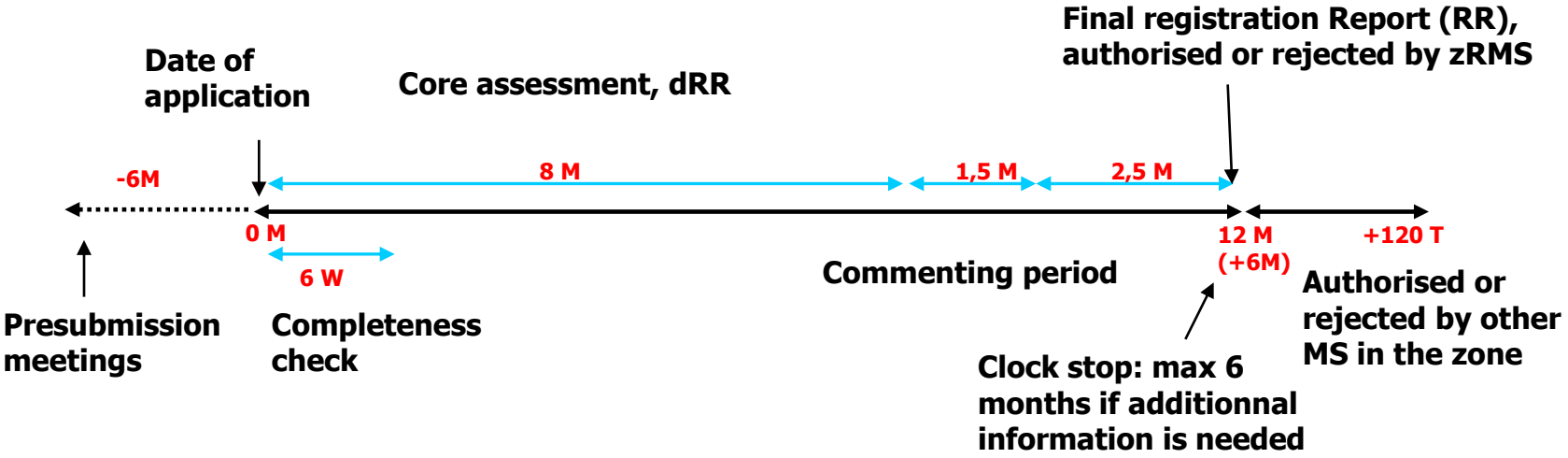
One Zone: A+B+C

Greenhouse uses, post-harvest treatment, treatment of empty storage rooms and seed treatment

2- Timelines

a) New Product- Zonal Evaluation (Art. 33-39)

- **Application according to Article 33 of 1107/2009 and GD SANCO/2010/13169 rev. 5:**



dRR: ***draft registration report***

The zonal procedure must be followed:
- **even if the application concerns only one MS**
- **for amendments of authorisations ("new" and "old" ones)**
- **for extensions of authorisations for minor uses**

1 year (zRMS)+120 days (cMS)

2- Timelines

a) New Product- Zonal Evaluation (Art. 33-39)

- **Application according to Article 37.3 of 1107/2009:**

  - for PPP containing a.s. **not yet approved**
  - if PPP is the same as in the DAR: zRMS has **6 months** after approval of the a.s. to finalise the RR and to decide on the application
  - cMSs have **120 days** after decision by zRMS to make a decision

6 months + 120 days

2- Timelines
b) Mutual recognition (Art. 40)

- **Application according to Article 40 of 1107/2009 and GD SANCO/2010/13169 rev. 5**:
  - registration in (one) MS
  - **same product and same use** (variation possible based on climatic and agricultural conditions?)

- **Mutual recognition based on PPPs registered according to Dir. 91/414/EEC:**
  - not all MSs grants MR based on "**91/414- registrations**"
  - precondition in other MSs:
    - evaluation according to Uniform Principals
    - copy of the evaluation report (in English!)
  - evaluation time could go over 120 days (not binding)

≥120 days

2- Timelines

c) Re-registrations after approval of a.s.

- **Step 2 (Re-registrations according to Dir. 91/414/EEC):**
  - **voluntary basis**
  - timelines binding according to inclusion directives (**2 years**)
  - attempt to keep to timelines according to Reg. 1107/2009

2 years (zRMS +cMS)

2- Timelines
d) Renewal of PPPs (Art. 43)

- **Renewal according to Article 43 of 1107/2009 and GD SANCO/2010/13170 rev. 7:**

  - application has to be made within **3 months following the renewal of approval of the a.s**

  - 6 months for Compliance check (step I) and assessment (step II) by zRMS – (-> zRMS`s RR)

  - 3 months for decision on renewal of authorisation by cMS in the zone

1 year (zRMS +cMS)

3- Workload- Keeping deadlines
a) Presubmission meeting(s)

Prior to application, **meetings between MS and applicant** are possible:

- **1st meeting:** information about procedure, format (dRR), time frame, fees, recommendations, principal requirements, specific issues (e.g. confirmatory data, new Annex II data…)
- **2nd meeting:** clarification of technical issues/problems concerning risk assessment, participation of the experts of all sections
  - ***AT: possible also as phone conference, e-mails***

***Note:* no guidance on presubmission; it is the responsibility of individual MSs**

Communication

3- Workload- Keeping deadlines
b) Importance of scheduling

- notification sheet to be submitted **in advance** to zRMS, cMS and all contact points of the zone, important for MS annual work plans
- dRR **recommended** to be submitted (including supporting documents/studies and information about formulations and GAPs) **prior to application** in order to avoid "clock stop" and possible issues during evaluation (workload, financial issues!)
- communication with the applicants (expert to expert)
- **"internal" solution**: Efficient coordination, **internal coordinator:** primary contact person for the applicant, responsible for administration/management of data, transmission of information, time scheduling,…
- **"external" solution:** cooperation with **MSs** (AT/ FR, CZ, SLO)

Communication

3- Workload- Keeping deadlines
c) Sharing between zones

- evaluations **by one MS** of **zone independent** sections (phys-chem, analytic, tox studies) for the 3 zones
- other zRMSs adopt this assessment
- zRMSs of the other zones participate in the commenting procedure
- applicant to be informed during pre-submission meeting (application at the **same time in the different zones**)
- *not yet practiced* but recommended to see how the system works
- GD for procedure needed?

Communication

3- Workload- Keeping deadlines
d) Quality of the draft registration report: dRR

- for **each formulation** a **separate dRR** should be provided (especially important for re-registrations)
- **each active to be addressed**! Reference to existing evaluations possible (e.g. DAR, EFSA Conclusion), but relevant summary in the dRR necessary!
- for interzonal projects, "mixed" products: **1 dRR for field uses, 1 dRR for greenhouse uses**
- **new dRR format** (separate section for assessment of groundwater metabolites; improved residue section)- to be applied by the 01.06.2012

3- Workload- Keeping deadlines
e) GAPs

- all intended/current uses should be addressed in the Core assessment
- identification of **cGAP**!
- harmonisation of GAPs within the zone as far as possible: new harmonised GAP table
- "**forgotten" uses/GAPs** and cMS might require a **new application**!
- minor uses/specialty crops to be submitted zonally

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G o r I**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)**	**Application**			**Application rate**			**PHI (days)**	**Remarks:** **e.g. g safener/synergist per ha**
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		

Thank you for your attention