



The CZSC secretariat and harmonisation in the zonal process

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- **Harmonisation in the zonal process**
- **CZSC, DCG and the CZSC secretariat**
- **Current activities**

Experiences with the zonal process

- **Agreed procedures, responsibilities, reporting (Registration Report), and language (English)**
 - Creation of the registration report is more time consuming than expected
 - The complete zonal evaluation has to be done by the zRMS
 - The interpretation of the Reg. 1107/2009 deviates between MS
 - Assessment and decision criteria are not fully harmonised
 - Decision criteria are sometimes based on national data requirements
 - Risk mitigation measures are not harmonised
- **Ideally, assessment and decision criteria would be harmonised**

Experiences with the zonal process

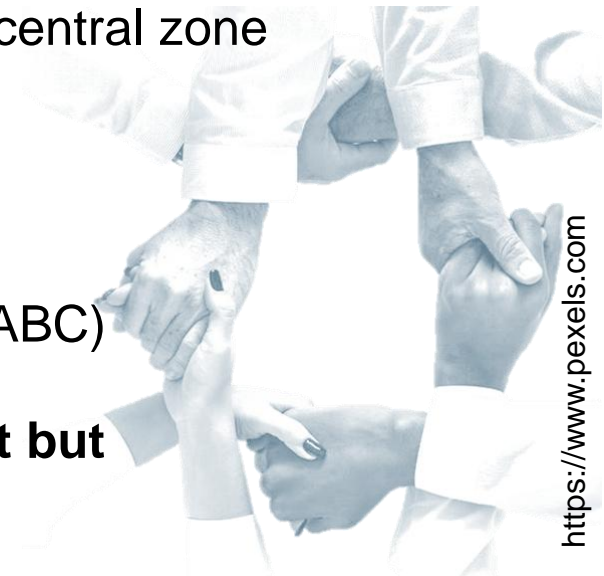
- **Not harmonised procedures cause problems**
 - High workload in the MS
 - The number of court cases in DE increases
 - DE was sentenced to accept the decisions of other MS
 - When DE is cMS, only Art. 36 (3) is allowed for rejection
 - Even if no complete dRR/RR (legal/administrative requirements) is available, DE has to take over the evaluation of the zRMS
- Unequal authorisations → Unequal ppp availability in MS
- **Unequal situation for users in contrast to the basic idea of the EU**



Harmonisation is important in the zonal process of Reg. 1107/2009

- **Coordination and cooperation between the national authorities in the Member States**
 - Three Zonal Steering Committees
 - Inter-Zonal Steering Committee
 - Directors Consultation Group (DCG) in the central zone
 - Post-Approval Issues group (EU-COM)
- **Further tools for harmonisation**
 - Development of EU Guidance Documents
 - Expert Meetings and Expert Groups (CIRCABC)

The process of harmonisation is very important but time consuming and leads to a high workload



<https://www.pexels.com>

Central Zone Steering Committee (CZSC)

- Guidance document on zonal evaluation and mutual recognition
SANCO/13169/2010
- CZSC established in 2010
- Five telephone conferences and one „face to face meeting“ per year
- **Promotion of harmonisation and cooperation by work sharing**
- Information of applicants via CIRCABC and annual „face to face“ meetings

Director's Consultation Group (DCG)

- Exchange on director's level
- DCG established in 2014
- Min. two telephone conferences and one „face to face meeting“ per year

The CZSC secretariat

- **Problem: The administrative burden for the chair has grown**
 - Lack of resources – not only in small MS
- **Solution: Secretarial support**
 - Chairmanship: rotates annually
 - Secretariat: DE and NL: **consistent responsibility**
 - **Administrative support in consultation with the chair**
 - Each member state can more easily take up the role of chair both for the CZSC and DCG
 - Secretariat established in 2017
- **Positive Feedback from MS and applicants**
 - DCG decided on continuation until 2023



<https://www.pexels.com>

- **Direct exchange with applicants following the annual CZSC face to face meeting**
- **Publication of agreements of the CZSC in the format of "Bullet points" in the public part of CIRCABC**
 - Path: /CircaBC/SANTE/PPP Zonal/Library/Center/Public information
 - URL: <https://circabc.europa.eu/w/browse/20a444e2-21c3-4e4b-85e3-671844b50135>
 - Recommendation: use the „notification“ function of CIRCABC to receive a notification email when documents are uploaded

Another established secretariat: Post Annex I issues group and IZSC

- **PAI and IZSC secretariat**
 - PAI and IZSC meetings are organised by the EU Commission
 - The chairs of the 3 zonal steering committees provide a summary of their recent meeting(s)
 - The secretariat is run by DE with support by AT and was established in June 2017



- **Harmonisation in the zonal process**
- **CZSC, DCG and the CZSC secretariat**
- **Current activities**

DCG

- **Meeting of DCG with NZ, SZ, COM and EFSA**
 - Goal: improve the communication between MS, EFSA and COM
 - Next steps for further **meetings between the MS of all three zones, EFSA and COM are under discussion**
- **RMM in ppp authorisation and active substance approval:**
 - The DCG works on a proposal to implement risk mitigation measures in the active substance approval process
- **Proposal from DCG to COM:**
 - Make available the final version of the *GD on Zonal Evaluation and Mutual Recognition* as “*noted by Standing Committee and agreed for formal adoption and publication as a Notice by the Commission. It should be used in the meantime from [date]*”.

CZSC

- **Worksharing: Allocation of zRMS for Art. 43 applications after renewal of AIR 4 batches**
- AIR 4 group 1-3:
 - Secretariat informed applicants in May 2019 about allocated zRMS
- AIR 4 group 4:
 - Approvals prolonged (31.07.2021 to 31.12.2024)
 - Allocation of zRMS will be started in spring 2021

CZSC

- **Interzonal assessment of protected crops**
 - Background: some areas of the risk assessment are not harmonised
- **Goal: harmonise and clarify the risk assessment under protected conditions for all three regulatory zones**
 - GD on protected crops (EFSA Journal 2014;12(3):3615)
 - Questionnaire on MS's practices in assessment of protected crops
 - Initiation of a working group by DE
 - Other zones will be informed and existing guidance and ongoing projects from the other zones will be taken into account.

CZSC

- **Assessment of non-professional uses**
 - Background: differences between MS – of great note for applicants
 - Questionnaire summarised by PL
- **Goal: provide information on harmonized procedures**
 - Bullet point under discussion
- **Goal: provide information on non-harmonized procedures**
 - Update of the table „National Requirements“ on CIRCABC

CZSC

- **BREXIT**

- UK accepts only national applications or as cMS. UK attempts to complete all open zonal applications as zRMS before 10/2019. For the remaining applications **fall-back zRMS are allocated**.
- MS accept a **shortened commenting period** of 3 weeks for Art. 29/33 applications so that UK can still complete the applications.
- UK remains a member of the EPPO zone and **efficacy studies from the UK are accepted** (as required by EPPO standards, GEP compliance and culture requirements)

DCG

- **At European level, a forum to address issues at a strategic level is needed.**
 - Agreements within zones: existing Committees are fit for purpose
 - No structures for rapid exchange/agreements at a **strategic level**
 - **All three European zones need to be brought together**
 - Currently discussed: NZ and SZ could be invited to join the DCG
 - “European Director’s summit”

Summary

- The process of harmonisation is time consuming and leads to a **high workload**
- The efforts of the Members States in the differed groups lead towards **harmonisation**
- The CZSC secretariat sucessfully **reduces the burden** of the chair of the CZSC
- At European level, a forum to **address issues at a strategic level** is needed



Thank you for your attention!

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