



The CZSC secretariat and harmonisation in the zonal process

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- **Harmonisation in the zonal process**
- **CZSC and DCG**
- **CZSC secretariat**
- **Other approaches for centralised decision processes**

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**

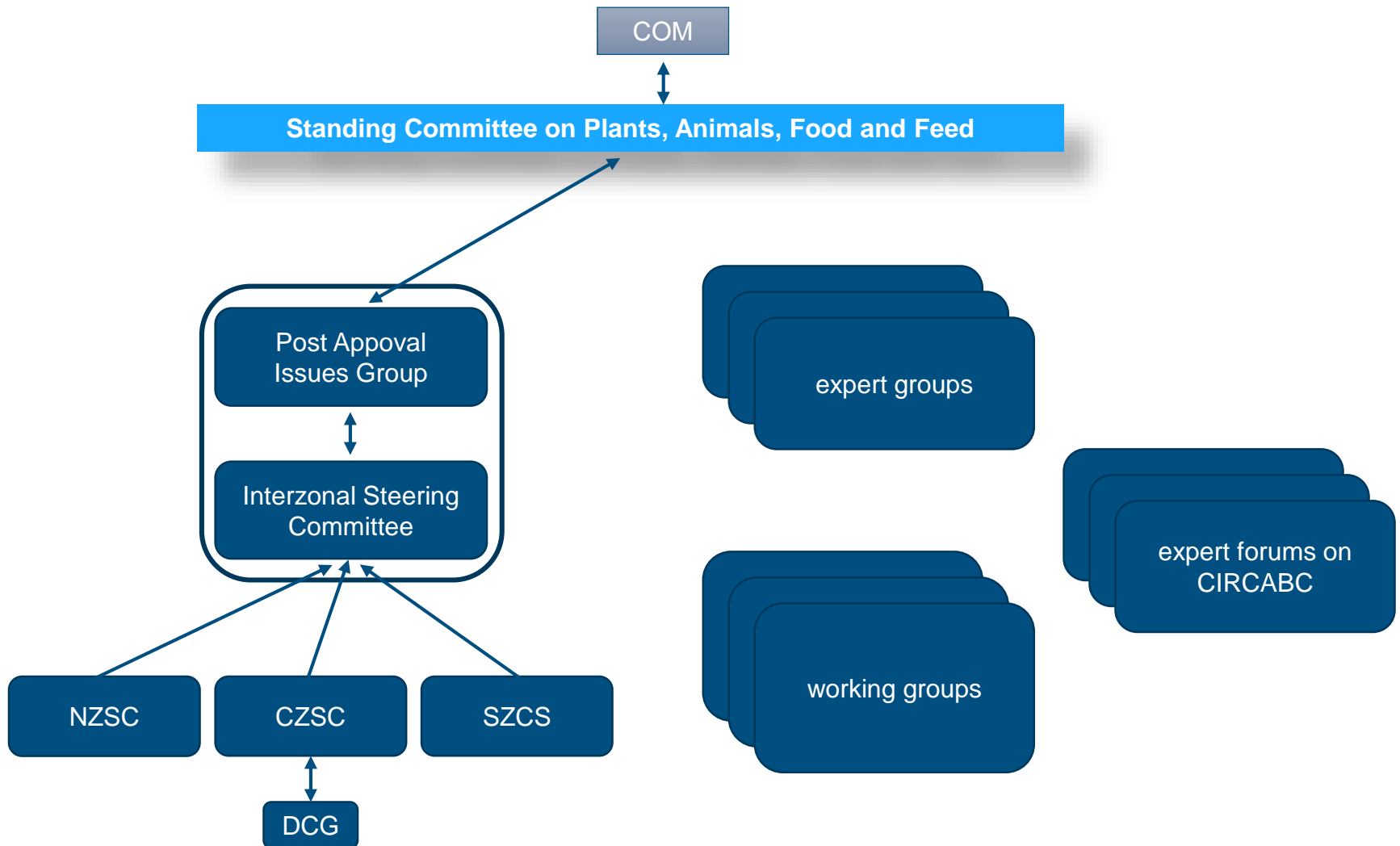
Experiences with the zonal process

- **Not harmonised procedures cause problems**
 - High workload in the MS
 - The number of court cases in DE increases
 - In two cases DE was sentenced to accept in principle 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

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
 - European Database on Authorisations

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



The CZSC

- Guidance document on zonal evaluation and mutual recognition SANCO/13169/2010
- The central zone steering committee (CZSC) was established in 2010
- Five telephone conferences per year
- One annual face to face meeting
- Platform where **information** is exchanged and **agreements** are found
- Promotion of **harmonisation and cooperation** by **work sharing**
- **Information of applicants** by
 - Publishing information about agreement in the form of publicly available „Bullet points“ on CIRCABC
 - One informational meeting after the face to face meeting

The DCG

- Need for exchange on directors level in order to achieve **commitment toward harmonisation in the central zone**
- Formation of the Directors Consultation Group (DCG) in 2014
- At least two telephone conference per year and as the need arises
- One annual face to face meeting

The CZSC secretariat

- **Problem: The administrative burden for the chair has grown**
 - Lack of human resources
 - Chairing the CZSC and DCG interferes with working on the dossiers of active substances and authorisation of plant protection products
- **Solution: Secretarial support**
 - A permanent group acting under the rotating chairmanship
 - Each member state could then more easily take up the role of chair both for the CZSC and DCG
- **The DCG decided to start a secretariat pilot in 2017**




Members of the CZSC secretariat

- **The responsibility is divided over 2 member states**
 - DE and NL
 - The work is estimated to take 1 full-time equivalent (0,5 fte per member state)
 - The secretariat does not have an actual office
 - Even if the secretariat consists of several people in different member states, they can organise and be in contact by virtual means (teleconference, telephone, e-mail)




Responsibilities of the Chair

- Decides on topics for the **agenda**, as compiled by the secretariat
- **Chairs the meetings** (CZSC and DCG)
- Organises the annual face to face meetings of CZSC and DCG, in cooperation with/supported by the secretariat
- Provides the technique for telephone conferences
- **Represents the central zone in the IZSC/PAI**

Responsibilities of the Secretariat

- **Administrative support in consultation with the chair**
 -  Proposes **meeting dates** of both DCG and CZSC
 -  Receives agenda proposals, **draws up the agenda**
 -  **Disseminates documents** both via e-mail and CIRCABC

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The screenshot shows the CIRCABC website interface. At the top right, there is a 'Contact' link and a language dropdown menu set to 'English (en)'. The main header features the European Commission logo and the CIRCABC logo. Below the header, a breadcrumb trail reads: 'EUROPA > European Commission > CIRCABC > SANTE > PPP Zonal'. On the left side, there is a navigation menu for 'PPP Zonal' with options for 'Information' and 'Library'. The 'Library' option is selected, showing a sub-menu with 'Add content' and 'Create space'. The main content area displays the 'Library' title and a description: 'The Library is the space where **contents** are stored, managed and shared.' Below this, it states: 'in this space, the documents are uploaded for the DCG and CZSC meetings that are organised with help of the Central Zone Secretariat (pilot phase 2017)' and '3 folders and 0 files in this space.' At the top right of the main content area, there are links for 'Http' and 'Back'.

Responsibilities of the Secretariat

- **Administrative support in consultation with the chair**
 - ☑ Proposes **meeting dates** of both DCG and CZSC
 - ☑ Receives agenda proposals, **draws up the agenda**
 - ☑ **Disseminates documents** both via e-mail and CIRCABC
 - ☑ Organises **teleconferences**
 - ☑ Attends all meetings of CZSC and DCG, takes notes, and draws up **minutes**
 - ☑ Prepares and disseminates the **input for the IZSC/PAI**
 - ☑ Prepares and publishes the „Bullet points“ for **information of the applicants**

Responsibilities: Secretariat

- Organises the allocation of AIR3 active substance containing products

Product No.	Product Name	Active Substance	Authorisation No.	Authorisation Date	Authorisation Validity	Authorisation Status	Authorisation Type	Authorisation Category	Authorisation Sub-category	Authorisation Description	Authorisation Details	Authorisation Status	Authorisation Type	Authorisation Category	Authorisation Sub-category	Authorisation Description	Authorisation Details
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Experiences

- **The pilot was evaluated via a survey by the DCG in October**
 - 8 MS participated
 - Conclusion: The secretariat is useful and in general financially feasible
 - **The DCG decided to continue the secretariat for 2018**
 - Challenge: Spacial seperation of the chair (AT) and the secretariat (DE, NL) in 2018

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Another recently established secretariat: Post Annex I issues group and IZSC

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



Other approaches for centralised decision processes

Thought starter to revisit the structure of groups and meetings for SCoPAFF

- In SCoPAFF October 2017 the MS agreed to map and where necessary revise the roles, tasks and responsibilities of the SCoPAFF and directly linked EU-committees: PSN, PAI, (I)ZSC.
- The goal is to improve the efficiency of EU-committees in the field of PPP by having a clear network of committees
- DE, AT, NL, SE, FR, PT work together on this thought starter

Other approaches for centralised decision processes

Group for Risk Assessment Decisions (GRAD)

- At the moment none of the EU-groups is capable of discussing actual problems relating to the risk assessment in zonal authorisation procedures
- No decisions can be taken
- The DCG identified a need for groups that should be able to decide on problems in risk assessments **regarding actual product authorisations**
- Participants should be the **heads of the units** of the designated authorities

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 pilot of the CZSC secretariat was successful in reducing the burden of the chair of the CZSC
- Other possible approaches for harmonisation are on their way

Thank you for your attention!

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Authorisation in Germany

Institutions involved

