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Article 43
Saviour or Nightmare?

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Overview

Regulatory points

- Timelines
- Evaluation work
- zRMS allocation
- Official/ legal basis
- Data to be submitted
- Brexit and consequences
- Low risk products

Specific points

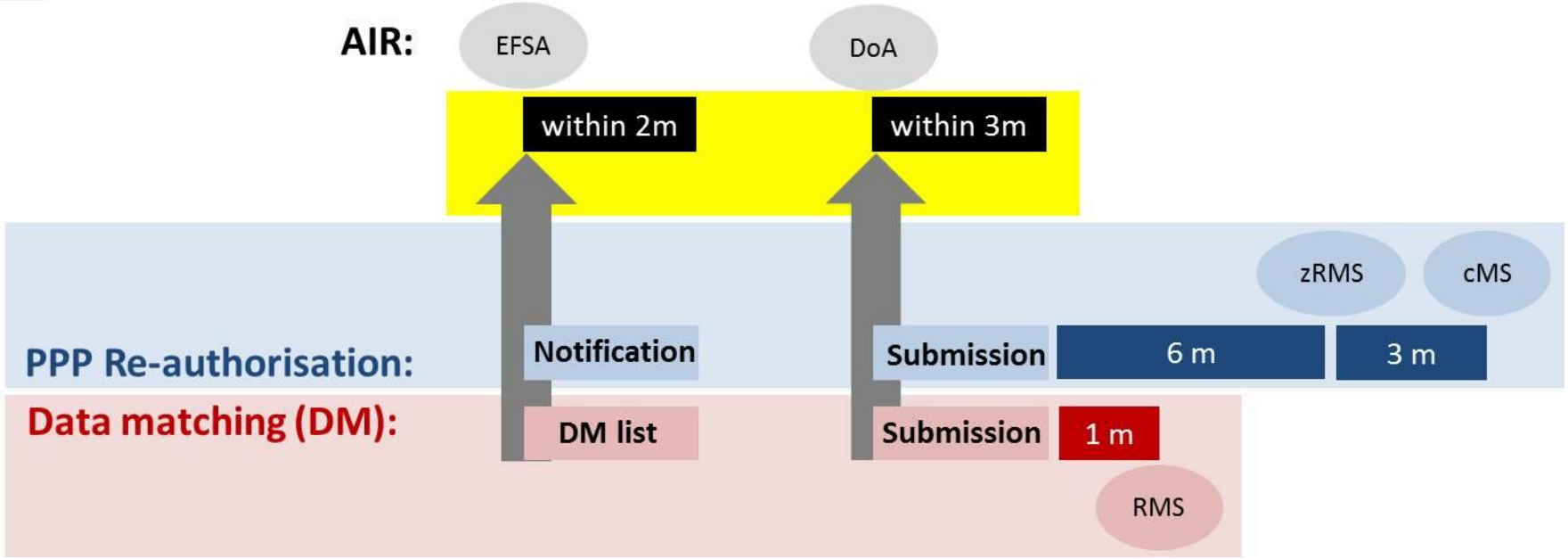
- Category 4 studies
- 5-Batch Analysis
- Delays

Harmonisation

- GAP
- Efficacy requirements
- Minor uses

Conclusion

Timelines (without Category 4 studies)



- Two parallel processes (PPP-re-auth. & DM) with mostly similar deadlines
- For Art. 43 statement confirming access to a.s. data necessary

- Differences
  - Data matching: RMS issue
  - Product renewal: zRMS issue

Evaluation work and allocation of the zRMS

- **1st challenge: Double evaluation work**
  - Art.43 : 3 zRMS do the same work at the same time
  - Data matching and Art. 43: 2 processes in parallel (up to 4 MSs to evaluate data)

- **Further challenge: How to find a zRMS?**
  - Theory: zSCs (or MSs): to ask APPs about desired zRMS (Excel lists) plus final decision
    - Excel lists too early (AIR IV.2 in SEZ; spring 2018 vs. end of Nov. 2023)
      => Not applied yet, on-going evaluation, defence unclear
  - Theory: Multiple applicants to find a common zRMS
    - No harmonisation between the applicants
  - Theory: a.s. (Co)RMS to act as PPP zRMS in its zone (even if PPP not registered in its country)
    - National law against non binding SANCO
      => Problem for Art. 43: e.g. BE, DE, HU, IE, PL
      => Problem for data matching: e.g. DK

Evaluation work and allocation of the zRMS

SANCO/2010/13170, point 3.7.5 (rev 15) / point 3.7.4 (rev 14):

"Where the renewal of the same product is sought in different zones, zonal RMSs are encouraged to reach an interzonal decision regarding the use of Art. 43(6)."

- **Proposal:**
  - Interzonal approach as a pre-requisite
    - One dRR for all zones
      => PhysChem, Analytic, Tox: One data package in all zones
      => Residues: 2 data packages to be evaluated
      => Fate / Etox: Some updates for national addenda needed
      => Efficacy: Not necessary for Article 43
  - Consolidation of Article 43 with data matching process
    - One MS to evaluate data matching plus the Art. 43 evaluation with amended timelines:
      => izRMS: 8 months evaluation time (1 month for data matching plus 7 months for Article 43)
      => cMSs: max of 2 months for Article 43 (only natl. addenda plus administrative process)
  - One izRMS (ideally the a.s. RMS)
  - Special cases
    - In case of a.s. with many products (e.g. Glyphosate, Mancozeb): Work distribution by izSC
    - Products with > 1 a.s.: Also only one evaluator or change to second RMS with 2nd submission?

Official/ legal basis and data to be submitted

Reg. (EC) 1107/2009

REGULATIONS

REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 21 October 2009

concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

This Regulation shall be binding in its entirety and directly applicable in all Member States.

SANCO/2010/13170

EUROPEAN COMMISSION
HEALTH & FOOD SAFETY DIRECTORATE-GENERAL

Safety of the food chain
Pesticides and Biocides

SANCO/2010/13170 rev. 14
7 October 2016

Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009

This document has been conceived as a guidance document of the Commission Services. It does not represent the official position of the Commission. It does not intend to produce legally binding effects. Only the European Court of Justice has jurisdiction to give preliminary rulings concerning the validity and interpretation of acts of the institutions of the EU pursuant to Article 267 of the Treaty.

Official/ legal basis and data to be submitted

- Reg (EC) 1107/2009 (Art. 43)
  - **43.2: Necessary information to be submitted within 3 months of the DoA:**
    - (a) Copy of PPP authorisation
    - (b) + (c) New information (new data requirements/ guidances/ criteria/ endpoints) plus justification
    - (d) Information that PPP complies with the requirements (conditions and restrictions)
    - (e) Monitoring report (where the authorisation was subject to monitoring)

- SANCO/2010/131370
  - ***Necessary information to be submitted within 2 months following the EFSA-conclusion:***
    - *Template to notify intended zonal applications [SANCO/12544/2014]*
    - *Indication which parts of the risk assessment need updating*
    - *An indicative "data matching list" and "data matching program" (if necessary)*
    - *Indication of agreement on needed studies (plus expected timeframe)*

Not any more in revision 15 !

  - **Necessary information to be submitted within 3 months of the DoA:**
    - Art. 43.2 requirements [see above]
    - Comparative assessment (where necessary) [Art.43.1 -> Art. 29 -> Art. 50 requirement]
    - List of intended uses plus statement “no significant changes to previous authorisations”
    - A product-specific dossier clearly indicating where there is new information

!

Official/ legal basis and data to be submitted

- **Problem:**
  - In principle **no (legal) requirement** to
    - Submit a dossier

    => Only stated in a Guidance document => No regulation available!

- **But:**
  - Complete dossier needed for RR preparation

- **Proposal:**
  - Maybe a legally binding regulation for Article 43 would be better!

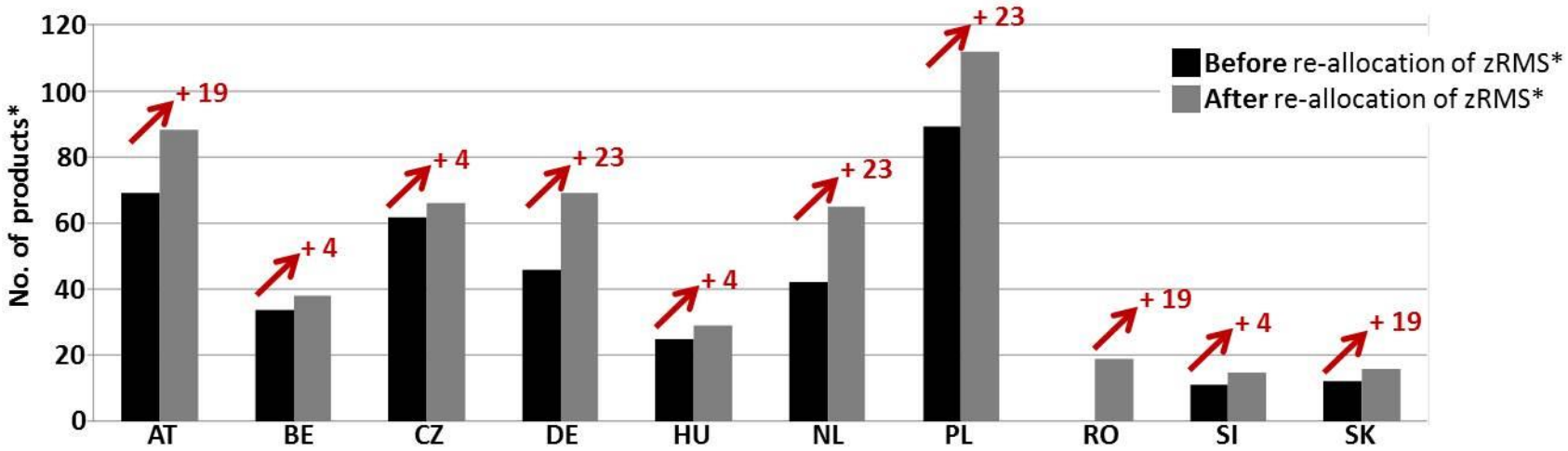
Brexit and consequences

- **Consequences after Brexit**
  - Prolongation of Mutual Recognitions (acc. to Dir. 91/414) with UK as country of origin
    - Some MSs not sure to follow the UK extension after the Brexit

- **Proposal**
  - Acceptance of MR-prolongations (also 91/414)
    - To be included in an Article 43 regulation

Brexit and consequences

- **Consequences after Brexit**
  - Higher workload for the CEZ-MSs
    - Industry to deal on PPP level of AIR 2 and AIR 3 batches 1-6 (no-re-allocation)
    - Re-allocation of AIR 3 batches 7-10



- **Proposal:**
  - Re-allocation of the outstanding groups AIR 2 and AIR 3 batches 1-6
  - Interzonal approach to distribute the workload to all zones

* Considering 528 products in the Central political zone containing active substances of AIR 3.3.7, AIR 3.3.8 , AIR 3.3.9 and AIR 3.4

Low risk products (LRP)

- **Having more Low risk products is a desired direction in the EU!**

- But for Low risk products
  - Same Art. 43 deadlines as for non-LRPs
  - Same evaluation time under Article 43 as for non-LRPs
  - Same authorisation period will be granted as for non-LRPs

- **Proposal:**
  - After a.s. is approved as LRAI:
    => Modified re-authorisation procedure (instead of Article 43), e.g.
    (1) Check if product is also low risk
    (2) Fast-track evaluation for LRP (120 days)
    (3) Granting authorisation without expiry date
  - Start of pilot data-call-in system only for LRP

Category 4 studies

SANCO/2010/13170 – point 3.5:
Cat. 4 = Data which are directly related to new guidance in place at the time of submission or to a new/revised endpoint ***decided at the time of the renewal of the approval of the a.s.*** *(endpoints as listed in the supporting information to the EFSA conclusions) and for which the time is too short from the publication of the EFSA conclusion to produce the requested study.*

- **Difficulties and question:**
  - Study preparation at time of EFSA conclusion?
    - But no legal endpoints and no final decision available
    - What about changes of endpoints afterwards (DoA time) => Again new study requested?

- **Proposal:**
  - Study preparation start at time of DoA

Category 4 studies

SANCO/2010/13170 – point 3.5:
The renewal dRR and the Cat. 4 studies should be submitted within 3 months of the final Cat. 4 study being finalised

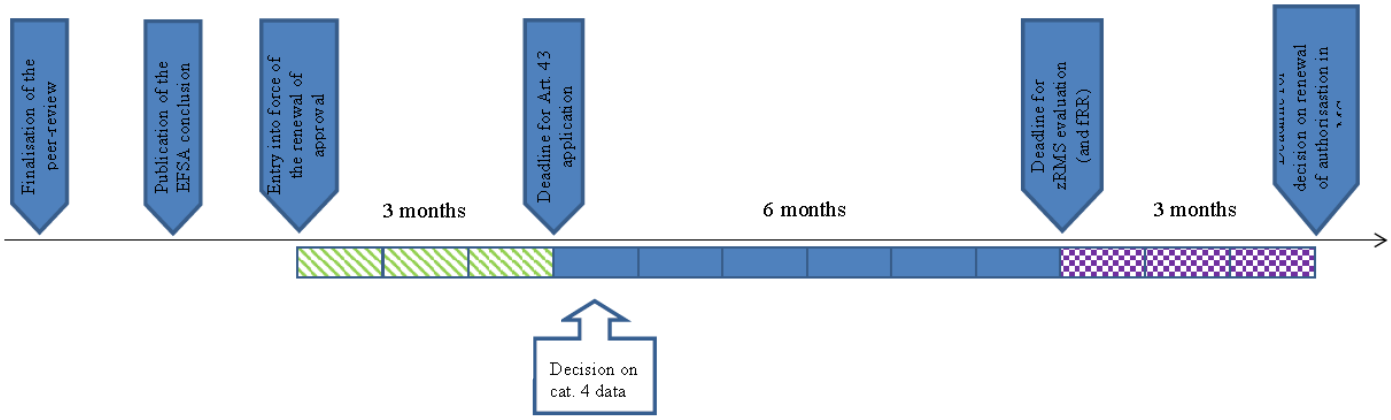
- **Difficulties and question:**
  - dRR to be submitted 3 months after Cat. 4 studies available => too short!

- **Proposal:**
  - Longer period for dRR preparation after Cat. 4 studies available (e.g. 6 months)

Article 43 – Specific points

Category 4 studies

Excerpt of Appendix II of GD rev. 15



- **Difficulties and question:**
  - Decision on Cat. 4 studies
    - Will be done in the 1st month after application deadline of Art. 43
    - In case of negative decision => No time for negotiations with competitors

- **Proposal:**
  - Negative decision on Cat. 4 studies: Time for negotiations needed (clock-stop)

New impurities – Need of new 5-Batch Analysis

- **5-Batch study needed for all non-Notifier [Data matching & Article 43]**
  - All new impurities must be analysed

Citation Draft Minutes czSC meeting (06.06.18):
"Art. 43 GD is clear on it as a missing 5 batch analysis is not to be considered as Cat.4"

- **Problem - Timelines**
  - Study preparation time = 6 months (at least)
  - Possible study start = as soon as new endpoints valid (= DoA; **not** EFSA conclusion)
  - Submission deadline = 3 months after DoA

- **Main question: When to prepare the study?**

- **Proposal:**
  - 5-Batch Study as Cat. 4 study
  - To start study preparation after DoA deadline

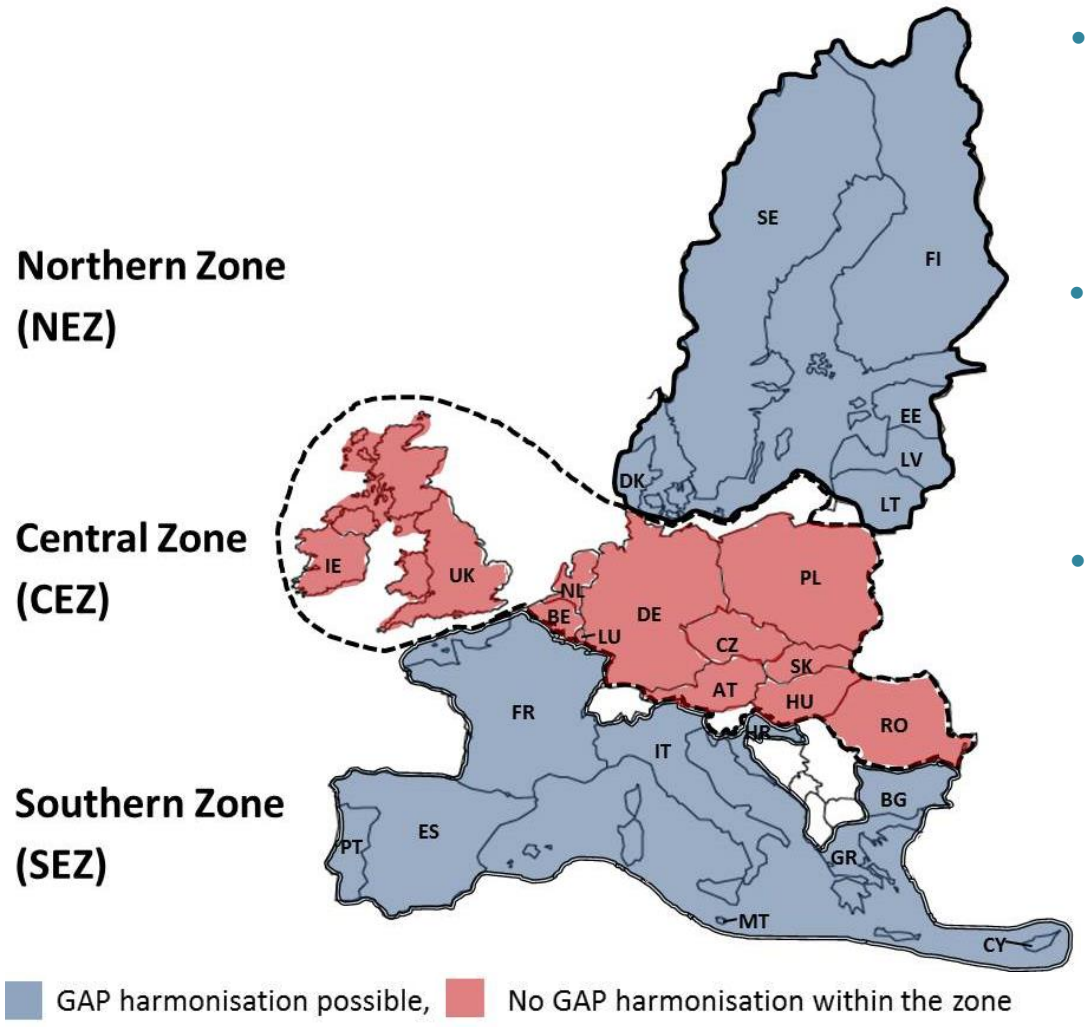
Delays

- **Problems**
  - Blocking innovation
    - Use extensions (e.g. GAP changes, new major uses, minor uses)
    - Mutual recognitions

- **Proposal:**
  - Combination of …
    - Art. 33 and Art. 43 applications (re-evaluation plus use extension)
    - Art. 40 and Art.43 applications (re-evaluation plus MR to new MSs)

  … at the same time and in one process

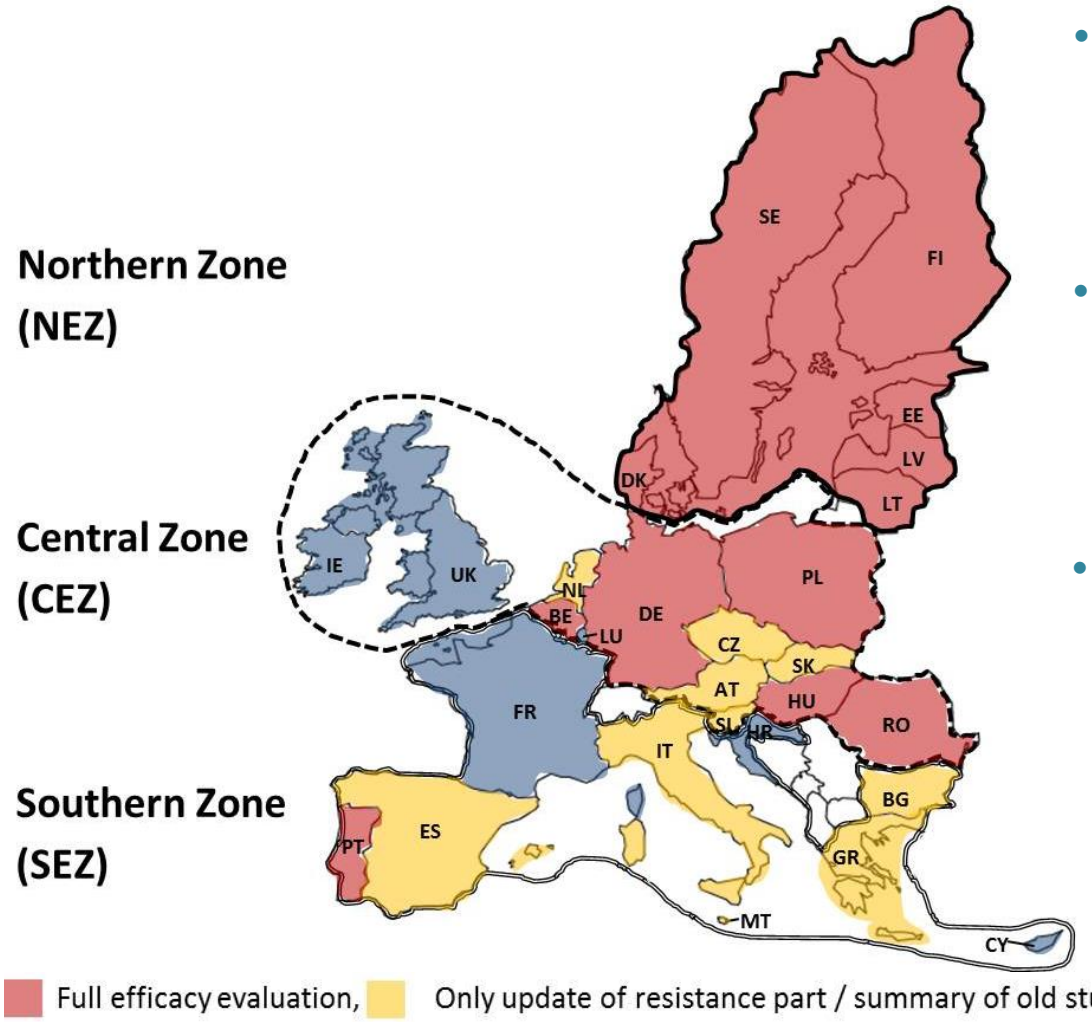
GAP harmonisation



- **Northern zone**
  - GAP harmonisation encouraged (with supporting data)
- **Central zone**
  - No harmonisation possible “due to tight deadlines”
- **Southern zone**
  - Harmonisation desired
  - To add the same uses in MSs where those are not authorised (Art. 43 plus Art 33)

Efficacy requirement – major uses

SANCO/2010/13170, point 3.7.5 : *"Where a GAP change is necessary, efficacy data addressing the revised GAP should be assessed. If not, only information about resistance should be assessed in the efficacy section."*



- **Northern zone**
  - Full efficacy evaluation necessary
- **Central zone**
  - Either only resistance or full data set to be submitted
- **Southern zone**
  - If no GAP change either … or:
    - Efficacy needed if data not evaluated acc. to Uniform Principles
    - Only resistance needed
    - Summary of study results needed

Minor uses, GAP and Efficacy

- **Further challenges Minor uses:**
  - Different approaches for the re-authorisation of minor uses (Art. 51 and Art. 43)
    - Article 51 application (e.g. DK)
    - Article 43 application (e.g. LT)
    - Sometimes full Efficacy data set necessary (e.g. MT)

- **Proposal:**
  - Clear harmonised rules needed (e.g. legally binding Regulation)
    - For GAP harmonisation
    - Efficacy requirements of major uses
  - Harmonisation for Minor use re-authorisations needed
    - Combination of Art. 43 and Art. 51 helpful

Conclusion

- **Main problems:**
  - In many cases Guidance documents not clear enough
    - Room for interpretation => Harmonisation difficult
  - Guidance documents are not binding

- **Need of:**
  - Implementation of interzonal approach
    - Introduction of an izRMS-system and and an izdRR
  - Combination of Art. 43 and
    - Data matching
    - Art. 51
    - Art. 33
    - Art. 40
  - Adapted deadlines for LRP (also in the re-authorisation procedure)
  - Harmonisation of
    - GAP between the MSs
    - Efficacy requirements for major uses: Only resistance necessary!

- **Regulation for Art. 43 needed**

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It is somewhere in-between!

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Thank you for your kind attention

Questions? …
Ideas ? …
Points for discussion? …

… Please do not hesitate to contact me:
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