



Product authorisation: Some challenges for Industry

Dr. Jeanne Roederer, ADAMA
Chairman of the CLE Product Authorisation Expert Group

*CropLife Europe conference
10 March 2021*

Overview



- Communication with industry on SC decisions
- Frozen period
- Commenting period during Zonal process
- Conclusion



Communication on Steering Committees decisions



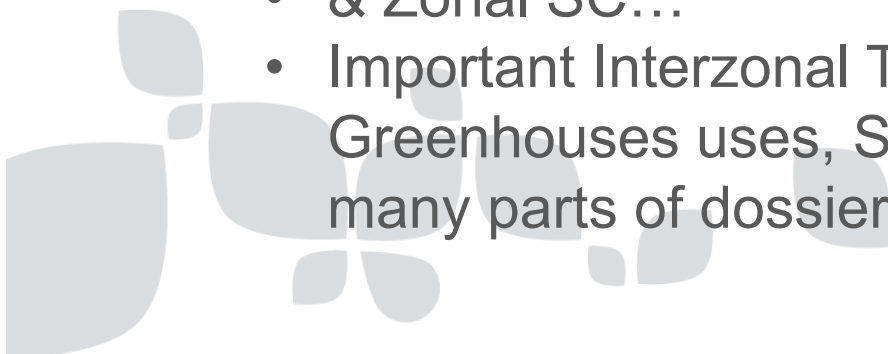
Zonal Guidance Documents

What would be the “Ideal” Guidance Document?

- It exists
- It contains information from all MS (no links to national websites)
- It is regularly updated, annually would be appreciated

Interzonal Steering Committee

- Great to see the minutes
- Further clarity on remits / composition
- & Zonal SC...
- Important Interzonal Topics from industry perspective: Greenhouses uses, Seed Treatments (one zone), and many parts of dossiers - possible work-sharing



Frozen period

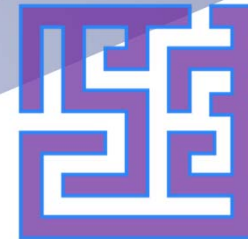


Sarreyer, Val de Bagnes (CH)

Frozen period



**Cat 4 Studies
+ Dossier Prep,
Submission**



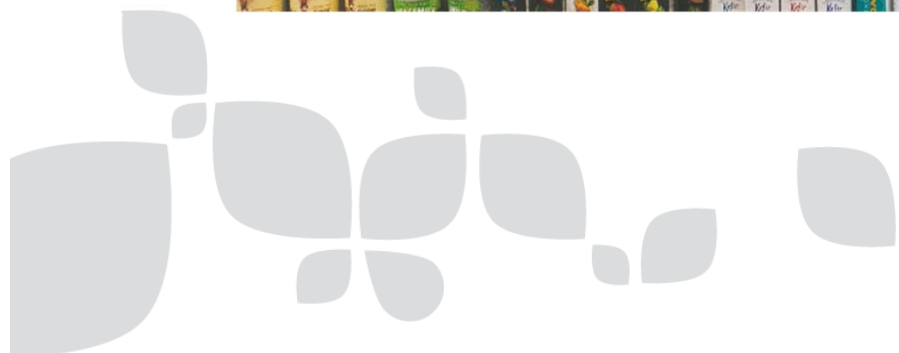
**RE-EVALUATION
PROCESS**



AS RENEWAL



Frozen period



Frozen period

Industry proposal for general principle

Allow processes with NO update of risk assessment in all MS

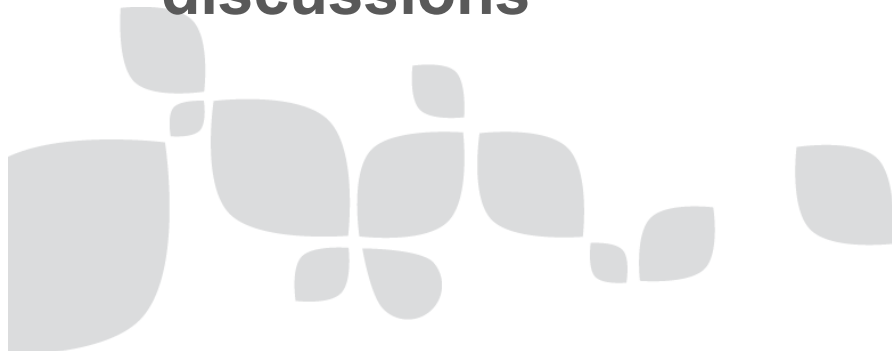
- Clone/distribution registration
- Transfer of registration
- Non significant composition change
- Addition of new source of active substance
- Change of production site
- Addition/change of packaging size
- Addition of Article 51 within risk envelop

Consistency on the principles needed : No clones or distributors allowed while parallel imports are!

Commenting period during Zonal process



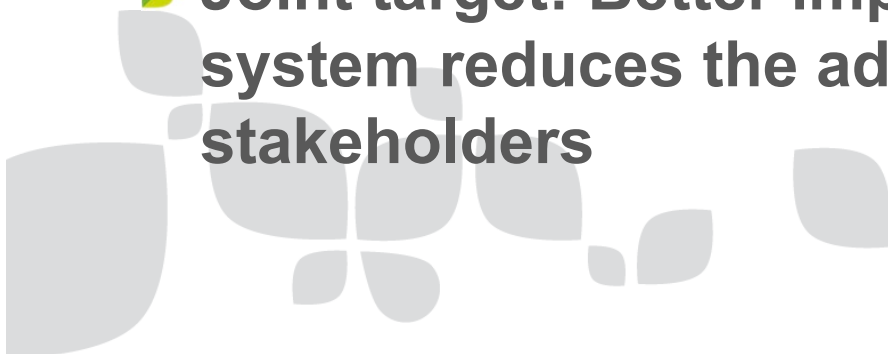
- Comments from cMS should be considered and addressed with arguments during the commenting period (noting is not sufficient, see 13169 rev11!)
- No refusal of registration on a point closed during commenting period
- Non commenting by cMS means agreement with zRMS
- Applicants always ready to scientifically support the discussions



Conclusion



- Appreciate all the efforts done in order to improve the process
- Further efforts on communication points outlined and harmonized approaches necessary
- One day zRMS, the other cMS
 - Clarity on requirements in the zones,
 - Confidence in the evaluations,
 - Communication during the evaluations... are **KEY**
- **Joint target: Better implementation of the zonal system reduces the administrative burden for all stakeholders**



Thank you for your attention

jeanne.roederer@adama.com

