SCC
WE CARE FOR YOUR SUCCESS

Regulation (EC) 1107/2009

Critical issues and possible amendments

Dr. Karin Lauber
Senior Manager Regulatory Affairs
Agrochemicals and Biopesticides
SCC Scientific Consulting Company

CEUREG 2017, Bratislava

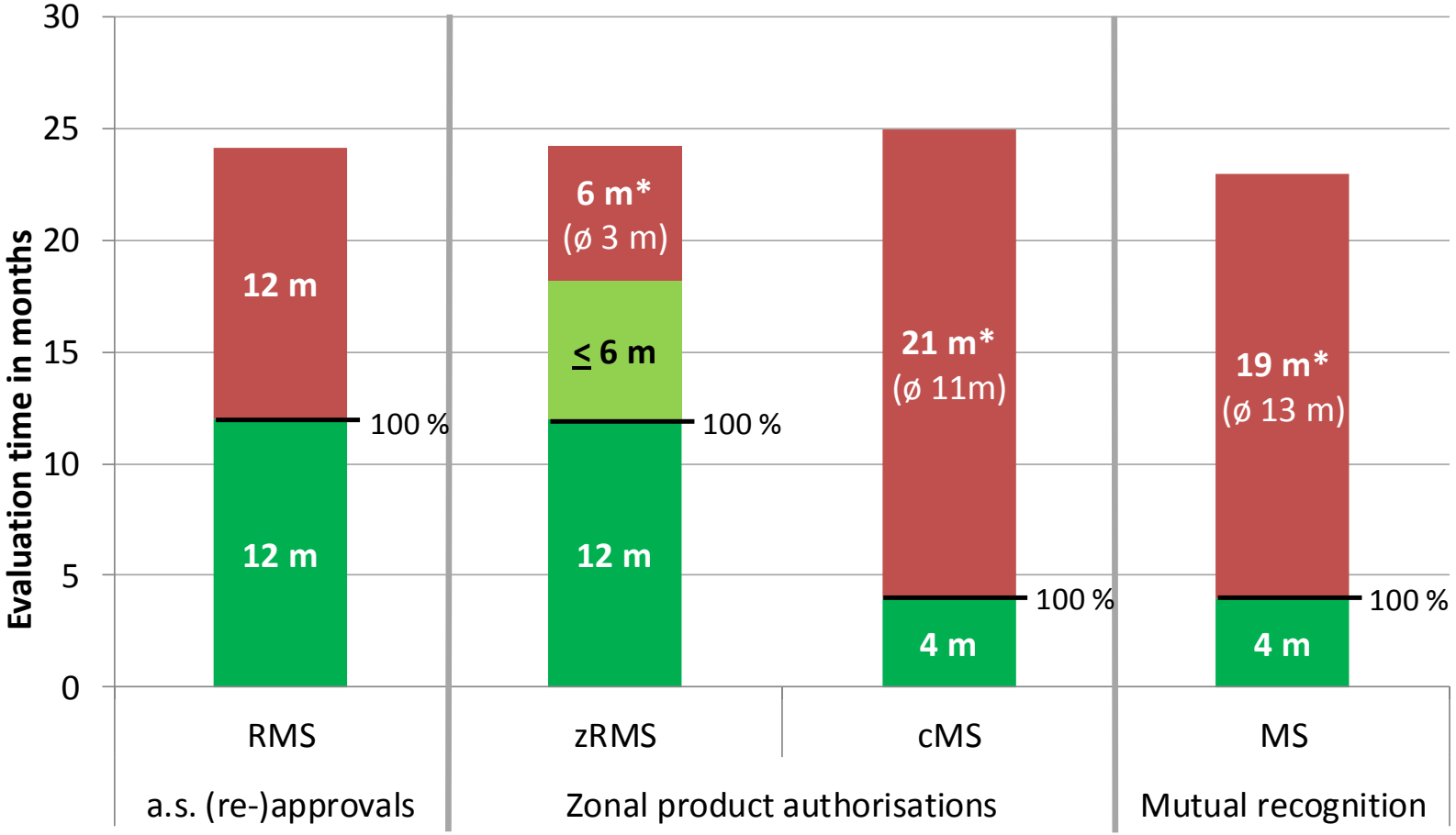
SCC
WE CARE FOR YOUR SUCCESS

The 4 main processes

1. Active substance (re)approvals (AIR and NAS) [Art. 4 – 24]
2. Product re-authorisations [Art. 43]
3. Zonal product authorisations [Art. 28 – 39]
4. Mutual recognitions [Art. 40 – 42]

Main problem for all processes

Significant delay in evaluation



Legal evaluation time Delay Clock-stop

** Source: DG(SANTE) 2017-6250 - MR*

SCC
WE CARE FOR YOUR SUCCESS

Challenges for the active substance evaluation

- Oversized AIR groups
- Too large GAPs
- No advantage for LRAI (low risk active substances)
- Brexit
- Separate MRL process
- No risk classes

Active substance (re)approval

AIR (Annex I renewal) and NAS (new active substances)

SCC
WE CARE FOR YOUR SUCCESS

Proposed solutions

- Oversized AIR groups

Excerpt of AIR 4 Group 1 with expiry date 30.04.2019 [SANTE-2016-10616 & COM. IMPL. REG. (EU) 2016/183]

Supplementary dossier (submission date: 30.10.2016) *			EFSA evaluation (start: Feb. 2018)
MS	RMS	Co-RMS	
AT	2 suppl. dossiers	---	28 RARs/dossiers
DE	3 suppl. dossiers	2 suppl. dossiers	
DK	5 suppl. dossiers	1 suppl. dossier	
EE	2 suppl. dossiers	---	
NL	**5 suppl. dossiers**	**10 suppl. dossiers**	
SE	**10 suppl. dossiers**	**---**	
UK	1 suppl. dossier	---	
* under consideration of only 1 notifier per substance			

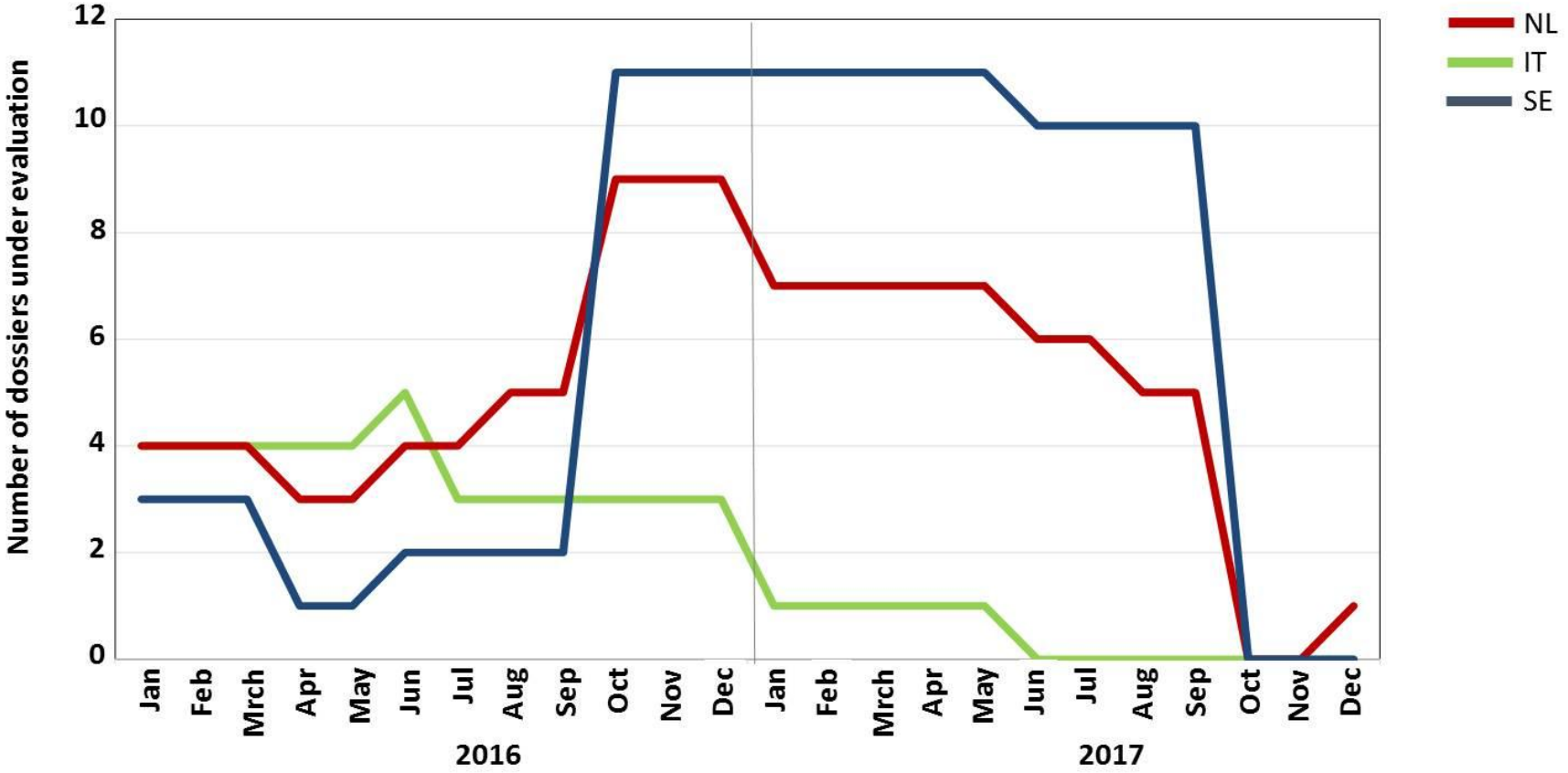
Active substance (re)approval

AIR (Annex I renewal) and NAS (new active substances)

SCC
WE CARE FOR YOUR SUCCESS

Proposed solutions (cont.)

Too many dossiers under evaluation at the same time



Under consideration of only 1 notifier per substance and AIR2, AIR 3 and AIR 4

SCC
WE CARE FOR YOUR SUCCESS

Proposed solutions (cont.)

- Oversized AIR groups
  - Prolongation of the current approvals to get smaller evaluation groups
    - But maybe legal problems with additional prolongation

- Too large GAPs
  - Max. number of “representative uses” necessary
  - e.g. maximum 5-7 uses (i.e. spring / autumn / greenhouse use; late / early application; high / low crop)

- No advantage for LRAI
  - Fast track procedure for LRAIs needed => Discussion on-going
  - Unlimited approval period with data call-in

SCC
WE CARE FOR YOUR SUCCESS

Proposed solutions (cont.)

- Brexit
  - AIR: 1 year evaluation as RMS plus delay
  - Considering all dossiers from March 2018 **=> 10 dossiers to be evaluated from UK**

- Alignment: Inclusion of MRL evaluation in the AIR procedure
  - New problem: More work for EFSA as all uses must be considered => Extension of staff needed
  - But: Reduction of workload, when risk classes will be used:

Proposal of risk classes

Class	Possible risk classes	Evaluation	Approval period (NAS and EAS)
V	Cut-off	RMS + EFSA + ECHA	No approval
IV	Candidate for substitution	RMS + EFSA + ECHA	10 years (instead of 7 years)
III	Specific risk	RMS + EFSA (ECHA upon request)	15 years (instead of 10 years)
II	Standard	Only RMS (EFSA upon request)	20 years (instead of 10-15 years)
I	Low risk	Only RMS (EFSA upon request)	Unlimited approval period (with data call-in)

SCC
WE CARE FOR YOUR SUCCESS

Challenges for product re-authorisation (Article 43)

- Too many applications at the same time
  - Too many dossiers to be evaluated in parallel
  - Cat. 4 studies only postpone the problem
- No advantage for LRAI products (low risk active substance products)
- Brexit

Product re-authorisation

Article 43 of regulation (EC) 1107/2009

Proposed solutions

- Too many applications at the same time

No. of dossiers (excerpt of AIR 4 Group 1) [4] [5]		
Evaluator [1]	**Supplementary dossier (submission date: 30.10.2016)**	**Art. 43 [3] (submission date: 30.07.2019)**
AT	2 suppl. dossiers (RMS)	2 – 10 dossiers
DE	3 suppl. dossiers (RMS)	3 – 15 dossiers
DK	5 suppl. dossiers (RMS) [+ 1 suppl. dossier as Co-RMS [2]]	6 – 30 dossiers
EE	2 suppl. dossiers (RMS)	2 – 10 dossiers
NL	**5 suppl. dossiers (RMS) [+ 7 suppl. dossiers as Co-RMS [2]]**	**12 – 60 dossiers**
SE	**10 suppl. dossiers (RMS)**	**10 – 50 dossiers**
UK	1 suppl. dossier (RMS)	1 – 5 dossiers

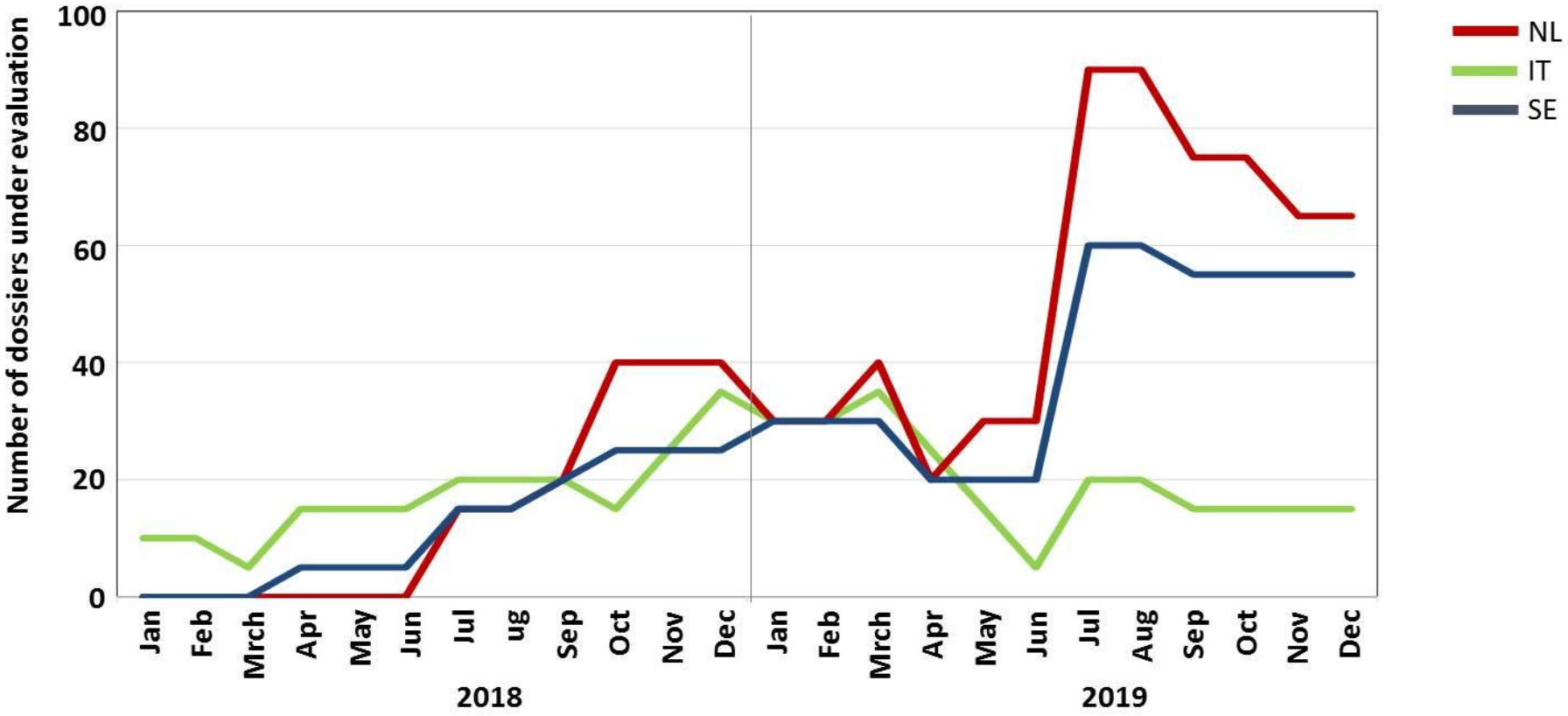
[1] RMS is zRMS in its zone; [2] RMS is from another zone and Co-RMS to be considered as zRMS of its zone; [3] Assuming 1-5 products in zRMS country; [4] SANTE-2016-10616 & COM. IMPL. REG. (EU) 2016/183; [5] Expiry date: 30.04.2019

Product re-authorisation

Article 43 of regulation (EC) 1107/2009

Proposed solutions (cont.)

- Too many dossiers under evaluation at the same time



Assumptions:

RMS is zRMS in its zone; RMS is from another zone => Co-RMS to be considered as zRMS of its zone; Assuming 5 products in zRMS country

SCC
WE CARE FOR YOUR SUCCESS

Proposed solutions (cont.)

- Too many applications at the same time
  - Smaller Art. 43 groups needed

- Fast track re-authorisation procedure for LRAI- containing products
  - Combination of Article 43 and Article 47 of the regulation => already under discussion
  - Unlimited authorisation period with data call-in (compliant to a.s. approach)

- Brexit
  - Art. 43: 6 months evaluation as zRMS plus delay
  - Considering all dossiers from October 2018 **=> 125 dossiers to be evaluated from UK**

SCC
WE CARE FOR YOUR SUCCESS

Challenges for the zonal approach (product authorisation)

- Difficult to find a zRMS
- Complete re-evaluation by cMSs
- No interzonal approaches
- No fast track procedure for use extensions
- No harmonisation of
  - evaluations
  - applications
  - zones
- No real attractivity for minor use applications
- No clearity of using Guidance documents

SCC
WE CARE FOR YOUR SUCCESS

Proposed solutions

- Difficult to find a zRMS
  - Either: It should be mandatory to accept all applications received, like in Germany
  - Alternative:
    - Zonal secretariat to distribute the work
    - Pre-notification to zonal secretariat with proposal of zRMS

- Complete re-evaluation by cMSs
  - cMSs should be regarded as mutual recognition => only administrative act
  - Elimination of cMS procedure => only zRMS and afterwards MR

- Interzonal approaches
  - Interzonal zRMS to be defined for several sections (e.g. PhysChem, Analytic, Toxicology)

- Fast track procedure for use extensions
  - No full evaluation needed any more (e.g. Toxicology, PhysChem …)

SCC
WE CARE FOR YOUR SUCCESS

Proposed solutions (cont.)

- Harmonised evaluation
  - Real harmonised evaluation needed
  - Better communication between the Member States
  - Elimination of national approaches
    - No national trials
    - No national addenda
    - No national risk assessments => EU risk assessment is sufficient!

- Harmonised application
  - One harmonised application form (as already realised in the Northern zone)
  - Electronic application needed, with automatic consideration of PPPAMS system

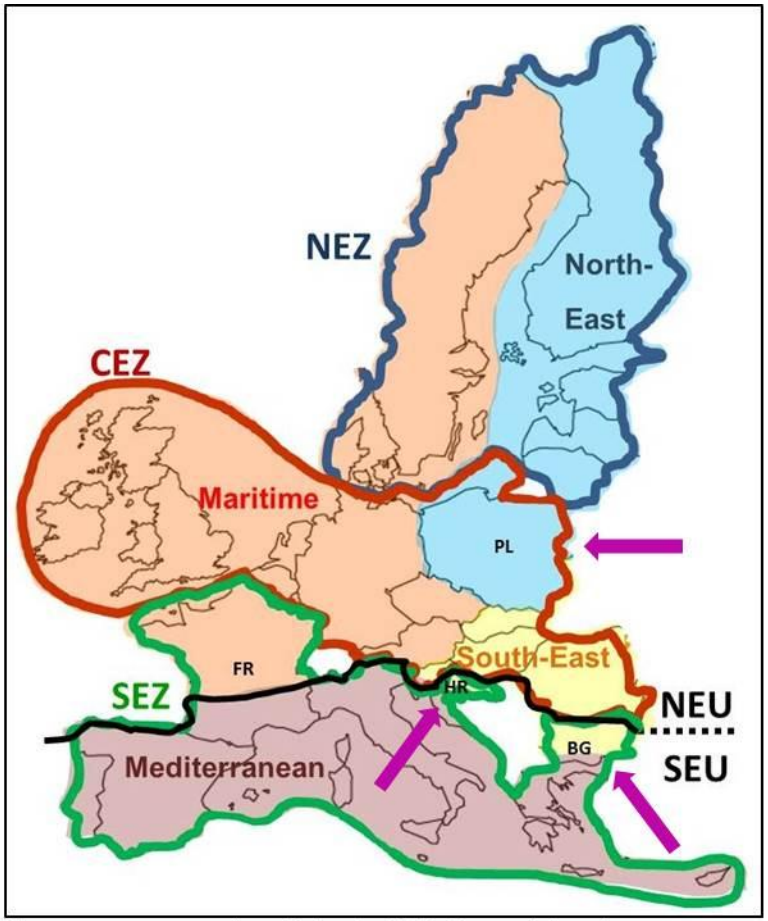
- Harmonisation between political, residue and EPPO zones
  - Re-organisation of zones (political vs. EPPO vs. residue zones) for efficacy and residue evaluation

Product authorisation

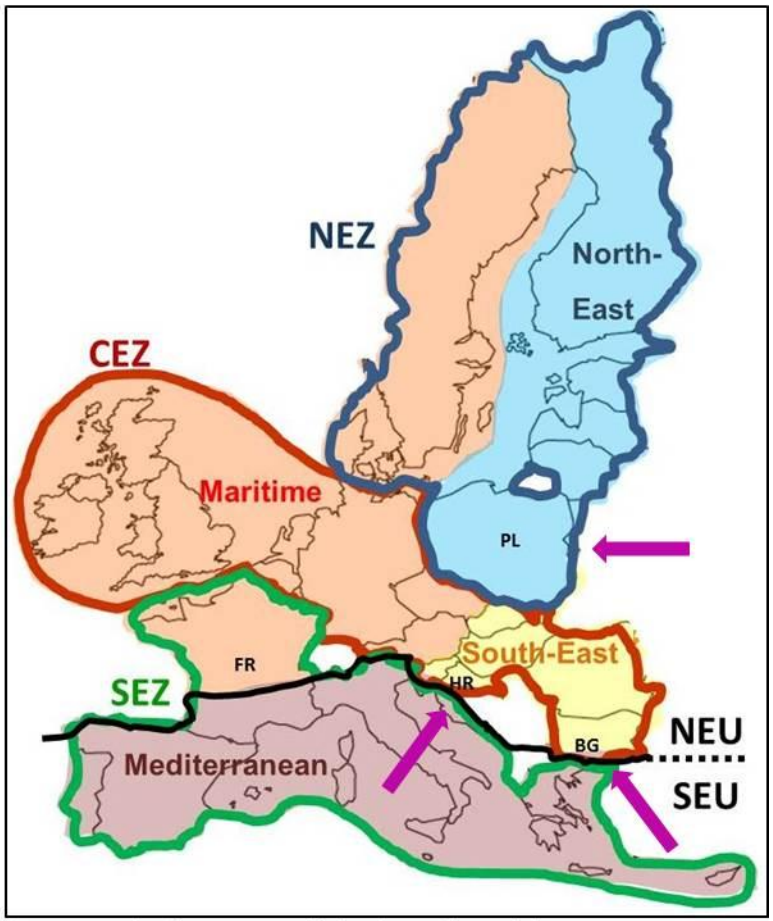
Zonal approach (Art. 29 and Art. 33 of regulation (EC) 1007/2009)

SCC
WE CARE FOR YOUR SUCCESS

Proposed solutions (cont.)



Current zones (political, EPPO, residue)
PL in CEZ, BG & HR & FR in SEZ



Proposal of new political and residue zones
PL in NEZ, BG & HR in CEZ, BG & HR in NEU

SCC
WE CARE FOR YOUR SUCCESS

Proposed solutions (cont.)

- More attractivity for minor use applications
  - Application acc. to Art. 51 without major use registration => Fast track procedure of minor use evaluation
  - Many actions are already on-going

- Clearity in using Guidance documents
  - Clear Entry into Force date needed for all Guidance documents
  - Avoidance of using draft guidances

SCC
WE CARE FOR YOUR SUCCESS

Challenges for mutual recognition

- Complete evaluation by MSs instead of mutual trust
- Interzonal MR is exceptional case
- Many national documents requested (e.g. national addenda)

SCC
WE CARE FOR YOUR SUCCESS

Proposed solutions

- No re-evaluation by MSs
  - MR should only be an administrative act => Legal requirement
    - No national documents (e.g. national addenda)
  - Timeframes to be controlled by the zonal secretariat
  - Should be the preferred way for all product applications => also in practice

- Interzonal MR should be allowed
  - Refusal only in exceptional cases (e.g. Olives from Spain to Finland)
  - Comparable agricultural practices only to be checked when different EPPO zones are involved

Overall conclusion

Main challenges and main solutions

SCC
WE CARE FOR YOUR SUCCESS

Main Challenges

Too high workload

Not enough mutual trust

Main solutions

Harmonisation

Replacement of cMS evaluations by Interzonal mutual recognition system

Pilot phase: Data-call in system for LRAI and LRAI products

Afterwards

After pilot phase: Data-call in system for all a.s. and all products

After extension of EFSA staff: *Replacement of RMSs by EFSA as sole European Rapporteur*

SCC

WE CARE FOR YOUR SUCCESS

Thank you for your kind attention