Implementation of Regulation 1107/2009, current issues and future challenges

CEUREG ,

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Content

- Agricultural focus
- Endocrine Disruption
- Candidates for Substitution and comparative assessment
- Guidance documents
- Product authorisations
- Renewal of authorisations (Post-AIR)

Agricultural focus

- **PPP Regulation designed to ensure high level of protection of both human and animal health and the environment...; while improving agricultural production**
- **In terms of self sufficiency and land use outside EU, the EU consumers rely more on imported food**
  -Consumer choice to buy local will not help if the solutions for fruit and veg, often minor crops, are not available
- **Regulatory process excludes experience eg monitoring data**
- **Need for the benefits to be evaluated (already case for Biocides and REACH) to support agricultural production**

Plant protection:
Trend in market introduction…

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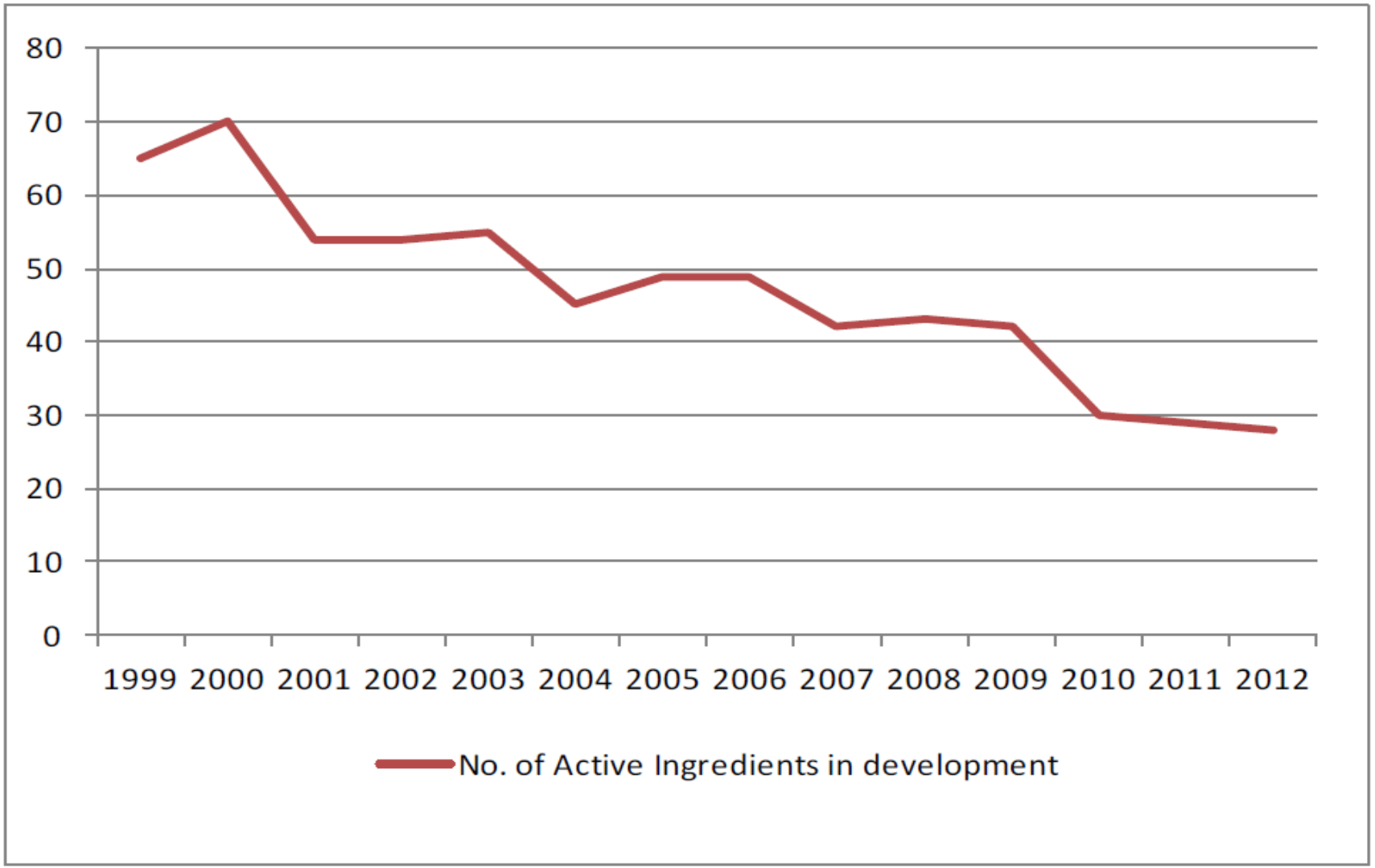
Figure 5: *Agrochemical Active Ingredients in development*



Regulatory challenges in 1107/2009

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Issue	Regulation date	Actual date
Minor use report (Article 51.9)	14-DEC-2011	05-2014
Candidates for Substitution (80.7)	14-DEC-2013	2015 ?
Endocrine Disruption (Annex II, 3.6.5)	14-DEC-2013	2016 ?
Data requirements for Safeners and Synergists (Article 26)	14-DEC-2014	Postponed to 2018
Report on functioning of regulation (82)	14-DEC-2014	2016 ?

ED: Key issues

- Support for risk based approach
- Criteria could severely reduce PPPs availability in EU
  - ***Good input into the impact assessment will be vital!!***
- Application of interim criteria

  - C2 & R2: should not trigger ‘cut-off’ when adverse effect is not mediated via endocrine MOA

ED regulation in the EU

ENVIRONMENT

Horizontal ED criteria for all sectors

HEALTH AND CONSUMERS

Pesticides	Biocides	REACH
Hazard-based cut-off	Hazard-based cut-off	ED may be SVHC
Limited derogations possible	Derogations possible	Authorisation based on risk assessment
ED criteria: proposal by December 2013	ED criteria: adoption by December 2013	ED criteria: no legal requirements

ENVIRONMENT

ENVIRONMENT

Harmonized criteria, but consequences differ

Looking at the potential impact…

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- **Potential impact of the ED criteria is extremely high**
  - Triazole family identified as being at risk
  - ***What could that mean?***

Top Ten Products, Poland, Sugarbeet, Fungicides (2011)

Brand	Net Area (000 ha)	Value (€m)
Duett Ultra	105.51	
Eminent 125 SL	9.05	
Alert	11.94	
Yamato	8.63	
Tebu 250 EW	9.34	
Topsin M 500 SC	6.72	
Orius 25 EW	5.76	
Optan 183 SE	2.52	
Horizon	2.94	
Moderator 303 SE	2.39	
Top Ten Total	164.80	2.78
Grand Total	369.72	2.90
Top Ten %	**45%**	**96%**

Key:
No longer authorised
Contains triazoles
Unaffected by ED

Candidates for Substitution

- **75 substances out of approx 400**
  -many more than envisaged as pragmatic **(10%)**
  -equates to 40% of products subject to C. Assessment
  -Multiple assessment with multiple review Post-AIR
- **Number a.s. could grow as substances are reviewed**
- **Need for clear communication from Commission and MS authorities**
  -substances already approved in EU after passing through one of most stringent reg system

Comparative Assessment

- **Will start from summer 2015? with the product re-authorisations (post-AIR2)**
- **Significant additional workload at a time when resources are stretched to the limit**
- **Pragmatic approach required to maintain farmers tool box**
  -maintain 4 modes of action for each solution
  -safeguard solutions for minor uses

Scientific Guidance Documents: Relevance for risk assessment

- **Need to ensure process for new guidance consider:**
  - Relevance of risk assessment scenarios
  - Screening capacity of the risk assessment
  - Testing needs and guideline availability
- **Need for a clear mandate from Commission**
- **Involve end users**
  - Regulatory risk assessors
  - Industry risk assessors

Implementation of GD

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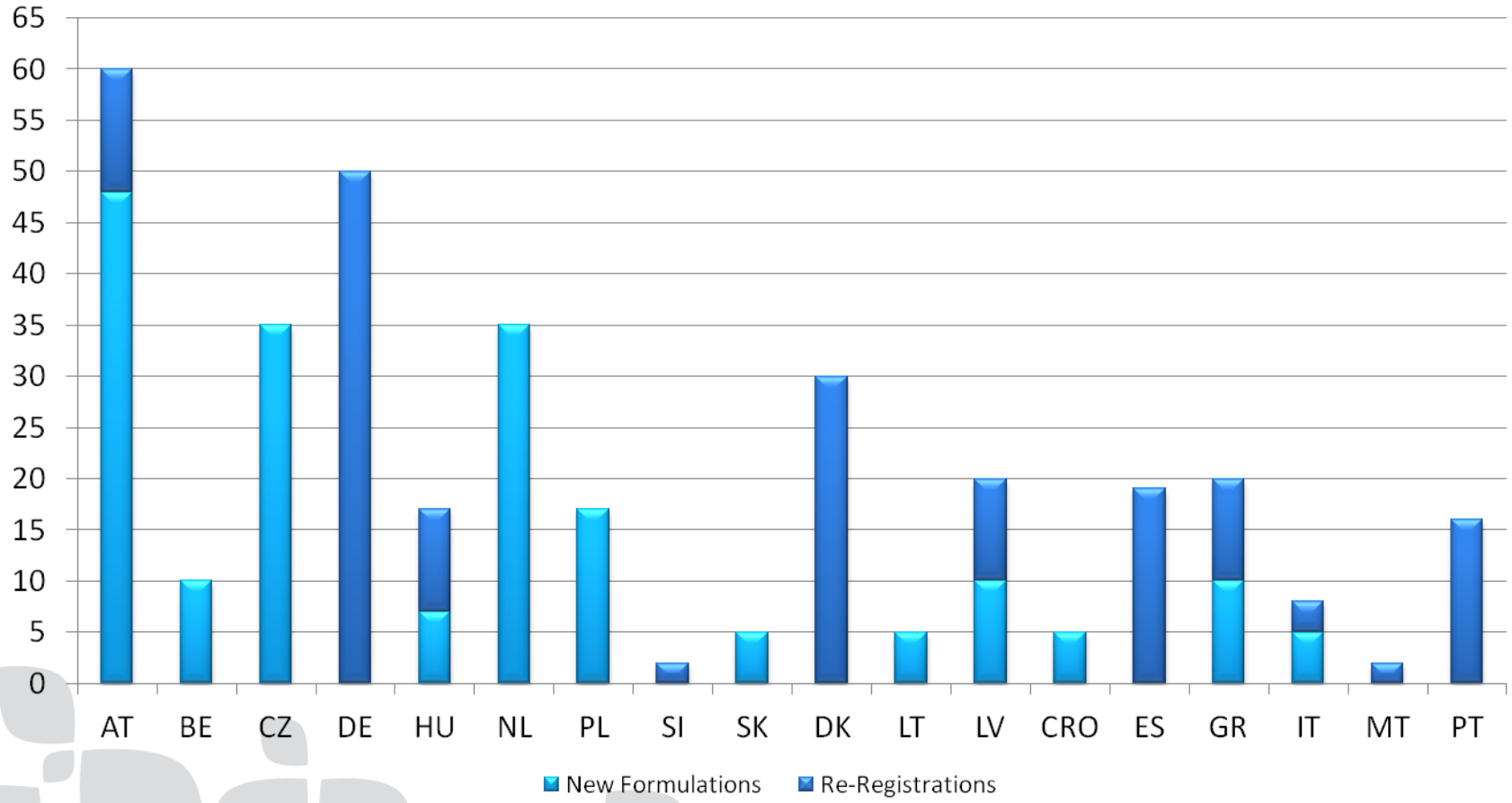
- Define realistic implementation timelines on the basis of testing capacity
- Plan feedback on the guidance document and adjustments
- ***Testing phase before full implementation would be a positive step***

ECPA Survey on MS Capacity 2015



Zonal process: what has been achieved so far?

- **South Zone**
  - Established ways of working
  - Agreed how to manage north zone residue data for applications including FR
  - Improvements in resourcing (fees to agencies)
- **Central Zone**
  - UK CRD harmonisation initiatives
  - NL Ctgb Tour of Directors
  - CZSC list of agreements
  - Increase in resources in some countries
  - Review of working practices between MSs (pilots)
- **Interzonal**
  - dRR Workgroup could improve harmonisation
  - Post Approval Issues Group – facilitating ways of working across EU
  - Indications of increased willingess to mutually recognise in some countries

The Key Outstanding Issues to be Resolved

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- **Increase resources to meet the demands of the regulation**
- **Remove the national requirements (technical and procedural)**
- **Increase zonal and interzonal co-operation**
  - Zonal Helpdesks to co-ordinate the work and improve efficiency
- **dRR quality**
- **Reconsideration of Article 43**
- **Article 75(3) requires MSs to ensure Authorities have sufficient resources**

Renewal program: Key concerns

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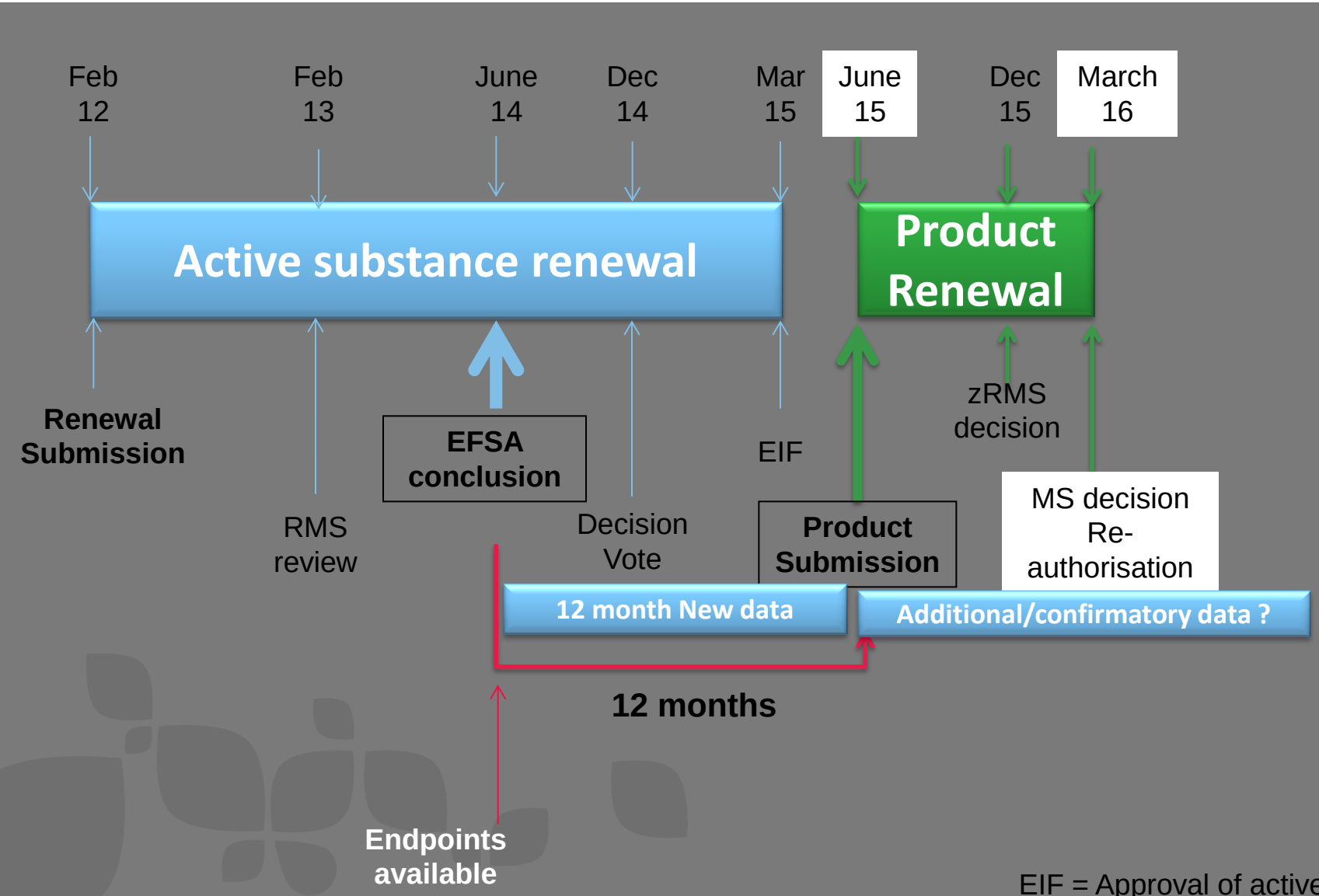
- Challenging timelines for evaluation (30 months) of actives
  -AIR1 significant delays
  -AIR2 also significant delays
- Timeline for Article 43 is not manageable
- A Specific PPP should only be **reviewed once**, and not after the approval of each active substance in the PPP
- Consequence of multiple reviews (1 before) of mixture products ->Resources of MS overloaded unncessessary

ECPA Propose a technical amendment of Article 43 only

Timeline: AIR 2 -Decision Dec 2014



EIF = Approval of active substance

Renewal of product authorisations (Article 43) : Guiding principles

- Relatively minor changes for Efficacy under Regulation 1107/2009 vs Directive 91/414
- Uniform Principles complied with and original Efficacy assessment remains valid
- **No need to resubmit original data**
- Do need updated Resistance Risk Analysis
- Guidance under development

Sue Mattock, CRD, Brighton Conference, 1st. Oct 2014

Accession to EU

- Good preparation and implementation of 1107/2009 principles before accession
- Implementation in advance improves one aspect of the dossier to be approved by existing MS to EU
- Good example Croatia, with a program of review of products to UP before accession

Conclusion

- **2015 will be challenging**
  -Start of comparative assessment ?
  -Progress on framework legislation for ED
  -Challenges in capacity for MS: Post-AIR2
- **Need for Action**
  -Make the zonal process work efficiently
  -Amend Article 43
- **Is agricultural production improving ?**

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Thank you for your attention

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