ECPA view of the major regulatory challenges

CEUREG XVII

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Content

- Cut-off issues
- Candidates for substitution
- Comparative assessment
- Guidance document development
- Zonal process
- Revision of Regulation 1107/2009
- Revision of Regulation 396/2005
- Endocrine disruption
- Bee guidance document

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PhillipsMcDougall
AGROCHEMICAL & BIOTECHNOLOGY CONSULTANTS

R&D trends

for chemical crop protection products and the position of the European Market

A consultancy study undertaken for ECPA

Phillips McDougall, September 2013

Plant protection: Cost of innovation

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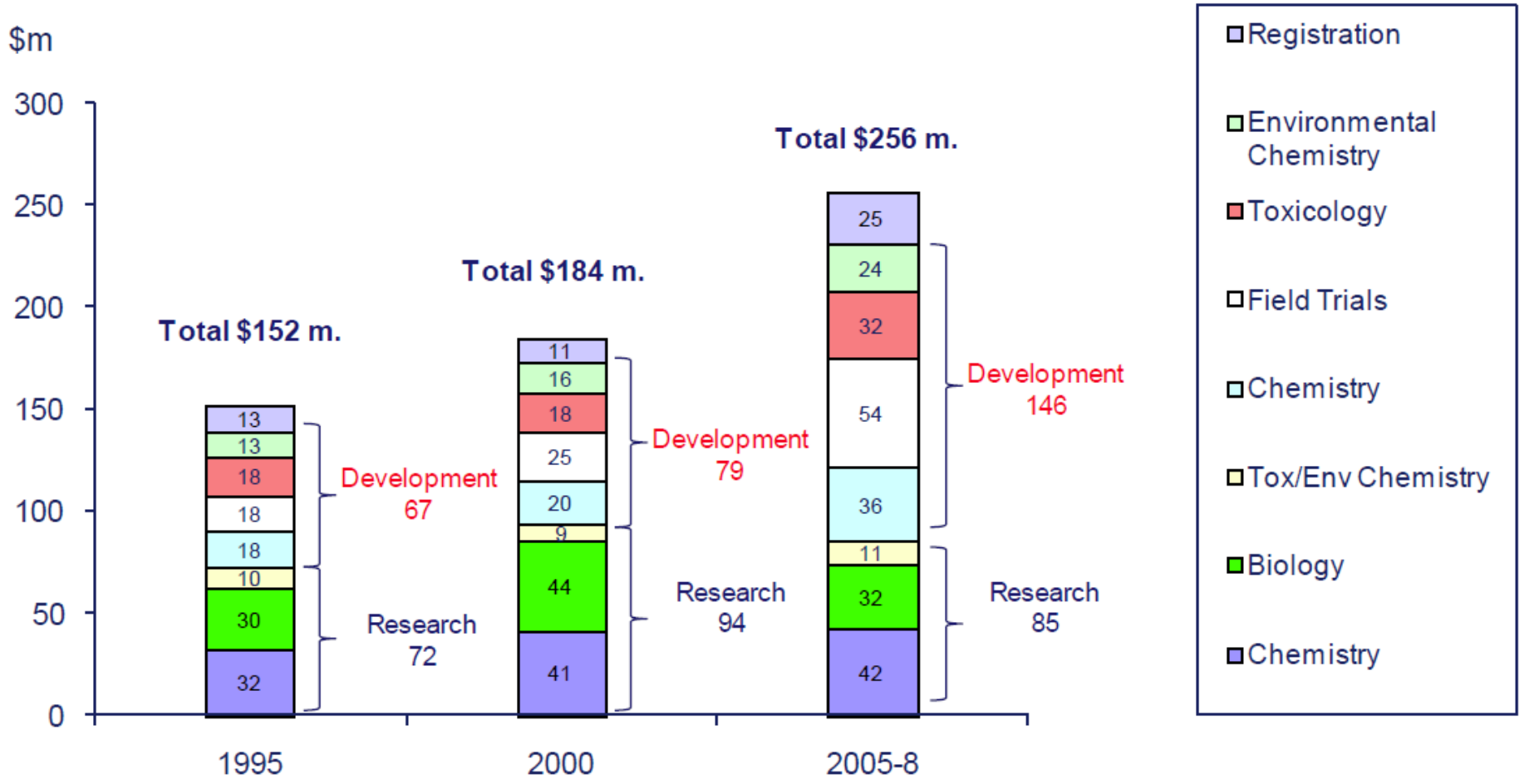
Figure 1: *The increasing cost of bringing a new Active Ingredient to the market**



* Results of a study undertaken for ECPA and CropLife America

Plant protection:
Trend in market introduction…

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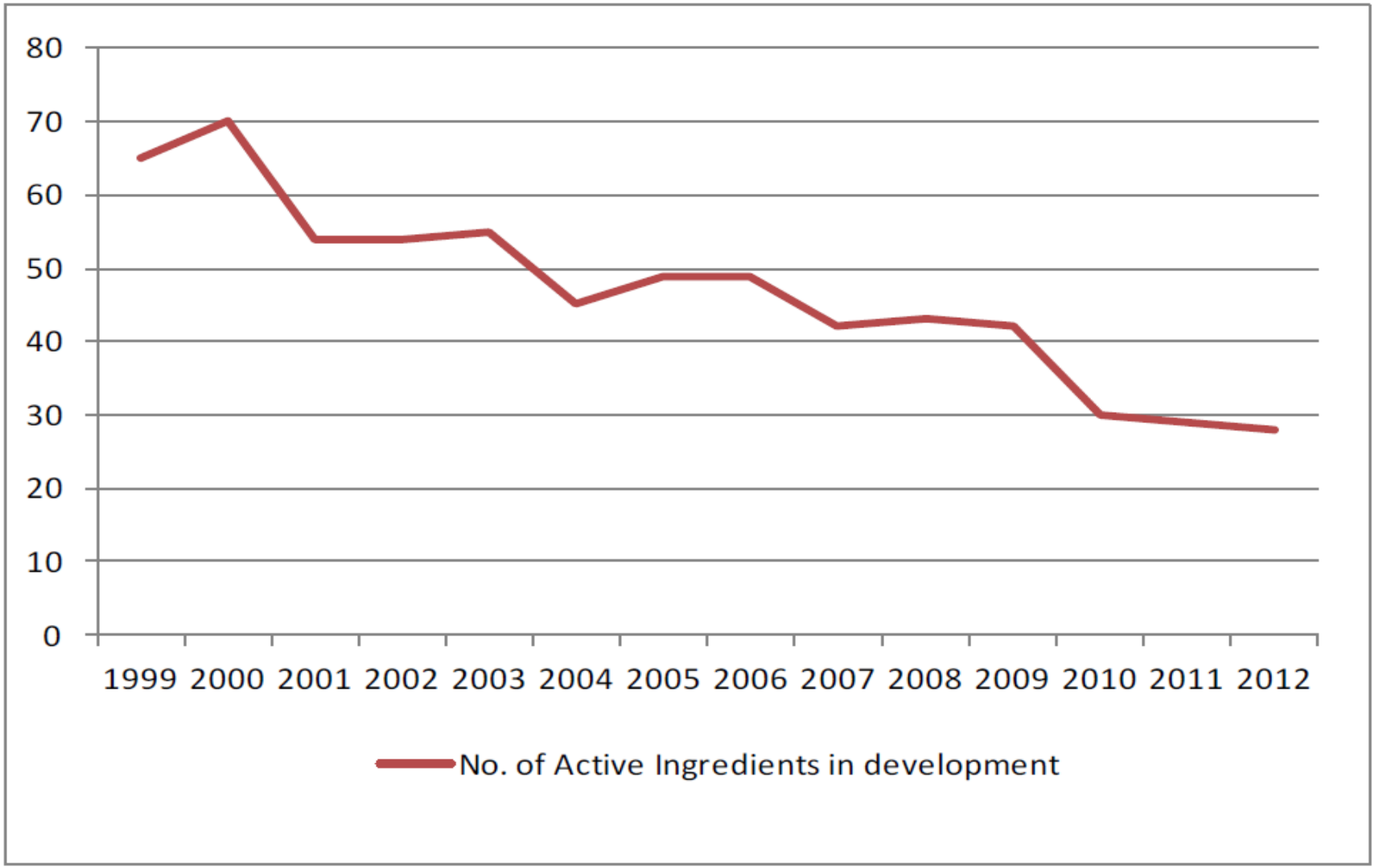
Figure 5: *Agrochemical Active Ingredients in development*



Crop protection:
Innovation and market introduction

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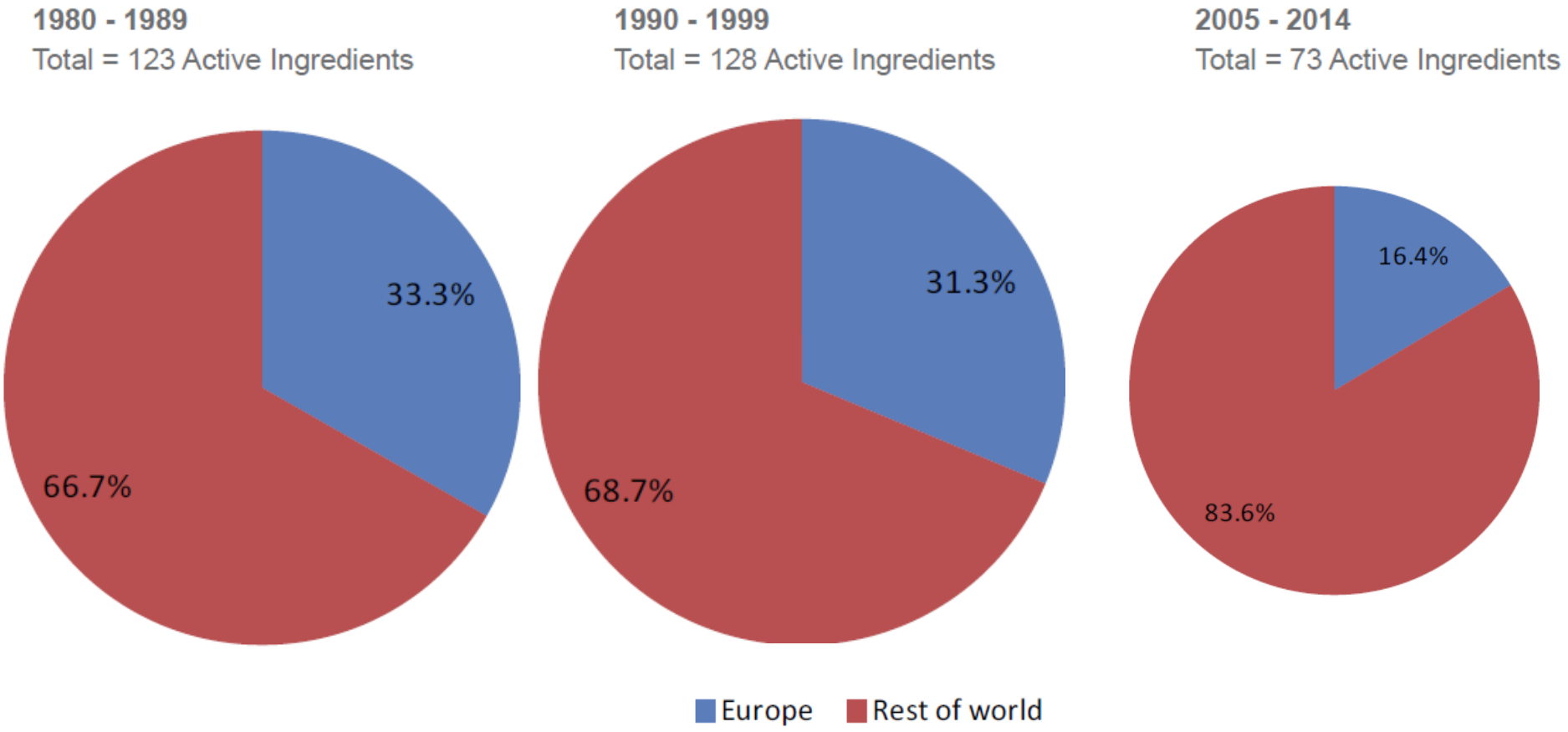
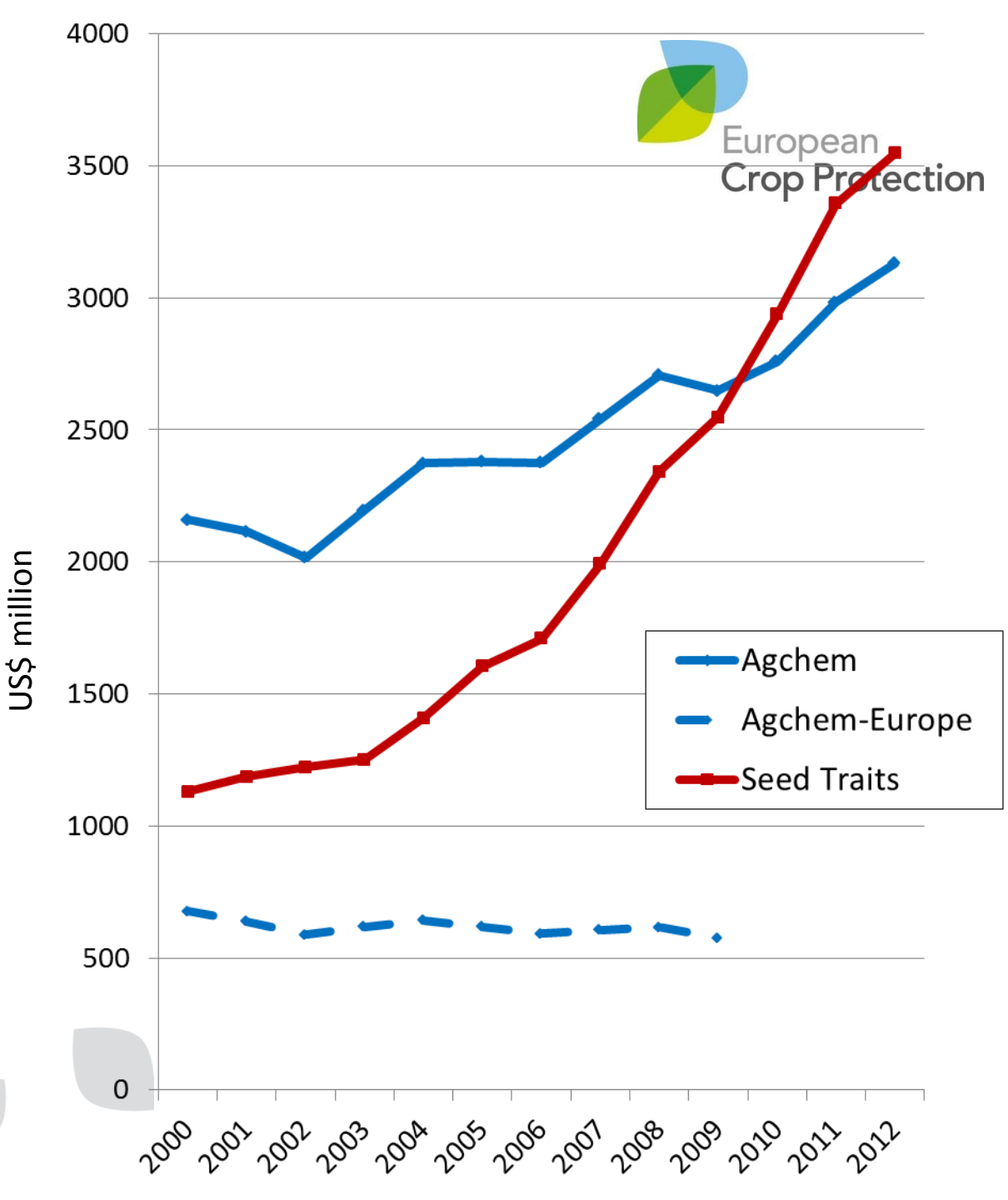
Figure 10: *Share of Active Ingredients introduced or in development*



Innovation – EU focus?

- **While global R&D spending increases, the European focus is decreasing**

  - 15% in 10 years
  - 30% in real terms!



What does this mean

- Substantial hurdles in authorisation process
  - *Which do not stimulate innovation!*
- New barriers in current Regulatory framework

Looking at some of the barriers & challenges…

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Cut-off issues

Cut-off issues

- **Defining negligible exposure**
- **Application of Article 4.7** (derogation to cut-off)
  - When can they be used?
  - When can industry apply?
- **Proposals for harmonised classification**
  - Decisions must be based on ECHA final classification

Candidates for substitution

Candidates for substitution

ECPA concerns

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- **Minismise number of ASs in list!**
- **Possible misinterpretation of list**
  - *Likely source of confusion for users / stakeholders*
  - *Need communication by authorities and industry*
- **Impact on (re)evaluation of PPPs and ASs**
  - *Complex comparative assessment process*
  - *High comparative assessment frequency*
  - *7-year approval of ASs*

Candidates for substitution

Key issues

- **Communication!** All candidates for substitution have undergone the same stringent evaluation and have been approved for use in the EU!!
  - Sufficient PPPs are need for sustainable agriculture (resistance management, minor use needs, etc.)

➢ ***Authorities should communicate to avoid misinterpretation and misuse of the list***

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Comparative assessment

Comparative assessment

Pragmatic implementation?

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- ECPA have highlighted the need for more clarity on comparative assessment process
- KEMI/SANCO draft GD now circulated

  ECPA comments

  - Swedish focus!!
  - Hazard based comparative assessment – ***NO!!***
  - Focus should be on mandatory comparative assessment
- ECPA supports process where notifiers prepare a ‘proposal for comparative assessment’

Comparative assessment

ECPA next steps

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- Further comments on Swedish proposal for comparative assessment process
- Complete ECPA proposal for a template to support comparative assessment
  - *Providing the basic tools for authorities to carry out the comparative assessment*

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Guidance documents

Guidance documents

ECPA letter to DG SANCO

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1. **Incorrect use of guidance**
   - Application of draft guidance before finalization
2. **GDs not fit for purpose – inc. for zonal evaluation**
   - Aim should be to provide clarity and harmonisation
3. **Not focused on needs of risk assessors & risk managers**
   - Clearer mandate would help!
4. **Not making use of relevant available data to set parameters for GDs**
   - This role is not only for industry!
5. **Relevant expertise and independence**
   - Experts should be able to support drafting
   - With independent review…

Guidance documents

Usefulness of for decision making

- **Need to verify:**
  - Relevance of risk assessment scenarios regarding decision making (not restricted to “protection goals”)
  - Implications for existing authorisations
  - Implications for harmonization
- **Involve risk managers all way through**

Guidance documents

Implementation

- 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***

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Zonal process

Zonal process

Main issues

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- Evaluation delays by zRMS
- Capacity limitations?
  - Application refusals until 2015…
- National data requirements
  - GD implementation / lack of guidance
  - Efficacy evaluations
- ***Not working efficiently – how can we improve?***
  - ***Central secretariat is needed***
  - ***Need for flexibility and cooperation between zones***

Product renewal (Article 43)

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- **SANCO working group looking for way forward**
  - Key challenges in terms of timing!
- **General process under discussion**
  - PPP submission 3 months after AS renewal
  - If additional data needed, max 2 years to submit
  - PPP extension to allow submission + evaluation
  - Full evaluations of mixture products not needed with each AS approval, but what timing?

➢ ***A major logistical challenge for authorities and industry – we need to get it right!!***

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Revision of Regulation 1107/2009

Looking to improve the regulatory process

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- **ECPA is looking at future changes in the regulatory process**
  - For both ***Reg.1107/2009*** and ***Reg.396/2005***

- **Suggestions in 4 phases…:**
  - ***Phase 1:*** Implementing the current framework
  - ***Phase 2:*** 2015 review
  - ***Phase 3:*** Data protection review
  - ***Phase 4:*** Long-term review

Improve the regulatory process: *Phase 1*

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Phase 1: Implementing the current framework

Zonal

- Removing national requirements
- Efficacy data needs
- Inter-zonal cooperation
- Zonal secretariat

AS evaluation

- Guidance document development
- EFSA dialogue

MRL evaluation

- Application of Article 12

Improve the regulatory process: *Phase 2*

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Phase 2: 2015 review

Zonal

- One-zone concept
- Changes in Article 43

AS evaluation

- Change/remove hazard based cut-off criteria
- Change/remove candidates for substitution criteria
- Unlimited approval period for ASs

MRL evaluation

- Fast-track MRLs (e.g. default MRLs, minor uses)
- Central (on-line?) evaluation system
- Remove scrutiny procedure for MRL setting

Improve the regulatory process: *Phases 3 & 4*

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Phase 3: Data protection review

AS evaluation

- Data call-in system for AS review
- Data sharing provisions in call-in system
- 10 years data protection

Phase 4: Long-term review

AS evaluation

- Single evaluation of ASs (with centralised coordination)
- Evaluation of the use benefits of uses/ASs

Improve the regulatory process

ECPA view

- There is a need to review Regulation 1107/2009 and Regulation 396/2005
  - **to improve efficiency and coordination**.

- ***ECPA proposes that the Commission prepare a report and proposal in 2015 to amend the legislation.***

MRL review process

Learning from implementation of Article 12 procedure…

Completion of Article 12 MRL reviews

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- **Difficulties experienced**
  - Procedural conflict in the Regulation
  - Unclear role of RMS, EMS, other MSs, EFSA & notifier
    - ***National decision linked to delayed MRL setting***
- EFSA proposes a process with longer timelines but not solving the problem

➢ ***ECPA have proposed a pragmatic solution to achieve review of MRLs.***

MRL reviews:
Way forward?

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Need a pragmatic solution which does not increase workload and reduces repeat reviews:

- Involves the notifier to verify correct data is used to complete the evaluation (early in the process)
- Avoids loss of uses and additional authorisation work, when a safe MRL is identified
- Uses the Article 6 process as a basis for a process to complete the Article 12 process

➢ ***Changes to Regulation 396/2005 are needed to ensure a workable and coherent process!!***

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Thank you!