European Crop Protection

Industry view on the implementation and review of Regulation 1107/2009

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   b) Article 4.7 and negligible exposure exceptions
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   b) Classification process for ASs
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   b) Article 43
2. **Looking for improvements**
   a) Review of 1107/2009 & 396/2005
   b) Data call-in system
   c) Guidance document development

Current situation

Current situation of crop protection

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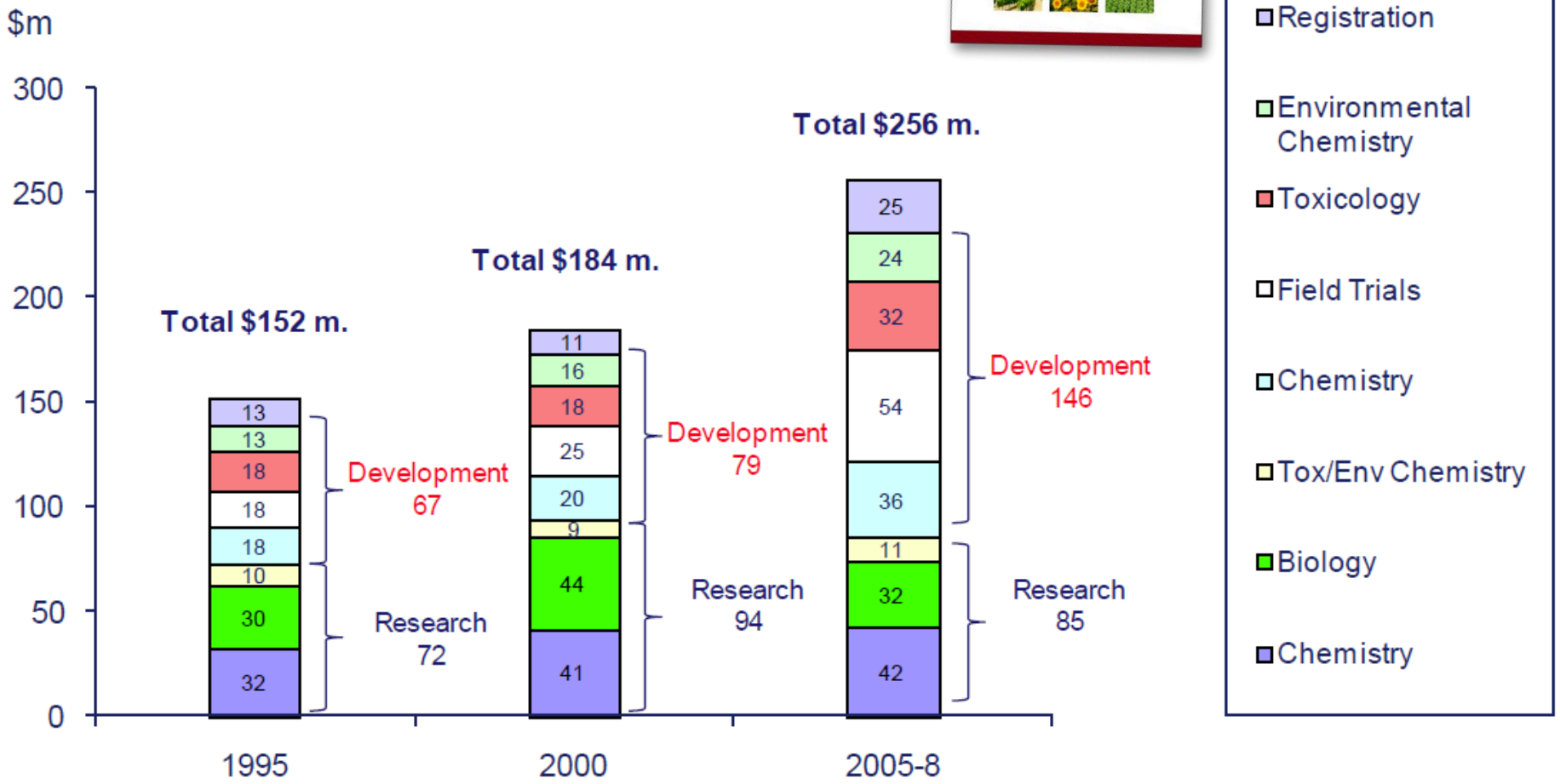
Figure 1: *The increasing cost of bringing a new Active Ingredient to the market*



* Results of a study undertaken for ECPA and CropLife America

Innovation framework

Market introduction

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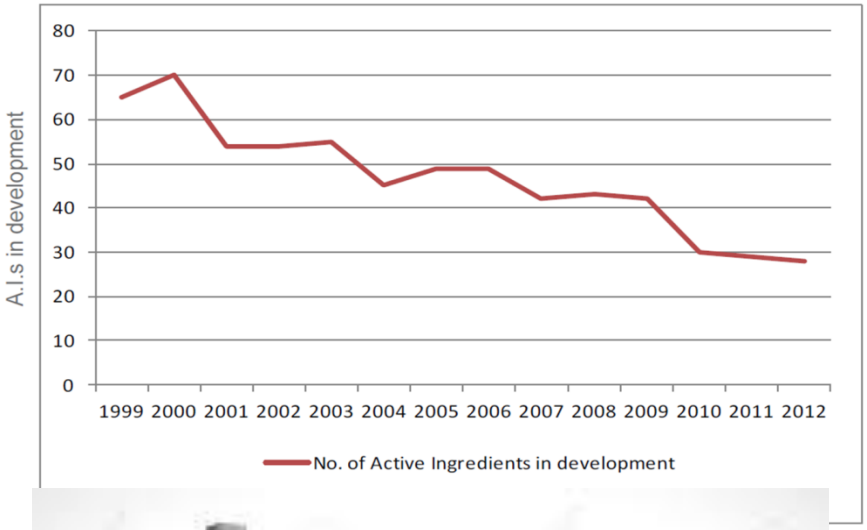
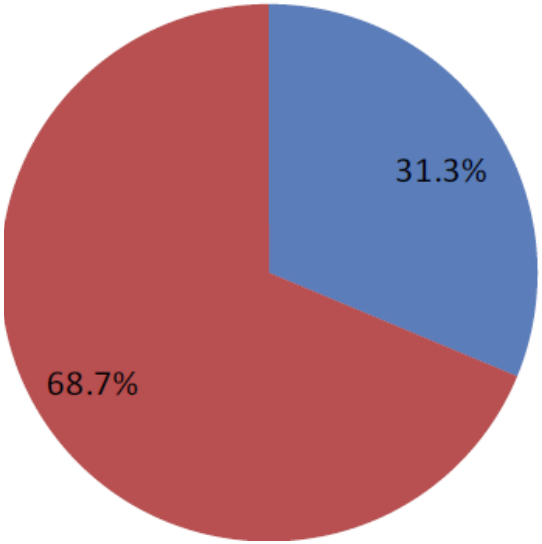
Figure 10: *Share of Active Ingredients introduced or in development*

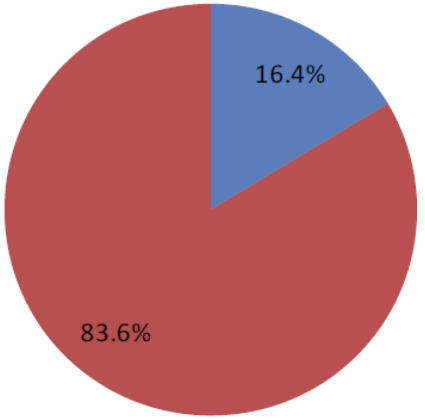
Figure 5: *Agrochemical Active Ingredients in development*



1990 - 1999
Total = 128 Active Ingredients



2005 - 2014
Total = 73 Active Ingredients



Europe Rest of world

Timelines for new active substances
Period: 2011-2016

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Regime	Submission to authorisation Average (m)	New Actives registered with products	Actives pending	Oldest pending active
Australia	33	5	0	NA
Brazil	79	1	4	March-13
Canada	30	4	0	NA
Japan	33	4	1	Mar-12
USA	30	3	0	NA
1107/2009	**48**	**3**	**6**	**Jul-11**

- **54 new substances submitted since June 2011**
- **23 substances have an Approval vote (3 non-approval)**
- **8 have products authorised - 4 conventional, 4 low risk**

Better reward for innovation in other markets
-EU farmers at competitive disavantage

Commission report: July 2017

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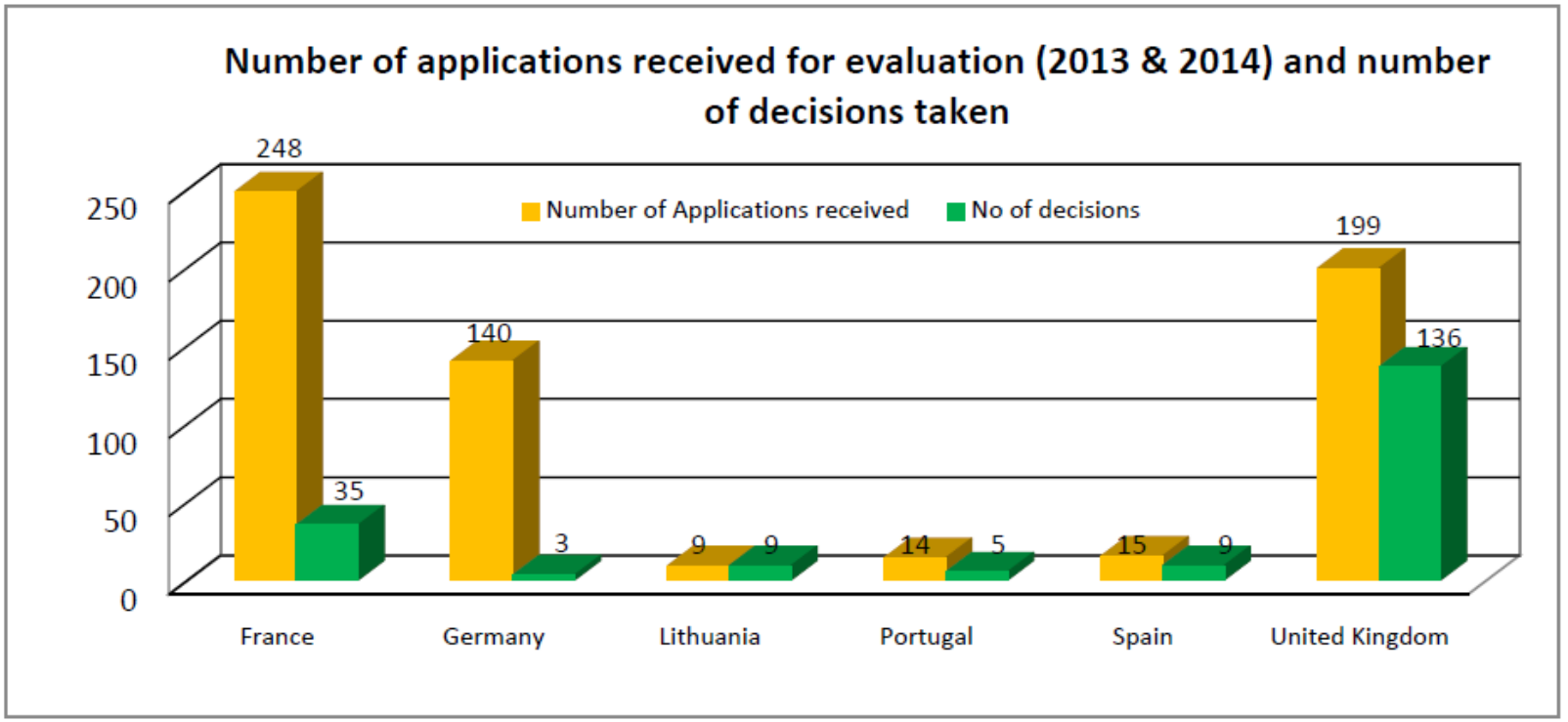

Chart 5 Number of applications received for evaluation (2013&2014) and decisions taken

Commission report: July 2017

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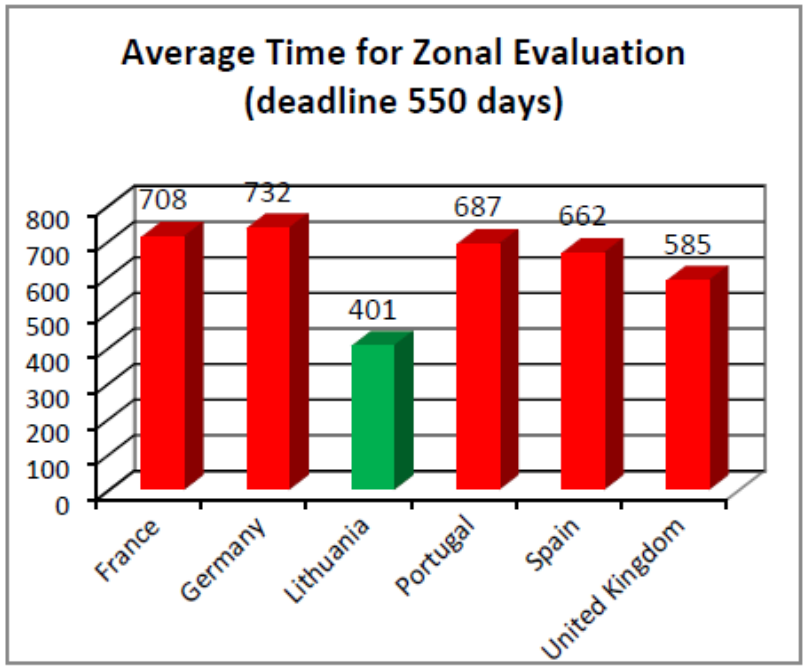


Chart 7 Average time for zonal evaluation

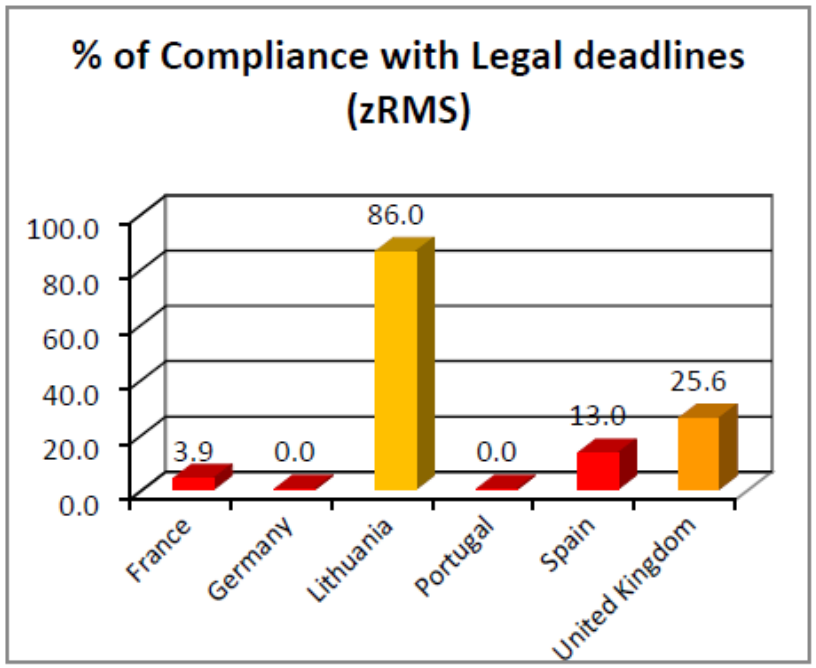
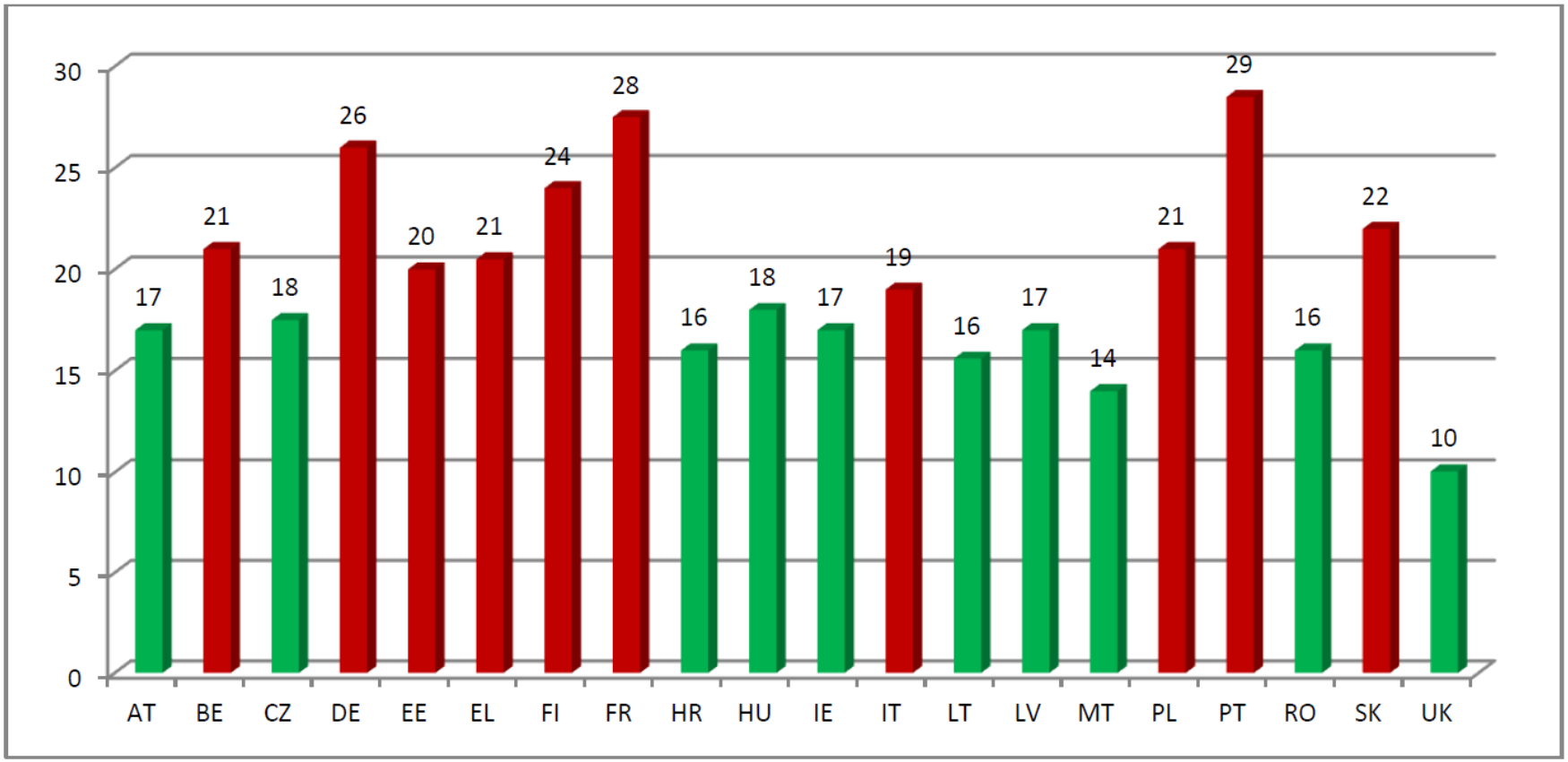


Chart 6 Percentage of compliance with legal deadlines (zRMS)

Products: past performance

Graph 4. Average decision time (in months) for decisions on applications 2012/2013



Source: Report by Directorate F: Implementation of the authorisation requirements of Regulation (EC) 1107/2009.

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Active substance evaluation

Endocrine Disruptors

ECPA position

- Criteria are not suitable for regulatory decision-making
  - *Limited to WHO/IPCS definition (hazard identification only)*
  - *No hazard characterisation (no potency)*
  - *Amendment to derogation omitted from proposal*

- However, we acknowledge MSs have decided to approve the criteria.
  - Now in the hands of the Parliament and Council…

➢ *As a next step, the amendment to the derogation must be re-introduced as promised by the Commission*

Article 4.7 & Negligible exposure

Issues/Challenges

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- Draft guidance for negligible exposure for human assessment available only, no draft for the environment
  - ***Draft GD is used as a basis for evaluation***
- Art 4(7) protocols for herbicides & insecticides, not fungicides – deficiencies in herbicide protocol identified
  - ***Little experience how to assess & unclear decision making process***

- **Next steps in decision making**
  - Policy discussion with SCoPAFF

Article 4.7 & Negligible exposure

ECPA position

- **Pragmatic implementation of the guidance on NE**
- **Approval through NE provision allows maintenance of some key substances in the farmers tool box**
- **Although Regulation 1107/2009 is hazard based a risk assessment is essential to demonstrate Negligible Human Exposure**
- **Future legislative proposals, like for Endocrine, should be based on Negligible risk**
  -already today for Biocides

EFSA Bee Guidance

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- **ECPA in dialogue with policy makers since 2012**
  - No substantial changes on the document since July 2013

POS/17/10/28028
09 June 2017

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Proposal for a protective and workable regulatory European bee risk assessment scheme based on the EFSA bee guidance and other new data and available approaches

Executive Summary

The crop protection industry recognizes the need to review the bee pollinator risk assessment based on scientific progress. However, the EFSA Bee Guidance Document issued in 2013 is not a realistically feasible way forward. It is based on extremely conservative assumptions, its study requirements lack clarity and are not workable and guidelines for a number of studies are unavailable or not validated. Industry therefore believes that a revision of the assessment scheme for use by regulatory authorities is needed. Building on an analysis of the proposed developments in the EFSA Bee Guidance Document, we suggest a proactive and *practical approach*.

This new approach is summarized in the following overview. It provides a comparable level of protection to the EFSA approach and is based on the current scientific state of the art for bee pollinator risk assessment. Key features of this approach are the focus on honey bees as a representative species, the definition of core data packages, concentration on main exposure routes and the proposal of more realistic assumptions for the risk assessment process.

Industry believes that this *Practical Approach* is both a realistic and protective way forward for bee risk assessment and would welcome the opportunity to engage in a technical discussion with Member States experts and EFSA on this topic in order to help establish a workable and protective solution as soon as possible.

1

- **Majority of Member States continue to oppose the formal adoption of the document (noting procedure)**
- **Implementation plan still on hold within DG SANTE**
  - Commission's "notice" would be enough to set up an implementation plan = no vote
  - Commission needs a vote in Standing Committee on amendment to the Uniform Principles regulation (trigger values change to be aligned with the GD content)
- **Industry proposal of EU bee risk assessment scheme finalised in June 2017 and shared with Commission/MS**

EFSA Bee Guidance

Industry proposal for refinement

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- **The EFSA document is not practical and cannot be used without major revisions before implementation**
  - In its current form, it is generating a number of uncertainties and data gaps in the conclusions of risk assessments, as observed in nearly all the EFSA journals on active substances published since January 2016

- **The ECPA Proposal summarize the outcome of over 3 years of research to propose refinements to the EFSA Bee Guidance that could be developed further with Member State & EFSA Experts**
  - It includes the outcome of collaboration with expert groups during workshops, as well as experience in method development

Industry is committed to pursue dialog with regulatory authorities and EFSA to share our experience and data to help develop a workable way forward

Import tolerances policy

Issues/Challenges

- **Hazard criteria will have a significant impact**
  - On product availability - *in EU*
  - On regulatory coherence - *globally*
- **Suggested EU policy on setting Import Tolerances communicated in SCoPAFF-Residues (June 2017)**
  - Would be incompatible with EU law and WTO rules
  - Would also impact EU MRL setting and EU production

➢ ***Continued input at political and trade level need for a workable policy***

Impact on production and trade

(Hazard based policy in setting import tolerances)

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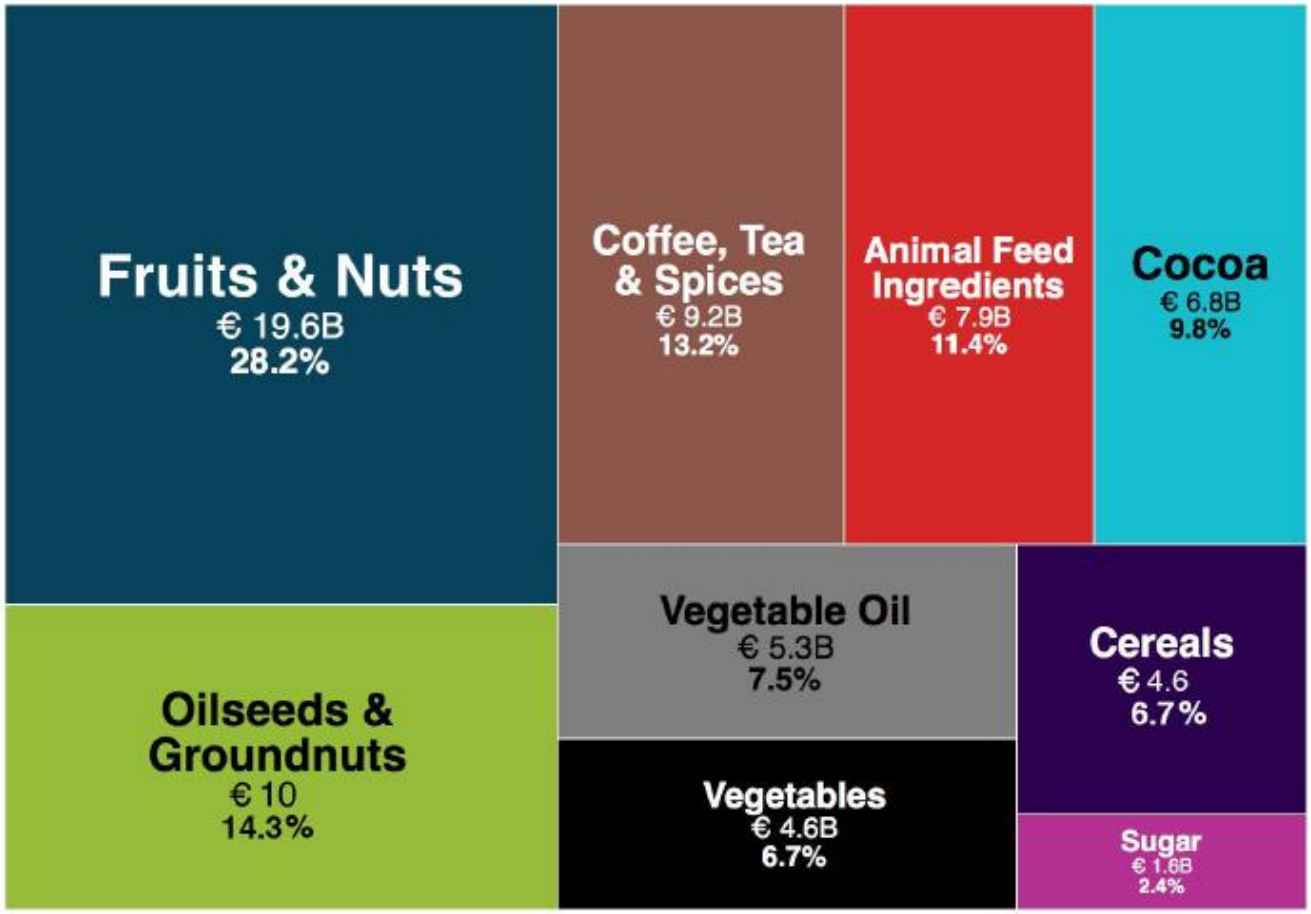
European Union 2016 Covered Commodity Imports, Value in Euros



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GLOBAL SOLUTIONS

Import tolerances
ECPA Position

- **ECPA supports approach "a" - to maintain existing (& set new) import tolerances after risk assessment**
  - ***As required under 396/2005!***

- **Approach "b" would lead to arbitrary set of different approval decisions**
  - Inconsistent with residues legislation
  - Incoherence with better regulation
  - Open to legal challenges in the EU & WTO

AIR process

AIR process

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Delays in evaluation of AIR

- Especially AIR-3, but leading to delays for AIR-4, AIR-5…
  - ***Options to ensure realistic timelines?***
  - ***Workload concerns for zRMS?***

EFSA role in peer review

- **Conservative conclusions makes decisions difficult**
  - Genotox
  - Classification
  - Etc…

- **PSN discussions on changes in process?**
  - Will this help the process?

Classification in AS evaluation

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- **EFSA suggestions for harmonised classification unhelpful**
  - Numerous proposals for new classifications
    - ***ECHA should lead the classification process!***
  - Classification template could help
  - Legislative measures needed to improve the process
    - ***Draft Regulation to be discussed in October SCoPAFF?***
- **ECHA classification process has challenges**
  - Key issues and future options?

Zonal process

zRMS Registrations
New Formulations

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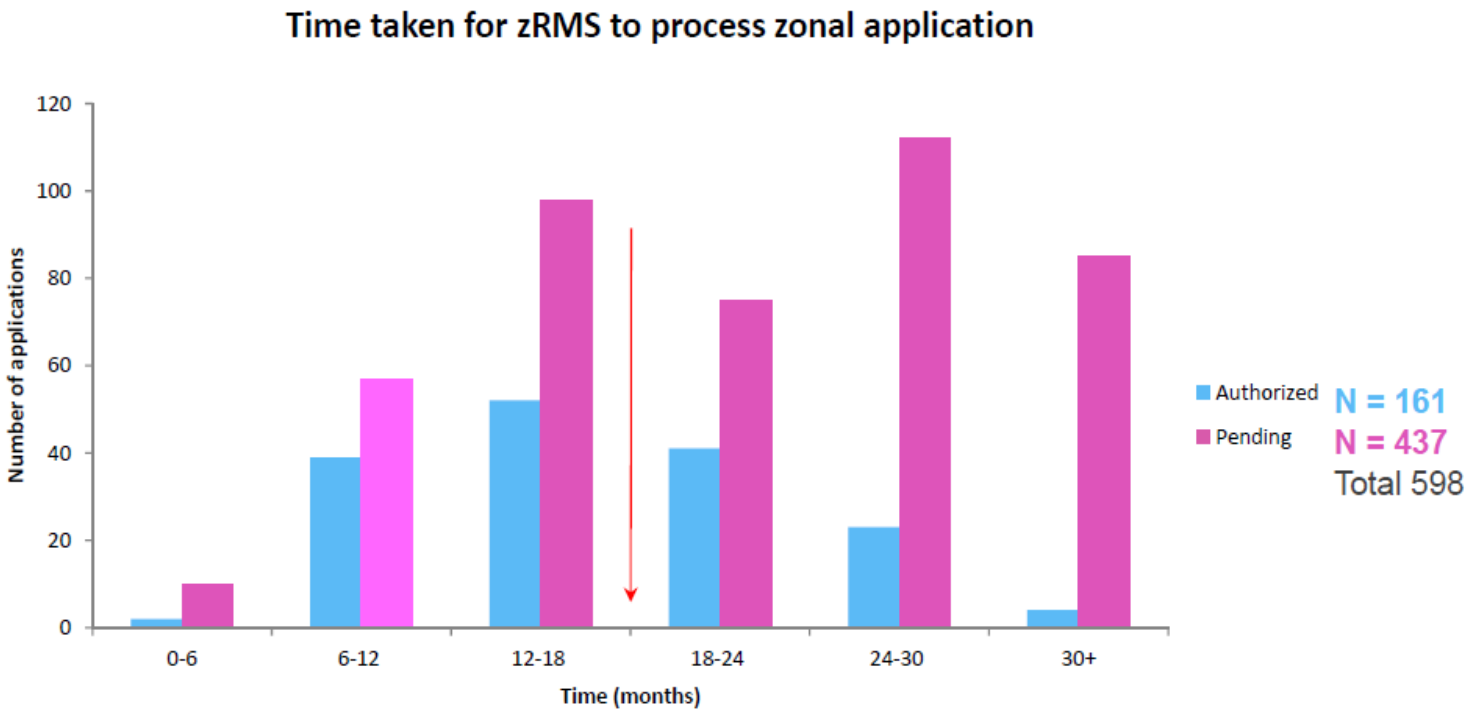

- Granted Zonal authorisations within 18 months or less = 21%
- Pending Zonal evaluations already exceeding 18 months = 62%

cMS Registrations
New Formulations

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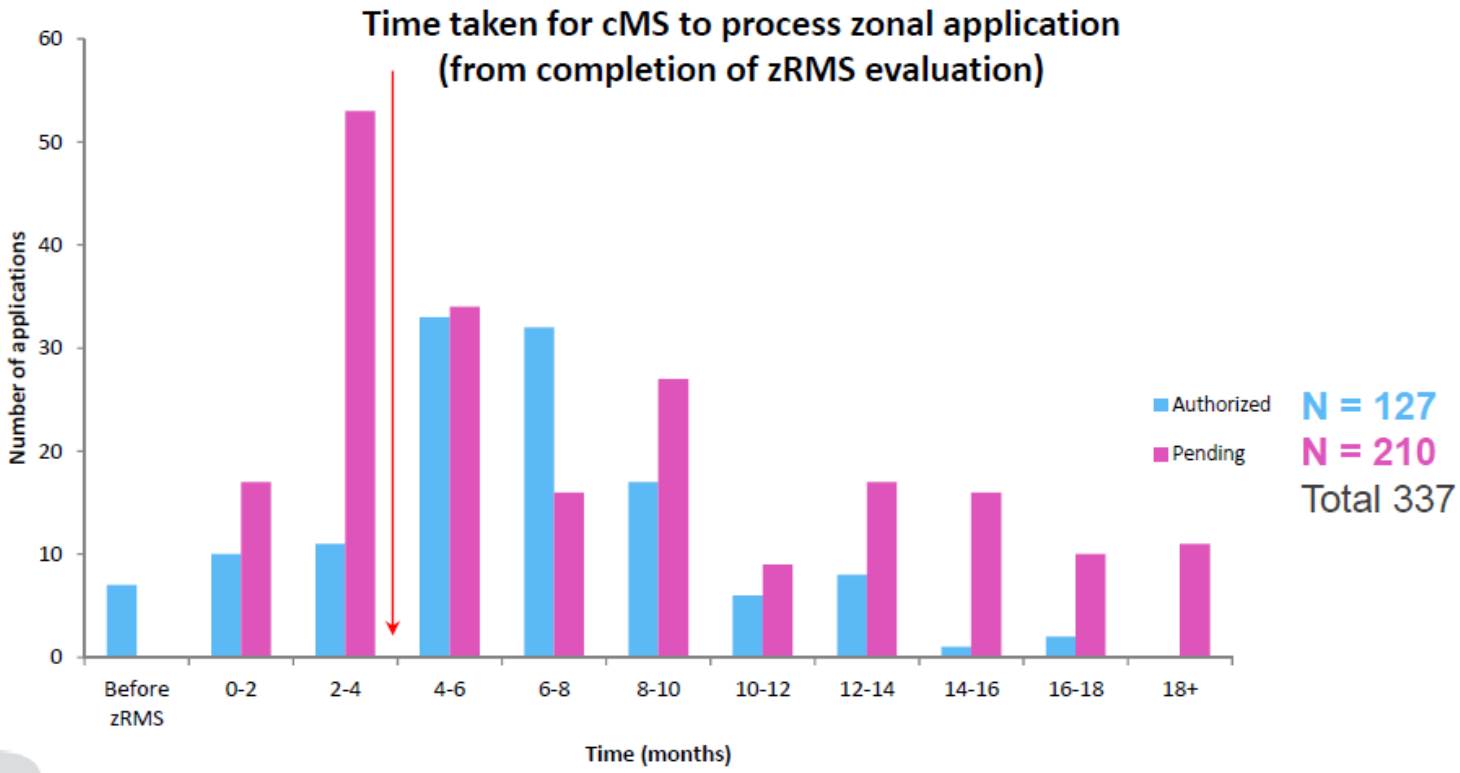

- Granted cMS authorisations **within 4 months or less = 10%**
- Pending cMS evaluations already **above 4 months = 67%**

Mutual Recognition

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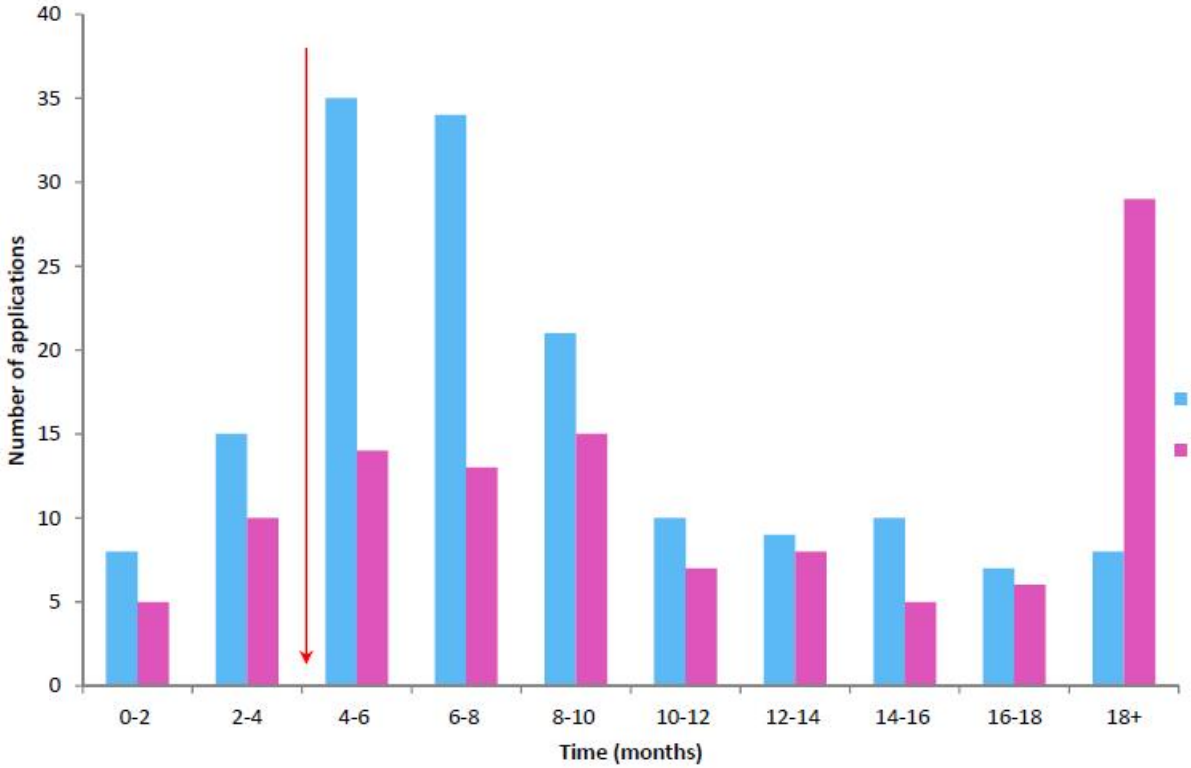

N = 157
N = 112
Total 269

- Granted MR authorisations — within 4 months or less = 9%
- Pending evaluations already — above 4 months = 84%
  above 8 months = 63%
  above 12 months = 43%

Emergency authorisations Art 53

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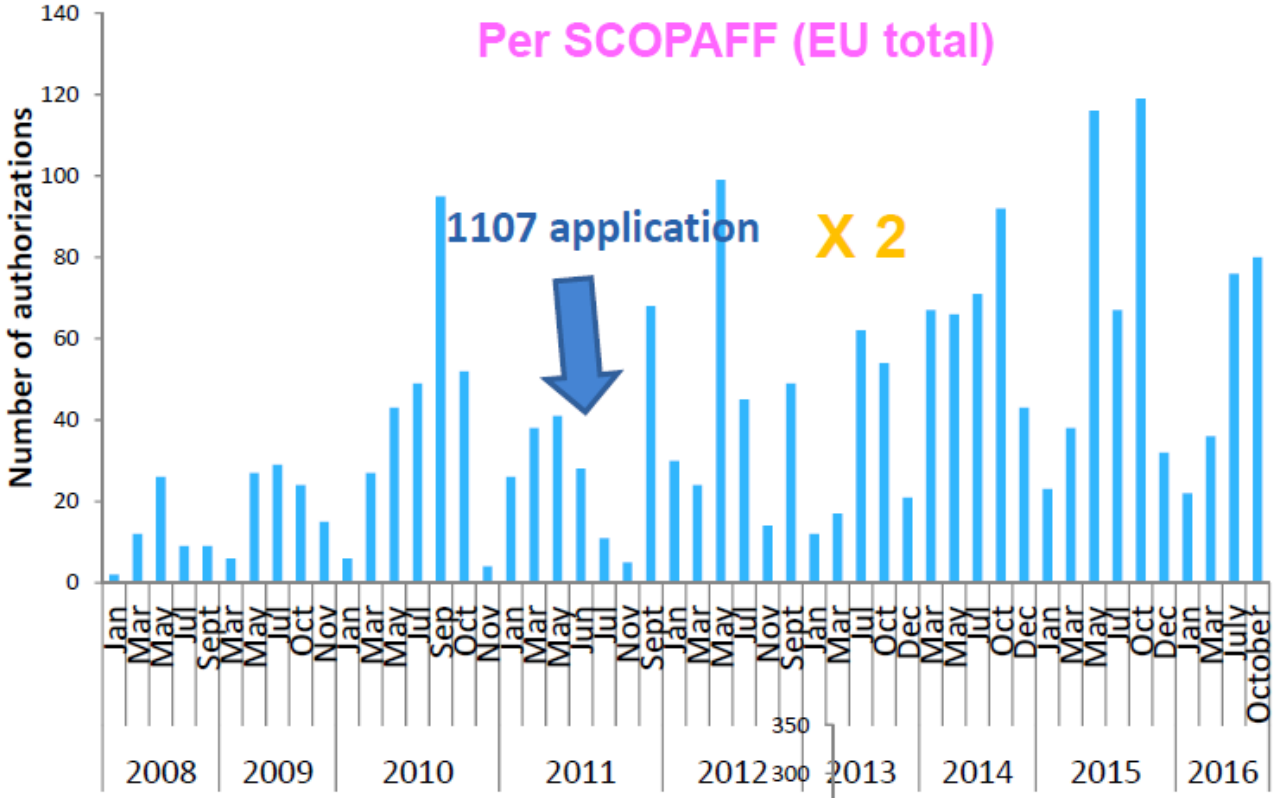

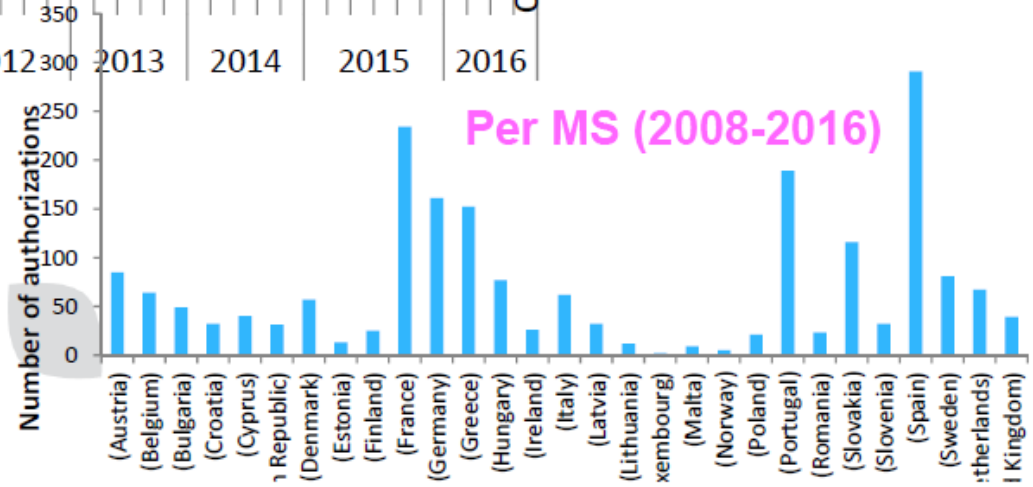

New MRLs (2014-16)

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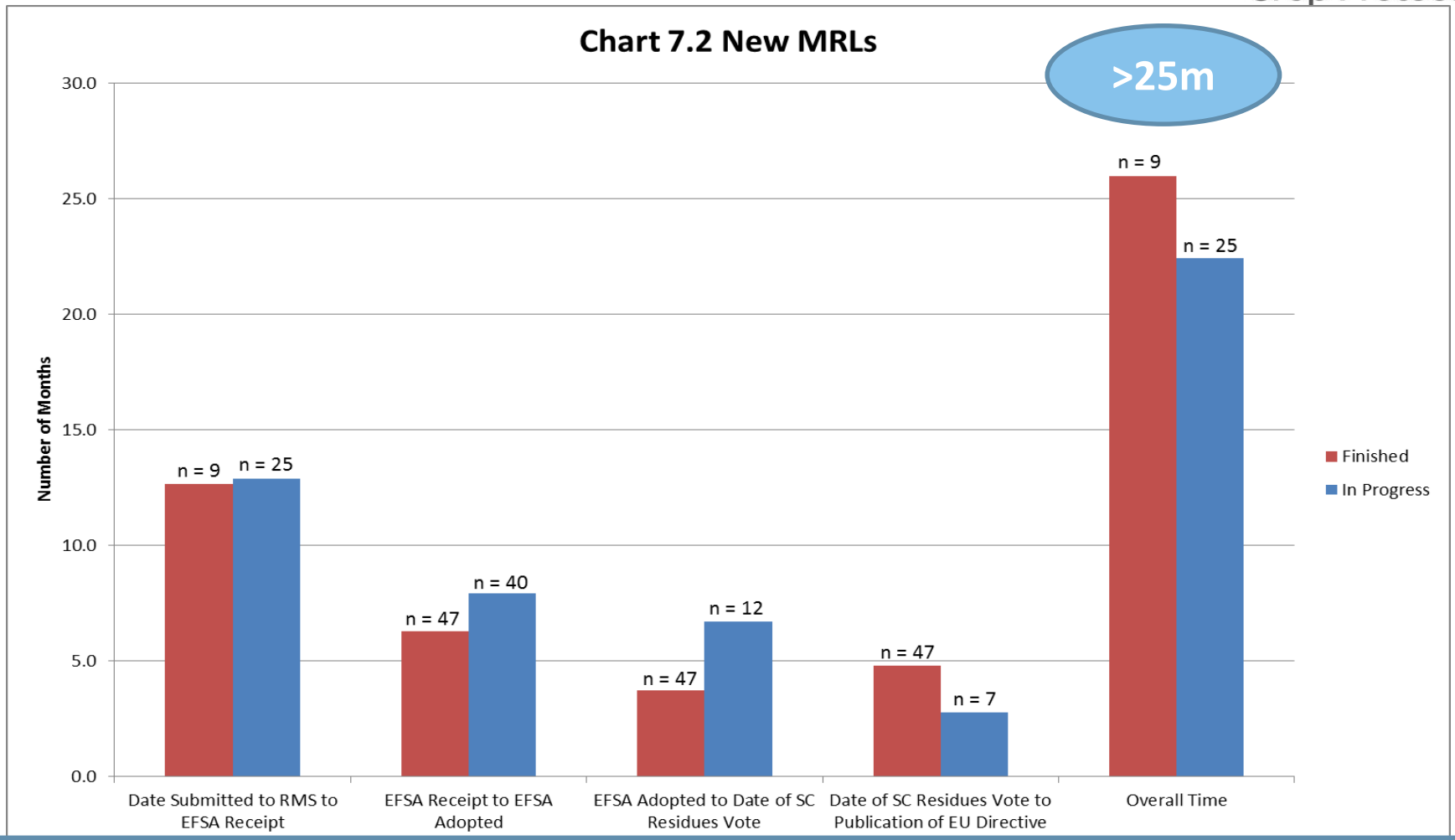

Delays in MRL process further delays introduction of new innovative products

Article 43 re-authorisations

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- **Some improvement in Guidance document**
  - Revised version adopted October 2016

- **Remaining, main difficulties**
  - MS to follow GD, diversity of interpretations
  - Timelines of zRMS Allocation
  - Timing of Category 4 studies decisions: only one submission
  - Mixtures: avoid *multiple* dossiers/timelines
  - Pending evaluations new products: allow update to new endpoints

Looking for improvement

Review of Regulations 1107/2009 & 396/2005

- Commission consultants have now started work
  - Stakeholder meetings and surveys in 2017
  - Final report expected mid-2018
- Other inputs into the debate…
  - Scientific Advice Mechanism (SAM) have been requested to provide input by November 2017
  - European Parliament report of Reg.1107/2009 evaluation report expected in March 2018 and vote on political report in July 2018.
- No date for legislative proposals…

ECPA view

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Phase 1: Implement current framework

AS evaluation

- Guidance document development
- EFSA dialogue

Zonal

- Application of Article 43
- Inter-zonal cooperation
- Zonal coordination helpdesk
- Reducing national requirements
- Efficacy evaluation

MRL evaluation

- Application of Article 12
- MRL revision after AS re-approval

Phase 2: Detailed legislative review

AS evaluation

- Re-focus on risk based system
- Consider benefits of crop protection
- Central evaluation (& central fees)
- Unlimited approval period for ASs
- Data call-in system
- Compulsory data access (& 10yr DP)

Zonal

- De-coupling review of ASs & PPPs
- Improvements in zonal concept
- Changes in Article 43

MRL evaluation

- Fast-track MRLs (default MRLs, MU)
- Central evaluation system (on-line)
- Remove scrutiny procedure for MRL

ECPA view

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View shared by ECPA-ECCA-IBMA:

- ***Data Call-In (DCI) principle*** **-** Introducing a data call-in system in Europe would ensure a more predictable process for the renewal of approvals.
- ***Decouple review of ASs & PPPs*** **-** Time needed for applicants and MS authorities to adjust PPP authorisations to changes resulting from the AS renewal.
- ***Realistic timelines*** **-** Pragmatic timelines required to improve predictability and allow forward planning by companies, MSs, EFSA and Commission.
- ***Definitions, Scope and Incentives*** **-** Definitions and the scope (Article 2) need to be revised (inc. Bio-stimulants, Protected crops…). Incentives for low-risk ASs & PPPs should also be revised.

Data call-in process

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Benefits

Learn from US/Canadian system

- Promotes cooperation for single dossier submission
- More predictable process (clarity on data required)
- Resources and workload can be properly balanced
  - **Submission linked to scientific need - not deadline**
  - Removes need for AS approval extensions…
  - Focus on new data and criteria
- Focus on issues and not active substances
  - Better comparison of submissions
  - Equal treatment?

Guidance document development

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GDs need be 'Fit for Purpose'…

- **Provide predictability and consistency, for:**
  - EU AS evaluations
  - MS/Zonal PPP evaluations
- **Be workable for all evaluators**
  - Focus on need of end-users by involving them!!
  - Clearly agreed protection goals
  - PPR Panel should ensure quality of science
- **Consistent and coherent implementation**

Guidance document development
ECPA view

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- **Involve end users in developing guidance**
  - Developed by working groups made up of end users
  - Taking into account the needs of all users!
  - PPR should review quality of science

- **Testing phase before full implementation**
  - Allowing feedback and adjustments where necessary

- **Define realistic implementation timelines, considering:**
  - Testing capacity
  - Time needed to update risk assessment

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Thank you!