Article 43 applications including comparative assessment – industry's role in managing the process

CEUREG ,

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Dr. Martyn Griffiths, Bayer SAS
Chairman of the ECPA Regulatory Policy Team

Content

- Renewal Program and Article 43 process
- Candidates for Substitution and comparative assessment
- Revision of Regulation 1107/2009

Renewal program: Key concerns

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- Challenging timelines for evaluation (30 months) of actives
  -AIR1 and 2 significant delays
  -AIR3 More than 50% substances delayed
  -AIR4 uncertainty: No RMS defined yet

Article 43 process

- Timelines for submissions
- Mixture products should only be reviewed once!
- What are the timelines with AIR 2 & 3 delays?
- Planning is a real challenge for MS and industry

Innovation should not be delayed due to the renewal program

Solutions for product renewal

- **Commission decided not to revise Article 43**
  - Change will only come with Revision of Regulation (Earliest 2017 ?)
- **Need to rely on guidance document**
  - Unpredictability in Member States implementation

- **Amended guidance adopted in July SANTE/2010/13170 rev.13**
  - Reviewed in COM workshop in Dublin 2-4 June 2015
  - To be revised according to experience (section 1)
- **Category 4 studies: seasonal studies**
  - Data related to new endpoint but insufficient time to be generated
  - Submit asap considering time necessary to conduct studies (~2 years)

Improved but still numerous uncertainties
Member States need to implement pragmatically!

Assessment of mixture products

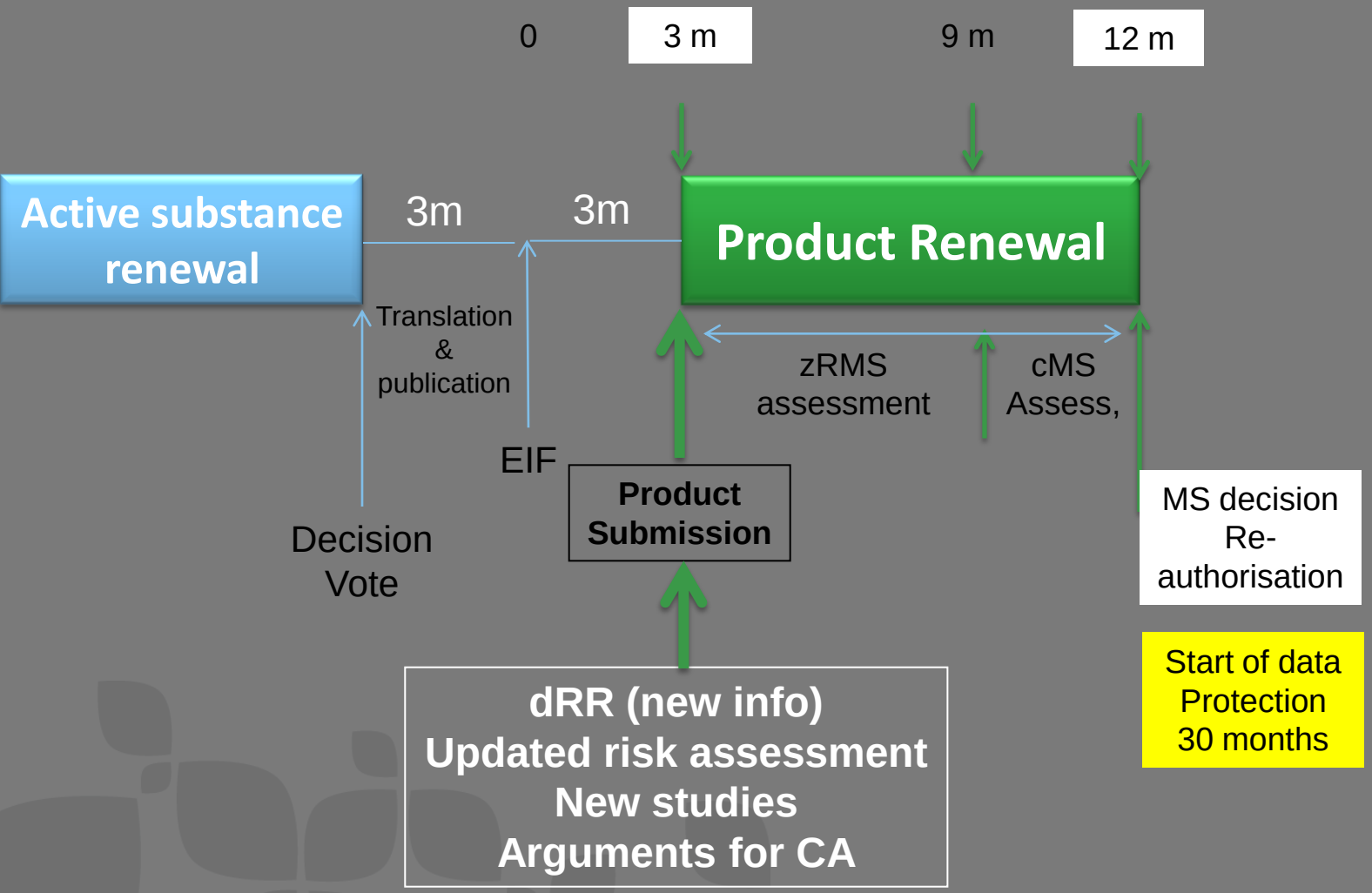
- ECPA have proposed that mixture products should only be evaluated once
  -but only possible if substances expire within 1 year
- If substances expire within 1 year, then product submission linked to 2nd active substance
- Products containing 2+ substances: when the 1st substance is renewed, no need to evaluate data related to the 2nd substance
- The assessment should focus only on the **new information** using the Guidance documents in force at the **time of application**

Key industry concerns

- Early appointment of ZRMS
  -choice of applicant or decision Steering Committee?
- In case no change of GAP only resistance statement required ?
- Harmonisation of GAP's across the zone
- Check to ensure data protection is respected
- How to complete authorisations in the Zone, eg 1 crop missing, 1 country missing

Post-AIR Timeline: AIR 3

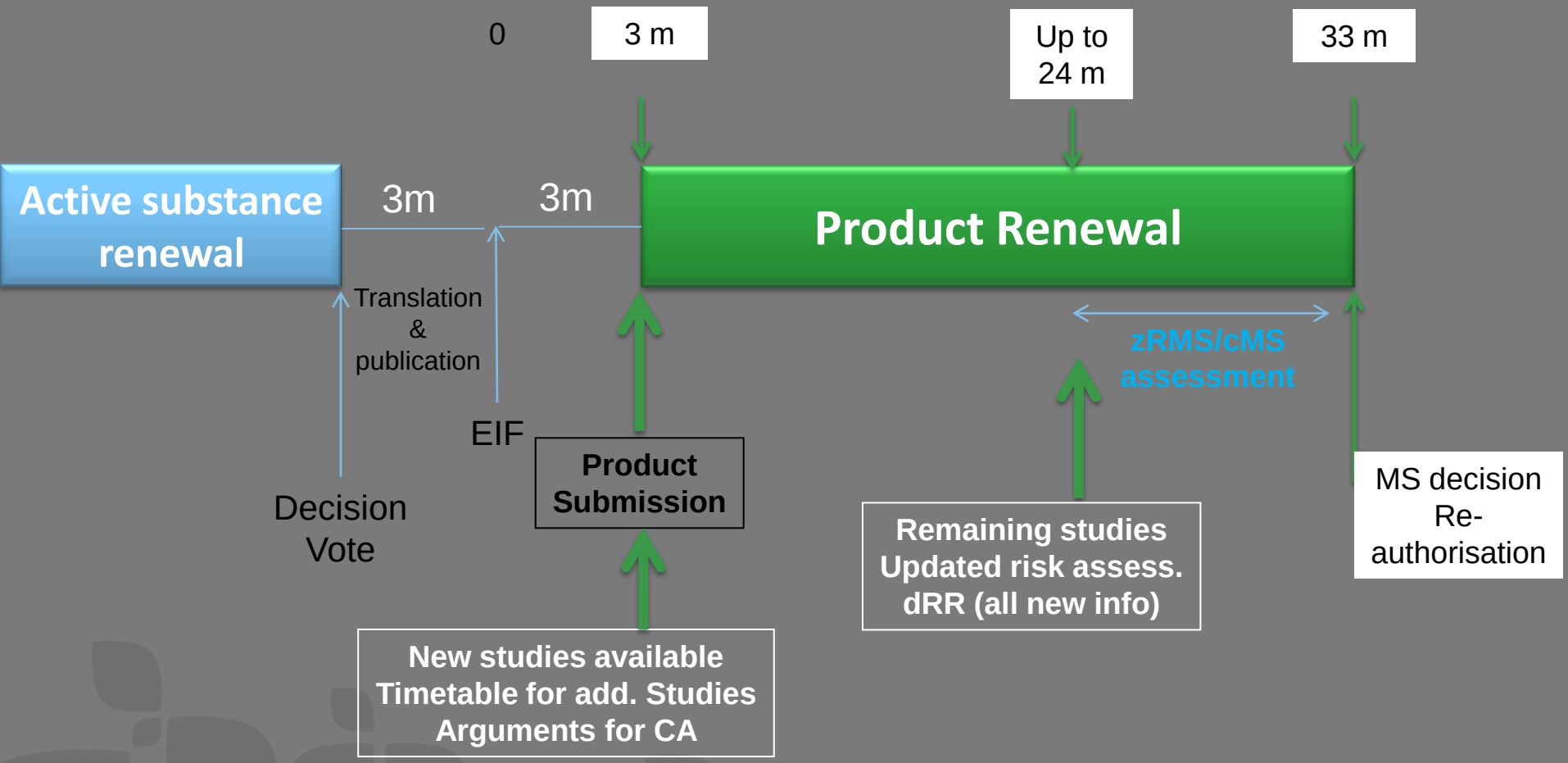
No GAP change, No residue definition change not 'Category 4' studies



EIF = Approval of active substance

Post-AIR Timeline: AIR 3

GAP change, need for Category 4 studies, eg Residue trials (seasonal studies)



EIF = Approval of active substance

Candidates for Substitution and comparative assessment

Candidates for Substitution

- **77 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 reviews Post-AIR
- **Number of CFS will 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 regulatory systems

Comparative Assessment

- Applicable from 1 August 2015 with new applications
- Very little practical experience
- Industry participated to pilot projects in NLD, UK, AUT
- Many MS have not finalised national procedures yet
- Tendency for MS to follow guidance from CRD with adaptations

Comparative assessment

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- **Derogation for New products for 5 years (Article 50.3) to support innovation**
  -New active substances
  -New mixture combinations
  -New crops/uses
- **Non-Chemical Methods**
  -Not necessarily preferable or safer in practice
  -Should be evaluated for safety and overall suitability
  -DEFRA have made comprehensive review

Microsoft Word
7 - 2003 Documer

A Practical guide

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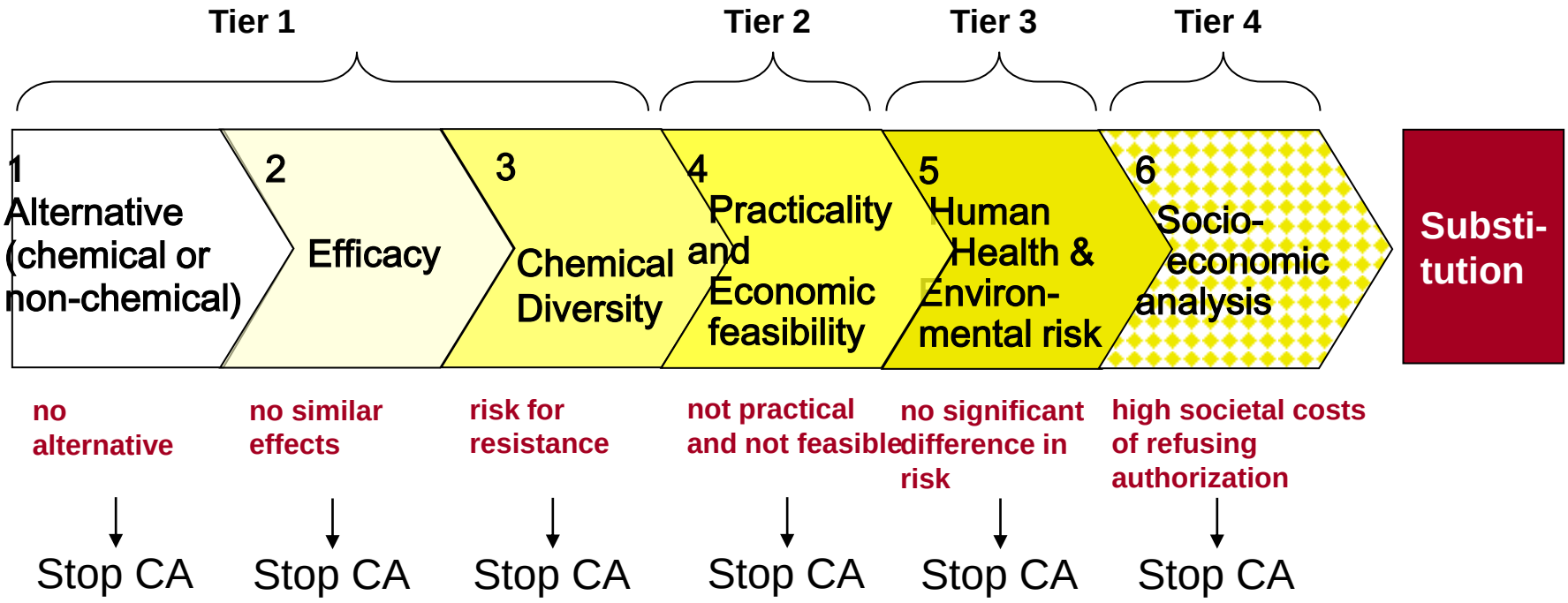
For a crop and pest/fungus/weed combination: compare Candidate Product with Alternative(s)



Industry role in CA

- **Provide relevant arguments to MS to demonstrate that substitution should be avoided in order that**
  -Four modes of action for each solution maintained
  -Safeguard solutions for minor uses
  -Workload for evalution is minimised
- **Pragmatic approach required to maintain farmers tool box**
  -Demonstrate benefits for PPP

Review of legislation

Review of EU legislation

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- **Commission report in 2016**
  - DG SANTE ‘roadmap’– with public consultation in late 2015
  - Consultant report to start in 2016, completed late 2016?

- **ECPA view**
  - ➢ Support joint review of both Regulations
    - Evaluate the implementation of the current legislation
    - Review options for future improvements
  - ➢ Any future amendments should be based on the review
    - ➢ ***But we have some ideas…***
  - ➢ **ECPA will however continue to focus on improving the workings of the current legislative frameworks**

Key areas for improvement

View of ECPA, IBMA, ECCA

- **Introduce a Data call-in process to ensure a predictable regulatory process**
- **Realistic timelines**
  - Experience has shown that they are not achievable without increased resources at EU/MS level
- **Decouple Active substance and Product Reviews**
- **Definitions & Scope of Regulation**
  - Compared to Fertiliser Regulation 2003/2003
- **Harmonisation across EU chemical legislation**
  - Pesticides, Biocides, REACH, Cosmetics

Data call-in process

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How should it work?

Learn from US/Canadian system

- Need for new data/dossier update identified
- Agreement on data required (data call-in)
  - With cooperation: authorities, notifiers & NGO's
- Agreed submission date
- Joint Data submission :all authorisation holders
  - Linked to compulsory data access process
  - Submission required to remain on the market
  - Data 'protected' from date of submission
- Evaluation of dossier
- Renewal/amendment of approvals
  - Confirmatory data >> new data call-in

Data call-in process

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- **Benefits**
  - Promotes cooperation for single dossier submission
  - More predictable process (clarity on data required/expected)
  - 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?

Conclusion

- **Article 43**
  -Pragmatic implementation
  -Should not delay new innovative products

- **Comparative Assessment**
  -Need more time for experience
  -Pragmatic implementation to keep farmers toolbox

- **Revision of Regulation 1107/2009**
  -Data call-in process to ensure efficient use of resources
  -Revision of process for Article 43

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Thank you for your attention

martyn.griffiths@bayer.com