ECPA view on the implementation and the adaptation of Regulation 1107/2009

ECPA ECCA Conference

Brussels March 2015

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

Euroblight Congress – May 11th 2015 Brasov Romania

Albert Schirring – Bayer CropScience AG

Content

- Agricultural focus
- Endocrine Disruption
- Candidates for Substitution
- Guidance documents
- Product authorisations
- Renewal of authorisations (Post-AIR)
- Review of 1107/2009

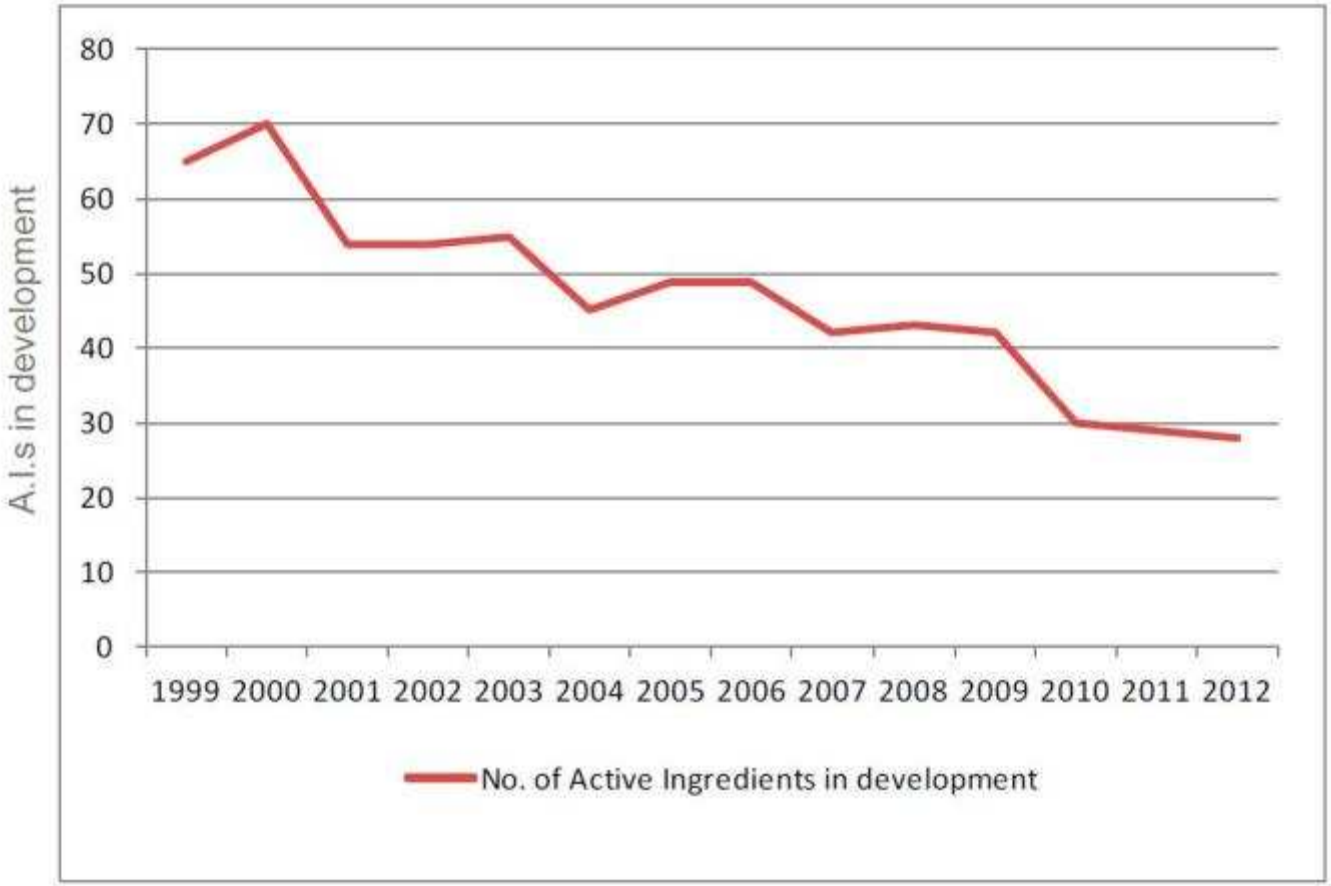
Agricultural focus

- **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 benefits to be evaluated for PPP (already case for Biocides and REACH) to support agricultural production**

Plant protection:
Trend in market introduction…

European Crop Protection

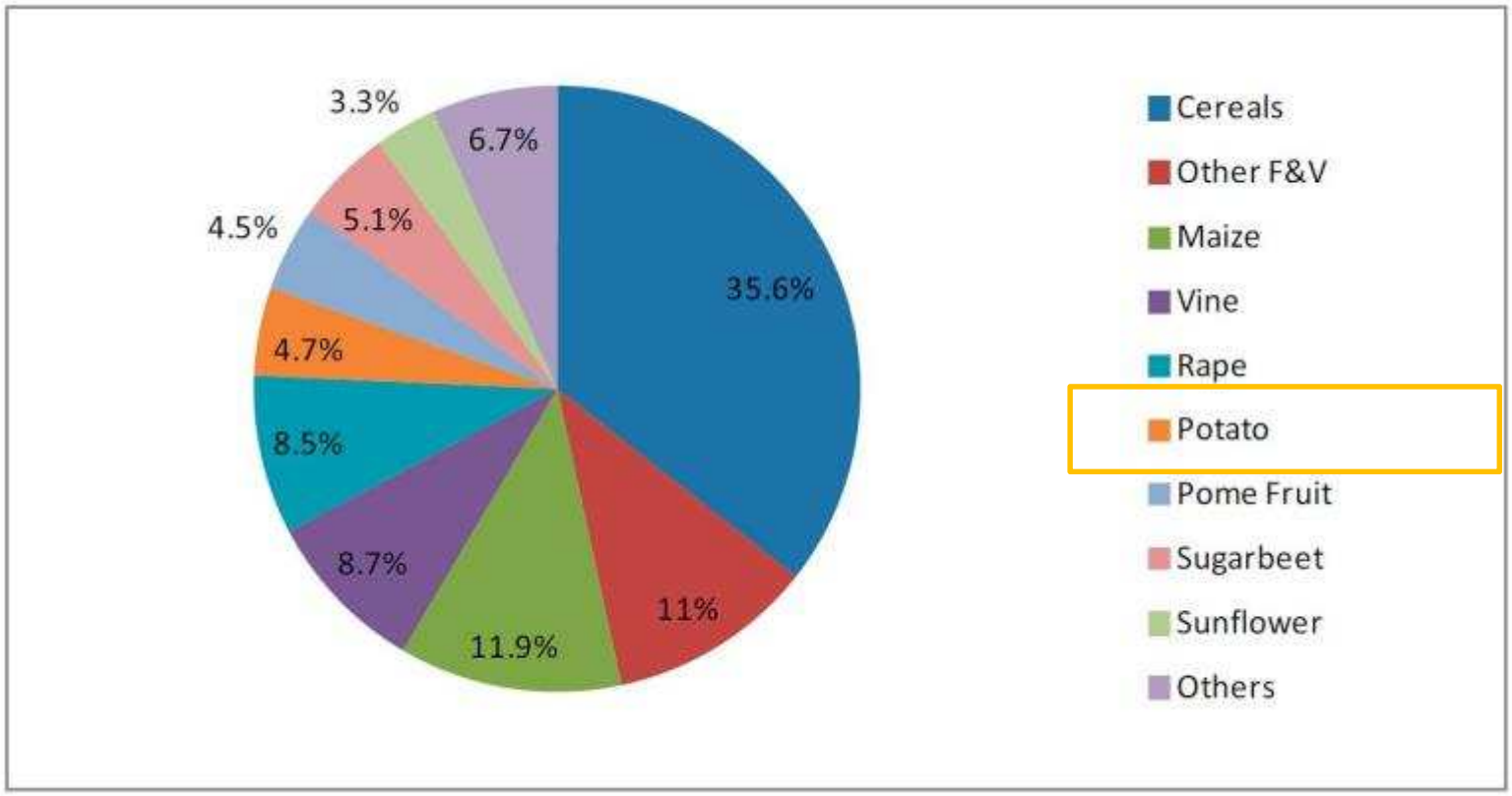
Crop protection Active Ingredients in development*



Source: R&D Trends Phillips McDougall - September 2013

Plant protection:
The position of the potato…

Potatoes represent ~ 4,7% of the EU Crop Protection market*



Source: R&D Trends Phillips McDougall - September 2013

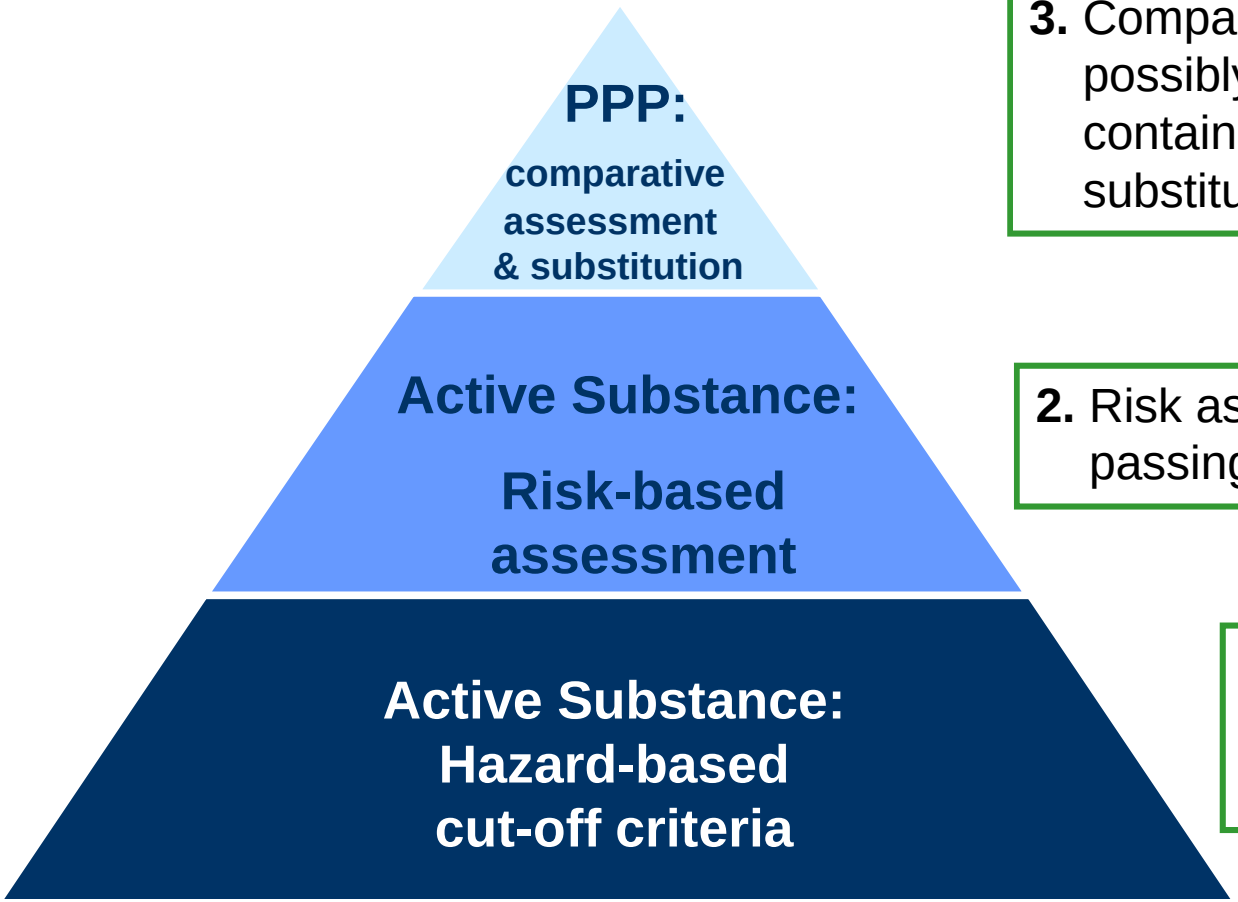
EU registration policy till 2010

European Crop Protection

EU Registration policy: evaluation benefits vs risks

- registration based on risk assessment
- evalation of all risks
- risks have to be acceptable

EU New regulatory Framework (EC 1107/2009)



3. Comparative assessment and possibly substitution for products containing ‘candidates for substitution’

2. Risk assessment for compounds passing step 1

1. Active substances will first be evaluated against cut-off criteria

3-Layer Process to authorisation of plant protection products (PPP)

Cut-off criteria

European Crop Protection

- **Human Health**
  - CMR classification (carcinogenicity, mutagenicity, reproductive toxicity, categories 1and 2)
  - Endocrine Disruption effects
- **Environmental Safety and Persistence**
  - POP, PBT, vPvB
- **Ecotoxicology**
  - Endocrine Disruption effects on non-target organisms

Cut-off criteria – *Endocrine Disruption*

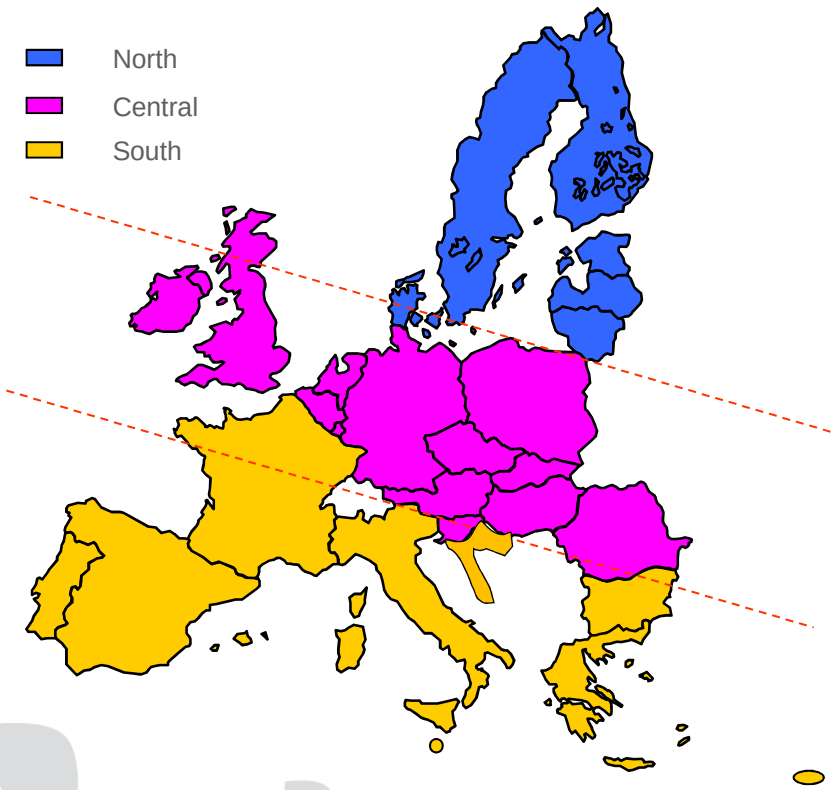
- Test guidelines, endpoints, guidelines for risk assessment and risk management are not in place.
- Currently legislative proposal expected for 4Q 2016
- Room for interpretation and uncertainties.

Candidates for Substitution (CfS)

- Candidates for substitution are defined at EU-level.
- Criteria*:*
  - **ADI, ArfD** or **AOEL** are **significantly lower** than for the majority of the approved substances
  - **Two** of the **PBT Criteria** are met
  - Critical effects **(e.g. Developmental-Neurotox, Immunotox)** which could still cause concern even with very restrictive risk management measures
  - Substances classified as **C1A/B, R1A/B**
  - Possible **endocrine effects** on humans
- Approval for 7 years only, can be renewed.

- Products containing Candidates for substitution are subject to comparative assessments (Product / Country / Pest / Crop).

Zonal Authorizations



- Authorizations granted by one Member State should be accepted by other MS (when ecological and climatic conditions are comparable), but MS can reject.
- Mutual recognition possible between zones (as long as this mutual recognition is not used for further approvals within that zone.
- Mutual recognition for greenhouse and post-harvest treatments, irrespective of zones.

Regulatory challenges in 1107/2009
DG Sante / EU Commission

European Crop Protection

Issue	Regulation date	Actual date
Minor use report (Article 51.9)	14-DEC-2011	05-2014
Candidates for Substitution (80.7)	14-DEC-2013	Voted 01-2015
Endocrine Disruption (Annex II, 3.6.5)	14-DEC-2013	2017 ?
Data requirements for Safeners and Synergists (Article 26)	14-DEC-2014	Postponed to 2018 ?
Report on functioning of regulation (82)	14-DEC-2014	End 2016 ?

More resources are required at EU and MS level to implement Regulation

Endocrine Disruption
Key issues

- Support for risk based approach
- Need to include hazard characterisation in criteria (***potency*** but also ***severity***, ***(ir)reversibility***, ***lead toxicity***)
- Criteria could severely reduce PPPs availability
  - ***Impact assessment vital for the final decision!***

- <u>Interim criteria</u>
  - Interim criteria will have potentially negative impact
  - C2 & R2 criteria should not trigger ‘cut-off’ when not mediated via endocrine MOA
  - No consistency in EFSA final report wordings

Endocrine disruption

Impact assessment

European Crop Protection

- **Two phases of Impact Assessment:**

1. **Assessing the impact on substances**
   - Will look at 700 substances (inc. REACH regulated)
   - 480 ASs used in plant protection & biocides
     - ***Work to be completed in Q3 2015?***
2. **Assessing the socio-economic impact**
   - Broad assessment including agronomic impact
     - ***For completion Q3 2016?***

Cut-off issues

- **Defining negligible exposure**
  - Guidance document under development
  - Needed for forthcoming Active Substance decision making…
- **Application of Article 4.7** (derogation to cut-off)
  - Important element but no clear process (e.g. when to apply for derogation?)
- **Proposals for harmonized classification**
  - Concerns about number of EFSA classification proposals
  - Decisions based on ECHA final classification

Candidates for Substitution

- **77 substances out of approx 400**

  30 - 40% of products subject to Comparitive Assessment
  Multiple assessment with multiple review Post-AIR

- **Number could grow as substances are reviewed**

- **Need for pragmatic implementation by MS**
  - ensure tool box of farmers is not compromised
  - 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 clearer mandate from Commission**

- **Involve end users**
  - Regulatory risk assessors
  - Industry risk assessors

Implementation Guidance Documents

European Crop Protection

- **Plan feedback on the guidance document and adjustments**
  - *Testing phase before implementation would be useful!*

- **Define realistic implementation timelines on the basis of testing capacity!**
  - 12 months minimum allows proper preparation
  - Communication of DG with EIF required immediately after SCOPAFF agreement!!

Zonal process: Make it work

European Crop Protection

- New products can be achieved in 12 months, but the majority take longer

- Renewal of authorisations including Comparative Assessment will require substantial resources
  - Evaluation of New innovative products should take priority

- Establishment of a zonal Helpdesk in 2015
  -facilitate the planning
  -facilitate the evaluation according to resources
  -efficient co-ordination of the evaluations between ZRMS


AC/DC
BLACK ICE

Renewal program: Key concerns

- Challenging timelines for evaluation (30 months) of actives
  -AIR1/2 significant delays
  -AIR3 very tight timelines
- Timeline (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 unnecessary

Challenging Process without additional resources

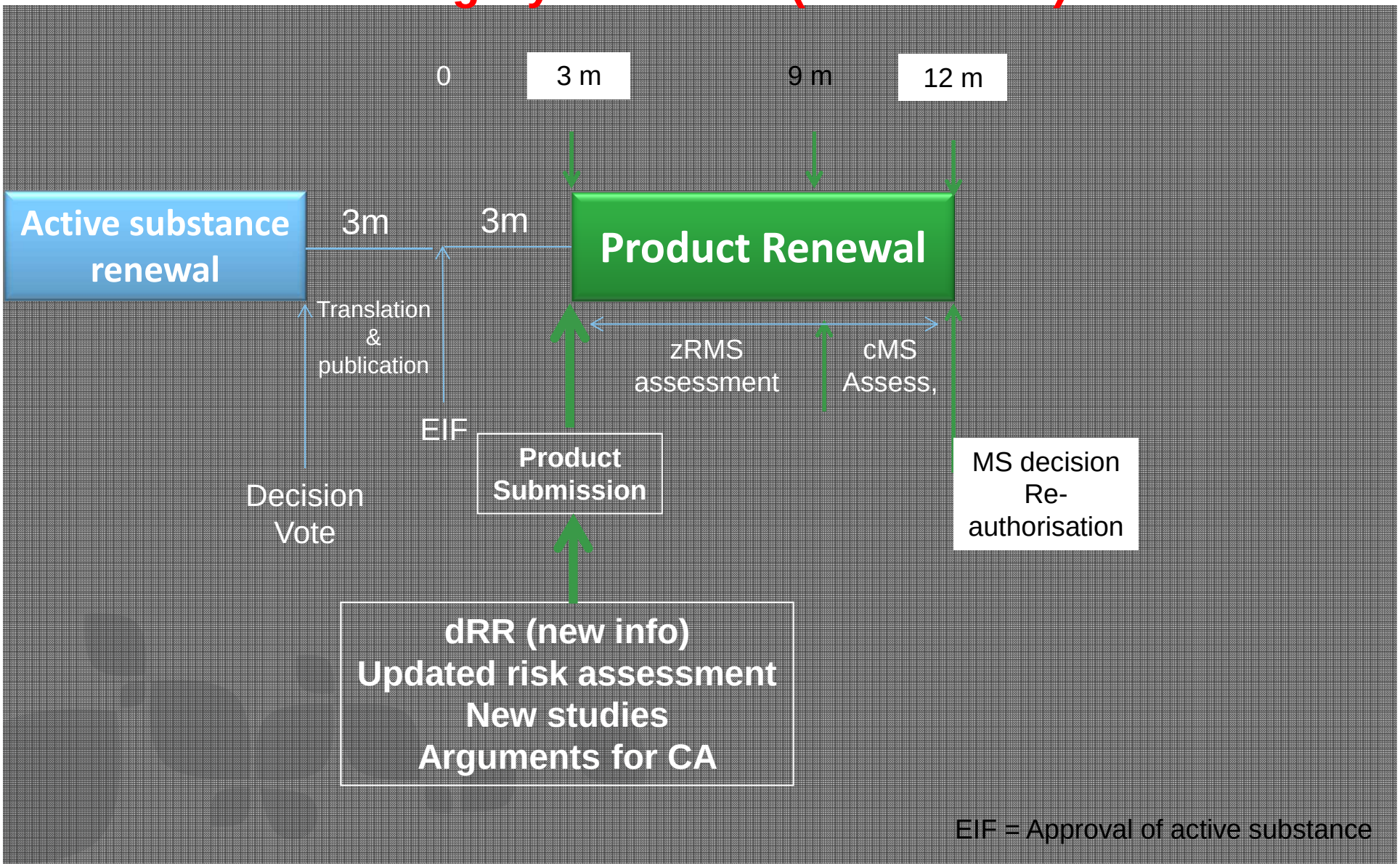
Status Renewal program

- AIR1 complete, post approval ongoing
- AIR2 all 29 Renewal Assessment Reports available, but only 1 decision (deadline end ‘15)
- AIR3 ongoing: New data requirements apply
- Next renewals with expiration date after Jan 2019
  -Application / Submission dates are fixed: start 3Q 2016
  -Planning difficult, no RMS / co-RMS identified yet
- 2016 Renewal of authorisations
  April 20 active substances with all products
  August Products of Glyphosate (‘63 man years’)
  October Products of 12 AIR-3 Assessments (submitted Jan 2014)

Phasing of authorisation renewal will be required
-ensure manageable workload for MS

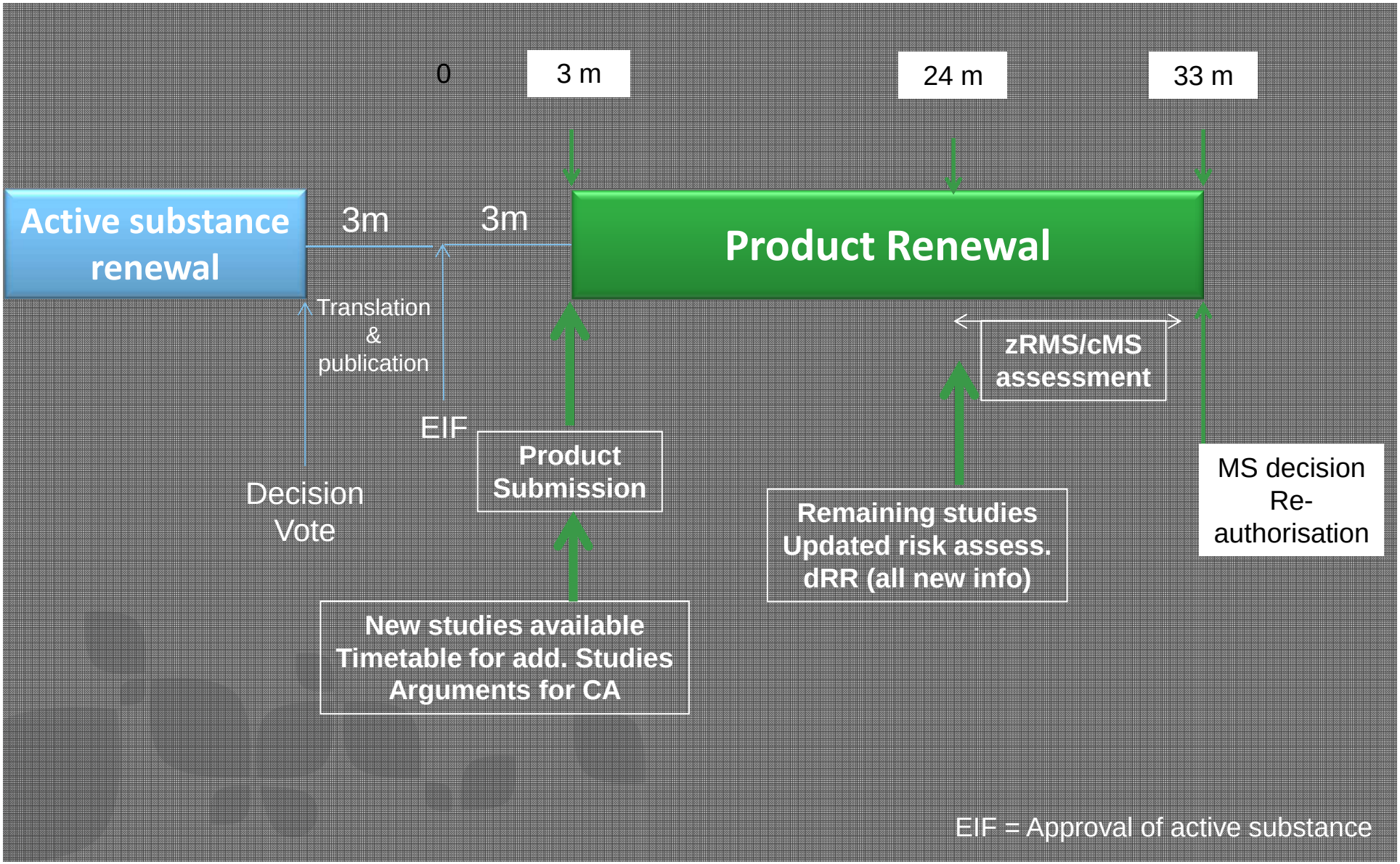
Post-AIR Timeline: AIR 2/3

No GAP change, No residue definition change not 'Category 4' studies (defined GD)



Post-AIR Timeline: AIR 2/3

GAP change, need for Category 4 studies, eg Residue trials



Improve the regulatory process:
ECPA view

To understand the challenges, blockers and future opportunities, there is a need to review 1107/2009 & 396/2005

ECPA requests a detailed review that will:

- Evaluate the implementation of the current legislation
- Review options for future improvements

While legislative amendments are required, proposals to change the legislation should be based on the conclusions of the review

ECPA will however continue to focus on improving the working 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

Impact Assessment Andersons* - UK

- **Availability of Plant Protection Products (PPP) threaten by**
  - Approval process at EU Level
  - Implementation of Water Framework Directive at national level
  - restriction on neonicotinoid seed treatments
- **Potential loss of PPP**
  - UK- out of 250 PPP's, 87 under threat, 40 likely to be restricted or lost
  - Loss of PPP will result in lower yields (range minus 4 – 50%)
- **Considerable social and economic loss**
  - Drop in farmer profitability: minus 36%, shift and restructuring
  - Gross value added by UK agriculture: minus £ 1,6 bn per annum
  - Food processing industry: loss of £ 2,5 bn per annum
- **Is agricultural production improving….**

*Source: Andersons UK – effect of the loss of Plant Protection Products on UK Agriculture 2014

Conclusion

- **2015 will be challenging**
  - -Start of comparative assessment
  - -Progress on framework legislation for ED
  - -Challenges in capacity for MS
- **Need for Action**
  - -Make the zonal process work efficiently
  - -Ensure fast introduction of new products
  - -Establish Zonal Helpdesk
  - -Efficient implementation of scientific guidance
- **Is agricultural production improving ?**

European Crop Protection

Thank you for your attention

martyn.griffiths@bayer.com

Back up organizations definitions

ECPA	- European Crop Protection Association
IBMA	- International Biocontrol Manufacturers Association
ECCA	- European Crop Care Association
EFSA	- European Food Safety Authority
DG Sante	- Directorate General Health and Food Safety
SCOPAFF	- Standing Committee of Plant Animal Food and Feed
AIR	- Annex I Renewal (for active substances)
EIF	- Entry Into Force
zRMS	- Zonal Rapporteur Member state