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

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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 e.g. monitoring data

- Need for benefits to be evaluated for PPP (already case for Biocides and REACH) to support agricultural production
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: evaluation benefits vs risks

- registration based on risk assessment
- evaluation of all risks
- risks have to be acceptable
EU New regulatory Framework (EC 1107/2009)

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

2. Risk assessment for compounds passing step 1.

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

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

Human Health
- CMR classification (carcinogenicity, mutagenicity, reproductive toxicity, categories 1 and 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**

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

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

Interim criteria
  - 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

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 Comparative 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
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

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
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)

0 
3 m 
9 m 
12 m 

Active substance renewal

Product Renewal

Translation & publication

EIF

Decision Vote

zRMS assessment

cMS Assess,

MS decision Re-authorisation

dRR (new info)
Updated risk assessment
New studies
Arguments for CA

EIF = Approval of active substance
Post-AIR Timeline: AIR 2/3

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

Active substance renewal

3m

Product Renewal

Translation & publication

EIF

Product Submission

3m

zRMS/cMS assessment

Remaining studies Updated risk assess. dRR (all new info)

New studies available Timetable for add. Studies Arguments for CA

Decision Vote

0 3 m 24 m 33 m

MS decision Re-authorisation

EIF = Approval of active substance
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
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?
Thank you for your attention

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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