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Implementing Regulation 1107/2009
Stage of Progress – An Industry Perspective

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Content

Stage of Progress:

Active substance approval criteria

Regulations and guidance documents

Comparative assessment & substitution

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Stage of Progress
Active Substance Approval

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Active substance approval criteria

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Endocrine Disruption:

- ‘State of the art’ review ongoing (Pr. Kortenkamp). Report expected June 2011 with ‘policy options’
- ECETOC proposal for science-based definition available
  - Based on symptoms, mode of action, relevance to humans and potency
- Germany and UK also proposed/proposing definitions for human health and non-target species - Same principles as ECETOC (human health)
- OECD guidance document on the assessment of ED under development

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Active substance criteria (cont'd)

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POP / PBT / vPvB: Criteria not specific enough for consistent implementation. ECPA developed position paper.

Main recommendations:

- Criteria need to be met in same environmental compartment
- Persistence: use geometric mean of normalized field half-lives
- Bioaccumulation: consider depuration phase
- Aquatic toxicity: use geometric mean of NOEC values
- Long range transport (air): consider DT50 only if residence in air possible

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Active substance criteria (cont'd)

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Article 4.7

- Define 'serious danger to plant health' case-by-case, not upfront or prescriptively
- Consider only 'suitable' alternatives. Assess 'suitability' using Annex IV criteria
- Evaluate chemical and non-chemical methods using same criteria


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Negligible exposure

- ECPA position under development…

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Stage of Progress
Regulations and Guidance

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Regulations and Guidance

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Active Substance Renewal

AIR2 regulation:

- Initial dossier should not be required systematically (clear wording needed)
- Clear wording needed relative to technical guidance applicable during evaluation (cannot be latest)
- No valid reasons why substances assumed to meet cut-off criteria should be submitted earlier than others

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Active Substance Renewal – AIR2 Guidance document

- ECPA overall supports content
- Classification dossier only required when change expected
- MRL info for ‘representative uses’ and existing uses but not future uses (separate procedure)
- Welcomes adoption of ‘efficacy template’
- Recommends adoption of ‘summary report’ template

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Active Substance Renewal – AIR3

- **The following information is urgently needed by industry:**
  - **Which substances will be submitted in 2013?**
  - **Which RMS?**
  - **When in 2013?**
- **ECPA recommendation for AIR3:**
  - **Cover all substances expiring between 2013-2018**
  - **Quarterly submission waves September 2013 – June 2016**
  - **Populate waves by order of expiry (no grouping by families)**

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New active substance regulation:

- **ECPA welcomes binding timelines for pending NAS**
- **National Provisional Authorizations must remain possible for such substances**

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Regulations amending technical data requirements:

- ECPA welcomes adoption under 1107
- Recommends unique 3-year implementation timeframe (should not apply to 2013 submissions)

- Detailed comments provided to Commission
- Literature search must balance workload and benefits

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Stage of Progress
Comparative Assessment & Substitution

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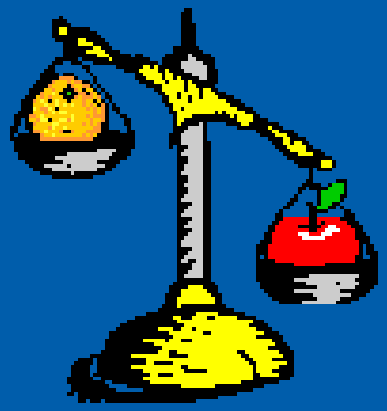
Comparative Assessment & Substitution



- **Realistic application timelines:**
  - **Possible for a (limited?) number of new active substances between by end 2013**
  - **Extensively after publication of Commission's list of candidates for substitution (Dec 2013 deadline)**
- **EPPO working on comparative assessment tiered approach**
- **Limited activity within Commission (MS?) and Industry Associations**

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Conclusions

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- *Keep food produced in Europe. Protect food diversity. Protect farmer's tool box*

- **Regulation 1107 can contribute! It requires:**
  - *Implementation based on pragmatism and robust science*
  - *Quality dialogue between stakeholders*
  - *Collective commitment*

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Thank you for your attention!