European Crop Protection

Regulation 1107/2009 and Directive 2009/128

Industry Experience with the Implementation of Plant Protection Products Legislation

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- **Regulation 1107/2009**
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Regulation 1107/2009

Review of specific provisions
Implementation progress and industry view
Industry experience feedback

Regulation 1107/2009
Approval criteria – Endocrine Disruption (1)

- **Parliament Report due February 2013**
  - MEP Westlund rapporteur
    - '*Assessment should be hazard-based'*
    - *'Regulatory classes should be created'*
    - *'Low dose and non-linear response to be taken into account*'

Regulation 1107/2009
Approval criteria – Endocrine Disruption (2)

- **In 2013, Commission expected to:**
  - Update thematic strategy on ED
  - Issue general regulatory framework (June communication?)
  - Adopt biocides regulatory criteria by Dec 2013
  - Propose pesticides ED criteria by Dec 2013
- **EFSA to issue an opinion on fundamental ED questions (Mar 2013)**

Regulation 1107/2009
Approval criteria – Endocrine Disruption (3)

- **Four MS have proposed regulatory criteria (DE, UK, FR, Dk)**
- **Industry:**
  - Challenges low dose effects significance
  - Promotes robust/balanced science
  - Promotes potency in defining ED criteria
  - Supports categorization for decisions but not classification
- **Authorities to provide inputs into discussions, support robust science and consider impact on agriculture?**

Regulation 1107/2009
Approval criteria – Endocrine Disruption (4)

- **Nomisma study: evaluation of the impact of a hypothetical loss of azole fungicides in EU-27 wheat production:**
  - Wheat production decrease 7% (2013) to12% (2020) (EU27)
  - EU27 to become net importer (from net exporter)
  - Immediate increase in grain prices and price volatility

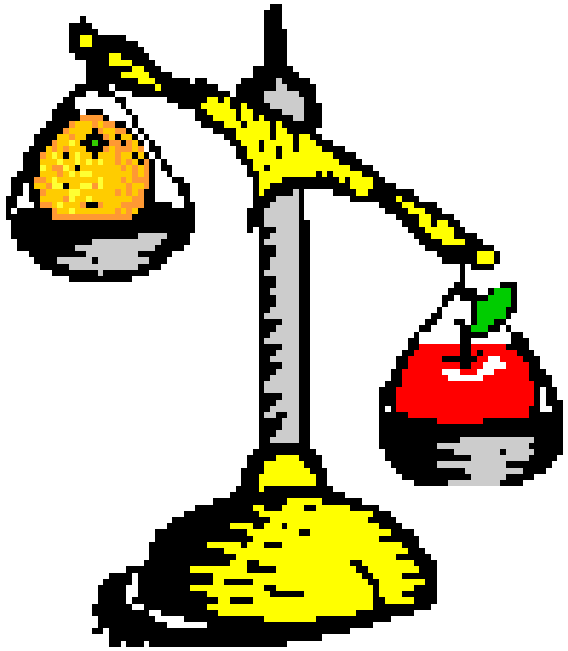
Regulation 1107/2009
Approval criteria – POP/PBT/vPvB

- **Commission working group looking at criteria for CfS and approval decisions**
- **Industry:**
  - Supports the overall balanced approach proposed
  - Promotes compartmentalization
  - Extension to metabolites not compliant with 1107
  - Recommends careful selection of aquatox endpoints
- **Authorities to ensure predictable criteria and consider impact on agriculture, particularly CfS?**

Regulation 1107/2009
Candidates for substitution

- **Commission to contract out draft list**
- **Industry:**
  - Keep list as short as possible
  - Supports robust scientific peer review & latest info to be taken into account
  - Communicates on vulnerability of CfS list
- **Authorities to support short list & robust review, to limit workload impact and actively communicate about list?**

Regulation 1107/2009
Comparative Assessment



- **Swedish draft process guidance (progress?)**
- **Industry guidance available:**
  - Minimize workload
  - Limit substitutions

Regulation 1107/2009
AIR

- Legislative package adopted
- Extension regulation(s) pending for 2nd and 3rd groups
- Industry overall OK with design

Regulation 1107/2009 Zonal

- Capacity reached/exceeded in most MS
- No real progress since application date
- No progress towards eliminating MS-specific requirements
- More dialogue between authorities required for finding solutions and minimize national requirements

Regulation 1107/2009
Miscellaneous

- **Confirmatory data:**
  - Block decisions in certain MS
  - Alternative notifiers should be allowed to submit
- **New data requirements:**
  - Welcome and less welcome changes
  - Undergoing adoption process with pending issues
- **Scientific guidance: need for consistent adoption / enforcement process**

Industry experience with implementation of Regulation 1107/2009 (October 2012) (1)

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Objectives of Regulation 1107/2009	Recitals	Industry view on progress		
Protect…				
… humans, animals, environment (high level of protection)	8, 24, 35			
Harmonize…				
… rules & criteria, active substances	9, 10, 55			
… rules & criteria, PPPs	25			
… list of active substances	10			
… availability and free movement of PPPs across Member States	9, 29			

Industry experience with implementation of Regulation 1107/2009 (October 2012) (2)

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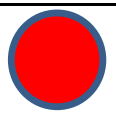
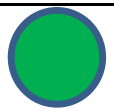
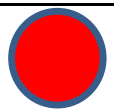
Objectives of Regulation 1107/2009	Recitals	Industry view on progress		
Promote …				
… predictability, efficiency and consistency, active substance approval	12			
… predictability, efficiency and consistency, PPP authorisation	25			
… transparency of the evaluation process	12			
… low risk a.s. and PPPs	17		?	
… minor uses	30			
… non-chemical methods	19, 20		?	
… non-animal testing methods	40		?	
… cooperation between MS	28, 37			
… innovation	34, 39			

Industry experience (cont'd)
Key observations

- **Commission/MS authorities very active in 2012: guidance documents, AIR package, etc.**
- **Persistent disconnect between available resources and 1107 obligations**
- **Disconcerting trends towards 'ever more':**
  - Data
  - Details
  - Conservatism
  - Safety
  - Redundancy
  - Costs
  - Etc.

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Directive 2009/128

Overall situation

Directive 2009/128
NAPs (1)

- **No overall view of NAPs and content**
  - Specific measures, indicators, etc.
- **Most MS claim to be on time (Nov2012 deadline)**
  - MS with existing schemes likely to be
- **Most MS pursue risk rather than volume reduction (but FR, Dk)**

Directive 2009/128
NAPs (2)

- Overall excellent stakeholder consultation reported (online, workshops, ad hoc committees, etc.). NGOs and industry often associated
- Exchange of experience between countries reported (e.g. CEUREG, international workshop on SUD organised by Germany, Spanish workshop with neighbors countries participation)

Directive 2009/128
IPM

- **No community developments – MS to adapt IPM to their national/regional/local situations**
- **IPM will become the standard in EU agriculture as from 2014:**
  - Important to ensure a pragmatic approach allowing farmers to use all necessary tools
  - Important to avoid putting European farmers at competitive disadvantage
  - Industry opposed to negative lists
- **Anything beyond implementation of Annex III principles should be voluntary**

Conclusions

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Large amount of pragmatism in regulatory community to 'make it work'

Impact on resources clearly underestimated by Legislators

Some trends unsustainable

- **Time to full functionality much longer than anticipated**
- **Urgent need for MS to 'staff up' or make larger use of mutual recognition**
- **Time for science, not politics**

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Thank you for your attention