The most important changes in the regulation of Plant Protection Products
An industry perspective

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Schedule

- New regulation replacing Directive 91/414/EEC adopted by Council on 24 September 2009
- Publication and entry into force 4Q2009
- Full application as from 2Q2011

What will change?
Approving Active Substances

- 91/414 decisions based on ***risk-based criteria*** only (Uniform Principles)

- New regulation adds a layer of ***hazard-based criteria*** to the risk criteria

What will change?
Approving Active Substances (cont'd)

- ***Long list of additional criteria*** to consider/apply when approving active substances (article 4, Annex II)
  - For example (non-exhaustive): effects on biodiversity, ecosystems and vulnerable human groups, coastal and estuarine waters, etc.
  - 'Sufficiently effective'
  - Hazard-based intrinsic properties

What will change?
Approving Active Substances (cont'd)

- 91/414 treated all substances equally
- Four (4) categories of active substances in new regulation with different rules (requirements, validity, process):
  - 'Normal'
  - Low risk
  - Basic
  - Candidates for substitution

What will change?
Authorizing Plant Protection Products

- All PPPs evaluated and decided based on common criteria under 91/414 (Uniform Principles)
- New regulation:
  - Some PPPs authorized after comparison with other protection solutions
  - Some PPPs authorized with limited data requirements (low risk)
  - Some PPPs placed on the market without evaluation (basic)

What will change?
Authorizing Plant Protection Products (cont'd)

- Work share through ***zonal system (3 zones)*** and elaborated mutual recognition provisions
- ***Comparative assessment/substitution***
- Conditions for ***national provisions authorizations*** more stringent (delayed access to PPPs containing new active substances)
- ***Minor uses*** specific provisions
- Community rules for ***parallel trade***
- ***Period of grace*** could be denied in majority of cases!

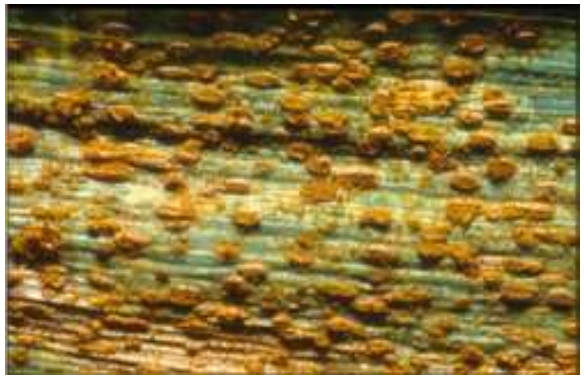
What will change?
Timelines

- Few timelines specified in Dir 91/414
- In new regulation, ***binding timelines for virtually all evaluation/decision steps***
- Some quite stringent timelines for submission (single-step re-authorization submission) and evaluation/decision (mutual recognition)

What will change?
Data Protection

- 91/414:
  - ***2-Level system*: protection triggered by Annex I inclusion (community) and PPP authorization (MS)**
  - ***Exclusive use* by data owner possible for most data (first a.s. inclusion, modification or renewal)**
- New regulation:
  - ***Single-level system*: protection by PPP authorization only**
  - **Mandatory *sharing of vertebrate data***
  - **Possible extension of data protection through *support of minor uses***
  - ***GLP or GEP* data only**

What will change?
Changes with positive potential



- Binding timelines + ‘stop clock’ provisions
- Promising zonal + mutual recognition system
- Minor uses well covered

- Clear binding parallel import rules
- Evaluation ‘using guidance available at the time of application’

What will change?
Changes perceived less positively

- Hazard-based criteria
- Delayed access to new active substances
- Re-authorisation timelines too short?
- Period of grace provisions

Reminder
Changes from other regulations

- Harmonized ***EU MRLs*** (Reg 396/2005)
- New ***Classification and Labelling*** rules (Reg. 1272/2008)
- Registration of PPP ***co-formulants under REACH*** (Reg. 1906/2006)
- ***Sustainable use*** directive and daughters regulations
- Others?

Changes in the regulation of PPPs
Concluding remarks

- Main principles of Directive 91/414 retained
- Significant changes introduced in evaluation, authorization and placing of PPPs on the market
- Significant adaptation efforts required from all stakeholders
  - ***More stringent timelines will require adequate planning and resourcing (applicants and regulators)***
- Quality dialogue/collaboration between industry, authorities and other stakeholders required for optimal implementation

Thank you for your attention !

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