The new Regulation for plant protection products in the EU

State of affairs of the recent EU Commission proposal

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Directive 91/414

- First harmonised legislation for pesticides in the EU
- Established the principle of **substance evaluation** at EU level and **product evaluation** at Member State (MS) level
- Established a **positive list** of active substances allowed for the use in plant protection products (**Annex I**) as well as **Uniform Principles** for the evaluation of applications in MS
- European Commission obliged to report to the European Parliament and the Council after 10 years
- **Progress report** from Commission on functioning of Directive 91/414/EEC was presented in July 2001 to the European Parliament and the Council and identified ways to amend Directive 91/414
Feed-back on progress report

- Avoid repetition of animal testing
- Simplify data protection rules
- Criteria for inclusion
- Low risk substances
- Comparative assessment and substitution
- Exclude hazardous substances
- Transparency
- Mutual recognition in zones
Proposed Regulation on PPP

- COM provided a proposal for a Regulation of the European Parliament and the Council
- It is now up to the European Parliament and the Council to discuss and to agree on the final text
- Schedule not exactly predictable
- The recent Annexes will become daughter Regulations to be adopted within 18 months
Coherence with other EU policy

- Reinforce the level of protection of human health and the environment
- Taking into account the Lisbon strategy
- Increase transparency
- Reflect the creation of the EFSA
- Avoid repetition of animal testing
- Extension and strengthening of the single market
- Simplify procedures
Main issues

- Different legal instrument (Regulation)
- Zonal mutual recognition
  - applies to PPP; no change for active substances
  - 3 zones for obligatory mutual recognition within a short fixed deadline
  - MS can impose additional risk mitigation for workers and bystanders
  - greenhouse and post-harvest uses are one zone all over the EU
- Provisional national authorisations
  - No longer compatible with recent MRL legislation
  - But this is counterbalanced by a predictable, shorter evaluation procedure
Main issues *cont’d*

**Comparative assessment**
- Comparative assessment at EU level based on hazard criteria to identify candidates for substitution
- Before deciding on a PPP containing a substance candidate for substitution, MS will have to verify whether there are sufficient effective alternatives

**Data protection**
- no change for PPP, only for active substances
- more detailed rules for vertebrate studies
- no new data protection at renewal of approval (“inclusion”)
Main issues *cont’d*

- **Information duty**
  - Records to be kept by farmers and to be made available on request to the drinking water industry and to neighbours
  - Authorisation may provide for an obligation to inform neighbours before spraying

- **Streamlined evaluation procedure**
  - Clear deadlines for the different steps
  - Aim is decision making within 25 months after dossier submission
Main issues  cont’d

Criteria for approval
- applicable if exposure is not negligible
- CMR cat. 1 or 2
- Endocrine disruptors
- PBT, vPvB

Low risk/basic substances
- Low risk substances (ex post) may be approved for 15 years, with 12 years of data protection
- Fixed deadlines for authorisation procedure for PPP made from low risk substances
- Basic substances (ex ante) may be approved for an unlimited period
- Criteria: not predominantly used as a ppp and no subst. of concern
- Application admissible for every interested party or Member State

New Commission proposal
Other issues

- Scope (safeners & synergists, co-formulants)
- Renewal of approval only once
- Role of EFSA
- Fees and charges (in line with recent rules)
- Data access / confidentiality
- GMO’s
- Minor Uses
- Monitoring and controls
- Human testing
New Commission proposal

...on the web:

EU guidance documents

- Guidance documents are intended to guide applicants and regulators
- Guidance documents are not legally binding
- Guidance documents are issued under the support of MS
- Guidance documents are based on the outcome of discussions in (small) expert groups
- Expertise from Member States and third Stakeholders (industry, academia, NGOs) is usually included during the drafting phase
Draft guidance documents (under progressive development)

- **Plant strengtheners** with low risk profile - Data requirements (doc. Sanco/1003/2000, rev. 3), 21 June 2001

- **Plant extracts** - data requirements (doc 10472, rev. 5), 6 July 2004

- **Chemical substances** - data requirements (doc 10473, rev. 4), 6 July 2004
Legal process within EU

1. Primary legislation (treaties): decisions taken on a long notice and for a long period; political leaders

2. Secondary legislation, Council and European Parliament: median timescale; high political and administrative level
   Regulation, Directive and Decision

3. Secondary legislation, Commission: median to short timescale, high to medium administrative level

4. Other instruments, e.g. Thematic Strategies, recommendations, guidance documents: long to short timescale, all levels may be involved, but with an emphasis on technical level, legally not binding