EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

# 1st Annual Biocontrol Industry Meeting

*Lucerne, 23-24 October 2006*

## 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

- Council Directive 91/414/EEC of 15 July 1991 concerning the placing on the market of plant protection products
- 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

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# Proposed Regulation on PPP

- Stakeholder consultations held in 2002, 2004, 2005 and 2006, an Impact Assessment done in 2005/2006
- 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

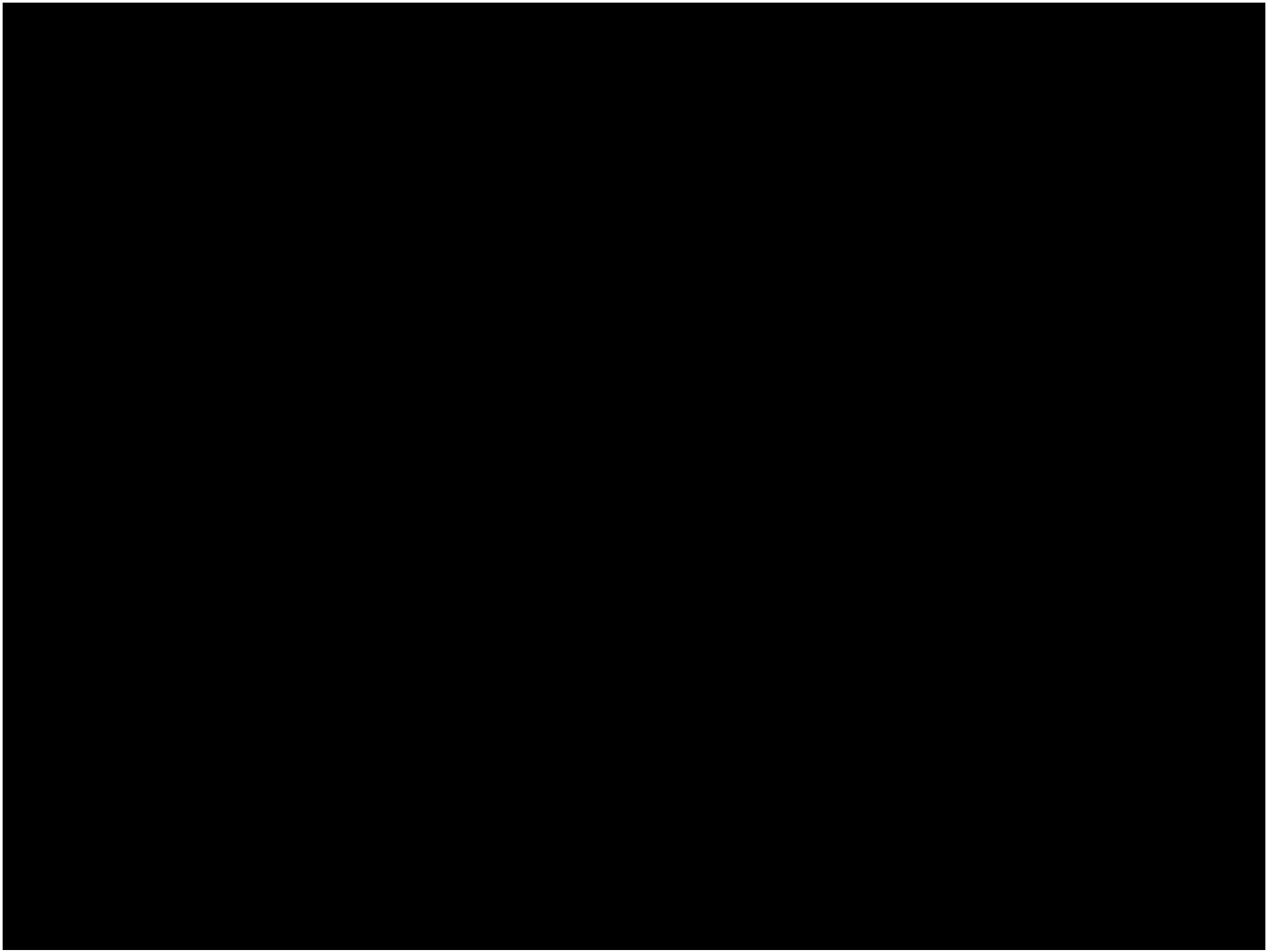
# Other issues

- 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:

**http://ec.europa.eu/food/plant/protection/evaluation/placing_market_en.htm**



# 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