The new Regulation concerning the placing of plant protection products on the market

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Pesticide Risk Assessment Peer Review (PRAPeR) Unit
• EFSA and pesticides: PRAPeR Unit and PPR Unit
• New regulation: elements of importance from an EFSA perspective
  - Data requirements
  - Procedure for approval of an active substance
  - Approval criteria
  - Acceptance of assessment methods
  - Other (guidance documents, treated seeds, …)
• The PRAPeR Unit is in charge of the peer review of new and existing active substances and produces EFSA conclusions on Draft Assessment Report prepared by the Rapporteur Member States

• The Commission bases its decision making (inclusion or not on the Annex I of Directive 91/414/EEC) on the EFSA conclusion
• The PRAPeR Unit evaluates the safety of new MRLs, of MRLs of concern and of existing MRLs after a decision on inclusion or non-inclusion of an a.s.

• The PRAPeR Unit is in charge of the drafting of the Annual Report on Pesticide Residues
**Summary:**
Total number of staff 34
AD 26
AST 5
CA 2
Interim 1
PPR panel and WGs

PPR Panel
21 experts

Working Group
Residues

Working Group
Toxicology

Working Group
Ecotoxicology

Working Group
Fate and behaviour

Working Groups updating and developing the GDs e.g. Persistence in soil, Terrestrial Ecotoxicology

Supported by the EFSA Secretariat = PPR Unit
Mandate of the PPR Panel

• **To produce scientific opinions** answering questions on risk assessment for specific pesticides (*e.g.* Q from Commission on deltamethrin) or related generic issues with regard to users, consumers and the environment (*e.g.* Q from Commission on the revision of the Annexes II and III)

• **Responsible of EU Guidance Documents** on pesticide Risk Assessment (*previously* DG SANCO)
  – **Revision** of existing GDs
  – **Development** of new GDs

  ➤ **Aim**: promotion of new and harmonized scientific approaches and methodologies in the EU
Data requirements

• Directive 91/414/EEC: data requirements laid down in the Annexes II (a.s.) and III (PPP)

• New Regulation: data requirements to be adopted as separate regulations within 18 months of the entry into force of the new regulation; in first instance, these data requirements will be copied from the Annexes II and III of the Directive
Data requirements

- Annexes II and III are under revision
- However, it is the Commission’s intention to copy the current data requirements into regulations by the end of 2009 (advisory procedure)
- These regulations will then be amended in order to take on board the ongoing revision of the data requirements (regulatory procedure with scrutiny)
Data requirements

• The PPR Panel is working on an updated opinion on the revision of the Annexes II and III

• Concerning the assessment of effects on honey bees, the Panel will reiterate its recommendation that the revised data requirements should be flexible enough to allow new risk assessment developments to be applied when available
Data requirements

• New element in the Regulation: the dossier must be completed with « scientific peer-reviewed open literature, as determined by the Authority, on the a.s. and its relevant metabolites dealing with side-effects on health, the environment and non-target species and published within the last ten years before the date of dossier submission »

• EFSA is working on a self-tasking in order to develop guidance for applicants
Approval of an active substance

- Directive 91/414/EEC: procedure of Annex I inclusion is not very detailed; roles of RMS and EFSA are not clarified
- New Regulation: procedure of a.s. approval is laid down in detail, clarifying role of all parties involved, establishing clear time lines
Approval procedure

- Application to a Member State (RMS)
- RMS checks the admissibility of the application
- Applicant makes dossier available to all MSs, EFSA, Commission
- EFSA makes the summary dossier available to the public
- The RMS assesses the dossier and prepares a draft assessment report (DAR); during the assessment, the RMS may at any time consult EFSA
Approval procedure

• Once finalised, the DAR is sent to the Commission and EFSA
• EFSA shall circulate the DAR for comments to the MSs and the applicant, and shall make it available to the public
• Where appropriate, EFSA shall organise a consultation of experts
Approval procedure

• Within 120 days (150 days where an expert consultation takes place), EFSA shall adopt a conclusion on whether the active substance can be expected to meet the approval criteria
• EFSA shall address the risk mitigation options identified in the DAR
Approval procedure

- EFSA shall establish the format for its conclusion which shall include details on the procedure and the properties of the a.s.
- The Commission may at any time review the approval of an active substance and may ask EFSA to provide an opinion or other scientific or technical assistance within 3 months
• Directive 91/414/EEC: it has to be demonstrated that representative uses of at least one PPP containing the a.s. evaluated can be used safely; no consideration of the effectiveness of the PPP
• New Regulation:
  - same principle, but effectiveness to be considered in view of approval (EFSA will have to address the effectiveness of the PPP in its conclusion)
  - A.s. must comply with the criteria of Annex II of the Regulation (including the so-called cut-off criteria)
• Criteria CMR, endocrine effects, fate and behaviour (POP, PBT, vPvB):
  - Where the assessment establishes that the approval criteria are not satisfied, the DAR shall be limited to these parts of the assessment
  - CMR, endocrine effects: « an a.s. shall only be approved if, on the basis of (...) testing (...) and other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not or has not to be classified… »
Approval criteria

• Honey bees: an a.s. can only be approved if its use:
  - Will result in negligible exposure, or
  - Will not lead to unacceptable acute or chronic effects on colony survival and development, taking into account effects on larvae and behaviour
Acceptance of assessment methods

- Residues shall have no harmful effects « taking into account known cumulative and synergistic effects »
- The use of PPPs (for instance in the workplace) shall have no harmful effects « taking into account known cumulative and synergistic effects »
Acceptance of assessment methods

• The use of PPPs shall have no harmful effects on the environment (water, air, soil, including long-range transportation; non-target species, including behaviour; biodiversity; ecosystem)

=> « where the scientific methods accepted by the Authority to assess such effects are available »
• Concerning cumulative effects of residues:
  - The PPR Panel has adopted a first opinion in 2008
  - An opinion on the triazole fungicides will be adopted in a few weeks time (test of different methodologies performed on a chemical class of pesticides)
  - A call will be launched for follow-up work (establishment of related groups of pesticides for which assessment of combined toxicity is needed)
• The Commission may adopt through the regulatory procedure technical and other guidance documents and « may ask the Authority to prepare or to contribute to such guidance documents »

• Safeners and synergists: added in the scope of the Regulation; a review programme for the existing substances will be initiated within 5 years; EFSA will be involved
Other elements important to EFSA

- Basic substances = not of concern, predominantly used for other purposes than plant protection, not placed on the market as a plant protection product
- No authorisation required if the basic substance is approved
- Approval of basic substance: any interested party can apply, no RMS involved, EFSA to deliver an opinion within 3 months
• Treated seeds:
  - Directive 91/414/EEC: no specific provisions at all; potential conflict with EU legislation on seeds
  - New Regulation: in case of serious risk, possibility to take measures (restriction or prohibition) in accordance with the regulatory procedure; Commission may request an opinion from EFSA
Other elements important to EFSA

- 120 day authorisation in emergency situations in plant protection: the Commission may ask EFSA to provide an opinion or other scientific or technical assistance within 1 month.
- Where the Commission is considering restriction or prohibition of an a.s., it may ask EFSA to provide an opinion.
Other elements important to EFSA

- Co-formulants: negative list of co-formulants that cannot be used in PPPs
- Detailed rules for co-formulants may be established in accordance with the regulatory procedure
- EFSA involvement not clear today (but probable)
Other elements important to EFSA

- Adjuvants: authorisation system to be put in place through a regulation adopted through the regulatory procedure with scrutiny
- No time schedule
- EFSA involvement not clear today (but probable)
Some other elements

- Zonal concept for the national authorisations
- Identification of candidates for substitution
- Application of comparative assessment
- Placing on the market of low-risk PPPs

=> It cannot be excluded that the Commission would ask EFSA to assist or to develop guidance