

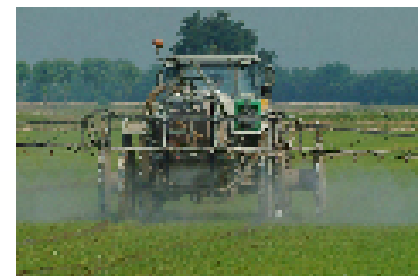


# **Plant Protection Products & their Residues (PPR) Panel**

**Presentation to the EFSA Management Board, Lisbon  
13<sup>th</sup> December 2007**

**Tony Hardy , Central Science Laboratory, UK, Chair of PPR Panel**

- Mandate
- How the Panel functions
- Types of work/activities
- Examples
- Issues
- Future work load



- Provides independent **scientific opinions** and **guidance** for the Community's legislation in the field of plant protection products (Directive 91/414/EEC).
- Deals with scientific questions relating to the risk assessment of plant protection products in relation to the **user/worker, the consumer of treated products and the environment.**

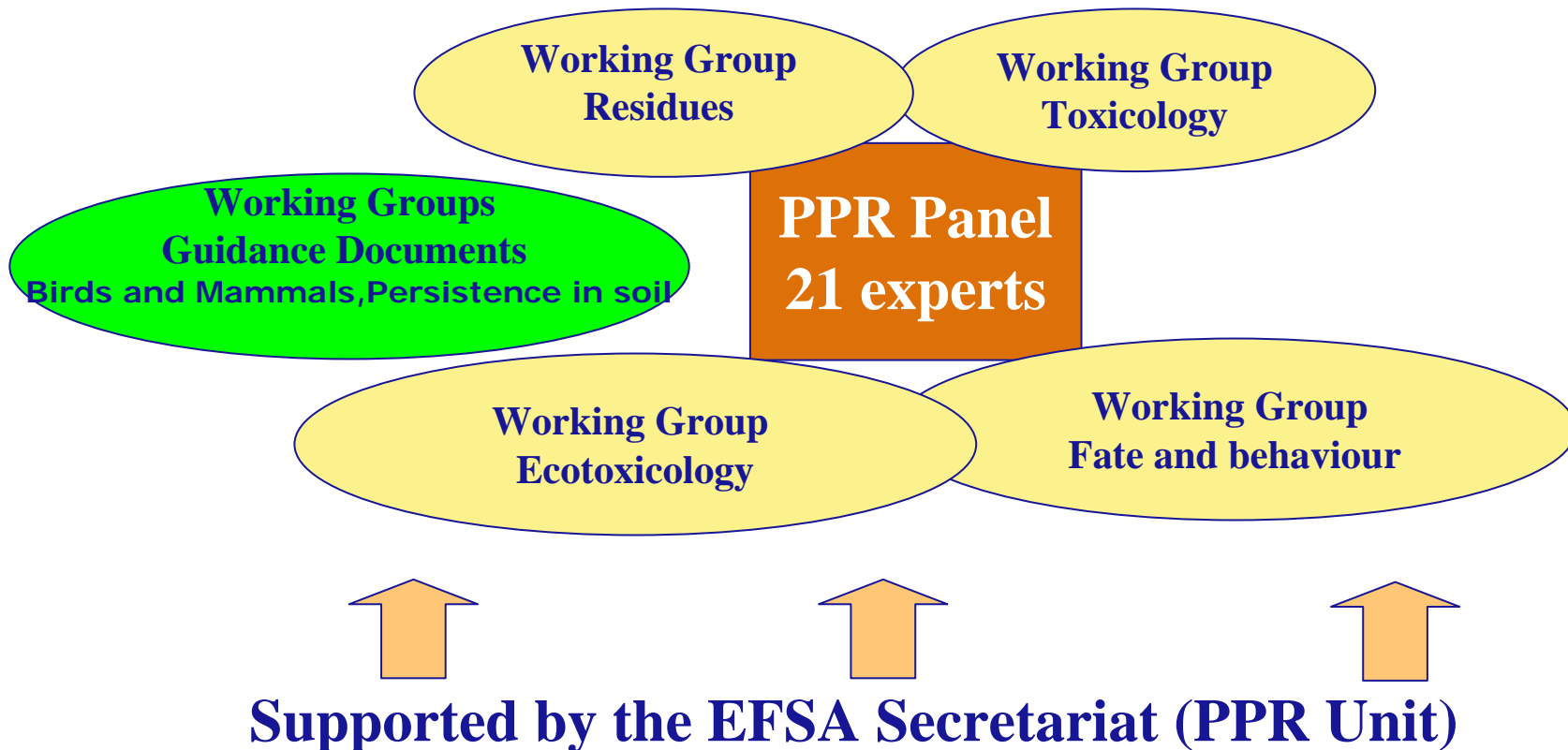
# The 2 fields of scientific activities

- Providing scientific opinions, on **generic** issues on pesticide risk assessment or on **specific active substances** on the basis of questions from the European Commission, EFSA's **PRAPeR** unit (self-tasking), the European Parliament or from Member States
- Updating existing and developing new **Guidance Documents** on pesticide risk assessment : promoting new and harmonized scientific approaches and methodologies

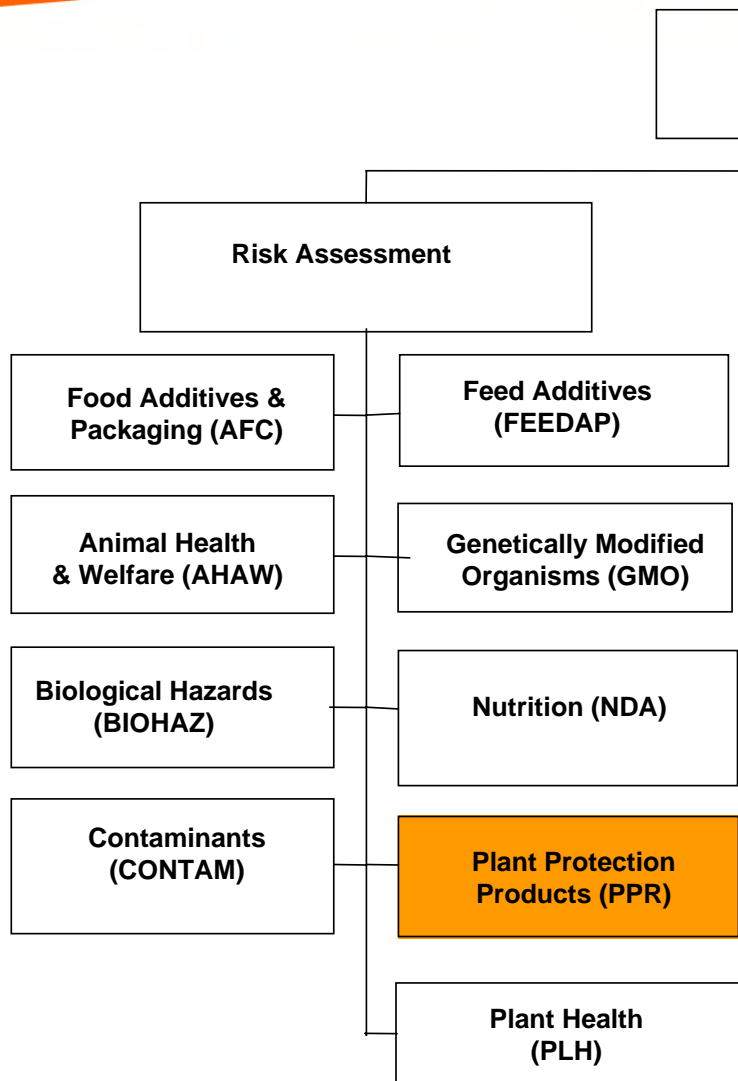
- 21 independent scientists
  - Toxicology (11), Environmental fate (5), Ecotoxicology (5)
  - BE(2), BU(1), CH(1), CY(1), DE(1), DK(2), ES(1), IT(3), NL(5), UK(4)
- supported by *ad hoc* experts (appointed for their relevant expertise) in specific areas in Working Groups which deal with related questions
- A rapporteur (Panel member) co-ordinates the work of the opinion in a relevant Working Group
- PPR Unit (8 staff) overall co-ordination of the work on the opinion and technical support
- 6/8 Plenary meetings/year, 38 WGs in 2006, 50 in 2007
- Adoption of an opinion in 6 months average (quorum of 2/3 members of the Panel) at a plenary meeting or by written procedure (circulation and agreement in 10 working days)
- The Panel members adopt the opinion, the *ad hoc* experts are acknowledged in the opinion
- Published on the internet, may include public consultation

# PPR panel and WGs

4 standing Working Groups and one variable one  
for Guidance Documents



# PPR Unit within EFSA



## •Scientific staff (5)

Muriel DUNIER-THOMANN (Head of Unit)

Christine FUELL (Ecotoxicology)

Karin NIENSTEDT (Ecotoxicology)

Mark EGMOSE (Fate and behaviour)

Istvan SEBESTYEN (Toxicology)

## •Administrative support (3)

Giorgia BOSCHETTO

Cinzia PERCIVALDI

Isabelle RHIHANI



**33 opinions adopted since 2003 by the PPR Panel in the areas, 3 more on 11th December:**

- Toxicology (10+2)
- Ecotoxicology (9)
- Fate and behaviour (7+1)
- Residues of pesticides (5)
- Analytical methods (1)
- Physico-chemical properties (1)



## On a specific active substance or regulation

### **(Questions from the Commission)**

- Acute reference dose for imazalil
- MRL for dieldrin
- Acute dietary exposure of pesticides residues in fruit and vegetables IESTI
- Toxicological relevance of a metabolite of tritosulfuron
- Revision of the Annexes II and III of Dir. 91/414: Toxicology
- Revision of the Annexes II and III of Dir. 91/414: Ecotoxicology
- Revision of the Annexes II and III of Dir. 91/414: Fate
- In 2006, adopted Annexes II and III on Residues, Analytical methods and Physico-Chemical properties

## On generic issues and on EU guidance documents (GD)

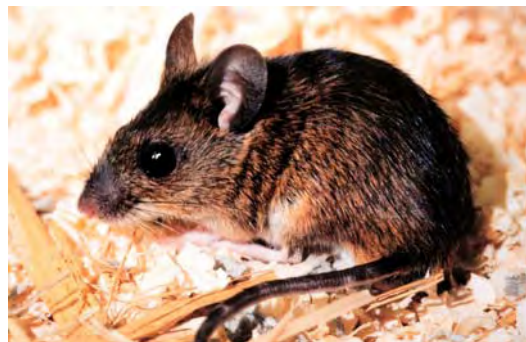
### **(Self-tasking questions from within EFSA)**

- FOCUS landscape and mitigation GD
- FOCUS air GD
- Birds and mammals GD (revision)
- Cumulative risk assessment of pesticides in human health
- Q10 default value for transformation rates of pesticides in soil
- Genotoxic and carcinogenic potential of buprofezin

- **(FORum for the Coordination of Exposure Models and their Use) FOCUS air report (DG SANCO): models for exposure assessment in air**
- **Q10 value used to describe the temperature effect on transformation rates of pesticides in soil**
- **Starting to update the GD on persistence of pesticides in soil**

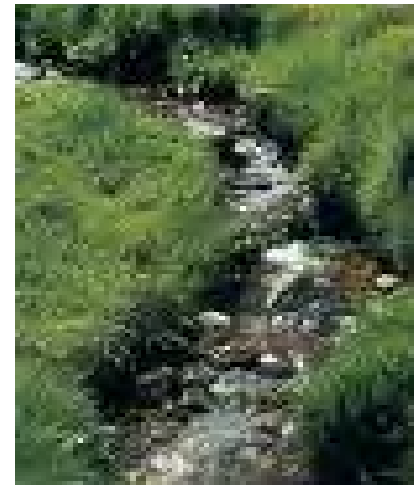


- **Aquatic risk assessment of cyprodinil (a fungicide) and the use of mesocosm studies**
- **Choice of endpoints to assess the long term risks to mammals in the field**
- **Revision of guidance document on risk assessment for birds and mammals**



# Risk Assessment for aquatic organisms

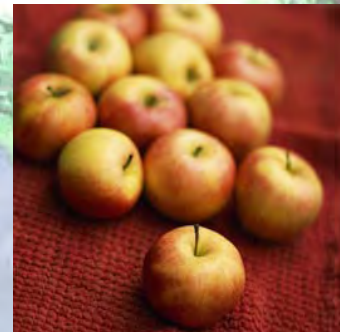
- Relevance of tests with case-specific design intended to simulate more realistic exposure scenarios?
- Reduction of the uncertainty in the RA by provision of additional data
- Concept of Ecotoxicologically Relevant Concentration & comparison of the concentration over time in the ecotoxicity study & the predicted environmental concentration (PEC).





# Residues WG      Consumer exposure

- Opinion on the request on the risks associated with an increase of the MRL for dieldrin on courgettes (**question from the Commission**)
- Opinion on how to evaluate the suitability of existing methodologies and the identification of new approaches to assess cumulative and synergistic risks from pesticides to human health with a view to set MRLs for those pesticides in the frame of regulation (EC) No. 336/2005 (**self-tasking question from EFSA**)



# The IESTI opinion

- The European Commission asked EFSA (PPR Panel) for an opinion on the acute dietary intake assessment of pesticide residues in fruit and vegetables with a view « to deciding about the use of the IESTI equation (International Estimate of Short Term Intake) to be used for future fixing of MRLs for pesticide residues»
- The opinion was adopted on 19 April 2007 and was part of the discussion for the EU position at the Codex Alimentarius and subsequent discussions with the Member States.



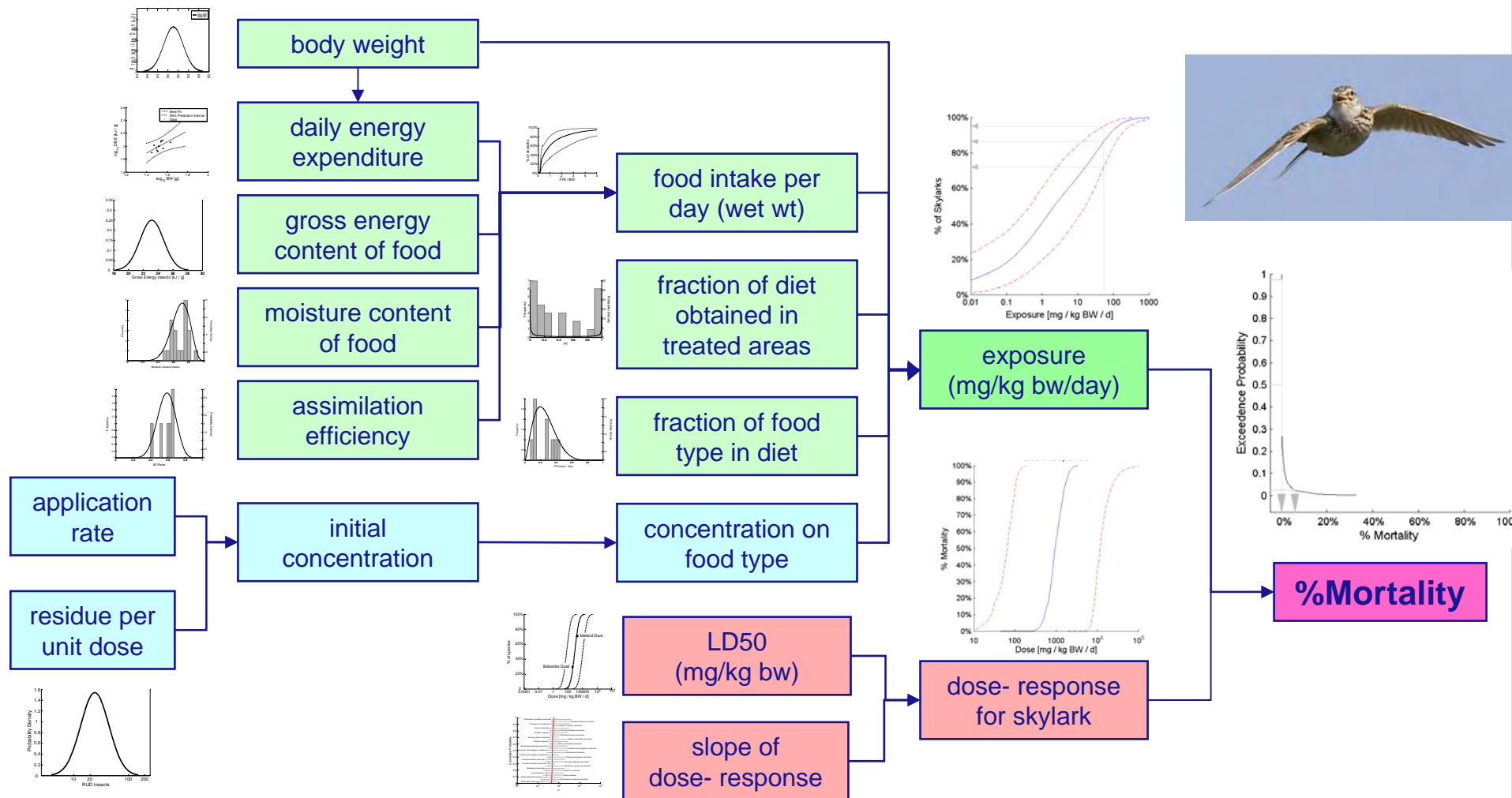


- Opinion on genotoxic and carcinogenic potential of buprofezin (an insecticide) in the context of the human risk assessment (self-tasking from EFSA PRAPeR Unit)
- Opinion on the toxicological relevance of the soil and ground water metabolite TBSA of tritosulfuron in the context of the human risk assessment (question from the Commission)



- EFSA's new mandate transferred from the Commission to update/develop EU Guidance Documents for the risk assessment of pesticides
- Priority list was established by Member States (summer 2006)
- EFSA proposes to accelerate the procedure in externalizing part of the work where possible
- Stakeholder consultations – at beginning, and at the end of updating or developing new GDs

# Exposure to pesticides in food, wildlife



# Guidance Document on Bird & Mammal Risk Assessment

- Original SANCO document (2002)
- Risk assessment mandate but good GD is wider
- Protection goals, triggers, risk management decisions
- Initial public consultation
- Workshop & consultation with stakeholders (MS as regulators and industry as practitioners)
- Public consultation on draft final guidance - current
- Status of Guidance Document
  - EFSA opinion
  - endorsement/adoption by SCFCAH & MSs ?

# Possible 'short circuit' Article 36 proposals

- Panel has heavy workload
- Tendered “Project to assess current approaches and knowledge with a view to develop a new Guidance Document for pesticide exposure assessment for workers, operators, bystanders and residents”
- A 9-month grant restricted to the list adopted by EFSA Management Board according to Article 36 of European Parliament and Council Regulation (EC) No 178/2002 [deadline 07/09/2007, contract under signature], a project to help the Toxicology WG to start its work.

- Need for clear specification of the tender (Panel involvement, conflicting interest)
- Independence of the successful contractor
- Project must be managed to deliver the contract
- The outcome must be usable/acceptable to the PPR Panel
- Time delays before the Panel picks up the issue - (9 months preparation until signature, 9 month contract to deliver)
- Attractive but not perfect solution. The timeline is not necessarily reduced

# Communication of opinions

- The PPR opinions are published on the EFSA website as EFSA Journal (summary translated in 3 languages FR, DE, IT) :  
[www.efsa.europa.eu](http://www.efsa.europa.eu)
- Press releases and web story on the opinions raise accessibility to wider public and stakeholder community
- Regular information to Member State competent authorities, stakeholders and the European Commission
- Regular presentations (and posters) in scientific fora, symposia and Workshops
- Peer-reviewed scientific publications





# Future Workload and Issues

- Review dossiers
- Risk assessment Guidance Document revisions
- Cumulative Risk assessment of pesticides
- Uncertainty evaluation and quantification of risks
- Dialogue (stakeholders, MS)
- Expansion and communication with MS
- Maintenance of expertise
- Smarter working, remuneration of experts







Thank you for your attention