EFSA opinion on the new regulation: revised data requirements for ecotoxicology studies

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PPR Panel Mandate

• EFSA is a risk assessment and risk communication organisation not regulatory

• PPR Panel provides independent scientific advice on the risk assessment for the user/worker, the consumer and the environment.

• Panel works closely with the Pesticide Risk Assessment Peer Review (PRAPeR). PPR Panel is asked for its opinion (called “self-tasking”) on any issues that cannot be resolved within this procedure or when further scientific guidance is needed, mostly in the field of toxicology, ecotoxicology, fate and behaviour of pesticides and residues.

• Updating the existing European Guidance Documents in risk assessment of plant protection products and to develop ones in new scientific areas.
21 independent scientists (2009-2012) inaugural meeting 2-3 July 2009

- **Fields:** Toxicology (6), Residues (4), Environmental fate (5), Ecotoxicology (6)
- **Nationalities:** BE(2), BU(1), DE(2), DK(2), ES(2), IT(3), NL(4), UK(2)
- 11 are from the previous Panel
PPR Panel mandate 2006-2009

• Revise SANCO working documents to revise Annexes II and III data requirements

• 6 opinions (2006 and 2007)
  – Physical and chemical properties
  – Analytical methods
  – Residues
  – Toxicological and metabolism studies
  – Fate and behaviour in the environment
  – Ecotoxicological studies (2007)

• Updating opinions (2009)

*The EFSA Journal (2007) 461, 1-44*

• Updating the opinion ............... Ecotoxicological studies

*The EFSA Journal (2009) 1165, 1-24*
Conclusions

- 2007 opinion valid, combine
- 2009 opinion focuses on reducing number of animals tested, harmonisation of RA quotients, ECx versus NOEC, honey bees, aquatic plants
- Requirements should be future-proofed and flexible enough to allow for RA developments
- Report additional toxicological effects from existing studies
- Additional animal (vertebrate) testing with standard/non-standard tests only if appropriate and properly justified
Reducing numbers of animals to be tested

- **Birds acute oral toxicity** – single species (Bobwhite/Japanese Quail)
- **Reduce (x2) no of birds tested eg draft OECD**
- **Birds short-term dietary toxicity** – only where dietary LD50 likely < acute oral LD50
- **Mammals acute** – if likely < 2000mg/kg then no limit test, OECD up & down only
- **Fish acute toxicity** – investigate not testing 2nd species if sensitivity < by order magnitude than other standard test spp.
- **Reduce test fish number in limit test**

**But**

- **Chronic fish testing** – fish full life cycle test rather than separate tests on different life stages
Harmonisation of risk assessment quotients

- Inconsistent across groups of organisms and EU legislation
- Toxicity/exposure ratios (TERs) for birds, mammals, aquatic organisms, soil macro-organisms, non-target terrestrial plants (larger the ratio, smaller the risk)
- Hazard quotient (HQ) honeybees (larger the ratio, larger the risk)
- REACH – hazard quotient – exposure/predicted no effect concentration[PNEC] (larger the ratio, larger the risk)
- Recommend harmonise as hazard quotients

- Inconsistent levels of protection - recommend validation of trigger values with comparison with impact in field studies
Use ECx instead of NOEC

- Traditional ecotox endpoints
  - No observed effect concentration (NOEC)
  - Lowest observed effect concentration (LOEC)

Affected by choice of concentrations tested, variability, low statistical power, no confidence limits

- ECx (concentration where x% effect was observed/calculated)
  Robust to variability in experimental design, concentration interval, replicates, variability, % effect defined, confidence intervals

Recommend

- Harmonise ( & REACH)
- Leave final open choice of x, further work PPR Panel
### Other issues

- Ecotoxicity tests with aquatic plants
- Updating the risk assessment for the honey bee
- Indirect effects
- Risk assessment for soil organisms
- Endocrine disruptors
- Nanomaterials
- New issues – marine, estuarine, coastal, transitional and groundwater protection
Thank you for your attention