



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

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Protection Products and their Residues Panel (PPR)
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- 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



- 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)



- Opinion of the Scientific Panel on Plant protection products and their Residues on a request from the Commission related to the revision of Annexes II and III to Council Directive 91/414/EEC concerning the placing of plant protection products on the market – Ecotoxicological studies

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, EC_x 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



New PPR Panel and Unit July 2009





Thank you for your attention