Occupational exposure to pesticides
Challenges for research, evaluation and prevention
Pesticide exposure assessment: developments and challenges

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Overview

• Occupational exposure assessment
  Operators and workers
  Risk assessment

• Historical perspective

• European regulatory requirements

• Short term challenges

• Longer term challenges
Which occupational exposures and why?

Occupational exposures:

Operators – directly exposed when handle and apply pesticides

Workers – secondary exposure e.g. when contact treated crops

Other occupational exposures e.g. during manufacture

Exposure assessment:

Will proposed use will comply with regulatory reference dose?

Other reasons:

To monitor compliance with exposure standards at work

To support epidemiological investigations
Exposure assessment as part of risk assessment

- Adverse effects
  - E.G. genotox, short-term, repeat dose, lifetime, reprotox & neurotox studies

- Dose response
  - No effect levels
  - Relevance to humans
  - Uncertainty factors

- Exposure assessment
  - Routes, level, duration & frequency
  - Uptake/absorption e.g. via skin, lungs

- Hazard identification

- Risk characterisation
  - Summary, integration, and evaluation
  - Incidence and severity of effects likely in exposed population?
Historical perspective (part 1)

1962

1980s
- Qualitative hazard based regulatory risk assessments common, exposure studies uncommon
- Mid 1970s USA FIFRA quantitative exposure data

Mid 1980s
- Quantitative regulatory risk assessments, supported by exposure data from individual studies become standard?

Late 1980s
- Generic databases/exposure models e.g.
  - POEM UK 1986
  - PHED USA/CAN 1991
  - German model 1992
  - NL model 1992
Historical perspective – Europe (part 2)


  • Requirement for quantitative assessment of risks to human health arising from intended pesticide use (i.e. “Good Plant Protection Practice”)

  • Requirement of no harm to health and established health based reference dose (AOEL) which on basis of available knowledge, represents the maximum systemic dose which can be repeatedly tolerated by operators, and other people, without risk of harm to health

  • Requires first exposure estimate based on suitable model

  • Requires realistic data to be used in preference to model

  • Proposed use unacceptable if exposure > AOEL

  • Differences between individual MS approaches not resolved

• Commission support EUROPOEM project

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Consequence of use of AOEL

Hazard identification
- Adverse effects
  - E.G. genotox, short-term, repeat dose, lifetime, reprotox & neurotox studies

Dose response
- No effect levels
- Relevance to humans
- Uncertainty factors
  - Health based reference doses

Exposure assessment
- Routes, level, duration & frequency
- Uptake/absorption e.g. via skin, lungs

Risk characterisation
- Limit uses to where exposure is predicted not to be >AOEL

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EUROPOEM project

• European Commission supported Concerted Action Grant

• Involving regulators (DE, DK, ES, FI, FR, IE, NL, UK) and industry (CH, DE, FR, USA, UK)

• Review available operator and worker data (≤1996) and build databases

• Observed large variation in occupational exposure measurement methods

• Proposed standard protocol
  
  • Discussed at international workshops - 1992 NL, 1993 Health Canada & NATO

  • 1997 OECD GD(97)148, Guidance Document for the Conduct of Studies of Occupational Exposure to Pesticides During Agricultural Application

• Final databases
EUROPOEM databases

• 2002 Large quantity of **operator exposure** mix/loading and application data – mainly from industry and a smaller quantity from government studies

• Large variation in data for individual techniques, - equipment? PPE?

• 2003 ILSI Workshop in BE, on probabilistic methods for the assessment of operator exposure to plant protection products concluded **assumed determinants of exposure do not adequately explain the variability observed in dermal and inhalation exposures in both EUROPOEM, and PHED**

• EU Commission and MS wait for industry to complete new US/CAN/EU database (AHED) - progress with software but then data delayed by US human subjects issues

• 2002 Very limited amount of **worker exposure** re-entry task data – published literature and government sponsored studies, but no industry data

• **Worker exposure model proposed based on US EPA approach and limited available data**
EFSA

• 2002 EFSA established and begins to develop its functions

• 2006 EU Commission, EFSA, MSs discuss pesticide guidance priorities – occupational exposure assessment is highlighted (with others)

• 2007 EFSA call to assess current approaches and knowledge with a view to developing guidance awarded to PSD (UK) and University of Ghent (BE)

• 2008 PSD/UG report completed

• 2010 EFSA PPR Panel considered PSD/UG report and publish proposed form of harmonised guidance using modified interpretations of currently accepted regulatory models/data (c.f. creating new models), also raises risk management questions for EU Commission

• 2011 EU Commission addressed RM issues and after dialogue EFSA established working group to produce Guidance Document published 2014
Other actions

• 2008 US EPA FIFRA SAP review large quantity of data owned by USA Agricultural Re-entry Exposure Task Force addressing worker exposure in response to EPA industry wide data call in. However, data not (yet) generally available to EU authorities

• 2009 EU 7th FP call to review, improve and extend the models currently used in the risk assessment of plant protection products (PPPs) to evaluate the exposure of operators and workers (and others)

• 2010 Contract awarded to BROWSE consortium, final report expected late 2014

• 2010-2013 ACROPOLIS EU 7th FP Research project to address combined exposures to multiple substances via multiple pathways and routes – focus on dietary intakes and established framework to include other exposures

• 2011-2013 BfR led technical and statistical review of modern EU operator exposure data, previously submitted as single studies (AOEM)
Immediate challenges

• Policy/legal requirement for harmonisation of exposure assessment models across the EU authorities and industry

  • EFSA, 28 MS (single zone, or northern/central/southern zone)

• Information to cover scenarios currently not adequately supported

  • E.G. Worker (re-entry) exposure data, less “common” application techniques such as weed wipers

• Policy/legal requirement to develop and employ cumulative risk assessment approaches

  • Combining several single precautionary estimates will often overestimate risks

• Need for realistic exposure distributions, integration of use and operator/worker behaviour information (see EFSA pilot surveys)
Consequences of cumulative assessment?

- Routes, level, **duration & frequency**
- Uptake/absorption

**Risk characterisation**
- summary, integration, & evaluation of major scientific evidence, reasoning & conclusions - including estimation of incidence & severity of effects likely to occur in exposed population
Longer term challenges

• Improvement of exposure monitoring
  
  • Uncertainty regarding passive dosimeters c.f. dynamic process
  
  • Uncertainty regarding dermal absorption (% c.f. flux)
  
  • Incidental oral contribution?

• Measurement methods
  
  • E.G active air sampling of vapour/particulates/droplets/aerosols in breathing zone (aerodynamic sizes, sampling efficiency, respiroable fraction?), absorbent cotton gloves, solvent swab/rinse, hand wash soap and water, face/head/neck estimation from surrogates (hat, shoulders, back, and chest dosimeters)
Longer term challenges

• Measurement methods (continued)

• Patch dosimeters, whole body dosimeters, outer and inner clothing (later as surrogate for skin)
Challenges: better use of TK information?

- Adverse effects
  - E.G. genotox, short-term, repeat dose, lifetime, reprotox & neurotox studies

- Hazard identification
  - Relevance to humans?
  - No effect levels
  - Uncertainty factors
  - Toxicokinetics

- Dose response
  - Routes, level, duration & frequency
  - Uptake/absorption e.g. via skin, lungs

- Exposure assessment

- Risk characterisation
  - Summary, integration, and evaluation
  - Incidence and severity of effects likely in exposed population?

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Post authorisation “checks”

- Epidemiological studies are an important potential “check” on regulatory risk assessments.
  - Regulatory toxicological models do not cover all potential adverse health effects.
  - Toxicological testing does not cover combinations of pesticides and other substances encountered by operators and workers.

- Historically epidemiologic studies have used surrogate measures of exposure which may contribute to some of the inconsistent results observed.

- Exposure measurements can support improved epidemiologic exposure models.
  - E.G US industry sponsored Farm Family Exposure Study, which in 2000 used biological monitoring to measure exposures of operators and their families under “real world conditions” of 106 applications, and US AHS.

- Such data also assist training of users.
The way forward

• Presentations to follow will expand on progress toward EU regulatory harmonisation; improved models; construction of approaches to address multiple exposures to difference substances via different pathways and routes; development of job-exposure matrices; and aspects relating to personal protective equipment.

• While much has been done an inevitable conclusion is that there remains more to do

• The EU policy objectives are high level of protection for human health, but also to support sustainable plant protection and to facilitate access to the market for acceptable products - hence zonal authorisations

  • Now it is less appropriate for individual regulatory bodies to work out answers to particular issues has been the past case, and official budgets are also declining

  • Prompt for whole industry to strengthen collective knowledge and give more support to addressing wider issues
Thank you for your attention