

H08**Bayesian evaluation of non-animal information to support decision making—Skin sensitization test case**

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Following increasing use of *in vitro/in chemico/in silico* tests in management of chemicals, there is an urgent need to develop data integration frameworks allowing interpreting results from test batteries and making an inference about an *in vivo* endpoint objective. The framework should be transparent and structured, and allow for consistent and rational reasoning. We developed a formal Weight of Evidence framework for a multiple test battery that meets these requirements. This approach uses Bayesian inference in a form of a Bayesian Network and generates a probability statement about activity of a chemical based on a specific battery outcome. It resolves conflicting evidence, reasons consistently given different data sets and/incomplete data sets. To assess skin sensitization we developed a Bayesian Network with the target variable LLNA assay and input variables grouped into 3 groups, or lines of evidence: bioavailability, peptide reactivity and dendritic cell activation. Inputs to bioavailability line of evidence are all generated *in silico* and include: Log Kow, and calculated variables related to penetration from a dynamic skin model: dose absorbed systemically, free chemical concentration in the skin, maximum concentration in the epidermis. Inputs to peptide reactivity line of evidence include data from *in chimico* tests such as lysine, cysteine, luciferase reactivity. Finally, the dendritic cells line of evidence is based on U937 CD86 expression and IL-8 production. The input variables are ranked relative to their importance in explaining a chemical's potency in the LLNA and help define an optimal testing strategy. Reduction in the certainty of the battery outcome due to conditional dependence between tests is demonstrated and taken into account while assessing information gain from multiple assays.

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H09**The use of assessment factors and the implicit safety margins in occupational exposure limits**

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In health risk assessments so called assessment factors are often used to handle scientific uncertainties. In this paper the size of assessment factors used to derive occupational exposure limits (OELs) are analysed and compared taking the following aspects into account: the type of critical effect reported, the type of effect data used as the point of departure (e.g. a NOAEL or LOAEL), the publication date of the risk assessment and the amount, coherence and quality of the available data set. If assessment factors are not explicitly reported, an *implicit safety margin* can be derived by dividing the dose used as point of departure in the risk assessment with the proposed OEL. In this investigation, inhalation data and OELs for

eleven substances and 49 risk assessment documents from eight different risk assessors were scrutinised. In only four of the 49 risk assessments an explicit assessment factor was stated. In none of these 49 documents did the safety factor or implicit safety margin exceed 100 from a NOAEL. The differences between the safety margins, depending on nature of the critical effect and type of dose used as point of departure, were unexpectedly small. It is concluded that if these examples are representative, increased openness about the applied safety margins would be beneficial to the transparency of the process to determine occupational exposure limits.

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H10**Risk Assessment and Management—European Training Programme (Risk ASSETs)**

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Within the EU there is a priority need to improve the availability of trained risk assessors for conducting consistent high quality assessments of health risks in accordance with EU policies and legislation, and to serve on EU risk assessment committees.

The Risk Assessment and Management—European Training Programme (Risk ASSETs) project aims to provide a comprehensive and concise training programme to address these gaps in risk assessment training to ensure consistency in the level of competency required, module content, form of delivery and qualifications to be obtained for risk assessors. This will include developing:

- a foundation course to provide a comprehensive understanding of the fundamental aspects of risk assessment and risk management (including piloting the course)
- course content for an intermediate and advance level training on risk assessment; and
- a proposed structure to enable the administration and coordination of the training programme, including ensuring adequate quality assurance and quality control.

The project proposes to undertake a review of existing training schemes and the needs of stakeholders and course participants and develop core competencies and a harmonised curriculum for risk assessment training throughout the EU. This will involve contacting stakeholders, running an international workshop and reviewing relevant material. Specific attention being paid to: toxicology, exposure assessment to chemicals, environmental and bio-monitoring, epidemiology, substances in cosmetics and electromagnetic fields.

This poster outlines the aims, objectives and workplan of the project with a view to engaging stakeholders as to the needs and requirements for risk assessment training throughout Europe.

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