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IOM	Institute of Occupational Medicine Workplace and Environmental Sciences Research Park North, Riccarton EH14 4AP Edinburgh United Kingdom	4	AC	3
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Objectives

The present project intends to help at reducing acute and chronic ill-health due to dermal exposure to chemicals, and has two *major* operational objectives.

- 1) Develop a validated predictive model for estimating dermal exposure for use in generic personal exposure risk assessment to chemicals (e.g. under the New and Existing Substances legislation, and its successor in European chemical policy: REACH, as well as the Biocidal Product Directive).
- 2) Develop a practical dermal exposure risk assessment and management Toolkit for use by small and medium-sized enterprises (SMEs) and others, in actual workplace situations (e.g. under the Chemical Agents Directive).

To achieve these objectives, a research programme comprising of four interrelated work parts, was carried out.

** Work part 1: qualitative dermal exposure survey*

Main objective: to create an overview of qualitative information about dermal exposure throughout Europe (processes, tasks, populations and determinants of dermal exposure).

** Work part 2: quantitative dermal exposure survey*

Main objective: gathering quantitative data on potential (and actual) dermal exposure in selected workplace situations in the Member States, chosen in part from the findings in work part 1.

** Work part 3: exposure model set*

Main objective: to develop an appropriate predictive exposure model (set) for generic assessment of dermal exposure of single chemicals based on actual measurements.

** Work part 4: risk assessment and management toolkit*

Main objective: to develop a risk assessment and management Toolkit for exposure and risk assessment (and management) of (specifically) dermal exposure in small and medium-sized enterprises (SMEs).

Results and Milestones

The four work parts delivered their objectives by employing a close working relationship between the partners in all work parts. This has resulted in a large database with information on determinants of dermal exposure for the qualitative survey carried out in various industry sectors throughout Europe (in nine Member States). Two large databases have been created containing the results of hand and body exposures based on the quantitative dermal exposure studies carried out in six Member States for a large series of different use scenarios for chemicals. These databases are available for use by policy makers, other researchers and exposure modellers as well.

On the basis of these results the two major products were prepared in accordance with the two main objectives of the project.

- A predictive dermal exposure model set structured according to the chosen format of six different dermal operation exposure units. Also a set of adaptations has been prepared for the Technical Guidance Document Risk Assessment for the new and existing substance regulations (currently being developed into REACH). This set of adaptations can easily be integrated if the Commission and Member States would like to do so.
- A Toolkit for risk assessment and risk management of dermal exposures has been developed and is available on CD-rom and on the internet, for use by competent authorities, labour inspectorates and SMEs.

The results of the project have been published or are being prepared for publication. The main route for peer reviewed publication is the Annals of Occupational Hygiene (Vol. 47/8; 2003 and Vol. 48/3; 2004). Further scientific publications and presentations have already been achieved and plans are in hand for further publications.

Benefits and Beneficiaries

The results of the RISKOFDERM project have been discussed at two implementation workshops, hosted by CEFIC, the largest European industry organisation dealing with chemicals. The workshop attendees were representatives of industry, competent authorities, labour inspectorates, trade unions, and occupational health services. The overall consensus conclusion of these two workshops dealing each with one of the two major products of the study, was that the RISKOFDERM project has (i) produced a significant amount of good quality data on dermal exposure patterns, (ii) developed approaches for dermal exposure risk assessment and management, and (iii) has helped in a significant way to take forward dermal exposure assessment techniques such as exposure prediction, assessment and management. This progress will be of great help to regulatory processes. However, the workshops concluded that the two main products require further development to achieve their full potential. The main recommendation of both workshops was to combine the efforts of various players (e.g. CEFIC and European institutions) and bring together their expertise and budget in order to improve and adapt the work done in a relatively short timeframe, since dermal exposure assessment is currently assessed in a way that needs this improvement. The Toolkit and the models should be discussed in detail by the relevant stakeholders, before actual implementation can take place. During the development the user-friendliness will again have to be considered. It was noted by the participants that the development of inhalation exposure assessment methods, including exposure modelling approaches required many decades, whereas the interest in dermal exposure assessment and modelling has a short history and the momentum for making progress just started.

Future Actions (if applicable)

At the above-mentioned implementation workshops, the following conclusions were drawn on future actions (largely taken from the consensus summary of the workshops).

- It was considered essential by the participants that the substantial efforts to obtain more and better information on dermal exposure and exposure determinants, as initiated in the RISKOFDERM project, should be continued in order to provide further information for the necessary improvements of the Toolkit and the Dermal exposure models that can fully be incorporated in regulatory decision-making processes. To reach this goal, appreciable scientific and confidence-building, as well as consensus-building efforts, are required.
- The workshop participants suggested that a plan for further actions should be prepared and discussed with the relevant stakeholders, which are competent authorities at European and national levels, industry (large and SMEs), as well as Trade Unions, Health and Safety Inspectorates and Occupational Safety and Health Services.
- A very important issue is the fact that the products of the RISKOFDERM project need to find a responsible 'owner' to take it forward, after completion of the project.
- Details of the above approach need to be discussed, before further research actions are taken, with representatives of DG Environment (ECB/JRC), competent authorities in Member States, and CEFIC (and other relevant industry associations) at a Technical Meeting or similar venue. This should be done as soon as is practicable. Such a meeting could indicate an appropriate person to take further initiatives to improve and extend the Toolkit and the Dermal exposure models. The co-ordinator of the RISKOFDERM project volunteers for this purpose in order to write the research and confidence-building plan, reach consensus on the aims with stakeholders, and acquire the necessary budget.
- The experimental databases should be updated with additional exposure data after first defining in- and exclusion criteria to build a database of high quality. It is hoped that this will be undertaken by the European Chemicals Bureau, using a version control group with relevant expertises, or on behalf of the Commission at some other dedicated institution.

Various participants in the project will hold national workshops to discuss the results of the RISKOFDERM project, especially the Toolkit. This will be done at least in Austria, Germany, the UK and The Netherlands. Furthermore, in The Netherlands a so-called generic substance manager for estimation of inhalation exposure is currently being adapted for use in different industry sectors. The possibilities of integrating the concept for inhalation with those of the Toolkit will be investigated. TNO will take the lead in attempting to bring the predictive dermal exposure models and the TGD adaptations in a form acceptable for use in the REACH programme in EUROPE. In part this will be done by using Bayesian statistics as already initiated in the Technical notes for Guidance for exposure assessment of biocidal products.

In 2004 the further developments of the RISKOFDERM products will form the central point of workshops at national professional societies in Member States and at the international X2004 exposure assessment conference in Utrecht, The Netherlands.