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Commentary

EASEing into the Future

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In this edition of the *Annals* you will find five papers relating to the Estimation and Assessment of Substance Exposure (EASE) model. There are papers on: the history of the development of the EASE model (Tickner *et al*., 2005), the evaluation and further development of the EASE model (Creely *et al*., 2005), the validity of the EASE dermal model (Hughson and Cherrie, 2005) and two papers on the validity of the inhalation model (Cherrie and Hughson, 2005; Johnston *et al*., 2005). Other earlier studies have looked at the validity of the EASE model (Vincent *et al*., 1996; Devillers *et al*., 1997; ECETOC, 1997; Van Rooij and Jongeneelen, 1999; Mark, 1999 and Bredendiek-Kamper, 2001)

The EASE model was first developed by the Health and Safety Executive (HSE) on behalf of the European Union (EU) in the early 1990s. EU legislation required evaluation of the health risk of new chemicals before they were placed on the market, and this required estimation of exposure during use. Obviously, there were unlikely to be exposure measurements available for new chemicals, and EASE was designed purely as a screening tool to assist the estimation.

There is currently much interest in and discussion of the changes to the European chemical supply legislation (http://europa.eu.int/comm/enterprise/reach/index.htm). This is reflected in the range of regulators, industry and academia supporting the work on EASE in this issue, including the UK HSE, the European Chemical Industry Council (CEFIC), The American Chemistry Council, the International Lead Zinc Research Organization (ILZRO) and the International Institute of Synthetic Rubber Producers. As EASE is the main model used for regulatory occupational exposure assessment in the EU, now is a good time to question whether or not the current model can be upgraded or whether a new model is needed to face the challenges in European regulatory risk assessment that are to come.

The basis for the development of EASE was the conceptual model outlined by Devine (Devine, 1993). This model postulates that the concentration of a substance could be predicted by analogy with similar situations, provided that the judgements made were calibrated by reference to measured exposure data that was sufficiently comprehensive, precise and representative. The model is based on three parameters: the tendency to become airborne, the way in which the substance is used and the means of control.

The first, MS-DOS, version of EASE was soon found to be too crude to produce useful predictions. The second, Windows, version was produced by HSE in 1997 and had been improved mainly by changing the software interface and fixing obvious deficiencies in the model structure. A third version was developed but was never distributed because problems arose during user trials.

The developers 'always considered that the EASE outputs should be regarded as broad estimates, being adapted by experienced occupational hygienists in light of experience and factors not covered by the scope of the model' (Tickner *et al*., 2005). EASE was not designed to be an 'all-singing all-dancing' exposure prediction model, so we should not be surprised that it does not perform well as a method of predicting individual sampling results (Johnston *et al*., 2005). It was designed to be an aid to regulatory exposure assessment, to be used by experienced occupational hygienists, where no real exposure data were available. How far the current model meets this aim is discussed in detail in the papers presented. The general opinion seems to be that for inhalation exposure EASE tends either to predict close to the measured values or to over-estimate. The dermal

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model gives considerable overestimates of actual exposure.

The use of the EASE model in regulatory risk assessment was included in the first edition of the EU Technical Guidance Document (TGD) in support of the Commission Directive on the risk assessment for new notified substances and the Commission Regulation on risk assessment for existing substances in 1996 (European Commission, 1996). The TGD was substantially revised and re-published in 2003 (http://ecb.jrc.it/existing-chemicals/). The working group which revised the occupational exposure section of the TGD, and whose members came from both regulators and industry, wanted to produce more realistic and pragmatic guidance on how to carry out a regulatory exposure and risk assessment. There had been comments that assessments of existing substances were not realistic, and this affected the resulting risk management outcomes. Also, much experience had been gained in the intervening years on better ways to carry out these assessments to improve consistency between assessors. One area in particular which needed clarification was how to use the outputs from EASE in the assessments. What exists in the revised version of the TGD is a pragmatic approach to exposure assessment in the context of EU regulation of chemicals on the market.

Where does this leave us in the light of the proposed changes to the European chemical supply legislation through REACH? There is still a need for transparent, consistent, scientifically valid and practically relevant exposure assessments. In the short term (if ever), it is not realistic to expect that occupational exposures to chemicals will be described in all workplaces throughout the EU. The validation studies reported in this issue and earlier have highlighted weaknesses in the current model and make a clear case for the need for improvements. HSE, CEFIC and The American Chemistry Council sponsored a study carried out by the Institute of Occupational Medicine (IOM) to examine the underlying structure and philosophy of the EASE model (version 2), to provide a critical assessment of its utility and performance to date and to make recommendations for the structure of a revised model. The report of this study is available via HSE's website (http://www.hse.gov.uk/research/rrhtm/rr136.htm).

The conclusion of the researchers was that although EASE has many characteristics that they believed to be superior to some of the other models reviewed, there was a need for an alternative, more radical approach. This is described in the paper by Creely *et al*., 2005 (see their figure 2). Essentially it proposes that both a deterministic model (including a Monte Carlo module) and information from an exposure database, with contextual information, be used in a Bayesian process to combine data and model output to produce exposure estimates.

In light of the recommendations in the IOM report, a workshop was organized in Edinburgh in November 2004 to try to reach a consensus among interested parties on the purpose, nature and intended use of a successor to EASE. A group of 21 people (regulators, industry and model developers) met to discuss what tools would be needed to meet the challenges of the proposed EU REACH legislation, both in the short and long term. The workshop participants were of the view that was a need for an advanced exposure assessment tool to assist in regulatory exposure assessment. Ideally, it should provide an integrated assessment of occupational exposure for all routes, but most importantly, at least to start with, for inhalation and dermal exposure. The assessment tool should provide more realistic estimates of exposure than is currently possible, and the assessment would need to be undertaken in such a way as to make the results clearly relevant to all European workers. Also, an assessment tool is needed that can also predict variability, as this would allow for a more scientifically justified risk assessment and it should also encourage the collection of new exposure data in order to help refine the exposure estimates. The Chemical Exposure MAnagement System (CEMAS) database, which is currently under development with the support of CEFIC, may be suitable for containing inhalation and dermal exposure measurements, including all of the related contextual data, and form an integral part of the new tool.

Obviously further development is needed before such an advanced exposure assessment tool can be produced. Preferably, the new exposure assessment tool would be developed by a consortium of groups from across the EU, to enable the resulting tool to be much more representative of current European workplace situations. These needs, and a report of the Edinburgh workshop, will be considered by a meeting of the EU New and Existing Substances Technical Committee, scheduled to be held in early March 2005.

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