

Letters to the Editor

Excluding Exposure Data of Very Poor Quality Is a Core Principle for Regulatory Risk Assessment

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In a recent issue of this journal, Money and Margary (2002) proposed some thoughtful guidelines for exposure assessment in regulatory risk assessment. Their structured approach acknowledges that currently available exposure data are of very variable quality (Northage and Marquart, 2001). We firmly underline their plea for a hierarchy in available exposure information sources, with a higher weight assigned to data with a lower level of uncertainty. The level of confidence an assessor has in the available exposure information should play an important role in the resultant risk assessment process. Moreover, the classification of data into different uncertainty categories should aid the assessor when conflicting exposure results are reported. Hence, a transparent system quantifying heterogeneity in data quality is crucial if one wants to arrive at consistent risk assessments.

The approach of Money and Margary largely coincides with and was to some extent complementary to our decision tree for data quality evaluation published in the same issue (Tielemans *et al.*, 2002). However, we question their statement that all exposure information sources should be considered as being potentially useful in the risk assessment process. On the contrary, it is our opinion that not all exposure information meets even the minimum requirements for incorporation in the exposure assessment process and the exclusion of such data should be the starting point for a transparent and robust exposure assessment. In our paper we defined minimum requirements for four different aspects, i.e. available occupational hygiene information, variability and precision issues, internal validity and external validity. We consider data sources to be unacceptable if very basic requirements are not fulfilled for these aspects. In these cases, the level of uncertainty or bias related to exposure data is in our view difficult to interpret in even a broad sense.

In order to evaluate the quality of data in current European Union risk assessments of existing substances, we conducted a small-scale inventory of exposure data. One exposure assessor of our department evaluated data quality of 40 measurement series selected out of five Risk Assessment Reports (RARs). A second researcher also evaluated 20 of these

sources in order to study agreement between assessors. The data classification was done according to both a strict and a lenient interpretation of our decision tree (Tielemans *et al.*, 2002). The former implies a rigid adherence of the assessor to the rules of the decision tree. Any non-compliance to the decision rules results in exclusion of the data. The latter refers to an approach that leaves more room for subjective assessment tailored to the specific exposure assessment situation. Table 1 describes the results of our inventory. It is a striking finding that 80% of the information sources were excluded when a strict classification was applied. A lenient approach also yielded exclusion of several measurement series (12.5%), although most ratings shifted towards supplementary information (80%). It should be noted that in both approaches only a small percentage of sources resulted in sufficient information. The percentage agreement between both assessors was 85 and 70% for a strict and lenient approach, respectively. This difference is in accordance with expectation, since a less rigorous approach relies to a larger extent on subjective judgement.

The outcome of our analysis clearly illustrates the contrast between a rigorous evaluation that dismisses most data as useless and a lenient approach that allows most data to be incorporated into the risk assessment process. It can be learned from this inventory that a large part of the investigated data is hampered by a poor documentation of occupational hygiene information, low precision or questionable validity. A scientifically rigorous assessment would classify these data as being of very little relevance. We agree with Money and Margary that, as a result of

Table 1. Classification of 40 exposure information sources according to a lenient and strict interpretation of our decision tree

	Strict (%)	Lenient (%)
Sufficient information ^a	5.0	7.5
Supplementary information ^a	15.0	80.0
Unacceptable ^a	80.0	12.5

^aFor a description of terminology, we refer to Tielemans *et al.* (2002).

the paucity of good-quality data, one has to employ a pragmatic or lenient approach in risk assessment. The emphasis should be on including and synthesizing as much as possible of the available exposure information in the assessment process. The decision tree should therefore not be used to dictate rigid rules but may be seen as a reference point, which facilitates a consistent evaluation of the level of uncertainty in existing data.

Yet, a pragmatic interpretation of the decision tree still requires the exclusion of data if minimum requirements are not met. The implication of even this limited survey is that some data are of such poor quality that they should be rejected. Such data sources do not provide information and only add noise to the assessment process or, even worse, may be seriously misleading. The cautious exclusion of such data enhances a consistent interpretation and weighting of the remainder of the exposure information in the assessment process. We therefore consider the exclusion of very poor data to be a core principle

in maintaining the integrity of exposure assessment and by extension risk assessment.

ERIK TIELEMANS, YVETTE CHRISTOPHER,
HANS MARQUART, MONIQUE GROENEWOLD
and JOOP VAN HEMMEN

*Department of Chemical Exposure Assessment, TNO
Chemistry, PO Box 360, 3700 AJ Zeist,
The Netherlands*

REFERENCES

- Money CD, Margary SA. (2002) Improved use of workplace exposure data in the regulatory risk assessment of chemicals within Europe. *Ann Occup Hyg*; 46: 279–85.
Northage C, Marquart H. (2001) Occupational exposure information needs for regulatory risk assessment of existing chemicals. *Appl Occup Environ Hyg*; 16: 315–8.
Tielemans E, Marquart H, de Cock J, Groenewold M, van Hemmen J. (2002) A proposal for evaluation of exposure data. *Ann Occup Hyg*; 46: 287–97.

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Reply

We acknowledge the view expressed in the above letter by Tielemans *et al.* that only data of a reasonable quality ought to be included in exposure assessments in order to improve their overall certainty. But we also consider that all exposure information has a role to play in regulatory exposure assessments, even though the weight that would be assigned to poor-quality data is low. Specifically, low-grade exposure information may not be useful for quantifying estimates of exposure, but can and ought to be utilized to help in their qualitative interpretation. This distinction is important.

The process by which the risks of chemicals are assessed and managed, such as that used for marketed substances in the European Union (European Communities, 1994), is one that extends beyond just the need to develop quantitative estimates of exposures to hazardous chemicals. Consideration must also be given to how these estimates relate to the interpretation of dose–response relationships when predicting risk, and the confidence that might be assigned to such ‘risk estimates’ when seen in the context of practical experience. Whilst low-grade exposure information does not have a substantive role to play in estimating exposure, it does help in the practical interpretation of such estimates. It is perhaps for this reason that the EU process for the risk assessment of chemicals does not automatically discount low-grade

data, but requires that ‘all available exposure-related information on the substance should be used’ (European Commission, 1996). But in recommending this, the EU also recognizes that ‘it is unlikely that...data will be of adequate quality to be used uncritically in exposure assessment’. These elements may, in some part, explain the nature of the findings shown in Table 1 of Tielemans *et al.*’s letter.

C. D. MONEY¹ and S. A. MARGARY²

¹*ExxonMobil Petroleum and Chemical, Hermeslaan
2, B-1831 Machelen, Belgium;* ²*Shell International
Ltd, Shell Centre, London SE1 7NA, UK*

REFERENCES

- European Commission. (1996) Technical guidance document in support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commission Regulation No. 1488/94 on Risk Assessment for Existing Substances. Luxembourg: Office for Official Publications of the European Communities.
European Communities. (1994) Council Regulation 1488/94 laying down the principles for the assessment of risks to man and the environment of existing substances in accordance with Council Regulation (EEC) no. 793/93. *Official Journal*; L161: 29 June.

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