

# **REACH: Implications and Opportunities for the practice and profession of Occupational Hygiene – An International Workshop**

**14-15 December 2005, Brussels**

**Report of workshop sessions and summary of conclusions**

**Christine Northage, HSE  
Jan Urbanus, CONCAWE  
Joop J. van Hemmen, TNO**

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**The views expressed in the presentations are those of the authors only. The summaries from the workshop sessions represent the views of the delegates who attended the workshop and do not necessarily reflect HSE or BOHS policy.**

## **Glossary**

BM	Biological monitoring
CAD	Chemicals Agent Directive
CMR	Carcinogenic, mutagenic, reprotoxicant
COSHH	Control of Substances Hazardous to Health
CSA	Chemical safety assessment
CSR	Chemical safety report
DNEL	Derived No Effect Level
ES	Exposure Scenario
DU	Downstream user
M/I	Manufacturer or importer
RIP	REACH Implementation Project
MSs	Member States
SEG	Stakeholder Expert Group
SMEs	Small and medium sized enterprises
SDS	Safety Data Sheet
RMMs	Risk Management Measures

## EXECUTIVE SUMMARY

A two-day workshop of European occupational hygienists and related experts examined practical aspects of the new EU chemicals legislation REACH with respect to worker health protection. The aims of the workshop were: to identify opportunities to improve occupational hygiene in workplaces across Europe; to prepare the occupational hygiene profession for REACH; to solicit inputs of practising occupational hygienists into the development of technical arrangements under REACH; to facilitate discussions between European national occupational hygiene groups; and to identify education training and competency needs.

The workshop started with a series of presentations to explain the concepts, terminology, development of technical guidance for REACH, as well as presentations on the likely future role of occupational hygienists in a variety of industrial, government and consultancy organisations. A number of potential interaction problems with existing legislation for health at work were highlighted.

The slides from the workshop presentations are available on:  
<http://www.bohs.org/eventDetails.aspx?event=43>

Break-out groups discussed issues around technical resource needs for exposure assessment and control under REACH, and possible competency and training requirements for occupational hygienists.

The workshop concluded that REACH is highly relevant to occupational hygiene in workplaces dealing with dangerous substances and preparations. The development exposure scenarios (ESs), which are required under REACH from manufacturers and importers (M/Is) of dangerous substances and preparations will give a new impetus to help control exposures in the workplace. The information on risk management measures (RMMs) given in ESs are likely to be generic in nature and will not totally replace the risk assessments currently required under health and safety legislation, e.g. the Chemical Agents Directive, as many local factors influence worker exposures in a specific workplace.

Compliance with REACH will require more human exposure information than is currently available. Interactions between M/I/suppliers and downstream users (DUs) will need to be structured in order to produce realistic and representative ESs which are appropriate for the level of risk.

The main technical resource needs appear to lie in the area of sharing exposure data and knowledge on RMMs on an EU level. Creation of exchange platforms would address this, but would need to be preceded by standardisation of terminology and concepts, as well as assurance that contributing individuals possess the required competency and expertise. Exposure data from different countries can be accepted if their validity can be demonstrated and there is suitable contextual information. It was concluded that in those countries where the occupational hygiene profession is formally recognised, the existing skills of practising hygienists would be very useful in assisting in the REACH-related

workplace requirements, although there may be some areas where additional training would be of benefit.

It is important that one or more national occupational hygiene bodies take the initiative to signal to policy-makers that the expertise and skill available among occupational hygienists would greatly benefit successful REACH implementation, particularly in the development of technical guidance for dossier compilation and evaluation.

A series of recommendations were inferred from the workshop proceedings for the British Occupational Hygiene Society (BOHS), and other national occupational hygiene societies, to consider. They should:

1. work together to publicise the work of occupational hygienists so that there is a greater awareness in the Commission (ECB/new Chemicals Agency) and industry, particularly in SMEs, of how their members can help in the implementation of the REACH Regulation.
2. try to influence the guidance being written for REACH by having the Society represented at the Stakeholder Expert Groups for the remaining REACH Implementation Projects.
3. evaluate the training they currently provide, and their competency requirements, to see if they need to be revised to take account of the skills needed for REACH.
4. look into the feasibility of setting up a series of REACH awareness raising events for i) occupational hygienists – to inform them of the opportunities and training/competency needs and ii) industry, particularly SMEs, – to advertise the services that hygienists can provide to help them with their responsibilities.
5. look into the feasibility of standardising training and competencies for occupational hygienists across the EU.

## 1. INTRODUCTION

The European Commission has proposed a new EU Chemicals policy, REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) in document COM(2003) 644 final, Brussels. The proposal is currently going through the EU legislative process with amendments introduced by the European Parliament and the Council of Member States (MSs) governments. Several changes have been made and although we do not yet have the final wording, the main ideas appear well established.

One of the main objectives of the new policy is that dangerous substances (manufactured or imported in quantities above a certain tonnage) will have to be used under demonstrated safe conditions for workers, consumers and the environment. This requires a chemical safety assessment (CSA) by the manufacturer or importer (M/I) for which the exposure scenarios (ESs) and the hazard assessment of the chemical are the essential elements. The term Exposure Scenario is currently defined as “the set of conditions that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment”.

As far as workers are concerned, REACH is a challenging opportunity for occupational (industrial) hygienists. In the REACH Implementation Projects (RIPs), the Commission is currently outlining the general framework of ESs and will provide guidance on the implementation in practice. This requires a complex interaction between M/Is and downstream users (DUs), to understand in full how the substance under consideration is used and what risk management measures (RMMs) are, or should be, in place. This is an essential step to produce effective and transparent ESs and to assist with their successful implementation.

REACH introduces a completely new system of dangerous substance/preparation regulation in the EU which will provide an important opportunity to help improve the health protection of workers, and thereby creating a unique opportunity to enhance the profile and status of the occupational hygiene profession. In particular, the REACH requirement to communicate safe handling recommendations for dangerous substances and preparations between all actors in the supply chain provides a new basis for improvement of occupational hygiene in all sizes of workplaces in the EU.

The professional occupational hygienist is one of the central experts that understand the requirements for ESs, and is therefore an essential asset for the regulatory process, in industry, Competent Authorities and Labour Inspectorates. A 2-day workshop was organised by the British Occupational Hygiene Society, in collaboration with the Belgian Society for Occupational Hygiene, bringing together experts in the field of occupational hygiene and policy makers to discuss opportunities for effective REACH implementation and consequences of the introduction of REACH for occupational hygiene competency. European Occupational Hygiene Associations and Societies provide an excellent channel to reach practicing hygienists and alert them to this development. Their membership comprises people from academia, industry, government and consultancies. They are also well placed to inform policy makers about existing, successful approaches to exposure

control in many EU countries, and as such could play an important role in the development of implementation guidance prior to the formal adoption of the REACH regulation in the EU.

The workshop covered the essential elements: overview of the proposed legislation; implementation guidance under development; how to prepare ESs; the assessment of exposure levels in these scenarios; and the use of exposure control measures to implement safe use. The second focus of the workshop was on the competency needs for the occupational hygiene profession that the introduction of REACH will introduce as REACH will place occupational hygienists in a central position to help with the implementation of the legislation.

## 2. AIMS OF THE WORKSHOP

The aims of the workshop had been formally defined as follows:

- to identify the opportunities for improved occupational hygiene in EU workplaces through REACH
- to prepare the occupational hygiene profession for REACH
- to signal to policy makers that there is a professional group capable of delivering one of the core elements of REACH, i.e. worker protection aspects of the Chemical Safety Assessment and Report, including exposure assessment and estimation, DNELs and development of ESs to define and communicate Risk Reduction Measures
- to facilitate discussion between and engage other European Occupational Hygiene professional groups, and
- to discuss needs for education and training for competency standards across the EU

The format of the workshop consisted of a series of presentations on the first day and parallel break-out discussions sessions on the second day. The detailed programme is shown in **Appendix 1**.

The first block of presentations addressed the legislative proposal, implementation guidance under development and interfaces with existing occupational health and safety legislation. The second block of presentations focussed on the role of the practising hygienist in various types of organisations. A third block looked at available tools to conduct the necessary exposure assessments and selection of RMMs .

Participants then went to parallel discussion sessions to examine a large number of technical discussion points that may impact on the successful implementation of REACH, or may need to be raised in advance, or during the development of the technical guidance. After a plenary feedback session, a second discussion was conducted in break-out groups on the competency requirements for practising occupational hygienists.

The slides from the workshop presentations were made available on:

<http://www.bohs.org/eventDetails.aspx?event=43>

### 3. SUMMARY OF PRESENTATIONS

#### Introductions

Introductions were made by BOHS President Chris Beach and by Workshop Chairman Joop J. van Hemmen.

#### SESSION 1

##### *The REACH Legislation*

Mark Blainey of the European Commission's Directorate-General Environment presented an overview of some of the main features of the new legislation. The legislation was still subject to negotiations between the EU MSs, the European Parliament and the Commission. Changes of detail, with potentially significant practical consequences for those that expected to be working in future with the new scheme, were still under review. The expected date of entry into force is 2007.

There was an underlying need to reform Europe's current chemicals management legislation which was viewed as inefficient. MSs and the Commission have therefore developed a new system which includes:

- Registration of chemical substances on the market and associated requirements for information and communication in the supply chain
- Evaluation of some substances by MSs
- Authorisation for **CH**emicals of high concern, based on health (e.g. carcinogens and mutagens) or environmental hazards (e.g. persistent and bioaccumulative)
- Restrictions on EU-level triggered by other concerns
- A centralised European agency (in Helsinki) to manage the system.

REACH introduces some fundamental changes from the current legislation. There is a new responsibility for manufacturing companies (and those importing into the EU) to demonstrate that the substances they produce can be used safely both on their own premises and by their customers (called 'Downstream Users'), throughout the entire life cycle of the substance. Hazardous properties must be determined, chemical safety assessments conducted, RMMs communicated to customers. All of the information is then documented in a registration dossier that companies must submit to the new Agency.

The principle is 'no data, no market'. The most significant aspects of REACH can be summarised as:

- more information on hazardous properties in particular for the many substances already on the market today which have not been fully tested, and
- more communication between actors in supply chains on safe working practices

##### *REACH and the existing health and safety at work legislation*

Heiner Wahl of the German Federal Ministry of Labour and Social Affairs discussed the future interactions between existing worker protection legislation and REACH. REACH

is not intended to change any of the existing provisions such as the Chemical Agents Directive (CAD) and the Carcinogens Directive (or the COSHH regulations), but there is a need for a number of points to be clarified. Firstly, REACH will be a European Regulation, therefore directly applicable in all EU countries, whereas health and safety legislation, which is based on Directives, require transposition into national law to come into force. As these Directives give a set of minimum requirements, there can be differences between Member States (MSs).

The REACH legislation will require the provision of test data which will help employers carry out the chemical risk assessments required under health and safety legislation as it provides more complete hazard information. The requirement to develop Derived No-Effect Levels (DNELs) for the 10,000 or so substances manufactured in quantities of 10 tons per year or more, will provide another important new tool for workplace risk assessment, in particular for comparison with exposure measurement data. On the other hand, the suggestion that M/Is would be allowed to use the fact that if very low exposures (one suggestion has been below 50 µg/m<sup>3</sup>) could be demonstrated, then certain tests would not be required, independent of the substance identity. This could potentially be in conflict with health and safety legislation.

A further complication was identified in the requirement for DUs to take account of the RMMs recommended by the M/I/supplier, in the ES. This may cause difficulty for the chemical user when conducting workplace risk assessments, because they need to take into account site specific considerations associated with the process or operation when doing their risk assessments. Authorisation of substances with CMR properties was also seen as posing an interaction problem, because of the existing requirements under the carcinogens-at-work directive to avoid or minimise exposures.

#### *Development of technical guidance*

Frans Christensen of the Commission's European Chemicals Bureau (ECB) presented the results from a series of recent projects (REACH Implementation Projects, or RIPs) aimed at developing technical guidance for the various actors (industries and authorities) in REACH. The guidance should be ready when REACH enters into force, which is expected in 2007. The guidance on the new concepts of DNELs and ESs was then discussed in more detail. DNELs are derived from toxicological no-effect levels, divided by assessment factors to account for uncertainties, e.g. inter-species extrapolation. They represent a safe working level and can be used to check if exposure is adequately controlled.

Exposure scenarios are defined as “an ES sets out how the substance can be used in a way that risks are adequately controlled by describing conditions for use including; process descriptions (incl. quantity used), operational conditions (incl. frequency and duration of specified operations), and RMMs (process and emission controls, PPE, good hygiene, etc)” . ESs will be developed on the basis of the exposure assessment, but explicitly incorporating a description of what constitutes adequate control. They must cover the manufacture and all identified uses, including all life cycle stages of the substance. The

ES will be communicated to downstream users in the form of an annex to the safety data sheet (SDS).

The ES should contain enough information on exposure determinants to allow the quantitative estimation of exposure (i.e. through modelling or analogies). ESs should at the same time show how to protect human health and the environment, therefore integrating controls on human exposure and on emissions to air and water. This will require new thinking outside traditional professional boundaries in the fields of environment, and health and safety.

Substance-specific DNELs and ESs will be the responsibility of manufacturing or importing companies, and as such represent key novelties introduced by REACH.

## **SESSION 2 - Implications of REACH for occupational hygiene practice**

### *1: Chemical Manufacturers and Importers*

Chris Money of ExxonMobil presented an overview of the potentially substantial contribution the occupational hygiene function could make to help a large international chemical manufacturer meet its REACH requirements. Delivering this contribution will require some changes to the way in which hygienists operate today, such as becoming involved in the development of ESs for customers. This may include retrieval and interpretation of exposure data held by customers and suppliers. The contribution will also include applications for authorisation or responding to restriction proposals by MSs. He recommended that in order to achieve efficiencies in that area, hygienists should aim to develop broad ESs and try to maximise initiatives on industry sector level or trade associations.

### *2: Downstream Chemical Formulators*

Hilde Willems of Dupont described the perspective from a large chemical company in the middle of the supply chain. In preparation for REACH, many companies have already made inventories of all the substances they purchase and have started contacting their suppliers to verify they have the intent to register the substances. This initiative up the supply chain will also serve to communicate existing RMMs so that these can be incorporated in ESs annexed to supplier's SDSs. She suggested that the relationship between existing Occupational Exposure Limits (OELs) and DNELs under the new legislation needs to be clarified.

### *3: Regulatory Bodies*

Robert Turner of the UK HSE reviewed the responsibility changes which will be brought about by REACH for hygienists in regulatory bodies. Whereas today in European substance risk assessment, the regulatory bodies conduct very comprehensive exposure assessments for a limited number of substances, in future under REACH the role will change to that of a reviewer of a much larger number of industry-authored risk

assessments. This is likely to require a more in-depth knowledge of RMMs, particularly for authorisation.

There will be important quality considerations when reviewing the dossiers, such as:

- are ESs realistic and representative?
- are exposure measurements relevant, of appropriate quality, sufficient in number and do they cover all intended substance uses?
- have appropriate models been used and in the correct way?
- are controls reasonable, 'good practice' and likely to provide the necessary degree of control?
- has impact of any variations across the EU been taken into account?

#### *4: SMEs using chemicals*

Paul Verspoor from Sitmae in the Netherlands talked about the issues in the flexible packaging sector where the main exposure is to solvents. This is a typical, complicated, sector with hundreds of suppliers and users. He highlighted a potential problem: what happens if two suppliers of a solvent provided different ESs annexed to their SDSs, which recommended different RMMs. Industrial and Trade associations should be encouraged to play role in the coordination of this and other similar issues. He stressed the importance of the workability of recommended measures. Where possible, existing RMMs should be retained if proven safe. Overly conservative advice, driven by liability concerns, would not be helpful, and suppliers should aim to 'get it right'.

#### *5: Independent Consultancy and Research*

Graeme Hughson of the Institute of Occupational Medicine (IOM) described the view from the perspective of an independent consultancy and research organisation. Whereas research activity tends to result in publicly available reports, consultancy work is usually confidential to clients. However this distinction is unlikely to matter in the context of developing CSAs. In contributing to a number of regulatory substance risk assessments under the current legislation, he had encountered several problems i.e. no exposure data at all, or where they did exist, contextual information was usually poor. In his view, REACH will provide an opportunity to continue developing occupational hygiene skills, such as monitoring and analysis of low-level air contaminants, dermal exposure assessment, predictive modelling and contributions to exposure databases.

### **SESSION 3 - Developments related to the implementation of REACH in the workplace**

#### *Examples of ESs including RMMs*

Hans Marquart of TNO presented some examples of ESs as developed in the European Commission's REACH Implementation Project 3.2, guidance for industry on how to carry out a CSA. For this he built on experience gained in the Dutch VASt project (Improved Hazardous Substance Management in the Workplace). He stressed the need for dialogue between suppliers and users of substances and for a combination of a top-

down approach (initiated by the M/I/supplier) and a bottom-up approach (initiated by the DU) for the effective development of ESs. An important disadvantage of the top-down approach is that the ES may not be presented in terms that are easily understood by the DU and this could lead to inadequate implementation by chemical users. On the other hand, bottom-up approaches are usually hampered by insufficient or absent exposure data.

#### *Improvements in exposure assessment tools for REACH*

John Cherrie of the IOM in the UK reviewed currently available approaches and future needs for estimation of exposures via inhalation, skin contact and ingestion. He highlighted the almost complete lack of consumer exposure data in comparison with the number of data on workers. The simple models currently in use, such as EASE, tend to introduce bias into the exposure estimation. However, measurement data may be equally misleading. He argued that the current practice of using measured data and modelled data as alternatives side by side should be abandoned and instead knowledge from both approaches should be integrated (for example, using Bayesian models). The tools for this type of approach have however not yet been developed, although there is a research initiative in this direction that will take advantage of a new database of chemical exposure measurements (CEMAS).

#### **4. TECHNICAL RESOURCE NEEDS FOR EXPOSURE ASSESSMENT AND CONTROL UNDER REACH: Breakout group discussions**

For this session there were four separate groups discussing a range of issues, some similar, some different. Each group had been provided with a set of statements to discuss and decide whether or not they agreed with them (Appendix 2). They also had a series of questions to try to answer. They were also asked to try and draw conclusions as to what technical resources may be needed for the future.

At the end of the session the Rapporteurs for each group gave a short (10 minute) presentation of their group's discussion. Chairs and Rapporteurs were asked to produce a written report of their groups' discussion after the Workshop so that this could be written for publication by BOHS and to provide feedback to the BOHS Annual Conference in April 2006.

The reports for each group are provided in Appendix 3. The Workshop Conclusions and Recommendations sections include the conclusions from each group.

#### **5. COMPETENCY AND TRAINING NEEDS: Breakout group discussions**

For this session there were four separate groups discussing the same issues. Each group had a series of questions to discuss and try to answer (see below). Conclusions were reported back in the plenary meeting.

Chairs and Rapporteurs were asked to produce a written report of their groups' discussion afterwards for the workshop report and as a basis for feedback at the BOHS Annual Conference in April 2006. Session reports are provided in Appendix 4.

## Questions

- Can we identify specific competencies that are likely to be required?
- Are they likely to be existing, modified or new competencies?
- How do these requirements fit in with the content of existing training / education programmes?
- What training/education programmes currently exist in the EU?
- Is there likely to be a need for specialist training? If so in what specific areas?
- What actions are going to be required to ensure that existing professional training / education programmes can meet the needs identified?

## 6. WORKSHOP CONCLUSIONS

The introduction of the REACH Regulation is seen to be highly relevant to the protection of workers who are exposed to dangerous substances and preparations in the EU. The aspects of REACH most likely to have a positive impact on worker health and safety can be summarised as:

- The provision of more information on the hazardous properties of the many substances already on the market today which have not been fully tested, and
- better communication between all the actors in supply chains on good control practice.

REACH is likely to benefit worker health protection through better informed risk assessments. However there are still many institutional hurdles to be overcome before effective implementation of the legislation can happen. Workshop participants were told of several interaction problems with existing health and safety legislation that need to be resolved. There is information on exposure levels and RMMs that can be used for the Technical Guidance on CSAs which will be required under REACH, but this information is currently not organised for this purpose.

The lively discussions of the workshop confirmed that occupational hygienists are well placed to play a key role in REACH implementation. Whether they work for a manufacturer, downstream user, government, or as consultants, all are likely to have some part to play and will have to adapt to the new requirements. They have technical expertise in, and access to, the information on exposure data and RMMs necessary for the development and implementation of the worker health protection part of ESs. Their professional organisations and learned societies bring together people working in government, industry, academia and consultancies, and can initiate programmes to help overcome some of the institutional hurdles.

A new type of communication needs to be created between the supplier and the user of dangerous substances or preparations, in which the supplier needs to know how the customer intends to use the substance and how the risks to health and the environment are controlled. Occupational Hygiene Societies can play a role in creating platforms for data standardisation and exchange.

A number of observations were made during the discussions on technical aspects of REACH:

- ESs under REACH are not a straightforward substitute for site specific risk assessment and management as required under health and safety at work legislation. They are at best generic guidance on safe use of substances. It is not expected that a limited number of RMMs with default values for effectiveness could provide sufficient specific information for users to know in detail how to control site specific exposures. The user will still have the responsibility to ensure safe use at the workplace.
- For occupational hygienists to develop ESs they need input from the M/I/supplier on hazard and risk characterisation, as well as exposure. From the DUs the need input on intended uses and their controls. These inputs need to be integrated properly in order to come to conclusions on suitable and workable RMMs. Implementation of RMMs will depend on site specific conditions.
- There is some scope for standardising efficiency levels of RMMs but this is complicated by the need to take into account other issues, such as worker behaviour. Ideally this should not lead to overly conservative default values, as this will result in over-specification of required RMMs.
- There is no reason why control banding should be restricted to “low hazard substances”. Properly described control bands can be used as a form of ES.
- There are clear differences between substance related risk assessments for REACH and occupational health and safety legislation workplace risk assessments.
  - Substance related risk assessments are more likely to use defaults and generic scenarios, which can often produce conservative estimates; e.g. the reasonable worst case approach. It is therefore important to develop ways of examining the representativity of the data.
  - ESs based on substance related risk assessments should not replace workplace risk assessments, as there are many site specific determinants and sources of variation that need to be taken into account. Effective risk management needs this site specific information. The ES is therefore only a starting point. However, it may well constitute a good step forward to encourage companies, particularly SMEs, to implement adequate controls.
- Systems of generic assessments, control banding and clustering of situations can be used for building ESs. Their applicability depends on several factors, including the hazard of the substance, and the variability and complexity of the use. Input from the DU and good collaboration between all the actors in the supply chain are essential to achieve workable ESs. Information can come from a variety of sources, including industry groups and Occupational Hygiene Societies.

- It would benefit REACH implementation if the dossier had to comply with certain technical standards, for example, RMMs have to adhere to the principles of good control practice.
- There is also a need for the people who compile dossiers to be competent in the technical specialisms that are needed. For example, qualified occupational hygienists are able to decide on appropriate RMMs for ESs but they are not usually competent to carry out a hazard assessment. It should be made clear what different technical specialists are needed to compile a dossier and what competency level they need to achieve to carry out that role.
- There is a clear need for sharing of exposure data and information on RMMs across Europe. This will require data standardisation initiatives and creation of RMM libraries. Terminology also needs to be standardised. Some form of recognition of the education, training and professional development of the people involved in creating the libraries will be required. Databases will need to have an owner, to ensure that they are maintained.
- In order to make the data sharing process work, it is important to ensure that there is 360 degree communication. The proposed way of encouraging this is to rely on Trade Associations and national authorities to make the benefits (and/or disadvantages) of this data sharing clear. Both time and energy need to be devoted to this, as it is a dynamic process that needs to be encouraged.
- In the environmental sector there appears to be a high level of activity on exposure measurements/monitoring. In the workplace there appears to be significantly less monitoring carried out. One of the suggestions put forward was that for authorisation under REACH, the quality and quantity of both environmental and occupational monitoring should be specified.
- REACH is likely to increase the focus on dermal exposure, but in current occupational practice there is a lack of systematic and quantified dermal exposure assessment. Extensive reliance on modelling will not solve this issue. However, it is hoped that the increased focus will also lead to improved occupational hygiene measures for skin protection.
- The ability to reliably develop assigned protection factors for gloves and coveralls is highly questionable, although such predictions are possible for respiratory protection.
- The introduction of DNELs is likely to result in a marginal increase in the amount of exposure monitoring. Without an explicit legal requirement to monitor exposure then it is unlikely that M/Is or DUs will be sufficiently stimulated to introduce new monitoring programmes. This is particularly relevant for companies who at present are adequately controlling the exposure to chemicals. In such situations carrying out of additional monitoring will not be perceived as bringing additional benefits.
- The REACH proposals do not currently require the sharing of exposure information. This was seen as being short-sighted as it was thought that there should be more detail on exposure assessment, including sharing of exposure information, in the text of the REACH Regulation. Since the Council have indicated that the CSA&R requirements should be reviewed within the next year

(i.e. before REACH comes into force) then this opportunity should be used to introduce more detailed requirements on exposure information within REACH.

In the discussions on competency and training needs, the following issues were highlighted:

- Skills in communication, business, occupational hygiene fieldwork and knowledge of best practices in engineering controls are required. Occupational hygienists, either alone or through team work can provide these. The work on implementation of CAD has provided highly valuable and relevant experience.
- The OH profession needs to 'market' their skills, to create awareness of the usefulness of the profession in implementing REACH. A comparison was made with the safety professional who excel in this area.
- In countries where the profession of occupational hygiene is formally recognised, the necessary competencies may already be available. However, there are many EU countries without a formal scheme.
- Additional training may be required in areas like toxicology and exposure modelling, as well as in the legal aspects of REACH, but it is not anticipated that current practising hygienists would need major additional training.
- Additional training on environmental aspects, as well as on techniques for consumer and general public exposure estimation would put hygienists in a good position with regard to REACH, but these areas may require more extensive efforts.
- Learning on the job will also be important. Company internships schemes are common in the USA, but less so in the UK. Can REACH offer wider opportunities to take this idea forward, for example could bigger organisations sponsor interns into their customers? Customers would have to be engaged to persuade them to recognise the value to them in such a scheme.
- It was suggested that the full range of occupational hygiene competencies was not required for all roles. The levels of skill and complexity for each role should be defined. This could be linked more explicitly with the levels of professional competence of occupational hygienists.
- The advent of REACH appears to be the time to start a discussion on Europe-wide certification/qualification. Currently there are situations where unqualified people are taking active occupational hygiene roles. This could be a Catch 22 situation as this further accreditation could make hygienists more expensive.

## **7. RECOMMENDATIONS**

1. BOHS, and other national occupational hygiene societies, work together to publicise the work of occupational hygienists so that there is a greater awareness in the Commission (ECB/new Chemicals Agency) and industry, particularly in SMEs, of how their members can help in the implementation of the REACH Regulation.

2. BOHS, and other national occupational hygiene societies, try to influence the guidance being written for REACH by having the Society represented at the SEGs for the remaining RIPs.
3. BOHS, and other national occupational hygiene societies, need to evaluate the training they currently provide, and their competency requirements, to see if they need to be revised to take account of the skills needed for REACH.
4. BOHS, and other national occupational hygiene societies, should look into the feasibility of setting up a series of REACH awareness raising events for i) occupational hygienists – to inform them of the opportunities and training/competency needs and ii) industry, particularly SMEs, – to advertise the services that hygienists can provide to help them with their responsibilities.
5. BOHS, and other national occupational hygiene societies, should look into the feasibility of standardising training and competencies for occupational hygienists across the EU.

## APPENDICES

### APPENDIX 1      WORKSHOP PROGRAMME

#### **14 December - Scene setting (14.00 – 19.00)**

- 14.00 Opening and Welcome                      Chris Beach, President BOHS
- Introduction to the workshop                      Joop J. van Hemmen, TNO, the Netherlands  
Chairperson of the Workshop

#### **Session 1 14.15-15.45 – Overview of REACH (focus on occupational hygiene aspects)**

- 14.15 REACH overview  
Mark Blainey, European Commission, Directorate-General Environment
- 14.45 REACH and occupational health legislation  
Heiner Wahl, German Federal Ministry for Economic Affairs and Labour
- 15.15 Technical Guidance in development  
Frans Christensen, European Commission, European Chemicals Bureau
- 15.45 – 16.15 Coffee

#### **Session 2 16.15 – 17.45 – Implications of REACH for occupational hygienists**

- 16.15 In manufacturing and importing companies  
Chris Money, ExxonMobil, Belgium
- 16.30 In downstream user industries - 1  
Hilde Willems, Dupont, Belgium
- 16.45 In national regulatory bodies  
Robert Turner, HSE, United Kingdom
- 17.00 In downstream users industries - 2  
Paul Verspoor, Sitmae, the Netherlands
- 17.15 In independent consultancy and research  
Graeme Hughson, IOM, United Kingdom
- 17.30 Questions
- 17.45 – 18.00 Short break

**Session 3 18.00 – 19.00 – Developments related to the implementation of REACH in the workplace**

Examples of ESs including RMMs  
Hans Marquart, TNO, the Netherlands

Improvements to exposure assessment tools necessary for REACH  
John Cherrie, IOM, United Kingdom

**December 15 - Technical Resource Needs, Competency Requirements and Training Needs (09.00 - 15.30)**

Session 4 09.00 – 12.00 Technical resource needs - exposure assessment and control under REACH

09.00 – 09.15 Introduction Christine Northage

09.15 – 10.45 Workshop breakout groups on:

- Group 1 ESs
- Group 2 RMMs communication
- Group 3 Exposure estimation and quantification
- Group 4 Exposure assessment tools and knowledge

10.45 – 11.00 Coffee

11.00 – 12.00 Feedback session (plenary) Joop J. van Hemmen

12.00 – 13.00 Lunch

**Session 5 13.00 – 15.15 Competency and training needs**

13.00 – 13.15 Introduction Terry McDonald,  
University of Greenwich and BOHS  
Faculty of Occupational Hygiene

13.15 – 14.30 Breakout groups

14.15 – 15.15 Feedback session (plenary) Terry McDonald

**15.15 – 15.30 Summary, Conclusions and Closure of the Workshop**  
Joop J. van Hemmen

## **APPENDIX 2 STATEMENTS AND QUESTIONS DISCUSSED IN BREAK-OUT GROUPS ON TECHNICAL RESOURCE NEEDS FOR EXPOSURE ASSESSMENT AND CONTROL UNDER REACH**

### **Group 1 Exposure Scenarios (ESs)**

#### **Statements for discussion**

1. ESs, by definition, (including RMMs) describe the safe use of a chemical.
2. The more hazardous the substance, the more specific the ES produced by the M/I should be.
3. Downstream users (sector-wise) need to develop fit-for-purpose ESs.
4. A specific ES can only reliably be developed (e.g. by producers) for the next stage in the supply chain.
5. Control banding is only acceptable for low-hazard substances and preparations.
6. ESs can only be developed with a set of default values for specific RMMs.
7. Typical and worst case efficiencies can be defined for RMMs. (Note the control hierarchy with respect to RMMs needs to be taken into account)
8. The required RMMs for a preparation are the sum of the RMMs for the individual ingredients in the mixture.
9. Typical exposure levels can be established across industries for some common operations (e.g. road tanker loading, drum filling).

#### **Questions for discussion**

10. Are there differences between DNELs and OELs? If there are differences, are DNELs a helpful concept for workplace risk assessment and risk management, or vice versa under the Chemical Agents Directive and/or the Carcinogens Directive?
11. Is the adoption of an ES communicated via a SDS a suitable substitute for a CAD RA?
12. Can workplace risk assessment be *reliably* undertaken by comparing estimated exposure with DNELs?
13. Should generic RMMs be used for authorisable substances?
14. RMMs have been developed in some countries based on extensive exposure monitoring in some sectors (e.g. the BIA folder in Germany). Are country specific RMMs capable of extension beyond national boundaries?
15. How would differences in the definition of reasonable practicability, depending on the scale and size of the company, be accommodated?
16. How should the protection offered by PPE be quantified? Can assigned protection factors be reliably developed for gloves and coveralls?
17. Is there a role for occupational hygiene societies in harmonisation of RMM in Europe? If yes, what could it be
18. Could the Bilbao Agency fulfil a useful role in this?
19. Sharing good/best practice via RMM libraries:
  - what exists already?
  - how to create the libraries?
  - how to make them accessible?
  - are there likely to be any language issues?

## **Group 2 Risk Management Measures (RMMs) communication**

### **Statements for discussion**

1. ESs, by definition, under REACH (including RMMs) describe safe use of a chemical.
2. The more hazardous the substance, the more specific the ES produced by the M/I should be.
3. Specific ES can only reliably be provided for the next stage in the supply chain.
4. Workplace risk assessments based on Chemical Agents (and/or Carcinogens) Directive should incorporate recommendations in ESs by M/I

### **Questions for discussion**

5. If it is beneficial for certain (e.g. high volume, commodity) chemicals to organise and harmonise RMMs through sector initiatives. How could this be achieved?
6. What are the features of operations where individual work practices are likely to be important drivers of exposure levels?
7. What are appropriate communication practices?
  - between companies;
  - between sectors.
8. Is there a role for occupational hygiene societies in harmonisation of RMM in Europe? If yes, what could it be?
9. SDSs are the proposed communication channel of information in REACH. Is this an efficient and effective way to get information along the supply chain?
10. Is this expectation naïve, e.g. for imported articles and preparations?
11. Is the adoption of an ES communicated via a SDS a suitable substitute for a CAD risk assessment?
12. Could/should generic RMMs be used for authorisable substances?
13. Sharing good/best practice via RMM libraries:
  - what exists already?
  - how to create the libraries?
  - how to make them accessible?
  - are there likely to be any language issues?
14. Could the Bilbao Agency fulfil a useful role in this?

## **Group 3 Exposure estimation and quantification**

### **Statements for discussion**

1. ESs (including RMMs), by definition, describe safe use of a chemical.
2. The more hazardous the substance, the more specific the ES produced by the M/I should be.
3. Typical exposure levels can be established across industries for some common operations (e.g. road tanker loading, drum filling).

4. Exposure models should only be applied when the user understands the model structure and defaults.
5. There is a lack of systematic and quantified assessment of (dermal) exposure in current occupational hygiene practice;
6. Current risk assessment methodologies tend to overestimate exposure
7. The role of BM in developing ‘adequate control’ should be (more precisely) defined.

### **Questions for discussion**

8. REACH does not require the sharing of exposure information. Is this short-sighted or a profound insight into the complexities of exposure assessment and risk assessment?
9. What is the basis for recognising validity of data from other countries?
10. Exposure database/s:
  - what will be needed?
  - which databases already exist that could be utilised?
  - what are minimum quality requirements?;
  - who does it/them need to be accessible to?
  - how would new ones be created?
  - what issues would there be relating to transferability of data between countries?
11. Will DNELs for chemicals without an OEL provide a stimulus for exposure monitoring in the workplace of the manufacturer?
12. What are the features of operations where individual work practices are likely to be important drivers of exposure levels?
13. What needs to be included in a suitable exposure monitoring strategies for REACH?

## **Group 4      Exposure assessment tools and knowledge**

### **Statements for discussion**

1. ESs (including RMMs), by definition, describe safe use of a chemical.
2. The more hazardous the substance, the more specific the ES produced by the M/I should be.
3. Typical exposure levels can be established across industries for some common operations (e.g. road tanker loading, drum filling)
4. There is a lack of systematic and quantified assessment of (dermal) exposure in current occupational hygiene practice;
5. Current risk assessment methodologies tend to overestimate exposure.
6. Exposure models should only be applied when the user understands the model structure and defaults.
7. There is a lack of appropriate exposure databases for the execution of REACH, which would help in the development of ESs (i.e. show proven safe use).
8. The ECETOC TRA tool provides a useful concept for first tier exposure and risk assessments.
9. For second tier exposure assessments, the development of an advanced tool using databases and theoretical mechanistic approaches with modern statistical techniques is essential.

10. The role of BM in developing ‘adequate control’ should be more precisely defined.

### **Questions for discussion**

11. RMMs have been developed in some countries based on extensive exposure monitoring in some sectors (e.g. the BIA folder in Germany). Are country specific RMMs capable of extension beyond national boundaries?

12. REACH does not require the sharing of exposure information. Is this short-sighted or a profound insight into the complexities of EA and RA?

13. Exposure database/s:

- what will be needed?
- what databases already exist that could be utilised?
- what are minimum quality requirements?;
- who does it/them need to be accessible to?
- how would new ones be created?
- what issues would there be relating to transferability of data between countries?

## APPENDIX 3 BREAK-OUT SESSION REPORTS: TECHNICAL RESOURCE NEEDS FOR EXPOSURE ASSESSMENT AND CONTROL UNDER REACH

### Group 1

**Chair: Chris Money**

**Rapporteur: Hans Marquart**

1. ESs, by definition, (including RMMs (RMMs)) describe the safe use of a chemical.
  - Preparations are mixtures and workplaces use several products with same substance; how to add-up?
  - ESs in REACH are substance based, not workplace based
  - Industrial processes and intermediates are not covered
  - Sometimes protection is to another substance and not to the (less hazardous) substance assessed; how to get this into the scenario?
  - How to describe a wide enough, but strict enough scenario; should you not start at user site for understanding use?
  - Different scenarios within a product; how to differentiate? how do things well?
  - ES describe "safe use" (but how); other people may use substance in a wrong way so ES should not necessarily describe every use;
  - "Safe" does not need to follow from ES; hazard should be included; ES only describes scenario?
  - At beginning standard RMM then compare with hazard level and iterate until safe
  - ES is only a "concept" Producers have to deliver concept of "best practices" as a start for Downstream users to find correct way to use substance; much additional information and training, e.g. on how to use LEV etc. is needed.

*Summary: ESs under REACH are not an straightforward substitute for proper risk assessment and management at the workplace. They at best describe general indications of safe use of substances.*

2. The more hazardous the substance, the more specific the ES produced by the M/I should be.
  - Is there a "rating" for more hazardous? No formal system.
  - We need risk driven process; whether a scenario needs to be more specific depends on the use and scenario. A simple scenario may be possible for hazardous substances, depending on application.
  - Recently proliferation of hazard groupings. Can we bring them together with GHS into single EU system? Needs will-power with stakeholders.
  - Certain things cannot be linked to hazard. Also combination of hazards to be taken into account, e.g. corrosive and explosive
  - Some hazards (e.g. corrosivity) may be seen as safety instead of health hazard. Compartmentalising risk evaluations?
  - General: greater hazard will lead to more specific ES, e.g. for authorized substances.

- But take into account "intrinsic" safe use

*Summary: Specificity and complexity of the ES will depend on both the hazard and the process involved. It is expected that more hazardous substances will often need more specific ES, but this is certainly not always necessary.*

3. Downstream users (sector-wise) need to develop fit-for-purpose ESs.

- For really appropriate ES DUs need to be involved
- Will still be very useful to have workplace assessments (CAD) although ES from REACH can be useful as well
- Will intermediates be in REACH and will their exposure be covered? So there will be need for workplace risk assessments, also for e.g. process fumes
- Should get a good combination of bottom-up and top-down approaches together. Within chemical industry generic scenarios are often OK. E.g. hazard driven and generic limit values. Users outside chemical industry need to develop their needs.
- Linkage will be at stage of the formulators, because they know the full set of chemicals as well as the applications.
- In The Netherlands there is a tool (Stoffenmanager) that can be expanded to build ES. The generic language used in tool such as this is not suitable for DUs. Now more sector specific tools are used together with DUs; that can also be useful for REACH. Generic tools too difficult for SMEs.
- Is there enough time, impetus and energy to develop such tools within the timetable presented by REACH?

*Summary: Involvement of downstream user (sectors) is expected to lead to more appropriate ES for downstream use. Both knowledge of the chemicals and of the use is necessary. Still, an ES made by downstream users will not replace a workplace risk assessment.*

4. A specific ES can only reliably be developed (e.g. by producers) for the next stage in the supply chain.

- In report RIP 3.2 what they call "generic" is actually specific and applicable in more than one place
- If users only rely on ES you will not provide safe workplace. Only user themselves can really determine how safe use can be reached, because they know the situation.
- It is very difficult to make ES and risk assessment in supply chain, because no-one has all information. Specifically contacts towards the next level is difficult.

*Summary: A really good ES needs sufficient information on the situation. This information is generally only available to the user.*

5. Control banding is only acceptable for low-hazard substances and preparations.

- What is a low hazard material? Are there good criteria for that?
- Could there be control banding in different sectors?
- You need validated control bands, but can be used in low and high hazard
- Much better than what is often used today
- If application is not complex, you can use control banding for high hazard materials as well

- If you do correct control banding it can be used for very hazardous substances
- Banding guides to necessary measures
- Control banding = (form of) ESs
- Control banding not only dependent on toxicity, but also on phys-chem and use (e.g. dispersive, fume production)

*Summary: There is no reason why control banding should be restricted to “low hazard substances”. Properly described control bands can be used as a form of ES.*

## 6. ESs can only be developed with a set of default values for specific RMMs.

(also answers question 7)

- i.e. there is an assumed effectiveness for specific RMMs
- The effectiveness may vary by orders of magnitude depending on circumstances, detail of implementation, maintenance, training of workers
- Go for default (i.e. RMM does not work (very well)) or assume certain level of protection
- Split up in two: the further down supply chain you can only assume levels of protection. At front end (production) only people knowledgeable in the job can find specific details of control. But further downstream more standardised protection values can be used.
- This approach is used for e.g. plant protection legislation, but that is a model approach
- You can look at robustness and adapt risk matrix for more or less secure controls (e.g. closed system is quite secure, while PPE is not)
- The more manual intervention, the less certain you are of RMM effectiveness
- Depends on how specific RMM (description) is. But if you use very specific RMM descriptions you will need very many ES!
- For confidence: you need detail, but can only be derived at individual workplace
- Important that there is knowledge at DUs. Info can never be sufficiently detailed and ensure proper implementation unless good expertise at user available.
- For DU it doesn't matter how to reach safe levels; they use whatever they like
- Major suppliers may overcompensate uncertainty by rather strict controls prescribed.
- For PPE the type of material should also be specified. Not done now in Risk Assessments.
- Problem with very strict PPE (suppliers protecting their interest - liability): may be not useable for DUs
- On other hand just saying: "rubber gloves" is also not very helpful'
- RMM in ES should be considered as "recommended" and DU should choose and implement controls of his choice. But then DU should document effectiveness of his choice.
- To protect liability of supplier you would want to send in a OH to check on how things are implemented

*Summary: It is not expected that a limited number of RMMs with default values for effectiveness could provide sufficient specific information for users to know in detail*

*how to control exposures. The user will still have the responsibility to ensure safe use at the workplace.*

7. Typical and worst case efficiencies can be defined for RMMs. [Note the control hierarchy with respect to RMMs needs to be taken into account)

- See statement 6

8. The required RMMs for a preparation are the sum of the RMMs for the individual ingredients in the mixture.

- Simple answer = "no"
- Also depends on other products used, etc.

9. Typical exposure levels can be established across industries for some common operations (e.g. road tanker loading, drum filling).

- No
- Yes
- Can be done on worst-case, but not on real case
- Can e.g. isocyanate producers characterise typical free isocyanate levels in car body painting?
- Partly possible (top-down)
- But bottom-up it is reasonably possible within one sector or industry
- But some unit operations across industries should also be possible
- Variation can be reduced by fencing in into certain boundaries
- Across industries there may be too many variables, e.g. all kinds of tanker loading equipment and careful vs non-careful workers. Still you need rather wide bands for estimated exposure.
- Would this lead to useful ES is still questionable
- There may be differences between MS in Europe
- Exposure is not just RMM in place, but also conditions and how things are done. Often within one industry (specifically chemical) there are commonalities of how things are done.
- Is also possible for DU sectors. You may get into very detailed workplace type RAs
- Also depends on what risk is. Some cases generic very low and very high situations can be found
- Proven technology sharing might be very useful (across industries)
- If you have sufficient users doing the same thing it is possible to build specific scenarios for "hot spots". But if everybody does things differently, it is more difficult.

*Summary: There are certainly some possibilities to reduce the level of variation in exposure by clustering similar situations. There will still be (substantial) residual variation within clustered situations and an optimum between level of variation and number and specificity of ESs needs to be found.*

Q. Will authorities divert attention from workplace protection towards supplier ES?

- We still need enforcement at companies and cannot do without workplace regulation.
- You need tailored advice to control risks
- It is not that DUs do not want to protect their workers. Is money the problem or other reasons?
- You can always decide not to supply to a bad customer

*Summary: Achieving proper workplace protection needs efforts of both suppliers, users and authorities.*

## Questions

10. Are there differences between DNELs and OELs? If there are differences, are DNELs a helpful concept for workplace risk assessment and risk management, or vice versa under the Chemical Agents Directive and/or the Carcinogens Directive?

- There are differences, because DNELs are an output of hazard characterisation, while OELs are a "RMMs" with an expert committee who decides good values.
- DNELs will not be screened by experts.
- In many countries technical and economic feasibility is also taken into account in setting OELs.
- DNEL is based on NOAEL of greatest concern, not necessarily chosen with sufficient expertise
- A decision on the DNEL needs to be made with sufficient expert judgement for it to be useful as an OEL.
- Merit of DNEL is that there will be one for all those chemicals that do not have OELs yet. DNELs should not replace existing 'good' OELs.
- DNEL might be preliminary OEL. If that leads to unreasonable situation a societal or company OEL should be made
- Will DNEL be better than generic hazard bands? Does it not follow from the same information
- NOAELs are rather different from hazard bands based on classification
- Reality: extreme lack of data on many substances so people try to set limits with very limited and conflicting data
- You need to look at all the data and all the models with expertise
- OEL is already too difficult for SME companies, DNELs are even more difficult.
- How to derive a DNEL for a preparation?? Nobody knows how to do this. But you also do not make OELs for products now
- But you measure substances and not preparations?
- Probably the assessments will all be highly conservative. Many conservative numbers add-up to a very conservative result
- If a DNEL is too low it cannot be implemented in real life at all.
- Giving best practice control advice is more helpful

*Summary: DNELs could be a basis for OELs for substances that do not currently have an OEL. They are not a replacement for OELs and/or other methods to assess or manage risks. Derivation of DNELs and OELs should be done with similar expertise. Both OELs and DNELs are not straightforward tools to use.*

11. Is the adoption of an ES communicated via a SDS a suitable substitute for a CAD RA?

- No
- May improve relevant information flow to make CAD RAs.

12. Can workplace risk assessment be *reliably* undertaken by comparing estimated exposure with DNELs?

- There is some possibility. But if people don't understand orders of magnitudes of differences e.g. between saturated concentrations, explosion limits and OELs it will be very difficult.
- If DNELs are too conservative it won't work.
- There are default margins of safety and if you compare them with the AFs and calculate "DNELs" are they then very conservative?
- In The Netherlands updating administrative OELs with DNEL procedure leads to lower values, but differences were not very large and largely because of OELs were based on old data
- Change "reliably" into "conservatively"

*Summary: It is highly questionable whether comparing estimated exposure with DNEL will lead to reliable and relevant workplace risk assessment. Conservative risk assessments appear to be possible.*

13. Should generic RMMs be used for authorisable substances?

- Depends on what the generic RMMs are.
- Yes: if applications are simple
- Why not?
- Could be e.g. "use a respirator"?
- In some cases we do have to target specific exposure situations, e.g. blood lead levels cannot be controlled by only RPE, so specific controls are needed.

*Summary: It depends on the situation whether generic RMMs can be used for authorisable substances.*

14. RMMs have been developed in some countries based on extensive exposure monitoring in some sectors (e.g. the BIA folder in Germany). Are country specific RMMs capable of extension beyond national boundaries?

- Yes, when things are not unique for country
- Sufficient qualifying information is needed
- Some cases show that things can be different between countries, so you have to be careful.
- Good characterisation of the situation is really needed
- Be careful in relation to different monitoring strategies between countries

*Summary: Country specific information can be extended beyond national boundaries if sufficient care is taken to account for potential differences.*

15. How would differences in the definition of reasonable practicability, depending on the scale and size of the company, be accommodated?

- Relates to best practices that are reasonable practicable.
- These concepts do not exist in REACH
- They are in the CAD.

16. How should the protection offered by PPE be quantified? Can assigned protection factors be reliably developed for gloves and coveralls?

- It is a matter of conditions of use. If used correctly, it protects. But if you use it incorrectly: it won't work
- Problem is more than one substance, so should he use more than one pair of gloves
- NIOSH is doing work on penetration with nanomaterials
- Practical things more difficult to specify, e.g. changing of gloves
- Level of protection very different in reality compared to what manufacturer states.
- What we want is "reasonable protection" for a workplace, covered by best practice on PPE (use)
- There may be conflicting advice from different suppliers

*Summary: The ability to reliably develop assigned protection factors for gloves and coveralls is highly questionable. Such predictions are possible for respiratory protection.*

17. Is there a role for occupational hygiene societies in harmonisation of RMM in Europe? If yes, what could it be?

(together with 18 and 19) are there opportunities by the European Health and Safety Agency in Bilbao, industry groups, OH societies?

- We should make best use of what is already available
- Funds should be cleverly used and not two groups do the same thing
- But if chemical companies cannot even agree on SDS? What do you expect from others
- Why should a branch or group of producers not make library of RMM
- Sector specific libraries are being made nowadays in several MS
- Don't do it in Bilbao!
- Present examples are in well-organized industries. What to do with not-well organized or small industries that cannot make their own RMM libraries and ES? There could be a role for Bilbao in those cases.
- We need in the end ES for every parts of industry
- Bilbao can be do useful things for communication and raising awareness for workers to draw analogies from different situations.

*Summary: There is a role for all kinds of groups in gathering and presenting useful information, but all groups have their limitations.*

18. Could the Bilbao Agency fulfil a useful role in this?

- see 17

19. Sharing good/best practice via RMM libraries;
- what exists already?
  - how to create the libraries?
  - how to make them accessible?
  - are there likely to be any language issues?
- ❖ see 17

### **General summary of discussion / points**

- ❖ There are clear differences between substance related risk assessments and workplace risk assessments.
  - Substance related risk assessments can be done using defaults and assumptions and generic scenarios
  - But ES based on substance related risk assessments do not replace workplace risk assessments, because there are too many site specific determinants and sources of variation. Proper, effective risk management needs this site specific information.
- ❖ Systems of generic assessments, control banding and clustering of situations can be used for building ES. Their applicability depends on several factors, not only on hazard of the substance, but also on e.g. the variability and complexity of the use.

Input from the downstream user and good collaboration between several stakeholders is essential to achieve sufficiently useful ES. Information can come from a variety of sources, including industry groups and OH societies

### **Group 2 Risk Management Measures (RMMs) communication**

**Chair: Christine Northage**

**Rapporteur: Dook Noy**

### **Outcome of discussions**

***Statement 1: ESs, by definition, under REACH (including RMMs) describe safe use of a chemical.***

Discussion:

- The answer is conditional. Competent people who understand the conditions in which you are applying RMMs will be needed. There is also a need for standards of competence.
- How do you know that a REACH dossier is written by a competent person? It should have to comply with certain benchmarks, for example the principles of good working practice. There is also a difference between preparing and implementing a document. These activities require different competences. For example, to prepare the document knowledge on risk assessment is needed, to implement it asks for competence in risk management.
- Finally it was decided to rephrase the statement: ESs, by definition, under REACH (including RMMs), *should* describe principles of safe use of a chemical.

***Statement 2: The more hazardous the substance, the more specific the ES produced by the M/I should be.***

Discussion:

- Most M/Is only have information on use of their products one or two levels down the supply chain. Therefore, in general it will be very difficult for a M/Is to produce specific ES for DUs.
- There is quite a difference between writing down RMMs and implementing them in the workplace. This implies that an ES has to be generic and not specific.
- RMMs in ESs are likely to be generic and therefore more like guidance. The first responsibility lies with the M/I to supply suitable information on RMMs. It is still the responsibility of the DU to implement the RMMs, as described by the M/I.
- Again it was decided to rephrase the statement: The more hazardous the substance, the more stringent RMMs should be.

***Statement 3: Specific ES can only reliably be provided for the next stage in the supply chain.***

Discussion:

- It was stated that most M/Is do not have a great deal of knowledge of how their product is used after the first line of customers. It is very difficult to find this information..
- Communication up and down the supply chain is the key issue. How can industry be helped in improving communication? (further addressed in Question 5)

***Statement 4: Workplace risk assessments based on the Chemical Agents (and/or Carcinogens Directive) should incorporate the recommendations given in ESs by M/Is.***

This statement was not discussed.

***Question 5: If it is beneficial for certain (e.g. high volume, commodity) chemicals to organise and harmonise RMMs through sector initiatives. How could this be achieved?***

Answer:

- First of all, the responsibilities of M/Is and DUs were discussed. The M/I is responsible for all identified uses of a chemical. The M/I has to provide ESs and RMMs for all intended uses. The DU has to follow the guidance given by M/I on RMMs if it is an intended use. However, if the DU is using a chemical outside the boundaries of the intended uses specified by the M/I, the DU has two options:
  - Reporting the different use of a chemical to the M/I and requesting the M/I to carry out a CSA and include it in their list of intended uses of a chemical. The M/I has 2 choices, either to add it or to turn down this request, which means the DU has to either change the chemical used or compile their own CSR.
  - If the DU does not report the different use of a chemical to the M/I (for example for commercial reasons) then the DU has to write its own REACH dossier, describe its own ES and RMMs and report the new intended use to the European Chemicals Agency.
- At the moment communication takes place top-down from M/I to DU. There is hardly any communication from the bottom up. Both M/I and DU need to improve communication from the bottom up for two main reasons:

- M/Is lack precise information on the use of their chemicals by DUs. This might lead to ESs that insufficiently describe the working conditions of DUs.
- DUs need to communicate their use of chemicals to M/Is in order to ensure that the resulting ESs represent their situations and that RMMs can be easily implemented.
- Currently DUs have often had a passive attitude. A more proactive approach from DUs will help them in obtaining relevant, understandable, recognizable RMMs that are easy to implement.
- There could be an intermediary role for branches/sectors in the supply chain to stimulate the two-way communication. It will be much easier to gather information on branch specific uses of a chemical through branch organisations than by direct communication between M/I and all DUs. It will also guarantee that ESs on the one hand will fulfil the requirements of REACH (the necessary level of detail) and on the other hand will be branch specific enough to give DUs sufficient information to use them in their specific working environment.

***Question 6: What are the features of operations where individual work practices are likely to be important drivers of exposure levels?***

This question was not discussed.

***Question 7: What are appropriate communication practices?***

This question was not discussed.

***Question 8: Is there a role for occupational hygiene societies in harmonisation of RMM in Europe? If yes, what could it be?***

Answer:

- The answer is YES.
- Possible roles are:
  - Stimulating, working on initiatives to build RMM-databases (sharing RMM information).
  - Building repositories of good practices (again sharing information).
  - Stimulate and/or start initiatives to gather information on good practices and to implement good practices in workplaces.
  - Creating networks of experts to start a dialogue on RMM issues and to stimulate them in sharing information.
- The Dutch VASSt programme is a good initiative in sharing information on good practices within and between branches. It was suggested that ECB find ways to extend this project to the rest of Europe (as a start a translation to English would make the information accessible to all relevant parties in MSs). Finding out whether other MSs have similar initiatives would be helpful as well.

***Question 9: SDSs are the proposed communication channel of information in REACH. Is this an efficient and effective way to get information along the supply chain?***

Answer:

- SDSs are seen as essential in communicating along the supply chain.

- SDSs are needed as a vehicle for communication in the chain. However there are other tools necessary to transform the information in the SDS into more practical information for the workplace. Examples are:
  - Labelling information: pictures, icons, colour coding: all strong communication instruments for use in the workplace; the main advantage of this kind of information is that it is language independent. There is a need for harmonising the different coding systems.
  - A simple format/sheet (1 page) is needed.
- Note: the information on RMMs resulting from ESs will be attached to a SDS in an extension (e-SDS)

***Question 10: Is this expectation naïve, e.g. for imported preparations?***

Answer:

- This question was not really answered. In the discussion questions were put (but not answered) for example: The real challenge is: how to prepare an ES for a preparation?
- Finally, all agreed on that this expectation is a little naïve.

***Question 11: Is the adoption of an ES communicated via a SDS a suitable substitute for a CAD risk assessment?***

Answer:

- At first the answer to this question was NO, during the discussion the answer shifted to MAYBE.
- For substances with low hazard and/or low risk this might be true; for substances with a higher hazard or higher risk, a comprehensive risk assessment will still be necessary to establish if the adopted RMMs will lead to adequate control.
- In all cases it will be necessary to document the situation and the measures taken. It has to be auditable.

***Question 12: Could/should generic RMMs be used for authorisable substances?***

Answer:

- MAYBE.
- Generic RMMs can be used for authorisable substances, only if a benchmark for their suitability and efficiency is available.
- It was felt there was a need for more practical examples to establish guidelines for the level of detail necessary for RMMs for authorisable substances.

***Question 13: Sharing good/best practice via RMM libraries:***

- *What exists already?*
- *How to create the libraries?*
- *How to make them accessible?*
- *Are there likely to be any language issues?*

This question has been addressed together with question 8. No concrete suggestions were made except for the example of the Dutch VAS project and COSHH Essentials.

***Question 14: Could the Bilbao Agency fulfil a useful role in this?***

- No clear opinions were given. The suggestion was made to ask them what role they see for themselves.

### **Group 3 Exposure estimation and quantification**

**Chair: Hans Kromhout**

**Rapporteur: Alick Morris**

#### **Outcome of discussions**

**A general point mentioned during the discussion which the group considered important but not addressed by the questions is summarised below:**

In the environmental sector there is a high level of activity on exposure measurements/monitoring. However, when it comes to exposure in the workplace, where the level of exposure is generally much higher and more direct, there appears to be significantly less monitoring carried out. Why is this? Is it an ethical issue that needs to be addressed? Is there significantly more enforcement of environmental legislation compared to worker protection legislation? Is this an issue that REACH should address? Perhaps Authorisation under REACH will specify requirements for the amount of environmental and worker exposure monitoring that should be carried out.

#### **Statements**

##### **1. ESs (including RMMs), by definition, describe safe use of a chemical.**

This is a good intention, however perhaps the statement should read "ESs (including RMMs) **should**, by definition, describe safe use of a chemical".

If the ES is too generic then it will not be very helpful, on the other hand if it is too detailed this will limit its practical value for the DU and may also be difficult for the M/I to develop.

The devil will be in the detail.

Site specific issues are important as they can affect the performance of RMMs e.g. LEV performance, this aspect will not be taken into account in the ES.

Communication, both upstream and downstream, between M/I and DUs will be important and there are likely to be challenges in achieving effective communication in practice. A key issue here is the complexity of the supply chain.

For an ES to be universally applicable it will probably result in the proposed RMMs being too conservative. This may result in the over-specification of RMMs – this has cost, and other, consequences for DUs.

Sector specific guidance on effective and practical RMMs should play an important part in the development of individual ESs.

**2. The more hazardous the substance, the more specific the ES produced by the M/I should be.**

Agree in part, though the key issue is not the intrinsic properties of the substance, the hazard, but rather the risk resulting from how it is used. Perhaps a more appropriate statement would be "the more hazardous the substance the more specific the exposure estimation/assessment should be".

For high hazard substances the RMM is often straight forward – closed process/containment.

**3. Typical exposure levels can be established across industries for some common operations (e.g. road tanker loading, drum filling).**

This can be true in certain situations for which it is possible to define typical conditions of use. However, local conditions can influence exposure e.g. ambient temperatures – significant variation across MSs.

**4. Exposure models should only be applied when the user understands the model structure and defaults.**

Generally agree with the statement. It is expected that models will more often be used by M/I compared to DUs and they will need to understand the limits of the model, the parameters that are taken into account and what it is actually predicting.

All models are wrong it is just that some are useful.

User may tend to prefer models that give the answer that they want to hear – i.e. the estimated exposure is within safe limits.

**5. There is a lack of systematic and quantified assessment of (dermal) exposure in current occupational hygiene practice;**

Agree. What effect will the introduction of REACH have on the level of quantified assessment of exposure?

REACH will probably increase the reliance on exposure modelling (as opposed to actual measurement) when compared to the current situation. This will result in a further reduction of systematic and quantified assessment of (dermal) exposure – need to consider the significance of this.

Where will M/I get exposure information from, will they rely on DUs who generally have little information on measured exposures? Will this result in the M/I have to carry out measurements in the DUs workplace?

Quantified exposure assessment plays an important role in validating models used for good occupational hygiene practice. Where good occupational hygiene measures are practiced this implies that the exposure assessment is good. So perhaps the answer is to ensure that good occupational hygiene practice is more widespread across all workplaces.

## **6. Current risk assessment methodologies tend to overestimate exposure**

All systems tend to be precautionary. The best ones, which are least precautionary, will better reflect actual exposures.

Is it good or bad to over-estimate exposure; the answer is that it is probably good but it is a question of degree of over-estimation since do not want to over-specify the RMMs.

## **7. The role of BM in developing 'adequate control' should be (more precisely) defined.**

Very few substances have a biological limit value or other form of biological exposure indicator. Therefore, the effect of REACH is likely to be negligible.

There are ethical issues to consider before introducing a more widespread use of BM.

BM is a useful tool that complements other more commonly used exposure assessment tools.

### **Questions**

## **8. REACH does not require the sharing of exposure information. Is this short-sighted or a profound insight into the complexities of exposure assessment and risk assessment?**

Yes, this is short sighted. There should be more detail on exposure assessment, including sharing of exposure information, in the text of the REACH Regulation. Since the Council have indicated that the CSA&R requirements should be reviewed within the next year (i.e. before REACH comes into force) then this opportunity should be used to introduce more detailed requirements on exposure information within REACH.

Data sharing is positive and perhaps essential for effective regulation. There is a need to have confidence in the data that is shared and it should include contextual information on exposure.

Sharing exposure information will reduce the burden on individual M/Is and DUs to collect this information.

"Commercial in confidence" issues need to be taken into account; therefore a central entity should be used to collect and share anonymous exposure information – e.g. the OSH Agency in Bilbao or the Chemicals Agency in Helsinki.

## **9. What is the basis for recognising validity of data from other countries?**

This issue needs to take account of the situation in the EU and in other countries.

The basis for recognition is confidence in the data. Who has collected it and how do you recognise their competence.

Need centralised guidance on what data to collect and how to collect it, e.g. validated measurement methodologies.

There is a role for professional bodies in the education, training and professional development of persons collecting data.

#### **10. Exposure database/s:**

**- what will be needed?**

**- what databases already exist that could be utilised?**

**- what are minimum quality requirements?;**

**- who does it/them need to be accessible to?**

**- how would new ones be created?**

**- what issues would there be relating to transferability of data between countries?**

Access to databases should be open to all persons who need information or who wish to contribute information – though for quality reasons need to consider who should be authorised to load information onto databases.

Databases should be useful to all end-users and not just professionals.

Databases should include information on RMMs.

Need a uniform approach to databases across the EU.

Perhaps there should be a single database containing EU-wide information; this could be managed by either the Bilbao OSH Agency or the Helsinki Chemicals Agency.

Need to consider how to effectively manage database over the long-term so that the exposure information is available over many years.

#### **11. Will DNELs for chemicals without an OEL provide a stimulus for exposure monitoring in the workplace of the manufacturer?**

The introduction of DNELs is likely to result in a marginal increase in the amount of exposure monitoring.

Without an explicit legal requirement to monitor exposure then it is unlikely that M/Is or DUs will be sufficiently stimulated to introduce new monitoring programmes. This is particularly relevant for companies who at present have adequately controlled the risk of exposure to chemicals – in such situations the carrying out of additional monitoring will not be perceived as bringing additional benefits.

Workers may demand that employers carry out additional monitoring to demonstrate that their exposure is below the DNEL.

#### **12. What are the features of operations where individual work practices are likely to be important drivers of exposure levels?**

There was not sufficient time to discuss this item.

### **13. What needs to be included in suitable exposure monitoring strategies for REACH?**

There was not sufficient time to discuss this item.

#### **Group 4 Exposure assessment tools and knowledge**

**Chair: John Cherrie**

**Rapporteur: Violaine Verougstraete**

#### **Outcome of discussions**

The Group agreed that ESs could constitute a useful ‘descriptive’ tool, but that the uncertainties that remain with regard to the latter’s implementation and use are obscuring the overall concept. For instance, variations in processes, exposures, etc. will characterise the ES and there is no guarantee that the downstream user will opt for the most appropriate ES. On the contrary, any endeavours to develop very generic ES will most probably only reflect part of the actual reality. It is not clear at present just how narrow or how broad an ES should be.

The process and main lessons of the COSHH Essentials were discussed. Experience with COSHH essentials indicates that the latter constitutes a good tool, but that there is still a communication issue with regard to the terminology used, which should be straightforward and simple. Working by process seems to be an advantage, but does not preclude variability.

Working behaviour is identified as an element that will influence the applicability of the ES. There is always a limit to the level of control we can exert at the workplace, depending on engineering, working behaviour and available skills. It should also be noted that the situation in developing countries is very different from that in the EU, and that ES developed for EU processes will probably not be relevant worldwide. The liability issue was also identified as something that will hamper the implementation of the ESs.

Overall, however, ES could well constitute a good step forward in encouraging SMEs to implement controls, and it will generate information and skills. This does mean, however, that the people who develop and use these ES must be trained and motivated to use the tool in an appropriate way.

With regard to the second statement (*The more hazardous the substance, the more specific the ES produced by the M/I should be*), the Group’s immediate response was that hazard and risk are equally important in providing guidance. It is not only hazardous properties, but also the exposure potential and physico-chemical properties (e.g. volatility) that should be taken into consideration. The fear is, however, that this might lead to the “over-controlling” of less hazardous substances, as ES might well be less specific. This will probably be more of an issue for bulk chemicals than for preparations. Overall, the way the ES will be written was identified as an issue here. The coverage of ES should be defined: do we conceive the ES as being a ‘cookbook’, or rather

information backed by general principles and guidelines? Whatever the route that ES take, workability should be kept in mind (600 pages of text should be avoided).

On the third statement, *Typical exposure levels can be established across industries for some common operations*, the group mentioned that currently, we are collecting information on exposure range (typical-RWC).

To have typical levels across industries for certain operations would mean having the same chemical, the same working conditions, the same control pattern, the same working behaviour, and the same sampling techniques (what about day-to-day, worker-to-worker variations?). We have all, however, learnt by experience that local conditions are important determining factors, and we can anticipate that the supplier will most probably be ignorant of these conditions. Processes and substances should be combined in order to have a representative ES.

The entire Group agreed that a systematic and quantified assessment of dermal exposure was lacking in current occupational hygiene practice, but noted that this statement also applied to biomonitoring.

Current risk assessment methodologies tend to overestimate exposure, which may be useful from the regulatory point of view, but which is not representative of what actually happens in the field. It was recalled here that, at the start, EASE was designed for use as a screening tool for new substances and not as a broad exposure assessment tool under ESR. The question remaining is how over-predictive the current methodologies for assessing exposure can or should be. Some delegates indicated that people in the field were already making corrections spontaneously.

Again, the Group agreed that exposure models should only be applied in cases where the user understands the model structure and defaults. It is important, indeed, to identify the caveats and assumptions, but it is probably unrealistic to expect to achieve a complete understanding. Factors such as a user-friendly interface also play a role here. The limitations of a model should be known in order to help with interpretation, but this means that active training is required.

With regard to the lack of appropriate exposure databases, the Group agreed that data sharing would be welcome. Existing available data are useful in order to describe general trends and to obtain an idea of the current distribution of exposure, but will probably not be specific enough to be used for ES. Data relative to end-users may be missing in particular. Consequently, the development of databases should be further encouraged.

Additional data are also available in companies. The Group spent some time discussing the barriers to data sharing: confidentiality and access issues need to be solved in order to encourage data sharing. The use of a common format would also be helpful in the interpretation of the data. The costs of, and willingness to participate in, data sharing are definitely factors that need to be taken into account – and they are not easy to overcome. Ways of examining the representativity of the data (best or WC scenarios?) should be worked out. Furthermore, there has been an overall decrease in the information that is

available. Among the proposed solutions, the Group referred to the definition of an effective format in order to turn databases into tools for the owners and users of the data, provide some help in interpreting the data (context, representativity), give explanations as to what one wants to collect, and the objectives of this, and make the data anonymous. CEMAS, Norway, is a good example of data standardisation.

*“For second tier exposure assessments, the development of an advanced tool using databases and theoretical mechanistic approaches with modern statistical techniques is essential”*: the Group agreed with this statement, noting that this was an issue for research. Overall, the need for a simple interface and a reality check of the ‘black-box’ numbers coming from the models was stressed.

Finally, it was acknowledged that *REACH would require the sharing of exposure information*. In order to make the sharing process work, however, we must ensure that there is vertical and horizontal communication on data sharing. The proposed way of encouraging this was to rely on the trade associations and national authorities to make the benefits (or disadvantages) of this data sharing clear...and to devote time and energy to it ... this is a dynamic process that needs to be encouraged.

## **APPENDIX 4            COMPETENCY AND TRAINING NEEDS DISCUSSIONS**

### **Group 1**

**Chair:            Chris Beach**  
**Rapporteur: Marie Coggins**

*Question 1. Can we identify specific competencies that are likely to be required?*

- **Communication competency**, Occupational hygienists (OHs) need to be able to communicate to all levels in the workplace, and be understood. Complicated and technical data from safety reports, SDSs etc needs to be communicated in a form which can be understood at all levels.
- **Business competency**: OHs need a better understanding of the business in which they work, so as to improve communication and secure resources. They need to develop better interpersonal skills, so they can influence the implementation of controls measures. Also need to develop a ‘predictive skill’ so as to learn how to fill in knowledge gaps efficiently.
- **Practical skills**: OHs need to maintain the ‘hands on’ skills, they need to maintain the link with the fundamentals such as risk and exposure assessment. Some may need mentoring in the use of predictive modelling skills, toxicology i.e. toxicological tests, difference between DNELS, OELS, chemistry, and engineering solutions. Important to this need is also the ability to recognize the limitations of their knowledge in these areas.
- **New monitoring/ measurement skills**: OHs will need mentoring on advances in monitoring techniques (e.g. dermal exposure assessment) and the use of

- biomarkers, consumer exposure assessment, and have an understanding of environmental exposures.
- OHs need to keep familiar with **best practices in engineering controls** and need to understand documents describing RMMs.

*Question 2. Are they likely to be existing, modified or new competencies?*

- The competencies defined in question 1 are likely to be modified and the new competencies added.

*Question 3. How do these requirements fit in with the content of existing training / education programmes?*

- There are some competency assessment courses available in the EU e.g. BOHS, however we don't have a unified 'EU type' competency course. IOHA may have a role here, as there are many OHs outside of the EU who will need to understand REACH.

*Question 4. What training/education programmes currently exist in the EU?*

- This question has been answered in Question 3; however just to recognize that there are many different standards across the EU on training and competency.

*Question 5. Is there likely to be a need for specialist training? If so in what specific areas?*

- There is likely to be a need for specialized training around the competencies identified in question 1, for both existing OHs and those new or interested in joining the profession. Special training for competencies identified in question 1. sector specific training may be needed, similar to what already occurs in Holland and the UK( special interest groups). There will be a need for training on RMMs and implementation skills. OHs have already developed skills from the implementation of CAD RA's, and also regulatory RA's for the ESR. There may be a need to develop two types of training here one for the field OH and another for the regulatory OH.

*Question 6. What actions are going to be required to ensure that existing professional training / education programmes can meet the needs identified?*

- Development of CPD type courses, workshops, REACH workshops with relevant stakeholders, work with various trade associations at EU and national level.
- The OH profession needs to 'market' their skills, create awareness of the usefulness of the profession in implementing REACH. A comparison was made with the safety professional who excel in this area.

**Group 2**

**Chair: Michel Guillemin**  
**Rapporteur: Tracey Boyle**

*Question 1. Can we identify specific competencies that are likely to be required?*

After some discussion the group came to the decision that a team approach to the implementation of REACH would be required as there are a number of different competencies required, including:

- Knowledge of chemistry
- Safety engineering
- Toxicology
- Routes of exposure
- Dose
- Occupational medicine
- Knowledge of industrial processes
- Knowledge of control measures
- Risk management (including risk analysis)
- Risk communication
- Influencing skills

It was decided that all of these skills would not be possessed by one person, but that a team of people would be required for the REACH programme. However, the competencies of the occupational hygienist in risk recognition, evaluation and control would be invaluable in working up exposure risk assessments.

*Question 2. Are they likely to be existing, modified or new competencies?*

The consensus was that the competencies would be existing in countries where the profession of occupational hygiene is recognised, but knowledge of REACH and an understanding of its requirements would be needed. The situation is varied across Europe. The hygienist has knowledge of industrial processes and this would be useful in the working up of ESs. It was also felt that knowledge of modelling techniques would be required for scenarios where exposure data was not available. The proviso in the use of modelling is that a familiarity of the limitations of the various modelling techniques would be necessary.

*Question 3. How do these requirements fit in with the content of existing training / education programmes?*

Where there are existing programmes for occupational hygienists, they are providing the skills required for implementation of REACH. However, these programmes may need to include specific information about REACH, and more on exposure assessment modelling.

There are several countries within the European Union that have no qualified hygienists. Often in these countries, safety professionals or occupational physicians may try to cover

the work that hygienists do in other countries. There were comments that they do not always have the skills and knowledge required.

*Question 4. What training/education programmes currently exist in the EU?*

There are existing programmes for training occupational hygienists in the UK, NL and Switzerland. Belgium has just started a new 18 month MSc course in occupational hygiene, but there are currently only 8 students on the course. In France, occupational hygiene is taught with an environmental or safety bias.

*Question 5. Is there likely to be a need for specialist training? If so in what specific areas?*

The consensus was that there was not a need for specialist training in order to be able to carry out ESs for REACH. In order to be able to implement REACH there was a need for a broad understanding of the principles of risk management.

*Question 6. What actions are going to be required to ensure that existing professional training / education programmes can meet the needs identified?*

There needs to be a recognition in Europe that the skill set needed to implement REACH are those of the occupational hygienist. The profession of occupational hygiene should be mentioned in guidance. The authorising bodies need to be educated to recognise the profession of occupational hygiene.

### **Group 3**

**Chair: Steve Bailey**

**Rapporteur: John Dobbie**

#### **1. Can we identify specific competencies that are likely to be required?**

- Extended SDS requires ES, new methodologies are needed for current MSDS authors are they competent? – will hygienists need to take a larger role – will this lead to increases in necessary competencies for hygienists. Differing competencies for generic rather than specific ESs?
- Do workplace assessments need to consider environmental exposures? Do hygienists have the skill set for this – consensus from room was team work needed.
- End user will want just one set of instructions – so overall coordination will be needed – should hygienists up skill for this role.
- Hygienists need to build commercial relationships to assist in communications up and down the supply chain. Do hygienists need a better understanding of business models in this area? Yes!
- Science-based and biased approach taken by hygienists, but they do not have wide enough knowledge of complex exposure assessment models etc.

- How far in to the supply chain should hygienists delve? Large companies already support direct customers. Problems could occur as demand may exceed supply. Liability issues, Professional Indemnity issues etc. Problem with skills based upon familiarity with own operations – difficult to operate in new workplaces?
- Look at new training processes to allow wider and deeper skills, knowledge & competencies. Do existing training sufficiently cover these, or do we need more transferable skills – this is being built into UK undergraduate programmes.
- In some cases hygienists are seen as too expensive for some simple health assessment roles, e.g. asthma programme in Dutch Bakeries.
- Does this mean we need to better define the roles & responsibility at each level of OH, do we need more lower skilled people – i.e. basic OH training to other professionals etc.
- Example given from the UK of training given to delivery drivers to enable them to recognise unsafe acts at customer premises, seen as powerful approach.

**2. Are they likely to be existing, modified or new competencies?**

- Existing competencies, but transferred to a new route
- Competencies also need to be developed in supply chain-facing organisation – this can be very time consuming and expensive, but does provide useful feedback on supply chain issues

**3. How do these requirements fit in with the content of existing training/education programmes?**

- Educational courses exist, but specific training on processes of REACH will be needed post guidance publication.
- More toxicology training needed.
- More environment training needed, and better understanding of legislative approach
- Learning on the job will also be important. How can we keep this mentoring based approach sustainable? Company internships schemes.. common in USA, but less so in UK. Students appreciate such schemes, but are companies recognising their real value? Can REACH offer wider opportunities in this – should bigger organisations sponsor interns into their customers?
- How do we educate our customers to engage them in recognising the value to them in such a scheme?
- REACH is regulation, so what is role of individual MSs regulators?
- Doubts about transfer up and down the supply chain - it doesn't work now, especially upwards, so what will REACH change?
- Additional tasks for Hygienist will be around authorisation, and technical arguments etc. Need new training on this.
- Can REACH address competency issue, where currently untrained people are taking active OH roles ... should we have Europe-wide certification/qualification – seen as Catch 22 could be a barrier to developing

some lower skilled roles to do basic work. Accreditation will make hygienists more expensive still.

#### **4. What training/education programmes currently exist in the EU?**

- Belgium – some education for OH technicians – now post graduate training in OH, regional responsibility for education. New Framework, based upon 5 multidisciplinary Prevention services, safety, Occupational medicine, ergonomics, psychosocial factors and health. Special post academic training on REACH itself, but mainly from environmental standpoint – evening course (20 nights).
- Sweden – have a certification system, which has been in place for about two years. Today it is thought that there are about nine certified hygienists. So the numbers of new certified hygienists are about three per year. In the Swedish association of occupational and environmental hygienists there are about 150 members. To get certified you have to be a member of the Swedish association. The number of members in the association has been more or less constant during the last 10 years, with about five new members every year and five members leaving.
- Sweden no longer has any formal education in occupational hygiene. They had, in the past, a Master of Science programme in chemistry that could be focused in the last year to occupational hygiene, but it had too few students so it does not exist any more. At the different Universities there are "free courses" that could be put together to something looking like an occupational hygiene programme. Today when people are hired as occupational hygienists it is preferable that they already have a BSc or MS exam that comprise some element of occupational or environmental hygiene or similar. These persons are then trained by the employers.
- UK – big range, BOHS, First degree and post graduate courses, two basic levels of hygienist – COC and Diploma. Problem with untrained hygienists running programmes. Like Netherlands demand is dropping. Increasing percentage of students from Far East.
- Finland – Environmental Sciences in Universities incorporate OH – 30 years in existence but no registration process, starting to evaluate competency based approach. Strong Institute of Occupational Health – few consultants. 6 regional institutes, each with 5 hygienists. When founded had special training programme, which although not certified had similar programme.
- USA – 30 - 40 undergraduate OH programmes, successful and growing. 20 – 30 MSc programmes, in decline over last 5 to 10 years. Typically each puts through about 5 – 7 students per year. Interest in problem solving started as driver, now maturity of profession means administrative role only.
- Overall gap, shortage of skilled hygienists in the right places globally

#### **5. Is there likely to be a need for specialist training?**

- EU supply side legislation to date has concentrated mainly on the hazard aspects of chemical management and control. Under REACH exposure is a

key consideration before actual risk can be understood. Specialist training will be required. If so in what specific areas?

- Basically two areas of specialist training will be required -  
a) provision to hygienists on hazard understanding, and classification ( e.g. toxicology);  
b) training by hygienists on understanding exposure and developing control strategies

**6. What actions are going to be required to ensure that existing professional training/education programmes can meet the needs identified?**

- Formalisation of training schemes under National/International professional bodies, e.g. BOHS/IOHA etc.

**7. What should hygiene training look like in 5 to 10 years?**

- Emphasis on more transferable skills
- More integration, e.g. workplace, consumer, environment etc.
- More multidisciplinary. Have to get over the “my function is the most important” syndrome.
- Wider role in the businesses.

**Group 4**

**Chair: Esther Martin**

**Rapporteur: Martie van Tongeren**

*Question 1. Can we identify specific competencies that are likely to be required?*

The specific skills and competency requirements for REACH depend to some extent on who you work for (importer/manufacturer, down stream user; government; research institute; consultancy service).

More emphasis may need to be placed on making more predictive use of existing information. Existing data and information need to be more generally available. Relatively few occupational hygienists have extensive knowledge and experience of sophisticated models (such as Bayesian or empirical models). Such models should become part of the tool box of the occupational hygienists, although it is very important to be aware of the limitations of models. On the other hand, it remains important not to lose sight of practical experience of what is happening in the workplace.

Communications are a key element in REACH. Occupational hygienist will need to make sure that they provide a link between down stream users and suppliers and between toxicology information and real life situations. One relatively new area for the occupational hygienist will be the development of (global) ESs.

Human behaviour is an important aspect to take into account when suggesting control measures and personal protective equipment.

Occupational hygienists are generally not experts in the area of consumer exposure (exposure due to use of consumer products). Similarly, exposure of general population through the environmental route, would be a new field. If occupational hygienists wish to be involved in these areas, this will require extensive training.

*Question 2. Are they likely to be existing, modified or new competencies?*

To a large extent the necessary skill set and competencies already exist in the occupational hygiene profession; such as: i) collecting data/standardisation of data collection; ii) risk assessment and management; iii) contextual information; iv) Evaluate control measures; v) transferring information to other situation. Most other skills and competency requirements mentioned under question 1 do exist to some extent already.

Possible exception to this are the aspects of human behaviour and communications with clients.

Consumer exposure and exposure through the environment have generally not been considered before by occupational hygienists.

*Question 3. How do these requirements fit in with the content of existing training / education programmes?*

All existing education programmes, probably have some gaps in their curriculum, including: i) development of ESS; ii) Global thinking; iii) Communication skills; iv) Risk Management; v) Hazard assessment, to interpret toxicological information; vi) Chemistry ; and vii) Effectiveness of control measures, including human interaction with control measures.

*Question 4. What training/education programmes currently exist in the EU?*

There are a number of countries where good training programmes exists, such as UK, The Netherlands, Spain. These countries also have a certification system. What is less clear is to what extent training programmes exist in other EU countries, and to what extent such programmes exist in the new EU MSs.

Training programmes and student numbers have declined compared to 1980s/early 90s.

*Question 5. Is there likely to be a need for specialist training? If so in what specific areas?*

Training courses in Occupational Hygiene should include the following elements:

- 1) Use of models in regulatory assessments;
- 2) Variable training in traditional OH skills across the EU;
- 3) Applied toxicology. Need to understand the hazard assessment. Understand what safety margins mean.
- 4) Impact assessments:
  - Human behaviour interaction with control measures

- Better understanding the strengths and limits of LEV.
- Effective Communicating
- Business awareness/ financial matters/cost of controls/economics

In addition, it may be necessary that short courses on these topics are provided in the various countries so that existing occupational hygienists are trained in these new skills

*Question 6. What actions are going to be required to ensure that existing professional training / education programmes can meet the needs identified?*

There is a role for the national professional bodies to make sure that new and modified skill sets and competencies are included in their curriculum and accreditation system. IOHA also need to play a role in ensuring that curriculum are compatible between countries.

National governments will need to start awareness campaigns on REACH for downstream users, to make sure that companies realise what is required from them. The Occupational Hygiene community should provide an input in such campaigns.

**APPENDIX 5****WORKSHOP PARTICIPANTS**

Abrahamsen Uno	Directorate of Labour Insp.
Ajanko Sirke	VTT Processes
Asnong Willy	Solvay SA
Bäck Beatrice	Uusimaa Reg Inst of Occ Hlth
Bailey Steve Mr	GlaxoSmithKline
Battersby Rodger Dr	EBRC Consulting
Beach Chris	BOHS President
Bender H Prof	BASF-AG
Bengtsson Leif Mr	Swedish Chem Inspectorate
Blainey Mark	European Commission
Boyle Tracey Mrs	Workplace Env' Solutions Ltd
Breum Niels Oluf Dr	Danish Nat'l Working Env Auth
Cahill Margaret	Janssen Pharmaceutical Ltd
Campbell David Mr	Chemical Industries Assoc
Chambers Helen	HSL
Chapman Robin Mr	BASF plc
Cherrie John Dr	IOM
Christensen Frans Mr	ECB
Coggins Marie Dr	National University of Ireland, Galway
Deygout Francois	Shell Global Solutions (France)
Dobbie John	Innovene
Eickhoff Peter Mr	Defence Ordnance Safety Group
Eie Roar	Occ Hyg Solutions AS
Eriksen Ragnhild	Directorate of Labour Insp.
Fieldsend Mark Mr	Unilever
Fish Marjory Mrs	Metronet Rail
Fladseth Geir Mr	Statens Arbeidsmiljøinstitutt
Flavin Nuala Ms	
Galvin Jennifer Dr	ConocoPhillips
Groenewold Monique Mrs	TNO Quality of Life
Grosjean Roger Mr	FPS Emp' Lab' & Social Dialogue
Guillemin Michel Prof	IST
Heussen G A H Dr	ArboUnie
Hughson Graeme Mr	IOM
Huizer Daan Mr	IRAS Utrecht University
Jeffery D J Mr	
Kindness Ann Ms	AOHS Ltd
Koppejan Jan	Marsh Risk Consulting
Kotsiki Christina	Hellenic Petroleum
Kromhout Hans Dr	Utrecht University
Larsen Poul Bo	Danish Env' Protection Agency
le Feber Maaïke	TNO
Lees Peter Prof	Johns Hopkins University
Linker Fenneke	DSM
Mäkinen Milja Dr	Finnish Inst. of Occ Health

Mallett Anthony Dr	Experien Hlth Sciences (Europe)
Marquart Hans Mr	TNO Quality of Life
Martin Esther	INSHT, Spain
McDonald Terry Mr	University of Greenwich
Michel Ingeged	AstraZeneca AB
Money Chris Mr	ExxonMobil
Morris Alick Mr	European Commission
Moscatelli Luigi	ENI SpA
Newell Martin	
Nordheim Eirik	European Aluminium Association
Nordlinder Rolf	Volvo Technology Corp
Northage Christine	HSE
Noy Dook	Arbo Unie
Orlien Niri	Norwegian Occ Hyg Assoc
Paulus Gerard	Innovene
Peers Jonathan Mr	
Pensis Ingeborg	Ankerpoort NV
Pizzella Giulia	ENI SpA
Pye Christopher Mr	Pilkington UK Ltd
Räisänen Jouni	National Product Control Agency
Reynier Martine	INRS
Ritchie Peter	IOM
Rogers Dave Dr	Parsons Brinckerhoff Ltd
Scheffers Theo	Royal Haskoning
Shrives Ian Mr	Corus
Smit Jack	Sovay N.N., Filiaal Nederland
Southern Mike Mr	Eurobitume
Spee Ton Dr	Arbouw
Syska Jytte	Ariel Research Corp Europe
Tielemans Erik Dr	TNO
Tinnerberg Håkan Dr	
Turner Robert Dr	HSE
Twisk Jan	Dow Chemical
Ulvøen en Steinar	STATOIL
Urbanus Jan	Concawe
van den Broeke Henry	DSM
van Hemmen Joop J. Dr	TNO Chemistry
van Parijs Koen	Bayer Antwerp
van Rijn M J Mr	
Van Rooij Joost Dr	IndusTox Consult
van Tongeren Martie	University of Manchester
Vangronsveld Erik Mr	Hunstman
Verougstraete V Dr	Eurometaux
Verspoor Paul	Sitmae Consultancy BV
Veulemens Hendrik	SOH President
Viinanen Riitta M	Neste Oil Corporation
Wahl Heiner	BMW

Walding Marianne  
Wangemann Frank Dr  
Webster Dawn  
Weeden Colin Mr  
West John  
Westra Jaco Dr  
Willems Hilde

Swedish Work EnvAuth  
COGNIS Deutschland  
Unifrax

Arbo Unie  
Ministry of Social Affairs & Emp'  
DuPont