European Experiences in the Development of Approaches for the Successful Control of Workplace Health Risks

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In recent years, several approaches have been proposed for the application of control banding concepts to the assessment and management of various workplace health and safety risks. Whilst many of the earlier approaches have originated in the UK, several of the most recent examples have been developed in Europe. The European schemes have attempted to build upon the lessons learned from the earlier control banding schemes and to apply them to new areas of health and safety. This paper analyses the evolution of the earlier approaches and reviews the more recent European developments in the context of continuing regulatory and societal demands for the improved assessment and regulation of workplace chemical risks.

Keywords: chemicals control; control banding; OEL; risk assessment; risk management

BACKGROUND

It is clearly desirable that, when undertaking an assessment of workplace risks, not only are the conclusions (or outputs) accurate, but there is also consistency across different risk assessors. The desire for both accuracy and consistency has resulted in the development of systematic structures within which risk assessments can be undertaken and progressed. Whilst for some profound societal risk, e.g. major hazardous installations, the resulting processes are complex, this does not need to be the case for more straightforward risks. Indeed, an ability to simplify the risk assessment process allows access for a wider range of potential users. The imperative to identify approaches to risk assessment that are both accurate and simple has led to the development of various schemes for evaluating and controlling risks. Most recently, the introduction of techniques of control banding for the management of chemical risks in the workplace (Health & Safety Executive, 1999, 2000) has introduced approaches that provide the required accuracy and simplicity and hence enable access and use by non-experts.

The origins and core principles for control banding

Although the development of control banding approaches for the assessment and management of workplace health risks has been a relatively recent phenomenon, the origin of control banding lies in the schemes developed by the chemical industry for the assessment of the health and safety risks arising from catastrophic failures at major chemical facilities. Such schemes first came to prominence in the 1970s (Lewis, 1980; American Institute of Chemical Engineers, 1994). In essence, the schemes develop a risk matrix that describes the likelihood and probable severity of the event of concern. The risk matrix is generally described as a function of two variables: first, the classification of the hazard presented by any facility or operation (and which is often a function of the intrinsic safety or health hazard of the material handled at that facility); and, second, the likelihood of a major incident occurring, e.g. an explosion or a release of toxic material. These two variables (or minor variations of them) serve as the basis for most risk matrices. Such a matrix can have desirable characteristics that provide a benchmark against which to evaluate other approaches.
1. Conceptually, the approaches must be user friendly. They need to be understandable not only by those who use the schemes, but, perhaps more importantly, also by those who are affected by their outputs. The tools therefore not only as a mechanism for evaluating risk, but also one for communicating such risks.

2. The schemes, whilst integrating elements which may be complex in themselves, e.g. how the toxicological or physical end-points of a property might be described, are based upon information that is generally freely available to the user. For example, the schemes often rely upon information that must be made available under European or national legislation, e.g. via safety data sheets. This helps in ensuring that the schemes are capable of being implemented with a minimum of expert training or specialized resource. It also means that they can be more readily used in areas where the availability of expert skills or resources is poor, e.g. within small and medium sized enterprises (SMEs).

3. The schemes deliver practical advice to the user. Whilst this may appear to be an obvious requirement for any successful approach to the assessment and management of risk, it is sometimes overlooked. For example, much guidance that has been produced in the past has tended to concentrate on those elements which should be considered when making judgements (process inputs), rather than describing the expected or likely conclusions for a defined set of conditions (process outputs). Approaches that are able to address how risks are best managed therefore possess a distinct advantage.

4. The schemes should also be user friendly (Hudspith and Hay, 1998). User friendliness is a measure that is difficult to specifically define and which is likely to present as a combination of considerations that vary between different users (Briggs and Crumbie, 2000). However, it is important that schemes present workable solutions that are acceptable across all groups holding an interest (regulators, employers and the workforce). Key elements that are relevant to the evaluation of ‘workability’ include whether the outputs from any scheme can be calibrated against the regulatory environment in which it operates and the societal or industrial relations contexts in which stakeholders will encounter it.

5. The scheme should engender confidence amongst those who use it and are affected by it. In part, the confidence will be determined by the nature of the outputs from the scheme (whether they are suitable for successfully controlling the risks that they are intended to manage) and the actions taken by an organization to implement these. This, in turn, suggests a further consideration for success: that schemes should be sufficiently flexible to adapt to the changing patterns of industry or the evolving regulatory demands of society.

6. Any scheme ought to provide its output in a transparent and consistent fashion. Unfortunately, these two aspects are sometimes overlooked when developing approaches for the evaluation of workplace risks. For example, models used to estimate exposure can be so mathematically complex that, despite any qualities of accuracy or reliability, they resemble a ‘black box’ to the layman. Whilst the outputs from such models may be valid, the results are often treated with scepticism because of the opacity of the process used to deliver them (Kingston-Howlett, 2001). A similar argument applies to models or approaches that are only valid within a limited range of applications.

The development of schemes for assessing workplace health risks

In recent years, several schemes have been proposed that are intended to address the risks to health arising within the workplace. The core concepts behind such schemes have their roots within the earlier safety risk management approaches. Figure 1 illustrates the evolution of some of the more recent schemes. There have been several stages in the development of the currently available approaches. Each new approach has tended to build upon the previous stage and/or to develop a new application for some other area of the workplace. The developments now appear to have reached a point where the recent schemes address most, if not all, of the core considerations necessary for success.

Figure 1 shows that approaches aimed at assessing, in a simple and structured manner, the risks associated with various safety events have been in use for many years. The earliest uses were in their application for hazardous installations. These schemes sought to define the likelihood of a serious event occurring, e.g. an explosion or release of a toxic substance. The basis for defining the likely risk was based on information that categorized the severity of the event (a form of hazard banding) and the frequency at which such events were known to be associated with particular plant or equipment (and equivalent, in health or environmental terms, to ‘exposure’). Various risk matrices have been proposed and subsequently developed based upon variations of these two descriptors (Institution of Chemical Engineers, 1985; American Institute of Chemical Engineers, 1992).

The first comprehensive attempt to apply safety risk concepts to the field of workplace health was
developed by the Royal Society of Chemistry (RSC) for use in laboratories (Royal Society of Chemistry, 1989). The need for a simplified approach to workplace health risk assessment was brought about by the introduction of the (then new) Control of Substances Hazardous to Health Regulations in the UK (HMSO, 1988). In essence, these Regulations required that a risk assessment was undertaken in all workplaces where hazardous materials were handled. The need for a simple approach that enabled risks to be evaluated from substances where very little information may be known about their hazardous properties was obvious. However, the RSC scheme went beyond this immediate need. It developed an approach that also delivered advice (outputs) that was consistent with good practice. Thus the RSC scheme was the first to successfully introduce the basic concepts of control banding, namely:

1. it categorized the hazard of the substance (using the R phrases of the substance);
2. it developed an approach for estimating the magnitude of exposure using a simple empirical model (and the relative accuracy of which was verified against a range of common laboratory activities);
3. it developed a workplace risk matrix using the hazard category and exposure estimates;
4. it used the risk matrix to identify (a limited number of) exposure control solutions that were appropriate to the degree of risk.

The basic concepts of the RSC laboratories approach have subsequently been further developed (Royal Society of Chemistry, 1996) and applied for use in other sectors of industry (Money, 1992a; Chemical Industries Association, 1993; Naumann et al., 1996). The sector-specific schemes again use R phrases as the basis for categorizing hazard, not least because this information has to be provided for the substance or product by chemical suppliers. The schemes also utilize simple algorithms for estimating the magnitude of exposures to chemicals (although they do not generally attempt to quantify such exposures). Finally, the schemes use the combination of hazard and exposure as the basis for guiding the user to suitable control solutions. These schemes, therefore, represent the first use of control banding concepts for wider use in industry.

The sector-specific approaches were also the first to develop the idea that the categorization of hazard might also form a logical basis for the development of generic exposure control standards. Although the relationship between R phrases and occupational exposure limits (OELs) had been previously examined (Gardner and Oldershaw, 1991), a coherent framework for the wider application of these ideas
was not available until first proposed in the sector-specific scheme for dyestuffs (Chemical Industries Association, 1993). Subsequently, a number of other approaches for categorizing hazards to develop generic OELs or control regimens have been proposed (Association of the British Pharmaceutical Industry, 1995; Technische Regeln für Gefahrstoffe, 1996; Chemical Industries Association, 1997).

A further development of the control banding approach has been its application for specific product classes and families (Chemical Industries Association, 1992; Money, 1992b). Focusing on a specific group of chemicals allows for the hazard categories to include a higher level of detail, for example by accounting for elements that are not addressed within the R phrases, e.g. potency and additive effects. Coupled with the fact that a specific product class is invariably associated with a more limited range of uses, then this enables these approaches (at least in theory) to be more accurate in their ability to identify appropriate control options for a set of conditions. Furthermore, because such conditions are limited, these schemes were the first to examine the relative impact and importance that ‘software’ (procedures, systems, etc.) has in terms of their role in managing risk.

Most recently, control banding concepts have been used to address the health risks arising from marketed chemicals in general. The COSHH essentials scheme (Health & Safety Executive, 1999) and its derivatives (Health & Safety Executive, 2000, 2001), developed by the UK Health & Safety Executive, has been described previously (Brooke, 1998; Maidment, 1998; Russell et al., 1998). Notably, it provides a validated basis for categorizing the hazard of chemical substances, the estimation of likely exposures and a comprehensive and structured approach for integrating the two to provide practical guidance for common industrial activities. Throughout the development of the approach, consultations were carried out with potential users, professional groups and other stakeholders (Marketing Works, 1998). Perhaps as a consequence of these consultations and the revisions that have been made following the piloting of early versions of the approach, the COSHH essentials scheme has received widespread support within the UK and has been verified as being valued by and useful for SMEs (Wiseman and Gilbert, 2002)

**EUROPEAN DEVELOPMENTS IN THE APPLICATION OF CONTROL BANDING CONCEPTS**

The development of control banding approaches for workplace health risks in the 1990s was followed with interest by occupational hygienists more widely within Europe. Within the European chemical industry, the benefits of the schemes were recognized, but their wider application was constrained by the prevailing legislative structures of member states during that period. However, the introduction of the Chemical Agents Directive (European Commission, 1998) provided the necessary stimulus to initiate a discussion within the industry on whether control banding approaches could usefully be applied in the European context.

Within France, control banding concepts have been applied to integrated safety, health and environmental considerations (Union des Industries Chimiques, 1999). The French scheme addresses the needs of chemical users. Specifically, it evaluates the likely effectiveness of risk management measures in operation at a company. Dependent upon the type of substance and how it is handled, it directs users at information sources that are intended to provide information on the effectiveness of current control measures or the need for further intervention. Because the scheme is aligned with how chemical exposures are addressed under French legislation, it supports the product stewardship obligations of the French chemical industry and has received support within France for this reason.

Whilst most control banding approaches have sought to address workplace health and safety issues, little attention has been paid to extending the concepts to the wider area of the regulation of marketed chemicals. However, the recent EU White Paper on a future chemicals policy (European Commission, 2001) creates a series of challenges that, in turn, demand a re-appraisal of how the wider risks of chemicals might be addressed. In particular, the White Paper clearly anticipates that better and more representative exposure information will become available in order that future societal and regulatory judgements on the control of chemicals can be risk based. The White Paper also proposes to reverse the burden of proof away from a situation where, currently, the competent authority is expected to demonstrate the presence of a risk before restrictions are applied to the marketing of a chemical (European Commission, 1994) to one where industry would be expected to demonstrate the acceptability of risks prior to a chemical being accepted (authorized) in the market. The new approach to regulation, termed REACH (registration, evaluation and authorisation of chemicals) would apply to the vast majority of chemical substances in commerce. Such an ambition presents both scientific and logistical challenges. Two recent developments within the European chemical industry aim to provide tools for delivering within this new regulatory paradigm and both incorporate control banding concepts at their core.

**CEFIC exposure management system (CEMAS)**

The difficulties of obtaining information on the uses of and exposures to chemical substances in
SMEs represent a major challenge for industry. The dearth of information constitutes a major impediment to a regulator’s ability to conclude that workplace health risks are satisfactorily managed across all industrial sectors (Northage and Marquat, 2001). The difficulties of implementing effective health and safety strategies within smaller enterprises have been well documented (Walters, 2001). Despite these, though, the chemical industry needs to obtain a better understanding of the nature of such uses and exposures in order that it will be able to meet its new obligations under REACH.

The European Chemical Industry Federation (CEFIC) has initiated a project which aims to develop a guidance tool for the small and medium sized users of chemicals as the basis for providing structured health and safety decision making in such organizations. CEFIC’s aspirations for this project have been reported previously (Money, 2001). In summary, the tool guides SMEs to collect workplace exposure information in a structured manner which, when coupled with available hazard information on the products in use, delivers advice on the nature of risks and any advisable actions that might be taken consequent to these. A schematic diagram of the approach is shown in Fig. 2.

The tool will advise when exposure monitoring may be required and will also constitute a basis by which critical information on the use of chemicals within smaller organizations can be analysed and disseminated. The tool will be freely available from CEFIC to those users who register an interest. This action will enable CEFIC to provide supporting product stewardship materials to the users dependent upon the chemicals used and activities undertaken by the organization. As a result, CEFIC will obtain a more accurate idea of the scope of chemical exposures in SMEs. The tool also has the ability to be interrogated by the user or remotely (with the permission of the host). This latter capability provides the opportunity to obtain a comprehensive picture of the nature of chemical uses and exposures amongst those organizations that choose to use the tool.

**ECETOC approach to tiered and targeted risk assessments**

A further expectation of the EU White Paper is that risk assessments will be undertaken by industry to support the requirement to register chemicals under REACH. It is estimated that up to 170,000 substances may require registration (Risk and Policy Analysts, 2002). Although guidance on the principles of risk assessment is available (European Commission, 1996), it is too complex to be realistically applicable to such a large number of substances within such a short period of time. Thus all stakeholders are keen to identify scientifically rigorous approaches that can evaluate the health and environmental risks of a substance and which are not resource intensive.

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**Fig. 2.** The CEFIC exposure management system (CEMAS).
ECETOC has approached the risk assessment challenge of REACH by adopting control banding concepts, but applying them in a tiered and selective manner, in order to evaluate the broader risks presented by substances (ECETOC, 2002). Figure 3 illustrates the basic elements of the ECETOC approach as it applies to the workplace. The first level (Tier 0) is a simple risk matrix that is intended to screen out those substances that present no immediate risk to man or the environment and which do not therefore represent a priority under REACH. The basis for categorizing the hazard potential is similar to that used in existing control banding approaches (Chemical Industries Association, 1993; Health & Safety Executive, 1999), but extends to both human and environmental end-points. The emissions potential is a descriptor of the overall likelihood of human or environmental exposure. Thus at the Tier 0 level, only low hazard materials with limited emissions, e.g. chemical intermediates or substances in matrices, are identified as being of low concern.

The subsequent level (Tier 1) again uses control banding concepts to evaluate the risks that are likely to occur in a range of common use scenarios. The aim of this Tier is to identify those uses of a substance that might constitute a concern, in order that these can be examined in greater detail at the Tier 2 level. At the Tier 1 level, the likely occupational uses of the substance (including preparations containing it) are identified from a checklist that describes where the substance might be encountered in industry. Estimates of exposure are then automatically generated for each scenario using the EASE exposure model (European Commission, 1996) and by reference to standard default assumptions for that scenario. The exposure estimates are compared with the generic OEL for the hazard category of the substance to derive a margin of exposure (MoE) for each scenario. The basis for the derivation of the specific generic OELs used in the ECETOC approach has been a detailed comparison of the basis for the hazard category with how substances with equivalent effects have been assigned OELs under various recognized OEL systems. The magnitude of the MoE determines whether the use will proceed to a Tier 2 assessment and the relative importance of different scenarios. A similar approach is also used to evaluate the risks arising from consumer exposures to chemicals.

The Tier 2 evaluation follows the risk assessment principles laid down by the EU (European Commission, 1996) but with a greater degree of targeting to uses identified as being of potential concern. The step allows for the incorporation of further exposure or effects data. The output of Tier 2 is either a refined risk assessment that demonstrates that the use is of low concern or an indication that further risk reduction measures need to be implemented prior to registration of the substance for such a use under REACH.

The ECETOC approach uses a tiered approach to target effort at those scenarios where risks are potentially elevated and require a more detailed evaluation. It utilizes control banding concepts in the screening
Initially outlined within existing regulatory schemes, the approach outputs are the concepts with those that already operate within stages (Tiers 0 and 1) of the approach. By aligning the concepts with those that already operate within existing regulatory schemes, the approach outputs are consistent with prevailing legislative expectations.

**DISCUSSION**

Control banding concepts have now been applied to a variety of approaches used to assess the risks arising from the workplace use of chemicals. From simple risk matrices, based in part upon the limited opportunities for exposure control in a defined setting, the approaches have now been developed into forms where their application is widespread. There now exist a range of schemes that are intended to address workplace and related risks. And some of these schemes are aimed at similar workplaces.

The European chemical industry has also recognized the many benefits of control banding. Approaches now exist that attempt to provide simple and coherent guidance throughout the chain of responsibility of chemical manufacturers and suppliers. Some of the recent developments also provide opportunities for targeting information to help SME users of chemicals manage risks and track performance more effectively.

Although some of the schemes appear to have undergone limited validation, either during their development or immediately consequent to their implementation, this is by no means universal. While several commentators have pointed out the merits of the schemes in terms of their relative simplicity for users, and this aspect has been reinforced in some surveys of users (Hay, 2000; Witana, 2001), no systematic evaluation of the actual impact and effectiveness of the schemes has been undertaken. As the major driver for the COSHH essentials scheme was the apparent failure by SMEs to understand and use OELs (Topping et al., 1998), the lack of post-implementation verification is perhaps surprising.

A period of reflection and critical evaluation would therefore appear to be advisable. It is clear from those surveys that have been undertaken of users that control banding approaches have a number of major attractions. However, there are shortcomings, not least in the fact that their simplicity, in some cases, necessarily simplifies what are often complex issues. Such a validation would be advisable in all areas where the approaches are intended for use, including their role in developing economies.

**CONCLUSIONS**

The value of generic approaches for the assessment of workplace health risks is now widely recognized. A number of schemes have been developed in recent years that seek to provide simple, targeted advice for various industrial sectors. More recently, a number of initiatives have sought to extend the basic principles of control banding in order to support the chemical industry’s wider responsibilities for the safe manufacture and supply of chemicals.

The potential utility of approaches using control banding is obvious. The underlying concepts are easy to understand and the outputs offer practical advice that is capable of being effectively translated into real action at the workplace level. However, no systematic assessment has been undertaken of the impact that control banding approaches have had on the management of risk at the workplace or other levels. Thus, in terms of future developments in the area, it would appear that before further refinements are considered, there needs to be an extensive and systematic evaluation of the uptake and impact of a number of the key approaches. Following on from such an exercise, it ought to be possible to identify where, if at all, the approaches need further development, including possible consolidation.

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