Ann. Occup. Hyg., Vol. 55, No. 5, pp. 451–464, 2011

doi:10.1093/annhyg/mer022

Commentary

Generic Exposure Scenarios: Their Development, Application, and Interpretation under REACH

CHRIS MONEY[1]*, ALISON MARGARY[2], DOOK NOIJ[3] and KEES HOMMES[4]

[1]ExxonMobil Petroleum and Chemical, Hermeslaan 2, Machelen 1831, Belgium; [2]Shell International Ltd, Shell Centre, London, SE1 7NA, UK; [3]Dow Benelux B.V., P.O. Box 48, 4530 Terneuzen, Netherlands; [4]LyondellBasell Industries, Weena 737, 3013 Rotterdam, Netherlands

Received 15 December 2010; in final form 13 March 2011; published online 6 May 2011

The European Union Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) Regulation (EC 1907/2006) places significant new obligations on the manufacturers or importers (M/Is) of chemicals in Europe. It also places new responsibilities on downstream users (DUs) of these chemicals i.e. those that purchase and use chemical products. In particular, for registered classified substances, the M/I is expected to communicate how any substance can be safely used without risk to man or the environment. This communication is in the form of an exposure scenario (ES), which is included in an Annex to the REACH extended safety data sheet. DUs then have certain obligations relating to adopting the control conditions described in the ES. The REACH Technical Guidance Documents lay down the expectations for the process of risk assessment that M/Is should adopt when developing ESs. But with many thousands of chemicals in daily commerce, it is also necessary to ensure that what is communicated to DUs not only meets the requirements of REACH but is also understandable to these groups, as well as being consistent across different chemical suppliers and supply chains. In cooperation with relevant DU groups, the European solvents industry has developed generic approaches for describing how solvents are commonly used, in order that these can subsequently be used as the basis for REACH registrations and related safety data sheet communications on health risk control. The utility of these approaches (termed 'generic exposure scenarios') is acknowledged under REACH and they are now publicly available for use both by M/Is and DUs.

Keywords: exposure assessment; exposure scenario; REACH; risk communication

INTRODUCTION

The Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) Regulation (EU, 2006) was introduced by the European Union (EU) in response to the view that the previous system of chemicals regulation was of limited success, as witnessed by the rate at which regulatory risk assessments had been completed and subsequent interventions made on the marketing and use of these chemicals (Christensen *et al.*, 2003; Van der Wielen, 2007). The previous system of chemicals regulation placed the primary responsibility on Member States to identify chemical risks of concern. One of the fundamental changes brought about by REACH is the requirement on industry to demonstrate that chemicals can be used safely (with respect to safety, health, and environment) across all their identified uses. These obligations are reflected in the broad registration requirements for chemicals under REACH and, particularly so, for those substances classified as hazardous. The REACH Regulation is extensive in its expectations for industry, whether this be

*Author to whom correspondence should be addressed.
Tel: +32(0)2 722 4230; fax: +32(0)2 722 3810;
e-mail: chris.money@exxonmobil.com

manufacturers or suppliers of chemicals, or the ultimate users of these products [or downstream users (DUs) as they are described under REACH]. The broad requirements of REACH have been extensively described elsewhere (van Hemmen, 2009; Williams *et al.*, 2009). However, for those groups who are expected to assess and manage health risks, the most relevant provisions are those that relate to how a REACH registrant fulfills their substance registration obligations in health risks; notably, the registrant [whether a manufacturer or importer (M/I) of a substance] has the responsibility to demonstrate the safe use of the substance throughout its life cycle, i.e. covering manufacture, distribution, formulation, and subsequent uses, including product recycling. The process that REACH lays down for demonstrating safe use is the chemical safety assessment (CSA; for list of abbreviations, see Table 1). Within the CSA, the uses of the substance are described in a series of exposure scenarios (ESs). The ES is the mechanism used to characterize the nature of risks (whether health, environmental, or safety) within any circumstance of use (Marquart *et al.*, 2007). Although REACH does not specify how an ES is developed, it is addressed within the supporting technical guidance. However, the Regulation does require that, for substances with a hazard classification as 'dangerous', the ES is communicated in an Annex to the safety data sheet (SDS) for the substance (which is then subsequently described as the extended safety data sheet, ext-SDS). The process of REACH registration requires different M/Is with a common interest in a substance to come together to determine the hazards of the substance and how it ought subsequently to be handled. For many substances, there are likely to be lots of uses linked with a substance and which can occur in a variety of sectors of industry. Within this context, there are clearly potentially hundreds of ESs associated with some commodity substances. Also, because the CSAs/ESs are expected to be independently developed by different industry groups in different supply chains, there is further potential for the ESs to be different (in terms of how they evaluate and communicate risks) between different supply chains.

The challenges that REACH has laid down for industry have been widely discussed (Rudén and Hansson, 2010; Schoeters, 2010). Most of this discussion has addressed those issues that affect registrants under REACH, i.e. M/Is of chemical substances. However, REACH also places significant new responsibilities on DUs of chemicals, i.e. those that purchase and use chemical products. During the initial (pre-registration) phase of REACH, DUs were encouraged to act with their suppliers and trade groups to ensure that the M/I's of their substances were aware of their uses and would commit to continue to support the use of the chemical under REACH. However, once the (classified) substance is registered, then the M/I is expected to communicate, in the form of an ES, the outcome of the CSA to the DU in the Annex of the REACH ext-SDS. This REACH SDS is both of a different format and content to that which prevailed under the previous EU regulatory regime (EC, 1991). Perhaps of most note, DUs now have a legal obligation under REACH (under Article 37) to follow the advice contained within the ES or, if not, to either develop their own DU CSA or to request a revised ES from their supplier (ECHA, 2008a). This approach to the communication of health risks differs to the previous regime where the information contained within the SDS was advisory. Therefore, it is clearly in the interests of the whole chemical supply chain that not only are chemical manufacturers aware of all the uses of their products but also that they evaluate the associated risks in a manner that is not only compliant with REACH but also consistent between substances across different supply chains. It is equally important that the outcome of this process, i.e. the SDS and its associated ES, is developed in a manner that is understandable and relevant for any DU.

The solvents industry recognized that achieving these aims required a partnership between chemical manufacturers and suppliers and DUs and initiated a series of activities. This process was led by the manufacturing trade group European Solvents Industry Group (ESIG) and supported by a platform of over 30 DU groups having major interests in the use of solvents [termed European Solvents Industry Platform (ESVOC)]. The activities aimed to:

1. ensure that solvent manufacturers and suppliers would be able to meet their REACH obligations in an efficient manner,
2. meet the specific expectations of DUs, i.e. consistency in the manner in which risks are evaluated and communicated across supply chains, and
3. ensure that the work products were understandable and relevant for DUs and consistent with other current regulatory advice in these areas.

The activities were expected to cover the risks experienced by workers, consumers, and the environment. This paper addresses only those activities affecting workers.

Table 1. Selected list of REACH abbreviations and acronyms

Acronym	Description and explanation
CE	COSHH essentials: the UK Health and Safety Executive scheme for providing advice on the control of chemical risks.
CEFIC	European Chemical Industry Council: the trade group of the European chemical industry.
CHESAR	Chemical safety assessment reporting: the ECHA tool for developing CSAs/ESs under REACH.
CMR	Carcinogenic, mutagenic, or reprotoxic: the health drivers affecting whether a substance is considered an SVHC (and which is a wider definition than used under the Carcinogens Directive).
CSA	Chemical safety assessment: part of the registration process and which, for a classified substance, includes an assessment of exposure and characterization of risk.
CSR	Chemical safety report: the document supporting the registration of a substance. Many elements of the CSR are published by the ECHA.
DNEL	Derived no effect level: defined by REACH as the level of exposure above which humans should not be exposed.
DMEL	Derived minimum effect level: are applied to SVHCs and are intended to represent levels where the associated risk (of contracting the disease) is considered to be very low.
DU	Downstream user: the term used in REACH that refers to users of chemicals 'downstream' from the point at which the substance is manufactured or imported, e.g. a supplier's customers.
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemicals: the scientific organization, funded by industry, that addresses how chemical risks should be evaluated and controlled.
ECHA	European Chemicals Agency: the Agency established in Helsinki to oversee REACH.
ES	Exposure scenario: addresses the set of conditions (OCs and RMMs), covering the substance life cycle, that describe how the substance should be safely handled to prevent unacceptable risks to man or the environment.
ESR	Existing substances regulation: the regulation that applied to the marketing of chemicals prior to the introduction of REACH.
ESIG	European Solvents Industry Group: the European trade group for solvent manufacturers and suppliers.
ESVOC	European Solvents Industry Platform: the organization established in Europe that brings together solvent manufacturers and users.
Ext-SDS	Extended safety data sheet: a safety data sheet (most likely for a classified substance) where relevant ESs are included an Annex to the SDS.
GES	Generic exposure scenario: the termed applied to how broad uses of chemicals have been described and grouped (by M/Is and DUs) in a manner that is relevant for REACH.
M/I	Manufacturer or importer: the term used in REACH to describe those with the primary duty to register substances.
OC	Operational condition: the UD that describes the boundary conditions on the use (if any) required to reduce exposures to acceptable levels, e.g. exposure duration.
PBT	Persistent bioaccumulative and toxic: a term used within REACH to describe environmental properties that would require the substance to be considered an SVHC.
PROC	Process category: the UD that helps DUs better understand the scope of activities covered by any identified use of the substance.
REACH	Registration, Evaluation, Authorization, and Restriction of Chemicals Regulation.
RCR	Risk characterization ratio: the term applied by REACH to determine 'safe use' (RCR of <1) and defined as the ratio of the predicted exposure to the reference value (DNEL, etc.).
RMM	Risk management measure: the UD that describes the form of control (if any) required to reduce exposures to acceptable levels (for the use).
SDS	Safety data sheet: the form and content of the SDSs under REACH is laid out in Annex II of REACH.
SU	Sector of use: the UD that describes the type of industry where a substance may be used.
SVHC	Substance of very high concern: the REACH term applied to substances that are CMRs, PBTs, or vPvBs.
TGD	Technical Guidance Document: the documentation developed by ECHA to describe how M/Is, ECHA, and the Member States are expected to be fulfill their various REACH obligations.
TRA	Targeted risk assessment: the term used by ECETOC and REACH to describe the process for determining when 'higher level' (more detailed) CSAs are necessary to demonstrate safe use.
UD	Use descriptor: the term applied to a series of different descriptors that are applied to ESs to help DUs better understand them.
vPvB	Very persistent very bioaccumulative: a term used within REACH to describe environmental properties that would require the substance to be considered an SVHC.

PROJECT AIMS

An extensive body of TGD has been developed by the European Chemicals Agency (ECHA), in consultation with various stakeholders (member states, industry, trade unions, and various non-governmental organizations) in order to ensure that the basic technical expectations of the Regulation are applied with good science (ECHA, 2010c). The TGD is comprehensive and detailed. For example, the Guidance that shapes how CSAs/ESs are developed and communicated (the Guidance on Information Requirements and CSA) totals 25 sections and extends to 2200 pages. The Guidance specifies terminology and lays out structures and processes which industry, as well as other bodies, including regulatory agencies, are expected to follow in order to meet their obligations within the many facets of REACH. Much of the guidance is an extension of that which prevailed under the previous Existing Substances Regulation (ESR) as the inherent scientific structures that supported that piece of legislation were felt to be robust, even though the rate at which ESR risk assessments were developed was considered slow (Munn and Hansen, 2002; Bodar *et al.*, 2003). If the ESR experiences were extrapolated to REACH, then the CSA and any supporting documentation could be expected to extend to several hundred pages. Such an expectation may be appropriate in a process requiring transparency, technical oversight, and scrutiny at the regulatory level. But communicating the outcome of that process in a manner that enables DUs to be in a position to identify key actions required on their part represents a challenge that was not directly considered by the authors of REACH.

To make REACH a success, a number of potentially competing interests need to be balanced and fulfilled. Industry must successfully register its substances for all the types of uses that have been identified, consistent with the expectations that REACH lays down for M/Is, so that industry can legitimately continue supply. And DUs must be in a position to respond to any new information contained within REACH ext-SDSs when these have been received. Moreover, when seen across the tens of thousands of chemical substances that are expected to be regulated under REACH, there is a need to foster efficient work processes that serve to benefit chemical suppliers, their customers and the other REACH stakeholders. Recognizing that this objective would probably not be achieved unless an appropriate activity was initiated before the registration of affected chemical substances, ESIG established a small task group with the following aims:

1. to describe common uses of solvents in a manner that is consistent with the expectations of REACH, that is understandable for DUs of solvent products and which aligns with current industry practice and regulatory advice in the area,
2. to test the approach to ensure it meets the expectations of DUs of solvent products and the expectation of regulatory agencies, as well as the obligations of chemical manufacturers,
3. to structure the descriptions so that they communicate clearly what was intended when the solvent was registered, and
4. to describe the approach using standard phrases, in order that the guidance can not only be incorporated into SDS systems but such phrases can also be used and applied by other sectors of industry.

While REACH places an obligation on the chemical manufacturer to undertake a CSA for any classified substance as part of its registration, undertaking a health risk assessment is not a new concept for health professionals. Indeed, the requirements to undertake workplace health risk assessments extend back over many years. For example, occupational exposure limits (OELs) of various forms have now been available for over 50 years (Henschler, 1984; Rappaport, 1993) and their derivation is a sort of CSA. More recently, generic systems of risk assessment such as those associated with control banding concepts have been developed and are now being actively applied (Money, 2003; Zalk and Nelson, 2008). These approaches use also risk-based approaches to propose controls and the experience can inform the CSA process under REACH.

STRUCTURE AND CONTENT OF GESs

The REACH guidance is both extensive and detailed in its requirements for how any CSA is undertaken (ECHA, 2010c). In essence, any use of a substance is expected to be described in a manner consistent with the nomenclature contained within the REACH use descriptor (UD) system, the likely exposures associated with the use must then be determined, and any necessary exposure controls (whether procedural or engineering) identified commensurate with the need to reduce exposures to below the relevant exposure control value [which is defined within REACH as the derived no effect level (DNEL)]. Conceptually, this process is straightforward and will be familiar to workplace health professionals; job or task-related exposures are compared against an appropriate health-based Reference Value

in order to judge the acceptability of the risk. However, there are lots of uses of many chemicals, resulting in the potential for several hundred permutations of UDs, which could be applied to these. Such an approach could be heavily bureaucratic, and a DU would most likely find it difficult to readily identify and understand the relevant use among the hundreds potentially listed in the ext-SDS. It was therefore apparent that a more efficient approach was required if the nature of the information on safe use that is intended to be contained within the ext-SDS was to be available for use by chemicals M/Is in their Phase 1 (2010) registrations.

Benefiting from some of the sector-based discussions that have taken place in the development of the UK Control of substances hazardous to health (COSHH) Essentials control banding scheme on how uses are described and communicated, such as the COSHH Essentials schemes for silica, welding, agrochemicals printing, etc. (HSE, 2010), ESIG worked with DU trade associations within ESVOC to identify and describe the broad uses of solvents in a manner that is relevant for REACH. A total of 22 uses have been identified covering a total of 32 areas of use (describing either industrial and/or professional applications). Some of these generic exposure scenarios (GESs) are listed in Table 2. Each title describes a common area of use of solvents within industry. The title is described in layman's terms (including colloquial terms for certain industry sectors) as well as reflecting a consensus amongst the supplier and user groups concerning the application of relevant associated REACH UDs. As described earlier, in order to meet the objectives of REACH, it is necessary for the chemical's M/I to demonstrate as part of the CSA that the substance can be safely used in each identified use. To accomplish this, REACH requires that a CSA is undertaken for affected substances and that the safe use (which is determined by reference to the risk characterization ratio, RCR, for the use) is communicated in an ES.

The process for the development of each GES, therefore, follows the expectations of the REACH TGD, i.e. it characterizes the use in the terms required under REACH, including likely associated (inhalation and dermal) exposures and then identifies the necessary exposure control conditions [which are described under REACH as either operating conditions (OCs) or risk management measures (RMMs)] required to successfully control exposures to within defined exposure bands. However, contrary to using a starting assumption that no exposure controls (beyond those described by the relevant UDs) are implemented during the use of chemicals, the GESs use the nature of typical existing controls for the use as their start point. This then enables, as a key output of the CSA, a distinction to be made between those controls which are apparently a direct requirement of REACH (i.e. those necessary to reduce exposures to less then any DNEL) and those that constitute good exposure control practice for the sector. Thus, this step enables an M/I not only to meet their REACH obligations but also to supplement these via appropriate product stewardship activities.

Many of the key elements of the GESs represent an extension of previous industry initiatives (CIA, 1993; ABPI, 1995; RSC, 1996). That is, the GES describes a defined set of exposure control conditions that are appropriate for a certain risk range or band (which is, in turn, described by a combination of the substance's volatility and DNEL/OEL range). Thus, the approach is applicable not only for different uses of solvents but also for different classes of solvents, e.g. hydrocarbon, oxygenated, halogenated, etc. Two aspects, however, represent a significant departure from previous initiatives in this area:

1. The development of the GESs represents a partnership of chemical suppliers and their customers. This is intended to ensure that the descriptions of the chemical risks and the requisite controls solutions are understandable to DUs and the manner of communication is likely to be consistent across different solvent supply chains. Clearly, the need for consistency in the manner in which risks are evaluated and communicated by solvent suppliers is of paramount importance for DUs. It not only provides an assurance regarding the provenance of the information received but is also in a language that is likely to be understandable, including reference to control terminology that is familiar to the sector.
2. The GESs are described using standard phrases. The reason for this is simple; ESs are required to be incorporated within SDSs, and SDSs must be available in all 27 of the European community languages. Therefore, any system, which is reliant on free text descriptions, is not amenable to manipulation within current SDS technologies. What is different between the standard phrases used to characterize much of the GES, and those that typically are used elsewhere in the SDS, is that the GES phrase is a reflection of the expected exposure reduction that the identified RMM would be expected to deliver. The ESIG GESs use the European Centre for Ecotoxicology and Toxicology of Chemicals Targeted Risk

Table 2. Indicative GES titles for solvents

Title of GES[a]	Principle areas of application	Scope of the GES[b]	Relevant REACH UDs	
			Sector of use (SU)	Process category (PROC)
Manufacture	Industrial	Manufacture of the substance or use as an intermediate or process chemical or extraction agent. Includes recycling/ recovery, material transfers, storage, maintenance, and loading (including marine vessel/barge, road/rail car, and bulk container).	3	1, 2, 3, 4, 8a, 8b, 15
Formulation and re-packing	Industrial	Formulation, packing, and re-packing of the substance and its mixtures in batch or continuous operations, including storage, materials transfers, mixing, large and small scale packing, equipment cleaning, and maintenance.	3	1, 2, 3, 4, 5, 8a, 8b, 9, 15
Use in coatings	Industrial, professional	Covers the use as a component of cleaning products including transfer from storage, pouring/unloading from drums, or containers. Exposures during mixing/diluting in the preparatory phase and cleaning activities (including spraying, brushing, dipping, wiping, automated, and by hand), related equipment cleaning, and maintenance.	3, 22	1, 2, 3, 4, 5, 7, 8a, 8b, 10, 13
Use in oil and gas field drilling and production operations	Industrial, professional	Oil and gas field well drilling and production operations (including drilling muds and well cleaning) including material transfers, on-site formulation, well head operations, shaker room activities, and related maintenance.	3, 22	1, 2, 3, 4, 8b, 9, 10
Lubricants	Industrial, professional	Covers the use in lubricants in closed and open systems including transfer operations, operation of machinery/ engines and similar articles, reworking on reject articles, equipment maintenance, and disposal of wastes.	3, 22	1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 13, 17, 18
Metal working fluids and rolling oils	Industrial, professional	Covers the use in metal working fluids/ rolling oils including transfer operations, rolling and annealing activities, cutting/ machining activities, automated and manual application of corrosion protections (including brushing, dipping, and spraying), equipment maintenance, draining, and disposal management of waste.	3, 22	1, 2, 3, 5, 7, 8a, 8b, 9, 10, 13, 17, 18
Road and construction applications	Professional	Application of surface coatings and binders in road and construction activities, including paving uses, manual mastic, and in the application of roofing and water-proofing membranes.	22	5, 8a, 8b, 9, 10, 11, 13
Use in laboratories	Industrial, professional	Use of the substance within laboratory settings, including material transfers and equipment cleaning.	3, 22	10, 15

[a]Titles may be abbreviations of full title. Refer to web page of supplier trade group for full list of titles.
[b]Scope statement only refer to industrial uses, unless GES only available for professionals. Statements for professional uses may differ slightly.

Assessment (ECETOC TRA model (ECETOC, 2009) as the basis for the underlying exposure predictions. This is consistent with the advice given within the REACH Guidance (ECHA, 2010b). For solvents, the TRA exposure predictions align well with actual exposure data on solvents, i.e. they are generally over predictive of and rarely under predictive of current exposure experiences within the industry (TNO, (unpublished report)). As the ECETOC TRA is a model which is dependent on only comparatively few exposure variables for its operation, then it has

been possible to develop phrases that are consistent with the exposure control conditions described within the TRA, but which, more importantly, are in a language that is understandable to DUs of solvents. Table 3 gives examples of some of these phrases together with their relationship to TRA exposure determinants. Over 130 phrases have now been developed within industry in order to effectively communicate the required exposure control conditions (RMMs and OCs) for the various uses of solvents and different forms of exposure controls encountered in these situations. This catalog of standard phrases, together with their associated exposure reduction efficiencies has now been incorporated into European phase catalogue of the library of REACH SDS standard phrases administered by the Bundesverband der Deutschen Industrie, Federation of German Industries (BDI, 2010). The phrases address both inhalation and dermal risks (ingestion is not considered a relevant exposure route for solvents). They also extend to circumstances of use that exist within consumer uses of solvents (although this aspect is not addressed in this paper).

PROCESS FOR THE USE OF GESs

The overall value and role that GESs play in helping to communicate REACH required information within supply chains has been acknowledged not only within the chemical industry (CEFIC, 2009) but also by ECHA (ECHA, 2008b). Specifically, the European Chemical Industry Council (CEFIC) guidance for CSA development foresees the GES occupying a central role for different substance trade groups as it serves to facilitate efficient and consistent communication on risks for similar substance types to different DU groups. For this reason, further GESs (beyond those listed in Table 2) have now been developed by various industry groups, and a 'web portal' exists at CEFIC to facilitate entry to these (CEFIC, 2010). Although this is essentially aimed at companies needing to register their substances, the portal is also a useful resource for DUs (such as formulators of preparations) wishing to access and apply the information.

The most comprehensive activity, however, remains that initiated by the solvents sector (ESIG, 2010). Its work products reflect those outlined in Table 2, i.e. a listing of available GES titles, their description in REACH UD terms, a mapping of use and

Table 3. Examples of standard phrases for use in developing and describing ESs

Standard phrase	European phase catalogue code	Assigned exposure reduction efficiency (%)	Comments
Emission			
Avoid carrying out activities involving exposure for >1 h	OC27	80	Only applies to exposures to substances exhibiting chronic (time-weighted) effects
Limit the substance content in the product to 25%	OC18	40	Phrase aimed at formulators and where exposure reduction linked to ECETOC TRA
Transmission			
Provide a good standard of general ventilation (not <3–5 air changes per hour)	E11	30	Exposure reduction consistent with published values (e.g. HSE, 2008)
Fill containers/cans at dedicated fill points supplied with local extract ventilation	E51	80/90	Assigned exposure reduction differs dependent on sector of use (and aligns with TRA defaults for professional and industrial use, respectively)
Handle within a fume cupboard or implement suitable equivalent methods to minimize exposure	E12	90	Exposure reduction consistent with published values (e.g. HSE, 2008)
Sample via a closed loop or other system to avoid exposure	E8	95	Only intended to be applied to industrial settings
Immission			
Wear a respirator conforming to EN140 with Type A filter or better	PPE22	90	Exposure reduction intended to reflect likely actual protection factor (APF)
Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training	PPE16	90	Exposure reduction intended to reflect combined effects of likely APF and training

control conditions typically encountered in the sector, generic CSAs for different volatility ranges, and resulting ESs for each use that differentiate the exposure controls/RMMs likely to be required under REACH, from those measures that might also be conveyed as part of a supplier's broader product stewardship communications. All the major work products are then made available via a GES 'library'. In the first instance, the libraries have been aimed at REACH registrants in that they serve as an information source that enables 'ready made' CSAs to be identified and evaluated with respect to their adequacy for REACH registration purposes. Hence, their primary purpose is to serve as an efficient start point when seen across registrants and supply chains that also provides the basis for consistent CSA evaluations and subsequent SDS communications. However, the libraries also serve as a resource for other groups with an interest in the management of workplace chemical health risks, e.g. formulators, DUs, and workers themselves.

Figure 1 outlines the process that is intended to be applied within industry for using GESs:

1. The start point is to determine the volatility and relevant DNELs for any substance. The volatility is defined in a manner consistent with the ECETOC TRA (ECETOC, 2009). Any DNEL is likely to have been derived as an outcome of the hazard assessment for the substance and in a manner consistent with the guidance offered in chapter R8 of the TGD.
2. The uses of the substance must be identified. This will be a process that uses both market information available to the supplier, together with responses from customers and other DUs resulting from supply chain communication activities.

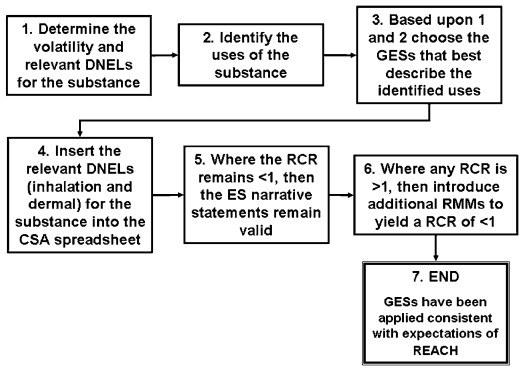


Fig. 1. How chemical manufacturers and suppliers should use GES libraries.

3. Based upon 1 and 2, the relevant GESs are chosen that best describe the known uses of the substance. The availability of GESs is shown within the library index.
4. For each use, the relevant (inhalation and dermal) DNELs for the substance are then inserted into the CSA template sheet (which is written in Microsoft™ Excel®). Once this step is completed, the sheet will auto-calculate the RCR for each of the contributing scenarios that describe the situations associated with handling the material that potentially gives rise to exposure.
5. Where the RCR remains <1, then the narrative statements (and which address the OCs and RMMs) associated with the GES remain valid, i.e. because the GES already represents a set of conditions that manage risk to an acceptable level, then providing the RCR remains <1, the suitability of the assigned phrases can be considered to have been verified. Since the GES is developed using DNEL bands, it is also advisable to determine whether it is appropriate to select alternative (and possibly less stringent) OCs and/or RMMs for the scenario, while ensuring the RCR still remains <1.
6. In those circumstances where the RCR is >1, then the user will need to implement additional RMMs (or more stringent OCs) to ensure that associated exposures are reduced such that the RCR is <1. In those instances, the associated ES will also need to be (manually) amended to ensure that any additional RMM or OC changes are also reflected in the narrative ES.
7. On completion of steps 1 to 6, users can consider that the GESs have been applied to the CSA process in a manner consistent with REACH, i.e. the GES serves a start point, but where, in line with the REACH Guidance (ECHA, 2008b, 2010a) the resulting CSA/ES has been refined and customized by reference to the specific characteristics of the substance being evaluated. The associated revised files then also form the basis for information that is be required to be contained within Sections 9 and 10 of any Chemical Safety Report for the substance.

DISCUSSION

Although an extensive number of GESs have now been developed, it is important to understand their limitations. First, they have been developed as a mechanism that aims to ensure that the obligations that chemical manufacturers and suppliers have under REACH to undertake an assessment of relevant

uses can be executed in a manner aligned with the expectations of the REACH guidance and communicated in an understandable manner to DUs. As a consequence, by their very nature, the GESs are 'generic'; they paint a picture of how solvents (or other materials) should be handled within an assumed typical workplace. The extensive consultation that has taken place with DUs during their development helps ensure that the GES will be practically valid across a wide range of workplaces. But there will always be exceptions.

Second, the approach uses the ECETOC TRA tool as the basis of the exposure predictions within the CSAs that are at the heart of each GES. The ECETOC TRA is based on an extension to the EASE model (ECETOC, 2004; Money *et al.*, 2007). The limitations of EASE have been well documented (Creely *et al.*, 2005). However, the updated TRA (ECETOC, 2009) has extensively revised the associated EASE predictions in order to develop exposure estimates that both better align with the expectations of REACH and represent more accurate exposure estimates for any scenario described by the REACH UD system. Furthermore, the revised TRA now applies EASE within the broader context of the source receptor approach to exposure modeling (Cherrie; Schneider, 1999), that is account can now also be taken of imission pathways as well as the emission and transfer pathways included in the original version. Any resulting exposure estimates are only as accurate as the extent to which the base model (in this case the TRA) has been validated. Beyond the work undertaken by ECETOC in refining the EASE estimates, only one (limited) independent comparison of the TRA has been undertaken, although for solvent-like materials the outcome demonstrated a generally good correlation with 'real exposures' and a clear tendency toward estimated exposures higher than those observed (TNO, [unpublished report]). The TRA has not been validated for gases or aerosols, however. Therefore, where co-exposures of this type exist, then other approaches to exposures estimation may be useful to consider such as the application of the prediction models of the EMKG (BAuA, 2010), COSHH essentials (HSE, 2009), StoffenManager (Marquart *et al.*, 2008; Arbo Unie, 2010), or the Advanced REACH Tool (Fransman *et al.*, 2009).

The experiences of using the GESs to date have been very positive. Currently, over 150 GESs are available for different workplace uses of different types of solvents (CEFIC, 2010). GESs are also available from other sector organizations that describe uses of other solvent-like materials, e.g. polymerization processes, use of blowing agents, and resin-based adhesives. The experience has also helped shape the manner in which supporting product stewardship information on the products and their uses can be better targeted to users of the substances. Figure 2 highlights this capability. It shows that:

1. GESs (such as those listed in Table 2) can be expected to be available for different classes (volatility ranges) of solvents. Within ESIG, three volatility ranges have been applied reflecting those described in the ECETOC TRA model (and covering high, moderate, and low volatilities). For solid substances, the classes are likely to reflect their dustiness, e.g. as described in the TRA or by COSHH Essentials.
2. GESs are likely to have been developed for different DNEL combinations that reflect relevant exposure routes (inhalation and/or dermal) for the use. For visual simplicity, Figure 2 only refers to inhalation exposures.
3. Generally, the GES will have been developed for exposure to the 'pure' (100%) substance. But for some uses, GESs may have also been further refined to account for the likely presence of the substance within simple formulations. In certain instances (as indicated by the GES reference numbers), the exposure control conditions (OCs and RMMs) required to manage the risks arising from the presence of a hazardous substance at a certain concentration level within a preparation might also be expected to reflect those necessary to manage the risks from exposures to higher concentration levels of a less hazardous solvent of a similar volatility.
4. The GESs can differ between industrial and professional uses. This is largely a function of the assumption contained within the REACH Guidance that exposures and exposure controls in non-industrial situations are likely to be different to those in industrial settings.

Figure 2 also demonstrates that for some solvent/use combinations, a GES may be unavailable. For example, the use of some classes of solvents for certain applications may either not be credible (e.g. a low volatility material being used as a propellant or a high volatility material as a binder) or generally unsupported across the industry (e.g. due to considerations of flammability or toxicity). In such instances, if a solvent of that type to be considered for that use, then there would be a need for a specific risk assessment that extended beyond the capabilities of

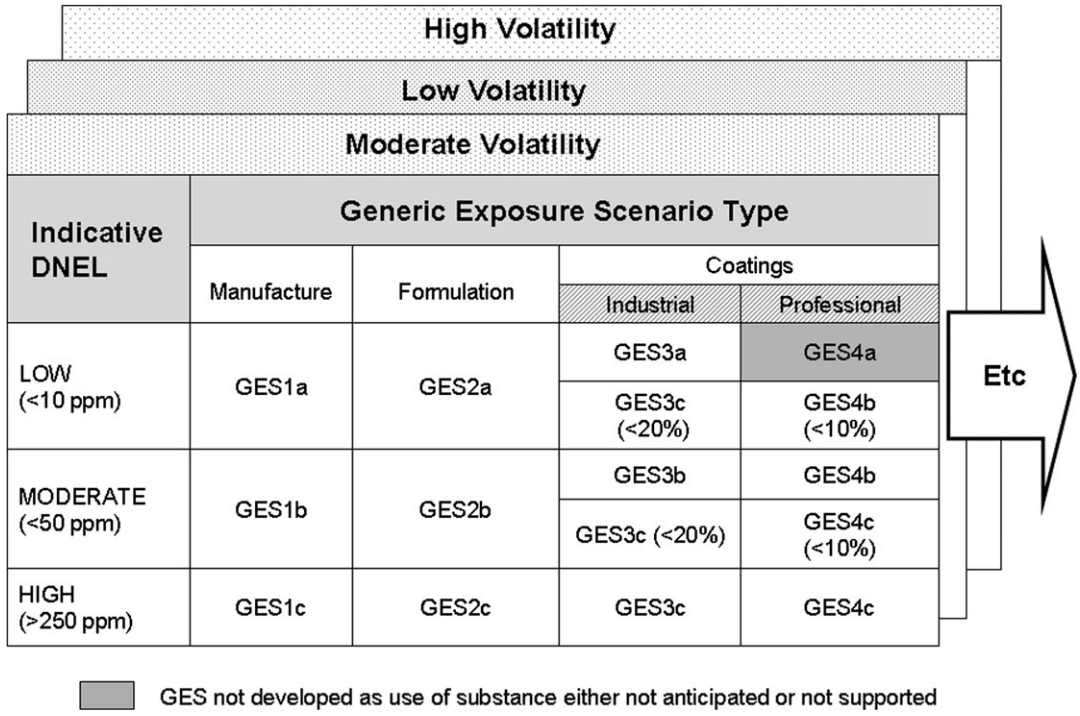


Fig. 2. The structure of GES libraries.

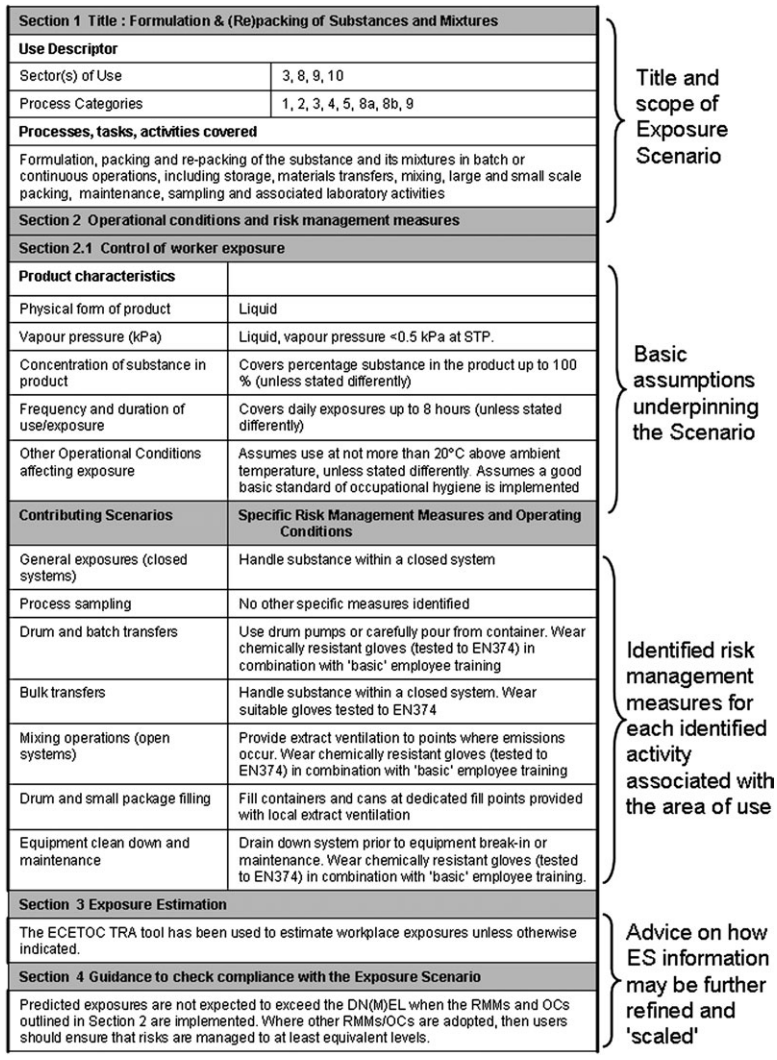
the GES and for which additional targeted product stewardship information is likely to be advisable, e.g. detailing monitoring and control methods, handling precautions, etc. Furthermore, these uses would also expect to be identified in the ext-SDS for the substance.

Although the elements underpinning GESs were initially developed for solvents, they are also likely to be applicable to other substances. For example, the manner in which key uses have been described through dialogue with DUs and their representatives suggests how other groups wishing to evaluate the risks presented from the use of their substances might proceed. In these situations, however, users will as a minimum need to (i) determine whether the volatility ranges are relevant to such materials, e.g. if the material were a solid, then users would need to substitute the exposure predictions contained within the Excel™-files within the library with those resulting from the application of the ECETOC TRA (or other suitable REACH endorsed exposure model) for the substance properties of interest and (ii) to develop suitable exposure control bands consistent with the DNEL ranges used within the ESIG activity. Consideration will also need to be given to the extent to which any GES adequately describes the circumstances of use of the substance and where it is insufficient or inappropriate, then the content within the Excel™ file will need to be refined accordingly.

One important attribute of the GES is the manner in which the outputs are presented as these are required to be communicated (for classified substances) as an Annex to the REACH SDSs. Figure 3 shows how the ES derived from the GES is likely to be communicated to DUs as an outcome of the CSA contained within the registration dossier for the substance.

The following characteristics should be noted:

1. As the GES is intended to represent the output of a generic CSA for a defined set of substance conditions, it is written in format consistent with the expectations of REACH using standard sentences (in order to facilitate ready translation into other languages).
2. The GES describes the range of activities or tasks that are typically associated with the use into a consolidated ES for the use. The associated risks for each of these 'contributing scenarios' are evaluated and, based upon the stated OCs, the required RMMs are identified. Depending upon the use, there may be up to a 15 different



Section 1 Title : Formulation & (Re)packing of Substances and Mixtures		
Use Descriptor		
Sector(s) of Use	3, 8, 9, 10	
Process Categories	1, 2, 3, 4, 5, 8a, 8b, 9	
Processes, tasks, activities covered		
Formulation, packing and re-packing of the substance and its mixtures in batch or continuous operations, including storage, materials transfers, mixing, large and small scale packing, maintenance, sampling and associated laboratory activities		
Section 2 Operational conditions and risk management measures		
Section 2.1 Control of worker exposure		
Product characteristics		
Physical form of product	Liquid	
Vapour pressure (kPa)	Liquid, vapour pressure <0.5 kPa at STP.	
Concentration of substance in product	Covers percentage substance in the product up to 100 % (unless stated differently)	
Frequency and duration of use/exposure	Covers daily exposures up to 8 hours (unless stated differently)	
Other Operational Conditions affecting exposure	Assumes use at not more than 20°C above ambient temperature, unless stated differently. Assumes a good basic standard of occupational hygiene is implemented	
Contributing Scenarios	**Specific Risk Management Measures and Operating Conditions**	
General exposures (closed systems)	Handle substance within a closed system	
Process sampling	No other specific measures identified	
Drum and batch transfers	Use drum pumps or carefully pour from container. Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training	
Bulk transfers	Handle substance within a closed system. Wear suitable gloves tested to EN374	
Mixing operations (open systems)	Provide extract ventilation to points where emissions occur. Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training	
Drum and small package filling	Fill containers and cans at dedicated fill points provided with local extract ventilation	
Equipment clean down and maintenance	Drain down system prior to equipment break-in or maintenance. Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training.	
Section 3 Exposure Estimation		
The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated.		
Section 4 Guidance to check compliance with the Exposure Scenario		
Predicted exposures are not expected to exceed the DN(M)EL when the RMMs and OCs outlined in Section 2 are implemented. Where other RMMs/OCs are adopted, then users should ensure that risks are managed to at least equivalent levels.		

Fig. 3. Structure and content of the ES.

contributing scenarios, e.g. covering material transfers, different application techniques, storage, and maintenance.

3. Broad information that explains the UDs covered by the ES, together with a simple explanation that is more likely to be understandable by the user/customer (and which in turn relates to information required to be contained in Section 1 of the SDS).
4. Basic information that states the assumptions (termed OCs) behind the ES, e.g. detail of the key physicochemical properties and that it covers daily exposures to 100% of the product.
5. Specific RMMs and/or further OCs that are considered necessary to manage the risks for particular activities associated with its area of use, e.g. the use of specific types of extract ventilation or personal protection when transferring or spraying the material, the need for specific forms of sampling when this activity is undertaken, etc. This information covers both the controls necessary to manage both human health and environmental risks.
6. Information that enables the DU to obtain an idea of the likely exposures associated with the use conditions described in the ES. Where the use conditions differ to those described in the ES, information that enables the DU to be able to 'scale' from the ES, i.e. how any DU may be able to determine whether the controls encountered at the local level might be considered to represent something that is equivalent to, better, or worse than those described in the ES.

The net implication of this activity is that the process is now more straightforward and far more efficient then would otherwise be the case. For a typical classified solvent, the SDS under REACH is likely to be ~50–100 pages, when the various ESs associated with the use of that solvent are considered. This compares with ext-SDSs of several hundred pages that would otherwise be the case if the original draft REACH guidance had been followed. Limited testing by industry has shown that, perhaps unsurprisingly, ESs that are communicated in a language that is straightforward and written in a form that aligns with the language commonly encountered within a sector are more likely to be understood and implemented than ESs written to fulfill the needs of regulatory risk assessments. DUs should, therefore, be able to better understand the (technical and procedural) measures necessary to manage the health risks associated with the use of the substance, as these are now described. This is not to say, however, that some users of chemicals will require access to detailed information on the nature of exposures and use. For example, formulators of substances may need to have recourse to this type of information when assessing the nature of the hazards and risks presented by the use of hazardous preparations.

The value of different aspects of GESs is recognized. For example, the Guidance on ES development (ECHA, 2008b) discusses the merits of GESs within the context of the need for coherency and alignment of supply chain communications to ensure that the downstream uses of a substance are effectively addressed within its registration dossier. CEFIC advocates GESs as the preferred basis for the development of the CSAs/ESs for substances in dispersive use (CEFIC, 2009). Finally, the CSA tool now developed by ECHA (and termed CHESAR) also applies many of the core ideas behind the GES (ECHA, 2010a). However, the key test of whether GESs are able to deliver many of their claimed attributes will only become evident following the introduction of REACH ext-SDSs by chemical suppliers and the ECHA/Member State activities aimed at evaluating substance registrations. If ext-SDSs are inconsistent in their form and content across major supply chains, then the potential of GESs will not have been realized. This will also be the case if the level of detail of GES-based CSAs is considered insufficient to reliably describe the risks for associated uses of the substance.

CONCLUSIONS

The introduction of the REACH Regulation will result in a marked increase in the amount of information that is communicated to users of chemicals in order that they are better able to safely use these materials. Specifically, REACH foresees the ES as the mechanism via which safe use information can be communicated to the users of chemicals (as an Annex to the SDSs of classified substances). But the communication of information alone will not necessarily lead to improvements in standards of workplace health and safety. Indeed, the communication of forms of information that are perceived as not relevant or are difficult to understand may be disregarded by the very groups the information is intended to assist (Briggs and Crumbie, 2000). In order to try to minimize the likelihood of this undesirable outcome, industry has sought to identify approaches for assessing and communicating workplace health risks that ensure that the information that is contained in ESs that are likely to be understandable and considered as relevant by DUs. The approach comprises a series of linked activities that, taken together, enable manufacturers and suppliers of chemicals to develop the CSA for their substances and communicate the outcomes (ESs) to their customers in a manner likely to be understood and capable of being processes by IT systems. Together, these are now referred to as GESs. This work has been accomplished through a close cooperation between the manufacturers/suppliers of solvents (who are responsible for many of the main duties under REACH) and representatives of the major DU associations for the affected product types and has now resulted the development of GES libraries for different substance supply chains (such as solvents).

The content of these libraries deliver significant benefits for industry and users of chemicals, not only do they provide an efficient and reliable basis by which the workplace health risks can be consistently evaluated and communicated but because they have been developed in conjunction with DUs, they are written in a manner that is likely most relevant for users of these chemicals. They also serve as a resource for those groups seeking further advice on the control of workplace health risks, e.g. for those substances with later phase-in dates under REACH. Moreover, because the approaches have similarities to existing schemes for evaluating workplace health risks (such as COSHH Essentials and the EMKG scheme of the BAuA) then the advice that is communicated as part of the supplier's SDS may also be expected to complement that which is already be

available from certain regulatory agencies. This is not to say that the introduction of ESs into ext-SDSs will be straightforward. For example, a commercial solvent may typically be associated with between 10 and 15 different industrial uses. This means that there will be a marked increase in the amount of information that is contained within SDSs over historical levels. Current indications are that SDS are likely to increase in size from 10 pages to >50 pages. This step change in the amount of information provided by chemical suppliers will create challenges not only for DUs but also for everyone with an interest in the control of workplace health risks, including occupational hygienists. However, without GESs, which enable consistency in health risk communications both within and across supply chains, the picture would be even more challenging.

FUNDING

The work described has received no research funding but has been developed with secretarial support from ESIG, CEFIC and CONCAWE.

Acknowledgements—The authors wish to thank Tony Newbould, European Council of Producers and Importers of Paints, Printing Inks and Artists' Colours; Sylvie Lemoine, International Association for Soaps, Detergents and Maintenance Products; Johannes Tolls, Association of European Adhesive and Sealant Industries; Marianne Lyngsae, European Association of Chemical Distributors; Reinhard Jacobi, DHC Solvents; Alain D'Haese, European Aerosol Federation, and Jan Urbanus, Shell, for their contributions to the development of many of the concepts and the subsequent population of the ESIG GES library.

REFERENCES

ABPI. (1995) Guidance for setting in-house occupational exposure limits for airborne therapeutic substances and their intermediates. London: Association of the British Pharmaceutical Industry.

Arbo Unie. (2010) Welcome to the Stoffenmanager. Utrecht, Netherlands. Available at: https://www.stoffenmanager.nl/default.aspx. Accessed 16 April 2011.

BAuA. (2010) EMKG EMKG-EXPO-TOOL is part of the 'Easy-to-use workplace control scheme for hazardous substances' (EMKG 'Einfaches Maßnahmenkonzept für Gefahrstoffe'). Available at: http://www.emkg.de/. Accessed 16 April 2011.

BDI. (2010) European standard phrase catalogue. Berlin, Germany: Bundesverband der Deutschen Industrie. Available at: http://reach.bdi.info/380.htm. Accessed 16 April 2011.

Bodar CW, Berthault F, de Bruijn JH *et al*. (2003) Evaluation of EU risk assessments existing chemicals (EC Regulation 793/93). Chemosphere; 53: 1039–47.

Briggs D, Crumbie N. (2000) Characteristics of people working with chemical products in small firms, Health & Safety Executive contract research report 278. Norwich, UK: Her Majesty's Stationery Office.

CEFIC. (2009) Developing generic exposure scenarios under REACH. Brussels, Belgium: European Chemical Industry Council. Available at: http://cefic.org/Industry-support/Implementing-reach/Documents-and-Tools1/. Accessed 16 April 2011.

CEFIC. (2010) Activities relevant to the REACH Libraries carried out by industry associations. Brussels, Belgium: European Chemical Industry Council. Available at: http://cefic.org/Industry-support/Implementing-reach/Libraries/. Accessed 16 April 2011.

Cherrie JW, Schneider T. (1999) Validation of a new method for structured subjective assessment of past concentrations. Ann Occup Hyg; 43: 235–245.

Christensen FM, de Bruijn JHM, Hansen BG *et al*. (2003) Assessment tools under the new European Union Chemicals Policy. Green Manag Int; 41: 5–19.

CIA. (1993) Safe handling of Colorants 2. London: Chemical Industries Association.

Creely KS, Tickner J, Soutar AJ *et al*. (2005) Evaluation and further development of EASE Model 2.0. Ann Occup Hyg; 49: 135–45.

EC. (1991) COMMISSION DIRECTIVE of 5 March 1991 defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 10 of Directive 88/379/EEC (91/155/EEC) (*Official Journal* L76/91) as amended by Commission Directive 93/112/EC of 10 December 1993 (*Official Journal* L314/93).

ECETOC. (2004) Targeted risk assessment. Brussels, Belgium: European Centre for the Ecotoxicology and Toxicology of Chemicals Technical Report No. 93.

ECETOC. (2009) Addendum to ECETOC targeted risk assessment report no. 93. Technical Report No. 107. Brussels, Belgium: European Centre for the Ecotoxicology and Toxicology of Chemicals.

ECHA. (2008a) Guidance for downstream users. Helsinki, Finland: European Chemicals Agency. Available at: http://guidance.echa.europa.eu/docs/guidance_document/du_en.pdf?vers=29_01_08. Accessed 16 April 2011.

ECHA. (2008b) Guidance on information requirements and chemical safety assessment: part D exposure scenario building. Helsinki, Finland: European Chemicals Agency. Available at: http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_part_d_en.pdf.

ECHA. (2010a) CHEmical Safety Assessment and Reporting tool. Available at: http://chesar.eu/. Accessed 16 April 2011.

ECHA. (2010b) Guidance on the different processes and methods under REACH. Helsinki, Finland: European Chemicals Agency. Available at: http://guidance.echa.europa.eu/guidance_en.htm. Accessed 16 April 2011.

ECHA. (2010c) Guidance on information requirements and chemical safety assessment chapter R14 occupational exposure estimation. Helsinki, Finland: European Chemicals Agency. Available at: http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r14_en.pdf?vers=27_05_10. Accessed 16 April 2011.

ESIG. (2010) Guidance on the use of GESs. Brussels, Belgium: European Solvents Industry Group. Available at: http://www.esig.org/en/regulatory-information/reach/ges-library/ges-library-3. Accessed 16 April 2011.

EU. (2006) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission

Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. *Official Journal* L 396, 30.12.2006, 1–849. Available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:396:0001:0849:EN:PDF. Accessed 16 April 2011.

Fransman W, Cherrie J, van Tongeren M *et al*. (2009) Development of a mechanistic model for the Advanced Tool, REACH Tool (ART). Report V8667. Zeist, The Netherlands: TNO. Available at: http://www.advancedreachtool.com/. Accessed 16 April 2011.

Henschler D. (1984) Exposure limits: history, philosophy, future developments. Ann Occup Hyg; 28: 79–92.

HSE. (2008) Controlling airborne contaminants at work: a guide to local exhaust ventilation (LEV), HSG258. London: Health & Safety Executive. Available at: http://www.hse.gov.uk/pubns/priced/hsg258.pdf. Accessed 16 April 2011.

HSE. (2009) The technical basis for COSHH essentials: easy steps to control chemicals. London: Health & Safety Executive. Available at: http://www.coshh-essentials.org.uk/assets/live/CETB.pdf. Accessed 16 April 2011.

HSE. (2010) Control of substances hazardous to health (COSHH) essentials guidance publications. Available at: http://www.hse.gov.uk/pubns/guidance/index.htm. Accessed 16 April 2011.

Marquart H, Heussen H, Le Feber M *et al*. (2008) 'Stoffenmanager', a web-based control banding tool using an exposure process model. Ann Occup Hyg; 52: 429–41.

Marquart H, Northage C, Money C. (2007) Exposure scenarios for workers. J Expo Sci Environ Epidemiol; 17: S16–25.

Money C. (2003) European approaches in the development of approaches for the successful control of workplace health risks. Ann Occup Hyg; 47: 533–40.

Money CD, Jacobi S, Penman M *et al*. (2007) The ECETOC approach to targeted risk assessment; lessons and experiences relevant to REACH. J Expo Sci Environ Epidemiol; 17: S67–71.

Munn SJ, Hansen BG. (2002) EU risk assessment: science and policy. Toxicology; 27: 181–281–5.

Rappaport SM. (1993) Threshold limit values, permissible exposure limits, and feasibility: the bases for exposure limits in the United States. Am J Ind Med 23: 683–94.

RSC. (1996) COSHH in laboratories. 2nd edn. London: Royal Society of Chemistry.

Rudén C, Hansson SO. (2010) Registration, Evaluation, and Authorization of Chemicals (REACH) is but the first step-how far will it take us? Six further steps to improve the European chemicals legislation. Environ Health Perspect; 118: 6–10.

Schoeters G. (2010) The REACH perspective: toward a new concept of toxicity testing. J Toxicol Environ Health B Crit Rev; 13: 232–41.

Van der Wielen A. (2007) REACH: next steps to sound chemicals management. J Expo Sci Environ Epidemiol; 17: S2–6.

van Hemmen JJ. (2009) REACH and the obligations of the chemical industry. Occup Environ Med; 66: 560–8.

Williams ES, Panko J, Paustenbach DJ. (2009) The European Union's REACH regulation: a review of its history and requirements. Crit Rev Toxicol; 39: 553–75.

Zalk DM, Nelson DI. (2008) History and evolution of control banding: a review. J Occup Environ Hyg; 5: 330–46.